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Advisory Committee on FDA Risk Communication

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P R O C E E D I N G S (8:00 a.m.)

Agenda Item: Call to Order and Conflict of Interest Statement

DR. PETERS: Good morning, everybody. I would like to welcome everyone to the second day of our 13th meeting of the Risk Communication Advisory Committee.

I'm Ellen Peters, and I'm the chair of the meeting. Sitting next to me is Dr. Lee Zwanziger, who is our designated federal officer. I'll go ahead and turn it over to her.

DR. ZWANZIGER: Thank you, Dr. Peters. Good morning to the members of the Risk Communication Advisory Committee, members of the public, press, and the FDA staff. Welcome to this meeting.

Before I say anything more, I want to say something to people who may be listening and watching our webcast. If you are joining us today, thank you. If you are joining us after our crashes yesterday, thanks for giving us another chance. I hope we'll be able to sort out whatever was the problem with our crashes yesterday.

For today, we welcome especially our two guest speakers, Drs. Castel and Zikmund-Fisher.

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 preclude even the

appearance of such at the meeting.

FDA has determined that members of this committee are in compliance with federal ethics and conflict-of-interest laws. Today's topic is the implications for strategic communication of recent theoretical developments on information use and decision making. The topic is a non-particular matter, so no interests in firms regulated by the Food and Drug Administration present the potential for conflict of interest or the appearance of such at this meeting. Should the discussion turn to some area of potential conflict or any area not on the agenda, participants are aware of the need to identify conflicts pertaining to them and refrain from participating, and statements of these exclusions would be noted for the record.

We have a period set aside for open public comments listed in the agenda. If anybody is not already signed up to speak and now wishes to request time, please see my colleague, Sean Charles (phonetic), at the sign-in table outside.

The entire meeting is being broadcast and transcribed. The transcript will be posted on our Web site. Please remember to turn on and speak into the microphones every time you are recognized to speak and turn them off when you are not speaking. I would suggest that

everybody turn cell phones and other devices to a silent mode.

Thanks.

DR. PETERS: Thank you, Lee, for keeping us on track and making sure we're following the rules.

At this point, why don't we go ahead and have the committee members briefly reintroduce themselves, in case some people in the audience were not here yesterday. Bill, maybe we could start with you today.

Agenda Item: Introductions of Committee Members

DR. HALLMAN: I'm Dr. Bill Hallman. I'm a psychologist and chairman of the Department of Human Ecology and director of the Food Policy Institute at Rutgers University.

DR. COL: I'm Nananda Col. I'm a decision scientist and I'm at the University of New England in Maine.

DR. ANDREWS: Good morning. I'm Craig Andrews. I'm professor and Kellstadt Chair at Marquette University. My focus is on consumer and advertising research.

DR. FREIMUTH: Good morning. I'm Vicki Freimuth. I direct the Center for Health and Risk Communication at the University of Georgia.

DR. PAUL: Good morning. I'm Kala Paul. I'm a neurologist and I'm president of the Corvallis Group, which

is a company that specializes in risk communication, with a particular interest in low-literacy patients.

DR. BREWER: I'm Noel Brewer. I study the psychology of medical decision making. I'm on faculty at the University of North Carolina, in the Gillings School of Global Public Health. My research focus is on medical testing and vaccination.

DR. PETERS: Again I'm Ellen Peters. I'm a faculty member in the psychology department at the Ohio State University.

DR. REYNA: Good morning. I'm Valerie Reyna. I'm a faculty member at Cornell University. I do research on memory, judgment, and decision making, especially risky decision making.

DR. HUNTLEY-FENNER: Good morning. I'm Gavin Huntley-Fenner. I have my own science and engineering consulting firm, where I focus on the human factors of risk communication, particularly warnings, labeling, instructions, and their impact on behavior.

DR. BROWN: Good morning. My name is Mary Brown. I'm a research associate with the College of Pharmacy at the University of Arizona. I have my own consulting firm. My focus is health communication, primarily at the interpersonal level.

DR. ENGELBERG: Good morning. I'm Moshe

Engelberg. I head up a management marketing consulting firm called ResearchWorks, where we specialize in health communication and social marketing, and I'm adjunct faculty member at San Diego State University School of Public Health.

MS. FINCH: Good morning. I'm Sokoya Finch, executive director with Florida Family Network. Our focus area is public health, but a special interest in health disparities.

DR. WOLF: Michael Wolf. I'm faculty in medicine and learning sciences at Northwestern University. My research is around adult literacy, medication safety and adherence.

DR. PETERS: Thank you. These are the members of our standing statutory committee. I appreciate you all introducing yourselves again.

We also have the fortune to have two speakers, first of all, who will introduce themselves later, when they actually give their talks. But we have a special guest today, Mr. Malcolm Bertoni, who is the commissioner for planning. I wonder if you might introduce yourself.

MR. BERTONI: Sure. Thank you. I'm assistant commissioner for planning and director of the Office of Planning, which includes the risk communication staff that helps manage this committee.

I'm just delighted to be here again. I want to thank again the committee members for your service and Dr. Peters for stepping up to chair the committee.

My background is interdisciplinary public policy, but also management science and operations research. I consider myself a real consumer of the decision sciences and risk communication work that you folks do. It's very important to the agency. As we often say, we can do the best science and make the best decisions, but if we can't communicate it effectively to the public, then we aren't going to have the impact that we need to have on public health. So we very much appreciate your contribution to our mission.

I also happen to currently be serving as the lead negotiation for the medical device user fee reauthorization negotiations. That responsibility requires me to dip out of here a little bit before 10:00 a.m. I want to apologize in advance for having to leave these wonderful presentations. I'll get a report back on the rest of the day.

Thank you very much.

DR. PETERS: Thank you very much, Mr. Bertoni.

At this point, we'll go ahead -- actually, we will start with me, with an introduction and an overview of what's to come. We then have three very interesting

speakers after this.

We also -- and I just want to make sure that everybody has them with you -- have a number of questions that FDA has posed that we will be turning to after the three speakers. Perhaps while I get set up, you could just make sure you have the questions available, as we'll want to turn to them after the speakers have gone through their material.

Agenda Item: Introduction and Overview

DR. PETERS: I thought what I might do today is just a brief overview that kind of takes us back a step to think about what's involved in the decision process.

Let me start by just going back to FDA's strategic plan for risk communication and what the strategic goals were within that strategic plan. There are three of them:

- Strengthening the science needed to support communications.
- Expanding FDA capacity to deliver those communications.
- Optimizing FDA policies on communicating risks and benefits.

Those of us on the committee have heard these quite a bit. As a committee, we hope to help FDA in a number of areas, because this communication is integral to

accomplishing FDA's mission. In particular, though, where we tend to help them the most is probably around strengthening the science -- strengthening the science that's needed to support communications. For example, we offer research-based recommendations. FDA comes to us in a couple of different ways around those research-based recommendations. We saw two of those examples yesterday. In one example there was a congressional mandate that asked us to take a look at this literature review on quantitative information.

FDA also comes to us with, not matters that are congressionally mandated, but just things that they would like to have advice on. As you noted as we were going around the table making introductions, we have a number of different areas of expertise and a wide variety of expertise around the table where we can offer a perspective from science, because it's evidence-based. We can offer a perspective from science to start to help FDA push in directions that perhaps will work a little bit better.

We also, though -- and this is more the topic of today's meeting -- get to highlight theory and evidence. What we are going to do today is take a look at more recent theoretical developments, and we will start to talk about how we might bring those more recent theoretical developments to bear on issues and matters that are

important to FDA in their communications.

Today's session is consistent with one of the underlying principles of the strategic plan for risk communication -- the idea that communication should be evidence-based and it should reflect the theory and the science of risk communication, because it can point efforts in the right direction. For those of you in the audience who weren't here yesterday, there is a new book that has come out that you might be interested in. I know the members of the committee are well-versed in the book. Many, if not all, of them are authors on one or more chapters.

One of the things that was discussed yesterday was the idea -- the review yesterday discussed a limitation, that few studies ended up considering what happened to behavior or behavioral intent. What is the effect of quantitative information on behavior or behavioral intent? That was one of the limitations that they pointed out.

I just want to underline the point that they did make in the review, but they didn't bring out very much yesterday that risk and benefit communication does concern more than behavior or behavioral intent, because there is often not a right answer. It depends on the values of the particular patient or consumer who is faced with the choice

that's being made. I just want to make sure that we thought about that. I think that Dr. Reyna is going to be bringing that up when she talks about fuzzy-trace theory today, this idea that values are important. It's not just that we're trying to push people towards a particular behavior. That is not FDA's job, at least in my opinion, and I believe they would agree.

What we're going to talk about today is the idea that considering the more complex information processes that lead up to informed choice, but also lead up to a value-concordant choice, will help in the design of risk communications -- and that's risk and benefit communications -- but it will also help us understand how we should be evaluating these communications. What kinds of measures, what kinds of processes should we be measuring in order to figure out whether we are doing it right, whether we are doing the best job we can?

To make informed and value-concordant decisions, patients have to have information. They have to have information about risks and benefits, and they are supposed to be done in a balanced fashion. The information has to be available, so it has to be out there somewhere. It has to be accurate. FDA is very good about that. It has to be given to the patient or consumer in a timely fashion, and it should be complete. But as the literature review

yesterday pointed out, there shouldn't be too much information, because that can be very overwhelming to a consumer or a patient.

Patients also have to be able to access the information. There are a couple of different things that I mean there in terms of access. They have to be able to access the information in terms of -- they have to see it. They have to go and look at it. There may be differences, for example, between having information right in front of you and having a Web site that you could go and click on or that you have to enter into a bar. There has been some research recently that has shown that there are differences among Medicare beneficiaries, for example, in their ability to make good choices around Medicare health plans, depending upon whether they were sent a letter that had just a Web site link in it or they were sent a letter that had the information available already. So there are differences in accessibility, in that sense.

There is also the notion that Moshe and, I believe, Noel brought up yesterday that accessing the information also means that you have to look at it. You have to attend to it. The information might be there, but people may not attend to the information because of processes of selective attention and exposure.

People also have to be able to understand the

information. I mean that in a couple of different ways. I'm going to talk about one first. They have to be able to identify the information. Assuming that the information is available, assuming that they actually access the information, they have to be able to identify that a 9 is a 9, for example, and possibly do some calculations on it.

I want to show you one example, a Dear Doctor letter that came out in 2008 in the *Eugene Register-Guard*. I thought it was a very interesting Dear Doctor letter. This is an 86-year-old who has written a letter to Dr. Donohue, who is a writer in the newspaper. This 86-year-old writes that he has been taking a variety of different pain killers, for different reasons, and he ended up in the hospital with a bleeding ulcer and an inflamed esophagus. At the very end of the letter, he asks, "Why aren't we told about the terrible things that drugs can do?"

Dr. Donohue has a very nice answer. He ends up concluding that there is a warning. There is a warning that exists on these labels. But most people don't read it.

Exactly why this ended up happening isn't entirely clear from the letter, but the doctor suggests that maybe it's a lack of attention. It could also be just a lack of comprehension, of being able to understand the information that's there. It's not entirely clear exactly

what's going on.

But this idea of accessing and understanding the information is very important.

We have to not only be able to identify the information, though, we have to be able to understand and remember its meaning. We talked about that a bit yesterday with numbers. Dr. Reyna will talk quite a bit more about that today, as I think Dr. Zikmund-Fisher probably will as well.

We sometimes have to remember the verbatim information. Sometimes verbatim information is really important. People have to remember what number of pills to take, for example, how many times a day and at what time, approximately at least, they should be taking the medication. Should it be with food or not with food? There are a number of verbatim pieces of information that are important to remember.

One thing that we haven't talked about particularly is the idea that sometimes people also have to understand the meaning of the outcomes themselves. For those of you who can't see this, this is a pharmacist behind a pharmacy counter, in the middle in blue, and there's a woman to the left who is apparently the customer, who is picking up a prescription. Then we have someone down on the floor, who is saying "Acck!" Obviously, this

is a very tongue-in-cheek example. This is not a recommendation to FDA. The caption at the bottom says, "The FDA now requires that we have an actor show you what kinds of side effects you might experience."

The idea is -- something that wasn't brought up yesterday, because we were talking about numbers -- the idea is that sometimes patients won't also understand the meaning of what that outcome might be. I just wanted to bring that point up as well.

Again, this is going a little too far for the sake of humor.

To make these informed and value-concordant decisions, patients also have to be able to apply the information. They have to be able to determine meaningful differences. This will also be linked with Dr. Reyna's gist-based processing that she will talk about in a moment. They have to be able to weight factors to match their needs and values. Of course, that means they have to be able to identify and they have to access their needs and values at the moment and be able to integrate them in with the information that is being presented to them. They have to make tradeoffs. Every drug comes with risks and it comes with benefits. So you have to be able to make tradeoffs: Is this gamble worth it to me?

Finally, they have to make some judgment or

decision or they have to take some behavior.

Today what we're going to be examining some of these more complex information processes that are based on recent theoretical developments and think about the implications for FDA's strategic communication. Dr. Valerie Reyna will first talk about her fuzzy-trace theory. This is a core underlying theory in how people process information and decision making.

Dr. Alan Castel will talk about supporting verbatim memory in particular, and especially for older adults. One of the things that I think we always want to keep in mind when it comes to pharmaceuticals is that these older adults are the largest per-capita consumers of prescribed medications. They are at the greatest risk for adverse side effects at the same time. For example, more than half of older adults, according to one recent study, take three or more prescriptions. So there's lots of room there for experiencing adverse side effects from that kind of polypharmacy. So these kinds of supports for verbatim memory among older adults in particular are really critical.

Finally, we're going to go back a little bit into application. Dr. Brian Zikmund-Fisher will talk about the importance of identifying and tailoring the goals of communication, of patient needs -- tailoring the precision

of provided information -- excuse me, identifying the goals of communication and then tailoring the precision of the provided information to those goals.

At this point, I would like to invite Dr. Reyna to come up to the podium.

Each of our speakers will talk. We will have questions for clarification after each speaker. At the end we will open up the discussion more broadly.

Thank you very much.

Agenda Item: Communicating the Gist of Risky

Decisions

DR. REYNA: Thank you very much for that excellent framework introduction. Good morning again, everybody. It's a pleasure to be here, and I must tell the committee again how inspiring I find your comments. It's wonderful to be part of a group that really cares.

