as to the net outcome and how it will be measured?

DR. O'DONOHUGHE: You are speaking in terms of the communication of risk, so the comprehension of the risk information?

DR. HOLT: I'm assuming that's the primary outcome, right?

DR. O'DONOHUGHE: Right. We haven't developed the questions yet, but we work on developing questions that do have discrimination. We have in the past used different types of questions, either true/false, or multiple choice, or some kinds of questions that get at more than recall, some kind of processing or application of the information.

DR. HOLT: So, are you envisioning that it would be a constellation of several questions that you would have sort of indexed in a way, or a key primary question that would be --

DR. O'DONOHUGHE: Most likely

several questions that could be indexed.

DR. HOLT: Yes, well then, as you consider that, I think many of the comments that have gone around that relate to, not just comprehension, but behavior, you know, what does it really mean when you say detract, you know. I don't know whether or not that's part of the plan to share that sort of questionnaire design, not just the sampling frame that we are talking now.

DR. O'DONOHUGHE: Well, certainly, I used the language detract because that's in FDAAA, it says does it distract from risk information, and I believe I mentioned during my design it could facilitate, it's an empirical question, we don't know if it detracts or facilitates, and that's one thing we are looking at.

And, with our experimental design, we'll be able to compare the conditions and look at the absolute levels of the comprehension, so that is our goal.

DR. HOLT: As you know, in the drug efficacy side there's a lot of discussion that says, well, does efficacy really mean? You know, so the same amount of rigor as to what does detract really mean, because that will be when people argue is there enough evidence that says I have to put this in my ad now, or evidence that says it improves or disproves.

And, it then relates to sample size.

CHAIRMAN FISCHOFF: Okay. Gavin, Madeline, Musa, David, Mike, Linda and Marielos. I don't have to call anybody after that, you all remember the order.

DR. HUNTLEY-FENNER: So, this is picking up on Ellen's comment. There's a framework that I think the committee was introduced to in the previous meeting, regarding warnings, comprehension, and warnings in behavior. I think it would be helpful for organizing the questions and, potentially, leading to an answer to your

question.

You need to know, you can't always take it for granted that folks will notice that there's this message, and if they've noticed it that they will read it, and if they've read it that they will comprehend it.

And, you also should be asking about potential behavior, and I know this is addressed by previous commenters, but that would be the last step that they would then consider and, potentially, act upon the information.

To that end, you'll want to look closely at the motivation. So, again, this question of motivation, whether the person has a related condition, whether even if it's a fictitious condition that can substantially impact their attention to the information that they are receiving.

The other thing I would suggest asking about is credibility, because both credibility and comprehension contribute to

overall perception of the risks.

And then finally, I would say that I fully understand the sort of off-label impact, the beneficial side effect of knowing that the agency sort of cares about side effects, and that, in and of itself, is a beneficial outcome.

And, maybe one can ask about the perception that's created, just by having this information in the ad, because I think that that's something that we value and that it would be important to test it.

I've been thinking about this professional driver closed course, whether that makes me feel that the car company cares about me. But, you know, that would be -- it's a question, it's an open question.

DR. O'DONOHUGHE: Can I ask a clarifying question? When you speak about credibility, are you talking about credibility of the agency, or credibility of the sponsor, or --

DR. HUNTLEY-FENNER: Credibility of the source of information about risks and benefits. But, you know, the overall message has a credibility attached to it for each of those components.

CHAIRMAN FISCHOFF: One of the topics that came up in our previous meeting was a discussion of something somebody called, what is the FDA brand? And, in some sense the better the FDA brand, teh better the pharmaceutical industry brand, because people in some sense don't want to have to have street smarts about all of these things, they'd like to believe that there's a system in place that will protect them.

So, I would just amplify this, and Musa said as well, that I think a major part of the assessment here, even if it's not in the legislation, but for FDA fulfilling its communications out, to see what is the big picture in terms of people's trust, and understanding what FDA can and can't do.

Madeline, Musa, David.

MS. LAWSON: I just would like to emphasize, based on all the comments that I've been hearing from my colleagues, I'd like to emphasize the involvement will partnership with the health profession on this. You know, you are going to put a lot of -- invest a lot of time and work into the message and the design work, and I think it's very important, and it's certainly another way of saying to the public that here we want to hear if you are having some side effects, and, certainly, we want to be concerned about those who tend not to get the information.

But, it's important that we have some involvement in some partnerships with the physicians and other health professionals. If one were experiencing a side effect, would you call the FDA or would you call your doctor? And, I think we have to really look at that. We want them to do both. I mean, we want you to call the 1-800 number, and once you do that

do we have people responding to the call that are really qualified to do the appropriate probing, like a physician, or a dentist, or a pharmacist, or is it someone who is just gathering information?

And so, once we have them, we don't want to lose them, and we certainly want to be of the greatest benefit. So, I think it would be good in the report to Congress to be able to report in addition to what you are planning to do with the 1-800 number, to also report that you are working very closely or you are establishing this partnership with the health professions associations to reinforce ways of getting the public to understand and to respond with any adverse effects or side effects of the drugs.

So, I'd like to emphasize the involvement of the health professions.

MS. MAYER: To follow on that, I think it would be really useful for the public to understand that we are all embarked on a

mission, if you will, after a drug is approved, to determine what the rare and unusual side effects of that drug will be that didn't show up in the initial clinical trials.

I mean, this is true with every drug, I think, and I don't think there is a public recognition of this at all.

And so, I think we constantly, we collectively, the public, feel betrayed when a new serious side effect emerges after an FDA approval. So, I see this as a really good corrective measure.

But, really why I asked to speak was just to say the other half of the equation. I wonder if you'd consider simplifying your study design to only include the extra prominent, because I think it's not only the hearing impaired who need to see text, it's also the visually impaired who need to hear the audio. So, I think if you are going to reach everyone, and that would be particularly meaningful, both would be

meaningful for the elderly population, who take more medications than anybody else.

So, I think if you are going to reach everyone, probably you should only be looking at the extra prominent notification. That's just my feeling about it.

CHAIRMAN FISCHOFF: David.

DR. MOXLEY: This is probably a bad analog, but I've spent a number of years doing research on 1-800 numbers for people who were in rights protection and advocacy situations. So, they tended to be people of diminished status and high vulnerability, who were in sort of restrictive kinds of settings. And, if you look at their sort of either ability or willingness to report what they considered to be a rights violation, and it really was very, very interesting relative to the kind of interpretations that they placed on what was going on for them.

And, often times what they would consider a violation was sort of packaged up

with the treatment. They would discount it, or it was the cost of treatment, or they were supposed to be tolerant, or they are in a situation where there wasn't availability of anyone to prompt them to interpret the situation, and the successful reports, with high severity, people would -- were often prompted by a caregiver who made that interpretation. Typically, that caregiver was a health professional.

And, even the health professional had to make a decision about whether they were going to report, just because of the structure of their job and number of responsibilities that they have.

Well, if you -- people who didn't call, and if you look at -- when we looked at adverse reports of people who did not call, and you interview those people about why they didn't call, they basically said it wasn't going to do any good.

And, you know, it's sort of bound

up with their self-efficacy, to what extent do I believe that I'm actually going to bring about an outcome that's going to change things, and there's going to be some confusion, I would imagine, around whether I'm providing information or I'm help seeking.

And, there may need to be a recognition within the system that both is going on, that I'm actually prompted, maybe it's an electronic prompt, to really call my physician or talk, or more importantly, with a pharmacist, or report it to a nurse or a social worker. A lot of people are prompters and mediate these kinds of things from my perspective.

In poor communities, although there's a prevalence of cell phones increasingly in our society, just in the Native American community, for example, in some many Native American communities there's 20-25 percent of households without telephones, and they are making a number --

they have to make a number of different steps to make those calls.

I'm thinking about Christine's idea of motivation, not only motivation to find a phone, but the motivation to think is this important enough, or what actually happened, or is the palpitation part of my illness, is it a side effect, is it something else that's going on, and to reach the kind of populations we were talking about yesterday we may need to make some heroic efforts that the stipulation from Congress may not actually appreciate, because it's fairly -- it's great legislative language, and it's enough to put into, you know, a structure design.

