I concur that it's amazing what the FDA is doing with limited resources.

The one point that was made this morning I want to make sure we don't forget is that the speaker talked about that the speed in which risks are presented is almost twice the speed at which benefits are presented and that this affects comprehension, and I think that this is important and needs to be studied to see that if you slowed down the presentation of risks, does that increase comprehension.

But then I was sitting here and had an even larger thought because we've kind of just been focusing on direct to consumer ads and pros and cons, is we don't necessarily know whether consumers are getting this information in their visits with their doctors and what they're comprehending, and are risks being presented and how fast are they presented in relation to benefits?

Because in my own research, we've

often found there's not a lot of time spent on medication. So I think we almost need to think of the research and even a larger framework of what are people getting from direct-to-consumer ads, what are they getting from their physicians, and then also what are they getting from these leaflets that they get in pharmacies?

I know that Nancy and others at the FDA are currently conducting a study looking at how benefits, risks, et cetera, are presented in these leaflets. I know for the past few weeks I've actually been reviewing some of them, and I hope our Committee will some day actually look at the results of that study because it's very sad to me that this information is still -- at least people are getting information, but it is presented in such a complicated, tiny font size. How can the public understand it?

And I think that those leaflets have the potential to help whatever is being

conveyed in direct-to-consumer advertisement, to reinforce messages. So I think this is more than just direct-to-consumer advertising, but what's happening in the system.

And then I'd echo what Michael said about research, that the agency, AHRQ, has these certs across the country that focus on medications in certain areas whether it's pediatrics, whether it's non-steroidals, et cetera, and they could do research probably at a relatively fast turnaround, and I would suggest putting out requests for applications in collaboration with AHRQ or NIH on topics, and maybe the Committee can help come up with topics that we would like to see studied because that has the potential to be constructive.

And then the last comment about special populations is the Latino population. We haven't talked about this, and we're currently doing some work in North Carolina, but they tend to buy medicines at these

markets where they're buying food, and then the problem is that's often regulated by the Department of Agriculture, not the same people that regulate pharmacies.

But I think that's a potential public service area that we need to think about because oftentimes they're buying medicines that were imported from their home countries, and there's potential for dangers because especially it's the use of -- they're purchasing antibiotics, pain killers, and other things. That's just an important area that I hope we consider for underserved populations.

DR. PETERS: I just wanted to make a quick follow-up to something Betsy said from AHRQ. AHRQ also has the Eisenberg Center for Communication that's set up to take the results from the different comparative effectiveness reviews and come up with products tested, empirically tested products to communicate that, the results of those

evidence based reviews out to patients, physicians and policy makers.

And it's another possible opportunity for a collaboration between FDA and AHRQ because these people are basically set up to be doing research around communications, around evidence based medicine.

CHAIRMAN FISCHHOFF: While people are recharging, I have a suggestion for FDA to consider, which is we're talking about evaluation and evaluation is expensive. You have to recruit your subjects, you have to expose it. You have to analyze the data. It seems to me that all the things that FDA reviews are tested. They're developed by industry. There's extensive testing. A lot of the testing is for things that are probably not of interest to FDA, some of them may be none of FDA's business. They're proprietary information on sales.

But it strikes me that it might be

possible for FDA to add some -- I don't know -- items to the evaluation protocol that could be collected at that time and submitted to FDA along with the ads that are being submitted for pre-review. Then submit the evaluation on the issues that are of concern for FDA.

The additional cost would be trivial. If it were a general procedure, you could, you know, battle with OMB once under the Paperwork Reduction Act and get, you know, one time approval for this protocol of forcing people to collect new data; that the people who do this work for industry, they're very good, and if you said, "Here's what we're looking for," and they saw it's not testing up so well, people aren't understanding the risks or they're exaggerating the benefits or the other way around, then they're very likely to redesign their communications because they want to do the right thing and they don't want any trouble. So it would give you a performance standard that they could deal

with.

And if I were the project manager of something, I'd much rather have a fixed standard of saying this is what FDA is going to judge me by rather than trying to predict who is going to be on the committee or, you know, overworked civil servant who's going to be looking at my product.

So it might be really a relatively cost free way of putting people on the same page. You'd want to think real hard about that, about what was in that consortium or what was in that evaluation, you know, but it could be work that would have a lot of, you know, leverage.