I was tasked with some very, very difficult questions, in particular this very specific question -- not only the state of the science, but when do people need gist information, more bottom-line meaning type of information, versus when do they need specific, or what we would call verbatim, quantitative information?

I'm not going to be able to present a lot about data, but there really are data. I swear, we have data. We have experiments and surveys and models and so on and so

forth. The work that I'm going to talk about -- fuzzy-trace theory I think of as a summary of data, and not just my own data. I think my own data are probably a small proportion of the evidence that supports the theory. We draw on prior scientific evidence that goes back as far as gestalt theory and things like that -- the gestalt, as in the gist. That's not coincidental, for those people who have a background in that. As you know, in gestalt theory, there was a distinction between what's called nonproductive thought -- this rote kind of thought, where you weren't thinking, you didn't transfer, you didn't retain information -- versus productive thought. That's more like gist-based reasoning and thinking.

So we draw on a lot of prior scientific evidence from psycholinguistic research. We have tried to really challenge ourselves by predicting new counterintuitive predictions, things that weren't what we already assumed.

In particular, the core distinction in the theory is to distinguish gist, which is the fuzzy traces in fuzzy-trace theory, from verbatim traces of information in memory. Those are those traces in memory.

Think about a concrete example. In particular, I want to distinguish between the information we provide patients and the public from what's happening inside their heads. If only what was on the page was in their heads, we

wouldn't need all of these additional assumptions about mental representations. But that's not necessarily what's in the head.

So this is a hypothetical sort of example -- let's just say it's hypothetical -- in which children of parents who refuse vaccine are told a particular piece of information: People who refuse the vaccine are 23 times more likely to get a particular disease compared to fully immunized children. You have some parents there. They are listening to the health-care provider, and the health-care provider is providing that very important information about 23 times greater risk. The verbatim information is just the surface form, the exact words -- 23 times more likely. But in addition to encoding a surface form, like a tape recorder, of that information, alongside that encoding, in parallel and independent from it, are multiple interpretations of that information, including something like, wow, that's a huge risk, 23 times more likely. So the gist would be, huge risk. It's an interpretation of that input. The verbatim would be the exact words.

Again, regardless of what's on the page, what we have given to people, they will encode both of these types of representation. Obviously, what's on the page and how it's presented can facilitate the encoding of particular kinds of gists or meanings or mental representations, but

these are distinct -- the format on the page versus the format in the head.

So both are encoded into the mind from the same information, usually multiple gist encodings.

To just develop that idea a little bit, here's another piece of information. I'm taking an isolated piece of information, just one at a time. Obviously, people encode a whole set of information. Let's just say you go to a Web site. You're a member of the public. You're thinking of taking a medication or a vaccine, and you see that there's a .001 percent of something bad. You encode your verbatim and your gist representation, and in particular you encode levels of gist. I'm going to name them, because they are going to come up again and again.

You have your liner/literal encoding, .001. Then you have various levels of gist that are encoded simultaneously. I want you to go back to your thinking about statistics, when you first learned about scales of measurement. You have your nominal scale, which is categorical -- some/none, pass/fail, male/female, those kinds of things. Then you have, at a higher level of precision, an ordinal scale -- low, medium, high -- where you don't know the intervals between them, but you can order things. Those different levels of distinction are encoded often when people are dealing with numbers, like

risks and probabilities. So they encode, gee, there's some risk to this medication, vaccine, whatever. They also encode ordinally: Is it a low risk? Is it a medium risk? Is it a high risk? That sort of thing. So simultaneously you encode these kinds of gists over and over when you are presented with different kinds of materials.

I should say, too, that you encode things at the level of the individual item, collections of items, like at the word, at the sentence, at the narrative level. A narrative, a story, is another level of gist -- a causal narrative, in fact. All of this is based on research in psycholinguistics, as well as more recent research.

To just get a little bit more technical about our definitions, we have gist being the bottom-line meaning of information. It's vague. It's qualitative. It's based on all the things that we know empirically affect the nature of meaning, which is emotion, identity, education, experience, worldview, et cetera. The verbatim representation, of course, is just the exact words or exact numbers.

We have extended this to lots of different stimuli. Basically, any stimulus that has meaning is encoded at the surface form and at a meaning level.

There's good news on the gist front -- namely, that gist seems empirically to be associated with better

decision making. We could be here probably a long time talking about what constitutes better decision making. But based on considerations of outcomes and internal coherence and a variety of things like that, we have found that gist generally improves performance -- in general, globally speaking.

In that first study, we're talking about cardiologists making decisions about patients with chest pain, both hypothetical patients and real patients in the emergency room. We looked at medical students, residents, family practice physicians who have domain-specific knowledge in cardiology but are not cardiologists, all the way up to cardiologists, and leading cardiologists who write the handbook chapters for the rest of the folks. If you look at that developmental trajectory, people who were more advanced were, in fact, making their decisions in a much more gist-based way. They were using the bottom line of information. They were using one dimension, not two -- is the patient at imminent risk of a heart attack? -- and they were doing so in a very all-or-none nominal gist kind of way. They would either go into intensive care or they would get discharged. You're at risk or you're not. So that kind of developmental change in gist-based decision making was associated with expertise and knowledge.

In another series of studies, as well as a review

of the literature, we have identified that adolescents whose decision making is based on more bottom-line gist seem to make healthier choices, engage in less unhealthy risk taking. Rather than trade off risks and benefits, they just don't go there in terms of certain kinds of risks, like HIV, the ones that are protecting themselves.

Adults' reasoning and decision making, when it's more accurate, is associated with gist.

Why would that be the case? Why would we be more accurate and our reasoning be superior if it were based on gist? First of all, it's meaning-based, rather than being rote. So that makes sense. Also gist representations are more stable, they are more enduring, and they are more robust -- all kinds of interference, noise in the room, literally, emotion, that sort of thing. If you organize your cognition around a robust representation, you're going to be less error-prone. We have shown, in fact, for example, that if you force people like doctors, for example -- I have done research on doctors' probability judgment -- if you force them to be more verbatim, you increase certain kinds of predictable errors.

But the downside of gist, obviously, is that it is contextual and meaning-based. Once you are experienced and you have insight, there are predictable biases that you will be subject to, because you're getting the gist and

going beyond the data, and that has certain predictable kinds of non-literal downfalls that can occur, like framing heuristics and biases and so on. Not all of those biases are meaning-based, but when they are, they increase with development and they increase with expertise -- so particular kinds of systematic biases.

However, there are barriers to getting the right gist. People extract the gist based on their own understanding of the facts. But your own understanding of the facts can be limited. You can lack numeracy, you can lack background knowledge, and so on and so forth. So the gist that you extract may not be the ideal or the best sense of the facts, from an independent point of view.

Just to step back a little bit -- because we really want to go beyond mental representations to the whole decision -- the ideal informed value-concordant decision making includes:

- Having background knowledge sufficient to understand the facts that are being presented to you.
- Getting the meaning of those key facts, representing the gist of the options appropriately.
- Then -- and these have all been shown in research to independently contribute to the accuracy of the response or to the nature of the decision that you make -- based on your take on the facts, retrieving values that are

relevant to you in that situation. We think, okay, maybe that's a trivial thing. If you strongly have a value, you are going to always retrieve it, right? No. It turns out that a lot of retrieval is so cue-dependent. It's remarkable. That's one of the reasons why our decisions are variable. We have to be reminded that we have this strongly held value and that it's relevant to the options we are considering.

- Finally, putting it all together.

So you have your representation, you have your value that you retrieve, and then you apply the value to the representation. That extra step -- again, which seems trivial -- turns out to be very, very difficult. To actually apply how we feel about things to our understanding of the options is a separate consideration.

What happens in real life? Well, these things are not always there. The requisite background knowledge, especially in medicine and public health -- things that we all take for granted, like herd immunity in vaccination -- doesn't everybody know that? Most people, in fact, have no concept of what herd immunity means. Representation -- do they get the meaning of the key facts or do they, instead, try to follow things in a verbatim, rote way, which has very definite pitfalls? Do they actually retrieve their values in context? Often not. They have to be reminded of

relevant values, and then they don't necessarily put them all together. So that's more of reality than the ideal.

One of the messages that I have today for you is that it's important to understand the locus of the problem when we are trying to remediate or we are trying to intervene. That's true, of course, in all of science. The HIV therapies, retroviral therapies, were based on a causal knowledge of exactly what the chain of events was in disease. Psychology and human behavior is no different.

So where is the problem? What's the locus of the problem? Is it a lack of background knowledge? Is it that the patient or the public is thinking very literally? Are they using the wrong gist? Do they have a misconception? Are they using the right gist, but failing to retrieve their values and principles, including their moral principles? Are they using the right gist, retrieving the values, but failing to put it all together?

In research, we have identified separate kinds of interventions that are effective for each one of these kinds of problems.

One of the important steps in fuzzy-trace theory, unlike some theories, is that you really have to have a sense of what the gist is if you want to communicate it. This is not a trivial exercise. You have to have a notion of what the essential bottom line of the options is. This

gist is again influenced by content and context. It's not the exact wording. It's how you interpret it, is the bottom-line gist. That really depends on the context. You can say a 15 percent chance of rain. How would you characterize that? That's a pretty low chance of rain. If you say a 15 percent chance of a heart attack, that's treated as a high risk in the unstable angina guidelines, for example. Anything above 15 percent and you're in intensive care. That means imminent risk of a heart risk. So 15 percent is not 15 percent. It depends on the context. And that's the difference between gist and verbatim.

One of the things I have recommended and that we have implemented in research is asking experienced people who have insight what the bottom line of the options really boils down to in the end. Empirically, it turns out that there are not an unlimited number of options. Usually people with prior knowledge and some experience tend to converge on a small set of gists that they characterize the options as being relevant to.

Finally, that last difficult bullet there: If only we could understand for people, if only we could exercise for people -- I would pay you. It's sort of like that. You have to do it for yourself. You have to have the insight yourself. We can facilitate that insight,

absolutely. You can facilitate understanding and comprehension. But at the end of the day, a person has to extract their own gist from the facts. They have to get it for themselves and they have to see -- because it's all about comprehension. They have to get it: Why is this the bottom line of the options?

We have some interventions we have used that have been effective -- this is just a sample -- in which we have implemented these ideas. We did a randomized, controlled trial, public health curriculum, in which we "gistified," to use a verb from yesterday, reducing the risk, which is an evidence-based sexual risk-taking curriculum with adolescents. There were about 834 subjects in that randomized, controlled trial, three arms: reducing the risk; reducing the risk, "gistified" version; and then a control curriculum that had to do with other things. We did about 22 outcome measures. There were significant differences over a 12-month period in reducing sexual initiation and a variety of other kinds of outcomes -- behavioral intention to take risks and number of partners and things like that.

One of the reasons gist, of course, is important in terms of interventions is that it endures over a period of time. You remember the gist of what you learned. You don't remember the exact details. So the idea is, if you

want not to have fadeout effects, if you want to have these interventions, you want to make sure that people get the gist, because that will last longer.

This is a paper that is submitted now, in which we took the gist of these very complicated rheumatoid arthritis medications, which have small probabilities of pretty bad side effects. Nevertheless, they can prevent major disabilities and progression of the disease. Based on a fuzzy-trace theory, gist-based enhancement of the information about the options, we went, with real patients, from 35 percent value-concordant decisions to take medication to 64 percent value-concordant decisions. I was kind of shocked myself. This is by clicking on things on the Web. So this is a kind of simple, cost-effective way to inform patients and seems to have some value.

We also have a number of other interventions that we have used with physicians to reduce things like base-rate neglect, based on the notion of what the causal underlying mechanisms are that are causing the base-rate neglect, the mechanisms I pointed out to you earlier, as well as biases like framing effects, conjunction and disjunction effects, and so on. These are all very, very simple kinds of interventions that are easily implemented.

I was asked a number of difficult questions, challenging questions and questions that really made me

think. One of them was, how do we know the amount of information people actually need to use in order to make a well-informed decision. A word like "rare," isn't that kind of vague? It could even be misleading. But a long list of detailed side effects, on the other hand, can be overwhelming. So what's the happy medium here? Does either of these promote good decision making, well-informed decision making?

In fuzzy-trace theory, the idea here for side effects would be to characterize the bottom line. If we think about something that is not a side effect but a disease, like HIV infection, if you have unprotected sex, you have a very low probability of contracting HIV. I wouldn't stress that too much to my teenagers at home, but the objective data are that it's a low-transmissibility virus, low-probability. On the other hand, it's a very bad consequence. Adults mostly think of this is an all-or-none fashion. Why take that catastrophic risk? That is, in fact, a word that came up yesterday and it's a word that we use in fuzzy-trace theory.

In terms of side effects and information, can we organize that information? Again, I wrote this slide before we had the discussion yesterday, but it's very much in the spirit of what we were talking about yesterday. There are many, many studies, stretching back to the 1990s,

in which we showed that if you organize information, like put it in a linear order, like a crescendo -- small, small, medium, medium, bigger, bigger, most, that kind of order -- people get the gist much more readily from that and they remember the gist later much more readily, than if you scramble and put everything in a kind of random order. In many domains, with many kinds of stimuli, we have shown these kinds of order effects. So you can facilitate -- and, again, I wrote this before people made some similar suggestions yesterday about organizing the side effects, categorizing them qualitatively and then organizing them within categories.

Rare side effects: Should we just say "rare"? When we talk about adverse effects, obviously, as many people have talked about, we are talking about probability and severity together, and we are talking about, when you put these together, a configural effect. Basically, when we say something is rare but really bad, we're trying to integrate that into a single concept in our minds. The example I gave here, in addition to the 15 percent ones you have already heard about, is a real example from a real person who was talking to a genetic counselor. A grandfather whose child had died of cystic fibrosis was talking to the genetic counselor and another child about the probability that his grandchild would have cystic

fibrosis. He said, "A 1 percent chance is too high for me." The grandfather was highly numerate. He knew that 1 percent was 1 out of 100, et cetera, et cetera. But the impact of that disease, what it really was like to experience it, to him was that profound. That's the qualitative aspect of gist that's so important.

So when we talk about rare adverse events, we have a categorical kind of initial decision. Am I going to treat this risk as, it's risky or it's not? Am I going to think about this as taking a risk or not? Then I have to decide, is that risk a nil risk or not? It's there. Everything has risk. Every medication has risk. So it's not zero. The idea is, do I treat that as nil or do I treat that as, hey, that's categorically important? That's the kind of fork in the road that people have to get to psychologically.

