U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

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FOOD AND DRUG ADMINISTRATION

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RISK COMMUNICATION ADVISORY COMMITTEE

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THURSDAY,
MAY 15, 2008

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The meeting convened at 8:00 a.m. in Plaza I and II of the Hilton Washington D.C./Rockville Hotel, 1750 Rockville Pike, Rockville, Maryland, Baruch Fischhoff, Ph.D., Chairman, presiding.

COMMITTEE MEMBERS PRESENT:

BARUCH FISCHHOFF, Ph.D., Chair
CHRISTINE M. BRUHN, Ph.D., Member
JACOB DeLaROSA, M.D., Member
ANNAMARIA DeSALVA, Member
MICHAEL GOLDSTEIN, M.D., Member
SALLY GREENBERG, Member
PRERNA MONA KHANNA, M.D., M.P.H., Member
MADELINE Y. LAWSON, M.S., Member
MUSA MAYER, M.S., M.F.A., Member
DAVID P. MOXLEY, M.S.W., Ph.D., D.P.A., Member
LINDA NEUHAUSER, Dr.P.H., M.P.H., Member
JOHN E. PALING, Ph.D., Member
ELLEN M. PETERS, Ph.D., Member
THEODORE F. REISS, M.D., Guest Industry Representative
BETSY LYNN SLEATH, Ph.D., Member
MARIELOS L. VEGA, B.S.N., R.N., Member

CONSULTANTS PRESENT:

J. CRAIG ANDREWS, Ph.D.
CHERYL L. HOLT, Ph.D.
GAVIN HUNTLEY-FENNER, Ph.D.
ELAINE H. MORRATO, Dr.P.H., M.P.H.

GUEST SPEAKER:

ANDREAS LORD, M.S., Eastern Research Group, Inc.

FDA PARTICIPANTS:

LEE L. ZWANZIGER, Ph.D., Designated Federal Officer/Executive Secretary
KRISTIN DAVIS, J.D., Deputy Director, Division of Drug Marketing, Advertising, and Communications, Center for Drug Evaluation and Research
KAREN FEIBUS, M.D., Medical Officer, Office of New Drugs, Center for Drug Evaluation and Research
ELLEN FRANK, Director, Division of Public Affairs, Office of Training and Communications, Center for Drug Evaluation and Research
MARY HITCH, Senior Policy Advisor, Office of External Relations, Office of the Commissioner
CATHERINE McDERMOTT, Director, Public Affairs/Information Branch, Division of Federal and State Relations, Office of Regulatory Affairs
NANCY M. OSTROVE, Ph.D., Senior Advisor for Risk Communication, Office of the Commissioner

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P R O C E E D I N G S

(8:02 a.m.)

CHAIRMAN FISCHHOFF: Let me welcome you all here. I'm Baruch Fischhoff, the Chair of the FDA Risk Communication Advisory Committee. Welcome. Thank you all for coming and for your contributions to our work and through it -- and providing advice to the Food and Drug Administration about these critical problems that we're going to be dealing with today and then another slice of those problems tomorrow.

I'd like to have each of the Committee members just sort of introduce yourself just with your name and your affiliation. Those who haven't seen them, you'll find at the FDA site -- fuller biographies of the Committee members. If you go there, you'll discover there's really quite a remarkable Committee with people with accomplishments in a very diverse set of areas, as is appropriate to the complicated

problems of helping the public to make better decisions about their health and the role of food and drugs in them.

So let me start. I'm Baruch Fischhoff. I'm at Carnegie-Mellon University.

DR. PETERS: I'm Ellen Peters. I'm a decision psychologist at Decision Research in Eugene, Oregon.

MS. VEGA: Good morning. My name is Marielos Vega, and I am a staff nurse at the New Jersey Medical School.

DR. SLEATH: I'm Betsy Sleath. I'm Professor of pharmaceutical outcomes and policy at the University of North Carolina, Chapel Hill.

DR. ANDREWS: I'm Craig Andrews from Marquette University. I'm a professor and the Kellstadt Chair.

DR. HOLT: I'm Cheryl Holt. I'm with the University of Alabama at Birmingham in the Division of Preventive Medicine. I'm a social psychologist and health communication

researcher.

DR. HUNTLEY-FENNER: I'm Gavin Huntley-Fenner. I'm a managing scientist with Exponent in the Human Factors practice.

DR. MORRATO: Elaine Morrato. I'm an Assistant Professor at University of Colorado, School of Public Health and Clinical Pharmacy, and my interest is in pharmaceutical risk management.

MS. DAVIS: I'm Kristin Davis, here from the FDA to speak today.

DR. OSTROVE: Nancy Ostrove, senior risk communication advisor with the Office of the Commissioner at FDA.

DR. REISS: I'm Ted Reiss from Clinical Research at Merck Research Laboratories.

MS. LAWSON: I'm Madeline Lawson, president and CEO of the Institute for Multi-culture Minority Medicine here in Washington, D.C.

MS. GREENBERG: I'm Sally

Greenberg. I'm Executive Director of the National Consumers League.

DR. GOLDSTEIN: Hello, everybody. I'm Michael Goldstein. I'm an Associate Director at the Institute for Healthcare Communication and I'm also at Brown Medical School.

MS. MAYER: I'm Musa Mayer. I'm a patient advocate. I work with breast cancer patients.

DR. MOXLEY: David Moxley from the University of Oklahoma, Norman.

DR. NEUHAUSER: Linda Neuhauser, School of Public Health, University of California at Berkeley.

DR. PALING: Good morning. I'm John Paling. I'm the Research Director of the Risk Communication Institute. We specialize in providing patient focused health for health care professionals trying to talk to patients, and yes, I am an American citizen.

DR. DeLaROSA: Dr. Jacob DeLaRosa,

a cardiothoracic surgeon at Idaho State University, Pocatello, Idaho.

DR. BRUHN: I'm Christine Bruhn with the University of California at Davis. I'm in the Department of Food Science and Technology and Director of the Center for Consumer Research.

CHAIRMAN FISCHHOFF: And next to me is Lee Zwanziger, who is the Designated Federal Officer for this Committee and who will now officially bring us to order.

DR. ZWANZIGER: Thank you, Dr. Fischhoff.

Good morning, and I want to welcome the members and consultants to the Risk Communication Advisory Committee, also members of the public and the FDA staff. Thank you all for coming to this meeting.

I believe we'll get the lights up a little bit in just a moment.

The following announcement addresses the issue of conflict of interest

with respect to this meeting and is made a part of the record to preclude even the appearance of such at this meeting.

Today the Risk Communication Advisory Committee will discuss points the FDA should consider in preparing a report to Congress about how direct-to-consumer advertising, that is, DTC, relates to communicating to subsets of the general population, such as the elderly, children, and racial and ethnic minority communities, and increased access to health information and decreased health disparities for these populations.

Tomorrow the Committee will turn to design considerations for studying the appropriateness of including televised DTC ads, a statement encouraging consumers to report negative side effects of prescription drugs to MedWatch, as is currently required for print DTC prescription drugs ads.

Any study would then be subject to

notice and comment in accord with the Paperwork Reduction Act.

Based on the submitted agenda for the meeting and all financial interests reported by the Committee participants, it has been determined that no interest in the firms regulated by the Food and Drug Administration present potential for conflict or appearance of conflict of interest at this meeting.

We'd like to note that Dr. Theodore Reiss, recent industry representative of the Pulmonary Allergy Drugs Advisory Committee for the Center for Drug Evaluation and Research, is participating as a guest industry representative in accord with the charter of the Risk Communication Advisory Committee.

We also note that today's guest speaker, Mr. Andreas Lord, is employed by the Eastern Research Group, ERG. ERG has a contract with the FDA to do a literature review, a portion of which Mr. Lord will present today.

In general, the Committee participants were aware of the need to exclude themselves from involvement in discussion of topics if their interests would be affected, and their exclusion will be noted for the record.

With respect to all other participants, we ask in the interest of fairness that they address any current or previous financial involvement with any firm whose products they might wish to comment upon.

We have a period for open public comment each day at the meeting listed in the agenda. If persons not already signed up to speak wish to request time, please see one of my colleagues at the sign-in table outside.