So, being a qualitative researcher, and being concerned about the statements about focus groups, I would underscore doing this, not even pre-testing, this sort of illuminative period where you actually begin to understand what we are asking of certain populations or subgroups, particularly, and we

haven't used this term, cognitive minorities in the United States, which there are diverse now groups of cognitive minorities who process different things in different ways, who actually whose social experience diminishes their trust in healthcare providers, and when they see an 800 number they are thinking about whether I trust this or not, and what does trust mean. Well, trust, you know, may mean that if I don't have it I may say I'm just really angry, I'm not going to provide any information. That may actually not be that conscious, but I do think it's -- in terms of the reach of this, and then trying to understand what -- how people interpret the message when there are social factors involved that you are not going to get to in a mall. You are just not.

And, that just may mean you are looking for the modal response, which -- or the upper income modal response, or, you know, the frequent mall-goer modal response, however

that is. But, I do think there is some, you know, that raises in my mind some questions about, I guess, the validity of the -- some validity factors.

CHAIRMAN FISCHOFF: Okay. Mike, Linda, and then Marielos.

DR. GOLDSTEIN: Just a process comment. This is what happens when you ask such a diverse group of knowledgeable informed people about a very specific question, you get very diverse answers, and very useful discussion that goes well beyond this question.

So, we could probably create an agenda from this for the rest of our committee's work about all the different ways we can enhance risk communication, other than through this study.

But, just to pile on a little bit, in terms of another question, that again has to do with relevance of the message and the signal,

The risk itself is going to be a factor in determining whether they remember it or not. So, that's another variable to think about manipulating. If there's a high risk that may result, you are going to have more people paying attention to that message than if it's, you may experience cramps every so often.

So, that's another thing that has to be built into some design, or at least considered if you are choosing multiple ads to vary the risk, or if you really want to get the signal, if you want to simplify and save money look at high risk, because that's what you are most concerned about, getting reports about the high risk events, and include that as part of the scenario that you are testing.

CHAIRMAN FISCHOFF: Nancy, and then Marielos.

DR. NEUHAUSER: I wanted to suggest first that we use the term co-design rather than pre-testing, just picking up on Dr.

Goldstein's comment, really talking about participatory design of the message, and the next step would be pre-testing of what's designed with other similar types of people not involved in the pre-design, and then a quantitative test to actually see the outcomes.

To the point made about the 800 numbers, I would suggest that if a pneumonic is used, like FDA, or side effect, or whatever it might be, or a safe drug, or something, that there be a pneumonic in English as well as in Spanish, and then you could think about, as Ms. Vega said, to have also the numbers listed afterwards. But, I have found with separate pneumonics it really works quite well in English and Spanish.

And, the third thing is that I am wondering how many messages we are talking about here. If I listen to the commentary here, it sounds like we have several messages. One message is the one that Ms. Mayer brought

up, which is that drugs have side effects, and to my view if that is the only message that gets through to the public that would be a very good message to have on ads.

The further message is that you can report side effects, or major side effects, whatever it would be, one person mentioned to your doctor, and also to the FDA line or internet URL. So, we are down to two or three messages.

One thought is that, in terms of the design, there could be a running footer on the ad with this information, like CNN does, running footer with these multiple messages that allows you not to override the other information that might be provided in the ad and text, et cetera. It might help not to distract, because people are used to seeing footers, and then a caveat would be whether the footer should be running or stationary. So, you might have several messages with a stationary footer, this drug has side effects,

or all drugs have side effects, another message coming after that would be, you can report side effects to your doctor and to the FDA at this number or on the internet.

So, I would suggest trying those out as a way to increase people's comprehension, keep it up longer, and also reduce distraction from other information provided.

CHAIRMAN FISCHOFF: Marielos.

MS. VEGA: Is there a legal relevance as to why you had to use a contractor, as opposed to work with groups that have already established relationships with these vulnerable populations, like the SPN Networks?

DR. O'DONOHUGHE: Well, when I say contractor, basically, Kit and I are the only social scientists in the unit doing this kind of research. We design the studies, and we analyze the studies, and interpret the data, but we don't personally have the resources to

collect the data. We just don't have time. And so, when we say contractor, we use the contractor only to collect the data.

We could certainly use a contractor and direct them to contact these groups. We could certainly work through these groups. And, I appreciate your suggestion, because those are valuable suggestions for getting at these populations that we have not gotten to this point.

MS. VEGA: Because collecting the data itself has a big impact into how these groups will participate in these type of studies.

My other question is, as a committee, are we going to be able to review this questionnaire, or whatever questions you come up with, before they go out?

DR. O'DONOHUGHE: Well, certainly, as I mentioned at first, we are going to have the public comment periods for any research that we do, so those, usually during that time

we'll have a design, we'll have questionnaire available, we might have stimuli available, and those will all be commented upon. And, we have the peer review process, so I'm not sure what the role of the advisory committee is in that. I think that probably there are so many of you that you wouldn't necessarily constitute a peer review group, but we could certainly meet with you in the future, and you would certainly have access to the information that goes out in the public comment periods.

CHAIRMAN FISCHOFF: I had a similar thought. So, let me volunteer the committee. My guess is that it's legal with some added burden on our staff, but we could probably have a conference call, you know, between now and then.

It seems to me there's, we're listing a set of design issues that, you know, have come up here that, you know, that if you would value our comment my guess is that you could probably get a bunch of people on the

phone, and it would probably have to be open to the public as well. I've been in calls with that on other advisory committees, and I think that that exists here.

Let me just flag, so one question that I think, you know, I would like to see, you know, I'd like to see the next -- I mean, we'd both like to serve you, and this is sort of what some of us do and really enjoy, so I think this would be -- that's why I think I can volunteer the committee, and that it would be -- and our consultants could join us, as well as members of the public.

So, one is the question of multiple ads, how do you simulate the multiple ad experience, because I think, you know, in comparison with what Christine and Ellen said, that I think you might get adverse effects, make very different effects on perceived risk and perceived benefits seeing it once and seeing it, you know, and seeing it multiple times. You might actually reverse the sign

with some of your effects.

I think if you did multiple -- presented multiple ads within the session, the effects might be rather different if you drew people's attention to this, or whether you did -- you know, we are going to show you a set of ads, and we are going to ask, you know, whatever marketers ask, how much you identify with the characters, has this ever occurred to you, and at the end ask them whether or not, you know, whether they've internalized the 1-800 number. That strikes me as, you know -- anyway, that would be my suggestion for the design. But, I think this, you know, the multiple ads, and I would actually suggest that, personal opinion, that I wouldn't bother doing the single ad, because that's not the experience that people are going to have.

I look at the single ads in the co-design to see whether you can get the best version of this insertion, but anyways, give us a proposal, I think we'd be happy to talk

about it.

A second thing is that you have a tradeoff here with the statistical power between how many conditions you have and how the precision of your understanding of the different groups. And so, my proposal here, and you may come up with another one, is to have relatively few cells, to rely on the existing literature to tell you duration, and speed, I mean, all -- as much as you can draw from the existing literature, FTC, FCC guidelines, and find, you know, two or four, you know, the minimum number of conditions of things where you really can't figure it out and you think it will make a big difference, and put the resources into getting a bigger sample so you really understand the populations that we talked about yesterday. And, exactly how you do that will require all kinds of details, and maybe we could help you there.

So, a third thing is, what is --

what are you going to show, what is it actually going to look at? I don't know if you were here yesterday, but there's a big comment about, a number of people made the comment that looking at story boards is not the same, you know, or text, is not the same as getting the whole experience. Some way of dummying, you know, as close as you can get to that kind of -- you know, there is some -- to see what it conveys.

You know, and then the concept, you know, will really make a difference. You know, so if it's there in English and Spanish, you know, for me as a consumer, you know, I'm the same thing, I can read the English, and I feel good that you have got the Spanish there as well.

And, you know, other people might have different affective reactions to that, and it may reduce their comprehension, but I think we can kind of help you with, you know, there's a variety of design things that, you

know, both the social scientists and the practitioners, and, you know, and so on, could help you with.

So, unless somebody calls me out on this I'd like to volunteer us for, you know, some intermediate input.

DR. ANDREWS: I just wanted to reiterate what Marielos had mentioned about the copy tests using mall intercepts. I've done this hundreds of times going way back. We had some major problems recently with a study on nutrition knowledge, nutrition claims, and some other aspects, where we were showing ad stimuli. And, a lot of these vendors now have moved to touch screen panels and other sorts of things, and it was a real problem with computer literacy coming in.

