

FOOD AND DRUG ADMINISTRATION

Advisory Committee on
Risk Communication

FDA White Oak Campus
10903 New Hampshire Ave.
Building 31 Room 1503
Silver Spring, MD

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Proceedings by:

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P R O C E E D I N G S (8:05 a.m.)**Agenda Item: Welcome**

DR. FISCHHOFF: Welcome everybody to the second day of the 12th meeting of the -- should be more of the FDA's Risk Communication Advisory Committee, and I welcome the audience, as well. And let me introduce Dr. Lee Zwanziger, who will do the official introduction.

DR. ZWANZIGER: Good morning to members of the Risk Communication Advisory Committee, members of the public and press, and the FDA staff, welcome to this meeting. The following announcement addresses the issue of conflict of interest with respect to this meeting, and is made a part of the public record to precluding the appearance of such at the meeting.

FDA has determined that members and temporary voting members of this committee are in compliance with federal ethics and conflict of interest laws. Today's topic is communicating risks and benefits, an evidence-based users' guide. This topic is a non-particular matter, so no interest in firms regulated by the Food and Drug Administration present potential for conflict of interest, or appearance of such at this meeting. Should the discussion turn any area possible conflict or an area not already on the agenda, participants are aware of the need to identify any conflicts pertaining to them, and refrain

from participating, and their statements and exclusions will be noted for the record.

We do have a period set aside for open public comment that is listed on the agenda. If anyone's not already signed up to speak and now wishes to request time, please see one of my colleagues at the sign-in table outside. If you wish to make a comment on the book, I'd encourage you to take this opportunity to sign up.

As I mentioned yesterday, we have a customer satisfaction survey for giving us feedback about our advisory committees as a venue for two-way communication, and I'd encourage you to fill that out or sign up to get sent a Survey Monkey link.

And I would also like to mention that this meeting represents the public reporting out of the risk communication editorial subcommittee, back to the full committee, in open session, and also the reporting out of the petitioner's perspective subcommittee in open session.

Finally, let me just remind us all that the meeting's being broadcast by internet and transcribed. The transcript will be posted on the FDA website. Please remember to turn on and speak into the microphones every time you return to speak, and then turn them off when you're not speaking. And also, it's probably going to be easiest for all of us if we turn our cell phones and other

devices to a silent mode, such as me right now. And then, otherwise, I just thank you very much and turn it back over to our chairman.

DR. FISCHHOFF: Thank you for coming. And the primary order of business today is to talk about a book that the present and past members, and consultants to the committee have put together. It's all in part an elaborate ruse to bring back a couple of our former members. And so, let me ask everybody to introduce themselves, beginning with our former members.

(Introduction of members of committee)

**Agenda Item: Communicating Risks and Benefits:
An Evidence-Based User's Guide - Overview and Reflections**

DR. FISCHHOFF: So as I mentioned, the order of business today is to talk about the book that we have assembled which I think nobody, other than Lee, has seen as yet. I understand we're going live at 11:00, and this has been quite an enterprise. And what we'd like to do is to tell you where the book came from, for each of the authors who are here to talk briefly about the areas that they represented, and then to enlist your help in thinking about how to make best use of the book, how to get it into the most hands, how to get feedback on it.

And then, we'll have a discussion of generally where our relations, we'll hear from Malcolm and then we'll

also have a general discussion about how best we can help FDA. We have an open-public hearing session after the break at 10:30. I welcome anybody who'd like to, who have come in with thoughts and hasn't signed up, or are stimulated by the discussion of the book, to check with Lee during the break. The open-public hearing is a special part of the Federal Advisory Committee ritual, and we really value those input. So it's not too late to sign up.

So I have some slides, and I'll present them from here. So the name of our book is an Evidence-Based Guide to Risk and Benefit Communication. And to deconstruct the title a little bit, this is meant to be a guide, so it's meant to be practical. It's meant to be evidence-based in two senses. One is that we'd like to use the best science where science exists, rather than relying on an intuition or a conventional wisdom or accepted best practices. Best practices can be terrible, they can be unfounded, so I'm trying to make this evidence-based.

It's communication about both risks and benefits, although the committee is called the Risk Communication Advisory Committee, it's been clear from our charge and from our discussion at the very beginning that the risks and benefits are always part of the message. FDA, in some sense, would not let anything on the market if it didn't have benefits, as well, so we're cognizant of both of

those.

Just to remind people very briefly, this committee is a statutory committee. It was actually begun as an internal edition of FDA staff. And then, before we had met for the first time, we were made a statutory committee, so we can't take any credit for that under the Amendments Act of 2007. So it's a permanent committee, it has some specific charges, such as advising FDA on recalls, on certain aspects of direct to consumer advertising. But perhaps our most greatest value is as a general consultation resource. My personal opinion is that our most valuable meetings have been ones where, like yesterday, where the staff has come to us, who said we've got a problem, perhaps you can help us.

Yesterday I found particularly rewarding because the staff came to us very early in our developmental. They had worked very hard, so it probably didn't feel early to them, but they had gotten to a place where they understood the contours of their problem, where trying to integrate the public all the way through. And as human factor specialists will tell us, the earlier you are and you involve the users, and in some sense, the research is a way of introducing the users in a systematic way. The earlier you involve the users in the design process, the better the design is going to be.

Our former roles have been as a channel to the science. We've had several research seminars, which are the genesis of today's meetings, and we've produced several recommendations, leading to the book, Evidence-Based Communications. So here's a list of our topics of our 12 meetings. In two of those meetings, we've devoted to the sciences of communication.

Where did this book come from? Malcolm and I ended up at National, waiting for a flight, and said there was some kind of magic here and how do we capture that for people, who weren't in the room or didn't capture the live video. And in parallel, Lee and Nancy Ostrove basically had the same conversation. And I called Lee on Monday and said could we do anything about, and they said, we're already working the problem. So that was really the genesis of the book.

So what have we tried to do? The goals that we set for ourselves, the book, to make communication science accessible. So for good reasons, we publish in impenetrable ways, or only penetrable to people, scientific communications, who are willing to work really hard. And even then, it's only accessible if you know the code, the short-hands, the things that we're all nervous about that we never say. So we thought that a barrier to using the science just is very hard to get access to that science, so

let's make the science accessible.

Second, we want to make evidence-based approaches possible for agencies. So agencies, first primarily FDA, but we hope that this will be valuable to anybody concerned with communication about risks and benefits. And the obstacle that most practical organizations face is they have limited resources, sometimes in terms of time, although you can expand the time available by recognizing that you need to build in a design process. They're always strapped for resources, and sometimes they're not staffed with people who have been trained in the social and decision of sciences that are relevant to it. So we thought, if people want to be guided by the evidence regarding their specific communications, and not just the evidence from the basic scientific literature, we needed to find some way to enable them to take advantage of the science, figuring that a little science and a little evidence will go a long way, and perhaps to begin a virtuous circle.

And once you started to collect data, evaluating your own communications, it leads you to collect more. If things aren't working right, it gives you some diagnostic hooks on why they're not working right. It gives you realistic expectations on the different kinds of communications. So any kind of collection of evidence, on

the communications that any agency is doing is welcome.

And finally, recognizing that there's expertise in doing this, we tried to produce the book in a way that would enhance the human capital of the Agency staff, that would ideally lead to the hiring of people who have been trained in this as a skill. And where that isn't possible, to make people into research, to the extent to which any of us are able to do quick communications. Part of it comes from our training, but also the long apprenticeship, the surprises, the data collection. So if we could help people to collect data that would be informative to them, they would gradually acquire those skills. You might hire other people, they'd be more sophisticated, purchasers of communication skills from the outside. So those were the goals in the book.

The strategy that we took to implement their goals is that most of the chapters, there's some introductory and conclusion chapters, but the meat of the book are some chapters that they're all 3000 words, and they all have the same structure. So there's a quick summary of what does the science say relevant to communicators, properly qualified in terms of just how strong the science is on the various places, figuring that the best guesses from the science are better than the best guesses from raw intuition and common wisdom. But

responsible sciences will let people know how strong the science is. So each chapter begins with a summary of the science.

Then, what does the science mean. We tried to extract our best guesses from the research, regarding guidelines for communication, not pretending. We've used the phrase, best guesses repeatedly, so as not to pretend that there are any hard and fast guidelines, that there are any panaceas for any communication. Communication is a continuing process. You can always do better, and anybody that claims that they can communicate something perfectly is unsupported by the evidence.

And then, finally to say here's what the science says, here's what the best guesses to use, recognizing that even those best guesses are going to be flawed, how do you collect evidence to see how well you're doing. And each of the evidence sections, each of the evaluations sections has recommendations for evaluation at three levels. Evaluation you can do with no budget at all, evaluation you can do with a little budget and evaluation that you can do with a budget appropriate to the problems, recognizing that individual's lives, agencies' reputations, people's political careers, corporate profits, all can suffer from inadequate communications. So we wanted to make people feel guilty if they don't do any evaluation at all, so we

say you can do it with a little bit of planning, but not additional resources.

So here's the table of contents of the book. We have some framing chapters, in terms of the strategy. We have a chapter on goals that Noah will talk about in a bit. Julie Downs was another editor and couldn't come here, did a chapter about evaluation. And I'll talk about that a little bit because it's so central to the enterprise. I wrote two chapters which I'll talk about in a minute, one on adequacy, by which I mean how can you tell whether your communication is good enough, so all communication will be imperfect. Can you tell whether it's good enough for you to risk the lives, profits and reputations on what you got, or do you need to go back or do you need to supplement your lead communications with ancillary efforts, in order to see that the job gets done.

And this sort of second chapter on what are these risks and benefits that we're talking about, basically trying to frame the issue. If you're missing the topic, if you're not talking about the right risks and the right benefits, it doesn't really matter if it's technically accomplished, because it's beside the point. We have a wonderful chapter by a former member, Musa Mayer, who's a general patient advocate, who had originally focused on issues related to metastatic breast cancer. She's also a

professional writer, and has a chapter talking about the use of language, and particularly of metaphor in communication.

There's naturally much of the communication that we do is in the jargon denotated. It talks about specific risks and specific benefits, but any communication has a sort of connotative ways in how you think about the overall problem and how you organize the evidence. So it's a wonderful chapter, and Musa talks about what does it mean to talk about a battle of cancer, there are different ways. And I think you could generalize from thinking about that metaphor to other ones. So it's from the side of humanities rather than the social sciences, but it bookmarks that that's an important issue.

Then, we have four chapters on the kinds of information. We talk about quantitative information, how big are the risks and benefits, and how tight are the (?) intervals around them. Qualitative information, that is information about how are risks created and controlled, so that people can feel that they understand where the estimates come from, feel confident to deal with problems, warnings and disclosures, persuasive communication.

You'll hear from the authors on this, so I'll go through these a little quickly. How to deal with issues where people of low literacy and issues of readability, how

to deal with emotion, which in some ways is related to Musa's topic, but it's a whole other area. It's an active research area, it effects how people think about risks, think and feel about risks and benefits. What are the lifespan issues, so this section is on the audiences.

The one dimension of variability in the audiences is their literacy and their ability to just comprehend what we're saying in various forms. Second is that we all have emotions as traits and states. The third is there are predictable differences in how people process information, think about their decisions, as a function of where they are in their lifespan.

There are issues to deal with underserved populations and again, ideally you'd like to, where the stakes are hard enough, deliver individual communications. One would like everybody to be entitled to the personalized tailored communication. But if you're thinking about broader band communication to different sectors, there are predictable things to think about, in dealing with underserved population. And finally, talking about communication with professionals.

And then finally, we have a section on media, so we have a section on decision aids. These are structured ways of putting information typically interactive, that people can use with them. We have a chapter on how the

roles that the mass media play or could play in communication about risks and benefits. Issues of design, and then finally, how to train people and how to create organizations that are structured to take advantage of the science within their constraints.

So that's the book, and you'll hear bits about most of the chapters. This was really a remarkable effort, under the constraints of the Federal Advisory Committee Act, which was so ably interpreted by Lee. This was a product of a subcommittee of the committee. It's a product of the whole committee. So it took a lot of doing to figure out how to do this in a way. And among other things, nobody saw any of the text, if they were not a member of the committee or a special government employee, who had either been formally on the committee or had been a consultant to one of us.

Working with that constraint meant kind of remarkable efforts on the basis of our committee members, who needed to serve as internal reviewers, who needed to meet really tight timelines. The authors needed to put up with this somewhat unusual structure of the chapters that Noel, Julie and I came up with just 3000 words on this. To tell everything you know while standing on one leg, but people put up with it.

And then, FDA staff just did a remarkable job in

figuring out how - we don't know much of what they did, but they solved, and are continuing to solve, all kinds of problems, so that we, in the broader community, get the full benefit of our work. So here are four people who make particular effort, Nancy Durrell who is an editor and writer, Jan Allecor(?), Helena Kettlehuck(?), Eric Amunos. There are other people at FDA. FDA, as an institution, stood behind and supported this remarkable, unusual enterprise, and finally, Lee just did an incredible job. I knew she wouldn't want this. (applause)

I didn't let Lee see my slides because I knew she wouldn't want this. But now, this is in the official record, so here it is. (applause).

And the picture here is from a vacation snapshot by Nancy Ostrove. I think nice color scheme. Not everybody's an expert on the effects of the motion on risk communication, but everybody is an expert on covers.

So let me talk a little bit about my chapters, and then we'll go around to the other chapters. This is Julie Down's chapter, so it's on my take on some of it. So we believe that research is always needed. Research in the two sense of, one, what does the science say, and how do you evaluate your best attempt to apply that science in a particular situation. It's always needed because for two reasons, one, we can't trust our intuitions, and second

that basic behavior research is indeterminate, so you need to evaluate the applications.

In some ways, academic psychologists make their living by demonstrating the limits to human intuition. And many of these limits are ones that reflect our ability to understand how well we're communicating, and how well we understand the people with whom we're communicating and how effectively we've conveyed our message. So here's a sample of things that will be familiar. Most of these will be familiar to people who have had Psych 101. So there's the common knowledge effect, so we exaggerate the extent to which other people, we share our knowledge. So we leave things unsaid, and thereby deny people the context for understanding what we're saying.

A variant of that is the false consensus of that, whereby we think that our values are more widely shared by others. There's the fundamental attribution here, which is our tendency to be highly sensitive to how our own behavior is restrained, by the context within which we're operating, and but to view other people as being driven by their personalities, and relatively obtuse to the circumstances. So that leads us not to appreciate the constraints, under which other people are operating, and in a communication context, giving them advice that they can't conceivably follow, or it doesn't address their actual concerns.

We're guilty of self-serving biases, that as we tend ourselves in a more favorable light, then is willing to in a communication context, that we tend not to notice situations in which we're part of the problem. And so we just won't address those issues. They myths that we have about particular aspects of human behavior, so the sociologists, the disaster researchers, find that although many people believe that panic is common in natural disasters. Then in fact, the opposite is true, that most people rise to the occasion or respond responsibility, often heroically, when there are emergencies. And people believe that adolescents do things that we wouldn't do or we wish they wouldn't do, or we can't remember having done when we were the same age, because they had an unique sense of vulnerability. Whereas the research is one that most people tend to have an unrealistic sense of optimism and vulnerability, and if anything, adolescents feel more vulnerable than adults.

And as another, that our feedback that on how good a job we're doing and how well we understand people and how well we're communicating. We have poor feedback in a way that keeps us from understanding how well we're doing and improving. So often, in sustained communications with people who are candid with you, you can finally get things across. So you can live with somebody for many years, and

still be surprised when you're not making yourself clear. But in many of our communicates, there's no feedback at all. You put out a message and you have no idea. You knew what you were saying, and if people don't do what you think they could do, you could say, well, nothing wrong with my communication, they were incapable of understanding, or they were unreasonable or they were hysterical or they were incompetent. So the feedback is absent, it's often can be distorted by how people present themselves, because we often don't want to confront people. We don't want to admit we don't want to understand things, so feedback can be distorted. It's often delayed. So lots of psychological research showing that when feedback is delayed, it has much less impact.