The entire meeting is being transcribed, and the transcript will be posted on the FDA Website. It can only contain what the transcriber can hear. So I remind all of us to please turn on and speak into the

microphones when you're recognized to speak, turn them off when you're finished speaking, and I'd suggest that we all now turn our cell phones and other communications devices to a silent mode.

Thank you very much.

CHAIRMAN FISCHHOFF: Okay, and our first speaker in this romantic atmosphere --

(Laughter.)

CHAIRMAN FISCHHOFF: -- will be Dr. Nancy Ostrove from FDA.

DR. OSTROVE: Good morning, everyone. Everybody can see okay back there, right? You've actually got some light. That's good.

Thank you all for being here, and we're starting out ahead of time. So we're in pretty good shape.

Direct-to-consumer advertising is, as I've put up here, this kind of evergreen issue. It's around. Sometimes some of the needles fall, but they are always back again,

as demonstrated, for instance, just recently. Many of you probably were listening or sitting in on a hearing just last week that the House Energy and Commerce Subcommittee on Oversight and Investigations held on direct-to-consumer advertising, where they heard testimony from researchers from the American Medical Association, from the Government Accountability Office, from Merck/Shering Plough, Ortho Biotech, and Pfizer, and I hope I didn't leave anyone out, and in fact, if you haven't listened to that or you would like to look at the prepared testimony that's available at the website, that's indicated underneath.

And I guess the other way, I was just thinking as I was sitting at the table of how this issue has been with us for a long time is hat I think that many of the slides that I'm using to give kind of an overview of how we regulate direct-to-consumer advertising today, I started using probably in 1995.

Still a lot of the misconceptions, at least that the public has concerning direct-to-consumer advertising, are still around. So the slides are evergreen as well, which kind of makes it easier to put together the presentations.

Now, I guess -- just a little caveat that I wanted to make today is that this particular meeting today is really not focused on direct-to-consumer advertising as a whole. It is really a very targeted meeting, as Lee pointed out in the initial disclaimer.

However, our sense is that in order for the Committee to be able to speak intelligently -- that sounded wrong -- in order for the Committee to be able to discuss these issues in an informed fashion, it was important for them to have the background and kind of the context in which to understand how, in fact, we do regulate direct-to-consumer advertising.

So that's how we got this little

piece at the beginning today.

Some of you know this. I apologize to those of you who have already been through this a number of times, but as teachers will tell you, it never hurts to repeat things over and over and over again.

When it comes to regulatory, the regulatory oversight that FDA has over drug promotion in general, it's split. Back in 1962, the Federal Food, Drug and Cosmetic Act was amended by the Kefauver-Harris amendments, and that is when FDA actually got oversight over advertising just in general, over advertising for prescription drugs, in general.

We had an agreement that we entered into with the Federal Trade Commission because prior to that time, and the Federal Trade Commission would assert even now, they also have jurisdiction over all advertising, and the agreements basically that the FTC, the Federal Trade Commission, has primary

jurisdiction over the advertising for over-the-counter drugs, whereas FDA has primary jurisdiction over the advertising for prescription drugs in terms of both their labeling and their advertising, and also we have primary jurisdiction over the drug labeling for over-the-counter drugs, which does not mean that either of the organizations is prohibited from taking action.

While we have primary jurisdiction over the advertising for prescription drugs, FTC could take action in that area if they felt that an advertisement was inconsistent with their mandates.

Now, an interesting thing that's very recent is until the FDA Amendments Act to the Federal Food, Drug, and Cosmetic Act, the FFDC Act, the Food, Drug, and Cosmetic Act, never really distinguished between advertising that was directed toward health care providers and advertising that was directed toward patients or consumers. There is no

distinction in the statute.

And it was like that until this past fall when the Amendments Act finally started talking about direct-to-consumer advertising, and in our implementing regulations, that is, the regulations that implement the act itself, there is no distinction at all between advertising that's directed to health care providers and advertising that's directed to patients or consumers.

So the bottom line on that, the nitty-gritty is that, historically the rules have been the same, and it has not mattered what the audience is. If it's advertising about prescription drugs, it's just advertising about prescription drugs, which presents certain challenges when it comes to communication issues.

Now, the other thing that I think -- oh, and by the way, when I say drugs, I mean drugs. Drugs includes the categories of

biologics and vaccines, and I would also add that FDA has jurisdiction over the labeling for medical devices and advertising for restricted medical devices. So we do not oversee the advertising for all devices, but we do have it over a very significant group of what are called restricted medical devices.

Now, that's not today's discussion. That's just, again, for kind of context and background.

Historically -- well, let's back up there. Many people believe that something changed in the late 1990s when it came to direct-to-consumer advertising, specifically advertising over broadcast venues like television, radio, and telephone communications systems. In fact, the regulations never changed. The law didn't change.

What did change was practice, and generally starting in the 1980s, the manufacturers didn't advertise to consumers.

They only advertised to health care providers. The practice changed.

And there's a lot of reasons for why that may have happened, but today's not the day to get into that discussion. So we're just going to let that go.

So that's something that I think is important for everyone to understand. The regulations didn't change.

In addition to that, something that the people generally don't kind of understand is that the act itself prohibits FDA from requiring pre-clearance of any advertisements, except under extraordinary circumstances. So we hear a lot of calls for FDA should be required to pre-clear advertisements, and in fact, the act says that we can't do that except under what the act terms as -- let's use the air quotes -- extraordinary circumstances, and what the FDA has determined extraordinary circumstances are are things like voluntary consent decrees that the agency

may enter into with specific entities who have perhaps had continuing problems in terms of their advertisements.

The agency affirmatively decided that direct-to-consumer advertising does not constitute extraordinary circumstances.

And finally, in terms of another background fact, the act itself requires that advertisements include -- and again, I'm using air quotes here because it's directly out of the statute -- include information in brief summary about products, risks and benefits. That's not the way the statute says it, but that's basically what it means.

So the term which many people have kind of wrinkled their brows over of brief summary, which is neither brief nor a summary, actually is a term of art that comes from the statute. So, again, just kind of background facts.

Another background fact that I didn't put on the slide but often comes up as

recently as the hearing last week is that generally we can't regulate where and when ads appear. That's not something that we have authority over, and in addition, we don't regulate certain issues, such as taste. As many people have said in the past in these kinds of things, we are not the good taste police. That's something that does not fall under our regulatory jurisdiction.

So with all of that kind of in the background there, let's talk a little bit about the fact that there's different classes of promotional materials. Now, someone in the public looking at promotion will not necessarily think about these distinctions in promotional materials. However, we have to think about them because they have implications for how we can regulate any particular advertisement or other promotional material.

And when I say that, it gets you right into the "what do you mean by

promotional materials?" Well, there's advertisements and there's labeling, and in fact, there's different types of labeling and all of these have regulatory implications.

So labeling -- let's talk about promotional labeling -- includes things like brochures and mailing pieces, detail aids that manufacturer's representatives use when they're talking about health care providers, calendars, price lists, et cetera, et cetera, and it even includes references that have the approved labeling in it, such as the Physicians Desk Reference, or the PDR, as many of us refer to it.

The other major type of promotional material are advertisements, and advertisements in the regulations are defined as advertisements that appear in journals, magazines, newspapers, other periodicals, or through broadcast media which are basically defined as TV, radio and telephone communication systems.

So there is a distinction, a regulatory distinction between labeling and advertisements. And on top of that, if there wasn't enough complication to start with, different types of advertisements have different regulatory implications.

So let's start with some of those. In fact, I'm going to address three different types of advertisements. The first one is especially interesting because if a manufacturer does this type of advertisement correctly, we don't regulate it. The Federal Trade Commission regulates it, and it's what we call help seeking advertisements. Sometimes in the past these were called see-your-doctor advertisements or disease oriented advertisements, and essentially what they are is that they're not drug ads. And as I said, if they're done properly, FDA doesn't regulate them. The FTC does.

This is a help-seeking advertisement. A help-seeking ad basically

focuses on the disease, does not imply that there's a particular treatment that we regulate that would help that disease and basically just gives people information to try to determine whether, in fact, this disease or condition is something that's relevant to them or one of their loved ones, and then encourages them to see the doctor, saying basically that your doctor has treatments.

