sense process of auditing different sources of information and applying it critically. You know, so that's probably where the synthesis and the professional judgment come in, is how is that relevant and how can that help shape your communication strategy in the moment when you can't go out and test your message, when you can't, you know, it's just unrealistic.

So, at least to my experience, that's -- and then having your networks, having the people that you know and trust who can be sounding boards. And can give you insights that maybe you haven't thought of, your warn you of potential missteps you might be taking. And then, that network does extend certainly, as you've just said, when it comes time to communicate, there's some overlap there in terms of engaging those same people, or groups as channels of communication.

So, -- but with emerging risk, I think that what you want to do is just structure it in a way that understanding what

people's process is going to be, forgetting the information and processing it. Which is why, you know, the learned intermediary is so important with emerging risk, is that you just really want to make sure that if people are consuming new information about an emerging risk, that there's a clear pathway for them to get the whole story, and for there to be good contacts provided at multiple different touch points in their world, but especially with their physician.

CHAIRMAN FISCHHOFF: Mike then Marielos.

MR. GOLDSTEIN: So, just to underline, because I think what AnnaMaria is saying is so important. This is about a process. We've talked about evidence, which is really important, evidence about how best to convey information. What we're not talking about a process for communicating when there's emergent risk, or there's a crisis.

And there are some best practices.

They may not be refined to the degree that we like, but there are some best practices. And you outline them. They're very clear. And a lot of them have to do with managing communication, managing information as it's coming in, and then managing how its used. And requires teamwork. That's what I heard at a deeper level.

So, that means having a team that you could turn to during these points of crisis that have multiple disciplines. People who know how to manage communication, people who know how to implement and act, people who know how to get feedback about that information that's gone out, evaluate, and then re-calibrate.

And it's those three steps again. Keep going back to the simple things, analyze, design, based on what we know, and then evaluate. And it's an iterative loop. It happens over and over again. And it happens more frequently in an emergent situation.

When it's on-going, you can spread it out a little bit. You still have to do it.

So, what I'm hearing -- as a recommendation, I -- and sometimes I get a little bit confused because I don't know if our role is to be individuals on this committee and just say what our expertise is and our understanding of the literature, or to endorse and recommend as a group. I think it's more powerful if we're seen as a group that's listening to each other.

So, I can endorse everything that AnnaMaria just said, and be a valuable thing to do, to create a process that could be turned to that has important members of the team with different expertise and relationships that are developed in order to formalize how you move once you have information and can act on it. I just wanted --

CHAIRMAN FISCHHOFF: Maybe I can make an intervention there.

MR. GOLDSTEIN: Yes.

CHAIRMAN FISCHHOFF: So, and I'm not quite sure about what the answer to that question is.

MR. GOLDSTEIN: Yes.

CHAIRMAN FISCHHOFF: We're just an advisory. We're not -- you know we don't reach conclusions like some of the other, or semi-binding conclusions, like some of the other committees. So, after the meetings, Lee and I have been taking notes, Nancy as well. We produce I'm very sure -- they produce and then I help a little bit, on very short notice produce sort of what seemed to us the sense of the meeting that can then be conveyed upstairs.

And I -- you know, from my -- I understand that you know, it happens and it's been listened to and we've gotten feedback suggesting that we've had some impact. We've typically not had formal resolutions before us, in part, for the reason that Musa gave us,

that we haven't always had, in another context, we haven't had a formal resolution, a full exposition of data, alternative things.

In trying to process, you know, what we're doing in -- so we will certainly do that here. I've been sort of -- it's kind of hard to listen to the meeting and process in real time, so maybe we'll take a lunch break at some point and then we can think about that. But let me put out two things that we might do. One is that I think we've had a number of suggestions for a kind of strategic planning that FDA might do. And I think from our panel yesterday in particular, I felt there was some receptiveness, maybe this is happening already.

And perhaps we could pull together our thoughts on what might be, you know, what the agenda might be for that strategic planning exercise. That might be one thing that we would do.

Secondly, maybe people have some

specific recommendations that they'd like to formulate after lunch, bring them to me and we'll -- we can think about them. So, I have one that I would like to have us talk about. And maybe I'd like the staff to tell us, you know, how you'd even frame this as a recommendation. So, we've -- you know, I would put together two suggestions that John made at his presentation, you know. Resolved: FDA should quantify, that in its communications FDA should provide quantitative risk and benefit information.

Now, I recognize that FDA has some legal constraints on -- there's things that it has to say, but I don't know that it's proscribed from saying other things. There may be ways that it can tier its -- so we heard a discussion yesterday about how -- the negotiated settlement on the Gardisil communication with EPA. So, there's certain things that had to be said first, and then the other things could be said.

So, I would say, if there were, we could have -- I would like to figure out how to present the resolution like that, for which I think we have -- see whether there's support for it, and then hear from the staff on you know, how that would have to be presented, you know -- in order, how that would have to be presented to be most effective.

And maybe we have some other concrete suggestions, slightly esoteric in the world of concrete suggestions. But they're pretty concrete suggestion.

MR. GOLDSTEIN: Yes, that's correct. I'd love that. I'll sign on that one.

CHAIRMAN FISCHHOFF: Yes. Okay. So, let me suggest in terms of process. One possibility, we could break now, and you could get to the place across the street, if that's where you want to eat, before the 12:00 o'clock rush. And then I could take suggestions from people to try to put together

an agenda, and start say, at a quarter to one? Shall we do that, I think? That make sense?

MR. GOLDSTEIN: Sure.

CHAIRMAN FISCHHOFF: Okay. Let's do that. So, let's break now, until a quarter to one. If you have suggestions, either now, or you know, anytime before, if you do, then we'll try to put together a, you know, more resolution-like agenda, with at least those two suggestions. Agenda for strategic planning and that -- and then take another look at these -- the suggestion questions that came from FDA. Okay. Thanks to everyone.

(Whereupon, the aforementioned proceeding went off the record at 11:53 a.m. and resumed at 12:56 p.m.)

CHAIRMAN FISCHHOFF: Everybody, welcome back. We worked over the break and have developed a proposal for the agenda for the remainder of our meeting and see if you like the agenda. If not, we can change it.

First of all, a clarification.

Although I appropriately stated that our recommendations are non-binding, so are those of the other FDA advisory committees. So the positive framing is that ours are every bit as binding as theirs, and the negative framing is that ours are as non-binding as theirs. So, you can choose to look at it the way you want, and I think there is a research project here.

