And that could be across the board specific for each of the topic areas.

And then the comment about what do we know about risk, and risk communication, and what people know. And I really would look forward to seeing the information that you would have to pull together, but I wanted to mention, also, that the University of Maryland has a relatively new, maybe five years old, Center for Risk Communication Research, and they do some things jointly with CFSAN. And maybe it would be wonderful to have one of those contracts where you've got a bright graduate student to work under the direction of a motivated professor to provide a literature review for us, so that we're not reading 50 pages of papers, but rather something that's concise with references, and let them do that and pull it together, and maybe without too much money, and great things for them.

MS. VEGA: Like someone said

before, the NCI has done extensive, and it's not just related to cancer, literature review on risk communications. And, actually, it's available on their website, all the articles. They have it in Word. I think it goes back to the 90s, the National Cancer Institute. And they do have -- I have sent, actually, the link. I can send it again to Lee. But it's very extensive, and it's not only related to cancer.

DR. FISCHOFF: While you're recharging, maybe I'll say a couple of things. One is, I mean, this theme of getting the risks and the benefits, they're not interested in the risks because they weren't benefits. And somehow or other, we've got one side -- generally speaking, one side is responsible for this, and the other side is responsible for that. And it sounds like each side has some inertia in coming together, and you have these things that are in sort of different idioms, different units. They're, in some

way, incommensurable, even if they were explained in the same units. And I guess I would like -- I think it might be interesting for perhaps the staff to see if there's some place where we might look at some, or they might ask us to look at some program within FDA that had particular freedom to put the risk and benefits on the same page in order to see how it could be done, because I think unless -- I think leaving it to these chaotic processes -- I mean, for all I know, maybe industry will figure out how to do it, and bring it to EPA. And they'll say oh, well, if industry wants it, maybe we can do it, or maybe it will be a foreign body, and they'll reject it, but that seems to be the sort of big, kind of a big unanswered question. And although the Committee is called the Committee on Risk Communication, I think the concept that we saw in the examples of our charge is risks related to the benefits, so that was one point. I think that's really critical, and we

could -- as somebody said, FDA is the content-provider, we're not providing the right content unless we work both sides.

And the second thing is that, I would say that if I thought about hundreds, thousands of papers on risk communication. An awful lot of them look at kind of summary data, or uncertainty in summary data. And it seems like an awful lot of -- the key -- we know a lot about how to do it, when it's harder, and so on, but a question that comes up, I think probably most from -- to understand -- that there's something about the epistemology of that data that's not captured in the statistical summary, that it comes out of a process, if it's short trials, or long trials. It's active surveillance, or passive surveillance, and to understand the quality of the evidence you really need to understand something about the process, a process whereby FDA approves things with varying degrees of enforcement or not.

I think that that's not hard for people to understand. It's not hard to -- I think with the right research, it wouldn't be hard to explain so that people would be able to put the evidence in context, that they wouldn't be -- feel like they've been cheated when surprises come up, because they understand what the quality of the evidence is. And my guess is that there's a way that one could do the science on that, and that there's a way -- I'm not sure whether this is quite branding, or this may be more kind of framing, that FDA may be required to just give the summary, nice if they gave the summaries in comparable quantitative units, but to embed those in an explanation of how they came about. I think that that would put the -- I think that would be good for the Agency so people wouldn't feel like they're fair game for target practice whenever they made a statement. And probably that's a kind of education that isn't being done now, and I

think it's quite tractable.

DR. YAROSS: Yes. Actually, for prescription drugs and Class III Medical Devices, when the product is approved, there's a summary of safety and effectiveness, which is an FDA document that's done collaboratively on the drug side, a summary basis of approval, which starts out as that summary of the risk and the benefit, and why the product was approvable. And then in the continuing marketplace, that's what the package insert is intended to convey. The problem, of course, is that that's not necessarily intelligible to all readers.

And as new information comes in, the process of updating it is a challenging one, to try and maintain that proper balance. But there is, at least, a starting point, I think, for that type of document.