So this particular ad focuses on hepatitis C and tells people that if you're ready to fight back, you can see your doctor. You'll never be stronger than you are today to stop the damage that hep C can do to your lives. Talk to your doctor.

And it also -- and, again, this is accepted under the regulations and under the law -- to give additional sources of information. So it provides in this case a URL for a website that people can go to. It provides an 800 -- well, a toll-free number for people to call to get additional

information, and in fact, although this particular ad doesn't, it could even include the name of the logo of the manufacturer who is sponsoring the ad.

If you follow the URL, this is where you would go to, at least when I picked this up, which admittedly was several months ago. So it may be out of date, and you would get more information about hepatitis C. As you can see, again, this focuses mostly on hep C, but there is a way to get more information here. If you kind of follow it through treatment, you'll get information about Roche's treatment for hepatitis C.

So that's the first type of advertisement, and remember we are talking about this. You know, we look at the advertisements on their face and what they say, basically on their face.

Now, the second type of advertisement is kind of the other end of the spectrum where help-seeking advertisements

only talk about the disease. Reminder advertisements only talk about the product.

And these were put in place, the regulations that kind of exempted advertisements from all the requirements that I'm going to talk to in a very short while so that you could have things like price lists and listings of products that a manufacturer might make available for use.

The focus is on the name, and it's basically designed to remind knowledgeable persons because these were meant initially when the regulations were put into place with this exemption, they were meant for who was being advertised to at the time, which was health care providers. We're talking about the 1960s.

And they knew what a product was for if they saw the name. They didn't need to be -- all they needed to do was be reminded of its availability.

The exemption requires that there

be no representations about the product aside from its brand name and generic name, its dosage form and packaging and potentially price information. So it's just meant for people who are knowledgeable to remind them of availability.

The one major piece of this that kind of restricts reminder advertisements is that they cannot be used for products that have boxed warnings in their approved labeling, and that's basically a product that's got a very serious risk associated with it that the FDA and the manufacturer have deemed to be serious and important enough so that it's put in a box in the labeling.

So you can't have reminder ads for products that have really, really serious risks. And this is a reminder ad. It can be very simple. No representations can be made about what it does.

The third type of advertisement, which is the one that basically kind of puts

everything together because it's about both the product and what the product does, we call these product claim advertisements. They communicate, as I said, both benefits and in addition to benefits, also communicates risk. So what it is, what it does, both in terms of the good things that it does and potentially the bad things that it does.

Product claim advertisements need to have the name of the product that's both the brand and the generic name of the product, the amount of the product in each unit. I used to have quantitative information because that's the way it's framed in the regulations, but then people got confused about the term "quantitative." So it's basically, okay, if it's a ten milligram pill, it will say ten milligram.

The approved use needs to be included, at least one approved use. Many products, of course, have more than one, but you need to have at least one, and that's

actually considered to be in some ways part of the brief summary. Remember that term of art from the statute.

And optionally, the ad can contain other substantiated claims. Any claims that are in an advertisement need to be substantiated by adequate and well controlled studies or there needs basically to be significant research that supports the claim or significant clinical experience that supports the claim.

And in addition to that, there's specific risk disclosure requirements for these product claim advertisements that will vary as a function of whether the ad is print or broadcast. We'll talk a little bit more about that.

And I am very careful to say that this is part of a product claim ad because it doesn't include the other part of the ad, which is what is euphemistically called the brief summary, all of the detailed risk

information. I'm not showing that piece, but what this does show you is claims that are made and then also that there is a lot of information about the risks of the product, and there is a reference for getting more information.

Now, the regulations specifically talk about the content of advertisements and what is required for the content, and specifically there are kind of three overarching themes. The content and ads can't be false or misleading. So, as I said before, any uses that are claimed for the product have to be consistent with the product's approved labeling.

And in addition to being consistent, they also have to be substantiated. But even if you have a claim that's substantiated, if it's not consistent with labeling, that would not be something that is permitted.

Secondly, they have to present a

fair balance between information about benefits and information about risks.

And third, ads cannot omit material facts, and what this comes down to basically is that advertisements have to communicate an accurate and a balanced picture of the product that is being advertised.

But in addition to that, there are these technical risk disclosure requirements, and what the particular ad is required to disclose is going to be a little bit different depending on whether it's classified as an advertisement or whether it's classified as promotional labeling. And these distinctions are probably not distinctions that are meaningful to a consumer audience, but they are meaningful, again, from a regulatory perspective, and in some ways they are relevant to the consumer audience as well because they're going to be getting information in different kinds of formats, and they may not understand why.

What it comes down to, the bottom line, is that advertisements require this brief summary, remember from the statute, whereas labeling promotional pieces require that the full package insert, that is, the full approved labeling for the product also be attached to whatever that promotional piece is.

There are different regulations for advertisements versus labeling, and that's why that is the case.

In addition to that if you, again, break advertisements down into the print versus the broadcast categorization, we find that there are technical differences there as well. Generally print ads will require that all product risks be included because that's the way the regulations were written.

However, FDA recognizing that this is not necessarily the best way to communicate with consumers because if you include all of the risks, then it may be that they're not

getting the most important risks because they're being overloaded by everything. So we actually put out, in 2004, an updated draft guidance that offered alternatives to including all of the information because what we were seeing is manufacturers reprinting all of the risk related portions of the approved product label along with each advertisement, which was not written in a way to be especially accessible or understandable to consumers.

So we put out this draft guidance that encourages using approved patient labeling. These are basically patient package inserts that are designed specifically for patients. They're not included for all drugs, but some drugs have this. All drugs have approved labeling. Only some drugs have approved patient labeling, and we have a further breakdown of patient labeling called medication guides, which are for especially risky drugs.

So the draft guidance says, well, if you have one of these, if you have approved patient labeling for your product, if you have a medication guide, use that for your brief summary. We're okay with that. We use this mechanism called enforcement discretion, where we would not take action against you. Even though technically it doesn't fulfill the requirements of the regulations, our sense is this would be better for consumers. So we'll let you get away with it.

The draft guidance also encourages manufacturers to consider translating the most important risk information into consumer friendly language and using the risk information that would be included in what we are calling the highlight section of the package insert. Again, this is a relatively newly instituted new piece of professional labeling that is short and designed to get at the most important information.

So we said you can use that, too.

Translate it into consumer friendly language, please, but that can be used in place of the brief summary.

So, for instance, this is a brief summary that uses a medication guide for the product that is being advertised, and as I say here, medication guides are a type of approved patient labeling, and you can see, just in terms of the formatting, that it's much more likely to be accessible to a consumer audience, and it's written in a way that consumers are more likely to understand it, which we believe is a better thing to do than to just kind of plop down the risk related sections of approved product labeling.

So what about broadcast ads? Well, as I said earlier, when I said things didn't change back in the late 1990s what did change is we put out a guidance that recognized that the communication environment had changed. The fact of the matter is that the regulations, even from the 1960s, had included

an option for broadcast advertisements that was different than what was required for print advertisements. Print advertisements, according to the regs, have to include all the risks.

But the option for broadcast advertisements, even before there was consumer directed advertising, was that the broadcast ads needed to include the major risks, the most important risks, what we call, euphemistically, the major statement. This is basically the statement of the major risks for the product; that it needed to include that, and that you had basically two alternatives then as a manufacturer if you wanted to do TV advertising or radio advertising. You could either include all the risks, just as you would for a print ad, or alternatively, you could make adequate provision -- that's in air quotes because that's from the regulations -- for disseminating the full product labeling. So, again, we're getting back here to

dissemination of the package insert, which remember, is already required for promotional labeling, but not for advertisements.

But what we're saying here is look. Either include all of the risks or make sure that you include the major risks in the ad itself, and then give people a way to get to all of the risks in the form of the package insert.

Prior to the middle 1990s we didn't think that was possible for consumers. How were they going to really have easy access to the package insert? But by the mid-1990s people were used to calling toll free numbers to get additional information. The Internet was becoming much more ubiquitous and people had access there. We knew, of course, they could always ask their doctors for it because their doctors would have a PDR available, and in addition to that, we had seen a proliferation of print advertising. And the print advertisements, while they didn't have

the full package insert associated with them, did have the brief summary which had all of the risks in them.