Secondly, that we have as I mentioned, there are four questions that everybody got of things that the FDA would like to have us answer. The minutes from this -- there is, eventually, there's a full transcript of the meeting that's presented. And then there are summary minutes are presented.

Those minutes iterate through the committee to make certain that we've captured the sense of the discussion and then a final version of those then become a public document. In preparing those minutes, we will, I think, be able to pull out

-- we will attempt to pull out all of the comments that people have made relative to those questions. But we ought to cycle, you know, you might just take another look and if there's something you think you didn't say, that we needed to say, then bring -- we'll -- then bring it up. But you'll also have a chance, if you, you know, to -- I guess anything that hasn't been said here, you should say.

If you get the draft and we've missed it in the minutes, then let us know at that time, because it will have been officially said at the meeting. But we'll try to summarize that. That seems like the sort of thing that might be -- unless something's been missed, that seems like something that's better done bureaucratically.

And so, how can we best take advantage of our being here. So, one thing is to get out ideas for future meetings. That again could be done through staff between

that. But one suggestion came up during the break, would be that we might workshop an issue for FDA, picking a topic and seeing whether we can pull together what guidance might be an "ad hoc" topic where guidance really doesn't exist, is on emerging risks.

And my guess -- our guess was, that there may be -- as concrete -- it would be good to be as concrete as possible to make us really think about the complexity of issues. There probably are problems with taking any actual issue. And there may be problems with taking any actual issue, but maybe we can get an issue.

That's -- we could come up with a case study that's representative of the sort of things that FDA does, with enough nuance that they -- FDA could see how we could think we could force one another to come up with concrete guidelines, just as in AnnaMaria's presentation. She made it, she took a -- she mocked out something that was -- that you

could imagine what a real one looked like.

So that was a topic, that was something that we might do well in a future meeting. And if you have other suggestions now, or later, let us know, and then we will try to do that.

As you know, we won't -- the next meeting -- our next meeting will not be until early next year. It's possible that members of the committee will be drawn into other FDA processes at an individual basis, which would be outside of the meeting of the committee, which requires -- there's two of us together, on committee business, then we've -- then there's a lot of rigamarole that needs to be done.

It's not impossible that maybe a task force would be created for something else. But our next meeting will be in six months. So we have plenty of time to think about that and to prepare it in a way that we would like.

MS. ZWANZIGER: We haven't scheduled meetings yet for 2009. I'll be polling everybody for their calendars before then. And then those tentative dates will be published as always. So, I wouldn't say precisely six months, but several months in advance anyway.

CHAIRMAN FISCHHOFF: Okay. And so then

-- so I think a good view, or a hypothesis, is that a good use of our time now is to see whether we've got some resolutions lurking in us.

And so I came up with four resolutions. And maybe you have some more. And if these are all slam dunks, then we can. So, one is -- and you can agree or disagree, but I thought it was better to have a concrete hypothesis out and that you could agree or disagree with. And then you're welcome to submit more.

One, FDA should consider risk

communication as a strategic function to be considered in designing its core processes. That's a possible resolution.

Two, FDA should engage in strategic planning of its risk communication activities. That's sort of, if we approve that, then some topics for that strategic planning might include some things that we would suggest here, or things that are already in the notes.

Three, FDA should find ways to do research more efficiently, ensuring the communications are designed in a timely fashion to a scientific standard. And that might include, and we've had various suggestions about dealing with its constraints, taking advantage of the research community.

And resolution four, FDA should routinely present quantitative risk and benefit information in formats consistent with its regulatory constraints.

So those are four proposals for

resolutions. And we could -- if the -- if people are happy going the resolution route, we could talk about each of those, or -- and entertain other ones that are on your minds. I think four or rive resolutions is probably what the system could handle. And these may or may not be the best. Musa.

MS. MAYER: This is only partially formed in my mind, but I'm still back with the four questions and particularly the fourth question. And my observation is that the simple use of the word safe and effective have created a certain understanding or impression, mis-impression in the minds of the media and the public.

And so, I would like to propose -- and bearing in mind, there is on the one hand the need for clarity and simplicity, and on the other, the need for accuracy in situations where you have very equivocal information, which is what led us to this problem in the first place.

That safe, as FDA uses the word, is a very qualified term. But that's not how it's transmitted. And I would suggest that there are a number -- that there is certain language that the FDA ought to examine really carefully and probably this should be evaluated and tested very thoroughly. No, I really agree that it should, with regard to the meaning and the impact on public understanding of words like safe and effective.

And likewise, I think the same kind of approach ought to be given to communicating information, in any situation, about risk where it's a developing or emerging process where there's partial information, partial knowledge over time.

I mean, those are two sort of different, but related issues. So, this is really a language prescription about precision of language and more research into understanding how media and the public

interpret FDA language.

CHAIRMAN FISCHHOFF: How would you propose that we pursue that?

MS. MAYER: Well, that's what I was hoping that the academic members of the panel could really help us out with.

MS. BRUHN: Actually, I -- this relates to her. You know, I'm afraid, I'm one of those visual learners. I need to see your first two ones, first statements first. But I believe what you have just said, Musa, would go under one of his. Because didn't you say that FDA should consider risk communication as a strategic process?

And isn't examining the meaning of the words, part of examining the effectiveness of risk communication? So, I see that as a sub topic under what has been presented.

MS. MAYER: Yes. But I think it's important to be explicit about the sub topics.

MS. BRUHN: I think it's --

MS. MAYER: Because other people

might define it quite differently.

MS. BRUHN: You know, I agree. And it should be listed as a sub topic. Because you are referring to it in the context of medicine and prescription drugs, but I believe --

MS. MAYER: Not only.

MS. BRUHN: Yes. I was thinking it pertains to other issues as well, including food. And I didn't have a chance to mention it before, but when you're in the midst of a food recall, to have someone say the food supply's the safest in the world, is contradictory and it breeds lack of confidence. Because it's not acknowledging what is obvious before you.

So, this is not limited just to prescription, but to a broad range of things and I support the concept that you are presenting.

MS. MAYER: Okay. Thank you. I think

-- I would dare say that the unifying factor here is any situation where there is uncertainty, incomplete knowledge, anything but, you know, a real clear message. The question is, how do you transmit a complex message with nuances, when what I guess the research is telling us, is that the public can only absorb simple, direct, clear messages.

How do we make the best of that that can be possibly made?

CHAIRMAN FISCHHOFF: So, Marielos.