And so, actually, we had to have helpers, as far as the interviewers there, absolutely on English language only. My point is, I'm very concerned with the current vendors, and especially the interviewers out

there, to handle a number of the vulnerable populations, especially, elderly, et cetera, who may not have familiarity with the newer methods of collecting data. So, that's a real concern.

The other thing is, to kind of follow up on what Baruch was saying, on the methodology, a little bit on number of cells, and the power, it might -- and what Elaine was saying earlier, I think it would be very fruitful to figure out exactly, is it an absolute threshold that you are looking at, or is it relative statistical comparisons between certain cells.

I just remember vividly a horrible review we had. We had an unbalanced design like this, and with some issues on cell comparisons, where you probably want to specify exactly what you are seeking as a relative cell comparison and statistical differences, which some of these may be important in a relative sense to keep some of

that, or is it an absolute threshold that you are looking for on that, up front.

DR. HUNTLEY-FENNER: I just wanted to underline something I think that Ellen Peters said yesterday. You may not see the perceived risk impacts in people's memory or comprehension of the stated risks. You might see it in the benefits.

To the extent that individuals believe that, the counter-factual, that risks and benefits are interrelated in the way that scientists know them to be correlated.

DR. NEUHAUSER: A comment on Dr. Andrews' idea about the threshold. If you use health literacy level as one of your variables, that would be a threshold. So, above 16, or say 16 and above, 16 or below, that could help a lot to manage your sample size.

DR. PALING: Dr. O'Donoghue, I'd like to thank you, as our Chairman did, for all your help today.

I've been hugely impressed by everyone from FDA that's ever been here before is you once more follow that great committed reputation, and I thank you.

I hope in return this day will be a great omen for you. Personally, I hope that your delivery is as smooth and successful as this one is, and that you also have 25-1/2 hours before you present. We really do thank you.

CHAIRMAN FISCHOFF: We have -- why don't we -- we have an open public hearing at 10:30, why don't we take, you know, a slightly longer, give you four extra minutes in your break, not every time, and then let's meet then and we may have some other comments.

(Whereupon, at 10:12 a.m., a recess until 10:32 a.m.)

CHAIRMAN FISCHOFF: Okay, let me now welcome you to the open public hearing part of our meeting. I will now read, there's a standard conflict of interest statement that

needs to be read into the record and for everyone to hear.

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

For this reason, FDA encourages you, the open public hearing speaker, at the beginning of your written or oral statement to advise the committee of any financial relationship that you may have with any company or group that may be affected by the topic of the meeting.

For example, the financial information may include a company's or a group's payment of your travel, lodging or other expenses, in connection with your attendance at the meeting.

Likewise, FDA encourages you at the beginning of your statement to advise the committee if you do not have any financial relationship. If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking."

Thank you.

I would like to request that each person state, or restate, his or her name, and speak directly into the microphone. So far, we have three people who have asked to speak. Each of them will have five to seven minutes, and we look forward to your comments.

They will be in this order, Elizabeth Foley, Kim Witczak, and Peter Pitts. So, thank you.

Please, Elizabeth Foley.

MS. FOLEY: Hello. Can you hear me okay?

My name is Elizabeth Foley. I work with Consumers' Union, a non-profit publisher

of Consumer Reports magazine, and I have no conflict of interest to report.

Consumers' Union strongly urges the FDA to require all television advertisements for prescription drugs to include a toll-free number and a website address for the public to report serious side effects to the agency.

As you are aware, the Food and Drug Administration Amendments Act, passed by Congress last year, requires this for print advertisements. We believe the FDA would benefit greatly if this requirement was extended to include TV advertisements.

By reaching wider audiences to report adverse events, the FDA would get a more comprehensive picture of the possible risks of all medications.

The FDA Commissioner has just announced that the agency will study this issue for two years before making a decision. Two years is too long to study whether the FDA should expand what's already required for

print ads to include TV ads. So, we urge the FDA to try to work to complete this study as soon as possible.

Before drugs enter the market, they have been tested on a relatively small number of people, typically, a few hundred to a few thousand patients. These studies may not include the elderly, children, pregnant women, or those on multiple medications. A study's participants may not be truly representative of the real world when the drug is eventually used.

In the last few years, Consumers' Union has heard from families and individuals across the country, whose lives have been impacted because of a safety problem with a prescription medication that they were not aware of. These families learned that serious side effects may not be fully understood until medication is on the market. Important information about a drug's safety may emerge after millions of people start taking it.

Considering the risks that may emerge after a drug is approved and comes on the market, Consumers' Union believes it is critical that consumers have a simple and understandable way to report serious side effects that they experience to the agency.

Adverse event reports have helped pull dangerous medications off the market, such as the statin drug Baycol. Because of under reporting, MedWatch catches only a small fraction of adverse events. Doctors and patients, those with the most direct experience with side effects, seldom report them. The Institute of Medicine found that in 2004 only 5 percent of adverse event reports that year came from doctors and patients.

We believe one way to improve reporting is to make sure consumers know they can report serious adverse events to the FDA.

A recent poll conducted by the Consumer Reports National Research Center asked consumers if they would know where to

report a serious side effect. Among them, the vast majority, 79 percent, said that they would report their problems to their doctor, followed by a pharmacist at 16 percent. Only 7 percent of that group said that they would file a report with the FDA.

Yet, not surprisingly, Americans are very familiar with drug advertising. 81 percent said that they had seen or heard an advertisement for prescription drugs within the past 30 days. Among them, virtually, all, 98 percent, viewed an ad on television.

Consumers' Union is concerned about the amount of advertising that can accompany a drug when it first reaches the market. Consumers are subjected to so much advertising on television that it's important to include information about reporting serious side effects similar to what is now provided in print ads. And, consumers agree that this information should be required in TV ads.

There is widespread support among

consumers for including MedWatch's number and website in TV ads. In our poll, 87 percent of consumers said TV ads should contain this information, and 90 percent said print ads should do the same.

Consumers' Union recently filed a citizens' petition with the FDA asking that the agency require this information to be in all TV drug ads. We circulated this petition, and almost 56,000 consumers signed on in support.

MedWatch reporting information is already required in print ads, yet, television drug ads run far more frequently. The average TV viewer spends about 100 minutes watching drug ads for every minute spent in a doctor's office. What better way then for consumers to find out about MedWatch than by including this information in TV ads.

Therefore, we urge the FDA to require this information be included in TV ads as soon as possible. You should not wait.

The more information that's available about potentially harmful drug side effects the better the FDA will be able to evaluate risks and inform healthcare professionals and consumers so they, in turn, can make better informed healthcare decisions.

Thank you very much for your time.

CHAIRMAN FISCHOFF: Thank you very much.

Next, I'd like to call Kim Witczak.

MS. WITCZAK: Good morning. My name is Kim Witczak, and I have no -- I'm here as a consumer individual, and I have no conflict of interest.

I'm from Minneapolis, Minnesota, and the reason I'm standing before you today is, five years ago this August I lost my healthy 37-year old husband to an undisclosed side effect of a drug he was on.

What he was given is the drug, teh anti-depressant Zoloft samples from his GP for insomnia. He had just started a new job as

Vice President of Sales with a start-up company and was having trouble sleeping.

Five weeks later he hung himself from the rafters of our garage. He had no history of depression or any other mental illness. His death made no sense, so immediately we started to research the only thing that had changed for him in his short time, and that was Zoloft.

This is my 36th trip out to D.C., after -- since my husband's death. Initially, we fought to get warnings on anti-depressants, but we quickly realized that it was not just anti-depressants, it was all the class of drugs, it was a systemic problem.

So, we started to lobby for stronger drug safety legislation. In fact, last March I was invited to testify before the U.S. Senate Health Committee and tell Woody's story, the lessons it holds, and present ideas on how we can make the drug safety system better in our country.

One of the ideas that I presented was this idea of adding the MedWatch information to all advertising, and, obviously, under the new legislation it did pass and it was put into print ads.

However, I could never understand why it needed to be studied for television. I mean, I often think it was the efforts of some good lobbying by the drug companies and the media companies, we'll give them print, but not TV, because we all know that print runs a lot less than television.

Two days ago, I received a fax from one of the congressional offices that I work with that the Commissioner explained why he needs more time over the six months originally Congress had asked for, and I know that there's, you know, congressional reasons and why it is going to take time to study, however, two years seems like a long time.

And, you know, consumers should get this information. If it is good enough for

print, it seems it should be good enough for television, regardless of the study.