So we decided that rather than have an environment where we were seeing more and more reminder ads that just gave the name of the product and no information about it and then some of these help seeking ads that would talk about a condition, but wouldn't tell you what are some potential treatments, that it would be better to have the product claim ads that gave people both pieces of the equation in a way that was regulatorily acceptable and useful for them.

So we put out this guidance, draft guidance in 1997 and finalized it in 1999, that basically said, well, look, for TV ads, for radio ads, here's the required risk disclosure. You have to give the major risks, and you can either give all of them, all of the risks or access to approved labeling.

Well, how do you give access to

approved labeling? Well, give people a number of different ways to get to it because different people are going to want to use different ways to get to the labeling. So some of them might be fine with calling a 1-800 number, and some of them might not want to have something appearing in their mailbox. So they would want anonymity. So give them the source, say, in a current print advertisement that they could go to get information or allow them to go to the Internet or give them the option. You should always give them the option of saying, well, you know, you can get more information from your doctor, from your health care provider, your doctor, your pharmacist, your nurse.

So that's kind of the quick, basic lowdown on the different types of advertisements and actually different types of promotion. What happens if there's a problem?

Well, this slide basically kind of talks about what FDA's enforcement options

are, and essentially what we will do, kind of the lowest -- I don't want to call it the lowest level -- but the most basic level of enforcement is to send a letter to the manufacturer saying, "Look, there's a problem with your advertisement. You really need to stop this."

That particular option is not mentioned in the regulations. It's just something that we do, and we get a very high level of voluntary compliance. So if we say stop using this, generally the manufacturer says, "Oh, okay. We don't agree with you. We think it's fine. We don't think it's false or misleading or lacking fair balance, but if you say so, we'll fix it."

The next level which generally is reserved for instances where we feel that the misimpression that has been generated by the advertisement or by the promotional labeling piece is so problematic that it needs to be corrected and so, therefore, we would be

asking for corrective action; that next level is called the warning letter. It is mentioned in the regulations. So it has more regulatory clout, and it often is a prelude to more serious action. Manufacturers know that. So they generally tend to pay even more attention, not to say that they don't pay attention to the lower level, quote the lower level, the more basic level, but they pay special attention to warning letters.

We can also seize product. We can bring injunctions. We can bring prosecutions against the advertisers. That doesn't happen very often for promotion related problems. Generally the threat of doing so is enough to result in, for instance, a voluntary consent decree. We have had a few of those over the years. We've threatened seizures. I don't think we've ever gone to the injunction or prosecution stage. Usually, again, you can handle these. FDA has been able to handle these things at a lower level.

So that's just kind of very basic information about enforcement.

If you have any questions, I would be happy to take them at this point, but that's the end of my prepared comments.

CHAIRMAN FISCHHOFF: Thank you, Nancy.

We have two members of the Committee who have come in during the talk, and I'd just like them to introduce themselves. Oh, you were here.

DR. KHANNA: Okay. Thank you, Baruch.

Dr. Mona Khanna, internist, specializations also in public health and occupational medicine. I'm a former reporter for the Wall Street Journal and CBS Television; currently the medical editor of a health information website called ICYou.com; and a member of the Disaster Medical Assistance Team and a Texas Medical Ranger.

CHAIRMAN FISCHHOFF: And then

AnnaMaria.

MS. DeSALVA: Good morning. I'm AnnaMaria DeSalva. I'm the global health care practice leader at Hill and Nolton, the public relations firm, and so I'm a communications professional, and I work typically with organizations throughout the health care sector. Some of them are private sector; some of them are public sector, on issues like risk communications, also trust and reputation, and primarily have focused when I was on the client side of the business at one of the large pharmaceutical companies in women's health and also international health.

CHAIRMAN FISCHHOFF: Okay. So let's open this to discussion.

Thank you for the informative presentation. You probably want to stay in the hot seat, if you're willing, or you could take your questions from there.

DR. OSTROVE: I'm fine.

CHAIRMAN FISCHHOFF: Yes, Linda,

please.

DR. NEUHAUSER: Thank you for your presentation. I have a question about whether the Internet or other digital broadcast type media, PDAs, et cetera, if those are regulated.

DR. OSTROVE: That's a very good question. Yes, they are. The reason I didn't actually refer to them specifically is because they're difficult to classify. So we haven't classified the Internet or any of these other means of advertising as either advertisements or labeling.

The reason I say that that's important to us is because it has these technical, you know, requirements that are a little bit different, but we do consider all of that promotional material. So we basically told manufacturers, "Pick your path. You know, you want to be considered an advertisement on the net? Then you'll have to include the brief summary. If you want to be

considered promotional labeling, include the package insert."

It's fairly easy to do either of them on the Internet, but we do regulate, and we have taken action in certain cases where we felt that there were violations.

CHAIRMAN FISCHHOFF: Is there anything in the law that's special to the topic of today? So today we're talking about impacts on subsets of the general population, with a focus on elderly, children, including teenagers, racial minorities, ethnic minorities, and the only difference, I guess, market segmenting I saw was there was a discussion you mentioned towards the end, diverse populations, but that was in terms of information seeking, which could be correlated with these groups, but it's not special to them.

DR. OSTROVE: Right, and in fact, the diverse populations was really more in our thinking than it was in the regulations or in

the statute. There's no reference to that in the law itself. That was just because our feeling was that in order to interpret adequate provision adequately.

So is there anything in the law that relates to today's specific topic? Not that I can think of. Kristin, can you think of anything? Is there a reasonable consumer kind of thing that you would want to bring up?

MS. DAVIS: There's not a lot of provisions that are specific to these populations, but actually in my presentation there are a couple that I'm going to go over. So I'm happy to go over them now or if you want to wait for the presentation.

CHAIRMAN FISCHHOFF: Is there anything in the evolving practice that won't be covered in the next talk regarding these populations?

DR. OSTROVE: Anything in evolving practice in terms of the manufacturers or --

CHAIRMAN FISCHHOFF: Well you

described how things have evolved. Has any that have been driven by impacts, you know, on specific populations or is this where things have changed? Has it been, you know, general problems that have been noted?

DR. OSTROVE: I think that in terms of applying the regulations and the law to the environment, we need to take into account what's happening in the environment. So to that extent when things change so that, for instance, if we see advertisements that are primarily in a particular language, then that has implications for how we would want to regulate in that arena.

So that, for instance, it can bring up a regulatory problem if you have an advertisement that is in Spanish, but you have a brief summary that's in English. So, you know, to that extent there are implications and it may bring up areas where we need to do some more work internally to kind of address those.

And I think we do anticipate that different populations have different needs.

CHAIRMAN FISCHHOFF: So it's legitimate, but it hasn't been addressed systematically, which is part of why we're here.

DR. OSTROVE: Right. This is the first that we've seen this kind of reference in either the statute or the regulation -- well, the regulations flow from the statute -- this is the first time that we've seen this kind of focus in the Amendments Act that came out this past fall.

CHAIRMAN FISCHHOFF: Thank you.

Marielos.

MS. VEGA: This is not a question, but a comment. In my opinion, labeling in advertisement is a very complex issue, especially when it comes to vulnerable populations. We have millions and millions of people in this country who are illiterate. So when it comes to advertisement and labeling,

I'm not sure how clear is the evidence that labels mean something to people.

I know for a fact, and I have seen it with my own eyes, people who are from other countries, from China, Latin America, who go back to buy medications there, who are prescription medications in this country, but know in their countries they can buy for a lot less, where regulations are not as strict. And to them this means nothing. I mean, the people are looking for that quick cure.

And I would be surprised if there is a large number of people who really read labels or who really understanding the repercussions of advertisement. So I think there's still a lot of work that we have to do in this area when it comes to vulnerable populations to get a better understanding of how these things that we are discussing today have an impact on them.

DR. DeLaROSA: Nancy, how do you regulate this? I mean, does every ad, every

commercial, does it go through you all that has to deal with drugs? Is it because of whistle blowers? Is it because somebody read something over the weekend, you know, in the bathroom and then comes in on Monday morning and says, "Look what I found"? Or how do you regulate?