MS. VEGA: I wanted to bring something to the table that actually was brought to me by two of the audience members. And I felt it was important enough. They couldn't bring it to the table, but I could bring it to the table. And it's related to the fact there are two types of risk.

And I will use a case example. I want all my patients who are 50 and older to get a screen for colorectal cancer. Ideally, I want them to get a colonoscopy. I have to

explain to them the risk of the procedure itself. That it's -- there can be perforation, and there can be risk associated with anesthesia. But I also have to make them understand that there is a risk that's associated if they don't get the procedure done. They can die.

So, it's important for consumers to understand that. And I think it's different than benefit. I mean, other the aspect of benefits. So, I'm not sure how we deal with that, but it has to be dealt with in terms of communicating about risk with consumers, especially the vulnerable populations.

CHAIRMAN FISCHHOFF: Okay.

MS. LAWSON: On the resolution number two, I believe, it's that FDA should engage in the strategic planning of its risk communication, I would just like -- and I'm sorry, but I missed part of Linda's presentation on yesterday that addressed that. But I would suggest that under number two,

that we include as a part of the strategic planning, that you look at the role, the important role that organizations that represent the constituents that we serve, both patients, consumers, those health professional organizations, the consumer organizations, and they represent all of the people we're serving, that you look at a formalized role for those organizations in information sharing.

So that if a press release is issued, you have in place, organizations that will also, you know, receive whatever information that's gone out from the agency, so that they can help to reinforce the messages that we're putting out there. And that you have an on-going relationship with those organizations, so that they really are considered allies, and they're there to help you to get your message out.

So, I know at one point, you might have done that. And I think you're doing it

with programs and projects. But I don't know if there is a formalized structure in place, where you have partners that cross the board in the centers that identified, if you know, if you use one organization, is that organization considered on the list of this all centers, that they will share information with them about what's going out.

So I think in looking at your strategic planning, that you look at the role of organizations, both professional and consumer. That could be very supportive of what you're doing.

CHAIRMAN FISCHHOFF: As a matter of -- just trying to structure things as we go, I think that -- I've ask Lee to put the -- my draft resolutions up and again, that can't hurt.

I think in terms of the relationship, on Musa's suggestion and Christine's answer, that if FDA was doing this strategically, they would get to this

particular topic. But I think Musa's claim would be that this topic is important enough, it should be gotten to sooner rather than later.

And I think that this -- my guess is, that this is a topic, you know, this would be a very good topic for our next meeting, and we should figure out how to deal with it, you know, in a systematic way. Because it somehow overlaps the emerging -- I mean, the emerging thing is the other thing, the safe is kind of the brand, and the strategy and maybe if we just took those two issues, they could be archetypes of other language issues.

I mean, sometimes it's the recall, the recall issue is in that class of language, you know, language issues. And maybe we want to flag that as something to deal with systemically. Does that make sense?

MS. MAYER: It does make sense. And I wanted to add also, that if you can envision a drug facts box that presents the

risks and benefits of a particular agent, side-by-side, right away, you're communicating something about the equivocal nature of the word safety, and the word advocate, and effectiveness, both of them.

So, the one approach can sort of inform the other. But I think that would be an excellent idea to have a meeting that would focus on language.

CHAIRMAN FISCHHOFF: Yes. It would get in collaborative, the cultural, you know.

MS. MAYER: And furthermore, I think it might be -- if we don't have the expertise around the table, it might be really interesting to get somebody who is an expert in linguistics to speak to us --

CHAIRMAN FISCHHOFF: Yes.

MS. MAYER: -- specifically about medicine, to speak to us. There must be such an expert.

CHAIRMAN FISCHHOFF: There are experts, yes. That's really good. I forget,

they -- so somebody's keeping track. Mike, Ellen, Linda and David.

MR. GOLDSTEIN: To respond to these, I can agree or endorse all four of these. And I think when we were just talking about, where parts of the strategic planning, so I think it was Madeline who said, somebody said, that the issue of the language, maybe it was Christine, is one of the levels in a framework for creating strategic risk communication.

And one of the things I would suggest that we do, is to help to create that framework. So, we'd include how we frame messages, how we define terms. That's one level. Then there's the level of how we link to channels of credible partners for the communication process, which is what Madeline was talking about.

Then there's the level of evaluation. How messages to the public are evaluated. Then there's the issue of

training, different levels of training. Training practitioners who have to participate in decision-making. Training the public. It's more of an educational function of helping them to learn.

So there's -- I'm suggesting, I'm getting specific now. But if we spent a meeting I bet we could come up with a framework of the different levels of strategic risk communication that we could then walk through as a committee, or say, we're going to be part of the strategic process, or advise the strategic process.

So, something that would help guide the strategic process, we can contribute to because of our unique backgrounds and expertise.

CHAIRMAN FISCHHOFF: So that's sort of a next meeting topic that -- and although we might help, that they beat us to the punch by having the strategic --

MR. GOLDSTEIN: Maybe they'll ask

us for that.

CHAIRMAN FISCHHOFF: But the strategic planning group won't wrap everything up in one meeting, so they won't beat us to the punch. Okay.

MS. PETERS: First I had a comment about the safe and effective issue that Musa brought up. There's some -- there's some experts in choosing words and labels and the importance of choosing the correct words and labels. And I tend to think of it from a -- as a marketing function. But I think that maybe if we were able to get an expert in this, in the importance of the right word choices, or the right label choices. Perhaps in a medical context, perhaps in a different context. I think that might be quite educational.

Because that choice of words can guide people's overall gestalt in understanding of a concept. And the overall brand name, for example, of the FDA. So that

was one just comment. I can't think of any names off hand. I might be able to go back in and find some names of people if you're interested.

The second thing had to do with what I think is the fourth recommendation from our esteemed chairman. Which is, quantifying the risks and benefits. I completely agree with that. I think that people need quantitative information. I think that there's lots of good empirical evidence that it will help to educate people, both about the risks and to quell some undue fears perhaps. But also, about the benefits, and perhaps not to hope for quite so much sometimes.

But, I would say, I have two comments on it. One is, it's sometimes very hard to come up with that quantification. So, because studies disagree on what quantity to put on the risk, and what quantity to put on the benefit. And those study themselves can differ in the quality of the studies as well.

So, that's just sort of a -- something to know about quantifying the risks and benefits when it comes to pharmaceuticals or potentially food risks as well.

The other thing I'd say, and I would just want to put this as a caveat on this, is that there are groups of people who may not do well with that numeric information, particularly elderly, less numerate people. And that should be studied. Just, what the impact of that would be, should be studied. And it should probably be studied in two ways.