So to begin with, our intuitions are flawed and life doesn't always help us to do better, although we're all kind of trainable under good circumstances. Secondly, so we should not rely on our intuitions, and we should rely on the research to the extent possible. And then, however, even that research is indeterminate. This is my take on Herbert Simon, a well-known polymath, would think about decision making. He would say that decision making follows simple principles. However, the set of those principles is very large, the contextual triggers are subtle and their interactions are complex. As a result, decision specific

research is needed.

So we know a lot about human behavior and all these things, so we know how to explain small portions of the variants in any situations. And how people are going to draw on their repertoire and possible behaviors is just unpredictable on first principles. You just can't say people will do X if you do Y. I just put, for the record, here are some of the principles that we have in judgment. These will be familiar to the psychologists here. Here are some principles of choice.

So knowing about these things will help you to predict things that you might not have thought of otherwise, but they won't tell you what's going to happen in particular situations. So as a result, empirical research is essential. Without scientifically sound data collection, one could only guess what people believe and want in any specific situation. You might get guess better if you've been trained in the social sciences, but it will still be guessing. And again, given the stakes, it makes no sense not to evaluate your communications.

And Julie organized this, and so Julie tells that story in slightly different terms. She, in presenting the science, talks about three kinds of evaluation research formative, that's deciding the basic research strategy. What are the things you're going to say, how are you going

to say them, what kind of communication process you're going to have. Second, process evaluation, how good is your implementation of your intention, and finally, the impacts. And you can evaluate the impacts. Just ensure that people have the appropriate knowledge, you can want to change people's attitudes to valuing exercise more than they did before, you can try to get behavior change, you can try to get people to make decisions that are better for themselves, without presuming to know what those decisions are. The distinction is sometimes called non-persuasive communication or purely informative communication.

In her section about research designs and outcome evaluation, for outcome evaluation, she talks about three basic kinds of design, rather than device control trials, observation of environmental changes and limited comparisons, pre- and post-communications. It talks about the strengths and weaknesses of each. Sometimes you can't do the kind of communication that you want, but at least you can be informed by the vast literature on what we know about things that attempt to go wrong when you can't do things right. That was the chapter on evaluation.

I wrote a chapter on adequacy, addressing the question of when we know enough, when the communication is good enough to go live. And it has examples of situations, examples of work, examples of some length. One looking at

what could be a very complicated communication action could be made very simple by thinking about what was the kernel of things you needed to get across. And another example where extremely elaborate, expensive communication system was inadequate to the task, where you could not rely on conveying information, in order to protect people. It's kind of anchoring that continuum.

So the chapter says, a communication is adequate is if it has the information that people need for effective decision making. If people can access that information, and people can comprehend what they access, and then, it offers operational tests for telling whether or not this is true, so whether or not you've achieved these standards. So communication, in terms of the content, is adequate if it contains any information that might affect the significant fraction of users' choices.

So here's the fire hose of things we could tell people what really matters for their choices. Like any evaluation, it requires listening to them, as we heard repeatedly yesterday, in order to find what decisions they're facing. Second, in terms of the accessibility of information, the communication is adequate if it puts most users within X degrees of separation, from the needed information given their normal search patterns. So you have to take people as you are and get the information to

them, not put it in a place that's inaccessible to them.

And finally, if we've got the right stuff, we've put it within arm's reach, do people understand it adequately? So communication is adequate if most users can extract enough information to make sound choices. And then, the chapter elaborates on each of these. And finally, it ends by saying that you can do the best science, but in the end, these are policy judgments of whether the communication is adequate. So the things in bold are the places where there are policy judgments. So the best communications will not serve everybody. What is a significant fraction of people who are being adequately served or inadequately served? Or how do we define users? And often, you're in a situation with a limited budget that you could try to reach a very large population, or a select population of people who are particularly vulnerable or have particular difficulty in gaining access to the information through other means.

So the definition of user is a policy choice. One could, as a policy judgment, hand deliver or provide individual counseling, and not do any broadband communication, if you decided that those users were particularly important. So the chapter concludes with the places where the communications researchers need to take their guidance from the policy people, as well as to help

the policy people to understand what are the hard choices that they inevitably face.

There are two more chapters and then somebody else will talk. So then the question is what are these risks and benefits that we're communicating about? So there is a science of deciding risks and benefits. I organized this little bit of repetition with the previous chapter, that the science shows that, first of all, people exaggerate how well they know what matters to other people, which means that one needs again to listen to your audience before starting anything.

Secondly, there's a pretty substantial literature, suggestion that people may not know what they want. And as we sometimes often think that decisions are difficult because we don't understand what the options are. But sometimes, particularly in the kind of difficult, health-related choices that FDA is entrusted with, it's just these are really hard choices, and you just don't know what's important to you until you've had help in thinking through the issues. So you don't need more facts, you need different perspectives, you need how of how experiences of other people who have been there.

Another way that psychologists make their living is by exploiting situations in which people are uncertain about their values. And we show that presenting issues in

different ways will produce context effects or framing effects that could, at least under experimental conditions, sometimes under real world conditions, can lead people to make different choices faced by the same set of facts, depending on the values that are evoked. So that's a behavioral reality that communication needs to deal with.

And finally, values, so for example, if you have the power to frame issues or to have context effects, that you may have an obligation to present things in different ways. So that would be an implication not to exploit your power to frame things, unless you're in a situation where your mission is to manipulate people to do something. And finally, the third point is that values are sometimes embedded in how choices are defined. And maybe this comes more from decision science than from the social sciences, so people who worry about formulating and doing risk analyses.

Imagine you're analyzing the risks of death. There are two ways you could define the risks, well, there are many ways, but two options that you have for defining the risks of death, is what's the probability of premature death. That is how many additional people will die as a result from side effects of the drug, presuming there are people who will live or prosper because of it. So what's the probability that somebody will die prematurely because

of it? Or you could say what treats a death as a death? Or you could say how many expected life years will be lost as a result of this, of using this product or exposure to this technology. If you look at expected life years lost, then you're placing particular value on deaths among young people.

And so the choice of measure depends on whether death is a death, or one values death in young people more. If you're taking a position, take a fundamental, ethical position, whether you do it one way or the other, for people who follow the controversies over risk and benefit analysis. Look at attempts by Office of Management and Budget to assign different dollar values to human life in evaluating the risks and benefits of programs, and trying to take into consideration the lives of people who are involved.

So these are things that, looks kind of obvious, but they're surprisingly subtle, and they're often not people who do or are accustomed to doing the analyses in one, or often not self-aware that they're doing it in health. And so there are people in the risk area that worry about how to extract these hidden values. There are many other things that you could take into consideration when you're analyzing risks. You could treat a death as a death, or a lost life year is a lost life year. Or you

could worry about the distributions, they break out, whether these risks are born by people who are and are not beneficiaries of a technology.

Or are these risks assumed voluntarily, and you could break out for the policymakers or the public's decision, whether or not they're assumed voluntarily or people have accepted these or people have these risks imposed on them. You need to do these things one way or the other, or present them in alternative ways. So the chapter talks quite a bit about how we can keep from embedding fundamental social values in risk analyses, in ways that manipulate decisions, perhaps deliberately, perhaps inadvertently.

So what practical advice does that science support? So use standard definitions based on that if we present things in the same way, then people will be able to make comparisons across different kinds of decisions reaching, so greater fluency in how they think about risks and benefits, as well as being able to perhaps achieve more consistent policies. The standard definitions need to be informed by this is the jargon of behavioral decision research, normative research, which is looking hard at the choices that people face, taking what some people call an inside view on their decisions, not what we think their decisions are, but what they tell us their decisions are.

Informed by subject matter expertise, that will tell us what really is at stake in a decision.

So providing the information, I want you to know what's important to me. But realize that I may not know what's important to me, if I don't know what's at stake in a particular situation. So this is the normative research. It's a disciplined way of looking at what people's decisions are. Descriptive research, what you're seeing what people believe and want, and finally prescriptive research, that are interventions to try to bridge the gap between this normative ideal and the descriptive reality, as we say.

And finally, the chapter talks about the three kinds of evaluation. So no expense, one can look at the face validity of the communication. Do they, for example, actually give people quantitative estimates of the risks and benefits that they're facing, with some expression of the quality of the evidence? You could not make a rational decision, either directly or helped by somebody else, unless you know at least the first approximation, how big the risks and benefits are, and how much the experts know. If the communication doesn't tell you that, and you can't be presumed to know it from some other way, then it lacks face validity. The chapters then talks about some simple ways of collecting data, and then finally what one might do

with a more elaborate evaluation, again, as warranted by the stakes riding on it.

I have a final chapter. I won't go through this now, but the slides will in the record that actually Julie Downs wrote, and I was the second author, which talks about what we call a quantitative information, which is what's known about how risks and benefits are created and controlled. And it talks about how there are situations in which people want or need that information, kind of the science underlying the estimates for three reasons. One, it enables people to understand and evaluate quantitative claims. You tell me the risk is very small or very large, tell me why that is, if it isn't consistent with my intuitions. Second, it affords the feeling of warranted self-efficacy. That is, in cases where people care about the decisions, they'd like to feel that they are somewhat in command of the facts and of their own situation. If my situation changes, and I just have categorical advice on what to do in my current situation, then I don't know what I need to do things differently. I can't tell when conditions are changed, if I don't have some theory and I can't know what to do.

And finally, telling people why we believe something to be the case, why we're giving them advice, why do we think the risks are large and small, as a way of

demonstrating extra respect for the lay audience. It's a way of showing that you believe that people are entitled to know that, and capable of understanding that, if you do your job right in presenting that information. Again, our goals in the book were to make communication science accessible, to facilitate evidence-based approaches, and to enhance the human capital of Agency staff, by allowing everybody with whatever budget, with whatever training, to do a better job. Communication is an essential human function. We're all, in a way, experts in this or we wouldn't have gotten this far.

On the other hand, we do tend to exaggerate our expertise, so taking advantage of the science can enable us to do better. Okay, thank you for bearing with me, all that talking. And now, we'll hear from the other authors, and then we'll have a general discussion among ourselves and to invite you. So Noel?

Agenda Item: Summary advice from selected chapters

DR. BREWER: I think I will just make my comments from here. I don't have slides, but I have only really really three things that I want to slide, and I'll lay them out. But before I do, I just want to sort of paint a little vignette for you. So you're a consultant, you're in Manhattan, and you go into meet with a new client. And

you're sort of apprehensive. You're a little distracted, thinking about stuff.

And you walk into this building, it's a pre-war building, a little dusty in that sort of sturdy way those buildings tend to be. And you walk in the elevator, and when you do, if you can bring up that slide, you see this sign. And it says, should the elevator doors fail to open, do not become alarmed. There's little danger of running out of air or this elevator dropping uncontrollably. Please use button marked as alarm or telephone, if furnished, to summon aid. Elevator companies are on call 24 hours a day for emergency service.

So of course you notice this after the elevator doors have closed. And you think, what on earth was on these people's mind? So this is a risk communication. The people who designed this sign had a plan. What was their plan? Well, I really don't know. I'm going to tell you at the end, I think they had a bad plan. But let me propose that there are goals, and that's the topic of my chapter, it's the second chapter or the first chapter or the third or whatever in the book.

Let me just propose that there are three goals to risk communication that we should contemplate. Our first goal is just saying it. The second one is to communicate risks in the way that changes people's beliefs. And then,

the third is that we can have a goal to change people's behavior. So those are the three things that I want to tell you about.

So let's start with the just say it one. A good chunk of risk communication is done to release the communicator from some form of legal liability or to satisfy some kind of statutory or regulatory requirement. So the package inserts for drugs that the FDA regulates really do follow that line. If you've ever sat down and tried to read them, they're largely impenetrable, they're very small type. They're really pretty much designed to not be read, although they have some very important information. So that is one kind of communication, and this just saying it can be done for good reasons, for wholesome reasons, but it can also be done for cynical reasons to manipulate people. So they've been given information that they're responsible for, and yet they couldn't possibly understand.

I actually believe that institutional review boards that regulate the research, such as the research that I do, often behave in unethical ways because they give risk information to study participants in ways that is basically impossible for them to understand. Having been a participant in several research studies recently, I can tell you I don't think I really understood all of what was

going to go down, especially in some of these biomedical studies. All right, so that is the first one is just say it, and I'm going to say that that's an inadequate goal, just saying it, having the risk information presented in whatever form, whether or not it's understood.

So it leads to the second goal, and that second goal is changing what people believe about their risks. And this can be changing their emotional state, it can be changing what they believe about how likely something is to happen, how bad the outcome can be. There are a lot of different kinds of risks beliefs we could concern ourselves with. But the goal of the second kind of risk communication is particularly useful when we don't know what the behavior is that people should engage in. There are various medical procedures that may or may not have a known outcome that everyone should engage in. In those cases then, fine, fair enough.

Prostate cancer screening may be harmful for some men, it may be helpful for some others. Certainly once you get to the point of treatment, it's really unknown what we should do. And so, for men who are making decisions about prostate cancers treatment, we want them to be informed about what their options are, but we don't have a single best option for everyone. So in those cases where we don't know the best outcome at the population level, it is very

appropriate to change risk beliefs.

Now, the third goal, which is to change behavior, let me propose is particularly suitable when we have a public health option that is well-defined. For example, cervical cancer screening for women with intact cervixes who are within a certain age range, for those women, it is highly appropriate that they get cervical cancer screening. This is a very potent public health tool, it saves lives. So in that case, we know that the best thing for the public's health is that everyone, all women who are within this target group, would get cervical cancer screening. And so, we know the best option, we simply want them to change their behavior.

But it requires that we know that best option. So in those cases, it may be, and this is the tough thing, risk communication is not always the best option. It's often a relatively weak way to change behavior. Risk communications don't always work, they often don't work. As a person from Department of Health Behavior and Health Education, I can tell you, health education has a long and checkered history. And some of it works great and a lot of it doesn't. So just the idea that we can put risk communication out there, and it will suddenly change people's behavior, maybe not.

The FDA has a process of recalls. The

regulations around this have changed recently, but voluntary recalls or required recalls or what have you, but the idea of a product recall is motivated because we believe those things out there are unsafe. So when certain foodstuffs are taken off the shelves, it's not because we've said, you know, there's a problem with these things, it's unhealthy. And we'll just tell people they should just not buy this stuff or people should get rid of it. The FDA actually regulates in a way, it's taken off the shelves, it's a policy move. So changes to policy can be incredibly powerful, as a way of protecting the public's health, and changing people's behavior. Because as it changes the environment that they operate within.

When that is not possible, or for example, in the case of food recalls where you can't get all the food stuffs off the shelf, or maybe there's some stuff that's already gone to people's home, then risk communication that attempts to change people's risk, understanding of their risk, is also a really important adjunct. So those are my three ideas here. You can just say it, which is not good enough. You can change people's risks beliefs, which has a certain place. And then, there's changing people's behavior, and risk communication is one of the many, many ways to change behaviors.

And then, finally, evolution. Baruch talked

about evaluation, but knowing what these risks communications do is really important. So when we all look at this sign from the elevator, we just laugh. If it weren't so alarming to be in an elevator with this thing on the wall and the doors shut and you're sailing up to the 33rd floor, it's a funny sign. But someone thought it was a good idea somewhere. I'm pretty certain that if you did some evaluation on this, you'd find out that this was a bad idea. So this is a risk communication that probably has the opposite effect of what's intended. The behavior is get on the elevator and just act normal. And the reaction is, are there stairs? At least my reaction is that.

There are other types of risk communication that can go the other way. So risk product information can elevate your risk unnecessarily, but it can also reduce risk or make things seem more desirable. There's an add that currently airs in the triangle of the Raleigh-Durham Chapel Hill area in North Carolina for a weight loss product. And that ad says something along the lines, in that sort of muttered voice that's intended to disguise certain problems with a product that are undesirable, but are required to be announced. It says, if you lose more than ten pounds in three weeks, you should see your doctor to have your medication adjusted. Which, ten pounds in three weeks, sounds pretty great, I'm sure, to most people

who are trying to lose weight. My guess is that that's not required, and that's actually a side effect that they sort of manufactured in a way to help sell their product. So the mechanics of this, in some ways, follow a bit of intuition. But in many ways, require external verification beyond just us and our own intuition. So that's my last plug there for evaluation. Thank you.