What does the choice boil down to? I'm sticking my neck out here, but I'm giving a couple of examples of what I mean by all this. If you look at that second bullet there, there's a choice between a likely major disability versus a very bad possibility that will never happen for most people. That, to me, was the gist of what I gleaned from the rheumatoid arthritis drugs. I'm probably going to be disabled -- major disability -- if I don't take these. This is for individual patients, of course. Say I'm an

individual patient and this is my trajectory. I'm going to have permanent, irreversible disability or I'm going to undertake a very bad possibility that probably will never happen. So that's kind of the bottom line of all of that.

Or take colonoscopy. It's a choice between discomfort for one day and preventing a common cancer and cause of death. That's what it boils down to. That's what it certainly boils down to for me, and I'm just grateful that there's the possibility out there to prevent a major cause of death.

Not everyone will have the same gist, but there are a lot of people that will share some of the most popular gist representations.

Let's talk a little bit about informed consent, like for surgery. Again, another concrete example here: This is from a real study with real patients who were given information about carotid endarterectomy. This is this Roto-Rooter kind of thing where your artery is clogged and you do preventive surgery to prevent a stroke. There's a probability in three years of getting a stroke if you don't have the surgery. There's a probability that if you are on the table, you are going to have a stroke or have some other problem. This is estimated, in this particular study, at 2 percent. When patients were asked later, after a very thorough exposure to these risks, what they

remembered about the numerical risks, they mostly didn't remember them accurately, even though it was gone over orally and in writing, and even though they were about to go into surgery. They were quizzed about it then, so it's functionally very relevant. They knew that surgery was less risky than not having surgery. That's good. That would be ordinal gist. But, crucially, the point I want to make is that if a patient recalls the risk of the surgery as 10 percent, they are better informed than if they recall the risk as zero. The risk is actually 2 percent. That red bar is supposed to represent the actual risk. If you say the risk is zero, you are much closer to 2 than if you say the risk is 10. In a verbatim, rote way, you're closer. But you don't get the bottom line, which is that if this is going to be informed consent for surgery, you realize you are undertaking a risk. That's a categorical thing. So that's the difference between gist and verbatim.

One of the things, too, that we understand is that sometimes the experts and the physicians do try to organize the gist of these things. They are trying to encode some of the same things, but they don't necessarily transmit them to patients.

This is based on -- I have not checked out all these numbers, so treat them as hypothetical for the moment -- based on my conversations with a clinician

recently. She said to me, look, there's a 95 percent adherence rate for HIV treatment, because if you don't adhere 95 percent, then outcomes start to cascade down. There's a 90 percent sort of break for immunosuppressive drugs for a kidney transplant. If we don't get 90 percent adherence in these teenagers, who are kind of erratic -- which is not good -- they take a chance on losing that kidney. There's an 80 percent adherence for high blood pressure medication. So there is a little bit more tolerance there.

Health-care providers have a gist of how bad non-adherence is. We tell patients, do everything I say. That would be ideal, I agree. Do everything your health-care provider says. But the patient needs to know, if they make a slip-up, how unforgiving the disease process is. Are they about to head over a cliff or not? When doctors look at this, they go, yes, there's a real steep cliff for HIV, a pretty steep cliff for immunosuppressive drugs, not quite as steep a cliff for blood pressure, but it's good to take your medication. Patients need to have some insight into that. How bad is this? Of all the terrible things that you are warning me about -- I could slip in the bathtub, this could happen, that could happen -- how bad is this? There is the sense of a precipice here that has to be conveyed. That's qualitative. That's qualitative, not

quantitative. I mean, it's sort of quantitative, but it's a threshold.

One of the things I want to argue is that gist is necessary, and not just nice. The initial question was, when do you need gist and when do you need verbatim? I think you need gist all the time, bottom line. Then you also sometimes need verbatim. You can misunderstand verbatim instructions if you don't know what you are following. The error in the manual -- if you have ever assembled things, you immediately know when instructions are wrong, and you ignore them selectively because you get the gist of how to hook up the stereo.

The "once" medication -- there is an actual example of somebody who was bilingual. *Once* means eleven in Spanish. They thought they were supposed to take the medication 11 times a day, not once a day. If you kind of have a sense of how much is a lot, you would know not to do that. Without the gist, you won't remember the verbatim. I would caution people that say we want to have people remember the verbatim. They are not going to do too well. Write it down. Use some kind of technology. The human mind is not so good for verbatim. We forget very rapidly, and we make sometimes these unforgiving errors.

A person who came up to me about car seats at a recent conference said, "Valerie, that's an exception. You

have to know the exact instructions for assembling those car seats. Millions of people are not doing it right, and these kids are going to be propelled through the windshield because they are not attaching the kids' car seats right. They have to follow the verbatim instructions."

I said to him, "Well, if you really understood physics, wouldn't you look at it and immediately know it was hooked up wrong, because of inertia, mass, and all this stuff?"

He thought for a minute and he said, "Yeah, you're right."

If you got the gist, even if the instructions left something out, you would know, because you understand how it works. That doesn't mean you also don't want to follow those instructions really carefully, too. I would highly recommend that.

Also you can derive sometimes what appears to be verbatim memory from gist memory. I referred to a math model that we published in *Psychological Review* in 2009. As a matter of fact, we talked, Ellen, about aging a lot in that paper. It's how people can compensate for lack of verbatim memory -- for example, in aging -- by reconstructing words on a list from the gist. It's remarkable how well, if you remember the meaning, you can actually generate things that were presented accurately.

We can actually estimate the number of words that people generate from gist as opposed to verbatim. If you look to people recalling those words, you would say they remember them exactly; they have verbatim memory. But they don't. We know from the math model that they are actually reconstructing them from meaning. Obviously, that's something we can teach older people to do more of and improve their performance.

If you understand the gist, you are not prey to certain kinds of misconceptions. You know whether the differences are big differences or not. This graceful and non-graceful degradation is just another way to say, is the process forgiving or not of small errors? Do you have to be very exact or is there some leeway?

Bottom line: I think gist is almost always helpful and can support following precise instructions. I think it's important to explain the ultimate fundamental why -- why this is what you're taking, what it's for -- rather than simply warn, persuade, and exhort. You have to underline when rote compliance is essential because the process or the outcome is unforgiving -- you are about to go over that precipice -- and to try to convey what the tipping points are. When do these things change qualitatively, so you are going to be really in trouble if you go over that line? If the action is categorical, say

so.

Just to pull out a little bit as I wrap up, I want to distinguish the dual-process theory of fuzzy-trace theory, which is a verbatim-versus-gist theory, from standard dichotomies. We draw on a lot of this literature. I don't want to completely disparage it or anything. But there are some sharp differences in prediction between standard dual process, which is this Cartesian notion that you have high-order deliberation, conscious thought, versus low-level emotion and that kind of thing. Based on work by Peters and others, we think that affect suffuses gist and is part of the gist. The functional significance of information has to do with is it good or bad for you to do. That's valence, right? Emotion has to do with the meaning of things, the significance of things. Is this a trivial thing or is this really important? Is this about who you are at your core? Things like that. That really influences gist.

Gist-based intuition is advanced in our theory. That's a major difference from standard Cartesian dualism or Epstein's dual-process theory or Kahneman's dual-process theory. We say that you do better by doing less in particular ways. It also differs from Gigerenzer et al.'s fast-and-frugal approach. It's not just, process less information to save cognitive load. You use gist even when

information is present in front of you and you don't have to remember it. You still use the gist, like in a framing task. You use it with familiar information, not just with unfamiliar, and it's not just fewer dimensions of information.

None of these other approaches that I have talked about really predict these kinds of crossover effects and double dissociations that you get in fuzzy-trace theory.

We also incorporate -- I haven't had a chance to talk about it much -- emotion, or affect, and inhibition. But we also add these concepts of the mental representation and the values to those concepts. So we try to conserve all the good things about things in the literature.

Again, this is just an overview. In particular, I wanted to point out that certain kinds of gists are misleading. I think one of the gists that can be particularly misleading is this notion of chemotherapy being poison and people not taking chemotherapy because they think of it as poison. I think probably a better metaphor would be something like, you're in a storm and the waves are pelting you and you're on the deck of the ship and you have this lifeline that's holding you to the mast. You're getting beat up because there's a storm. You're in a storm. You have cancer. You're in a storm. It's a bumpy ride. But at the end of the day, that's going to

hold you fast and you are going to get through this.

That's a very different metaphor for chemotherapy than, it's poison, don't take it.

People think of cancer as the tumor. Therefore, what's the answer if the tumor is the cancer? Take it out, surgery. That's the obvious thing that comes from that kind of conception of the gist and so on.

Bottom line: Presented facts are not the way you make decisions. You make decisions on your representations of the facts, your subjective interpretation of the facts, and the values that you bring to that situation.

I'm not going to go over this, but if people want me to, I will later. Basically, certain kinds of formats convey certain kinds of gists more readily. Obviously a line that goes up conveys that something increases. It increases in magnitude. A bar graph's relative height indicates this is bigger than this. Pie charts -- which is most, which is least? So there are certain kinds of what Gibson would probably call affordances, or ways in which these representations convey a particular kind of categorical gist or relative-magnitude gist or linear-ordering gist and so on.

Bottom line: You need to know two things about some of these very adverse side effects. You need to know what it is qualitatively, what it's going to feel like to

have this side effect, to be blind, to lose cognitive ability. What's that like? I have to know qualitatively what that's like to know if I'm going to entertain that risk -- just the possibility that it's going to occur, what it is. I did actually start off studying probability words and metaphor, and somehow it has all kind of come together. That was in my dissertation. And you would have to have a sense of the absolute magnitude -- a sense of it. Are we talking about a small, nil thing? Are we talking about very low? Are we talking about medium? Are we talking about very high? Then the gist really tries to integrate all of that. What's the overall summary of the risks and the benefits, with a sense of perspective, the kind of perspective people get when they have experience and insight?

Thank you. Those are some resources.

DR. PETERS: Thank you very much, Valerie. That was a great overview of your theory, but also I thought you made some very important points about its application to issues that are important to FDA.

We're actually kind of low on time. If someone has a burning clarification question or two, we probably have time for that. Nan?

DR. COL: That was brilliant, as always, Val.

I was curious about the statement that gist

memory is less subject to interference from emotion. The follow-up concept that I'm concerned about is, when we are talking about using these insights for advertisement, the gist that -- I can imagine if you do a brilliant job with the lines and the words, but the context in which the ad is placed is, there's a healthy, sexy-looking man, with a sexy-looking woman, talking about why certain treatments for ED are wonderful, and there's lovely music playing in the background. The gist that the person -- there's a bombardment of all these other factors that affect gist, including visual, sound, other imagery. We know in other areas that narratives -- when you are giving factual information and narratives, the impact of the characteristics of the narrator can trump the actual information that's presented.

So when we're talking about this in context with ads, which is, I think, our general context, what happens when you have a very strong scientific gist message, which is the words and the data, but there is an opposing imagery? What gets remembered?

DR. REYNA: Craig and I are nodding because we are thinking of all this research that's relevant, I think. I can't really read your mind, but I have a feeling we're thinking of some similar things. There's a lot of research on this question. I won't go into all of it, don't worry.

But to summarize, there's this notion, when you really don't have a gist for something -- again, in this context, you get this multiple-syllable word that they don't know -- it's not a familiar stimulus that we are trying to communicate about. They don't have, necessarily, background knowledge. But you can tap into that and say it's like something you do know. The ad will try to communicate a certain kind of gist for it, with music and people and so on. As I said, all of that goes into your extraction of the gist. It's not just the words and the facts. It's the overall gestalt of the whole thing, and especially when you are not familiar with what you are trying to think about, that will override, and you have a fuzzy processing preference.

So it's the battle of the gists here. It's how to convey in a competitive way one gist versus another. But gist will be more robust to all kinds of interference effects compared to verbatim.

DR. PETERS: I think we're going to stop there, actually, and go ahead and continue, because a lot of this is actually going into the questions that we're going to be discussing also. So go ahead and have Craig and then I'll hold the other two comments for later.

DR. ANDREWS: We have actually studied this on nutrient content claims -- one-third less sodium, healthy,

all of that. That's the opposing gist, in a way. Then you are providing information, absolute, relative, evaluative language to cut through the disclosures. But what's fascinating is on the bottom line where you have the wrong outcome. We call it inferencing or generalizations that are misleading, in a way.

I'm going to turn this around. One question that I have for you is, do you think that there is baggage -- and we have detected this a little bit coming in, where they think, oh, soup is good for you. Everything is great. You can't really provide information that would overcome that without extremely high nutrition knowledge or literacy. Is there baggage there prior -- fatalistic views, I guess, on prescription drugs and just the diseases, where it's extremely challenging to overcome that?

DR. REYNA: Yes, I think you are absolutely right. We have a gist of soup. It's a comforting, good, healthy thing. But, remember, at one point in this country there was a gist of smoking. They had ads with doctors in them saying it's good for you, it helps you digestion. So we have really changed behavior a lot. It wasn't hundreds of years. It was 1964. It's not 100 years ago yet. So there are ways to turn the gist around. People do have misconceptions and then they sometimes don't have them

after a while. There are public health campaigns that really get at the essence of things.

There are many examples. For example, now in law they say eyewitness testimony is not the most reliable. What could be a more compelling intuition than, if you see a crime happen, it must be correct. That has to be the best form of evidence. But now, due to all the counterintuitive research on false memory, people don't -- you see people on talk shows saying, "Now, we all know that eyewitnesses are unreliable." That got into the public consciousness.

So it is possible to combat. If you think about combating gist and combating images and get the essence of things in a new way, I think my knowledge, for example, of donuts has been radically altered. I didn't think they were that bad and then I learned about donuts. I still like donuts, but I have a whole different conception of donuts now than I once did. So I think it is possible to have people comprehend things in a new way.

DR. PETERS: I think this is a great conversation. I think it's a conversation that we are also going to continue as we talk about the other questions, after we have had all three speakers come up to the podium.

At this point I would like to introduce Dr. Alan Castel. Alan, I wonder if you might be able to just give a

brief introduction to yourself before beginning your talk. Then Alan will go on to talk about "Making Numbers Meaningful, Memorable, and Useful for Older Adults."

Agenda Item: Making Numbers Meaningful, Memorable, and Useful for Older Adults: Value-Directed Remembering Across the Lifespan

DR. CASTEL: Thank you. Thank you for inviting me. It's a real honor and pleasure to be here.