DR. GOLDSTEIN: Just to throw something else into the hopper here. The discussions that we're having have centered a

lot around messages, and communication vehicles, and we have mentioned the importance of the educational process, too. And I have to remember back to what Commissioner Von Eschenbach said, communication isn't just the message. It isn't just how we package or frame the information, it is an iterative process of giving information, and then seeing the impact that that information has. How is it perceived? How is it appreciated? How is it acted upon?

And to the degree that we can see communication as a process, not an event, I think we can begin to craft both vehicles that we can consider to be useful for conveying the message, but also vehicles for making sure that the loop is closed, that the message is getting through, that the receiver has gotten what we hoped they will, and that that's helping them to make informed decisions. So put in a pitch for that, as well, as we move along.

MS. DeSALVA: Just real quick, and forgive me if I'm stating the obvious, but one of my major take-aways from today's conversation is -- has to do with the opportunity, both the obligation and the opportunity to introduce more evaluation into risk communication here, particularly at the Agency, because communication can transform outcome in healthcare, which I'm sure we all know and believe. That can be both good and bad, so it would seem that there is an obligation to understand what is the impact of FDA communications around risk. And then what is the opportunity to learn from that, and to advance knowledge and practice much more broadly based on those learnings. And it just seems like kind of a golden chance to kind of create a laboratory that would be very valuable at this point in time. And that, possibly, a wonderful place to start, if we were just to pick something very concrete and specific to start with, the area of emergent

risk is so important. There are so many important areas, but emergent risk might be an interesting place to start.

DR. FISCHOFF: Okay. Last call.

DR. GORELICK: This sort of takes us slightly away, but I wanted to share my epiphany of the day, which is, our university, as well as many universities for a whole host of reasons are now engaged in a sort of reviews of their general education requirements. I don't know for how many of you that -- my wife is chairing that at another university. I stayed away from it at mine, but this whole day has made me think a lot, and our numeracy expert maybe can help here about the difference between mathematics and statics, and probability. And how they fit together in terms of learning.

The reason I ask this is, there's always sort of hammering on campuses and at the federal level about the extent of -- where the Math SAT score is, and Math learning.

And, yet, more and more, and your paper, especially, made me think of this about numeracy, more and more it's in a complex world with evidence-based medicine coming up, and all -- it's the ability C- statistics and probability are becoming absolutely key life skills. And what I can't -- what I really don't know the answer to is whether the current emphasis in most general education on the mathematics course, you know, get up to pre-calc, or calculus and then you're done. Does that solve this? Does that address this? If it doesn't, and it doesn't, the reason I sort of asked it, knowing it doesn't, because I had a low SAT score, and I ended up a statistician, so I know there must be some difference here. And I'm beginning to think that at least some larger discussion, and maybe not here in this group, but about the extent to which we introduce the basic issues of probability into general education on the secondary, and on the college level; not only

for medical risk and stuff, but the ability to understand opinion polling, and all sorts of other things which, again, I'm not sure are served by a rigorous math requirement.

DR. FISCHOFF: John.

DR. PALING: The first one is a brief remark that Lee and yourself, Mr. Chairman, can answer quite quickly. Is a typical pattern for these meetings, the end of our deliberations, you define tasks that you'd like your members to do prior to the next meeting, or do we just let it lie on the table, and when we come together, we'll have a new agenda with new specifics? Are we, in other words, going to be tasked with things, either as one group, or subgroups, between now and three months time? And I have a follow-up question to what -- from that, depending on the answer.

DR. FISCHOFF: I'm interested in the answer, too. We'll have one of those Men In Black neuralizers. We'll just blank this

all out, and we'll restart next time.

DR. ZWANZIGER: As for what's typical, it varies. Most meetings, the advice of the Committee is given in the context of the meeting when the meeting is, of course, transcribed. We'll also write up minutes, which you will all have an opportunity to approve and correct. And that's the advice from this meeting.

Then we can certainly start new questions. We would try and make all of this available openly to the public, so that it doesn't happen kind of in-between meetings, which then might not be available for the public.