I have spent the last 20 years of my life in my career in advertising, and the main goal of advertising is to promote a product and brand in order to gain market share or sales, which, ultimately, translates to profits for the advertisers.

In the past couple years, I've noticed drug company ads have gotten clever and positioned their advertising as educational in purpose. If that's truly the case, then why not use this as an opportunity to educate the consumer that they have the right to report side effects to the FDA. It's good will.

By the FDA's own admission, you know, only 1 to 10 percent of drug -- adverse drug effects get reported to the FDA. If they are really serious about protecting, it's a great way to hear from the consumers, and encourage the reporting of adverse side

effects.

True, these aren't scientific, and they are not meant to be. Rather, they are part of the whole drug safety equation. Not all serious side effects emerge in the clinical trial, many of them don't show up until millions of them start taking them.

These reports potentially serve as a safety signal that if the FDA sees a pattern emerging it could trigger warnings or additional safety studies.

And, I believe it was the MedWatch system that just recently detected the suicides with the allergy medication, Singular. Just imagine how many people, if the public actually knew that they could report, you'll often wonder if there were more of them.

Last week, Congress held hearings on DTC advertising, and one of the concerns that we heard was that, you know, the concern that people would go to the FDA instead of

going to their doctor. You know, I have to say that this idea is not about replacing that conversation, and besides, I think it's quickly resolved by the person who is either answering the phone or a question on the website that says, have you reported this to your doctor? In my opinion, it's a non-issue.

Yes, there are practical issues that the FDA has to consider. Are they properly equipped with this website? Do they have the proper staff to handle increased volume? Will reports be properly coded? How will they be reviewed? But, I have to wonder, you know, the perception it gives me is, does the FDA really want to know from the public, because once these reports are made to MedWatch they are now subject to be FOIAed by the public, consumer groups and educational groups and institutions can actually discover how long information has been sitting at the FDA, and, you know, what kind of side effects have been reported.

I, actually, think this is a great way, it's another public watch dog opportunity.

It is evident by the 56,000 signatures that signed on to this petition, the American people think the FDA should take further steps to educate us. This is our FDA, and the public deserves to know how to use it. I wish the hundreds, if not thousands, of people who suffered the same side effects that my husband did had known about this valuable tool and would have alerted the FDA into action.

I, wholeheartedly, believe that if this easy solution had existed, warnings would have been placed on anti-depressants years before the FDA finally acted on it in 2004.

The FDA has the authority to do it now, and certainly doesn't need two years to study this event, or this idea. Why is it the FDA is always synonymous with delay? Delays can mean the difference between life and

death.

And, in the meantime, I would encourage you, as you are taking time to do this study, is maybe the FDA or public groups can get together and do a public service announcement, letting the public know that the FDA is collecting information. That would be as good use of the FDA that would not affect the drug advertising.

So, thank you very much, I appreciate you listening to my comments.

CHAIRMAN FISCHOFF: Thank you very much for your input.

And, our third speaker is Peter Pitts.

MR. PITTS: Good morning. My name is Peter Pitts. I'm the President for the Center for Medicine in the Public Interest, Director of Global Healthcare, Manning, Selvage & Lee. I'm a former FDA Associate Commissioner, and I serve as a consultant to this committee, but I'm not here today as a

consultant to the committee, I'm here on my own.

I just wanted to make a couple of comments based on the discussion this morning, and the first is that in many respects the FDA is a victim of its own success. Drugs in this country for so many years have been considered so safe that people consider them entirely safe. The discussion of, the robust and important discussion of risks and benefits is crucial. It's crucial to the FDA. It's crucial, I believe, to the pharmaceutical industry, and most importantly it's crucial to the public health at large, it has to happen, but that does not mean, and I think it's dangerous to allow this to become a roller coaster ride of regulation by anecdote and by politics. It needs to be separate, and I think the conversation today goes a long way towards making that happen.

A couple of thoughts apropos of Amy's presentation this morning. The first

is, we've interchangeably been using the phrases side effects and adverse events, and they are not the same thing. And, when you -- the Center for Medicine in the Public Interest does anecdotal interviews of people, they are completely confused. They think that they are the same thing, and it needs to be clarified.

So, certainly, I think in the research that the FDA is beginning to develop, that concept needs to be thought about in terms of explaining to people what it is they are being asked to identify.

Lacking that, and assuming that a more robust reporting mechanism can be put into place, more information is going to be gathered by the FDA that's going to be of questionable quality, and if early safety signals are going to be based upon that, consequences, I think, will be relatively negative.

Also, yesterday, Professor Andrews, you spoke about the concept of power of

suggestion during some of your comments, as did other of the panel. What role does a super imposer, a spoken number, play on that issue of the power of suggestion and, certainly, in the under-served communities that were discussed yesterday?

Thirdly, the issue of all drugs being alike is certainly not true. Some drugs have different -- all drugs have different risk/benefit analyses, and to assume that all drugs need to have the same types of warning mechanisms may, again, send the wrong signal. So, something I think for the committee to consider, and the FDA to think about, is if the FDA chooses to move forward with some type of an 800 number for television advertising, does it need to be for all television advertisements, should it be relative to what the FDA feels are drugs that have a higher risk/benefit analyses, similar to the REMS plans, also put forward through FDAAA.

Lastly, I would add that the FDA

and the committee might be interested to look at if you wanted to cross over divisions to the Center for Food Safety and Applied Nutrition, the report that they did a couple of years ago called, "The Better Health Through Better Nutrition," where there was a fair degree of research done on consumers' knowledge and use of nutrition facts, what you generally refer to as the food label, and what they take out of it, and what they don't. There's some interesting things, and, while again it's not directly applicable to the situation today, it does kind of lend an ear to the types of research protocols that can be put forward to understand how people use information that's regulated by the FDA for their own benefits.

Thank you.

CHAIRMAN FISCHOFF: Thank you for your comments.

Let's return now to the committee as a whole, just our formal -- just to remind

us that our formal charge was to advise the FDA on how to design this -- how to conduct this study, and then things around it. We were asked, I just want to read this again, "Are you aware of research that is relevant to the task set before us by Congress in Section 906 of the FDA Amendment Act? If so, provide the research or alternatively a bibliography. Does the approach reflected in the material provided seem like a reasonable approach to address the task set before FDA by Congress? In your answer, please advise regarding sampling design and proposed stimuli."

So, I think we've touched extensively on this, as well as some of the other communications responsibilities that are associated with this project, and let me throw the floor up again to additional comments.

John?

DR. PALING: Mr. Chairman, I apologize interrupting you. We all appreciate the time and input of our group. Is it not

our policy to allow time for questions after their presentation? I do not have a question, but I'm just anxious that you didn't overlook the opportunity should a committee member wish to ask them one.

But, whatever is the norm, it just struck me that we normally asked any committee member who might wish to ask a further question. I'm just drawing it to your attention.

DR. ZWANZIGER: If committee members have a few clarifying questions they can ask the open public hearing speakers. It's usually not a time for extended discussion.

MS. LAWSON: I did have a question of Ms. Foley, if she's still here.

You mentioned that in the reports on adverse side effects, I believe from the IOM report that only 5 percent of the reports are going to physicians. Is that correct?

MS. FOLEY: 5 percent of the

reports that they received in 2004 came from physicians and consumers.

MS. LAWSON: And, 75 percent of the reports go to physicians, as opposed to coming to FDA or elsewhere?

MS. FOLEY: Right, 79 percent of the people that were in our poll said that they would first report a serious side effect to their doctor.

MS. LAWSON: To the doctors.

Was there any consideration given to whether you thought there should be some collaboration between physicians and the agency on how to improve reporting across the board?

MS. FOLEY: In terms of in our poll, specifically?

MS. LAWSON: Right.

MS. FOLEY: Well, in asking that question we asked people but didn't give them sort of -- it was unaided, basically, so we asked people if you suffered from a serious

side effect from a medication where would you report it, and we allowed people to give two unaided responses.

So, what we found is that the majority of people that we asked said that they would report a side effect to their doctor, and only 7 percent said that they would report a side effect to the FDA. So, we didn't go further into that, and I actually -- it might help with some of these questions, I have copies of our poll that I could actually give out now if that's okay.

DR. MORRATO: I had just a quick point of clarification. Is it true then, as we think about the design of the study, that until this study is conducted, and there's results that come from it, the decision to put the FDA 1-800 number into DTC advertising won't occur? Is that correct?