DR. FISCHHOFF: Angie?

DR. FAGERLIN: So the topic we were given is the role of innumeracy in medical decision making, in the sense that a lot of people just don't understand numbers. My favorite example is that about 50 percent of people cannot calculate correctly a tip. Now, as a former waitress, I love that statistic because it now explains why I got those bad tips. It was never my waitressing, of course. But it's this idea that we can't just present numbers in any old way and people will understand them, but we have to be more wise in the way we present data.

So in our chapter, we begin by discussion innumeracy and really trying to give the people the perspective of the problem of innumeracy in America. Even within a study that Isaac Lipkus conducted in the early 2000s, about 20 percent of people couldn't tell what is a bigger risk, a one, a five or a ten percent risk. So we have a lot of work to do in presenting this information.

And what Ellen Peters and I did was go through probably about ten different methods for communicating information in a better way, to help improve the likelihood that people can understand the risks and benefits presented in educational materials.

So one of the things that we first spoke about was this idea that a lot of people think, well, people don't understand numbers, so why should we even present numbers. What's the point? Let's just say it's a small risk, it's a medium risk, it's a large risk. And so, we reviewed some of the research that suggests why that is not an appropriate method. And let's just put it in very clear example is, a smaller risk to me might be a medium risk to Noel, sorry, you're right across from me. And how everybody defines a small risk.

Similarly, if you tell them you have a small risk of a sore arm after a flu vaccine, that's a very different perception that I hold, then if you tell me I have a small chance of having a miscarriage following an amniocentesis. So even within the same context, words can mean very different things.

Some of the ideas we gave for improving people's understanding is presenting information using absolute risk information. So if you tell somebody that a drug has a likelihood of reducing your risk of breast cancer by 50

percent, it sounds pretty amazing, give it to me now. That's using a relative risk presentation. But if I tell you actually it reduces your five-year risk from two percent to one percent, that drug no longer seems so appealing, does it? And so, we talk about not just using that relative risk information, and presenting it in terms of absolute risk.

We also talk about, I think this is what IRBs has, to go back to what Noel says, this insane desire to include every piece of information you could possibly need to know, so much so that nobody reads it. Sometimes less is actually more. And we say some of Ellen's work and some of the work that my colleague, Brian Zikmund-Fisher, and I have done, which shows that actually including less information can improve people's comprehension of the key information you're trying to communicate.

We also talk about different types of graphical communication that you could use to improve people's understanding, using things that are called pictographs or icon rays, which shows both the numerator and the denominator very clearly, so people can see how many people are affected. We also talk about using consistent denominators in the presentation of data. So sometimes you see, well, your risk of this is one out of five, and your risk of this is one out of 20, and your risk of this is one

out of 1000. And it just makes it very difficult for people to compare the risks. Similarly, using consistent time spans, it's really hard if you say, your risk of this over five years is Y and then your risk of this over ten years is Z, and people again can't make those comparisons.

In discussing how to test communications prior to implementation, which we obviously think is very important, we presented three different ways to do it. One, the cheap way is which what we have to do in terms of piloting is getting the people in the cafeteria, the janitors, people who have very different kind of illiteracies and experiences than we do, to look over our tools first, to see if they could understand it, do some and see how they deal with it.

You can do it very quickly or you can do these very cognitive interviews, where you interview them, ask them for their reactions. And then, the ideal, especially in health education materials, is getting a literacy expert to go through. We try really hard to write at low literacy. But even with great attention to it, we regularly fail. And so we call people like Sue Stableford from Maine and have her come and make it much better. So I think when you have a lot of money, to have someone with that kind of expertise is really helpful.

And then, obviously, conducting randomized

controlled trials to see if it actually does improve understanding or behavior, versus other kinds of interventions, or no interventions at all.

DR. FISCHHOFF: Thank you. Mary and Christine?

Agenda Item: Basic Processes

DR. BROWN: I was very fortunate to collaborate with Christine Bruhn on this chapter, and I want to thank her for working with me. We were asked to write about informative and persuasive public health communication, which is a huge topic. And so, our challenge was to provide some useful information, without getting too high of an overview, which was a challenge for me, at any rate.

So our premise in this chapter was that public information or communication about health risk is both informative and persuasive, in that it aims to inform the public or publics, provide them with information that enables them to make the best decision under the circumstances, and in some situations, also change their behavior. So we think of this information as both informative and persuasive.

And so what factors improve effectiveness of this kind of broad informative and influential, in some aspects, information? And so, we divided the chapter into looking at characteristics of the basic elements of communication, which are the sender, the message, the channel, the

receiver and the environment. And that's how we organized the chapter.

What I will do is just give you an overview of some of the elements or the findings about the channel, and then we'll talk more in-depth a little bit on the message, because we have only five minutes. So just a few things that are important about channels, and I chose the internet and TV because those are the main ones that are being used these days, and also radio. But the internet is a primary source for health information seekers, for those people who are perhaps more sophisticated, more educated and actively seek information.

Certainly social media is effective for quick delivery of urgent messages. We had a whole meeting surrounding the topic of social media at our last meeting. And I think more and more, social media are going to be utilized, especially in urgent situations. For instance, the CDC's H1N1, used the social media in that instance. But important to remember that the internet is not accessible to non-readers. It's not accessible to people who don't use computers very well. So we leave people out when we just use internet.

Radio and TV, particularly TV, on the other hand, is the primary source for the more passive audience, the non-health oriented persons. And it promotes awareness and

knowledge through redundancy, but does not provide specifics, and when the information is complex, it's not the best approach in and of itself. And then, of course, it has the broadest reach to the widest audience.

Speaking about the messages portion of the equation and communication, we don't have strong empirical or experimental evidence here, but we have a good consensus among the wide range of experts on using plain language for high readability. And I know that many of these things are touched on by other authors. So I'm sure there will be some redundancy here.

But here are some features that make written messages more effective. Use fourth to eight grade reading level, and again, it's very difficult to achieve that without someone who is an expert in lower literacy. Use many pictures or charts, labeled clearly, very important. Use everyday words, familiar words and familiar examples. Use short and simple sentences. And here we have some research that says use relative risk, not absolute risk, and I would say use them both. And then, finally, I'm going to go ahead and have Christine finish up. Thanks.

DR. BRUHN: Thank you, Mary. We wanted to stress the importance of tailoring the message to the audience. As Baruch mentioned earlier today, we, because of our specialized training, whatever it might be, may well see

the world and the problem differently than the audience. So we need to find out, first of all, what the audience knows about the issue or the question, your target audience, so that you can begin your communication with what they know and then build from there.

And then, as part of respect for the audience, we think it's very important to find out what they want to know about the particular topic and address that first. We often, as educators, have what we want to tell them. Maybe they're the same thing. But we should first address their concerns, and then slip in the message we feel is important for them to have, in a way that can be relevant to them.

By conversing and directly speaking with them, communicating with them, identify the information sources that they use and what they want to use. What they think is credible and reliable, so that they can receive information in a way that fits within their lifestyle. We feel that it would be more likely that they would get the information in that regard.

The message needs to be developed specifically for the audience, and being sensitive to their lifestyle and culture. Now, in our chapter, we have a few examples of this, where we refer to problems that we're sensitive to the culture and work within the culture, so that people didn't have to change their way of life or their

traditions, but were provided information to enhance safety. These were examples that described on how to approach issues in a positive fashion rather than a negative, and they were effective in initiating change.

We also point out the importance of including recommendations that are actionable, that are specific. You don't just tell people what to do. You tell people the details of how to do it. Don't, for example, just say, wash your hands. Wash hands under running water, with soap, dry with a clean paper towel. If they need the specifics, give them the specifics so that they can actually perform the task you feel is important.

It's very important to make a message personable. People may know information, but they don't act upon it. So it's important for them to see that the message applies to them as an individual. It's not for other people, it's for you. Use examples that the audience can relate to, so they can see themselves in the situation, and realize that this is something that impacts them. And the behavior you're describing is something that they are able to accomplish.

And my pet peeve, for those of you who have been to the meeting a long time, know that I am very concerned that we use information or terminology that is inclusive, rather than exclusive. And my pet peeve is, I don't want

to see elderly on any publication from a public institution, because you know, elderly is older than you are. And if you're 20, elderly is kind of those 30-year olds. And you can be sure if you're 50, elderly is those 60s. And those people who are 80, elderly is those people who are pushing 100. So let's use a more inclusive and more positive term, like older.

As the others have stated, we'll repeat here. A message should be developed with the audience, if possible, and then it should be pre-tested with that audience. And when you pretest, you don't just give it to them, you talk to them and you find out how they responded to it, what made sense and what didn't. You're monitoring the response. Then you deliver that message, you go forward with your communication, and that monitoring continues. And based upon the monitoring, you may well make some modifications, so be it. You're evaluating all the time.

And as with the other chapters, have the least cost, just a few dollars, and the more modest amount, if you have the funds, on how you can evaluate. I think one of the richest parts that I enjoyed seeing and developing is the references to other works, places to get information, examples. So this, I believe, is probably in other chapters, but I especially think it's rich here. So it's a bibliography that's annotated, so words you can go

for and what you're likely to find at those spots. Thank you.

DR. REYNA: Why don't I start off as the slides are coming up with one of the bottom lines of my presentation, and that is that information that is not processed is the same as no information at all. Information that's not remembered is the same as no information at all. So it's important to take advantage of the science in tough economic times that improves and helps us understand how the public and professionals remember information, and put that information into action.

So in tough economic times, we can't afford the luxury of ignorance. And in particular, we need to take advantage of science. So there is hope, and that hope, I think, is in research and the people over here in this room, and in particular, this book about risk communication, which allows us to take advantage of the science.

I'm going to focus on a small part of that, the memory and information processing. And I'm going to talk about changes from childhood to old age, which are quite dramatic, in fact. And I want to remind you about all of the enormous information processing demands that health messages often incur. And many of these things, as professionals, you may take for granted.

So just a tiny little list in small type here. The information processing and knowledge demands the things like diabetes. Children who have to avoid peanuts, for example, all the different forms that peanuts can occur in, that a child has to memorize or otherwise they can have a life-threatening emergency, and on and on. So this is a lot of information to remember and to process for people, in order to preserve their health.

So what are my two bottom line messages in this presentation? Memory is much more than memorization, and age changes in memory are dramatic and qualitative. By qualitative, I mean there's more than just a little bit more memory, a little less memory. The nature of memory itself changes across the lifespan.

So here's an overview of the chapter. As we all know, risk communication is everywhere, it's in movies. Lady Gaga engages in risk communication, as we all know, because she sings songs about things that involve taking risks. And there's a variety of other forms of risk communication messages. Messages that have an impact are processed and remembered, thank you Noel for pointing that out. These cognitive abilities change dramatically. If you think of them as a hole, there's an inverted U-shaped pattern that I'm going to talk about, a gradual improvement from childhood to young adulthood, in information

processing and memory. And then after that, decline, so that's an inverted U.

However, the ability to remember the gist remains stable after adulthood. It's persevered in old age, except if there's a disease process. And in fact, that's very important because remembering the gist of information, as opposed to just the verbatim facts, it lasts longer, but it also is the memory representation that people rely on when they make decisions, when they change their behavior, when they process health messages. It's not the facts or numbers on the page, it's the meaning that they extract and recall and take with them that makes the difference. And instilling the gist, therefore, ought to be a goal of risk communication, and this can be assessed in a variety of very simple and cost-effective ways.

So just to quickly give you a tour of information processing across the lifespan. There we have our little U-shaped curves. The increasing speed of information processing, from childhood through young adulthood, and then, more slowly from adulthood to old age. You have increasing myelination in childhood, which is a kind of insulation in the brain that allows the electrical impulses to be conducted very rapidly. So that insulation actually, or myelination, develops from childhood to adulthood, so you get faster and faster information processing.

However, in aging, you have demyelination, you have a loss of this myelin, so you get a general slowing of processing. And why is any of this important? Well, speed affects the quality of information processing. So the rate at which messages can be received changes across the lifespan, and that influences the quality of the message that's taken away. Short-term and long-term memory, these are two distinct memory abilities or information processing abilities. These, too, change over the lifespan. Working memory capacity, the ability to hold chunks of information as you're working on it, in order to form a belief or to make a decision or to perceive a risk. This changes and becomes bigger.

You can have more information as you get older in childhood. So children need more repetition, they need smaller chunks of information. If you're trying to give a child instructions, for example, how to take insulin or something like that, you can't use long dependent clauses. They just don't process the rest of that. So this is just examples of the kinds of things in the chapter.

Long-term memory is an entirely different animal than short-term memory. It includes things like recall and recognition. So what were the side effects that the doctor told me about, as I'm walking up the office. If you ask a patient, they won't remember most of what was said. And

often, they're relying on recall and not even recognition. Recognition is easier. Was fever a side effect or not, and so on.

So what about long-term memory? I talked about this verbatim versus gist, and I'm giving you a concrete simple example here from a lot of experiments that have been run. So imagine you're presented a list of words, sour, candy, sugar, good, taste and so on, and you have to recall that list of words. The verbatim memory is the exact list of words that were said to you.

However, about more than half the time, when people are presented a list such as this or a list such as this, they recall a word like sweet that was never presented, because the word sweet captures the theme or gist of that list. Now, you might say, what does this have to do with the kinds of complex health messages or narratives that people encounter in real life? Well, the models based on these memories for words also fit the models for narrative. So we fit the exact same mathematical models for verbatim memory, just remembering what was presented verbatim or recall, and remembering the gist of the list. Those models also predict memory for narrative equally well.

So if you look in the changes in memory across the lifespan, this is in youth from five years of age all

the way to 20, you see in that list of words that I gave you, improving memory or recall for the words that were actually presented, that would be the verbatim memory. You also see this enormous and more rapid rise in memory for words that were never presented at all. So this is actually in accurate, and it increases with age dramatically. The memory for the gist or the meaning increases more than the memory for what was presented, and these are false memories because they were never presented.

So as you can see, information processing in childhood becomes more and more organized around the gist of the message, the meaning of events and information, rather than what was said. So what's your health message? It's the meaning that people take away, and increasingly in youth. If you look at old age, and I will make this busy slide a little bit easier to understand here, through the miracles of mathematical models, we were able to estimate how these different faculties in memory change.

So if you look at estimates of verbatim memory you get from children to adolescents, adolescents to younger adults, younger adults to older adults, you get that familiar inverted U, where verbatim memory increases and then comes down with age. And here, by the way, we look at Alzheimer's patients, too, and as you can see, there's a decline in verbatim memory. If you look at gist,

however, you get a different life pattern, from children to adolescence, gist goes up and it stays up. And in fact, even in mild Alzheimer's, as you can see, there's a conservation of gist memory, which is kind of remarkable. It's a strength that is, in fact, retained in the healthy brain, and to some degree, even in the diseased brain.

So what are the recommendations? Obviously there are many recommendations. As Baruch alluded earlier, when you understand a process, you can apply it in different situations. If you understand how the mind works and what people are paying attention to, you can design messages that are much more effective and long lasting in their impact. So the kinds of things you can do with children is, since they don't tend to focus on the meaning as much, you can give them advance organizers that organize semantically the information they're about to hear.

So you can say things like, these are all vegetables, even though they look quite different from one another, and they will make us strong, as the following graphic illustrates. That's a carrot being carried by a weightlifter. I hope you feel sorry for me because I'm not a good artist, but you get the gist, though.

So what are the main messages? The gist of the message today was that memory is much more than memorization. It's about bottom line meaning or gist, and

it changes in memory dramatically from childhood, from the very young brain, this is the five-year brain, all the way to the 20-year old brain, and this is the aging brain.

Thank you.

DR. FISCHHOFF: That was great. Betsy?