Can you comment, please?

DR. OSTROVE: That's good. Actually it's kind of all of those. Now, specifically when a manufacturer goes out with any kind of a promotional piece, they are required to submit it to FDA at about the same time that they go out to the public with it. So we have thousands of these pieces that come in and go to the division.

Well, when they're for drugs, there's two groups within the agency that regulate. There's the Division of Drug Marketing, Advertising and Communications within the Center for Drug Evaluation and Research, and then there's the Advertising and

Promotional Labeling Branch within the Center for Biologics, but basically all of that information comes to the agency.

Do we look at every single piece? No, that's not possible. We don't have the person-power to do that, but we try to kind of take a risk perspective, and we look, for instance, very closely at launch campaigns, introductory campaigns, because that's what's creating the first impression. so we'll pay a lot of attention to those.

If there's been particular problems with particular products, we'll pay attention to those. Direct-to-consumer advertising gets a lot of attention, and in addition to that, we will get reports from health care providers, from competitors. Competitors are a big source of complaints about their competitors' advertisements. So pay attention to those.

People internally, I remember when I was actually kind of on the ground doing

this. I would look at all of the TV ads in great detail, and I'm sure everyone who is in DDMAC, the division who oversees this, still does that. I don't anymore. It's kind of a relief to do that, but now I only look at ones that concern me.

So, yes, it comes in from all those different sources.

DR. REISS: A question, Nancy. You said that the Federal Trade Commission regulates OTC advertising. Is there any implication here for us? Do they do things the same way or how do they approach these problems, these issues?

DR. OSTROVE: Well, as I said, the FTC has primary jurisdiction over over-the-counter advertisements. I wouldn't say that we would never ever, you know, but generally they do -- I guess it's an opinion to say they seem to be doing a fairly good job.

Their statutes are different than our statutes. Really, they look at deceptive

practices, and actually one of our consultants today, Craig Andrews, has worked much more closely with the FTC than I have. So he would probably be a better person to kind of address that particular -- you know, the way that they do things.

DR. ANDREWS: I guess to answer your question, mostly the three-part standard on deception, and they take a look at misleadingness, the reasonable consumer that we were talking about before, and materiality, but it's a net impression of the ad that was used.

And, again, my tour of duty was a few years ago.

DR. OSTROVE: But it's pretty similar, and I think they've actually made the argument that it's not that dissimilar from the way that we look at things.

DR. ANDREWS: There's another category of unfairness, which is a difficult task on substantial injury with vulnerable

populations. That's a little more difficult.

Nancy, I had a question for you, something I've always been wondering about on the adequate provision. Do you have an idea of the extent that maybe older consumers and other vulnerable populations go to the Internet and these other particular areas, see our ad in a certain magazine, go to this particular website? Is there any data or anything indicating the extent to which, you know, they might go in certain areas?

DR. OSTROVE: I'm not sure that we've looked at that closely. I do know that at least in some past surveys, national surveys that Prevention magazine has sponsored, that they have asked that question, and it may be possible to break the data down, you know, as a function of the demographics of the population, but off the top of my head, I think a little of that has been done, but it's not in there.

DR. PETERS: I had what I think may

be a follow-up question to what Baruch asked earlier. I'm wondering is there anything in the law that distinguishes between providing information, so putting it out there somewhere, versus the impact of that information on the individual in terms of comprehension or use or even the ability to navigate in an Internet site.

DR. OSTROVE: Not that I am aware of. Kristin, you're the attorney here. Can you?

MS. DAVIS: I think one of the things that makes the new legislation interesting is that there wasn't anything before that, but one of the provisions separate from this DTC report that we're here to talk about today does actually mandate that the agency in pre-reviewing TV ads take into account the impact of the advertised drug on specific populations including the ones that we're talking about today in the context of the report.

So it's one of the reasons why FDAAA is really notable, is this new focus on not just consumers, but on, you know, to all the different subpopulations trying to get accurate and reliable information to them.

DR. OSTROVE: So it's there, but it's new. So we haven't really kind of fleshed it out.

Yes.

MS. LAWSON: I have a question about the patient package inserts and what guidance is provided from the agency on the development of the inserts. I've seen some that are very lengthy, and I know for many, many consumers it would be very confusing. Some of the suggested directions really pose conflicts with what the doctors have prescribed, and so I just wonder how much direction is provided from the agency in the development of them.

DR. OSTROVE: When it comes to medication guides, there's actually a

regulation in the Code of Federal Regulations. It's Section 208 that specifies kind of the headings that are supposed to be included in the medication. Again, this is labeling for especially problematic drugs, problematic in the sense of having greater risks than normal or, you know, needing to have really good instructions about how to use.

So there actually are regulations for medication guides. For patient package inserts as a whole, they've kind of been voluntary generally over the years. I mean, the agency may have requested that a manufacturer use them.

Do we provide much guidance? We're looking at that now. There is certainly -- I would say that there's a fair amount of variation among them. Some are better than others, and the Center for Drug Evaluation and I'm sure the Center for Biologics Evaluation and Research, as well, are kind of talking about how to handle those.

While we have provided guidance for how we evaluate patient information that comes out from independent vendors, I do not believe that we have provided guidance for how to actually write approved patient labeling and what kinds of things to take into account, except that we all understand that the patient labeling needs to be consistent with the professional labeling.

So there should not be distinctions in terms of, you know, the kinds of instructions given in patient labeling compared with the kind of instructions for the same product given in the professional labeling.

DR. NEUHAUSER: I have a comment to Dr. Andrews' question. The best scientifically based information about use of the Internet by older people for health information is on the Health Information National Trends Survey, a nationally representative survey conducted by the

National Cancer Institute.

So it does not directly look at direct-to-consumer advertising, but there's a lot of other information about how older people use the Internet.

And then I have a question for Nancy Ostrove, and that is about in response to some other comments here, looking at whether this information might be accessible, understandable to diverse audiences. I was intrigued by the risk disclosure draft guidance and the use of the term "consumer friendly language." And my question is is there a definition of that, and more importantly, are there any criteria about what constitutes consumer friendly language?

DR. OSTROVE: You know, I have to admit that I wrote "consumer friendly language" on the slide. I have not read the guidance recently, and I don't remember whether it said "consumer friendly language" or specifically said "language that is

understandable to the consumer population," which may be more like it.

But as far as I'm aware, there was no specific definition in the guidance, and certainly one could quibble saying, "Well, what do you mean by 'consumers'? That's a pretty diverse group, and are you talking about the ones with the highest literacy levels or the ones that, you know, have minimal literacy?" But the guidance does not get into that.

DR. KHANNA: Nancy, another resource for survey of Internet users could be the Pew Charitable Trust survey of Internet users, which was done just recently, but my question is Internet use, as we all know, is exploding. Do the guidelines for advertising on the Internet follow more closely guidelines for print advertising or broadcast advertising?

And to your knowledge, have there been any issues with that so far? Any red

flags raised?

DR. OSTROVE: Well, we don't have guidelines that specifically speak to the Internet. The only guidance we have, and I use that term "guidance" because we don't really have guidelines. We have guidance. It has this kind of technical; it's not legally binding and all this stuff. But we really have not put out guidance on the Internet.

And in terms of the way -- I could not speak to how we are currently looking at it. The people in DDMAC might be able to. I may have missed a piece of the question, and so I apologize, but in terms of advertising or labeling, we've said, "Decide what you want it to be and just provide the necessary technical disclosure that's consistent with that decision."

So we would accept either kind of the brief summary interpretation or the package insert interpretation. Either one of them would be okay.

Now, getting outside of my FDA, you know, kind of role, it would be very easy to say, well, what good is the professional package insert for a consumer population, and that's certainly a question that we had, but the issue is what do the regulations require?

So, you know, I would say that conceptually it would be nicer for the manufacturer -- I can't say that because I'm kind of here as an FDA representative. Okay. So let's strike that. Sorry.

CHAIRMAN FISCHHOFF: Let me thank our FDA representative, Nancy.

DR. OSTROVE: Thank you.