DR. PALING: Because I'm involved neither in the finances, nor other people's time involvement, my guess would be that it might be a helpful thought to sub-divide these different topics, and perhaps give us each opportunities to come up with ideas back to the group. And because of the need for public

openness, the daylight regulations, we should do that through you. But I felt that might be a useful way to go.

If something like that were to happen, here's a thought that may be totally off the wall. When we had our questions from our guests out there, I realized that I knew relatively little at the depth that many of our friends do. And the suggestion was made well, perhaps we should let our risk experts talk to you as a Committee, so that you will be better enabled to see the broader perspective. In other words, to get a steep learning curve. With that, I agree. I pretend nothing other than that I try to come objectively at this. I have a fairly strong background, but I do not have the answers to the complex questions that we have.

All that leads to this. I'm wondering whether there were a way for a website to be opened either within FDA, or separately, where we could agree various

specific questions, and invite all interested parties to give their answer within 100 words. Things like how do you, whoever the you reading this is, think that we should deal with the communication of the risks and the benefits? How do we deal with uncertainties?

I would guarantee -- I mean, I don't know how many people would respond to that opportunity, but I would grow greatly as a member of this Committee by just seeing the sorts of responses that came in. I'm not suggesting we should reply to them. What I'm trying to suggest is, I would love to do a good job on this Committee by being willing to listen and learn to a depth that I don't at present have. And if it were possible to do that electronically, to me, that would be a great benefit.

DR. FISCHOFF: Let me -- go ahead.

DR. ZWANZIGER: I was just going to say, I will --

MS. VEGA: My question, when we had

the presentation in terms of the mandates, there are some items within the mandates, for example, the Advisory Committee shall say Direct-to-consumer advertisement as it relates to increased access to health information, and the great health disparities for these populations." And there are other mandates then, it seems to me require action of the Committee other than at the meeting time to implement, how are we going to accomplish this?

DR. OSTROVE: It depends on what FDA wants. And those are the kind of discussions that we're going to have to have, that Lee and I, for instance, are going to have to have internally with some of the groups that are involved in this process. So, for instance, the Direct-to-consumer advertising focus on some of those, we would work with the Center for Drug Evaluation and Research, specifically, the Division of Drug Marketing, Advertising, and Communications, to

kind of decide with them, with their lawyers, with their social scientists, to decide how we're interpreting the statute.

The statute is -- it is what it is. And the question is how do we interpret that? And then we would then follow-up with that with the Committee, as a function of what FDA decides it needs from the Committee. Does that kind of C- I mean, it comes down to our decision, ultimately, in terms of the agendas. Now, we've kind of talked about this from an administrative standpoint, but, essentially, FDA kind of sets the agendas. You're here because we need your advice, and we will probably have a lot of things that we need your advice on. There are some things that we're required to get your advice on. Then the issue is how do we do that? What are the kinds of questions are we going to ask? And we need to work with our people internally to make those determinations. And you will, undoubtedly, be hearing about the DTC stuff,

most likely pretty soon, because the statute mandates that there be reports within a certain period of time.

So given that, I hope this sounds relatively straightforward. It's kind of hard, because we haven't discussed those internally, yet. So it's hard for us to say how we're going to ask for your advice, and to what extent we're going to ask you to do stuff outside, and to what extent we actually are permitted to do that. That's something that we'll also have to work with our internal people on to figure out. So we're kind of at the beginning here, and we're just kind of working it out as things go along. And I hope that that's not too vague for you.

DR. FISCHOFF: Let me, in closing, just remind, just check me on this, to remind the panelists that we're not allowed -- the Committee members are not allowed to talk about any issues that are on the agenda, so if you don't like your dinner, don't -- if you

want to send back your dinner, it's not a recall. Use some other term.

We are free, however, to talk about our own process, so if anybody has feedback for me on how the meeting was run, or perhaps even any thoughts about how we'd like to organize ourselves, I think that that's probably fair game, as long as we're not talking about FDA issues.

Okay. So let me just thank everybody for staying with it so intently, and let me just thank our audience for coming, and those who presented to us, and 8:00 tomorrow.

(Applause.)

(Whereupon, the proceedings in the above-entitled matter were concluded at 5:05 p.m.)