I received my Ph.D. in 2004 from the University of Toronto in cognitive psychology. I'm now a faculty member at UCLA.

I'll tell you a little bit about my research interests. I study memory and aging, and how memory and attention change as a function of age. I'm specifically interested in cognitive aging, so a lot of the research I'll talk about tests younger, college-age students and compares them to relatively healthy older adults between the ages of 65 and 75 or 80. I'm also interested in metacognition and memory. This is how people monitor or think of their memory -- when people are overconfident, when they think they will remember things, but then later forget them. I'm very interested in those areas. I have also done a lot of research on visual attention, working memory, expertise, and how people process numbers. Of course, I'm here today because I'm interested in

applications of all of this research.

One common complaint of older adults is that they have difficulty remembering names and faces. This has been illustrated in the literature by showing that older adults really have challenges remembering associations, or links between information, sometimes names and faces, sometimes source information -- remembering a headline, but not remembering where you read the headline, in a newspaper, in a magazine, on the Internet.

One way to think of this is this binding problem of linking arbitrary units of information together. This is what leads to this dissociative deficit often found for names and faces. This presents a particular problem when it comes to numbers, because numbers are, in fact, very difficult to process and make meaningful.

So numbers are very challenging to remember. I don't need to tell this group that. But there are a number of reasons why this might be the case:

- One is that there's a lot of interference. You can remember your current phone number, but you might have trouble remembering previous phone numbers.

- Or that we are simply overloaded with a lot of numerical information when we are reading something that's very precise.

- Or that we need to remember very specific

numerical information as opposed to remembering gist sometimes. You might remember your hotel room number, but tomorrow you won't. But you might remember what floor you were on. That suggests you might still retain some of this gist information over time, as Valerie was talking about.

I have become very interested in the use of gist in old age -- specifically, when older adults rely on gist and why. Is it because that's all that left or can older adults still extract some verbatim information, but only under special, certain circumstances? That could be very relevant to how we remember numerical information.

Numbers can be remembered in certain places and when we have some contextual information in which we can interpret the numerical information. I'll talk a little bit about some research that examines how people use organized bodies or knowledge, or schemas, how they can use experience or prior knowledge to interpret numerical information. Then in the second half of this presentation, I'll talk about how older adults and younger adults can selectively focus on important information and use numerical values to guide how we attend to information. In general, I'm very interested in how people remember information and can be selective about what they remember. In fact, if you can't remember everything from this talk, you might only want to remember the important things. But

determining what's important is, in fact, a very challenging issue.

When talking about binding numerical information, one interesting thing about numbers is that they can be very meaningful in some contexts, but in other situations they don't have a lot of meaning. If I asked you to try to remember these numbers on the screen, it might be fairly challenging. However, if they are linked to other information, then all of a sudden these numbers can become very meaningful, like a very hot summer day or a close presidential election or the price of house in Los Angeles. But they can still be less meaningful even when they are tied to certain things, depending on what sort of background knowledge you have. Remembering a flight number might be very difficult because there's no semantic context where you can interpret that, although maybe a pilot might, or remembering course code numbers, Social Security numbers, phone numbers. When there is very little semantic value, we have trouble remembering information.

We have tried to study this in a number of contexts by looking at how people can remember verbal information compared to numerical information. I'll talk about a few experiments. I will just mention that we have done some work where we have asked people to remember phrases, such as 36 horses on a farm, and then we later

test them: What was on the farm, and how many? Both younger and older adults can remember there were horses on the farm, but older adults have real trouble remembering how many there were. They might remember there were about 40 or 50. They have difficulty remembering specifically that there were 36.

In a more real-world context, we have been looking at how schematic support can influence this binding process by looking at how people remember price information. A lot of the older adults that we test will often say in these memory experiments, this information isn't important for me to remember. We use word pairs, names and faces of people they don't know. So we have started to use materials that might lend themselves a little bit better to the challenges everyone faces. We presented people with grocery prices and items that reflected market value, but also items that were overpriced or unusually priced items. Then we gave them a cued recall test, in which people are just presented the pictures of the items again and they have to recall the price, with the idea being that maybe under these circumstances, older adults would do quite well at binding or remembering the link between the market value prices compared to these very unusually priced items.

For example, if you participated in this

experiment, we would present something like this and you would have to remember this and then be presented with a second item. Of course, this is the overpriced condition. You would have to remember this. Then later you would have some distracter task, and then a few minutes later, you would be re-presented with each item. Here's your test. You would have to recall the price of this item. Many of you can do that, even early in the morning. Then you would have to recall the price of this item. This is where older adults actually start to have some trouble. They will say things like, I know that one was overpriced, but I can't remember how much, or they say, oh, that was about \$17, maybe \$20, or they will make funny remarks like, this is a Whole Foods price. These prices are much higher than what I remember. I'm not used to shopping at stores like this, which suggests that they are processing these items to a certain degree. They are just thinking that these prices don't mean anything to them or, I don't want to pay that price, so I'll just encode it as too high.

I'll show you the results from this study. This is recall accuracy, scoring recall as only correct if people get the exact price correct. All the prices ended in 9. What we find for the regular-priced items is actually no difference. If anything, older adults are doing slightly better than younger adults in terms of

remembering the prices for the regular-priced items. This is sometimes hard to find when you are testing younger and older adults, situations where older adults are doing just as well as younger adults. But for these unusually priced items, both groups do worse, and this age difference is much larger. Younger adults can still hold onto that precise verbatim trace for these overpriced items, whereas older adults can't remember the exact price under these circumstances.

We followed up on this study by looking at how this benefit from schematic support, or organizing information with prior knowledge, in terms of how people can remember more general levels of associative information or just remembering a more general link between the item and the price. This is what Valerie would be talking about for gist information.

Can older adults still remember that certain items were overpriced, but still not get at the exact price? In this experiment, we presented younger and older adults with underpriced items, overpriced items, and market value-priced items. At test they are presented with these items one at a time and they were told they had to recall the exact price, but also the value category. If they couldn't recall the price or if they were guessing, they should indicate whether the items were overpriced,

underpriced, or market value.

In this case you might be shown that eggs are 19 cents. That's underpriced. Peanut butter is \$11.89, so that's overpriced, although I have been told by many older adults that peanut butter prices are going up, so that might not actually be too inaccurate. Then pickles are \$2.79, the market value price.

Later you would be tested. You would be presented with the items one at a time. You have to recall the price. You can participate if you want. Then you would also be asked to recall the category. You might remember 19 cents and it was underpriced. You might recall that the peanut was overpriced, but maybe around \$11 or \$12, and then the pickles were market value, \$2.79.

Here are the results. This is recall performance, again scored only correct if people recalled the exact price correctly. We find again for the market value prices, there is actually no age difference. Again, if anything, older adults are doing slightly better than younger adults at remembering these market value prices. But it's for these overpriced and underpriced items that younger adults do better than older adults. It's clear here, under these circumstances, there are larger age differences, because these numbers might not necessarily be meaningful or interpreted in an appropriate context.

Sometimes I get some contexts that maybe those underpriced ones should be better remembered because you can interpret them as being on sale, although these prices were -- you would be worried if you were buying your eggs for 19 cents. But there might be ways to then present situations where lower-priced items might be better remembered if they were interpreted as being on sale.

Here is the second part of the results. This is when we asked people to classify these items in terms of just the general value category of market price, overpriced, or underpriced. Here we find that there are actually no age differences across the board. Both age groups are doing well at being able to classify these items as, that was an overpriced one, that was an underpriced one, that was a market value one.

For this sort of study, older adults seem to be able to remember certain associations or links between items and prices. This might represent, again, a difference between general and specific access to associative information, or verbatim versus gist again. Older adults may adopt or rely on a different encoding or retrieval operation when they see these items. As I said, sometimes older adults wouldn't even really try to remember that the ice cream is \$17.89. They just say, oh, it's much too expensive or it's around \$17. Later, at retrieval,

that's all they are accessing, the manner in which they initially encoded it.

This could reflect differences in the control over grain size, really just the degree of precision in which people try to remember information, especially when you are presented with a lot of information. You might decide, I can't remember all of this, so I'm going to focus on either ones that are more important to me or I'm going to study them in a way such that I can access the information that I need later.

This idea of grain size has been looked at in a number of contexts, that one chooses the level of detail or generality to study information and later remember it. This could even be retrieving facts that you might know somewhat, like what year the Berlin Wall came down -- maybe you know it wasn't 80 years ago, but you can't remember the precise date -- or remembering what time your flight leaves. Instead of remembering that it leaves at 12:06, you encode it simply as around noon. I should get to the airport at around 10:00. That might save us time. But some people can still remember, under certain circumstances, the exact time your flight leaves, or in the case of the grocery price study, that maybe the cookies were \$11.89 or you just encode that as \$12, and in the context of taking medication, remembering precise

medication amounts or more general things, such as how many pills to take.

This also has implications for how older adults might remember things like when they are using their credit card. If they are later billed a certain amount, can they remember, when they initially made that charge, how much the charge was for? Or if there are small fluctuations in what their bill later reflects, are they able to detect that or not? If it's consistent with their schemas, if \$80 for a restaurant charge seems reasonable and, in fact, it was only \$68, will they be able to detect those differences -- or misremembering drug dose information if inconsistent with prior experience. If a drug dose changes after five years of taking a specific one, it might be difficult to update that information.

One other important issue is how older adults determine whether information is indeed important to remember later. If we have strategic control and we decide to exercise it to determine what information is important to remember, that can lead to certain changes in how we remember information. For example, today you might say, what part of this talk is important to remember? I know I'm not going to remember all of it. Students will often ask, what do I need to know for the test, implying that they don't want to remember everything or that they can't

study everything, but they want to know what's important. So it's a very challenging thing to then say what is important. That's sometimes a very subjective issue, but sometimes it can be very objective. We frequently assign value to information, and that guides how we study or how we choose to make notes, what things we choose to write down. This value can then influence behavior and also what we later remember.

To examine this, we have examined how strategic control can influence how people study and retrieve information using an attentional control task, where selection can influence what information is actively processed and retained. You might think, if it's important, then I'll remember it. But maybe what is more accurate is, if it's important, then I'll try to remember it, to guide knowing that we can't remember everything. It might be the case that older adults use value to guide memory even more so than younger adults. A lot of college-age students are capable of memorizing vast amounts of information, whereas as we get older, we might have better knowledge of how our memory works and know that we can't remember everything. Sometimes younger adults will even say, tell me what's important, because I know I can't remember everything, or older adults will say, there's just too much information for me to remember. Either tell me

what's important or I will try to determine what's important. But it might be the case that under certain conditions older adults might be just as good as younger adults in terms of remembering what is high-value information, but worse at remembering lower-value information.

To examine this issue, we have set up an experimental task where people are presented with words one at a time that range in point values, or the importance of remembering the words. Your job is to maximize your score, to remember the words paired with the higher point values, which is the sum of the point values of the words that you later recall. This allows participants to be somewhat strategic in light of capacity. If you know you can only remember three or four words, you will only focus on the top three or four words. But if you think you can remember all of the words, value shouldn't matter. If you think you can remember half of the words, maybe you will choose to study that's paired with a point value of 6 or higher.

To give you a feel for how this task works, I'll run you through a quick trial. Don't write the words down. Your ask is to try to remember as many words as you can to maximize your score. So it's advantageous to remember the words paired with the higher point values. But I will tell you that the words go by fairly quickly, so you might not

be able to remember all of them.

So now you would be asked to recall as many words as you can. Many of you might recall "ticket," "house," or "pizza." Those were the 12-, 11-, and 10-point value words. That would result in a fairly good score. But you also might remember some other words that were on the list that were of lower value, like "snow" or "guitar," for whatever reason.

We can look at various measures: First, the number of words recalled. That's what most people typically look at in these memory tasks: How much are you remembering. But we can also look at the value of the words recalled -- that reflects also your total score -- and the selectivity. Are you recalling the highest-value words? If you are only recalling a few words, are you selectively recalling the highest-value words?

This is the probability of recalling the words as a function of the point value of the words. I should mention that we do this with many lists, and people are given feedback. You just did one quick list. You would be told your score is 27. Try to do better on the next list. Then you repeat this with different words maybe 12 times or 20 times. People are given feedback. They typically learn quite quickly how many words they can remember, and if their score is quite low, they learn how to selectively

remember the higher-value words. As you might see from these results, older adults learn to do this fairly well.

The younger adults -- as I said, these are college-age students -- are very sensitive to value and recall more of the high-value words relative to the lower-value words. The older adults are also very sensitive to value. You do find age-related differences for the lower-value words, but what's interesting is that you don't find any age-related differences for these higher-value words. If memory was just worse in old age, you would expect this function to just be lower. But what's interesting is that with task experience, older adults learn to selectively focus on these high-value words. They can't remember all of them, but for these three high-value words, there are no age-related differences.

We have also tested this in healthy older adults, as I have talked about already, but also older adults who show very early signs of Alzheimer's disease, and find that these older adults show poorer memory performance, but it's not like their memory is considerably worse across the board. They are actually recalling more of the lower-value words than these healthy older adults and fewer of the high-value words. This might suggest that attention plays an important role in this process, selectively attending to the high-value words, but also inhibiting or not attending

to the low-value words and then not recalling them later.

We have tested this in children with ADHD as well and find similar results.

For this selectivity task, we find fairly predictable changes in memory performance. Older adults will recall fewer words than younger adults. But this selectivity is maintained in adulthood. Older adults are being just as selective, if not more so, than younger adults. This might have some sort of metacognitive component. Older adults know they can't remember as many words, so they selectively focus on fewer words, but will remember those words well. That typically occurs with a lot of task experience, doing this task several times and being given feedback about scores.

As I said, we have tested this in children and children with ADHD, who seem to have real trouble selectively attending to the high-value words, but also will then later recall some of the lower-value words. That might tell us a little bit about the brain mechanisms that are involved, as well as the role of attention.

We followed up on this study to really get at the metacognitive component. When I say metacognitive, I mean how well people can monitor their own memory. Do you know that you won't be able to remember all 12 words or everything from this talk? If you know that, how do you

change your behavior in a strategic manner so that you can remember the important things, not just the first few things from the talk or the last few things from the talk?