(Laughter.)

CHAIRMAN FISCHHOFF: And then invite our next FDA representative, Kristin Davis, please.

MS. DAVIS: Good morning, everyone. Today I'm going to be focusing on giving an overview of what FDAAA requires us to do today and what the agency has done so far in order

to implement the different provisions of FDAAA, and first I should start by saying that FDAAA is my way of referring to the Food and Drug Administration Amendments Act of 2007. That passed last September, and one big part of that was reauthorizing the user fee legislation for the agency, but there's also a lot of other interesting provisions, and one entitled "The Report on DTC Advertising" is what brings us here today.

And let me start by just introducing myself a little more fully. I'm from the Division of Drug Marketing, Advertising, and Communications in the Center for Drug Evaluation and Research, and as Nancy said, we're the group within the Center for Drugs that regulates prescription drug advertising.

There's also another group that works on prescription drug advertising and biologics in the Center for Biologics, and that's the Advertising and Promotional

Labeling Branch, and I've seen some of them come in today.

But we came here today to meet with all of you because of this provision in FDAAA that I'm going to go over, and first I want to just give you an idea of the framework because this legislation is notable. It's the first time that there's been legislation that has focused on direct-to-consumer advertising, and there are actually three separate sections in this statute that focus on direct-to-consumer advertising. Section 901 is what brings us here today, but I'm just going to briefly give you background on the other two sections so that you have an idea of what else is in there.

The first Section 104, this was a user fee program for the review of direct-to-consumer television advertisements. This program was actually not able to legally commence because the agency wasn't given the authority in an appropriations act to collect

these fees, but this would have been geared towards getting user fee dollars from industry to review television advertisements before they were broadcast within set time frames.

And then Section 906 is actually the focus of tomorrow's discussion, and so I'm going to leave that until tomorrow because Dr. Kit Aikin for DDMAC will actually be giving you an overview of that.

But in Section 901, there are actually several different provisions related to direct-to-consumer advertising, and I've listed them in the order that they appear. It's the last one that we're here for today, but again, just to give you an idea of what else is in there, the first provision is pre-review of direct-to-consumer television advertisements, and this gives the agency the authority to ask companies to submit their direct-to-consumer drug advertisements to the agency 45 days before they're publicly aired, and then the agency is supposed to review them

and provide recommendations on those ads.

Before this, we didn't have the authority to require companies to submit TV ads before they were disseminated. The only types of products that we saw the provision for before they went out were what's called accelerated approval products, and those are products that are approved based on a surrogate endpoint or where human clinical studies aren't ethical or feasible.

So this was a notable addition, and actually I'm going to be going over this one in a little more detail later on because it has some language that's, I think interesting in light of what we're here for today.

The next requirement is the clear, conspicuous and neutral manner major statement requirement, and what this is is it's in addition to the Food, Drug and Cosmetic Act of a new standard for broadcast advertisements for prescription drugs. So that's radio and television advertisements, and it requires

that major statement of risk information that Nancy talked about in broadcast ads. It has to be in a clear, conspicuous and neutral manner, and the agency actually has to issue regulations to establish standards for determining whether a major statement meets this requirement within 30 months of the date that FDAAA was passed.

And then the last one before we get to the report on DTC advertising is a civil monetary penalty provision. Nancy went over the enforcement options, the traditional enforcement options that the agency has had when it comes to false or misleading advertising, but what we have now is a new provision. It's specific to direct-to-consumer advertising, and it gives the agency the authority to seek civil monetary penalties if a company runs a false or misleading direct-to-consumer advertisement, and the penalties are set at $250,000 for your first violation and then up to $500,000 for any

subsequent violation in a three-year period.

And now, the report on DTC advertising. So in FDAAA there's a provision that says that by September 27th of 2009, we have to report to Congress on direct-to-consumer advertising and it's ability to communicate to subsets of the general population, and the specific subsets mentioned are the elderly, the children, and racial and ethnic minority communities.

And FDAAA mandates that we utilize this Committee to advise us with respect to this report, which we're very happy to do today, and this goes on to say that this Committee is going to study direct-to-consumer advertising as it relates to increased access to health information and decreased health disparities for these populations.

And our report, when we ultimately report on this to Congress, has to recommend effective ways to present and disseminate information to these populations.

There's one more provision in this report, and this is about a different topic than direct-to-consumer advertising. It's actually about inclusion in clinical trials of these different populations that are mentioned, as well as medically underserved populations, and there can be some overlap. And then the agency in this report is also supposed to recommend best practice approaches for increasing the inclusion of these subsets of the general population in clinical drug trials.

This is actually something that is being considered separately. We're not here today to focus on that and to explain why, I'm going to give you an overview of what the agency is actually doing to fulfill all of its different mandates under FDAAA, and what the agency has done is it has formed a number of working groups to work on all of the different provisions in this legislation that we have to enact and implement over time, and one of the

working groups is focusing on the direct-to-consumer advertising provisions, and it's that working group that one of the members of that asked to come meet with you all today, and because we don't have the expertise on clinical trial issues, that's why that's going to be considered by a separate working group in FDA, but we are working on all the different provisions that relate to direct-to-consumer advertising, including this report, and what we've done is we've kind of gathered expertise within the agency to serve on the working group to help inform us on these issues, first members from the different groups that do regulate advertising. So from the advertising and promotional labeling branch in CBER, from DDMAC in CDER. We also have members from the Office of New Drugs in CDER, Office of Regulatory Policy, Office of Surveillance and Epidemiology, just a whole different cross-section of people.

We're meeting with all of you

today, and we're really looking forward to getting information and advice from you. We've identified some consultants that we're very pleased can come today to sit on the Committee and help give us information on this topic. We're hoping that during the open public hearing we also get information from members of the public.

And then we've also opened a docket to get information from members of the public that maybe can't come today and have data and information that they can submit that will help inform this report.

And then the other thing that we're doing has just totally escaped my mind. So I think that that's probably a pretty good summary of what we're doing. Hopefully I haven't missed anything major, but that's kind of where we are in trying to implement these different provisions of FDAAA.

So, now that I've gone over what the language in the report is, and, you know,

our basic duties under that report, what we have to report on, what we have to consider, what we have to study, the other thing I want to do is just give you guys some more background on other provisions that are relevant.

And first I want to reiterate what Nancy said, that before FDAAA, there really was nothing in the prescription drug advertising provisions that focused on specific audiences. The entire focus was on looking at the four corners of the piece itself, not who it was intended for, but within those four corners, was there anything that was false, that was misleading? Was it omitting something that was a material disclosure? Did it not have a fair balance of risks and benefits?

But now, in FDAAA, we have not only a focus on just specifically direct-to-consumer advertising, but also these subsets of the general population, and in the report,

you see that we're told to study this, and provide recommendations to Congress, but there's other provisions, too, that I think highlight Congress' focus on these different groups, and seem intended to give the agency more tools to really ensure that direct-to-consumer advertising communicates clearly and reliably to all the different subsets of the population.

So the pre-review provision, which I've already really briefly covered, when we review these ads that we asked to be pre-reviewed, we're looking at, not only what was kind of already in the regulations about, you know, is it false or misleading, is it consistent with the approved product labeling, but we also now are told that we can make recommendations with respect to information that companies should add to the promotional piece about the specific efficacy of the drug as it relates to specific populations, and the listed populations are the same ones that

we're looking at in the report, the elderly, the children in racially and ethnically diverse communities.

So that's really a new change. One thing, just as background for this, when we are evaluating prescription drug advertisements, I mean, you might be asking how we would make these recommendations, what we would base them on. The regulations that determine what should be in the approved product labeling for a drug, they already have kind of provision for some of this information.

For example, in the indications and usage section, if there are any major limitations on your use, for example, if your drug has not been shown not to have an effect in certain subpopulations, you're supposed to note that.

And kind of along the same lines, if you've only been shown to have an effect in specific populations, for example, only those

65 and older, you have to note that, as well, in your indications and usage.

The other thing is there is the whole section in labeling - you're probably all familiar with this - about special populations, and two of the groups that we're looking at today, the elderly and children, are specifically listed. So it's pediatrics, which is 16 and under, and then geriatrics, 65 and older, that are mentioned specifically in the approved product labeling.