One way would be to look at, if you give them the numbers, what happens? What, do they understand it, what kind of reactions do they have to that? So, basically, if you force the numbers on them, what happens?

The second thing would be -- and it might make the first irrelevant, by the way, the second one would be, okay, in the real world, did they look? Do they have contact with it? Is it really going to make a

difference? Because if you're someone who is elderly and less numerate, it may not have much of an impact because I don't care. I'm not going to look. And so, both of those sort of research questions could be important there.

CHAIRMAN FISCHHOFF: So, thinking about this, this is probably not something that we could do here. If we chose to endorse this recommendation, I guess I would crash some supporting language that would -- or elaborating language that would you know, sort of capture the spirit of what John and other people said.

And also, via the design should be supported by research. It might -- it should reflect the research that's already out there. It should be supported by research to do the best job. But also, that it should, you know, it should recognize that the information may not be used directly.

Because I think, I mean, you know,

there's been you know, there's push back for both legitimate and illegitimate reasons for providing quantitative information that couched in terms of people's inability to understand. So, there's people who are legitimately afraid that people will be confused and they'll miss those themselves, because they understand but don't. And there's people who don't want to provide the information and don't want it to be available to anybody that are saying, well, out there, there's some people who might be confused, so we don't want to make it available at all.

MS. PETERS: If I could just add to that. If there is a sub population of people, where the numbers just don't work very well, or there's some adverse effects because of providing them the advice that I would suggest, if they come in contact with it, with the numbers, and so those adverse effects are possible, would be that there are intermediaries. And that there may be some

additional intervention by intermediaries that are needed in those cases, whether those intermediaries be their physicians, or friends, relatives, et cetera.

CHAIRMAN FISCHHOFF: So let me say, that on all of these, if we will you know, if we endorse these -- which ever of these resolutions we endorse, I will produce some supporting text that will then be circulated, and people can comment on the supporting text, and we'll take out anything that people are particularly allergic to.

MS. PETERS: That would be part of the minutes?

CHAIRMAN FISCHHOFF: Yes.

MS. ZWANZIGER: Right. It's not a continuation of the meeting.

CHAIRMAN FISCHHOFF: Right. It would be whether or not I have accurately captured what has been said in the minutes -- in the meeting. Yes.

MS. ZWANZIGER: That's right. Just

explained that what I was just mentioned is that we can't continue a meeting after the meeting's been adjourned. We're just reporting what happened at the meeting.

CHAIRMAN FISCHHOFF: That's right. And so my attempt would be to capture what's been said in the meeting. That's what I was saying earlier in terms of research topics, or strategic planning, you know, responses to the questions. If you haven't said it, make certain that it's said now, and then we can make certain that it's captured in the meeting minutes.

MS. MAYER: So to the issue of what -- I mean, again, I'm using the issue of drugs. Because drugs have labels that are approved by the FDA, and a label of a drug incorporates the evidence from the research studies that led to the drug's approval. That is the data that should be incorporated in a drug facts box. I'd be very -- I mean, I'm saying that, because I'd be very surprised if

FDA could under any circumstances, include any other data about drugs.

I think that would be -- am I, Nancy, tell me if I'm wrong?

MS. OSTROVE: Well, there's, I guess just -- there's a couple things I guess that I would want to clarify. One, is that I wish Paul was here, because I don't know exactly you know, what the context is of the work that he's doing with the Dartmouth people in terms of the drug facts box.

You know, I'm not sure exactly how they're anticipating using that. So that's one piece. So, I'm not sure we can speak knowledgeably to that.

Secondly, FDA in promotion, okay, for a prescription drug, say, you can make claims that are not in the labeling. They just have to be consistent with the labeling and be supported by substantial evidence. So, it's not that it must be in the labeling. It certainly -- we would never say you know, that

something that was inconsistent with labeling was okay. But it wouldn't necessarily have to be taken directly from the labeling.

MS. MAYER: I guess I was just making the assumption that the drug facts box was part of the patient information sheet. But if that's not the case --

MS. OSTROVE: I don't know.

MS. MAYER: -- then obviously different, yes, thank you.

MS. OSTROVE: Right. Then that's what I'm saying. If Paul was here, we could get more detail about that. But I'm not privy to that stuff. So, I wouldn't necessarily make that assumption.

MS. NEUHAUSER: Just a comment about the language person we talked about. There are people called social linguists. I think that's the kind of person you want, and especially someone who specializes in this kind of area. Ellen, I bet you have come across somebody in your travels that will pop

up into your brain.

But if not, you know, we could all be thinking. I have worked with a few social linguists, but in very particular areas. So, I don't know that they transfer well across, but they might. If anybody knows more about this, that would be helpful.

So, a couple of suggestions to add here. One would be, a recommendation to develop a participatory design and testing process for FDA communication that would include vulnerable groups, diverse by reason of literacy, language and culture. Perhaps disability too, insofar as it relates to cognition of communication.

So, that specifically to design a process that would be different than the one that is going on right now. In my talk, I outlined about six or seven steps for a process that I use that could be helpful model to consider. But it would have to be adapted to this agency.

Another one would be --

CHAIRMAN FISCHHOFF: Let me just --

MS. NEUHAUSER: Oh, go ahead.

CHAIRMAN FISCHHOFF: Sort of procedural intervention. I -- let me suggest that for that, and I'm guess on these things that come, that this would be language that would -- this would be elaborating language. Because I don't think we're in a position -- we haven't gone through a process whereby we've endorse any framework, or any particular methodology. But we've certainly had discussion of how do you address all of those issues.

So, the elaborate -- you know, in terms of its done, the research is done, these are the issues that it would need to do.

MS. NEUHAUSER: Right. The how part would have to be figured out.

CHAIRMAN FISCHHOFF: That's right. The how we can't agree on. But that they ought to do it.

MS. NEUHAUSER: Exactly.

CHAIRMAN FISCHHOFF: And if they do it right --

MS. NEUHAUSER: Exactly.

CHAIRMAN FISCHHOFF: -- it will include these elements.

MS. NEUHAUSER: This outcome would be such-and-such. You would have a process developed.

MR. GOLDSTEIN: So I think that word is very important. I know it's a methodology.

CHAIRMAN FISCHHOFF: Yes.