DR. SLEATH: I don't have slides. I wrote this chapter with Michael Goldstein, who is a physician. And this chapter focuses on the literature on health care provider, patient communication about risks and benefits. And unlike a lot of other areas, there is not a large literature in this area. It's actually kind of sad. But I want to put it in a larger context. There's a big push right now in our health care system, to focus on patient-centered care in provider-patient relationships. The Institute of Medicine has had a report out on it, and many health care systems were attempting to move to this type of care. So there's not even a lot of research in that area, so then if you then move down to looking at what has been published about provider patient communication, about risk benefit communication, the literature is even smaller.

So we do talk about a few studies in our chapter, where people have actually looked at physician and patient encounters audio taped or video taped. And in the small amount of studies that have been done, very little risk benefit communication is occurring. And so, we very much

emphasize that there needs to be a lot of future research that not only looks at what risk benefit communication is presented to patients when they start a new therapy or treatment, but also what happens in terms of monitoring people that have been on therapies, say for a month, a few months, how well are physicians, pharmacists, etcetera, monitoring the risks, side effects, benefits, people are experiencing.

We then reviewed the pharmacist-patient communication area, and again, there's a few studies out there. One of the best studies actually was sponsored by the FDA. Bonnie Swarstead(?) conducted it in eight states, where shoppers went into pharmacies with new prescriptions and they collected the written information the pharmacies gave them. But they also recorded what types of verbal communication they received. They found that younger pharmacists were more likely to provide risk information, and that just makes sense, because pharmacists are now being trained that they should provide this type of information.

But even more interestingly, they found that in states with more intense pharmacy regulations, that patients were more likely to receive risk information. So for example, there are states out there that require pharmacists to provide face-to-face counseling in person

when new prescriptions are presented. Unfortunately, Noel and I live in a state where a technician offers to counsel. Oftentimes, you don't even realize you're getting the offer to be counseled. And therefore, in states unfortunately like our own, risk communication is less likely to occur.

The other thing that we reviewed is written information that's provided in pharmacies, physician offices. There was a recent Cochran review that found that there actually is not enough research or evidence that shows that written information necessarily improves patient understanding of how to take their medications, or their behavior or adherence in taking them. So another message of our chapter is a lot more work needs to be done in that area.

And also, the literature suggests that patients not only want verbal communication, they would like it supplemented with written communication. And for bilingual patients, one study found that patients wanted it in both languages, English and Spanish, that particular study looked at that. In terms of practical advice, one of our messages is that health care providers needs to be better trained on how to communicate about risks and benefits, whether it's medications or other treatments. The best work in this area is actually out of Wales. Glen Elwin's group did a randomized trial where they trained physicians

in workshops. And they found that it greatly increased risk communication about certain treatments, and it also increased the physician's use of visual formats to communicate risk information to patients.

There's one study done in the US by Nate Rickels, who's up in the northeast, with pharmacists, where they found patients started on new antidepressants who saw pharmacists trained in educating them and monitoring their use. They actually reported greater changes in improving depressive symptoms and fewer side effects. But there's hardly any randomized trials out there, so we hope that more research is done to see what can be done to improve provider-patient communication about risks and benefits.

Another recommendation our chapter makes is state pharmacy boards should consider requiring counseling on all new prescriptions, to make sure that patients understand the risks, benefits of the medications. And this has implications for potentially lowering health care costs and preventing mistakes or unnecessary things happening. The other thing is we suggest providers need to provide useful written information about risks and benefits to complement their verbal communication. But again, more work is even needed to understand what's the best way to present written information to patients, and how does it improve their comprehension and behavior.

And finally, we emphasize that providers should be better trained, how to use strategies that activate patients to participate in their care, to ask more questions about risks and benefits, so that they're better managers of their own health, and can call attention to things that may be going wrong when they're on certain treatments.

DR. FISCHHOFF: Thank you. Linda?

Agenda Item: Communication Design

DR. NEUHAUSER: Good morning everyone. Kala Paul and I have done a chapter about readability, comprehension and usability. And I'd like to start out with a few words about why this area is one that we should pay attention to.

In my view, some of the most dramatic findings from communication research over the past two decades have been that most health information, especially that that is about risk, are too difficult for people to understand and act on. For example, risk communication is often written at the college level, and by contrast, the average American adult reads at about an eight-grade level. So you can see that we have a huge gap there. And as Valerie just mentioned, information that can't be processed is the same thing as no information at all.

And poor reading ability is just one issue that we're dealing with, with our risk communication. There are

many other factors that make risk communication hard for people to understand and act on. It's not surprising, therefore, that only about a third of Americans are actually taking their medications correctly. And there's more and more information about the gap between people's abilities to understand the information they get about their medications, and their abilities to actually take those medications safely and over time.

The confusing quality of risk communication is such a serious problem that it prompted Congress last year to pass the Plain Communication Act, that now requires federal agencies to communicate clearly with the public. And of course, this is of great concern to pharma and health care organizations and many others that deal with health information.

So the challenge we face is how can we take a risk communication that is already very carefully crafted to be scientifically accurate. And certainly, the FDA is known for having scientifically accurate information, as do many other health care organizations. How can we take that and transform this, so that it is clear to people in the public? And that has become a very big issue, and of course, one of the main reasons why we have created this book.

Fortunately, there is excellent scientific

guidance and also very practical advice. And Kala Paul and I have done our best to summarize this state of science, and of the practical tips about how to do better with risk communication to make it more comprehensible and more actionable. So I'll turn to Kala for a few highlights from the chapter.

DR. PAUL: Thank you, Linda. What we did in the chapter is take some of the information on how you get from the idea of a risk communication and the technical terminology, to a useable wording and format for patients. Looking at things like readability and readability assessments as tools to help you, comprehension testing, because readability and comprehension are not the same thing, design of materials and all of those in the format of patient interactions in terms of the design of the communication.

One of the things is we actually went through and talked about each of these individual tasks in the chapter. For instance, with readability testing, we talked about using the various readability formulas as a way to test the document that you have at least drafted. Understanding that you drafted this document and knew ahead of time that you should be using short sentences and chunking of ideas, lots of white space, bullets and all of the tricks of the trade for simplifying your message, including using simple

words, as well as simple sentences.

But you test it for readability, to get the readability statistics, using something like the Flesch-Kincaid, which is a computerized paradigm, or the Fry or the SMOG, which stands for Summary Measure of Gobbledygook, or the Lexile or various other ways in which you would use a paradigm to assess what the grade reading level was, understanding fully that this, A, is a general reading level, not health literacy, so you're not necessarily dealing with health literacy terms, and it does not indicate in any way whether somebody reading at the sixth grade level could actually understand that.

Most of these paradigms work as well backwards as forwards, which the messages don't. So you have to go ahead and look at what does the patient, the recipient, the public understand about what you have written. So comprehension testing is part of what you need to do, once you've found out what your readability levels are from a readability statistical point. And the various things have been talked about, and I think Valerie made a very excellent point about recall and recognition, in terms of the messages that are found in the documents that we write. And we are writing, and I think Noel made a very important point. We do simply write, we put the message down on paper.

But this is the basis for all messages, even when we think about these things, when they're presented on the web or on TV or on a piece of paper or even when we speak. It's really the same thing, we're giving that message to people, we want to make it simple and understood. And part of this crafting this message, there's another assessment besides the patient readability statistics and the comprehension testing that Linda has advocated very strongly, I think in this committee even, which is the SAM or Suitability Assessment Materials, which also helps you assess how well this particular message may play with your audience in terms of things like format, comprehension, readability and other aspects of that messaging.

However, again, your final test is, does somebody who needs to get this message, are they able to read it, readability? Are they able to understand it, comprehension? And what did they remember from it? What were they able to recall, what were they able to recognize? What biases were they able to bring to it? Did you make a mistake in writing? Are there internal errors in your communication? Did you say something that was wrong in terms of how the patients will understand it?

One of my favorite issues is, we were talking about using statistics and trying to get patients to do comparative understanding of the relative risk with a

placebo and with a drug. And we used the sugar pill for placebo and taking it to the population, we had the response, I don't have diabetes, why should I worry about a sugar pill? So knowing that, you know that you have to recraft your message, and there's no way you could know that, other than I told you, or you actually asked the patient who had to read what you wrote, and found out that they thought that they were supposed to take it with food, when you didn't write clearly that they shouldn't take it with food. It was the way you presented it, not there. You have both the sender and the receiver on the messages.

So what we also presented in talking about ways you assess your material, to make sure that the message is clear, the receiver is receiving, and that the items are actionable. We talked about ways in which you could assess this with recipients, either in finding people around you that's been mentioned, doing formal qualitative and even more formal quantitative comprehension testing, depending on your budget.

DR. FISCHHOFF: Wonderful, thank you. I'm amazed at how everybody got all their reporting into 3000 words. It's really quite remarkable, so read the book. Craig?

DR. ANDREWS: Baruch, I think it was 2999. First of all, I'd like to thank Baruch, Noel and Julie for putting this all together, and comments from Gavin, Lee and

others. It's a tremendous experience in putting together decades of research on warnings and disclosures. This was chapter 15 in the book. And I'm going to spare you from the sound effects that I think I had out there, some shocking sound effects about a year and a half ago, to brace people from warnings.

Warnings and disclosures are everywhere. They're ubiquitous. In our everyday life, we see them, just like Noel had up with the elevator sign. Maybe I should have scanned that in with the other ones up here. In fact, I added one that we're testing up at the top there with the hook, without a license to try to expand some of the research I'm going to talk about in a second.

But my favorite is the low pressure warning on tires. In the winter, in Wisconsin, when that piercing noise comes off when your PSI goes down, so they're everywhere. And the big question is, do they work? And so, there's a lot of evidence out there where people are saying that maybe there's reactants, they don't work, they're overblown, etcetera. And I think the comment that I have is just based on a review of literally hundreds of studies, six decades of research, and many meta analyses, it depends.

So like anything, I think it's very important, like yesterday, that we really take a look at our audiences

and our target markets out there. That's critical in trying to match up the right objectives. For example, if it's awareness, if it's comprehension, persuasion, behavioral change, we're the target audiences, that's very, very important.

Also, that a lot of design issues out there, as well, as we well know. Many of you have been reviewers of papers, I'm sure, where you see the studies and you look, gees, it's just loaded up there. There's no way that they're going to be able to stimulate or comprehend the particular disclosures or warnings. So it's failed to begin with. So design issues, message content, modality issues, receiver effects. In fact, Baruch was talking about false intuition effects earlier, so all of that really has to be thought about.

I'd like to thank Gavin for our suggestion. One of our colleagues, Michael Wogalter had his communication health information processing steps really based on McGuire's work. And again, it's the right match with a target audience with these different steps and other factors. It is attention, is it comprehension, are we looking at persuasion and so forth.

One of my favorite studies was with Dave Stewart and Ingram Martin, a number of years ago, on why consumers fail to attend the warnings. In fact, in a recent study we

just had, the first point was very, very important. Measures do matter. So, for example, they talked about the type of recall, or verbatim as Val was talking about, is very important. So when you take a look at the net impression of a message, that may be different from a little warning that's buried in the particular ad or message.

I'm going to follow up on that in a second, a little bit on just, I guess, using the term loosely versus some verbatim issues. Personal relevance, involvement, motivation, ability to process, opportunity to process, familiar of facts is very important, especially early on, and information processing, where people think they're familiar, they're experts, they're not actually processing the material.

Distraction, desensitization, if you look at the alcohol warnings that are out there, or the text-based warnings on cigarettes, all of us can see where that desensitization occurs. In the area of disclosures, there's a lot of good stuff going way back. Actually, the FDC, they had their clear and conspicuous standard, and a lot of this was based on research. Things like dual modality helps, things such as avoiding distraction, understanding audiences, vulnerable populations, or all very important considerations, where you see this, time and

time again, where designers are not thinking about these issues. And then, they say inevitably, disclosures fail or warnings fail.

Okay, just a little bit about a study. I don't know how bright that is, but I shared some of this at the last year and a half ago. And I just wanted to point out some issues with measures and why these things are so important. This was a study that appeared last fall in the Journal of Public Policy and Marketing. And we had a randomized assignment of a number of different stimuli, to 500 smokers in the US and Canada. And it was a control group.

This was based on pre-testing. In fact, Christine talked about the importance of pre-testing early. And so we went through a pre-test to come up with a low based stimuli, medium and high, before we went through the main study. The point being, measures do matter. And what we found that's interesting is that, first of all, there were main effects that we found, and we found little country effects, too. They still work in Canada, but because they've had the warnings there, it was a little more prominent in the US.

We found that it evoked fear, or if I'm losing this loosely, gist, in a way, fully mediated the effects on the mediation tests, so the graphic visuals on intentions

to quit smoking for the smokers. Whereas, warning recall, I guess similar to verbatim issues, where they're trying to recall a text warning, did not at all. So I got some implications from our study. The more graphic the depiction, the stronger were they intentions to quit. Now, you have to keep this in context. We were talking about engrained beliefs with smokers, and so persuasion, a lot of times, can be very, very difficult.

Evoked fear fully mediated these effects, the warning message recall and also package attitudes did not. There's important implications for federal copy testing. I was involved in this at the FDC, and it was all verbatim based, recall based. And I think there's really a role for just effect and all of this, in taking a look at copy testing, etcetera.

And obviously, a lot of this will be coming out - very important issues, October 2012, where we actually have the visuals coming out on the packages. And all of this is very, very important. We're going to continue our testing with adolescents, as well.

Finally, if you take a look at the overview, it depends on all warnings and disclosures. The match is very important to the objectives that you had in the audiences. All of these design issues, modality, the source, priors, initial beliefs. And then finally, I put this in red, pre-

testing is very, very important when you're going into these things. And accounting for confounds of the moderators really, really important, as well as I think Gavin pointed this out earlier, he needs to take a look. It's not just a warning or disclosure, per se, but the entire integrated marketing communication programs, so thank you.

DR. FISCHHOFF: Thank you. Gavin?

DR. HUNTLEY-FENNER: My chapter was on human factors and human factors is an interdisciplinary field. My background is in the area of cognitive psychology, and so what the work I do is related to applied cognitive psychology. I look at how human capabilities and limitations impact our ability to interpret safety messages and act on them. And I thought I would tell you just a little bit about a project that I did, as a way of giving you the gist of my chapter, which basically tried to summarize what was going on in the field.

So I was recently contacted a few years by a client who manufactured wheelchairs. And they made some changes in the design of the wheelchairs. Some of the changes had to do with the sort of physical configuration of the device, but others had to do with labeling the instructions. They've added a new video tape that went along with the product. This is one of the motorized

wheelchairs. And they had a new training curriculum. And embedded in all of those materials were various warnings regarding safety. And so, their concern was, are we doing an effective job of communicating the risks and benefits to the likely user population? How can be sure of that?

So I helped them think through what they could do, and we actually did some testing. They wanted to avoid things like recalls and, of course, lawsuits, and probably their legal department told them, call Gavin. In any event, what we ended up doing with them is trying to understand, first of all, what were the risks and benefits, not just as observed as by the company, but in the research literature, in publicly assessable databases, what were the kinds of things that could go wrong to someone who was using this particular device.

And we started to focus on a few areas where there were high likelihood and relatively high severity outcomes. And we decided that we were going to prioritize, in addition to having sort of mandated warning statements, we're going to prioritize communications having to do with those risks. And in this case, we were looking at things like the risk of someone falling or being dropped when they were lifted in or out of the chair. Or when they're going up inclines or doing inclines, maybe going too fast. And then another, as it turns out, was visibility on the

street. If you're crossing the street, how do you make sure the cars can see you.

So what we did was we ended up highlighting in particular those kinds of messages relating to those kinds of activities. And when we looked and made decisions about what to put in the video, or what to highlight in the graphic that went along with the written instructions, we tried to focus on those things that were pretty significant from a risk perspective. When that was all done, we went out and decided to figure out whether the target population would actually understand what was being communicated, particularly about the incline risk, because they talk about angles and etcetera.

So we basically beat the bushes for older persons who were in the target marketplace, and presented them with the various sources of information and then did some comprehension testing. Tweaked our message and then put together the final design. The value of having a human factor person work with you in designing messages is you can get someone who will be skilled in experimental methods, who understands cognitive and behavioral limitations, and in particular this case, developmental course of those limitations.