In this task, we ask people to choose which word-value pairs they want to remember to maximize their payoff, but now they have to bet on the words. If you bet on, let's say, apple and it's paired with 10 points and you later recall that word, then you get 10 points. But if you bet on apple and then later fail to recall that word, you will lose 10 points. Now it's kind of introducing this risky choice, potentially. Do you want to go for the high-value/high-payoff or do you want to go for lower-value/lower-payoff? Then do you want to change this strategy that you use with task experience? We then, as I said, repeat this with many study list trials to see if people might, on the first list, bet on many words, but maybe to recall all of them, but then on later lists, learn to bet on fewer words -- maybe the lower-value words or maybe the higher-value words -- to kind of enhance their score.

This is what we find. This is the average score that people achieve on each list. In this case they did six lists. As you can see just from the axis here, score can range from negative to positive. Younger adults do fairly well, although on the first list they are only

getting around 10 points, even though they are recalling maybe four or five words. People learn how many words they can remember and learn from that accordingly. What's interesting is that older adults will actually start off with a slightly negative score. They might be overconfident. They will bet on more words than they actually later recall or higher-value words. But with task experience and feedback -- they are told about the score here -- they learn to selectively remember certain words and also higher-value words.

This seems to reflect a metacognitive component. As I mentioned, there might be a metacognitive failure early on, that older adults are somewhat overconfident at first. They see all of these words. This task is at a much slower presentation rate, and they all feel like they might be able to remember seven or eight of these words, and they will bet on these words. But then later they are only recalling three or four of these words. But with task experience and feedback, older adults seem to learn to bet on fewer words, but they will still bet on the high-value words. They know that they can remember fewer, but are confident in the fewer words that they will remember. This suggests some awareness about capacity or how much information can be remembered, and also the goals that are involved to get a high score, which can be achieved by

recalling many words or fewer words but the higher-value ones.

So those are some of the experimental tasks. There can also be potential applications of this value-directed remembering approach. As Ellen mentioned, older adults often take many different types of medication. There are adverse and unknown side effects that can lead to hospitalization. How can presentation format specifically help older adults to remember important side effects, as opposed to just all of the side effects?

Given some of the findings from the previous task, you can present all of the information and tell people these are all the side effects or you can incorporate ways that might include value that help people remember the important side effects. But, of course, it's difficult to conceptualize or define what important might mean. You could put them in order from most common to least common side effects, or include some sort of perceptually informative component, where some side effects might be in larger font and some in smaller font, or include all the information, even the prevalence rates, so you have this verbatim information if you want it, but that verbatim information is also encoded in a way that allows people to selectively remember the top ones.

These aren't suggestions. These are just ways we

have been thinking of setting up experiments to look at this.

There might also be some side effects that are not very common, but if they occur, they are quite important to remember. There might be a way to communicate that. We have been trying to do some experiments somewhat along these lines, but also more things -- if you are going on a trip and you pack 15 items, what are the first three items you want to remember? Can older adults selectively remember those first three items? If you forget items that might not be as important, like a toothbrush, you can still remember your wallet, your keys, your passport. This would also be an application of this value-directed remembering approach.

These results from value-directed remembering experiments do suggest that older adults remember less information -- that's not a new thing -- but that older adults can learn to remember high-value information under certain circumstances. This can lead to an efficient use of memory, both in younger adults and especially for older adults. There might be an important metacognitive component here.

I'll end with a quote: "It is a triumph of life that old people lose their memories of inessential things, though memory does not often fail with regards to things

that are of real interest to us. Cicero illustrated this with the stroke of a pen: No old man forgets where he has hidden his treasure."

Thank you. Any questions or comments?

DR. PETERS: Why don't we start with Kala?

DR. PAUL: Thank you, Alan. It made the cab ride with you worth it.

I have some questions concerning the presentation of data that you just showed, and understanding what we might want people to remember from the adverse experiences that we tell them. It's more than just decision making, which is another issue altogether. In your last three lists, you had an interesting display of the information for patients for the purpose of showing us. But it seemed to me that one of the most important things that you are going to talk about is the order in which things are presented, as well as the differences in the font size and the implied reason for that order.

I was curious, when you were looking at those experiments with older people, did the order in which the information was given to them -- the word list -- did the order of the words affect how well they remembered them, because they saw "apple" and "house" and "snow" first and then lost interest after that? You have those two things. It's a very direct thing. You have fever and rash, and

call your doctor -- those two very important things bolded at the bottom of the list. I'm wondering if you have looked at the effect of order.

DR. CASTEL: It's a great question. In a lot of memory research, people look at order effects, primacy and recency effects. People remember the first few items, the last few items. In the selectivity task, we try to get rid of those effects by using many lists with values sometimes occurring at the beginning, middle, or end of the list. But some patient populations will still only remember the first few items or the last few items, even if they are not important ones. It's almost like you need to overcome these effects to score highly in this task. It's a very important issue. People still typically remember the first few items and the last few items. If we put an important item in the middle, people almost have to overcome that. Instead of saying the last few words that they just saw, they need to recall a word from the middle. Sometimes people start to do that, but it's only with task experience, where they are really focusing on score, as opposed to just trying to recall as many words as they can.

DR. PAUL: That has tremendous implication for the formatting that we do when we look at presenting adverse experiences. We are doing more than just making decision-making information available. We are trying to

also give them information on when to contact their doctor and under what circumstances. So much of that gets buried in the formatting, because we do it in alphabetical order, say, or we do it in a different order that isn't productive.

This is a very, very useful information. Thank you.

DR. CASTEL: Great comments. Thanks.

DR. PETERS: Craig, Gavin, and we'll see if we can get further than that.

DR. ANDREWS: Thank you very much, Alan. I was intrigued by the brand-price studies. I recall in advertising and branding research that there has been a lot of criticism of brand recall or ad recall and even aided recall scores, where they moved more to recognition tests. I was just curious if some of those differences might have been attenuated or gone away with this sort of recognition. If you have multiple-choice items with both the brand-price information in that -- any consideration on that?

DR. CASTEL: It's a good question. We have done some work where we then later present all of the items and ask people to rank-order them. Maybe older adults just consider these prices overpriced, but maybe they can still remember that the cookies are more expensive than pickles.

DR. ANDREWS: Right, or maybe there are

inherently wrong ones that are listed multiple choice, but they can pick it out, pick out the brand-price combination.

DR. CASTEL: Yes. We haven't done exactly that study, but we have done it where we give everything at the end and they have to move things around to indicate which one might be more or less, kind of like Valerie's work on gist. They can still remember that, but there are also some predictable errors that people might make. If they can't remember, they might just rely on prior knowledge. If cookies were, in fact, less expensive than the pickles but in this experiment they weren't, sometimes older adults will rely on their prior experience.

DR. ANDREWS: In our area, in the medical applications, pill boxes and other cues and things like that might be very, very important.

DR. CASTEL: Yes.

DR. PETERS: Gavin.

DR. HUNTLEY-FENNER: I'm curious about the individual differences and what sorts of errors your subjects made when they misremembered price.

DR. CASTEL: We did collect some background measures on how frequently people went grocery shopping. Older adults would report going more frequently than younger adults. Not so much in the grocery price study, but we also had some accountants in one of the other

studies. We haven't done thorough individual differences, like Ellen's work has done with numeracy. But these accountants did very well at remembering there were 36 horses on the farm, whereas most older adults would not remember that information. That's somewhat surprising, because accountants can do well when it's in their domain of expertise, let's say, but this is -- these are materials that are in their domain of expertise, but in a very different domain.

So ability, past performance -- the grocery one is kind of getting away from that, because we were hoping everyone had a lot of experience evaluating these sorts of things.

DR. HUNTLEY-FENNER: Was there a relationship between the quantity that folks proposed and the actual quantity they were supposed to remember?

DR. CASTEL: Sorry?

DR. HUNTLEY-FENNER: For example, if you are supposed to remember that something was \$11.59, were you more likely to say \$12 than \$15?

DR. CASTEL: Yes. We did find that their scores -- actually, both the young and the old -- were off by about the same amount, which is kind of interesting and consistent with this reliance on gist. On the other hand, there were occasions -- and this is where it gets more

difficult to analyze -- where older adults were just misremembering the prices. They misremembered \$17 for the pickles when, in fact, it was the cookies that were \$17 -- kind of a binding error as opposed to a gist error. That would happen more frequently with the older adults than the younger adults. And that's interesting, because there are likely multiple mechanisms that might be impaired or compensating in older adults, whereas younger adults would still remember more of the gist.

DR. HUNTLEY-FENNER: I see. So the noisiness of the quantity memory was the same for the older and younger.

DR. CASTEL: Yes.

DR. HUNTLEY-FENNER: Interesting. Okay, thanks.

DR. PETERS: I think we are going to move on to our next speaker at this point. Thank you very much, Dr. Castel. I thought this was just terrific.

A couple of things I want to point out from this are the important notion that came out from Kala's question around something we have talked about a lot before, this idea that prioritizing information matters -- it matters in terms of memory in particular, as Alan pointed out -- and the notion also that maybe there are things that we can do -- and I think we'll talk about this a little bit further -- in order to help older adults and younger adults determine what is of value here. Ordering might be one way

of doing that. There may be other ways of doing that as well.

The other thing that I want to point out, because no one has brought it up yet, is the really interesting experiment where you had people go through multiple rounds, so they gained additional experience. With feedback at least, the older adults actually ended up being about as good as the younger adults at doing the task. I think something that we may want to think about is that in medicine people get a lot of experience. They may not get much feedback, though. Is there a way in medication adherence maybe or -- I can't think of another example -- is there a way where feedback can be provided on a more regular basis and take advantage of some of the results that Alan pointed out?

At this point, I would like to switch gears and have Dr. Zikmund-Fisher take the stand. Again, Brian, if you would, just do a brief introduction of yourself.

Agenda Item: To "Know" Your Risk: Some Thoughts on Goals in Risk Communication

DR. ZIKMUND-FISHER: Thank you very much for inviting me. I'm glad to have the opportunity to speak.

My name is Brian Zikmund-Fisher. I'm a decision psychologist and behavioral economist by training. I am a faculty member. My primary appointment is in the

Department of Health Behavior and Health Education in the School of Public Health at Michigan. I hold a secondary appointment in internal medicine as well.

I will talk some about data, but I actually want to make an argument today, and to make an argument that stems from my spending the last 10 years wrestling with challenges in how to communicate quantitative information to people in ways that make them understand what it means to them. I guess I would like to start by motivating this discussion with an example.

I would like you all to imagine Robert. Robert is a middle-aged man who is curious and concerned about his risk of having a heart attack in the future. So he goes to an online risk calculator. There are tons of them out there. He finds one that says "Calculate Your Heart Disease Risk Score." So he goes to it and he enters the standard stuff that you have to enter into these calculators -- his age, his weight, his cholesterol values, et cetera. Then the calculator comes back and says, your 10-year risk of having cardiovascular disease is 14.52 percent. So Robert goes home and he's talking with a friend of his over, let's say, a barbecue later that night and he tells them, "I've used this risk calculator, and it told me what my risk is. But I'm still confused. Am I high-risk or not?"

There are a couple of problems here. Is Robert informed about his cardiovascular disease risk? He may well have been given the best answer science has for what his risk is. For all we know, that calculator used the best available prognostic algorithms. He has that information. Yet somehow he is not satisfied. I think there are couple of reasons why.

First of all, that estimate of 14.52 percent has excess precision. I highly doubt that, answering the handful of questions, with all of the error that comes along with whatever memory he may have about what his cholesterol level is, what his actual weight is today, et cetera, it can estimate his risk to a 100th of a percent. In fact, Holly Witteman and I recently published a paper, with some coauthors, that made this argument: When you present risk estimates at high degrees of apparent precision, people actually have less trust in the resulting information. Using integers not only increases comprehension, but engenders greater trust in the results.

But I want to talk today about the other major problem here, which is, I think, that there are some fundamental unmet information needs. Robert wants this: He wants to know that he is a person who has a high risk or a low risk of this happening. But this is just one of the kinds of knowing that we might want somebody to do. If you

look at this table, you could have a whole range of different kinds of concepts of knowing my risk. I can know that something could happen to me. This is very similar to what Valerie Reyna has talked about and what others here have talked about . I could know that something could happen to me or I could have a much more complicated sense of, my risk change this much if I do something.

What I would like to do is propose a taxonomy, a language, of talking about different types of risk concepts, ranging at the top from, in some sense, the most simple and basic concepts of possibility -- something might happen, it might not. That only distinguishes the circumstance from certainty, situations in which it definitely will happen versus it definitely will not happen. Moving down, you get into relative possibility, to know that something has a higher chance of happening as opposed to lower or equal. I may not know the magnitude, but I know that gist, that it is higher. In the middle here we have some of the standard probability representations -- relative probability, absolute probability. Down toward the bottom we add in the context, which is often so important -- being able to compare 12 percent versus 8 percent or know the incremental difference between two probabilities.

Notice that this also has an effect on the

feelings, the emotional responses we may have. Even when we are translating this into this is a risk of a negative event occurring -- and so we know that if it occurs, this will be bad -- possibility just says, I am at risk. Relative possibility says, I am at worse risk, worse than whatever I am less than. More complicated representations quantify that in a more precise way. But the question becomes, is that quantification actually necessary, useful for decision making?

I want to make the following point: Just because we have data doesn't necessarily make it meaningful data. Most risk data that we have is generated through some systematic processes that give us probability or relative probability forms. When we run epidemiological studies, we count how many events occur within a population. We get rates of occurrence. When we do clinical trials, we get odds ratios or absolute probabilities, the percentage of patients in the control arm or in the experimental arm who had a particular experience, experienced a particular event, achieved a particular level of therapeutic effectiveness, whatever.

But there's something called "the curse of knowledge." Just because it's meaningful to us as scientists, as practitioners, does not mean that we are good judges of what will be meaningful to the end

recipients. That means, to me, that the original format in which the data is being received is not always going to be the best format for it to be presented.

The concept here is an idea that has been talked about -- Christopher Hsee brought this up in the 1990s, and I published a little bit on it a few years ago -- the idea of information evaluability. The idea here is that the meaning of a number is dependent upon whether you evaluate it by itself or you evaluate it in comparison with other statistics. The point I want to make here is that evaluability is very important when we're talking about probability statements. It's not important or not as affecting the degree to which somebody can draw meaning from it when we're talking about possibility statements, because possibility statements are inherently evaluable. I don't need more information than just what the possibility statements says in order to grasp its inherent meaning for my decision making.