So, really, this study becomes a rate limiter piece of information for that decision-making, is that true?

MS. DAVIS: That's correct, because if we want this to be in TV ads after we do the study and we determine whether it's appropriate, we actually have to issue regulations before this can be required in TV ads.

So, we don't have the authority right now to require it in TV ads, we'd have to issue regulations, and Congress has mandated that before we do that we have to first study it. So, it's the study, the issuance of regulations, and then it would be in TV ads.

DR. MORRATO: I just toss it out then that that should be part of the consideration as we look to designing the optimal study, also consider, as was mentioned by one of the public speakers, sort of the public health impact of delay or not, and what's sort of the risk/benefit of optimizing versus not getting something out there.

CHAIRMAN FISCHOFF: Let me thank

John for reminding me about that, I'm getting tired.

Marielos, and then Linda, and then Mona.

MS. VEGA: I want to thank the representatives from the public for speaking today.

As I was listening to them, one of the things that was coming into my mind is that we really need to have a better understanding if the public -- of what the public's understanding is in terms of risk effects and side effects or adverse events.

We have done some work with Hispanic communities in terms of domestic violence and child abuse, and the perception is so different as to what is said in the definition of child abuse and domestic violence in this country. In the Latino community, especially, for immigrants, I'm not talking about Hispanics who are born here, it's okay to punish a child, I mean as to

behavior modification. So, I think when it comes to understanding what an adverse event is, they might not think it's so significant as we do.

I am involved in an initiative that is sponsored by the Robert Wood Johnson Foundation, that is going to be looking at childhood obesity in the Latino community, and one of their research agendas is the development of media literacy classes to help children and to educate them to be better critical viewers of advertisements, to be able to understand what advertisements are presenting to them, and the message is relined to them.

So, I think when it comes to medications, it will be probably nice to do something like that, it's not only about health literacy, but now it's about media literacy, too.

So, thank you again for your presentations.

DR. NEUHAUSER: I also appreciated your presentations, and I thought that Ms. Witczak's suggestion about considering a PSA could be a very good complimentary way to try to address the issue we have been discussing with the small amount of space and time that we have to get across a very important educational message about the safety of drugs.

So, I would suggest that that be considered at some future time, and that the language in that PSA also be tightly linked with whatever language is in our smaller version and the advertisements themselves.

Second, Mr. Pitts' comment about distinguishing between side effects and adverse events, appreciate that, will be sure to keep that in mind.

CHAIRMAN FISCHOFF: Could I ask you to elaborate a little bit, Linda, on what you envision as this PSA?

DR. NEUHAUSER: Well, I'm just sitting here trying to envision it, but I

think it could be, one way a PSA could be done is a very simple message to get across a few more messages than we've talked about here. So, one would be that all drugs, or most drugs, have side effects that can be serious, and I don't know, whatever the messages would be here, but the steps would be, you need to report them to your doctor, we encourage you to report, whether it's side effects of serious side effects, to the FDA using this phone number or this URL. Those messages could also be separately done in Spanish on ethnic media, and in other languages.

I think as an educational campaign, it might be more effective than what's on an individual advertisement, but in any case it would be a good complimentary, hopefully, synergistic communication approach to try to educate the public about this very important issue.

You could combine this with some, I'd say some short video in which you show,

for example, caregivers' concerns about medicine for their children, issues that relate to other vulnerable populations like the elderly. We heard a lot about Medicines Un Ny Home yesterday. Those messages could be incorporated into some short PSAs, taking maybe one issue at a time, always with the subtext that the safety issue is there, and here's what you can do about it, report it to your doctor, and then report it to the FDA.

CHAIRMAN FISCHOFF: Could I fill in here, to pick up on a comment of Elaine's. do you have some estimate, so once a study was done and reported, how long does the regulatory process likely to take?

MS. DAVIS: You're probably looking at another couple years.

CHAIRMAN FISCHOFF: Mona --

DR. NEUHAUSER: And, one further comment, I think we are all sensitive to the issue of timing here, as was brought up by the audience, and that the idea of doing a PSA

does not have to be expensive, probably would be put on free by most stations. I think ethnic media would really appreciate having this kind of information, that that could be something, that could be a powerful way to in the meantime get information out.

And, as I suggested or hypothesized here, it might be a more powerful way to address this issue than, actually, the small amount of information that people would see on any one ad.

DR. DeLaROSA: I have a question and a comment. My first question is, if you did a Public Service Announcement, how long would that take to get started? Could it be done right away? Does it still take --

MS. DAVIS: Well, I think that what we would do is, we would look at some of the people that you heard from yesterday in FDA to see what we can do.

One of the issues is, obviously, signing a partnership to do this messaging,

because we don't have the budget to do some sort of, you know, broad campaign just based on the FDA funds for this kind of outreach, but, you know, I'd have to talk to the people that do that.

But, another thing is, just as this is going to be included in, you know, already it's included in print ads, and we are talking now about including it in television advertisements, I think one interim step would be at least including this information in PSAs that we are working on right now.

Obviously, the ideal is to focus a PSA on this topic, and giving more information, but I think we could certainly explore at least putting this, you know, some kind of information along the lines that we are contemplating for prescription drug advertisements in FDA communications.

MR. DeLaROSA: My other comment is, is that, you know, I've heard a lot about the study, et cetera, and that's what we've been asked to do, but the point about, you know, adverse events versus side effects, and as a practicing physician I deal with phone calls every day, at my office every day. I just called and I had a lot of phone calls, questions leading from Plavix, et cetera, all the cardiovascular drugs.

But, I think it's important to understand that all medicines have adverse events. All medicines have side effects. It's just that some of those side effects is what you want to have happen. And, I think people have to understand that, that that's why it's important to share it, that all drugs are bad, except they have some good side effects, and that's what we use them for.

And, I think, again, this is a comment as a practicing physician, when people come to me and ask for medicine, or ask for

medications, et cetera, but every drug has its good and bad. Every single drug has it, from the diarrhea, to the vomiting, to the upset stomach, to thinning blood so they don't have a heart attack, to bleeding in their eyes. I mean, that's what happens every day, and I think it's important that you do need to distinguish that, because, I mean, it would be every single person would be able to call with a side effect or an adverse event.

And so, I think that's a very important point, and how do you distinguish those two, the side effect and the adverse event.

DR. KHANNA: I have a few comments. The first is, I wanted to address the issue of PSAs.

The Federal Communications Commission has some very stringent regulations and rules for stations, television stations, and they do have an allotment of community service programming that they require for

every television station to air. So, it would not be a difficult task at all to get a Public Service Announcement aired on stations. So, that's kind of a slam dunk one.

The PSA is, of course, developed, created and developed. I've heard time mentioned several times during the sessions, and I think it's important to recognize that while we do want to effectively create something that will take effect as quickly as possible, a time lag sometimes is necessary. This ia very difficult charge, to design a study that is really fraught with interpretation bias and selection bias. I mean, interpretation bias, Dr. DeLaRosa just talked about adverse events of every medication, well, there are some folks in our vulnerable populations that have a higher threshold than others. What may be troublesome to one and be considered, you know, a negative adverse event that affects their daily life functioning, you know, may be

tolerated better by someone else. So, that's the kind of biases that we have to recognize, that we will encounter when doing this type of study, in addition, of course, to the selection bias.

So, while we do want to effectively create something that gets out there as quickly as possible, we need to properly design the study and properly interpret it, and probably make sure it's implemented so that the methods are as stringent as they can be in this type of a study, to get to where we need to go.

I also wanted to conclude with some of the things that we talked about. Video and audio for broadcast ads, both very, very important. Somebody mentioned the time frame, and I personally, as a broadcaster, don't think five seconds is enough. I would like, whether we put on the SUPER the actual website or the phone number, I'd like to see it longer than five seconds if possible.

We also need to take into consideration, as was mentioned, educational levels when designing this study, and always I think first and foremost, since we are talking about broadcasting keep in mind that the demographics of the viewers in broadcasting are very, very different from, perhaps, the study that may have been done to analyze the print MedWatch campaign.

DR. HUNTLEY-FENNER: I, too, wanted to thank the members of the audience and the public for their comments.

There are a couple of things that I wanted to say. We should be cautioned about moving too quickly here, because there is a down side risk if FDA is to maintain a standard of credibility based on a scientific approach to the establishment of public policy. We are going to want to be sure that we are at least careful in meeting the very basic scientific standards that we are -- that we purport to uphold.