MR. GOLDSTEIN: But I would --

CHAIRMAN FISCHHOFF: Let me say, you know, speaking as a social scientist, I would say, I think of the kind of research that I do as being participatory, but it's quite different from what Linda does, and it's different from what Ellen and Christine, and you know, and Betsy does, or what, you know, or what David -- or what David does,

participatory just means different things to different people.

And I don't -- I think we need to avoid endorsing any particular methodology or working out our terminology in the next -- you know, in the next half hour. So, I think we can flag the importance of insuring that there is appropriate inputs from appropriate people.

MS. NEUHAUSER: Yes. That's enough to do now, and just to highlight that although a lot of groups that do, federal agencies that do communication they often will at least test the message they've designed with diverse groups. But they usually look at diversity as a matter of say, culture, language, perhaps sometimes income. And I have really never seen an agency look at the lower literate group as a specific diversity group.

Now, it may be happening, but I just wanted to flag that as one aspect of who would be participating in such a process.

CHAIRMAN FISCHHOFF: Also, could I ask you I don't know how good Linda's note taking is, but mine is flagging a little bit now. So, could I ask you, given that this is now part of the record, since you've said it, could you send us your words afterwards?

MS. NEUHAUSER: Yes. I will send you words.

A couple other suggestions. One would be to assess the reading level of a sample of FDA communication, consumer communication. And those would be, you know, there's a whole range of things for consumers. But to sample that, assess the reading level using the validated tests. And I'll just clarify here, that Microsoft Word tests, the one that's available on computers, is not a well -- it's often used because it's cheap and available. But it is -- gives falsely low results. So, just saying that should not be used. And there are three others that are good. So that would be one, to assess the

reading level.

Right now the communication that would be helpful to know whether there's a need to do better in this area, and as an adjunct to that, to assess the navigational features of the new website with respect to the Department of Health and Human Services usability guidelines. And I can provide that reference. It's in my slides. But I can provide that exact reference. I think you might have it.

But it's, you know, there's a set of guidelines that are published on usability.gov from NCI, through DHHS, and it perhaps, a guidebook that's updated about every year from DHHS.

And the third, is to develop, this is a little bit different from the one you mentioned, Baruch, about more efficient research, which by the way, I endorse. But this would be one to set a research agenda for priority risk communication issues. Perhaps

those could be linked together. But I think what you were talking about, was a little bit different, you know, having efficiently available.

CHAIRMAN FISCHHOFF: I was talking about mechanisms for --

MS. NEUHAUSER: Right. Process.

CHAIRMAN FISCHHOFF: -- bringing people in, reaching out --

MS. NEUHAUSER: Exactly.

CHAIRMAN FISCHHOFF: -- getting general clearances. And you're talking about the content.

MS. NEUHAUSER: Yes.

CHAIRMAN FISCHHOFF: And so let me suggest again, procedurally, that, I think that this research agenda ought to be part of the strategic planning.

MS. NEUHAUSER: Yes. I agree.

CHAIRMAN FISCHHOFF: Yes. Okay. And I will fold it in there. David.

MR. SMITH: Living in an

environment where we have to do strategic planning, and it becomes a onerous task, I'd just like to actually step back and ask Lee and Nancy, you know, it -- I think it's a great idea, but is it a practical idea, and is it a useful committee time to talk about this? And is that something that's feasible to do? And do it in some sort of reasonable time frame and with this group? Or, is that something that needs to come from HHS to FDA, down the chain and need to be done internally and held internally?

MS. OSTROVE: I think that's something that we need -- we do strategic planning, just in general. The agency does strategic planning. The department does strategic planning.

I guess when you think about strategic planning, you can think about it, you know, in the big S and the little s. And we -- one of our centers, in fact, a couple of our centers, are in the process of putting

together a strategic plans for communications for instances.

So, but I think the big question here is, who should be doing it? And that's something that I think we need to address with our management. You know, I'm not sure that they would necessarily agree that it's something that the committee should be doing.

But rather than it's probably something that the FDA needs to engage in, and it's one of the things that, at least I anticipate that we would then, you know, if we came -- assuming that we will come up with a strategic plan, that it would then be something that we would bring to the committee for discussion. But it would not be something that the committee would come up with. Because frankly --

MR. SMITH: No, that's not -- I agree. I didn't mean that the committee should do it.

CHAIRMAN FISCHHOFF: And that

wasn't the intent.

MS. OSTROVE: Oh, okay. All right.

MR. SMITH: It was more, have some sort of interaction in the process, if that's even feasible or and is there any precedent for that in some other group.

MS. OSTROVE: That's something that we would have to -- I'm not sure if there is precedent for that. We'd have to look into it. And again, since it would need to be kind of a public -- since anything we do with the committee needs to be a public process, there may be issues that get brought up in strategic planning that would not necessarily kind of work, bringing it to a public process.

Because you have to think about priorities and all kinds of other things. So, I think it's something that I welcome the resolution. I hope that's not going too far. You know, but it's something that we would need to kind of work out the details internally.

MR. SMITH: I just had two follow up comments. I think on the third one, I don't know, if it's something we do now, or that's something that you guys do as a followup. But I think it would be important to put some kind of parameters on that, rather than just say, do it more efficiently.

I think, it sounds like with the expertise you have here, you could probably have a reasonable gauge for what's feasible that you guys think that 25 percent increase, or you can do, you can reach twice the amount of people, or some sort of parameter to gauge the effectiveness of what does that really mean, rather than just saying, do it more efficiently.

CHAIRMAN FISCHHOFF: Okay. So, yes.

MR. SMITH: I think that's really vague.

CHAIRMAN FISCHHOFF: So there was the attempt there, that there would be

explanatory language that --

MR. SMITH: Right.

CHAIRMAN FISCHHOFF: -- that would try to get at that.

MR. SMITH: Yes. And similarly in the last one, you know, how do you test? I think we got to make sure that we test those things and evaluate them and all that. So, they need to be broadened.

CHAIRMAN FISCHHOFF: Okay. Mike.

MR. GOLDSTEIN: We caught up. This is getting at the explanatory language, and I assume that's something you still want to do? We want to?

CHAIRMAN FISCHHOFF: Yes, yes.

MR. GOLDSTEIN: To go down a little --

CHAIRMAN FISCHHOFF: It has to be said here so that it can go into that, and it will be a lot easier if you say it now, than if we do it by correspondence.

MR. GOLDSTEIN: Right. At the

level of the strategic planning, an element of that is determining the appropriate audiences for communication and developing specific strategic plans for each of those audiences, general public, people who have a condition who are at risk, healthcare providers, industry, there are others that I haven't mentioned. But, so it's, I think the strategy needs to be tailored, and then it needs to take into account the different levels.