DR. BRUHN: You know, I think that's very clever because putting the expense on the group that is creating it because they're the ones who's creating the ad. I hate to say I'm a little concerned about we lose transparency, and this is proprietary work. I mean, I'm sure they have evaluated

the effectiveness of their ads. We found there was very little data.

I bet that companies know how effective their ads are, and they know who they're reaching and who they're not reaching and they've decided on their target audience, and they're doing it the way that it works.

But as we know, advertisements are a great deal of promotion and puffery, and all of that information is proprietary. So the idea of putting some of the burden on the industry, I think, is positive, but if FDA wants to be sure, they are under public scrutiny. Then the results of the effectiveness and the impact of this communication must also be under public scrutiny.

So you've got to maintain the transparency and the objectivity that we are seeking, and I know you would agree with that, too, but I just wanted to add that as a caveat, that whatever method is used, that

aspect must be maintained.

CHAIRMAN FISCHHOFF: And my thinking was that there are -- you know, I think of the communication as being part of the product, and there's a set of procedures under PDUFA and so on for insuring the transparency and always someone could write in, you know, some routine or randomly selected third party validation, repetition of the evaluation.

So I agree entirely, and I think, again, without a lot of expense, I think one could add that as well.

MS. VEGA: I just had a comment regarding what Dr. Paling said about the children, and I don't think he's so far off. The National Academy of Family Physicians had this campaign, and it's kind of in alignment with this campaign that has a curriculum for children in school, but the campaign is about smoking cessation. It's called Tar Wars, and they have a curriculum. It's both in English

and in Spanish, and each state has a state Academy of Family Physicians. So each state runs that program.

And what they do is the physicians volunteer their time or they use medical students or nursing students to go out and teach the curriculum in the schools and they have a pre- and post-test evaluation of what the children have learned.

But they go a little beyond that, and what they do is there is a poster contest and the children draw posters in terms of what they have learned about tobacco, smoking cessation, and a big focus of the curriculum and advertisement from the tobacco companies about cigarettes to children. So often there is no regulation for that.

So the children draw the posters on what they have learned on why they think it's so important to stop smoking, and they have a national conference, and there is a winner from each state that comes to Washington. The

conference is always in Washington, and the children who had won go to meet their Senators. They take them to maybe the Senators from each of their states.

And the kids become the ambassadors for that campaign, and they use the posters for publicity, and also there has been a study and there are some peer reviewed publications that have come out of that campaign.

So it is possible, and I think you were right on target when it comes to the children.

DR. REISS: I just want to make one additional comment. Then I apologize to everyone. I'll have to leave.

But within the context of talking about collaboration and having industry be involved in this process, which I think it obviously should be and it has the same goals as everybody, and that's to as best we can increase public health.

The other group to think about

collaboration with is PhRMA. We haven't really talked about that at all today. I think there is going to be some leadership change within PhRMA in the near future, and I think these questions that we've been talking about today are going to be on their agenda, at least what I hear. I don't know that for certain, but I think it's going to be, and I think that's another avenue for the agency as part of this collaborative effort that we were talking about.

MS. GREENBERG: Yes. I'm going to have to excuse myself a little bit early, too, and I apologize for that, but I'm going to sort of jump on the bandwagon in terms of industry and their perspective because I think a number of us inherently understand that industry knows a whole lot about communicating to a number of these communities and has really, really good marketing data.

And one of the things that I've come to appreciate in my new role as the head

of the National Consumers League is this partnership where you have government, consumer groups, and industry sort of working together where there's kind of a wall between the industry control and content, but you have industry support for various messages, and you've got government and consumer groups in our case getting information out to the public, and I think it's a very potent formula for communicating because as we've seen from these FDA presentations, there's a whole lot of stuff going on to get to hard to reach communities. They really have a lot of expertise, have been doing it for a long time, and we know industry has a huge amount of data that we may not be privy to here for proprietary reasons, but to not take advantage of that, as my colleague here have suggested is kind of silly.

I know there's a trustworthy or concern about industry influencing content, et cetera, but I think there's a way to use

industry's expertise and sort of say, now, you know, give us your expertise and back off in terms of content and getting out.

The National Consumers League works really closely with FDA on a number of these programs, and we do so at times with industry support, but without having industry influencing the actual content.