So when we look at the range of risk concepts that I introduced earlier, what you can see is that evaluability is particularly high at the ends of the spectrum. Simple statements, like this could happen to you, are inherently evaluable. Relative possibility, even though it's vague in its level of precision, is inherently evaluable to somebody. I know that I am at higher risk

instantly. I may not know the magnitude of it, but I know, and that gist is explicit. I don't need more information in order to process that and remember it.

At the other end of the perspective, when we need detail -- and I'll talk more about needs in a moment -- comparative statements allow us to draw more meaning from numerical data.

But notice in the middle that absolute probability statement. The information that Robert got back is low evaluability. He needed more information in order for that to be meaningful to him, and he didn't get it.

So Robert could have known his risk better if we had done a couple of different things. One is, we could have provided other numbers for context to help him understand how his risk relates to other standards, whether that be the average, whether that be some threshold of concern, et cetera. But, of course, the meaning -- and this has been discussed before in this meeting -- that he might take away from that would change, depending upon which numbers were provided to him. We would need to think hard about which numbers would provide the kind of context that would allow him to draw the meaning that he needs for his decision making. Or we could have given his risk that category label. We could have told him, you are at high

risk. The problem there, of course, is that I would expect that he would not remember the number. Whether that's a good thing or a bad thing depends upon whether he needs that number for other purposes.

To put this into context, I would like for you to imagine another person. I would like for you to imagine Sarah. Sarah is a middle-aged woman who just, after she went and got her mammogram done, was diagnosed with stage I breast cancer. She decides to go forward and has a lumpectomy, has this cancer removed through surgery. But now she faces a more complicated decision. She faces a decision between multiple different possible adjuvant therapies, therapies that are designed to reduce the risk of that cancer coming back in the future. Her question is, what should she do in order to minimize her risk of recurrence? What are the burdens that she is going to face through those different therapies? She can take chemotherapy. She can take hormonal therapy. She can take both. She can take neither. How does she make that choice?

She goes to her clinician, and the clinician uses some of the available tools to assess the risk of recurrence. Then she says to her, "Congratulations. You, in fact, have a very low chance of recurrence."

My question again is, what's happening here?

Sarah goes home. She talks with her husband. She says, "They tested my tumor to see if it was likely to come back, and they told me I have a low risk. That's great. But I'm still confused. Just how low is low? And won't these therapies help me to some degree? Do I want to try it anyway?"

The fact that she has been told it's a low risk hasn't actually answered the question that she is trying to face.

Again, is Sarah informed about her cancer risk? She got exactly what Robert wanted. She got that evaluative label that clarified that she was at low risk. But for her needs, that wasn't enough. Sarah's needs -- she has to be able to figure out how low is low enough for chemotherapy not to be worth it for her. This is a risk-to-values question, connecting not just the quantity, but the implications for her. She doesn't just need precise risk information, she needs precise incremental risk-reduction information. Yet she needs it presented simply enough that she can make sense of it.

This is a problem that I have wrestled with a lot in the last few years. I'll just give you some data examples from a couple of studies.

One way in which this information is available to clinicians right now is through a tool called Adjuvant

Online. This is a screen shot of it. This allows a clinician to input different patient characteristics -- tumor size, age, whether it has spread to lymph nodes -- and get back a visual display of the chance of recurrence, mortality risks, with no additional therapy, with chemotherapy, hormonal therapy, or both.

What's good here? I think there are a number of good things here. First of all, we have personalized risk estimates. This is a tool designed to take the conversation out from what happened to the average person in this clinical trial down to the level of what's going to happen to this woman, of her age, with a tumor of this size and these characteristics. That has important psychological meanings, not just predictive meanings.

Second, we have visual displays. I'm a longstanding fan of visual displays as a way of helping people to represent the part-whole relationships inherent in a risk statistic.

Third, I give tools like this credit for highlighting the incremental effect of treatment. If you go back here, that yellow part there is marking -- and they even say here -- the benefit, 4.7 alive with hormonal therapy.

My question was, however, can we do better? I and my colleagues at Michigan and many other research

groups around the world have recently done a number of studies that have examined icon arrays as a method of representing risk. You could take that kind of output and reframe it -- without changing the words, without changing the numbers -- in a format like this.

The advantage of this type of format is that when you look at those yellow squares, your eye is immediately drawn to them. You can count how many of them are there. You can look under that hormonal therapy column and see nine more women are alive are due to therapy. You can go and count there, seven there, two down below. That's the nine. Those are the nine people who would benefit from therapy. The rest of them would not.

Of course, Dr. Peters and others have commented on the fact that sometimes less is more, that including less information can help choice and comprehension of the critical information. I would like to give you an example of this where it really did matter how we presented the information for those who were lower in numeracy skills.

Meaning in practice -- and this is where I work. I really work in trying to translate the lessons from decision psychology into practical applications for public health communication and for medical risk communication. What I think this means for practice is that we need to start removing redundant information.

Instead of having all those colors that I have to look at and try to compare to, why can't we just represent the same information with the minimal amount of it.

Mortality is just the inverse of survival. So we tested whether a simplified graphical representation like this would make a difference versus one that had all of those different colors and all of those different outcomes. The answer is, yes, it does. People's understanding is better. People's ability to make decisions is better.

But in addition -- and this is what I really want to focus on -- I think there's an argument to be made for what I will call one-at-a-time decisions and one-at-a-time presentations of information rather than all at once. In the adjuvant therapy decision that I'm talking about here, there are four options to be considered: no additional therapy, hormonal therapy, chemotherapy, and the combination. And that's probably a simplification of the true clinical problem here.

You can get all of this information at once. But what about an alternate approach that recognizes that the fact that the first choice that most people face is the choice of the treatment that has the highest potential return with the lowest potential cost. In the context of, for example, a patient with an estrogen receptor-positive tumor, one that will be sensitive to hormonal therapy,

hormonal therapy fits that definition.

Thus, what if we simply start by giving that binary choice? Same representation, same visual, but here's your binary choice: Do you want nothing or do you want hormonal therapy?

Once that person has processed that information, thought about how much benefit they would get, how valuable it would be, and how much potential burden or other risks they would run by taking hormonal therapy, we can then take the incremental decision of saying, okay, now let's recast what the baseline is here. We have converted these yellow squares that were over on the first decision into green squares, women that are going to be alive with hormonal therapy as the baseline, and incrementally highlighted the effect of chemotherapy on top of hormonal therapy. So the incremental effect of each treatment is separately processed.

Does this make a difference? In a paper that I published recently, we presented this type of information to women who were both higher-numerate and less-numerate. I'll show you the results separately.

The higher-numerate women you see here. As part of the study, we varied how much benefit chemotherapy would offer on top of hormonal therapy. It either offered a 1 percent benefit or a 5 percent benefit. The higher-

numerate participants in our study were sensitive to this manipulation, regardless of which way we presented it, whether we gave it to them all at once or whether we gave it to them one at a time. There was a main effect in terms of reducing intention to take chemotherapy when we presented it one at a time. I think that's because that sequential presentation clarified for people that they got the majority of benefit from the first step, from the hormonal therapy piece of that combination. So they were less interested in adding it on top of hormonal therapy because they recognized that it was going to have a smaller incremental benefit. But at least they are sensitive in both cases.

However, when we look at the less numerate participants, what we see is this. When all of the information was presented at once, less numerate women were completely insensitive to the magnitude of benefit that they could have gotten from chemotherapy. They were just as likely to choose chemotherapy when it offered a 5 percent benefit versus when it offered a 1 percent benefit.

That, to me, is a marker of a failure of risk communication. This isn't just about knowledge, although there are plenty of results about knowledge as well. It's a failure to understand the gist, the fact that the magnitude of benefit here really is a critical element to

the decision making. They were insensitive to changes in that.

Simply by taking this same information and breaking it into two binary pieces of information, two binary choices, we enabled even the less numerate women in our participant pool to become sensitive to that difference. They weren't quite as sensitive as the highly numerate women were. That's understandable. But they were sensitive to it, and thus they were able to make decisions that responded to the information that we presented them.

Returning to our two illustrative patients, how can we help Robert and Sarah -- and all other patients -- know their risks better when what knowing means is different in different context? The argument I want to make here is that patients fundamentally have different informational needs in different situations. Sometimes what patients need are, in fact, simpler concepts, and sometimes we need detail. If we want to be effective, perhaps we need to not just think about how we give people information and hope that they can get the gist, but maybe just start from the gist at the beginning, to start with presenting them information in formats that are most congruent to their needs in that particular situation.

I would like to go through a few different types of needs that patients have. Sometimes patients have needs

to avoid surprise or regret. They need to know that something might happen to them, because if they get there and they have never imagined that possibility, they are going to be surprised, they are going to be upset, and they are going to regret having made a choice that took them somewhere they never wanted to be able to go.

My point here is that simple possibility statements accomplish that goal without any numbers. If I know that this might happen to me, I have accomplished that goal. My need has been met. Now, sometimes I need more than that. But if that's all I need to know -- let's say we're talking about a rare but catastrophic complication of a particular procedure or a device -- as long as I know that this is a really bad thing and it might happen, that might be all I need to make my decision.

Sometimes patients need to recognize dominant options. Think of an example in which a patient is choosing between different medications to treat their arthritis. They are going to take something. This is a given. What they really want to know is, of this set of choices, which one has the lowest risk of, let's say, the side effect that they care most about? That's simply a relative possibility. If they can identify which complication they care most about and identify which one has that lowest risk, then relative possibility statements

are sufficient for meeting their need.

Sometimes patients want motivation. They want to know when they need to act. They want to know when they don't need to act. That's what Robert wanted. He wanted to know whether he needed to act. Categorical labels, evaluative labels are well tailored for that need. Even though patients may forget the particular numbers, if they take away that gist, or even if we don't give them those numbers up front from the start, that need is being met.

Sometimes patients need to make multi-attribute tradeoff decisions. An example that pops to my mind is prostate cancer treatment decisions, where the different treatment options have very, very different experiences. Different types of risks are experienced in one pathway versus another. These are situations in which you definitely need comparative information. Whether you need the precision of a numerical probability estimate is going to depend upon the context. Sometimes yes and sometimes no. But you definitely need that kind of comparative structure.

Sometimes, like Sarah, patients need to make magnitude-dependent decisions. They care that the risk is this, X percent, not Y percent. In those kinds of contexts, precise comparative or incremental probabilities are just going to be necessary.

The broader point here is that sometimes what we care about is detail, but sometimes what we simply want to do is relate behaviors or actions to risk, to know that something connects to risk. The broader point here is that I don't always feel that data is necessary for that. If we know that the relationship is the most important thing we want the patient to walk away with, then perhaps we should be willing to consider focusing our initial communication effort on that gist meaning and allow the precision to be perhaps put in a secondary position -- something that somebody who wants it can go find, but somebody who does not want it, does not need it, does not have to be distracted by it in order to find what they need in order to make their decision.

If our task as communicators isn't just to provide information, our task really is to identify needs and really wrestle with what specific understanding is needed in different contexts and by different patients, and then to move forward tailoring the information formats that we use to be congruent with those concrete informational goals. Ideally, what we want to be doing is not just giving people information, but giving them the right tools that they need to make the right choice at the right time.

Ultimately -- and I love this comic as a way of sort of wrapping this up -- ultimately this is not about

what curve looks like. It's not about what the numbers look like. Probability is fun. I'm a geek. I understand that probability can be fun. But when you get to be patient -- and I have been the patient who sat on the table and tried to wrestle with what those numbers mean for what my life will be moving forward -- that ultimately is the thing we ought to care most about, and hence, perhaps we ought to focus on first when considering what data we need to be presenting to people.

Here are some references. I'd be happy to take some questions.

DR. PETERS: Kala and then Nan.

DR. PAUL: Thank you for that presentation. I have been struggling with some presentations of even just icons for telling patients how to take medication. Icons are really tricky. Graphic representations can be tricky.

I was curious about, not so much the all-in-one versus the one-at-a-time, but the effect of including in those patients whose response to chemotherapy couldn't be evaluated because they die of other causes. You have three categories for the patients. I'm wondering, regardless of the scientific validity of your 100 set, is it necessary to present all that information to get a good gist? Are you skewing the data? Would patients respond differently if said, of patients who either lived or died with cancer,

this is what happened to that data, as opposed to adding in those who were in the cohort, but didn't make it because they got hit by a car or had a heart attack?

DR. ZIKMUND-FISHER: I hate to sound like a broke record, to use an old metaphor, but I think the answer to that question does depend upon the decision you are asking the patient to be making. If the context in which somebody is making that choice really fundamentally depends upon the incremental survival that will be achieved by undertaking a particular intervention or not, whether their pathway through life is going to be different -- whether they are going to potentially die from other causes or die from their cancer or live, regardless of what treatment they do, those other outcomes are not necessarily informative to the assessment of the magnitude of benefit of that particular choice.

At the same time, there are plenty of other circumstances in which understanding the magnitude of the benefit achievable through an intervention or, let's say, through a screening test is put in better context by comparing it against the risk of mortality from other causes. I think of, for example, the context of cancer screening in older adults, in which their lifespan and the other causes of mortality are really a critical contextual piece of information in evaluating the potential value of a

cancer screening test. In that kind of a context, where we need them to be putting this magnitude of benefit in context against the overall mortality risks they run, let's say, as an 85-year-old man, that data might be more important.

So I think we have to be willing to say no one representation is going to be the right representation for all situations, but be willing to take information out when it will be distracting and put it back in when it's necessary to provide that kind of confidence.

DR. PAUL: Thank you. It just seemed to me that in this particular case it was a distraction to have those patients in there, and that unnecessarily complicated the choice. But it does skew it, actually, toward making it look better for the chemotherapy or the treatment, because you are taking out those eight or 10 patients and then increasing your number.

Thank you.

DR. PETERS: Nan and then Moshe.

DR. COL: That was possibly the clearest presentation I have ever seen on this topic. Thank you.

My question also ties into the previous speaker, about that excellent table about need-congruent types of risk knowledge, about regression to the existing gist. It ties in, in some of the areas where the difference in

performance of older people -- and I was thinking, possibly, when older people think about the price of a jar of pickles, they may be thinking about when they first discovered the price and it was a nickel, say, whereas a younger person -- their gist memory for things -- your gist memory for what a stamp costs, postage, is the first time you actually had to buy a stamp. So you sort of have your regression to the gist, but you often see older people always going back to the days when coffee cost a nickel or this. And I'm wondering -- and the relevance here is, in your need-congruent types of risk knowledge, often what happens -- I think maybe there's another line here that says, combat existing gist, if that gist is incorrect. You mentioned prostate cancer. One of the incorrect gists is that cancer has to be taken out. The assumption is that cancer is always deadly and it has to be taken out. How you do that -- and also screening is always good. Screening is not always good. That's a new concept.