Second, in terms of the research part, research question. That we -- it's one of the questions that we were asked to address. We need to as a group, refine the outcomes that are appropriate for the different levels of research. And I would make a case that we need to include not only comprehension, which is really important, but also assess impact on behavior and that's -- the broader question is, part of the research agenda, should be identify the appropriate outcomes and any appropriate measures for

those outcomes.

And we can help with that, others can help with that. As well as the design and methodologies, we should throw in too, which has already been said. I would endorse that.

CHAIRMAN FISCHHOFF: I have to say whatever design process produce these microphones, you know, hid -- makes it impossible to see where you're looking, whether you're on or not. And there is a little light down here. So, I think we could show leadership in the design of electronic technology as well, by participating -- anyways.

Okay. I think I'm sharing frustration of other people on the committee. Okay. So, let us -- let's see whether people -- do people agree with the first recommendation -- the first resolution. I'll read it out loud.

FDA should consider risk communication as a strategic function to be

considered in designing its core processes. People agree? Okay. Thank you. Okay. Thank you.

I was going to make an aside, and then I turned the mike off. I'm just wearing down. That's my fault. That's operator error.

Okay. Just make one -- well, I guess there should be design for tired operators.

One thing that we, you know, my aside was going to be that both FDA and the committee has conceptualized our task as communication generally, not just risk communication. And I think we should just leave it as risk communication here because that's what we're chartered for. But it's clear by the last resolution -- the last of these resolutions should it be adopted, that we're viewing it more broadly and you know, we should think about some -- you know, we should think about how to make certain that that's --

somehow people understand what we're talking about. Okay.

Second resolution. FDA should engage in strategic planning of its risk communication activities. And just to followup, David's aside here, this is FDA should do it, perhaps in consultation with us. But this is our charge to them.

Okay. Do people support? Okay.

MS. ZWANZIGER: I don't think -- are we just taking consensus here?

CHAIRMAN FISCHHOFF: I don't know. You're the designated federal officer.

(Laughter.)

MS. ZWANZIGER: I've been taking these as sort of general affirmations.

CHAIRMAN FISCHHOFF: Well, everybody's whose still here supported them. And I think we still have a quorum.

MS. ZWANZIGER: Oh, we do, yes.

CHAIRMAN FISCHHOFF: Okay.

MS. ZWANZIGER: I'd let you know if

we didn't.

CHAIRMAN FISCHHOFF: Okay. I thought everybody had their hand up. But I should -- okay, as a matter of procedure. Okay.

On the first resolution -- let's vote again, so that Lee can do it. On the first resolution, those supporting the first resolution. Those opposed. Thank you.

Second resolution. Those supporting the second resolution, those opposed? A couple of hands in the audience. No.

Third resolution. FDA should find ways to do research more efficiently, insuring the communications are designed in a timely fashion to a scientific standard. Those in favor of that resolution?

MS. MAYER: I'm not in favor as currently worded. It's not specific enough. What research? Research about what?

CHAIRMAN FISCHHOFF: So, it would

be --

MS. MAYER: I think it needs to be risk communication --

CHAIRMAN FISCHHOFF: Risk communication.

MS. MAYER: -- research. And moreover, I think you -- we could avoid imprecision by adding a consensus definition of risk communication here to this. Since it's obvious that different people have different definitions.

CHAIRMAN FISCHHOFF: So, as chair, I will suggest my intuition that that's a long discussion, and we would need to -- if we're not willing to live with this ambiguity, we should -- we would need to resolve that, and then go back and revisit the first two resolutions if we have a specific definition that may be done there. And I would, unless there's strong desire to resolve -- I'm actually not up to that.

MS. MAYER: Yes. No, I hear you,

but --

CHAIRMAN FISCHHOFF: If you really think that needs to be done, I would say, vote against it.

MS. MAYER: No, Baruch, the only reason I brought that up was that I thought all that we had talked about was a part of risk communication. But obviously you did not. So, it just seemed to me, that right here, there was an expression of two different --

CHAIRMAN FISCHHOFF: So, let's say that risk communication is -- the term of art here is risk communication as it is understood by the members of this committee.

MR. GOLDSTEIN: I was just going to add to that one. You did have some qualifying comments from the group about having an appropriate methodology, having that series of topics, having a set of audiences and set of evaluation elements. That would help to clarify a little bit.

CHAIRMAN FISCHHOFF: Yes. So, my -- you know, so I am asking you -- Lee could you just take out all the stuff you took, just put in risk communication, R.C., just leave that there. That wold be the resolution we should vote on, thanks. And no parenthesis. Thanks. There.

So, I withdraw my aside. I mean, we have this -- the point I was trying to make, and maybe lost whatever clarity I had, was that this committee has been called the risk communication committee, even though, in as I understand FDA's initial conceptualization, that we were -- that that was the term of art for all sorts of -- for the communication that FDA does. Which, where FDA regulates on risk, but it regulates on risk in the context of benefits, so that we should use the term that's been the term of the committee. But I just sort of wanted to flag that it's, you know, it's not a narrowly construed risk communication.

But I think it's -- I think it's a swamp in general, and I think it's certainly a -- it's maybe even shaking earth, trembling earth, to deal with -- it may be trembling earth to deal with in general, but certainly in the next 15 minutes.

So, I would say, let's say that I never said it. And if we're using risk communication as people understand that term and as it will be understood by FDA who we're asking to act on this.

MS. PETERS: And I might add, as it is in the charter, which talks about risk and benefit.

CHAIRMAN FISCHHOFF: Thank you.

MS. BRUHN: I'd suggest that we remove the word more. Because it implies that FDA is currently not working efficiently. And I think what we really feel is that they are being constrained by factors beyond their control. And they're doing the best they can within their constraints. And our focus is, that we're hoping some of those constraints can be lifted. And I'm

referring of course, to MOB, or OMB. OMB. Thank you.

CHAIRMAN FISCHHOFF: I'm sort of sometimes thought of as MOB, but hardly. The -- let me as the proposer of the amendment -- we're not following Roberts Rules of Order, because I don't think, I don't know if the chair's entitled to propose.

But let me take that out. Because I think if this were read out of context -- out of the context of our discussion, it might be implied criticism of FDA staff, who I think we've supported all the way through for doing a tremendous amount of work, under you know, great bureaucratic and resource constraints. So, let's -- before -- so let's take that. We haven't voted on this. Let's take, I think we should take that out. Mike.