Also, we were able to integrate the latest stats on injury, which often corporate, our clients would not

have access to. In my chapter, I basically make four recommendations. One is that when you're using risk-based communications design to streamline messages, for example, you should use risk priority information to help tell you what messages to duplicate and what not to duplicate.

Use research to guide choices and test your messages to avoid unintended consequences. Target the message for your audience, for when they're most likely to be receptive. When you know that people who get complex devices will be more likely to read the message before they read the manual, if you will, before they use the device, and less likely to do it later on. And there's certain parts of the manual that they are going to be focused on. And finally, to boost message credibility, you need to ensure that both the message and the messengers can create trust. Thank you.

DR. FISCHHOFF: Thank you. Nan?

DR. COL: First, I would like to thank. I had great editorial contribution to my chapter, Noel, Baruch and Angie really helped shape the chapter. I'm still going to talk about shared decision making, and more from the patient-physician perspective. So medical decisions are especially difficult when there are two or more reasonable options to choose from, and each option has good and bad features that different people could weigh differently.

Because what's important for one person could be different for another person, and there's no clear answer that applies to everyone.

Now, shared decision making is intended to pertain to these kinds of situations, and it's an attempt to fundamentally change patient provider communication, by involving patients in clinical decision making and partnership with their provider. So shared decision making really refers to the process by which clinical decisions are made, and it's a process in which patients and clinicians share information, and come to an agreement on preferred treatment.

Many medical organizations are recommending shared decision making, and the Health Care Reform Act of 2010 supports national shared decision making program, as well. So the most common type of shared decision making intervention are called decisions aids. And these are educational interventions that are targeted on very specific treatment decisions. And they try to help patients make decisions by providing objective information about what their options are and about the likely consequences, both benefits and harms, of each of those options. They can come in a variety of different formats, videos, interactive web programs or printed material. Most typically, we think about videos and print as decision

aids.

So why the interest in shared decision making? It occurs infrequently in clinical practice. It's actually quite rare. And part of the reason is that shared decision making requires a substantial time and attention for patients to process complex risk information and to make difficult, often stressful, trade-offs. So patient interest in shared decision making is quite variable, understandably, and it ranges between around 20 percent to 70 percent, with higher interest among younger and more educated patients.

So patient barriers to share decision making include being unaware that there is a decision to make, believing that clinicians prescribe the only treatment that's available, discomfort or inexperience with being involved with shared decision making, or preconceptions about care. It has been quite difficult to embed shared decision making interventions and decision aids into clinical practice. Physical barriers have been studied and they include physician concerns about that it would take more time to do that, lack of training on the part of clinicians, their pessimism about patient's ability to assume a more active role. Often they believe it's not applicable to their patients, to that clinical situation, or to the clinical care pattern in which they participate.

And there are also concerns that decision aids could bias patients to choose less expensive options.

So what do we know about the impact of shared decision making on health care and patients. Most of our knowledge is based on clinical trials of decision aids that compared outcome among patients exposed to decision aids, versus those just using standard care, in a range of health context. The Cochran Collaborative reviews randomized trials. The most recent review was presented in the papers and press now, review 85 randomized trials of decision aids. Its major findings are that decision aids improve knowledge about options and outcomes, and led to more realistic expectations. It helped patients match their values to their choices. It reduced decisional conflict and passivity in decision making, and it helped the undecided to make a decision.

They were not shown to consistently improve satisfaction with the decision, decision satisfaction with the process of decision making, or satisfaction with the preparation for decision making. A few trials have looked at adherence and they have not been able to find that decision aids have had a consistent impact on improving adherence to medications. The impact on decision aids on treatment choice, that is actually what is prescribed and what patients do, has been modest and variable.

Decision aids have been shown to decrease rates for prostate cancer by about 15 percent. They increased the screening rates for colorectal cancer by about 20 percent, that was a non-significant increase. This was pooled estimates, and they had no impact on genetic testing rates uptake. The impact of decision aids on elective surgery has been highly publicized, and it varies by procedure and setting. Decision aids have had no impact on minor surgery, such as circumcision, surgical abortion or dental surgery.

But decision aids targeting surgical, invasive procedures perceived to be overused, tended to lead to a decreased use. But the few trials that examine decision aids in the setting of overuse found that they tended to increase the use. So they do tend to nudge decisions for use, up or down, depending.

And what about the harms? Decision aids have no negative effect on anxiety, depression or emotional distress. Some decision aids reported a higher net cost per patient and longer physician consultation time, but these finds are variable, and the data in this area is not particularly robust at this time, which goes down to their limitations of the evidence and controversies. Many decision aids were developed without any clear conceptual framework as to how they might influence decisions. There

was also debate about how to measure a good decision. In many of the short-term and process outcomes that are being used to measure the impact of them have been questioned, such as the impact on knowledge and decisional conflict. The impact on how that actually leads to better decision is not entirely clear.

Limitations of the evidence are many. It's a field that's quite nascent. Studies to date have focused predominantly on video-based decision aids, with scant attention to other types of decision aids or other approaches to shared decision making, such as training practitioners in shared decision making, incentivizing to engage in shared decision making, or restructuring care by using a coach or other people to help patients participate.

In addition, many of the decision aid trials, in fact, most of them were too short or too narrowly defined, to examine their effect on long-term health outcomes. Many of the null effects that are reported were probably because the trials were inadequately designed to capture those end points.

Another major issue is that the impact of decision aides in the real world is often incorrectly assumed to equal the impact observed in clinical trials. For example, a frequently cited study of the impact of decision aids in reducing surgery for low back pain. They

report that there was a 22 percent reduction in surgery among the decision aids, and this figure has been widely cited in healthcare reform debate. But when you look at the data, only 11 percent of potentially eligible patients with back pain participated, most of the patients were excluded for clinical reasons, many refused. So this 22 percent reduction in surgery in the decision aid group, corresponded to a 2.4 reduction among the referred population. So accounting for eligibility and interest in shared decision making, dilutes the impact of interventions for shared decision making by an order of magnitude.

So a number of areas need further investigation. One is, what constitutes good decision-making when there is no clear right choice? We're not dealing with a smoking cessation, where the more people who quit, the better. It's not really clear. We only target places where it depends. So is a good decision one that is made using a good decision process, regardless of the outcome, or one that is correct for that individual, where the choice is consistent with the patient values, but the outcome may not be very good? Or one that is correct for society, that is the most cost effective choice. These questions have not been addressed.

How does shared decision making interventions affect health care delivery, resource use, unwanted

variation and clinician outcomes? The few trials that were, again, not really designed to measure that. There's a lot of inferences being made from that. We really don't know the cost effectiveness of shared decision making or of different approaches to shared decision making. I think it's a critical question we need to explore.

We don't know really how to integrate your decision making into routine clinical care. There are many ongoing pilots, and typically, when the funding is withdrawn from the study, interest in the intervention seems to decline. And we haven't figured out why that happens. The question, are we giving patients the right information to help them with decisions? Decision aids, presently we present treatment associated risks based from national samples, and we know that there's a lot of variation, depending on where you live, where you seek care, who's providing the surgery, a whole lot of these regional factors. Probably those variations, they're probably swamps variation in the other areas, but we don't have that data to give to patients. So we give them kind of the flashlight, where we have light shining on the data, and it may not be the right data.

How do we ensure quality of control of decision aids, which could be created as marketing tools to encourage patients to choose more or less expensive

options, depending on who's designing the decision aids? How do different approaches to promoting shared decision making compare? There are no head-to-head comparisons of different approaches again. Most of them just focus on video-based decision aids, compared to no intervention.

So what general practical advice can the science support? I think the premise is that patients have a right to be involved in decisions about their health, and should be encouraged to do so, to the level that they desire. Now, the question is, how to get there. So there are five practical pointers for facilitating your decision making, and these are mainly targeted at clinicians. One is to identify and prioritize decisions appropriate per shared decision making. And this recognizes that shared decision making is neither appropriate nor feasible for all clinical decisions, especially for decisions such as cranial chemo prevention. And the principles that clinicians have no obligation to initiate discussion about services, that either have no benefit or have a net harm. And given the constraints, it really is important that this prioritization happens.

Number two, inform patients when they need to make a decision, and this is because patients are often unaware that there is a decision to be made. Three is explain why patient input matters. Patients often don't

understand how their preferences and values factor in a decision, and simply assume that their physician or clinician knows best. So clinicians explain that there is more than one way to deal with a problem, that options have pros and cons that need to be considered, and there is a genuine professional uncertainty as to the best way of managing a problem.

Number four is screening patients for their desired level of participation, recognizing not all patients want to participate. And five, is help patients be more involved in shared decision making, and there's a variety of ways we describe in the chapter how to do that. A caution is that informing patients of all options and all consequences, all risks and benefits associated with all of their options, is often unfeasible and undesirable, because too much information can confuse patients. Of course, the challenge is figuring out what's the most important to present.

How does one evaluate communications in this area? In the no budget area, it's a little tricky here because we're talking about how do you evaluate. If you want to use a decision aid, your clinician, the easiest way to do that is there's an inventory of decision aids that's really available on line. The Ottawa A to Z Inventory and there's a database and you can search a problem, such as

prostate cancer, and find which decision aids have been developed for that. And there are ratings for the decision aid on that website. And it also will tell you whether they're free of charge, and if they are free of charge, you can actually download the decision aids there. So that's if you're trying to find and evaluate which decision aids to use in clinical care.

If you're trying to take a sort of a broader or higher level, and trying to evaluate, in introducing shared decision making into your clinical setting, either by training your providers or using a tool, there are questionnaires, previously evaluated questionnaires, that you can incorporate into clinical practice, to measure the impact of this change in provider communication. And there are a variety of those that measure preparation for decision making, whether or not shared decision making occurred, and some of them target the patient, some of them target the provider.

And there actually are two new quality improvement measures from the NCQA HEDIS addressing shared decision making, that can also be used. So these are all freely available and the references are given in the chapter. There are two high-cost approaches for evaluating this, and I actually would strongly recommend, given how early the field is in shared decision making. And I think

how important it is, because this is really where the rubber hits the gravel. Is one, I think, convening an NIH state of the science shared decision making, I think would be very timely and needed to guide future research in this area, and to inform the proposed National Shared Decision Making program, of which millions and millions of taxpayer dollars are slated to be invested in this.

And because there have been really a limited number of shared decision making intervention, and a different very limited number of different approaches to shared decision making that have been developed, we really need rigorous randomized trials, to compare alternative approaches for facilitating and integrating shared decision making into clinical practice.

So in conclusion, I think shared decision making has the potential to improve risk communication between patients and practitioners, and can influence treatment choice, but the field is nascent. More clarity is needed on what constitutes your decision making, what shared decision making interventions should accomplish, what are realistic expectations for their impact in different settings, and new approaches for shared decision making are needed, that can be implemented in a range of clinical settings.

DR. FISCHHOFF: Thank you. Let's do this in

terms of our time. We have one speaker registered for the open public hearing, who's able to stay a little bit later. Why don't we take a very short break, let's say a 10 minute break, come back here right at 10:30, and then we'll finish the last few presentations in the book. We'll have an opportunity to talk and interact with our guests, and then we'll go into the discussion of how do we take the best advantage of kind of the remarkable work that Nan and others have put into this book. So 10 minutes, so okay, thanks everyone.

(Break)

Agenda Item: Communication Design (cont'd)

DR. FISCHHOFF: We will now have the final chapters from the book and then we will have our open public hearing and then everybody in the back -- full attention, but the back of your mind thinking about how to take best advantage of the work that we have had here. Our next speaker will be Gary Schwitzer.

MR. SCHWITZER: Well, mine is perhaps the quirkiest chapter in the book. And Lee, if you were kind to me then you would remove that from the index of the final addition where it is a quirky chapter, but that is because I probably have the most specific focus. I did not address risk communication issues in the mass media in general but rather specifically my area of specialization

and that is how health care journalism, how new stories deal or don't deal often with communication of harms and benefits. It is also quirky in that -- I think I wrote that chapter before I had ever met any of you and before I had attended my first meeting, but I really thank the group for involving me in this effort because I think that even though this is a very specific focus this is highly relevant as we think about the impact on the public of these messages.

The chapter was entitled I believe in the end although I didn't look at the final version, News Coverage Exaggerates Benefits and Minimizes Risk or Harms. That is a real data-driven comment, driven largely by a project that I lead called healthnewsreview.org, a website that is now more than 5 years old that grades online and notifies journalists that they have been graded; health news stories that include claims of efficacy or safety in health care interventions.

And we apply 10 standardized criteria to the review of every story. The three biggest, I think, and the three worst performers are that about 70 percent of stories fail to discuss the costs of this wonderful new idea, but more germane to this discussion failed to adequately quantify harms and benefits. When Angie and others have talked about the importance of absolute risk information or

absolute at least in addition to relative risk reduction information we hold the bar that high that a story will get an unsatisfactory grade if it doesn't use -- in almost all cases it will get an unsatisfactory grade if it doesn't absolute risk benefit data.

Examples of what we look at and the ones that stand out in my almost 40-year history -- I am a veteran health care journalist who now just works full time in doing journalism about health care journalism. And the worst episode was the news coverage of the US Preventive Services Taskforce fall 2009 revised recommendations on mammography where again benefits were exaggerated and risks were either minimized or totally ignored as if there could not possibly be a potential harm from a screening test like this.

More recent example just last week -- you probably all saw the rampant news coverage of an important research study and experimental approach gene therapy for leukemia in three people in which news coverage was talking about cure and a breakthrough and perhaps the most significant advance in cancer research in a decade. This was in three people that have been followed for a year.

It is interesting. A couple of years ago I wrote an article that got a lot of traction: The Seven Words You Shouldn't Use in Medical News. I think all seven of those

were used in news coverage of that leukemia experiment: cure, miracle, breakthrough, promising, on and on.

In my mind this is low-hanging fruit. I have talked with some committee members about this because we know -- many surveys show that many Americans get most of their health care information from news stories. Unfortunately much of it is from television news which is where I cut my teeth. If you can improve news coverage, potentially you could ride that improvement to an improved communication to the public on some of these issues.

Despite the grade that I gave you on Harms, Benefits, Cost which was concerning, there is a lot of room for optimism and there is increasing literature in this field. An Australian journalist, Ray Moynihan, actually I think led the charge with an article in the New England Journal back in 2002 where he and a team analyzed news coverage of risks and benefits on three leading prescription drugs. Woloshin and Schwartz and Gil Welch at Dartmouth have become frequent publishers not only on broader communication issues, but on health journalism issues. Gerd Gigerenzer, the German risk communication guru, often writes about how journalism performs in this area. And then when you get into journalism trade publications, Trudy Lieberman at the Columbia Journalism Review. Shannon Brownlee writes a lot about these things.

And then our own efforts which are now more than 5 years old and are matched by and I am really encouraged by this our US site of healthnewsreview.org is matched by now five international collaborators, let's call them. Colleagues doing almost the identical same thing the identical same way as we do. They are all called media doctor sites in -- the pioneering one was in Australia, Canada, a German site that I helped train and launch called Media Doctor, the German Health News Review. There are sites in Japan and Hong Kong and I know there are interested parties in Sweden and in Italy who would like to launch similar efforts in their country.

When you think about the possible, cumulative impact of five, six, seven, eight international efforts all doing the same things and if we ever did get together to pool our data, it could be a very powerful message to journalists and editorial decision makers around the world about what they are doing and what they are not doing.

Other reasons for optimism. I have long been a member of a really good group. I think a leader in quality improvement in all of journalism -- it happens to be in health journalism, the Association of Health Care Journalists has about 1100 members. They actually got a Robert Wood Johnson grant and sent part of it my way to write a guide which is now given out free to their members

on how to do a better job covering research and medical studies.

I mentioned Woloshin and Schwartz. They along with Barry Kramer at NIH, for 9 years have led terrific workshops called, NIH Medicine in the Media workshops. There are other workshops, many of them funded by the Knight Foundation. I mentioned a couple yesterday. The Knight Fellowships that are at CDC for a 3-month period. Knight Boot Camps that are a week long largely touching on evidence-based health care journalism. There are foundations that are now supporting improved health care journalism. The Kaiser Family Foundation supports a Kaiser Health News effort based here in Washington. ProPublica does investigative health care journalism with foundation support. The California Endowment does. It is interesting that even the National Breast Cancer Coalition now offers training in how to evaluate evidence to its breast cancer survivor advocate members in a terrific effort that I have done a few guest appearances at called Project Lead.