But I think if -- and I'm not sure how you would combat previous gists about -- you gave examples that it can be done. But maybe there is a way -- if there are beliefs that are fundamental and that are really gist-based beliefs, which I think we often encounter, we may want to include that as the kind of information we want to present to combat. I don't know how you might do that.

DR. ZIKMUND-FISHER: I think what you are highlighting is really part of the process I'm describing in terms of a needs assessment. Let's take the context of cancer treatment. We have to take the cancer out. Just how much benefit is that going to achieve? Highlighting that difference may be part of the standard we're trying to compare it against.

One of the things that you saw in the data I presented was that even among the higher-numerate subjects, when we went to this one-at-a-time presentation, they were less interested in chemotherapy. I think the reason for that was that natural assumption that I need to do everything -- my gist walking in is that I need to do everything to fight this cancer. By highlighting just how small that incremental benefit of chemotherapy was, once you had already undertaken hormonal therapy, that combated that assumption that I have to do everything. Well, there aren't that many squares being filled in there. That's not actually that much benefit. Maybe I don't have to do this. That doesn't mean that it's a wrong choice for any one particular woman, because it might be for them. But across that population we see that reduction, because it's highlighting in a way that counteracts their expectations.

DR. COL: Yes, I appreciate that. But some of these gists may be based on fear, irrational kind of

things. If, in fact, the notion that cancer is bad, evil, and it has to come out, I'm wondering -- and if that's based upon a more fundamental emotional, affective reaction to things, I wonder if giving knowledge, facts, will be adequate, or maybe this is a time to try to draw upon other ways of re-detonating the term "cancer," working directly at that affective component, which seems to be triggered.

DR. ZIKMUND-FISHER: I could go on about this at length, but let me highlight one particular example that leaps to my mind. You will notice that at the end of that needs table, I put the idea that sometimes all we need to do is to explain conceptual relationships. If you think about the context of cancer screening, I think one of the fundamental misconceptions about cancer screening is that cancer screening necessarily prevents cancer. If you recognize that conceptual misunderstanding, sometimes maybe what we need to be doing is reshaping people's understanding of what cancer screening is, what it's doing, and by reshaping that at the mental model level, shape what their expectations are that they bring to that conversation.

Once you change the idea that cancer screening has potential risks associated with it and isn't necessarily going to prevent everything, now you can start to have a tradeoff conversation and we can potentially

bring to bear some of the kinds of data that we have that will be informative.

Without that conceptual-level readjustment, you could present them with that data, and it will not stick because it doesn't agree with their fundamental mental model and they don't know what to do with it.

DR. PETERS: I think these points about the need for assessing patient needs and then how to combat previous gists are really interesting and important. Whether combating that previous gist might take a change in a mental model or whether even some of these formats might, in fact, combat a previous gist I think is a very interesting empirical question also.

DR. ZIKMUND-FISHER: Absolutely.

DR. PETERS: At this point why don't we take one more question, from Moshe? After that, we will be taking a break.

DR. ENGELBERG: First, I want to say thank you for highlighting what I would consider a patient-centric approach that really begins with understanding the specific information needs a patient has and then providing congruent information. Related to that, I wonder if you have in mind a simple tool that a provider could use, or maybe a patient or a consumer could use, to figure out what kind of information they need.

DR. ZIKMUND-FISHER: You don't ask for much, do you? My short answer is, the first and most important step is the one that we don't do often enough, which is to simply ask the question, why am I here? Why am I trying to get information? What is the question that I'm trying to answer? If we had asked Robert that question -- if his clinician had asked, what do you want to know? -- and really explored that with him, he would have said, I want to know if I'm high-risk or not. Then we could have known, okay, that's the level of information he needs to know.

Similarly, in my story about Sarah, Sarah says, how low is low? That's a cue right there to tell me that just saying a category isn't going to be enough. I'm going to need to be more precise. I'm going to need to get into precise magnitudes and have that values-concordant conversation with her.

I wish I could say that there is a simple tool to say I'll know instantly in two minutes what this patient wants in this particular situation. I think it's a larger conversation and an empirical conversation, one that's going to require input from clinicians about what level of information is necessary for efficient self-management, for efficient decision making about a particular problem. It's going to require input from patients about what level they can process information at under different circumstances.

It's going to require input from us, as practitioners of risk communication, to try to find, as was described earlier, the sweet spot that balances those needs in the best way possible.

My takeaway message is simply that it's going to be complicated. I think that's the right takeaway message. I don't want us to think that there is a simple answer here. I think that will lead us astray.

DR. PETERS: Brian, thank you very much for joining us today and for presenting this really interesting patient-centered approach.

What we're going to do at this point is take a 15-minute break. If people on the committee and also in the public audience could take a look at the questions, we'll probably start with some more clarifying questions for speakers, if any remain. I know I had a couple of people, like Vicki and Kala, left over from the very first talk. You might want to think about whether you still have those clarifying questions.

Exactly when we return, though, we're actually going to have an open public hearing. There aren't currently any speakers on that agenda. If by chance you would like to be a speaker in that open hearing, please talk to Lee during the break.

Thank you very much.

(Brief recess)

DR. PETERS: I would like to welcome everybody back to the meeting.

We officially have an open public hearing at this point. We don't happen to have any public hearing speakers who have signed up today. So I would like to officially open and officially close the open public hearing all at the same time. You have to do it officially. Lee is really good at keeping me on task and making sure I'm following the rules.

What we are going to do now is go ahead and continue our discussion from this morning. We had a few people who wanted to ask questions earlier who didn't have a chance. So I'm going to go ahead and prioritize them now. But we'll also go ahead and start taking names from additional people.

Who I'm going to start with at this point are Vicki, Kala, Moshe, and then Noel. Then we can go on from there.

Agenda Item: Committee Discussion, Session III

DR. FREIMUTH: Thanks. I wanted to come back to the values issue, first to just make sure I completely understood. It has been referred to in a couple of different presentations, but let me direct the first question to Valerie.

I guess the first question is, whose values? It seemed to me that in your presentation you were talking about the individual consumer's values and tapping into those and sort of retrieving those. But I think later in some of the presentations we were talking about value in a different way, which is some external assessment of the importance of the information. I think that's a really important difference to keep in mind.

But, Valerie, on your issue, I was having more trouble understanding -- if you could give an example of the way you would help someone in a message retrieve their own values. You have made the point that they often don't do that. Can you give an example of how you might do that?

DR. REYNA: Yes. And thank you for putting your finger on a major source of ambiguity. You are absolutely right. Especially in decision making, people use the word "value" in very different ways. I meant exactly what you gleaned from what I was saying -- namely, individual values.

I think people have values stored in long-term memory in a very simple form -- like, life is better than death, and health is better than illness. We say sometimes that people don't know what they value, but actually they do. They really don't want to be dead and they don't want to be disabled and they don't want to suffer pain. They

are really clear about that. Again, we laugh, but in my field we talk about construction of preferences. What I just said is not the dominant view. I agree.

Values are things like that. I mentioned things like cognitive disability, that people don't want to necessarily be cognitively impaired. There's a famous story by a very famous person in decision making, Ward Edwards. He has a textbook that he wrote on behavioral decision making that's sort of the bible. In it he talks about decision trees and deciding on the one hand/on the other hand, and a friend of his who had to go in for surgery, a real case. In the end, the real consequence that mattered to his friend was this cognitive disability. He didn't realize that this particular surgery had a major risk of, not killing him, but putting him in a vegetative state. If he had realized it, that would have changed his decision tree in a very profound way. So rather than tweak a little branch here and add a few more dots there, that would have just been a determining factor for this particular individual.

I think people have these kinds of values that they don't necessarily retrieve. This all actually, in real life, works together. Your construal of your options makes you think of certain values. If you see your options as being about cognitive disability or being a choice

between inevitable, major disability versus taking a risk on a very small probability of brain cancer -- I'm thinking about the arthritis drugs -- if you realize that, then that cues certain values. How do I feel about the possibility of physical disability, not using my hands? What would that be like? So that reminds you, what do I value in life? What am I getting satisfaction from? What are the things that really matter? That causes you to remember those things and cue those values and connect them up to the choices in a meaningful way.

DR. FREIMUTH: Just to follow up for one minute, what you are saying is that by presenting options, you are not doing anything in the message to explicitly cue values, but by presenting options to people, it's sort of an automatic process that happens. That was what was confusing me.

DR. REYNA: It's not that the options necessarily cue the values. That's like a separate operation. They often do. Once you see what things boil down to, it reminds you of what's important. But sometimes that's not sufficient. You have to actually remind people: What is it that matters to you? In the end, it's really my family. What is it that matters? It's my painting. What are the core things that matter to you? Sometimes they have to be reminded. I think having a list with cues sometimes can be

very helpful in clarifying the retrieval process for people.

DR. FREIMUTH: And could you see doing that in a print ad? Is this something that has to be done on an interpersonal level or could you see doing it in a mass media format?

DR. REYNA: I can definitely see doing it in mass media format, with the caveat that the perfect is the enemy of the good. In other words, there are many common values that we know -- an experienced patient, an insightful clinician who has seen this before will now in the end, like end-of-life decisions. There are a couple of things that people tend to miss that a lot of people value. Those kinds of things could be put in a very succinct way, I think, reminders.

DR. PETERS: I wonder if I could ask one quick follow-up on that, Valerie. In your opinion, if it's more difficult to obtain the gist meaning -- and I guess this could be either of the likelihoods or of the outcomes -- is it less likely that people will retrieve those values or less likely that they will apply them to a decision?

DR. REYNA: Yes, and I think there's a lot of research showing that. If you fail on the initial couple of steps, the background knowledge to understand your options and then whether you get the gist of the options --

if you don't get the gist of the options, you may entirely miss the relevance of certain key values to those choices. Again, if you don't know what your choices boil down to, it's sort of difficult to then retrieve what would be the relevant values.

DR. PETERS: Kala.

DR. PAUL: This is a question both for Alan and for Valerie. It has to do with how you present information, gist, and not so much decision making. Valerie, you were talking a lot about decision making when you were looking at, actually, a parameter that we don't present in patient information when we write it for FDA-regulated documents, like the patient package inserts and the med guides, which is, what is the risk for X, Y, Z bad outcome -- pancreatitis, hepatorenal failure -- versus the risk of not treating the disease? We do not present that data.

One of the things that we have to present, though, is, if you are going to get pancreatitis or hepatorenal failure, how are you going to recognize it? Then we list a bucket-load of symptoms that you should tell your doctor about, in sometimes a complex, sometimes a simple manner.

The other thing that we have is, oftentimes there are three or four very serious adverse experiences that we

are telling people about, and then we list either the individual symptoms or doctor-notification terms under the individual adverse experience or we have the option to list them all at the end as, call your doctor for any of these, regardless of what bad, adverse experience they relate to.

Just in terms of your gist and your outcomes and the effectiveness of the information, how would you see this warning being most effective? If we related the individual warning signs that you call your doctor for to the individual bad outcomes -- call your doctor if you turn yellow, if you have rash -- or if you put that in a list, say, for the three adverse experiences, to call your doctor for this -- rash, turn yellow, you can't pee, you can't breathe -- which may have nothing to do with any individual one, the one that they are listed under, but you have grouped them so the patients get that gestalt, when they should call their doctor? Is that where we should be going rather than, call your doctor for this, which means you might be having that problem?

Am I making myself clear?

DR. REYNA: I think so. I think, yes, it is a good idea to organize these things in a meaningful organization. We talked about level of adversity, grouping them that way. But what you are getting at is a more causal way. There are a couple of signs that patients can

look for in particular that signal certain things. If we give them at least some idea of what it is they are signaling, like certain kinds of things indicate postoperative infection -- so you want to look at this, this, and this, for that reason, and that's really bad and this is why it's really bad and this is why you have to call your doctor. Any explanation like that that gives at least a simple causal narrative will be better comprehended and better retained, and more likely, therefore, to be acted on. Again, we have lots of research from the psycholinguistic literature to support that.

DR. PAUL: Just to recap that, Val, what you are saying is that if I have three serious adverse experiences and there are two or three symptom warning signs for each one of them, I had better be putting the symptom warning signs under the individual adverse experience, so that I can put it in context.

DR. REYNA: Yes. Organizing and chunking the list in an explanatory manner is exactly what will improve retention. There's an old paper, "Seven Plus or Minus Two," that people always refer to. This is George Miller's paper. We have seven plus or minus two chunks of information that we can retain in working memory. But what people fail to remember about that paper is that the seven could be seven words, seven sentences. So depending on how

you chunk and organize information, you increase the capacity of memory, and you do so because you organize the list, so that when people recall things, they recall them in categories. If you group these things in these meaningful categories, then they make more sense and then the patient knows what they are supposed to be doing.

DR. PETERS: Alan.

DR. CASTEL: I think that completely makes sense. Maybe I'll just add that for older adults, it would be especially helpful to group them such that they can understand the causal relationship, if they, in fact, read all of them. It will help them later remember it, too. Oftentimes you need to know this information, but it's hours later that you experience this. For older adults, keeping this information in long-term memory is going to be challenging, but crucial. That sort of organization would probably help considerably.

DR. PAUL: Thank you. That's really helpful. I have seen it both ways. The long list sometimes looks like it's easier. You don't have to repeat things. But what you are saying actually makes it more cognitively available and likely to be remembered.

DR. PETERS: Moshe, Noel, and then Val.

DR. ENGELBERG: I keep thinking of application. Val, this is a question for you. Two things you said --

well, you said a lot of things -- of the two that I'm referring to, one is that we can't think for other people, and second, there are a limited number of gists for any given situation, and it's smaller than we might think.

DR. REYNA: The top ones are smaller. There's always that infinite possibility for individual people. But, yes, for most people most of the time.

DR. ENGELBERG: Okay. Then my application question is this. I'm thinking of the relative value of giving people predigested gists, where they are not thinking, we are prescribing, versus giving them information by which to develop their own.