So that's kind of the primary information source when we're reviewing advertisements, when we're making recommendations, and I guess that would be the first place we would look when we're implementing this provision.

Just to give you a little more information, this became effective March 27th of this year, but so far, it hasn't been fully implemented. Our working group's still working on that.

The other thing to note, I mentioned this a little bit earlier during the question session after Nancy's presentation, but this provision, this pre-review provision also says that FDA has to take into account the impact of the drug on the elderly populations, children, and racially and ethnically diverse communities. This is really notable, because this is not talking about what's in the advertisement. This is actually talking about the impact of the advertised drug on these communities.

So again, this legislation, this part of the legislation, it's really an interesting new change in that there is this focus on these communities, and this, you know, when you try to read the intent of Congress, you can always run into trouble, but there does seem to be a real intent here to give FDA tools to help make sure that direct-to-consumer advertising is a clear and accurate communication tool for these

communities.

And one other thing to note is that we can't require any changes in ads when we're doing this peer review. These are all recommendations, except for a couple of categories that aren't too relevant to what we're talking about today.

And then the last thing, before I'll take questions, in our regulations, which have been around for a while, there are just a couple more provisions that, although they weren't really focusing on specific audiences, they're kind of relevant to what we're looking at today, and the first is foreign language pieces. There's two provisions about that, and these just talk about the basic requirement that everything needs to be in English. All your labeling needs to be in English, except that, if you make any representation, or, you know, if you make any of your required statements in a foreign language, you need to have all the required

information in that foreign language.

So what happens is basically, if you want to do a foreign language version of a promotional piece, you have to do, you know, everything that is needed for that, add all the risk disclosure, the full indication in that foreign language, and you also have to have an English version of it available.

The one exception is, if you're in a territory where the language is something other than English, usually that's kind of, Puerto Rico is the prime example of that, you can do everything in just that foreign language. So in Puerto Rico, you could do your piece entirely in Spanish without having the same thing in English available.

And then the second provision is kind of interesting. There was some discussion, actually, at the first meeting of this committee, which I attended about, when you do translate into foreign languages, there are -- you can translate, you know, within a

foreign language, say, Spanish, different words different ways, and it can have a different meaning.

So this provision is actually about, you know, in Spanish language pieces, it mandate certain translations for some of the required statements. This one is about the prescription only statement, because there are different ways you can interpret that. So it gives a specific way that you have to present that.

And then the last regulation talks about pieces that actually promote the efficacy of the drug in a selected class of patients. One of the classes mentioned in this regulation is geriatric patients, and what this says is that, when you do that, you have to make sure that, if there's any considerations that, you know, relate to risk, or the dosage and administration of the drug for that specific population, you have to present it in conjunction with the claims

about, you know, how well the drug works in that population.

So, although this wasn't really focused on, you know, if that population was the target audience, it does indicate that you need to give a full disclosure of information about a specific population if you're going to start talking about your efficacy in that population.

And that's all I have today. So I'm happy to take any questions that you have.

CHAIRMAN FISCHHOFF: Thank you very much.

Please. Musa.

MS. MAYER: Thank you.

I have a sort of overarching question about FDA resources in light of the new FDAAA potential, and in light of the tremendous volume of direct-to-consumer materials that your department reviews. So this is sort of a two-part question.

Up until this point, what

proportion of materials were you actually able to review in relation to what you feel is necessary to review?

That's sort of an awkward way of asking it, and how do you see this impacted by the changes in regulation, not only with regard to TV ads, but overall direct-to-consumer advertising?

MS. DAVIS: As far as what we look at versus what we feel we should, or what we would like to look at, I mean, one answer to that question is, in an ideal world, we'd look at everything, but just to give you an idea, maybe, of what we do look at, just -- we don't have exact numbers, but there are two different, sort of tracks that pieces can take in coming into us, and one is that they can be submitted in draft form for our advisory comments before a company goes out so that the company has the benefit of our advice, and our opinion on the piece, and they can fix any problems before they actually disseminate it.

And for those pieces, those kind of advisory pieces, which that whole process is a voluntary one, we look at the vast majority. Sometimes, we can't review something in the time frame that the company has, but we look at most of those.

The other way that pieces come in, and Nancy talked about this a little, is every company is required to submit, when they are actually going out publicly with a piece, a copy of the piece on what's called Form 2253. We got, I think, 68,000 of those last year. So we don't track exactly how many we look at, but we're not, I mean, we're definitely not getting to all of those. We just don't have the staffing resources, and we would, you know, in an ideal world, like to be able to get to all of those, but we would need a big increase in staff to review every single one of those, but in light of what's in the legislation, and, I think, in particular, this pre-review provision is one where we have a

clock. You know, we have 45 days to look at these pieces, and once we, you know, are implementing this, and asking companies to submit their ads, you need a certain level of resources to be able to turn things around that quickly, depending on the volume of material.

But one thing is that, you know, Congress did, for this fiscal year, appropriate additional monies for the review of direct-to-consumer advertising, four million dollars. So we do have some increased staffing that's kind of coming down that will help us with this, but, you know, we still won't be able to get to everything, but what we do to kind of make up for that is we prioritize, so that we're trying to look at the highest impact pieces.

For example, although we don't get to everything, we look at every TV ad that comes in, because that can reach, you know, a broad national audience. We look at, as Nancy

was saying, the launch campaigns. That's the first impression of a piece. We try to make sure that companies are getting right at the beginning, and then also, if we've noted a problem, if we've received complaints, if there's any signal of that, or if we're concerned about a new risk that might have been added, we'll look at the pieces to make sure that's being added.

So we try to triage the different pieces to get to the ones that might have the biggest impact.

MS. MAYER: Would you care to comment on the decrease in the number of warning letters from your department in recent years?

MS. DAVIS: You phrase that in an interesting way that kind of gets me off the hook, but I think, you know, again, with warning letters, you know, it's public knowledge that there have been less, but there's a new process, too. I mean, I guess

new is not really the word at this point, but there's more levels of review that these go through. Again, that takes resources. So that can decrease the number.

But what we're doing to make up for that is we are trying to look, again, at pieces with the highest impact, and the other thing to note is that, although our notice of violation letters have decreased, our warning letters have actually increased over the years. So we are trying to take on those most serious, most significant violations, and make sure that correct information is disseminated to the public.

DR. GOLDSTEIN: In an earlier question, Dr. Peters asked about the kind of impacts that can be the purview of the FDA, and in one of the slides, Slide 9, now the FDA apparently has to take into account the impact, and it sounds like impact is being thought of as something other than just understandability, but also behavior change,

or what the public does as a result of having access to the advertisement.

Has any group yet made some kinds of determinations of what appropriate impacts would be to look at, what kinds of behaviors, what kinds of outcomes would be important to track?

MS. DAVIS: I think, at this point, where we're starting from is actually then the language in the DTC report provision, which talks about increased access to health information, and decreased health disparities. So some of the things we'd like to look at, and that we're hoping to get information on are kind of underserved populations actually getting these messages, and then, what happens next.

Are they, as a result, going to their doctor, and maybe getting treatment for a condition that they otherwise wouldn't have gotten, you know, treatment for?

And, you know, at the end of the

day, we, you know, we're looking to protect the public health, and, you know, as a kind of corollary to that, if, through direct-to-consumer advertising, we can improve the public health for some groups, you know, by ensuring the accuracy, by looking at, you know, this is a communication tool, we'd really like to do that.

So that's kind of where we're starting from, but we're hoping to gather information. I can't say that we have that information yet.

DR. GOLDSTEIN: But just a comment on that, as a follow-up. If you're actually going to follow that request to reduce health disparities, you can interpret that as actually, not just access to care, but also changes in the actual health of those populations, which we know have great disparities. That, I think, is probably behind the thrust of this regulation.

So it may behoove the FDA to get

very clear about what kinds of outcomes we want to begin to look at, what kinds of impacts, besides just access to health information, if, indeed, you're going to meet the requirements of that one piece of language in there about reducing health disparities.