My bottom line in this chapter is that it pays to invest at any level in any effort in helping health journalists do a better job. It is clear that journalism can and sometimes does do so much good, but it is perhaps more clear that it can and often does do so much harm. Uwe Reinhardt, the Princeton health economists, asks where has

civic education failed on many of these basic health care reform issues. And as a journalist I always look in the mirror first and think that we journalists have to take a great deal of responsibility for the failure and for the low quality public discussion that we have.

I think that this chapter is relevant not only for journalists, but for medical journals who of course love to get their materials covered by journalists, by academic medical centers who love to publish news releases to keep publicity and money coming their way, by academic researchers who face the publish or perish or publicize pressures. I really welcome partnerships for many efforts. I have tried to push journals and those who write news releases to include our 10 criteria that we use to the review of news stories to include them in their communications efforts because I really think they could become a good baseline for communicating at any level including in your interactions with your physician on some of these issues.

In our project which is reflected with a much broader literature search and interventions at different cost levels and described in this chapter, we have sort of carved this out as our life's work now and we look forward to having other partners join us on this. If it is not crossing a line, Lee will hold up the tin cup. We look for

partners or financial support as well. Thank you.

DR. FISCHHOFF: Thank you, Gary. And you will find in Gary's chapters direct links to many of the sites that he mentioned and they will be hot links through diligent efforts by FDA. You will find hot links in the PDF version of this that will go live in a few minutes.

We will hear now about three -- briefly about the three concluding chapters, one from Nancy about how her role view and how all of this came about from an agency perspective, from Lee about her subcommittee of practitioners -- a moment or two about the final chapter and how this fits in with FDA's strategic plan with risk communication and perhaps analogous plans and other organizations could adopt.

Agenda Item: Implementation

DR. OSTROVE: Good morning. Thanks by the way to both Linda and Baruch for their comments on the chapter and Lee. The chapter I contributed to the guide just before I retired was to lay out some of the challenges to implementing evidence-based communication at FDA. One important point is to recognize a very basic challenge associated with FDA communications. That is specifically the significant uncertainties associated with the data that FDA uses to make its decisions regardless of whether those data derived from randomized control trials or real world

observational studies. It is kind of a neat coincidence that the challenge of communicating uncertainty in data and decisions surface multiple times in yesterday's discussion. We keep hearing about it over and over.

Layering on this kind of fundamental challenge is a series of practical challenges. Most of them are in fact shared by other agencies in one way or another hence the wide applicability of the information in this volume outside of FDA or at least that is certainly what we believe. Many are also shared by any organization that has to respond quickly to changing circumstances within legal and ethical constraints.

What are these challenges? Many of them are related to FDA's need for better knowledge about our audiences and the impacts of our communications on our audiences, again, reinforcing some of yesterday's discussion themes and today's. The knowledge needed includes not just what the public knows and what it doesn't know about product risks and benefits, but also what the public believes about FDA and other communicators as being credible and trustworthy sources and how not to undermine credibility and trustworthiness.

Further, how do FDA's communications affect audience knowledge, attitudes and behavior? Again, we have been hearing about this. And how does the impact differ

based on the range of audience needs including critical characteristics such as health literacy and numeracy? But just getting this knowledge can be much more of a challenge than many might believe. Regulations that are designed to protect the public from unnecessary or duplicative requests for information, make it very difficult to collect sufficiently timely and useful data about audiences' needs, perceptions and reactions to communications.

Many of you have heard -- this is nothing new to those of you who have been in on these meetings since February of 2008. Also, the wide range of FDA covered products and regulatory authorities and laws that appropriately protect intellectual property rights and therefore have implications for when and how certain information can be disclosed. These create challenges not just for regulating, but also for communicating about products.

Learning and applying lessons from one communication situation to others is a challenge. Internal subject matter experts are charged with more than working on communications, however, important they may be. That is what makes them subject matter experts. When a particular crisis or situation is over, they have to go back to doing what they do. Learning from the experiences and then taking those lessons and applying them to the newer

experiences often becomes -- it is a challenge going back to using that word.

It is also a challenge to identify, obtain, and appropriately employ the range of personnel that are needed to implement effective evidence-based communications and to empower and support internal communications professionals and psychologists, decision analysts to work as equals along with the product subject matter experts and attorneys to produce understandable and actionable communications. It can be difficult for product subject matter experts to recognize that being a product expert doesn't mean being an expert on how to develop and deliver communications about the products, benefits, and risks.

It can be difficult for attorneys to accept that communicating every nuance of a regulatory issue can actually obfuscate a communication to the point that no one understands and thus essentially defeating its purpose.

In addition to facilitating effective evidence-based communication meeting this challenge is critical to addressing the challenge of appropriately balancing precision which often translates to complete comprehensiveness of all the information against understandability in particular communications.

Despite these difficulties, however, over the past few years FDA has addressed these challenges. It has

taken significant steps to address these challenges in substantive ways and to move toward evidence-based, enlightened communication about the benefits and risks of regulated products. These ways include the establishment and use of this advisory committee, the development and issuance of FDA's strategic plan for risk communication and the implementation and completion of some already of the strategic plans actions including publication of this guide, the public issuance of a research agenda to encourage outside researchers, to consider FDA's research needs and the establishment of multiple generic clearances to facilitate more expeditious conduct of communications relevant research.

DR. FISCHHOFF: Thank you.

DR. ZWANZIGER: Thank you. Chapter 20 of the book is called Practitioner Perspectives. This came out of our wish to include some of the observations and accumulated wisdom of some of the members and former members of the committee who engage in risk communication on the front lines. We went over this with Dr. Jacob DeLaRosa, AnnaMaria DeSalva, Sokoya Finch, Sally Greenberg, Mona Khanna, Madeline Lawson, Kala Paul, and Mary Ellis Vega.

Of these individuals only Ms. Finch and Dr. Paul are here with us today, but we reflected the thoughts of

all of them, I hope, based on their comments and previous meetings on subsequent phone and emails. We went through all previous meetings looking at the comments made in open public hearing by open public hearing speakers.

From this we then gleaned some pointers that we would suggest that communicators should take care to be brief, to give key messages at the start of the communication, speak to the target audience meaning first of all you have to figure out your target audience and speak to them and let them know who they are so they know the message applies to them, shape the message to the needs of that target audience so that it is relevant to their needs, sensitive to their situation, and accessible to them in form and content and the language that is used.

We had a discussion about the importance of using pictures and stories for illustration and break up text and to establish personal connections, and also again strongly recommend checking audience understanding after having attempted communication and emphasize also that we need to plan ahead for predictable emergencies. We can predict there is going to be emergencies. We don't which emergency is going to arise, but we should be planning ahead so that the communication itself is not the emergency that we can focus on the content and making the connection.

Do either of you want to say anything further?

DR. FINCH: You pretty much said everything that I was going to say, but first let me just thank Lee and Nancy for your leadership, our esteemed chair, Noel, and Julie for their editorial eye and pen.

I don't know who said this quote but it goes we are as strong as our weakest link and I want to transform that to we are as effective as our reach to the neediest, underserved, under insured, and those with low literacy skills. I think we had a good staff with this book in terms of covering the basis of those targeted populations.

I just wanted to say just a little bit just add on to what Lee had said. Knowing your audience is critical, but more than that is knowing how to connect with them. The key points that were brought out were language barriers. According to the 2000 Census, 18 percent of our population speaks more than one language in a household. We have talked over the last couple of years about the importance of language and that right now our majority of the population of the US population is the minorities, the combination of different minority groups, which speaks abundance of variety of different languages. How do you communicate effectively to that particular audience and trying to be inclusive of all? We basically said just clear, concise, precise, short, simple, sweet, to the point. And we all bring different skills and expertise to

that to make that happen. Conquering language barriers.

Cultural context is so important when you are crafting the message. And then what we found through the evidence base is that pictures speak more than a thousand words. They are much stronger than words. And even that would have to go through a cultural kind of an analysis to make sure that it speaks to everyone. But pictures and stories tend to knock down communication and language barriers. We found that to be straightforward, to the point, concise, precise, and clear.

And one last thing is that the real science of risk communication is in its effectiveness of the message not only for the general public, but again for those that are underserved, under insured, and those with low literacy skills. And if we can target that population with clear, concise, to the point information then we have captured everyone including the practitioners and the providers. That is it in a nutshell.

DR. PAUL: I just want to say that between Sokoya and Lee you have heard the most eloquent expounding of what was in that chapter and I think the fine point Lee and Sokoya touched on are the fact that it was both for practitioners who are dealing with individuals as well as those who were writing for large groups in risk communication. I have nothing to add to that.

DR. FISCHHOFF: Thank you all. I would just say that in the history of the committee, we have been very fortunate to have had practitioners and researchers as well who sort of kept us grounded, giving us the challenges, showed us places where we need new research. And sadly the one -- and doubly sadly, the one chapter that we didn't get from the book is from David Moxley who is an initial founding member of the committee. He is a social work professor. He had been at Wayne State. He is now at the University of Oklahoma. He works with the homeless, who is going to write a chapter. He sent in a wonderful outline and then had some family health problems that precluded him from completing the chapter. That is in fact an omission and sad the reason and sad that it is not there to provide that needed information.

The final chapter which Julie and Noel and I wrote, talks about the organizational challenges of building on the kind of framework that FDA has created with its strategic plan for risk communication and adapting these principles to the varied settings in which we have different kinds of context with user communities like those that we dealt with yesterday. Noel, do you have a final word?

DR. BREWER: I do want to thank all the coauthors in the book. You all did a great job. You made this a lot

easier than otherwise it would be. And of course the FDA staff who just put in a tremendous amount of work. The book reflects just a huge number of hours. A little bit on my part.

I also especially want to thank Baruch who took on I think the larger portion of the -- a substantially larger portion of the editorial work as things progressed. I thank you, Baruch.

Agenda Item: Open Public Hearing

DR. FISCHHOFF: I think it was really kind of amazing that we did it. Pat ourselves on the back. We will talk about the distribution and so on in a few minutes. But now it is my pleasure to open the open public hearing. I will read a short statement which I am sure all the committee has memorized by now.

Welcome to the open public hearing. Please state your name and your affiliation if relevant to this meeting. If you have any financial interest relevant to the meeting such as a company's or group's payment of your travel or other expenses, FDA encourages you to state the interest as you begin. If you do not have any such interest, you may wish to state that for the record. If you prefer not to address financial interest, you may still give your comment. It is my pleasure to welcome Edward Morowitz who speaks to us and who was good enough to send both his

comments and some background information in advanced.

Welcome.

MR. MOROWITZ: Thank you. First of all my name is Edward Morowitz. I have no interest in any particular companies or anything else. I come as a member of the public. I paid my own way here today.

I am the parent of two children. I have a passionate and personal interest in the issue of communicating post marketing drug safety information to patients receiving FDA approved drugs. I provided Dr. Zwanziger with a copy of this statement as well as additional background information which members of the committee already have.

I attended the last meeting of the risk communication advisory committee held on May 5, 2011 and was very pleased that the committee discussed the importance of ensuring that the information in drug safety communications or DSCs is accurately and effectively conveyed to patients, providers, and the public. At that meeting the committee also discussed how best to directly reach out to specific groups of patients and providers who most need to know about particular DSCs.

I will speak today mostly about two recent drug safety communications issued by FDA in August 2009 and April 2011. However, I believe my statement has broader

applicability to any drug safety communication that needs to be targeted to a specific group of patients and providers.

On May 2, 2008 my son, Christopher, died of a cancer called hepatosplenic T-cell lymphoma at the age of 20 years old. Hepatosplenic T-cell lymphoma is a rare form of non-Hodgkin's lymphoma which is both extremely aggressive and incurable. At the time that Chris developed HSTCL he had been receiving a combination of thiopurine and biologic immune suppressants to treat his Crohn's disease for just over 2 years.

Crohn's disease and ulcerative colitis which is closely related to Crohn's collectively referred to as inflammatory bowel disease or IBD. I have described some of the symptoms and treatments of IBD in the background statement that I provided to the committee.

Chris was diagnosed with IBD just after his 17th birthday in January 2005. By October 2005 he was receiving thiopurine, immune suppressant drug, called 6-mercaptopurine as well as a second biologic immunosuppressant called Remicade. When his doctor recommended adding Remicade to Chris' treatment, he told us that there were a few unsubstantiated reports of lymphoma among patients receiving Remicade. That information led us to seek a second opinion at the Johns Hopkins University

Hospital and the doctor there told us that the risk of any lymphoma was "infinitesimally small" and that taking Remicade and 6-MP together would "give Chris' life back". Two and half years later after he began receiving this combined immunotherapy the drugs that were supposed to give Chris' life back had killed him. He lived less than 5 months after he was diagnosed with cancer and less than 3 months after his cancer was identified as hepatosplenic T-cell lymphoma.

When Chris died in May 2008, he was 13th IBD patient known by FDA to have developed hepatosplenic T-cell lymphoma after receiving immune suppression. On April 14, 2011 FDA issued a drug safety communication. I am not going to read the title here because it is very long. And that drug safety communication reported that by the end of 2010 only 2 and half years after Chris' death the number of known cases of HSTCL among immune suppressed IBD patients had tripled from 13 to 39.

As explained in my background statement, the actual number of IBD patients who have died of HSTCL is undoubtedly much higher due to under reporting and to the difficulty of and distinguishing HSTCL as the specific cause of death. Among the 39 IBD patients reported by FDA to have developed this fatal cancer, 33 of the 36 individuals for whom gender was known were young boys and

men most between the ages of 12 and 31 years. Thus, it is fair to conclude as FDA did recently that HSTCL appears to be strongly associated with immunosuppressant therapy for IBD in young male patients ages 12 to 31. FDA's concern about this treatment especially for young men was echoed last month in the Gastrointestinal Drugs Advisory Committee's 14 to 1 vote that "there are safety concerns that have not been adequately addressed regarding the use of immune suppression to treat IBD."

Unfortunately there is a gap between FDA's concerns and its effectiveness in communicating those concerns to the IBD patients who need this information to make truly informed treatment decisions. Although the April 14 DSC was the second safety communication issued by FDA in the past 2 years that dealt in whole or in part with a link between HSTCL and the use of immune suppression to treat IBD, the safety communications have not received broad circulation among patients or providers dealing with inflammatory bowel disease. In addition because FDA did not clearly explain that the two drug safety communications it issued were reporting on different populations and different adverse events, those who have been lucky enough to find and read the drug safety communications remain confused about the safety message there intended to convey.

The safety communications do not clearly explain

to readers the relative risks and benefits of immune suppressive treatment of IBD. They lack data on how many individuals especially in what appears to be the high-risk group of young men between the ages of 12 and 31, how many individuals receive immunosuppressive treatment for IBD, and they do not discuss the relative risks and benefits of other types of treatment for moderate to severe IBD.

By posting the DSCs on its website, the FDA has taken an important first step toward making this information publicly accessible. Yet, except for these occasional Internet postings, FDA has not developed a way to make this safety information easily accessible or directly available to those who most need it: the patients and providers who are right now today deciding how and whether to use immunosuppressants to treat their IBD. Until FDA finds a better way to disseminate this information and until FDA can better describe the risks of HSTCL and other cancers associated with immunosuppression IBD patients and their doctors will lack the information they need to make truly informed treatment decisions. It is, therefore, imperative that FDA find ways to ensure that this information is disseminated directly to IBD patients, many of whom receive thiopurine or combined immune suppression without fully understanding the risks.

My recommendations to this committee are detailed

in the background information supplied to you before the meeting. In brief, I am urging the committee to make the following recommendations to FDA. That it quickly update its 2009 and 2011 drug safety communications to reflect all known cases of pediatric and adult cancers including HSTCL through June 30, 2011.

Next that the two updated drug safety communications is issued simultaneously, that they clearly explain to the public how they differ from one another, and that they emphasize the fact that the data sources used by FDA to identify cases of malignancy understate the actual incidence of cancers in the population being examined.