I would say that I do take to heart the life and death impact of early detection, and the importance of dealing with those issues in effective and expeditious -- as expeditious a manner as possible. So, I'm mindful of both sides of this question.

I wanted to just add a comment here, that both yesterday and today an emerging theme with respect to the impact of direct-to-consumer advertising is what -- the question is about what happens in the doctor's office.

We heard yesterday that there are difference among demographic groups with respect to how frequently they come to doctors with -- because of something they saw in an ad, or whether they actually request a prescription, and, furthermore, whether a prescription, once requested, is granted. And, I think that that's an important question that we ought to be thinking about, and I know it doesn't fall within the purview of the

particular issue we are looking at today, but I want to put it before the committee as an important question.

And, on the flip side, today we also heard the implication, I think, that there is a disconnect between the rate of reporting of events into doctors and the rate of doctors reporting to the FDA. I don't necessarily think that that case has been made. I mean, I haven't looked at the data, it would be very interesting to look at what the support is for that argument, but given that implication I think we do need to ask the question, why is it the case that, potentially, our most trusted source, which would be the physicians who know their patients, who understand the drugs, who understand the relationship between the patients and the medications that they are taking, and who monitor patients more closely than any of us could certainly from this vantage point, why is it there might be such a

disconnect. And, it will be important to understand the impact of direct-to-consumer advertising on that conversation that happens within the doctor's office.

DR. GOLDSTEIN: Yes, I, too, want to thank the folks who made the public comments, particularly, the person who shared her loss of her husband, such a tragic event.

And, I, too, want to endorse the idea of FDA considering a Public Service Announcement, and I was impressed yesterday with all you are doing, including Medicines In My Home, which is, potentially, another vehicle for getting out the message about reporting these kinds of events.

And, actually, looking at the drug label itself on all the elements that are in the drug facts label, there isn't a mention of the MedWatch number. That might be another consideration, to really drive those who are using the drug, who are using the label, hopefully, turning to the label when they are

concerned about what's happening, to have that number right there, so that they can report it.

I also want to endorse the idea, and this is another, perhaps, topic for us to consider as a committee, how we can work with clinicians to help them to report these events more expeditiously, and to provide mechanisms for them to do this in an effective way.

We can throw out ideas. With teh advent of electronic medical records, with prescribing that is occurring electronically, there is a way, potentially, to build in easier ways for clinicians to report when there is an adverse event, or even to have surveillance at the pharmacy, so that when medications aren't being refilled there could be a trigger for identifying the reasons, and having that information gathered in that way.

So, I think there's a lot that can be done to enhance the frequency, the quality of the reporting that's done, and there are

some mechanisms that you've already identified for communicating with the public to get to use those in your other efforts.

And, obviously, that's not the question that's specifically being asked of us today, but since we are having this other conversation I think it raises these additional points for future consideration.

CHAIRMAN FISCHOFF: Nancy had a comment to the previous one, and I didn't catch her.

DR. NEUHAUSER: It's really more of a clarification. I don't have the specific numbers, but I think it's important to recognize that what many healthcare providers undoubtedly do is, they don't report directly to FDA if there's an adverse event, but they do report to the manufacturer. And, in fact, most of the reports that come in to the FDA come from the manufacturers, when the manufacturers get these reports they are required to submit them.

If it's a serious, an especially serious report, there's actually a 15-day reporting time frame under which they have to send these to FDA, and for others that are not considered, you know, under this category, there is a different time frame, and then there's annual reports that the manufacturers also have to put in.

So, at this point in time, most of the reports that the agency is getting from healthcare providers are coming through the manufacturers, which is not to say that we are not looking, you know, to increase the number that's coming in directly, I just wanted to clarify that so people were aware that that is happening as well, and has been happening for a long time.

DR. DeLaROSA: I'll make a comment to that also, and something also to think about in your study.

The question was asked, is why don't physicians or healthcare providers, the

most trusted people, contact the FDA sooner? And, I think it's important to understand that people that we are dealing with are older Americans, older people, and it is very unique and uncommon to be a mono medication. But, most people are poly, and most people are on six, and seven, and eight medications, and these have all been placed by other physicians.

So, to say that one drug is causing a problem, it's very difficult to pinpoint one. So, I think that's one of the reasons that, you know, I've never called the FDA, because there's too many medications to choose from. And, I think that is an issue to think about in doing this about risk, et cetera, is it really that drug that caused the problem, or is it the other drugs interacting with it? So, that's something to take into account, that there, again, these people we are looking at are poly med people.

DR. HUNTLEY-FENNER: It's hard for

a physician, let alone for someone who hasn't been trained. I mean, the attribution of the symptom, the side effect, I mean, it's a fundamental problem, and partly why you need to have either an informed, knowledgeable input person or somebody receiving the input who can ask the right questions to try to get at those issues.

CHAIRMAN FISCHOFF: Madeline, Elaine, Betsy and Musa.

MS. LAWSON: I think we all agree that we want to have well-informed consumers, and as we look at what appears to be the long-term plan, which is the toll-free number for TV ads, I think we should, as I've heard others mention, a short-term plan, which would be the PSAs.

And, I would suggest that within FDA, within each of the offices that we heard from yesterday that has such extraordinary campaigns, educational campaigns, that we look at how the agency could team up with the

National Medical Association or the American Medical -- and/or the American Medical Association, to develop PSAs that could be aired much sooner. And, I think this would be a great way to get the message to our consumers, while you are currently pursuing the long-term plan, which is the toll-free number.

CHAIRMAN FISCHOFF: Thank you.

So, Elaine, Betsy, Ellen and Musa, and Linda.

DR. MORRATO: I agree with what Ms. Lawson just said, and I just wanted to make sure that the committee was aware that there's an ongoing campaign that's sponsored by AHRQQ and also in joint with the Ad Council, that's been running, I've noticed it in Newsweek at least for the last year, so I don't know where it stands right now, but the campaign is geared towards getting patients to have discussions with their doctor. So, you see an ad that says, "Want better healthcare? Start

asking more questions to your doctor, to your pharmacist, to your nurse." And, they include, specifically, not only what are your test results, but what about side effects, don't fully understand your prescriptions, don't leave confused, and they have contact information with ten questions you should be asking as part of your doctor interface or appointment.

So, it would seem to me that there would be a natural way to piggyback onto that, or to at least develop some sort of synergy there. They are already focused on side effects. They are already focused on having that discussion with your physician. What have they learned as part of that campaign would be one question, and is there opportunity to provide the 1-800 line on the top ten questions, or some information that could link them back to FDA information, as a way to help with that education.

So, that was one comment, but the

other piece I wanted to add on to what Gavin and Dr. DeLaRosa were saying about the issue around poly pharmacy and, therefore, might that be contributing to a screening effect or filtering effect of what you really should call in.

The other piece, just to mention into that, is this notion of expected versus unexpected adverse events. So, on the drug labeling, there is a listing of adverse events that are known, and I would imagine that what you are trying to capture is not people calling in with all of the known adverse events that are just contributing to that, but you are really trying to get at the serious or the unexpected, et cetera.

And so, whether that's the point, as you are saying Gavin, the filtering of what -- trying to suggest what should be reported, or whether it's a way that you are differentiating that interface with the call coming in from a consumer or not, you know, I

know that's a tough piece in clinical trials, is trying to make that attribution and how do you analyze it. It's a conversation you can have with the physician reporting it. It may be a much more difficult conversation to have with the consumer reporting that information.

Thanks.

DR. SLEATH: I just have a basic question, being a healthcare professional, and thinking about health care professionals and how busy they are, and are they really going to have the phone numbers of all the manufacturers at their fingertips to call them versus calling the FDA.

One basic question I have, and then I have some follow-up points, is how long does it take when you call this 800 number to make a report, because that's a pharmacist that would affect whether they are going to call or not.

So, could someone just, I don't know if other panel members would like to know

this, too, but I would just like a sense of how long does it take, what are you asked, would you rather have doctors call you, then call the manufacturers, because I truly don't believe we are doing enough educating physicians or pharmacists about this program.

So, one idea I had was like the Medicines in the Home and the whole educational campaigns, maybe you need to develop educational campaigns for the physicians and the pharmacists that people like me that teach in health profession schools could use.

But, if you could comment on that, how long does it take to make a report?