I think FDA has got very strict rules on that as well, and that's very helpful, and the National Consumers League has also very strict rules on being able to control the content once we have a grant or whatever. So I'm going to put in a pitch for that. We should use everybody who has got all of this information and expertise around the table. It would be a shame not to take advantage of that.

Thank you.

DR. BRUHN: An inspiring comment there, Sally. Thank you.

Are you thinking perhaps of a drug

related partnership like Fight BAC is for food safety? I mean that's a classic partnership. You've got the industry. You've got the health groups. You've got FDA. You've got USDA, and they have pulled together not only an educational campaign, but I think don't they even sponsor some research sometimes?

I know the results of some of the educational materials. The results of some of the research have gone in to developing and validating some of the educational materials. So one might not need to go that far, but when you mention partnership, that just popped to me.

MS. GREENBERG: Yes, I'm not familiar with the specifics of that program, but that sounds like from what you said the formula I'm thinking about.

DR. BRUHN: When you go home and you get your computer, just put in Google "Fight BAC," capital B-A-C, and you'll see a whole bunch of materials for health educators

as well as for the public and teachers and everything.

DR. HUNTLEY-FENNER: I just wanted to echo a point, I think from very early this morning about information seeking, and tie that to the notion that there is clearly a massive disparity in the capacity that's available to the FDA relative to the -- I don't know -- $5 billion or so that was spent last year on marketing direct to consumers.

In particular, it seems to me that educating, working with young people is actually a very critical piece of this. And as we think about that, I think we'll want to think about literacy probably more broadly than we have been thinking about it. It's not just a matter of parsing text. There's elements of visual literacy. There's an element of health literacy as well.

And when we're introducing -- as a person that's involved in education, I know how difficult it is to introduce new programs

into the schools. We can rely on nursing students or public health officials, but really to be most effective, given the large number of educational institutions that are involved K-12 are going to want to increase the uptake within school systems, and they're tying programs to existing curriculum and being very careful about making that work for school districts that are looking to provide new programs for kids as an important piece of the puzzle as well.

So DARE is an interesting case. I think that DARE has the infrastructure. It's an interesting case from the point of view of a partner. They have an infrastructure that is in place in lots of different schools, but effectiveness is a question.

I do think that at some level it's beyond the purview of this Committee. At some level we ought to be thinking about whether those funds are better spent looking at health issues written more broadly, and I certainly

think that that's something we ought to be pushing for.

Finally, I don't want us to let go of the fact that self-medication is a concern within school settings. You have students who are under a great deal of stress. You have students who suffer from depression, and to some degree the availability of pharmaceuticals in that environment lends itself naturally to all kinds of abuse.

I know we have cases of children sharing prescription drugs when they shouldn't be on an experimental basis, but I think partly what's going on is children are looking for something to help them manage what it is that they're experiencing.

And so we'll want to tie whatever curricula we come up with to mental health and how students are dealing with mental health in school environments.

DR. GOLDSTEIN: Dr. Sleath's comments triggered some thoughts because I

agree the need for clinicians to have some help in having effective conversations with their patients about the medications and the other interventions that they're using, it made me think of another potential way of reaching those in most need, the most vulnerable populations.

The community health centers, the Bureau of Primary Health Care supports the health disparities collaboratives, they call them. This is a massive Public Health Service, Bureau of Primary Health Care effort to reduce disparities because the Public Health community health centers are in settings where folks who are most vulnerable are getting their care.

And wouldn't it be great to have a special educational campaign to help those sites and help the providers that work there learn how to communicate more effectively with their patients around decisions about medication use.

And they are set up to do this. They have a national network to test different interventions. They have an evaluation system for evaluating the impact of those interventions, and that might be a good place to do some interventions and evaluation.

MS. MAYER: Though I can't make specific recommendations, it seems to me that insurers and other payers are the natural allies of an educational effort like this. From CMS to HMOs, major insurers and so on, all have a vested interest.

One thing I've learned in my years at the Institute of Medicine on the forum on drug discovery development and translation is that nothing happens without incentives for it to happen. So I'm sitting here thinking, now, who really has a vested interest in more evidence based use of medications in this country, and it just seems to me that the payers have the most vested interest, aside from the public, of course.