Fourth, that FDA require the manufacturers of immunosuppressants to develop risk evaluation and mitigation strategies or REMS which will outline how manufacturers will communicate to IBD patients and providers the findings of the two updated drug safety communications.

Fifth, that FDA staff make regular presentations to patient and provider groups to summarize the results of these updated drug safety communications and finally that FDA can be in a joint meeting of the Gastrointestinal Drug Advisory Committee and the Drug Safety and Risk Management Advisory Committee no later than June 20, 2012 to discuss whether a national registry of IBD patients receiving

immunosuppressive therapy can and should be developed. I thank you for the opportunity to speak. I am most eager to discuss this issue further with the committee today or at some future day.

Agenda Item: Committee Discussion

DR. FISCHHOFF: Thank you very much. Let me frame the discussion under the federal advisory committee. I have been thinking about how to do this in consultation with Lee. For us to discuss, we are not in a position to or not allowed really to discuss the particulars of any case. It is not impossible, but Lee would have done a conflict of interest screening for all us whether we had stock in any related companies.

But what we can do is we can discuss the general class of problems that you are dealing with. And if we get too specific, Lee will stop us. Let me try to model the kind of issues that we might discuss. The committee has typically -- other than the things that we are mandated to do typically have responded to requests that have come from parts of the agency that have been concerned to get our input. One could imagine a possible client which I think you as a citizen or the staff or anybody could approach would be the office that creates the drug safety communications or the offices that it works with that produce the kinds of inputs that drug safety communications

would convey. I think that that would be properly screened. I think -- that would be an interesting discussion.

It seems like the situation you are dealing with is one where, again trying to stay general, that the analysis might be done differently. The risk analysis might be done differently if it were driven by communication needs as opposed to the communication people taking what comes out of a process that is constructed perhaps for other reasons, for surveillance, for regulatory. FDA has these many hats. There probably are situations in which thinking about what are the accessibility issues for particular groups and then how to aggregate the data might be worthy of some general discussion.

We did have a meeting - in one of our 2009 meetings, we were asked by FDA to look at the general class of what we called the merging issues. These are situations in which this would be one of them, but you have them with food and medical devices, really with all the FDA's regulated products where it looks like something is happening. It looks like something might be happening but the data are imperfect. The dataset is small partly because it is a low probability event. The dataset is imperfect because it may rely on passive reporting or the

categories are not -- you don't have the data you want, but you think there is something there. You don't want to -- and then how do you communicate in a way that gets the right balance between needlessly frightening people so that they don't get an advantage. It might be a potentially useful product, but not leaving it with the information that they need in order to decide what gambles they are taking.

We have addressed that general class of issues. Actually in yesterday's discussion we addressed the first class which is how do users' needs might lead to formulating the risk analysis on food-related issues.

I think that is the sort of thing that the committee has dealt with in part and might conceivably deal with in the specific context of drug safety communications because the kind of situations that you described must be something that the office and then the analysts that they work with must wrestle with all the time.

Are there other --

DR. NEUHAUSER: I just wanted to first thank Mr. Morowitz for coming and I am very sorry to hear about your loss. We certainly appreciate you coming with your very specific information and your ideas. I do understand the complexity of what this committee could recommend or the FDA. I just wanted to comment that I am doing research

with Crohn's patients right now about communication. And one of the things that I note is that they tend to be young men who are typically of course computer savvy these days. And one of the things that I frequently hear from them is that they would like a way to have a real-time communication let's say place on the Internet where they can go as a patient interest group and record their experiences and information and their findings.

This is something that I have been doing a lot of thinking about is how might something like that be an approach that the FDA could support. And I don't know -- there may be people here who could comment on whether that is a direction the FDA is going into support patient interest groups and get out information to them real time as well as correct information from them about say adverse events or other concerns that they might have. My response really is to ask a question.

DR. BREWER: Thank you very much for coming and speaking. It is one thing to talk in an academic sense even as practitioners. It is another thing entirely to speak from the powerful personal experience that you were speaking from. My condolences on your loss.

There is a piece of your written testimony or material that you provided ahead of time that you did not read and if you don't mind, I would like to read it because

I think it actually really drives your point home. In other words, if I was the parent of a teenager or young adult with moderate or severe Crohn's disease or ulcerative colitis today, the FDA's DSCs would not provide me with the information to help me decide whether my son or daughter should receive immunosuppressive treatment, what type or types of immunosuppression are safe and effective for adolescents or how to determine the relative risks or benefits of immune suppression surgery or other forms of treatment for IBD.

MR. MOROWITZ: Thank you for extending my time because I wanted to read it but I saw the signs going up.

DR. BREWER: That is a lot to not be able to do. That is really the fundamentals of not having the information you need. I really think that is a powerful statement.

I think one of the more general issues here is an issue of completeness and timeliness. Maybe a year ago a mom came and talked about her son who she also lost. One of her concerns was about a side effect of the medication that he was taking from -- I think it was for allergies actually. And one of the side effects it turns out was suicide ideation and he committed suicide. She was extremely concerned at the completeness of drug information.

One of the complexities here of course is how to have what kind of information. The issue there was that she wanted all information more prominently placed. Yours I think is just that you want I think the timeliness in part completeness, but also just the timeliness that we know this information and we want the information out now and not later.

MR. MOROWITZ: Definitely. Just to make one additional comment. I am very aware of the fact that I struggle with this all time. I know what happened to my son and obviously that is a preeminent importance to me. I also know many other people with Crohn's who are benefiting from taking immunosuppression. We don't know a lot about long term what will happen with those people. Will they be more likely to develop problems including serious problems like malignancy? I would never come here today and say darn it this drug should not be around or these drugs should not be around because clearly they are doing a lot of good.

The problem to me is an issue of communication. What we had going into the process was inadequate. I think that our experience was more likely typical than atypical in not having enough information even after we went to a major university hospital to get a second opinion. We were given vague reassurances and a lack of detailed

information. That is what I would like to see changed is the ability for people to know about this possibility and to weigh that against other risks of alternative therapy.

DR. FISCHHOFF: Let me thank you. We understand the problem and we certainly appreciate it. This is one of the -- again, the process for the committee has been that things have gone -- and the FDA has figured out where is the opportunity to move things. I think there are the foundations here for action on this class of issues that might perhaps weren't even there at the time that you all really needed them. Thank you.

DR. BREWER: Mr. Morowitz asked us to make recommendations on six issues and as I understand, we actually can't. We would not be able to really even engage in these six.

DR. FISCHHOFF: No, because we would have to have cleared on conflict of interest.

DR. BREWER: Exactly. This document -- will it be forwarded? Maybe my question is for Lee. Will this document make its way, percolate its way through the FDA to maybe the relevant people who would be either able to act on this or at least to whom these sorts of recommendations are being most relevant?

DR. ZWANZIGER: Thanks. Yes, I do try and make documents like this that will be of obvious interest to

different, specific offices available.

DR. PAUL: Mr. Morowitz, I act all the sentiments that have been expressed here. But I think you have brought up a whole range of issues on risk communication. From the very first of signal detection and Lee would maybe hear about something for any product device and not know whether it was attributable and therefore the idea of when do you communicate, what do you know, when you communicate what you know. And you also brought up the issue of distribution of that information.

I think that we certainly as a committee can stand behind you in asking that when we know something and when the FDA is sure of it that the information is made appropriately available. I don't know whether your physicians just didn't have the information and it was too early in the process or whether oversight. But I think we as a committee obviously look for ways to encourage appropriate, clear and direct communication.

I thought Linda's suggestion about a portal is something that was an interesting suggestion in terms of how do we get information out to a targeted audience whether we push it or whether we make it available just as something to consider in the whole overall picture of risk communication from the agency about any number of things.

While this is a much more grave issue, it is the

same kind of thing we have talked about with other kinds of risks and food risks and dangers and so forth communicating to the public. When do you know you have something to communicate and how do you get that out of there?

You have given us a face and it becomes infinitely more important in seeing that so thank you.

DR. FISCHHOFF: We have one other speaker who is Andy Benson from the International Food Information Council who will as I understand have some short remarks on how we can take best advantage of our book and then we will kick off a discussion of how to do that. Thank you, Andy. Thanks for coming back and for helping.

MR. BENSON: Thank you. I will be very brief, but first of all I can't let the opportunity pass without extending my sympathies to Mr. Morowitz and thank him for his input here. My comments will seem very trite by comparison and may well be covered in the next session which is called committee discussion, but I really have no idea of what is going to come out of that. Forgive me if I am asking the obvious.

Mr. Morowitz' remarks clearly stress the vital importance of timely and effective risk communication. And I think the work of this committee and the subcommittee in developing the book has come up with a gold mine of resources that can really help practitioners and

stakeholders and apply risk communication more effectively.

There is, however, one problem of gold in a gold mine. It is usually buried under the earth. It is usually known by the miners, in this case the experts around the table here, but the public and other stakeholders don't even know it is there yet they love to have access to it.

My question is what next and where does this go from here. I would really like to build a little bit on something Dr. Brewer said about we can just say it and that is one thing. But then people need to believe it. And then they need to change their behavior and to implement this.

My question is how do we make people who need to get the gist of this book and I use that word very guardedly, who are they, how do we get the gist to them, how do we make them aware of the existence of this treasure trove in the first place, and then how do we proactively engage them in using and employing the excellent recommendations within the book.

Now, you may begin to tell me all about this, but my first question which hasn't been -- how do I get the book. Fifth grade question. You did say that this needs to come into the public domain -- fifth grade question. And I am sure you will address this.

But some questions to think about and these have

all been brought up by the speakers today is this accessible on the FDA website. Can this be reproduced on other sites? Are you thinking of having press conferences? Have you thought of using webcasts of the top line information and posting them on websites? Has there been thought given to using URL video links of the key findings so that it can be done in a visual as well as a written format? And a question that somebody asked me yesterday is has there been any thought given to workshops and training modules to distill this down so that the gist can be disseminated, replicated, and widely used. And Internet communications. Those are universal, downloadable, adaptable, and accessible. They have some limitations but it is clearly a very good path for outreach. And how is that being employed and used?

And just to really wind this up, something that Dr. Fischhoff said, he encouraged homogenous activity programs with other interested stakeholders a way of duplicating, replicating, multiplying, extending reach, extending influence. I would love to hear some discussion on how that might work out in practice.

And finally some remarks by Gary Schwitzer, who I thought made some very good comments that if you pick the right partners and engage with key international bodies and authorities it is amazing how effectively this can be

duplicated and can take wings around the world. I am campaigning for that as you may have known from my comments yesterday and a couple of weeks ago. I would love to talk more about that and sharing the wealth that those can really make use of that wealth. I think also he made some comment about public/private partnering, leveraging resources and working together to extend the outreach. Where to from here and I look forward to your comments in the committee discussion. Thank you.

DR. FISCHHOFF: Thank you very much. That is a good charge. It sounds like we have collectively communicated not too badly this morning. Thank you.

Let me do a little more schedule juggling and call an end to the open public hearing and then skip directly to our guest Malcolm Bertoni, who is the Assistant Commissioner for Planning for FDA. I asked Malcolm to speak to us and have some time to talk because I understand Malcolm needs to go at noon.

**Agenda Item: Remarks and Presentation of
Certificates for Retiring Members**

DR. BERTONI: Good morning. I want to spend just a few minutes this morning giving folks a bit of a sense of where we are with this committee because this is an important milestone and that we have some retiring members including the chair. I think it is a good time to take

stock about where we have been and hopefully where we are going.

I guess the message really is three fold. One is congratulations. A second though is that we are going to continue to need your help and we really appreciate the ongoing support and advice, and finally, just a big thank you for all the work that you have done.

Just to provide a little bit of context -- I think Baruch already mentioned that we had started to formulate this committee when Congress made it even easier and better from the standpoint of making this a statutory committee that did not require us to continually go through some administrative procedures to keep it going. We appreciate that and I think it reflects the importance of this particular topic because I think as many people have said before we can do the best job with understanding the science, understanding the law and the regulations and coming up with great decisions that are going to protect and promote the public health. But if we fall down in the communication phase then much of all that good work simply doesn't have the impact that it needs to have in much of the discussion over the past 2 days I think has just reinforced that idea.

The first meeting was in February 2008. Here we are in the 12th meeting in August. There really has been

quite an impressive and broad set of topics that have been discussed. Some of them have been mentioned. I will just give you a little sample of the kind of breadth. Certainly there was discussion of directed consumer advertising early on. There was some discussion of consumer medication information, improving patient information. Obviously a lot of work needs to be done in those areas.

There was a discussion and I think we really appreciate what this committee did to get the agency to develop a strategic plan for risk communication and that was discussed back in April of 2009.

There was some discussion of the FDA Transparency Taskforce and the new Center for Tobacco Products that was a new regulatory responsibility that the agency received. You heard certainly more recently yesterday about a lot of important issues around food safety. The topics have ranged throughout the different products that we regulate as well as many of the different important subject matter areas.

We have had staggered terms because this was the initial time of setting up the committee. We are now having the -- the inaugural members have reached the end of their 4 years so we are celebrating and thanking them for their service today.

Just to acknowledge some of the important

accomplishments and milestones. I just mentioned a minute ago the strategic plan for risk communication which we have fondly called the SPRC. I think it has been a spark in that it has provided greater awareness of many of the themes here. Most importantly perhaps the fact that just because you are brilliant PhD scientists or you are an accomplished medical officer doesn't mean that you are necessarily an expert in communicating the impact and the important messages to the right audiences in the right channels. I think raising that awareness has been important.

I think we have seen some progress, but there is probably a lot further that we need to go that this strategic plan really laid out I think an excellent framework for how we can go about doing that both from the research standpoint and filling in some gaps and research needs as well as building some capacity for doing better risk communication across the agency and looking at the different policies that we have. I think the risk communication staff that works in the Office of Planning particularly under the leadership of Nancy Ostrove while she was here before she retired has been outstanding. And we have really had some great accomplishments along the way of implementing what that strategic plan laid out.

The research agenda, I think, is another

important accomplishment of this committee is really helping clarify what the needs are and helping communicate that out to the research community because obviously we can't do it all ourselves here at FDA and many of you are making important contributions that we need to incorporate into our work.

We have had a number of other investigative projects and different vehicles for implementing them that this committee has helped. We have had this little pilot where we do take some employees of the federal government and test some messages on them through an informal message testing network that is not perfect science in a sense, but it is something that we can do inexpensively and something that we can do without running a file of certain rules that OMB has. I think a lot of people have appreciated that. We get good reports from the offices that have used these services and it seems to be growing. I appreciate Brian Lappin and other staff who have been working on that and it seems to be successful thus far. Maybe we need to do some evaluation of how successful, but it is I think helping folks and raising the awareness of the importance of these areas.

I have to say this book I think really is a remarkable accomplishment. And I am hoping that we can find a way to really promote its availability and make sure

that people are aware of it, but not just the miners or where the gold is buried. Let's get it to the surface. Maybe panning for gold on the surface is -- I am from California so I am thinking of the old 49ers.

I think really when you think about the things that a committee can do, a lot of one offs and those are important, but here is an opportunity to really amplify and propagate the knowledge and hopefully best practices and best guesses that we have. I really appreciate and I think it is just a great accomplishment that everyone here who has been involved in this should feel proud of. Let's hope that it becomes a best seller.

I think we can say -- we would like to believe the Risk Communication Advisory Committee is vibrant, effective, and continuing. It has certainly been an important milestone in the agency's history I believe. Yet, I think we have to also take a sober view of where all the federal government is going to be in the coming years with debt reduction and trying to be more productive and efficient and looking at budgets and so on. It seems to me that it is going to be especially important to view risk communication and the work that we have done here as an absolutely essential integral part of what we do. It is not nice to have a thing that gets added on and therefore is subject to cut backs. It is something that in fact

leverages and multiplies the effectiveness of what we do. And if it is viewed that way hopefully people will recognize the value of strengthening this particular function in the years ahead.