DR. OSTROVE: I can't tell you that. I honestly just don't know. I don't know whether there's anyone from FDA in the audience who has that information. I know we have some people here from CDRS, OTCOM and the Drug Information Group, but I'm not even sure whether they, specifically, have that

information.

I can tell you that I know that there is an outreach effort going on with health professional organizations that is coming from our Office of Special Health Issues, and I can put you in touch with the people there, and I can get you this information as well. I just do not have it at my fingertips.

DR. SLEATH: Yes, I just think that's important, because once you start this campaign, you know, and also being a consumer, I have a busy life, and if I'm on hold for, you know, ten minutes I'm most likely going to hang up and not report it.

So, I just think that's really important to figure out all that before you embark on giving out the 800 number.

DR. OSTROVE: Yes, that's more than a fair point, that's a very good point, and I think it goes along with some of the other things that we've been hearing as well, and

it's not just how long would you be on the phone, but if you go to the website we've certainly gotten some feedback that -- and we are working on improving the interface that we have for MedWatch reporting on the website. That is currently in progress.

So, you know, I can't say anymore than that, because it's all internal, but it is -- it's an active area of work at this particular time.

DR. PETERS: On the issue of a speedy PSA, or speedier than the four-year process it sounds like the TV ad change might take. I'd encourage you to think about what the -- I generally like the idea, but I encourage you to think about what the purpose of purposes of it are.

One purpose is what Musa brought up earlier, that it's a message out to consumers that side effects exist and you should go to talk to your doctor, or your pharmacist, or your -- whichever healthcare provider you see

as fit.

And, in that case I think the PSA is a great idea, and it's a great message to get out there that, perhaps, isn't out there enough.

But, the second purpose, which is really what MedWatch is designed for, I think, is that it's information to be communicated then back out to the public and to healthcare providers about as an early signal of side effects or adverse events that may occur that didn't show up in the original clinical testing.

At that point, you need to balance speed with science. The speediness is great for the first purpose, but maybe not so great for the second purpose, because then we need to go back and bring up some of the issues that Dr. Huntley-Fenner brought up earlier, the idea that you need to think about how to communicate to consumers what you want from them, because you need to be able to improve,

you want to get as good a signal as you can get, because you are going to have noise there.

And, I would suggest that you not only have to think about how to communicate that, but you really should test that. I mean, there's some testing that has to happen here, I think, in order to be sure that you are getting the best signal.

You want to understand the effects of this new source of reporting on the signal to noise ratio that Dr. Huntley-Fenner brought up earlier, you know, there are issues involved here if you are really going to use this data as a communication tool later on that you should understand earlier rather than wait and see what happens.

CHAIRMAN FISCHOFF: I guess that's one way of thinking about that procedurally, is that in the Amendment Act it's clear that the Congress is concerned about communication from consumers, as well as communication to

consumers, and so the systematic processing of the signal that we are giving them ought to be within the brief of the committee.

MS. MAYER: I'm concerned that in our careful review of all of the potential elements of this study that we don't unwittingly extend even beyond the two-year period the time that it would take to design a study, to complete a study.

You know, sometimes when a study is mandated by Congress it's for legitimate reasons, and sometimes one has to suspect that it's a delaying tactic so that no action will be taken, or, you know, years will elapse before action is taken.

And, I'm not sure what we, as a committee, could possibly do to address that, but I feel like it just needs to be said, perhaps, and I appreciate the people who spoke at the open public hearing making that -- or not that specific point, but talking about the timely nature of this.

My other point really has to do with our process as a committee. It's clear to me from a lot of the discussion today that we really could have benefitted from some background presentation on the MedWatch program, and on the MedWatch program in the larger context of adverse event reporting, and how that's being approached, and what's planned, what the agency sees as shortcomings and directions that it might take, because I don't think we were given -- obviously, we are intellectually curious and thoughtful people, though I know we were instructed only to discuss this issue, it's clear to me that every time a very specific question is brought before us we are going to want to have the larger context, and we are going to want to talk about that.

So, I would just encourage you to think about presenting the context to us in the future.

DR. NEUHAUSER: And, along those

same lines, in response to Dr. Peters' question about what are the purposes of this PSA we are talking about, I'd say -- I would respond that one purpose that would go to the broader mission of this committee would be to put a more human face on the FDA, and a very specific face. We heard yesterday from Dr. Ostrove that under consideration is the idea of identifying an FDA spokesperson that might be the Commissioner, for example.

So, one thing I would suggest be considered is that a PSA could feature, for example, the Commissioner talking about what FDA does, talking about the issue of drug safety, just a lot of things that people brought up here, that drugs are tested, and they get approval, but there are many things we still don't know about them, and we need input from the public to help understand adverse events and so forth.

So, I think having a PSA, where it would show, let's say, continuously, you'd

really get -- you would get to the challenge that we talked about in the February meeting of having a human face, understanding that the FDA's mission is to protect the public, and understanding that this is a two-way process with, you know, the help from the agency and the input from the public.

DR. GOLDSTEIN: And, to follow up on that even a little more, and also to pick up on what Ms. Mayer said about the process, this is one specific study that you asked us to review. And, we got lots of good input, and now we've brought in the conversation and the recommendations to look at how to address this important issue of detecting serious adverse events when they are happening in a community.

But, what I'm hearing from others, and I think would be valuable for us to consider in the future, is not just an individual event like a study, but a process, helping FDA to come up with a process for

improving the way in which they study the impact of any intervention that they make to try and improve risk communication. So that, it's not so much what you do with this study, but what you do after you choose the mechanism for testing the ad, or launching a PSA, and how you gather subsequent information, so that you can inform the next round of studies, the next round of Public Service Announcements, the next round of interventions to enhance the outcomes you are looking for.

So, I think we should consider as a committee ways that we can help FDA to put into place an iterative process of designing, developing, and testing, and then going back and doing it again, so that you have internally a capacity to improve the quality of the research that you are doing in this area.

CHAIRMAN FISCHOFF: I think that that would also fit with Musa's point that this needs to be integrated, we should draw on

other skills within FDA and feed those activities.

Cheryl?

DR. HOLT: Thank you.

There's been a lot of talk about a PSA, and I think that's a very good idea, and something that should be done. Probably not the only thing that could be done, or should be done, and I know we are widening the scope of our original intent to look at the study design, but our experience with PSAs, and maybe others have also tried to get them run, is that television stations are often bombarded with a lot of PSAs. They are often run at, you know, odd hours, of course, and what we found is that when we circulated our PSA to the local television stations it often needed a lot of prompting and following up, and still not necessarily -- didn't necessarily get the air time that we would have hoped for.

Definitely worth doing, but not

necessarily a whole lot of bang for a buck either. So, some strength, there's also some limitations of what happens when you try to get PSAs run, because, you know, unless you have money to get air time it is the S part.

DR. DeLaROSA: One comment from -- back to Dr. Holt, I think we heard yesterday some ingenious people and some passionate people that are working for the FDA that you had a group that's running, basically, a million dollar campaign, a multi-million dollar campaign on $40,000. And, I think that they are ingenuous. I hope they'd be ingenious enough that they'd be able to piggyback a PSA with some of these companies as far as good nature, et cetera.

So, an idea also to throw out, I think it was Ellen yesterday that was saying that.

DR. HUNTLEY-FENNER: Also, it might be, I don't know if easier is quite the right word, but maybe more efficient, if you are

working with a national market as opposed to, I don't know how many dozens of local markets, you might have some more success and a broader reach that way.

MS. LAWSON: Of course, that's why, I guess, another reason I suggested a partnership with the National Medical Association, American Medical Association, because many of their members, as you all know, have relationships in the communities around the country, relationships with the national and local media, and that certainly would enhance the outreach with the PSAs, to get the message both on TV and radio. And, I think that's very important to do.

DR. MORRATO: I had wanted to get back to Dr. Sleath's point earlier, around education of knowing how to report, or is there information on that. I had meant to include that I know MedWatch has developed sort of educational training modules that you can have on line, and they are supposed to be

geared towards schools of pharmacy, schools of medicine, to try and educate incoming new healthcare providers as to what MedWatch is and how to do reporting.

So, as you think of a larger campaign that you are mentioning, and how all these pieces fit together in risk communication and education, you know, there may be building blocks that we heard yesterday that were a lot of the activities, there may be other building blocks in other areas that could be put together to think in a larger framework that may already exist.