So that's probably the first place that I would think of looking.

DR. GOLDSTEIN: And then there's the government payers.

MS. MAYER: Yes, I included CMS in that first and foremost.

DR. NEUHAUSER: And the VA.

MS. MAYER: And the VA, yes.

DR. GOLDSTEIN: And the VA.

DR. ANDREWS: I just had a random thought on industry testing of some of the ads. You have to be careful on occasion from my experience. I think you have to set the guidelines a little bit on what you're seeking. So, for example, the National Youth Anti-drug Media Campaign was a wonderful model, I felt, as far as specifying a behavioral brief with research objectives and specifically what you're looking for in a full copy testing, focused groups and tracking data because it could be all over the map.

And creative briefs in advertising,

the bottom line is the net take-away or net impression, and certainly you want to make sure that consumers in different vulnerable segments have the right take-away as far as risks and benefits from the materials.

So my recollection is a little dim, but back at the FTC it was all over the map from the data that you would see sometimes from industry. So just a word of caution.

MS. VEGA: I just wanted to comment on something. During the break I was approached by a member of industry, and he asked me what recommendations do I have for doing translations, and the reason why he asked that question, he said it was because to his knowledge in industry they are required when it comes to translations to translate word by word. So he felt that it would be very important for this Committee to educate industry about the right ways of doing that type of work.

DR. ZWANZIGER: Just informally for

the Committee, one of our offices that manages advisory committees would love to have a sample photo of an advisory committee in action. If anybody would object to having such a photo, not a posed group photo, but just a photo taken like now or whenever, if you would object, could you please let me know? Otherwise they will probably show up with a camera and just stand up and take a picture tomorrow and that will be that.

That's all.

CHAIRMAN FISCHHOFF: A casting call for federal advisory committees.

DR. ZWANZIGER: No.

CHAIRMAN FISCHHOFF: Do people have more -- we've all worked really hard since 8:00 a.m. Do people have more to say? Yes.

DR. MORRATO: Just one quick thing since it came up this morning, but in the report around advertising then with children, clarify what does that really mean when it says we're communicating to children. Does it

mean they are the audience? Does it mean we're trying to have better safe use with children?

I know there was some lack of clarity maybe in what's in the statute, but so that that would be clarified in whatever report so that it's clear.

Does that make sense? You can't hear? Okay.

So the report is talking about communicating to subpopulations, including children. So is children the audience you're trying to communicate to and get them to understand, comprehend, change behavior, what have you, that we heard about medicines in the home, for example, as OTC, or is the direct-to-consumer advertising communicating to children to insure that caregivers are having the right information and are seeking information from physicians, et cetera? And so what does children really mean in that context?

DR. OSTROVE: I think that what we found is that Congress wasn't exactly clear.

MS. DAVIS: So are you asking that we seek clarification from Congress on that?

DR. OSTROVE: Sometimes we can do that and sometimes we can get the clarification. Sometimes it's a little harder to get the clarification, but it's certainly something we need to do.

But the other option, of course, is if we can't get clarification, is to kind of address both pieces of it.

DR. MORRATO: Right, exactly, just so that it's clear in your report what does that mean.

MS. DAVIS: Absolutely. A very good point. Thank you.

CHAIRMAN FISCHHOFF: John.

DR. PALING: As one of the most important things that we all know, it's for doctors to ask patients if, in fact, the patients either will repeat back or the level

of understanding they have.

Mr. Chairman, if we truly have time, I would be fascinated if our audience members, if they choose, would without identifying themselves or their affiliation just give me or us a feedback of what good ideas they felt might have been merged during the course of the day, if that's with your approval.

CHAIRMAN FISCHHOFF: I think that that's not allowed.

(Laughter.)

DR. PALING: Like all my good ideas.

CHAIRMAN FISCHHOFF: You can whisper to us in the corridors.

Nancy will be good enough to give us some feedback and sort of wrap up and maybe a benediction.

DR. OSTROVE: Well, actually, I think this is a good time. As Dr. DeLaRosa asked kind of for some feedback about where

things are since the last meeting, I mean, I probably can't give you all of the information that you would like to have, but I can try at least to tell you what I can tell you in a public forum that we can make available.

Many of the ideas that the comments that we heard from you during the last meeting take a good deal of internal work, and I think you've all kind of acknowledged that already, and so you know, quick results are not something that we're likely to find.