MR. GOLDSTEIN: Another friendly amendment. I'm sorry. We can get a little bit more specific if we say, FDA should develop a research agenda and plan to conduct research

efficiently, the rest of the sentence.

CHAIRMAN FISCHHOFF: No. I would -- so, I as the proposer, I would say, I'd like to leave the research to the strategic planning. And this is really just on the process. How do you get the research done in time. That's what this is about. You could vote against it. But this is meant to talk about efficiency.

MR. GOLDSTEIN: Just efficiency?

CHAIRMAN FISCHHOFF: Yes. Just efficiency. That is, it's so hard -- so the rationale is that, we've heard how hard it is for FDA, there's research they need, that they know needs to get done. And it takes them forever to do it. They are Congressionally required to do studies within period of time that they're unable to do because of the administrative framework within their function. Those are efficiency questions.

MR. GOLDSTEIN: Yes.

CHAIRMAN FISCHHOFF: Some of those efficiency questions may be addressed by farming

things out, bringing people in, so there's a range of solutions. It's not all OMB, but the efficiency's important. Because if the work doesn't get done, the American public isn't protected, industry isn't given clear guidance and you know, and a fair evaluation. So, this is just about efficiency.

MR. GOLDSTEIN: So what about the other points?

CHAIRMAN FISCHHOFF: So the research agenda, the priorities would go -- would be in the expanded language on the strategic planning to come up with that agenda. We would hope that they would consult with us, you know -- what's key to them is what we think hasn't been solved yet, and could be solved and what they are -- they really are hungry for.

MR. GOLDSTEIN: Yes. I just want to make sure we say that then.

CHAIRMAN FISCHHOFF: Yes. So that would -- that's, I will try to capture the spirit of what has been said.

MR. GOLDSTEIN: Okay.

CHAIRMAN FISCHHOFF: Under there. John.

MR. PALING: Mr. Chairman, I don't want to obstruct, and will not obstruct what you're doing in any way. I'd like just to comment about why I'm being unusually silent. I have a medical condition which is an allergy to wordsmithing in committees, which is purely a personal thing. And I have no experience of it. I've avoided jobs where I was required that I do that.

And I say that in no disparaging way. I certainly will not obstruct my committee's doing. I would just however like to say that I am cautious that if we get too bureaucratic and even academic in the way we're doing this, we might lose the punch of a simple message that needs to be delivered.

I mean, to one extreme, there's a trade off between deciding what we want to say, saying it clearly as Musa did in my point of view, why we think it's important, and making it simple,

direct, without being as complicated as this.

Clearly, my colleagues have far more experience in this field than I do. And I certainly would not object to anything that you decide to do. But I have no expertise, and I just want to tell you why, unless there's a need for my vote, I would go for the down and dirty and say what you need to say. But that's not the way that bureaucracies work. So, I'm just explaining my silence.

And I'm sure you're doing the right thing. I have confidence in you as colleagues.

CHAIRMAN FISCHHOFF: Resolved, throw the bums out.

(Laughter.)

CHAIRMAN FISCHHOFF: Could I -- yes.

MR. GOLDSTEIN: I think what we're doing now, is making sure we're all on the same page. So it's the process of clarifying the meaning of what was in the comment. That I actually didn't know that Baruch meant efficiency. It was in there as a word. I didn't know that

that was the focus. So,

I --

CHAIRMAN FISCHHOFF: And in fact, neither did, I think, Linda missed it as well.

MR. GOLDSTEIN: So what we're doing is, not word smithing. I think we're checking for understanding and meaning.

MR. PALING: I didn't mean it disparaging.

CHAIRMAN FISCHHOFF: Okay. So we have a resolution here about efficiency of getting research done. And we have I think, I would agree, we have improved language. Let's put it to a vote. How many people would support this resolution. How many people would oppose it. And I guess we have an abstention?

MR. PALING: I would vote -- I'm not against it. I just have no knowledge to assess this.

CHAIRMAN FISCHHOFF: So is that -- Lee wasn't to know --

MR. PALING: I support it. I support

it.

CHAIRMAN FISCHHOFF: And then finally, FDA -- the fourth resolution, FDA should routines present quantitative risk and benefit information in formats consistent with its regulatory constraints. Additional thoughts? In support, all those in favor? All those oppose. Thank you.

Okay, all present support it, all four resolutions. Thank you. It's true, but I was put up to it. Of the record. Let me open up to -- so we have an additional resolution from Linda, which let me, a proposal for a resolution, from Linda. Let me read this out, and then let's have a little discussion. We could type it in if we wish.

FDA should develop a participatory design and testing process for FDA consumer communications. The process should include vulnerable groups with barriers related to literacy, language, and culture. Is there a discussion? Musa.

MS. MAYER: I believe that should go under three, although if three addresses only

efficiency, no. Under one. Sorry. It just strikes me that that's a specific. It's like what I suggested. It's a specific that should be, perhaps we could just sketch in as you had it, topics might include, or something like that. Where -- as a place marker. Not to vote on this necessarily, but to indicate our intent.

CHAIRMAN FISCHHOFF: My thought actually was to in the exchange with Linda, actually was to include some of these concepts, and perhaps even language in three was well. Because to a scientific standard would ensure that you got you know, that you got this kind of process involved. And that's something that you have to do in advance. You can't round up, participate and so on, when you're putting out fires.

So that would be -- and if that had been my intent, I'm not -- that had been my intent as well as being part of the research agenda. But that doesn't speak to whether we want to vote on. We should talk about the resolution as well. I'm

just clarifying my intent.

MS. NEUHAUSER: I think it relates to other resolutions here. Certainly, to the efficient research one, but the proposal here really is to set in process a different kind of process, of participatory process, to develop and test communication. So, it's a new function, a new approach of doing work, rather than a general aspect of doing research.

MR. GOLDSTEIN: Yes. Okay. I'd just underline that it's -- it would go beyond just research agenda. It would be a part of all that the committee does. All that the FDA does in designing and testing communication.

CHAIRMAN FISCHHOFF: Other comments. Let's see. Let me ask --

MR. GOLDSTEIN: Are there any other barriers that we want to put up to there that are important, like socio-economic status is one that comes to mind.

MS. NEUHAUSER: I would suggest that socio-economic status in general would be captured

under low literacy.

MR. GOLDSTEIN: Okay.