MS. MAYER: During the break, I was talking with a member of the audience who made the suggestion to me that, perhaps, the industry, the pharmaceutical companies, might be willing to actually fund some sort of Public Service Announcement, and, perhaps, I mean, now, this is not something he suggested, but I'm thinking, especially in light of all the recent safety issues this would really be

a sort of good faith, could be a good faith effort that could be done by a whole consortium, to actually buy air time and give this kind of message the prominence that we would like to see it given.

I sort of doubt that PSAs done in the usual manner, that we've been talking about, would really get much attention, or get much air time. I think we might have better luck with the advertising expertise of the industry, to do such a thing.

DR. ANDREWS: I agree with all of what's been said here.

Something that's important in the marketing field, and some of you may know this, integrated marketing communication efforts, and I'm sure the industry knows this, where you've got multiple ways of reaching different target markets.

So, all of these could be included, it's not just to be one PSA. So, in general, you are looking at sales promotion, event

marketing, sponsorships, in-store presence, you know, in addition to advertising, but the key is to have a single theme, a single take-away on the adverse events, side effects, single voice so to speak, and for all that to be coordinated.

So, all these ideas are great, but I think trying to coordinate that with a single theme, including internet presence if possible, and I agree there's not a lot of money out there, but certainly the folks yesterday were very creative in trying to do some of those sort of things.

DR. NEUHAUSER: One further thought about this time gap between, perhaps, doing a PSA and the longer time it will take to do a study, I would think that, perhaps, it might be necessary to start with the PSA to build awareness, so that whatever is communicated in the ads people have some context to understand what this is about. If they've never heard, necessarily, of the FDA in this kind of role,

they might need to be told that this is something new that the FDA is doing.

Perhaps, even say in a year announce that pretty soon you'll be seeing something on ads. You may not have noticed this before, but this is important for you to understand about the safety of the medications you take, here's what this means, here's what you should do, so that like many advertising campaigns you build awareness, you build credibility with the public face, and then people are alerted to what's coming in teh ad, rather than just maybe ignoring it, being distracted by it, all the other things that we are concerned about.

MS. DAVIS: I have to thank you all again. I think I've heard more than I could have ever hoped for, so thank you again for all your time and all your -- no, I mean that in a very good way, I really appreciate all the input.

My brain is, you know, spinning

through everything that you've given us today to think about, and I think we have a lot to go back and discuss with other people from the agency, too, to see what we can do to follow through on some of your recommendations, and then thank you again for all your comments earlier, too, on the study and the design.

So, I think that's all we could have asked for.

Thank you.

CHAIRMAN FISCHOFF: Okay, thank you very much.

So, let me just say -- I think we've kind of sort of moved kind of naturally in the last discussion to pulling together some themes of how we are advising FDA strategically, as well as tactically, if you will. Here's a very specific problem, we've tried to give input. We've seen how this has been embedded, we are sort of learning how FDA works and what its constraints and opportunities are.

So, let me throw the discussion open to anything, yet more input for Kristin, but also any good general discussion about advice for FDA, or ways that we should structure our future meetings.

I think Mike had something, and then Marielos.

DR. GOLDSTEIN: Just to pick up on what Dr. Morrato said earlier about linkages with AHRQ, and a spokesperson that has a face being an important part of the message delivery.

Carolyn Clancy, who is the Director, now goes around to major medical meetings, American Academy of Family Physicians, American College of Physicians, and shows the video that you mentioned about communication, and it includes these other messages about sharing information about adverse events, and it's part of their patient safety initiative. It's their major focus, priority, along with preparedness as well.

So, there's a real opportunity to make linkages there and to work collaboratively to develop ways to at least reach the provider community in an effective way.

So, I just want to endorse that, and we should probably have a session that focuses more specifically on how we can engage the provider community and helping them to focus and encourage risk communication in the context of the work that they do regularly, so that the issues that we've heard about from the clinicians around the table can better be addressed as a future topic.

MS. VEGA: I have a question. Is the current FDA website a new website? Is the current FDA website a new website?

DR. OSTROVE: The FDA website has evolved. It depends on how you -- I don't want to sound like ex-President Clinton, it depends on how you define new. It's been around for a long time, and it's evolved in

kind of a fragmented way, because the -- as I think we kind of talked about the last time that we met, you know, we had these separate centers that focus on different products, so if you look at our website you'll see that there is no common look and feel, because each one of the centers kind of evolved its own website kind of on its own.

Now, that has been changing and we have a centralized group now and a process in place for integrating and trying to make sure that eventually we end up with a site that is more user friendly and navigable, and I think the last time around I showed you kind of a draft of what then about a week or so later became our new home page. So, that's new.

MS. VEGA: Okay, that was actually my question there, about the home page.

DR. OSTROVE: Okay, yes, the home page is new, sorry.

MS. VEGA: Well, because I went to the home page, and I was looking for the link

to the Spanish information, and most of the -- like the NCI, the CDC, the NIH, and all major organizations, have the link up in the upper-right corner, and it's very easy to locate it next to the -- if you have to go back next to the English site.

But, in the FDA website, in the front page, it's in the lower left side. It took me a while to find it.

And, one of the things that is very interesting about the CDC and other organizations, NIH, is then once you try to leave the website there will be a question, a consumer satisfaction survey, and actually when I went to the Spanish links, actually, the survey is in Spanish.

So, I think that would be maybe interesting, in terms for the future for the FDA to see what is the satisfaction, in terms of the public accessing the website, but I think it's very important to move that link for the Spanish information to the upper right

corner, because that's where most people tend to look for it, because most websites have it.

DR. OSTROVE: Well, I appreciate that, and I will -- I'll bring that comment back to our web staff people, but there's two things, I guess, I would want to note. One is that I know that they did extensive useability testing before they launched that. I don't know whether they looked at that specifically, but if they have data that indicates that, you know, people are getting it, then I think that they will go with the evidence basis.

However, the point that you make about, you know, in other sites it's in another place so people may be used to it makes me think maybe they didn't look at that specifically.

So, as I said, I will bring that back.

Your second point about customer satisfaction is something that we are working on now.

CHAIRMAN FISCHOFF: We have the room until 2:30, and we haven't finished the snacks.

Last call?

DR. DeLaROSA: I think we'll hear it again, just like our last meeting, and again, a single voice, a single message, to have a face, a spokesperson, et cetera, it's been echoed, and again, you know, Nancy told us yesterday they are in discussion about that, but I think it's very important, again, a single voice, a single message.

DR. NEUHAUSER: And, I wanted to thank Dr. DeLaRosa for bringing that idea up at our last meeting, really appreciate it.

So, one comment about -- and a further comment about that, I think we have a huge gap in our society for having a public face on public health. I'm not just talking about the FDA, but the FDA could have a major leadership role here in providing something that all Americans need, which is a person who

speaks to them about really, really important health issues.

And, if a PSA were done, other things, and the face of, say, the Commissioner were out there, when an emergency issue comes up, issue of Heparin, spinach, whatever, that person would become a recognizable figure and a believable figure, and I think it would serve many of the purposes that we've talked about in general.

A further comment about the website. I am wondering what kind of people are doing the useability testing. In my experience, when I look into the way websites have been useability tested, and often they are not, so I applaud the FDA for doing this, but often the people selected are the easier people to find, those with a higher education and so forth.

So, I think it would be important, now that the digital divide is narrowed so much that we have people of lower education

using it, that we make sure that those people with lower health literacy are in on the testing.

And, unfortunately, the DHHS useability guidelines do not include very specific guidance about low literacy -- navigation for people who have low literacy. There are ways to do that, and I would suggest that at some point we look at that a little more specifically, some of those navigation issues for lower literate people.

CHAIRMAN FISCHOFF: Well, you're one last chance. The clock is ticking.

Let me just -- while people are thinking if they have one more thing to say. Let me just thank the staff, or the support staff, who has brought us here and made all the technical arrangements work. Let me thank Nancy and Lee for just doing an incredible job of setting up the agenda, getting people here, finding this excellent group of consultants, and I think we see the tip of the iceberg of

the work that they put in.

Let me thank the FDA staff who made the presentations today, who have come to listen to our pearls of wisdom through yesterday and today.

So, maybe just a little round of applause for them.

(Applause.)

CHAIRMAN FISCHOFF: Okay, well, let me thank you all for coming, and we'll see everybody in August, and maybe a conference call before then.

(Whereupon, the above-entitled matter was concluded at 11:49 a.m.)