MS. DAVIS: I think that's a really good point, and also something that we'd really appreciate any input from this Committee today on what we should be looking at while we're gathering information and readiness report.

CHAIRMAN FISCHHOFF: John.

DR. PALING: When I introduced myself at the first meeting, I admitted that I was the least academically qualified of all this group. That is still the case, but with your definition a few minutes ago, I now define myself as the least qualified geriatric member of this group.

(Laughter.)

DR. PALING: And with that in mind,

I hope you will forgive my senility if I ask you a question that comes from my heart. This group of subpopulations we all respect to be very important. However, it is my opinion that, if regular members of the community do not, using your words, clearly and reliably understand the risks that are associated with the products that you regulate, I hope you might agree that it is unlikely that anything we say will have relatively little effect upon improving the comprehension of those people who are in these subpopulations.

With that in mind, and with no wish to be discourteous to my dear friends at the FDA, who I recognize are tremendous - this is not a wait for the "but" statement - I have worked with several agencies, and I've been hugely impressed by every single person, including yourself, their dedication, and their knowledge.

But I also noticed and respect that you are, by training, a lawyer. I'm wondering

whether the request of us to recommend best practice approaches for increasing the inclusion of these various subsets would equally authorize this group to try and define what are the best practices for communication to regular members of the public, not to try and hijack the agenda that our Chairman has put in front of us, but nevertheless, it's, to me, a huge issue that's really the elephant in the room, and the unspoken one.

So my question is, I have come to give the best of my limited senile opinions about the issues that we're specifically being asked to contribute to, but I see this huge chasm that has emerged from an earlier meeting when, two years ago, there was a big public forum about this.

If we don't know what constitute good best practice, or best practices for communicating the, quote, information, can you help me by suggesting whether we may take this request to expand it from this special subset

to people in general?

MS. DAVIS: Well, I think that, you know, we're starting from what Congress has told us to do, but I think you raise really good points. Communication and, kind of reaching these populations, there are two parts. One is that, is this message, is health information even reaching these populations, and then, if it is, is it communicating to them effectively?

And I think that some of the issues that you might be getting at, do you just -- you know, consumers that are a member of the, quote, general population, is direct-to-consumer advertising clearly and reliably communicating to them?

If it's not, I think that the recommendations we would make, the kind of, you know, techniques that you would use to improve your communication, I think that they could have broad applicability. Our focus in the report is supposed to be on these

populations, but certainly, I think some communication techniques, tools, or considerations are more universal than that, so they would definitely have a place in the report.

And just one other thing, too. The other thing we're doing, which I completely forgot to mention, is that we're also looking at communicators within FDA, and what they've learned from their experiences, and we have a panel of them that are going to be talking to you this afternoon, but that's another issue. First is communicating to consumers, and I think that we're trying to get some of that expertise for them, too, what they've learned, their kind of best practices in reaching out with health information to, not just all of these different populations, but just, you know, reaching out in general with this information.

CHAIRMAN FISCHHOFF: Elaine.

DR. MORRATO: Thank you.

I had a question with regard to the provisions around communicating to children, and what the intent behind that was, given that these are prescription medications that we're talking about.

So is the intent on focusing on children as a primary audience of the advertising, in terms of either reaching them, or best communicating to children, or is it really more about including information, considering them more as an indirect audience, which might be information, relevant use in children, as you mentioned, or perhaps the impact of use in children?

Thank you.

MS. DAVIS: That's a good question, and I think a sensitive issue, too. There's actually, not that I'm aware of, there's no legislative history on this provision. So we're kind of trying to interpret the intent of Congress.

I think these are prescription

medications, and that one thing that this may be looking at is more communications to caregivers of children where, you know, it's talking about the efficacy of the drug in children, and then the clinical trial part is more straightforward, where it's inclusion of children in clinical trials.

But, you know, there's no prohibition on reaching out to children as an audience, but it does have a -- you know, there are considerations attached with that, and it's not something that's really commonly seen now with prescription drug promotion.

DR. MORRATO: So then I'll just add, it gets back to the larger question, if really you're intending to reach the people that take care of the children, then it gets back to the general audience concerns around how do you best communicate in general.

MS. DAVIS: I think that's correct.

CHAIRMAN FISCHHOFF: Okay. Marielos, and then Craig.

MS. VEGA: Ms. Davis, I am someone who is, not only a health care provider to minority populations, but also someone who is a consumer, and someone who belongs to a group who is considered vulnerable group. Does your office have a division, or someone who is monitoring once the advertisement is approved?

Because even for someone like me, going into the Web is like going into a jungle. There is not a place that it will tell me, if you want approved regulated information, go here, or if you want information that is questionable, go here.

You open the Web, and you can go anywhere. How is the public supposed to make a decision into -- I'm not sure to what degree the general population knows what the role of the FDA is in advertisement.

MS. DAVIS: I think my division, you know, our focus is on just regulating the actual promotion that comes in, but that's an issue that I think is very much on the

agency's radar, and I think one of the things that we're trying to do is, for people that do go to the Web, and are wondering where they can find accurate and reliable information, we're trying to make the FDA website really user friendly, and really just kind of a repository of a lot of that information.

The thing that my division does is we do regulate the prescription drug promotion done by, or on behalf of, the companies that make the drug on the internet. So, you know, the website for the drug, if there's something wrong with it, we would hope to take action and correct it. If they submit it for comments, we would hope to give them advice to make it, you know, a good communication tool, and something that's accurate and non-misleading.

But I can't say that every one of the, you know, thousands of websites up there is something that's been looked at or, you know, that we would necessarily have seen it

yet if there is a problem. But I think that's one of the reasons, too, why FDA is really working on its own communication efforts, as someone who isn't manufacturing one of the drugs is trying to give that type of information.

And I think, if you have any more questions on that effort, I think Nancy knows a lot about what we've been doing with the website, you know, the whole FDA website, all the different centers, all the different divisions to try to make it, you know, the most useful tool it can be for consumers.

DR. ANDREWS: Kristin, I had a great observation here. I was glad to see the clear and conspicuous statement provision. I was wondering, if you took a look at the FTC's clear and conspicuous statement, going back to, with disclosures. Basically, if there's deceptive advertising, one of the provisions is on, if there's a disclosure, that there's a list of about eight items regarding dual

modality, presentation rate, type size, et cetera. Is that a --

MS. DAVIS: That's the first thing we did, actually. Yes, and it's very useful to have the FTC as a resource, you know, for how they approach, because although with prescription drugs, there are some unique things about the kind of risk and benefit disclosure, a lot of the communication tools we try to look for any guidance and advice, you know, we can get from them, and sort of vice versa to address these issues, because we're all looking at, you know, what is the net impression? Does this clearly communicate? Is this appropriately conspicuous? Are there things that are taking away from the risk disclosure like, you know, the competing modalities, things like that.

DR. ANDREWS: Yes, occasionally there can be some push-back for manufacturers, too, at least at the FTC on consent agreements.

CHAIRMAN FISCHHOFF: For those who are following the schedule, and wondering whether we're getting behind, I'm taking the Chair's prerogative to let this part of the discussion go on, because I think that it's important for us to understand the constraints within which we're working, and the problem that we have to solve before getting the input of what's known about these different things, and we have quite a bit of slack built into the program.

So next will be Gavin.

DR. HUNTLEY-FENNER: My question goes back to a question I think Committee Member Mayer raised, and it has to do with the review of ads, and the criteria for prioritization. You mentioned reach and, for example, TV ads are important, whether you were talking about a launch campaign as an initial introduction. There's also, being important, risk, of course. Known risks, or potential risks are important criteria.

But you also mentioned that there's a sourcing criteria, as well, namely, competitive complaints, and I'm wondering if you can tell me the degree to which some of those complaints are orthogonal to some of the criteria, the other criteria, and the degree to which those orthogonal complaints require resources when you're looking through these 68,000 odd pieces.

MS. DAVIS: I think that the complaints -- and just to clarify, some of them are from competitors, but they're also from consumers. They're from health care providers. In some ways, promotion tends to follow some of the other criteria, like around the launch period, when a drug is first introduced, there's usually a lot of promotion, and that is usually when your competitors are kind of looking at what impact you're going to have on their market share,