MS. NEUHAUSER: An issue that I thought about but didn't put in there was the issue of disability. It could be here. I mean, it would take some description of what that is. But certainly for website usage, disability is an important factor. So I think it should be added to the list.

MS. BRUHN: I don't think you want to be too specific. I think you're getting the guideline here. I mean, what if your disability is, you've got I don't know, you're missing -- you have one leg instead of two. Really doesn't affect how you perceive a particular message about glasses. So, I think vulnerable groups, you're giving examples, literacy, language, culture. I think the -- you need to look at what the message is for. And look at disability only if it would be specifically relevant to this particular issue.

MS. NEUHAUSER: You know, specifically relevant would be disabilities that prevent people

from using online information, but that's already covered under Section 508 of the Workforce Reinvestment Act that requires that federal online information meet certain requirements. So, that's really why I didn't put it in there. Because it's already required.

MS. BRUHN: I'm just trying not to enhance the bureaucracy, you know, by having too many sub points.

MS. PETERS: Could I add -- could I just very quickly. I actually agree with that. And I wonder if we should end the sentence at barriers. One group for example, that's been overlooked is the elderly. It's related to literacy, but there are other issues as well. And there may be other groups we're not thinking of. The hearing-impaired, for example, would -- they may not have an issue with websites, but they will with -- so there are groups we may be missing here.

MR. GOLDSTEIN: How about access.

MS. NEUHAUSER: Perhaps we could say barriers to access as a general term.

MS. BRUHN: And the issue is not just access. Because you can be a low literate person who has a lot of information at your disposal, but you may not understand it. So, I would -- yes. There you go.

MR. GOLDSTEIN: That's good.

MS. BRUHN: Yes.

CHAIRMAN FISCHHOFF: This is good. Any other, further discussion? Okay. How many people support this resolution? Opposed? Okay. I just don't understand it. I don't feel like I've had enough discussion to -- I believe I support the spirit of it, but I don't know what it means enough to support it, so. So, my opposition.

Are there other resolution?

MS. LAWSON: This is not a resolution. I just wondered. Under the -- I had recommended that we consider the different organizations, the role of organizations in the strategic planning of risk communications. And I wondered if that should be itemized under that, so that there's no confusion when you're looking at it later.

CHAIRMAN FISCHHOFF: So my intent was that one of the elements of strategic, of the strategic planning would be coming up with an appropriate process, including the other groups with whom FDA should partner, and you know.

MS. LAWSON: Okay.

CHAIRMAN FISCHHOFF: Partnership in the full sense in including in its process, decision-making processes as appropriate.

MS. LAWSON: Okay. So, you don't need to list?

CHAIRMAN FISCHHOFF: I don't think it needs a separate resolution.

MS. LAWSON: No, no, no. I didn't intend separate resolution. I just though like under the resolution, that you would say, which includes, and lists whatever, include any organizations and any other suggestions that may have come through it.

CHAIRMAN FISCHHOFF: Yes. Thank you. Yes, Linda.

MS. OSTROVE: And I -- this may be

covered under strategic planning, but just about everybody from the FDA staff who brought up issues, said that they were having trouble figuring out who to do evaluation. I mean, I know resources are a problem. But the design aspect, you know, how do you actually do this. What should we do.

So, if people think that's a strategic planning issue, that's sort of across the board, maybe that's the best place to put it. But I think it should be acknowledged some place. Because we really have not discussed that in much detail here.

I don't know. It may be even a sort of work group-type issue, task force issue.

CHAIRMAN FISCHHOFF: I'm thinking about, given the sort of the variety of challenges in situations, it may be kind of working if we did decide to workshop some, you know, one or two things next time, that insuring that the evaluation were an important part of it, that would -- maybe that would be the best way. And

maybe some of the confusion -- the difficultly comes from thinking that there is a way to evaluate as opposed to being you know, you get a PhD learning how to evaluate something.

It's not something you can just turn on. I mean, my observation is that there's -- there are an awful lot of -- you know, there's an industry of people who do, essentially useless evaluations on small budgets. You know, the many social programs, I know from -- there are lots of programs that are required to do evaluations, are given no budgets and there's an industry of people who do evaluations that are of no value, and if anything distort the programs by reducing them to countables, rather than the real changes you would like to have.

So, I think, maybe resisting a simple answer, and giving a complicated one is the best way we could serve FDA.

MS. NEUHAUSER: So, you might consider in your point number, was it point number three, the one about research efficiency, you might

consider putting the -- adding the word, valuation. Because it would probably be helpful. I don't know the resources available to FDA. But it would probably be helpful, given what people are saying, that they also have access to evaluators of various types, who could help them think through designs. I mean, obviously, all the designs have to be fairly specific to the question or questions that are answered.

So, some of these issues relate to research per se, more basic issues like we discussed here. And some relate to more every day, how do we pick an evaluation design that fits our budget, and for which we would actually get some useful, rather than useless information, as you pointed out. It's very easy to get useless information by counting.

But there are probably a lot of opportunities here that are being missed to do evaluation of what's going on and it's effectiveness. And that requires access to people who know how to do X, Y and Z type of valuation.

There would be some on this committee, of course, and then there may be other situations for which other people would be needed, you know, efficiently.

CHAIRMAN FISCHHOFF: Are there other comments, questions? Mike.

MR. GOLDSTEIN: I want to thank you for engaging us in this process. Because it feels good to have some specific recommendations that we have consensus on. It helps me to feel like the work we're going to be subsequently doing together, but also, what the FDA is going to be doing, will be as productive as possible. So, thanks.

CHAIRMAN FISCHHOFF: Well, thank every body -- thank whoever thought of doing resolutions. It wasn't me. So, let me thank the staff for getting us here, and getting all of the staff here, and all of the staff who came.

And thank you in the audience for having come an engaged some of us in the breaks. And not knowing exactly who you are, for doing the

work, that you know, makes some value of what we're bringing to you. So, let me thank everybody. And Linda.

MS. NEUHAUSER: And if we are adjourning, I just wanted to add my thanks. I have really enjoyed being on the committee. I'm just starting to understand what it's all about. And I appreciate all of you, and all that you've brought. I think the charge of this committee is extremely important and that all of Nancy and Lee and all of the FDA staff are doing fabulous work. So, I am available to help in whatever way you wish. And just offering my assistance. Thank you all.

CHAIRMAN FISCHHOFF: Thank you. You haven't heard the last from us. Well, let me thank everybody. And the meeting is adjourned.(Whereupon, the meeting in the above-referenced proceeding was adjourned at 2:05 p.m.)

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