We have, in fact, raised to our senior management a number of issues that came up in the last meeting that were kind of highlighted in the minutes that you all have been looking at, including pre-testing, more pre-testing and evaluation of messages and trying to build in communication issues at the start, perhaps, you know, providing one or two spokespeople who can be clearly identified with the agency, and again, there are a number of kind of logistical issues surrounding that,

but that's being looked at.

Attending to the needs of diverse audiences, especially with regard to language and health literacy, that's something that we brought up as well, and we're pursuing all of these, and there has been a lot of interest and a great deal of support from a senior level to these.

Now, the challenges of how to respond to them range from kind of broad questions surrounding regulation itself and consistent practices across the agency, which you all also brought up, to relatively mundane matters like who's going to do it. You know, where do we set up the necessary structures and mechanisms internally, and what kind of implications is that going to have for then if you pull someone out to do this, what's going to happen to what that person does now?

So it's also a matter obviously of dealing with what the priorities are and how to figure that out. So that's kind of with

regard to the comments and recommendations we got from you the first day of the meeting on February 28th.

Now, with regard to the 29th, where basically you were focusing on the draft press release for recall announcements, in fact, the cross-agency working group that's working on that has met. There has been a revision which took into account your comments specifically, and that draft template has been updated to incorporate your suggestions, but that is still in the works.

But it is moving forward, and one of the things that we really took to heart is your comments -- I believe especially one of Linda's comments -- about testing what we have before we just go out with it, and so that's going to take a little bit of time for us to do. We're probably going to end up doing that on an informal basis so that we don't have to go through the whole clearance process, which we explained to you in great detail the last

time around. But that is moving forward.

In addition to that, as a function of one of the comments that we heard during the open public hearing, we are investigating the implications of a suggestion that was made by one of the industry representatives, not the industry representative sitting at the table with us, but at the open public hearing, on identifying a regular pool of industry representatives for this Committee who would actually have more expertise in the risk communication arena rather than borrowing industry representatives who are on other committees that don't necessarily have that focus.

So we're looking at the implications of that. We're figuring out kind of how we can go about doing that, and in the meantime, of course, and unfortunately Dr. Reiss is gone already, but in the meantime we wanted to say that we appreciate our guest industry representatives who have been able to

participate, but that is ongoing work. We have ongoing work on a number of these things, and we hope you approve of that. I'm really looking forward to the day when we can come in and say, "Oh, look. We have gotten this. This is done," and I anticipate that that will be coming before I retire from FDA.

(Laughter.)

DR. OSTROVE: So some time in the relatively near future or soon, as I like to say it in government time, which of course has large confidence bounds around it.

So that's kind of your update for today, and I'd also like to thank you all again for being here and for giving of yourselves. I wanted to specially note really that we sincerely appreciate all of the input, and again, building on what I just said, we take very seriously what you tell us. We also take very seriously what the public tells us.

There are a lot of people -- I've spoken to a lot of people who say, "Oh, come

on. You know, you put something in the docket or your Committee is meeting and you pretty much ignore them," and that is not the case. That has never been my experience, and certainly it's not my experience with this group, specifically.

So thank you, again, sincerely from the heart.

And I think Kristin wanted to --

MS. DAVIS: I'd just like to echo Nancy's thanks and let you know again that the feedback that you've given us today, the recommendations as far as what to think about with communication, and then also the really good points you've raised about gaps in our knowledge, the research that should be done and ways that we can do that given limited resources, all of that is going to inform our report and the actions that we take.

So thank you so much to the Committee, to the consultants, to the speakers. We really appreciate your time and

your expertise and everything that you've given us on this.

CHAIRMAN FISCHHOFF: Thank you as well. It was very helpful, and you know, we want to feel like we want to come back and we want to feel like you want us to come back. So I think our incentives are compatible here.

Lee, do you have any final comment?

So let me just thank everyone on the Committee for their work. Let me thank everybody in the audience for coming, and I hope that we've been useful to you and thank you, everyone, for their input and we'll see everybody tomorrow at 8:00 a.m.

(Whereupon, at 4:56 p.m., the meeting was adjourned, to reconvene at 8:00 a.m., Friday, May 16, 2008.)