Just as a practical matter, we are completing the process of getting the nomination packages for the new members. That seems to be progressing very well from what I understand. We have some topics that are lining up for future meetings. Our work with the different offices here at FDA continues to be productive and collaborative and bringing relevant and timely topics to you.

And we certainly expect to continue the consultation sort of have been very valuable with the committee members and individual special government employees as consultants.

We do also continue to look at the strategic plan for risk communication, look at the implementation plan that we have developed for that, and try to develop specific objectives for the coming years. We try to tie these things in with the practical accountability mechanisms that we have with annual performance plans and things of that nature. We will continue to use these tools as we go forward.

I do want to thank and I also just want say since Nancy Ostrove is here today, and she has recently retired

from the FDA -- I really want to thank her for her service and for her leadership in helping establish the Risk Communication Advisory Committee. She was the first director of our risk communication staff and has built a program and has done a tremendous job in raising awareness and providing a lot of expertise and support on particular projects. I think her strategic vision was essential in the success that we have seen at the agency in making some advances. We all know that there is a lot more that we need to do, but I think she really made a big difference.

As a matter of fact I want to ask for a round of applause for Nancy for your work.

(Applause)

Now is the time when we get to recognize those retiring committee members. Now there are a couple who are not here today. Dr. DeLaRosa was called back to his hospital yesterday evening, but we certainly appreciate his observations from the perspective of a practicing surgeon communicating with patients and that has been extremely helpful and valuable to the committee. And also Sally Greenberg is not here due to a scheduling conflict, but we certainly have appreciated here consumer advocacy perspective.

But we do have with us today Dr. Christine Bruhn who is retiring from the committee and we really want to

thank you and of course we appreciated your input about communicating and about food safety which we were able to take full advantage of in this meeting with yesterday's discussion. I was able to attend some of it, not all of it, but I know in talking with Dr. Morgan that she was very pleased with the input that we got and appreciated all the committee's input. Dr. Bruhn, I have here a letter from the commissioner of thanks and a plaque. I want to thank you very much for your service.

(Applause)

DR. BERTONI: And last, the chair of the committee Dr. Baruch Fischhoff, is retiring. We really want to thank you in particular for your leadership, your advice on matters scientific, strategic and specific. Your leadership throughout this time is standing this up, knowing where to go, working with us, and navigating with Lee all of the particulars and generalities of how to make this particular somewhat unique advisory committee work. And I really hope that you and others will view this capstone meeting with the book as being an important accomplishment and evidence of the good work that you have done and just really want to thank you so much for your help and your leadership and your service. And, again, we have a letter from the commissioner and a plaque.

(Applause)

Dr. BERTONI: We are very fortunate to have such imminent experts and thoughtful people to help us here at the agency. I know that is going to continue going forward and that is really all I want to say other than another big thank you to all of you. I know you are very busy. And the work that you do here though does have an impact on the agency and it does influence the thinking and it helps us tremendously and I think it is very important. Thank you again.

DR. FISCHHOFF: Thank you, Malcolm. I just have to thank you and Lee and Nancy and Chevon and Karen and all the other people who support us. Personally I am very proud to be associated with FDA. I show probably the cover sheet from the strategic plan for risk communication is a staple in my talks. I think FDA is really leading the way and I hope that by our collective contributions that we are helping to take full advantage of the technical staff that FDA has which the American public depends on that the world depends on to take full advantage of what you are doing and as well as I hope in some ways to protect the franchise from unfair criticism by showing people what you are doing and what you are allowed to do and what you are not allowed to do. I hope that there will be continuing and lasting contribution to your work. We are all proud to serve. Thank you.

We have our sleeves rolled up. What do we do with this book? A tiny earl would be a good place to start. Actually, Lee, why don't you tell us just a little bit about where we are on a technical basis. There are some interesting technical complications, but I think we should -- let's hear what we have done and what some of the problems are that Lee and her colleagues are still working with and then let's forget about all of them and in Andy's spirit let's think big and we will work together to take full advantage of what everyone has done.

Agenda Item: Committee Discussion

DR. ZWANZIGER: Thank you. Just briefly, first let me say that one way to get to this page is -- the FDA web page, o to science, more science, and then pick risk communication. This report is displayed with the other report that gleaned on the committee. It certainly came from committee advice is SPRC.

We have now put this book in full as a PDF on the FDA's website so it is now in public domain. We ourselves are -- risk communication staff is not exactly a publishing house. We have pretty small print run that we did of some hard copies thinking that the fastest, cheapest and most widely accessible way to get the book would be online first.

Then we have some other potential options. One

of them to make it more accessible might be to go back and throw it up as an HTML file which would be a bit easier to revise links as they get broken and so on. If somebody wanted to republish it, my understanding is they can do that.

I have contacted our government printing office to see if there is interest there. I am not entirely sure what is going to be the outcome yet. It is a little difficult for -- I kicked around ideas about making the text available in an eReader format. There is something to be done with making it available in eReader. And sometimes in terms of making the book most widely available aside from putting on a website it would be nice to market it by some office other than myself as I am not set up to be a business operation. We are exploring hopefully some ways that we can make the physical book available for sale. I don't yet know what the final outcome of that is going to be, but we are open to other people stepping in and assisting us with this.

DR. FISCHHOFF: I wasn't able to raise fda.gov. Maybe that is my browser. It is an invalid URL. Let's think big about where we would do at the meetings we would put it too and let's just get -- I understand that the cabs are coming at 12:15 so let's think fast and furious and then Lee and Noel and I will put our heads together

afterwards. Let's share the ideas.

DR. NEUHAUSER: Well, I think our commentator from the last session brought up a lot of good ideas in a sense that this is a really important milestone and then our job or someone's job needs to take this and get it out to the public researchers, practitioners, government, and different formats.

I really like the idea of some kind of eReader, iPad, so forth that really would make it useful for practitioners who will be able to find what they want, annotate that, and use that in their daily work.

The other thing I would suggest is to think about how this book can be infused into the public health system because we need to think about which audiences in particular might find it useful. We know most people are confused about risk communication. And I think a really important audience or the public information officers or the PIOs. Every state has those. There are many at county and city levels. And to have a book like this available to them I think would be very important. I would put that out there as a suggestion to get those to all 50 states. The PIOs also come together usually at CC every August. They may be coming together right about now. Reaching them at one of their conferences would be useful too. Thinking the book is something to infuse around the public health and

medical and other networks.

DR. BRUHN: I strongly support of course Linda's statements, but I think that it would behoove us to look at groups that are already involved in presenting information to these networks that have already established connections and have a history of success and Andy Benson's International Food Information Council is certainly one of them. I am very familiar with that organization. I know they put on workshops both stand alone. They do also webinars and they do programs at various professional meetings so an organization like that and others who are interested in collaborating. Our goal is to get this message and information out and we need to look at all the sources that are effective in doing that.

DR. FISCHHOFF: Craig and then Kala and then Nan and then Mary and then Val. Let's make this easier on the -- let's just go in order.

DR. COL: Just quickly. There are a lot of groups that are organized on Facebook for shared decision making. There is a group of, I think, 400 of us that are pretty active. If there is a link on Facebook, at least we can get the PDF version. And once we figure out how to get the print version you can simply -- that could be set up.

PARTICIPANT: (off mic)

DR. COL: Yes. If there is a way of having it as

a link or something, you could actually drag into these various groups that are within Facebook, but there are several of them that are hundreds of people that are internationally that would be very interested in this. If you could put something out that could easily spread amongst the groups in Facebook.

DR. PAUL: -- has similar groups like they have a drug safety group and thinks like that. I think Gary ought to put it in his newsletter.

MR. SCHWITZER: If I could jump in, I took the liberty of already blogging and more important tweeting about it and here is early feedback from -- I believe she is the current president of the National Association of Science Writers. Without any steering from me she writes in 140 characters free gold for health medical reporters, new FDA guide to evidence-based risks and benefits. That is the way it is already being reviewed. Free gold.

DR. PAUL: The other thing is that I -- last June I was at a DIA meeting and DIA is just one -- Drug Information Association, one professional group that is involved in risk communication -- food groups, all the other device manufacturers, but each of these organizations have trade shows or educational programs and the FDA quite often has a booth there. For instance, the FDA had a group of publications both CDER and CBER had booths and

publications at FDA. I think all these organizations where any place where FDA distributes its published material would be a place to have that --

DR. ANDREWS: It might be helpful. I have an email out to all of us who I know. We know many organizations out there. More specifically I know researchers in our field who have had a risk communication workshop. In fact, Baruch, I think, was involved in that in the marketing public policy conference. There are literally hundreds of researchers that would be interested in this. In fact, there have been books similar to this going back in history, going back through the decades. ELMAR with the marketing professors as well as ACR Listerv would be interested.

DR. FISCHHOFF: One thing we might all do is just follow Gary's lead and send the links out. Just have it in our mind to get it out to people and whatever our natural modes of communication. I think Lee always dreamed of having a bookstore but not a bookstore with just one book. We need to be fair to her over the long run.

DR. BROWN: I want to echo also what Linda suggested as a former person who worked in a State of California PIO office. This would be very valuable for them. One of the things that I would recommend is not necessarily a press conference because I know those take

resources, but at least a news release in both print -- well, they are all in electronic form now, but to go out to various audiences.

I think it is very important that other regulatory agencies at both the national and the state level have access to this because many of them deal with a public that doesn't understand well what they do and have to climb over a lot of myths. I really encourage you to get the word out either with electronic format news releases and/or general news releases out to the general news publishing organization.

And also to take full advantage of the many partners that we have and that FDA has, the patient advocacy groups, the public consumer focus groups, academic and trade groups, all can assist to get the word out. Picking the right partners. A good idea. And there are many of them.

I love the idea of webcasts. And working with whomever it is that is your FDA web designer masters to make sure that the links work well and that for instance you can put even a little news release on a home page of FDA. I am not sure what the internal limitations for that are, but I know that would be valuable. And also taking a look at making sure that the language is searchable by Google. I am sure you have people in your web design

department who can help you with that.

I do think that navigation issues on web pages are very important and especially with FDA. It is hard to find things on government websites. I am working with another agency on that because they have so much depth and they cover so much to maybe look at ways to not get buried in the risk advisory committee page, but also on other pages. Maybe URLs within -- links within the FDA website.

DR. FISCHHOFF: Thanks.

DR. REYNA: I just wanted to make clear that this material is available without worrying about copyright issues. People can download it freely as long as it is government publication. And also I have already taken the liberty myself to send information about the publication to the extension system at Cornell. I am director of extension and I would encourage people through the land grant, colleges and universities that have extension system to make this available through newsletter and other sites. We have an electronic site that we maintain at Cornell and we will put this link up as soon as possible.

DR. HUNTLEY-FENNER: I would love to echo everyone's remarks, but I am going to refrain from that today. I am going to re-tweet instead Gary's tweet. I think that the news releases are a great idea. One benefit of those is that we could actually take them back to our

institution and they just cut and paste and they have their own local network. It makes it easier for us to have our own institutions promote the book as well.

DR. FAGERLIN: I think we need to think about what other organizations to look at. I just shared the link with each group which is a bunch of shared decision making people. We can send out to listservs like the -- listserv, SJDM, SMDM, food science. I only know the psychology ones because I am a psychologist. We all have these listservs that we belong to, put in our own Facebooks, just these things where the people we know will be interested in. I just think we can take our responsibility each one of us. If each one of us sends it out to three or four organizations that we are involved with, it will spread very quickly and it is free.

MR. SCHWITZER: Just a real time update. An Australian public health journalist has tweeted health care news stories often exaggerate benefits and minimize harms and then links to the guide. We should try to make an effort to reach out to the growing number of health comm masters programs in this country and the much smaller number of health journalism graduate programs as somebody who launched a health journalism grant program at Minnesota. There is no perfect textbook and maybe we have pushed that up the hill a bit. And when you think about

the costs, I always was concerned about the textbook cost to students. What a bonanza for them.

DR. NEUHAUSER: A couple more comments. One really useful place to put this would be on the CDC's website under risk communication. That will get to a lot of people. And if there are other formats of this so CDC, for example, has a lot of risk communication. If this could be taken and put in to some other kind of format, it would be useful for perhaps them to consider for interactive training. They have very good interactive free online training for health literacy and other things and this could be added to that.

And then I am wondering what the best way might be to get this to industry that the FDA regulates farm and device, food manufacturers and maybe there are lists or some easy way to do that, but I think some of you would know the answer to that question.

DR. SLEATH: I would suggest also putting on AHRQ's website through their safety initiative and I would go through pharma to get to the industry. I have a contact if you guys don't about how to get it on their listservs and things like that.

Another important area I think would be even organizations like the American Association of Retired People, the National Consumers Union. I don't think this

is just for providers. I think lots of groups would benefit by it.

And finally in terms of like medicine, pharmacy, nursing our organization is called the American Association of Colleges of Pharmacy and I am sure that they would send it to their listserv. I don't necessarily have the privileges to be able to do that. And then I am sure that medicine, nursing and others have similar organizations. And then finally Michael Wolf who is a member of the committee is having a big conference in October on health care communication and their group I think is called the American Academy on Communication in Healthcare. Maybe plugging it there and asking him specifically to do it at the conference.

DR. FISCHHOFF: Everybody should feel deputized to do all they can.

DR. FINCH: I would also say public health, schools of public health, and then also tapping into the partnerships on a state level maybe a lot at the state health offices, but contacting the communication officer. Each one of them has a communication officer. And with the news release that speaks on the book there may be some language to the connecting -- that the health department is connecting with the local or county health departments for those who are totally like on the ground working with those

folks that would need to be able to know how risk communication should be implemented in lieu of emergencies and recalls. I think that is about it.

DR. FISCHHOFF: Noel, do you have anything else? Christine and then Ann again.

DR. BRUHN: This is all a wonderful flash, but we need to go more than just tell them about the book. I think we should look at our professional societies because we are each different and we should plan either a session in our professional societies or a webinar that is directed to our partner, but let's not just say here is a great book. Let's say and these are some of the chapters or some of the sessions, some of the advice that pertains specifically to the kinds of communication that we are involved in including maybe ourselves or others that we know that can lecture and demonstrate. We tell them and show them. We don't just say read this.

DR. COL: I don't know if anybody mentioned a press release because if you could prepare one, we could send those to local newspapers. We come from all over the country here. People read those kinds of things. I don't know if you are allowed to do that.

DR. ZWANZIGER: I can certainly send you a blurb. The cover of the book that we are doing -- it has been out for quite a while, but certainly we can get a short blurb

to people to send around.

DR. FISCHHOFF: There is even text right there. Everybody do everything you possibly can and we will put our heads together and do some other things and if it is duplicative, we know that repetition helps

DR. BREWER: Baruch deputized me to put together a marketing plan and I think you all just kind of write it. Lots of notes here and we will organize these. Along with much of our advice. There is a limited amount of us to go around. What we will probably do is prioritize a few of these things. Some of them are more doable than others. All of them are doable given a certain amount of time and resources. I am just not sure if we -- the RCAC has other things they will have to continue doing. I really like these ideas. We will come up a list here and maybe who can do them. There are a couple of these kinds of things that each of you can participate in some way and we will try to be in touch with you about what you and can't do.

Another idea that came up that we haven't discussed yet is the idea of actually having a publisher pick up the book outside the federal government. Oxford Press or Cambridge Press or one of those that likes this particular kind of thing. I think is a really good idea. The extent to which people can buy this book I think in some ways it will create a market for it. Being free is

really useful, but I also think that for some people having a hard bound copy or a soft bound copy on their shelf they can hand to people at least for academics is how we operate. I think for other people the PDF will be exactly what they need. That is something that I will also add to our plan. But thank you. Those are really outstanding ideas.

DR. FISCHHOFF: Everybody rush to their tweeters or your quills depending on your technology age. Let me bring the meeting to a close. Let me just tell everybody what an honor it has been to be the chair of this committee. This has been a spectacular group of people. We have the support of the agency and it just has really been an honor to be a chair of this committee and I feel the new people -- too bad you didn't know the old people. You really would have liked them. I brought a camera so I would like everybody to take a picture when we are done. Thank you all.

(Whereupon, at 12:10 p.m., the meeting was adjourned.)