DR. REYNA: I love this committee. That is a really good question. That's why I put that up there. I'm struggling with exactly that. I can tell you, based again on the literature, what we know. If the predigested information gives you an insight, if it gives you a bit of an "oh, I get it," so you can connect it to something familiar -- when I tried that gist out on you, here are arthritis medications. It's likely that you are going to have a major disability or you take a chance on a very bad but very unlikely possibility, one that will probably never happen to you, but if it does, it's really bad. If that helps you go, "oh," I think it's because people with experience, adults -- now, remember, I study children, too.

That's a wonderful sort of control group. They don't have that life experience. They don't go "oh." But we kind of go "oh," because we can draw on things that have happened to us like that, and we go "ah." If you have that "ah," then, yes, you can predigest that gist, and then when people want more details, they can click and that sort of thing. That would be effective, if you can tap into people's experience, either metaphorically or by analogy or by catching something that they can get, they can recognize.

However, obviously, in medicine you sometimes have that mapping problem, where there isn't the background knowledge. So predigesting something may not make sense. You really have to think, can I tap into prior knowledge or prior insight?

DR. PETERS: We have done some research on this also, where we provided some sort of predigested information, in a sense. It was in a different context. We were dealing with a context that people are relatively unfamiliar with, looking at quality-of-care ratings among hospitals and quality-of-care ratings among health insurance plans. What we did was, we were looking at the effects of providing some predigested labels of how good or bad a numeric quality-of-care indicator was. What we were interested in was, does it have an effect on judgment, in

the sense that people can digest more information, they can take into account more information across multiple quality-of-care indicators? That was one of the questions.

Another question was, does it actually influence choice?

In the choice situations, there is not a right answer. There are tradeoffs between things. In the judgment situation, there was sort of a normative best answer. You want people to digest more information. In particular, we chose information that experts believed *a priori* was important. We worked with experts to develop the data.

What we found was that in this kind of unfamiliar context -- because people really don't know how to use these quality-of-care indicators -- it made a difference. It did help people to digest more information. It particularly helped the less numerate people, in a couple of ways. It did influence choice. I can't say if that's good or bad, but it did influence choice. What it seemed to influence was the accessibility of affective feelings. People accessed their feelings about, in this case, health plans faster in the presence of those predigested labels, whether it's good or bad, compared to the absence of those labels.

It actually didn't affect their memory. It

didn't affect their verbatim memory for the information. People had similar verbatim memory for the information whether the labels were there or not. They also actually had similar gist memory. They remembered the direction of the effect, whether one health insurance plan was better or worse. They remembered that direction just as well.

So the presence of the labels didn't seem to influence how deeply they processed the numeric information, but it did influence judgment and it did influence choice.

That may be one of those situations where people weren't familiar enough with the situation to be able to have any idea of how good or bad this survival rating is, and so it produced an, oh, okay, this is a good one and that's a bad one. I think it probably still fits within the context, although it didn't bring a particular experience to bear, I don't think.

DR. REYNA: I like that study. The difficulty, though, with deciding whether a number is low or high is because the number is not low or high. It really does depend on the context, just like a word depends on the context. This is the same problem, by the way, that people in intelligence have. They are getting all this conversation on the phone and they are trying to figure out if there's a threat in there somewhere. You have to have

the context. You can't just take the sentences out of context.

That's one of the rate-limiting steps here. When we say, for one person, a 1 percent cystic fibrosis risk is high, and for another person, a 12 percent cystic fibrosis -- they glean that as high. That gleaning process, whether you can generalize and the degree to which you can generalize, is one of the issues.

DR. ENGELBERG: A quick follow-up. A takeaway, in my mind -- and I don't know if I would call this a fuzzy trace or a gist or whatever, and I'll articulate it as best I can -- is that rather than exclusively focus on the stuff of the information, the manifest content -- should it be a number, should it be words, should it be relative, all that stuff -- while that's important, it seems to me from all three talks and from what you just said as well, Ellen, that maybe a bigger purpose is to trigger people to use a certain part of their brain and certain cognitive mechanisms to -- I don't have a better word than "trigger." I'm trying to distinguish between the manifest content that has numbers and words, and the cognitive response that triggers it, maybe independent of the specific information, but it gets people to think of their values and value concordance, to do the stuff that we have been talking about.

I wish I could articulate it better, but it's fuzzy.

DR. REYNA: Let's try together. I agree. I think that was one of my points. The surface form, the words or the numbers -- numbers do provide a sense of precision so that you can glean your own gist from that. If you tell what the numbers are, I can decide for myself if that's high or low. I think you are talking about triggering a mental representation in your mind based on what's on the page -- that's what matters; the effective stimulus is what's in your mind -- and then also retrieving from long-term memory your values, your other experiences, and applying them to the representation of what's in front of you. Those have to coordinate.

DR. ENGELBERG: Yes, and I was referring to triggering the application so people will retrieve those other pieces and apply them to their gist.

DR. PETERS: The other thing I would add -- and this is really more from Brian's talk -- is that what the needed gist is may be different. So understanding ahead of time what the goal of the communication is, based on patient needs, is a critical piece of this, as I think Brian pointed out quite nicely.

Why don't we move forward and have Noel and then back to Val again?

DR. BREWER: Alan, I have questions for you. My first question is sort of a big-picture question. At first, I decided that I was okay generalizing your stuff, from your purchase price stuff to medications and, say, vaccines. But then I thought, really? Is it generalizable? I'm just curious to have you speak to that. You gave an example, but maybe just get into it a little bit more, why you believe that would be generalizable.

The reason I say this is, as a person trained in psychology, I think a psychologist would just sort of nod their head and say yes, but in the public health world, we live in a world where there's a difference research in communicating breast cancer incidence risk as opposed to recurrence risk. Those are completely different fields. You would never generalize from one to the other.

Help us know why we would generalize.

DR. CASTEL: Sure, I would be cautious, too, generalizing. I tried to just present it and let you generalize it, if you think it's valid. My speculation would be that there may be ways that, if you have prior knowledge or background knowledge, you can remember incoming information, but that background knowledge could change. As someone pointed out, for an older adult, they might have even more interfering background knowledge, if they remember when pickles were 5 cents a jar, but now they

are \$2.79 a jar. So there's a lot of interference. If you are taking a lot of medication and your dosage rates change or one changes to another dosage rate that is very similar to another one, there will probably be massive amounts of interference. Older adults have a lot of proactive interference, sometimes having trouble forgetting old information or incorporating that with new information.

A lot of these studies look at things in isolation. But as soon as you have multiple medications or changing rates, updating, that can be especially challenging for older adults. I think under those circumstances there could be a lot of problems.

But to look at ways in which older adults can remember or process information, I think maybe the grocery prices experiment might be valid. If you put it in a context that they are familiar with, they can then make decisions about whether this is important to remember, whether this is consistent with prior knowledge or completely inconsistent, but I'll still code it as too much or too little. They will then kind of boil it down to the gist because they know they can't remember the specifics.

DR. BREWER: Thank you. I agree.

My second question is, I'm trying to figure out who has a problem here. Is it the younger folks or the older folks? When I look at some of what the older folks

were doing, it seemed pretty good to me. They were acting a little more like experts, as Valerie would say. They were operating in a gist-like world. They were not remembering, in many ways, irrelevant details, like eggs at 19 cents. Yet when it comes down to the world they live in, where maybe these are prices of things they might afford -- many of them are probably living on fixed incomes -- I think, good for you. I want to be that person who remembers the stuff they are supposed to remember and maybe not the other.

I understand that your research is in a much larger context of research on aging and memory. Maybe you can comment a little bit on what's good here. How do we know what a good finding is?

DR. CASTEL: That's a great question. I think the larger context in memory and aging has typically shown various impairments. Older adults can't remember as much. They can't remember a source. They can't remember associations. So anytime you find older adults doing better, it's newsworthy and interesting. On the other hand, I think this is almost more a metacognitive question. Even though memory might be worse in old age, older adults know that, to a certain degree, and then can selectively focus attentional resources appropriately, if the conditions allow for it. There are still many cases where

there is just too much information and they are drawn in various directions because of attentional issues. But if there are some goals in place, then older adults can be even more judicious about what they try to remember. Sometimes the environment can help them -- putting things in larger font or bolding things to tell them what's important. But if not, then older adults will start to decide what's important. In a lot of our memory experiments, they will say, this wasn't very important for me to remember. That's frustrating from our perspective, because we are assuming that anything we put in front of them they will try to remember. But, in fact, what they will sometimes say is, if it's too much information, I'm going to try to figure out why this is important or what I can selectively focus on.

DR. BREWER: That gets me to the last question. I'm trying to decide whether older adults -- are we just lazy? I'm starting to feel like an older adult, even though I'm only 45. Many of these sort of memory tricks just seem very familiar to me.

But I'm still not convinced -- you get a 68-year-old participant in your study and you are showing them a 19-cent carton of eggs -- that that's something they really should be motivated to remember. Do you see what I'm saying? A college student who is in there and is excited

about being in a lab and thinks this is kind of cool -- you are in a university and it's high-prestige -- then you sort of move over to somebody who has kind of been around the block a little bit and sits there thinking, "This is sort of interesting. I get to go talk to the young folks for a while. And, oh, my God, there's the egg thing again."

How much do you think that really is an issue, whether older adults are just simply not all that engaged by this particular process, but when you put something that they are engaged in, then it's different? That's a very different way of looking at even a broader literature.

DR. CASTEL: Yes. I completely agree. Typically we try to say, let's use word pairs or let's use something everyone has familiarity with, where the vocabulary is high for both groups. But when you do that, you find these striking and huge age differences. Then if you step back and say why this is, there are brain mechanisms, certainly, but you can also look at strategies. Both groups differ in terms of the types of strategies they might use. Why are they using different strategies?

I'm not sure it's a laziness thing, but it certainly could be a motivational question. Motivation is such a difficult thing, to say what motivates certain people or certain groups more than others. If we pay them, is that going to motivate them? Like you said, some people

are on fixed incomes. Some people aren't spending money the way other groups are.

Good questions. Tough to know exactly how to address them.

DR. PETERS: Val.

DR. REYNA: Just a quick response. By the way, I think it's wonderful that you actively manipulate motivation by studying value. That's cool. Then you can really get some answers.

I can say that the older folks that we interview in my lab are extremely motivated to do well on these memory tests. They take it very seriously. One of the number-one complaints in aging is memory impairment or cognitive impairment. It's often ahead of physical complaints that you would consider very serious. People strike me as being extremely motivated to do well. We have to add instructions that when people commit errors, that isn't so bad for research, and all of this other stuff, because we don't want people to feel bad that they can't remember a supraspan list, for example.

DR. CASTEL: Just to add to that, I think our older adults are very motivated. They are often coming in to volunteer. They are not doing it for money. They are not doing it for course credit, like some of the younger adults. But they also know their memory is impaired. As

soon as you say, this is a memory task, this is a memory study, there are other issues, like anxiety, stereotypes, that can kind of lead them to either use different strategies or just not feel as comfortable that their memory is going to work well. But they are still motivated to be there and to do the task.

DR. COL: I just -- I just -- by way of confession about how memory works as one ages, one of the strategies that I use, if I realize something is going to be really engaging of my brain and if it's not worth it, I save it for the stuff when I really want to be engaged, because you realize you only have two or three really good hours in a day when you can really get that super focus. I don't want to waste it on stupid stuff. I really time it. This is a good -- I don't -- and then I do the stuff that requires less ability at different times. So I do, like, the fonts, minor editing. But I do the big writing stuff when I've -- and I don't want to waste it. I really strategize about -- and I wonder -- I think older people -- when you're younger, you don't think about that. You just go until you burn out and then you go to a bar or something. But when -- so I wonder if there might be an intentional saving their brain for what they consider to be more important uses of their high-power time.

DR. CASTEL: That's a great point. I think it

kind of leads into this metacognitive issue, getting to know how your memory works and also knowing that it's limited. That might be coming with wisdom or coming with experience, or it might come with realizing that you can't focus for eight hours a day, and so what are you going to focus on? Maybe college students know that, but they will still push themselves, or they still think they can remember these things. This overconfidence in memory might actually be reduced with experience, but also with using appropriate strategies, not just strategies to remember information, but strategies to put yourself in a situation where you can remember what's important, as you are saying, and doing things at an optimal time of day.

DR. PETERS: I think there are a couple of direct follow-ups to this. Kala, I think you had a direct follow-up, and then Noel.

DR. PAUL: Noel, if you are questioning the motivation of these people and you think maybe you notice a difference, you don't have the same age-impaired memory problems. It's the kind of thing where it doesn't necessarily completely obviate normal functioning, but when you put your keys down and don't remember where they are and it becomes routine -- you know you have lost your keys, you know that you don't remember the way to go someplace, you know that you put something somewhere and it isn't

there when you go back -- these are things that start becoming part of your daily life. They are real, and you are aware of them as an adult with declining memory function.

What was I saying?

(Laughter)

It's on point, but I'm getting off point.

Alan, I was wondering, did you do any external corroboration in terms of the cognitive functioning of your adult population with something like Folstein Mini-Mental State, where you look at cognitive functioning and memory, as a corollary to having these people in your study and showed that -- this is really gross test -- they have normal mental function?

DR. CASTEL: Yes. At least the research that I have been doing focuses on healthy, normal aging. These are all high-functioning people who score highly on Mini-Mental status. If anything, they are probably what are considered the worried well. They are really interested in their memory. They think it's getting worse. They are worried. But they are actually doing just fine, relatively speaking.

It's the sample that we tend to attract when we do this sort of recruiting. But you could also start testing other samples that aren't as interested in coming

into a memory lab to get their memory tested and so on. But if you go out in the field, you might see a very different story. A lot of the grocery price studies come from people who are very concerned about getting a good deal in a grocery store. In fact, they will drive three miles away to get their oranges cheaper, and they will talk about these things, like they are important to them. So they are motivated in many ways and they are high-functioning.

DR. BREWER: I want to follow up briefly. I guess what I didn't ask very well in my earlier question is -- I'm struck by your findings that with training, relatively little training, older adults do really well, more or less as well as younger adults did in some of these trials. That's kind of extraordinary. It tells a very different story. One possibility is that the cognitive declines that we see with age have as much to do, perhaps, with heuristics making us a little mentally flabby. In other words, yes, we saved energy by doing it, but don't exercise our minds in whatever way that would help us be as good out of the gate as it might be for younger people.

I guess I'm trying to get at how much of the declines we are seeing in age, in your opinion -- this is a very general question -- how much of these sorts of declines is due to our being a little lazy or out of

practice -- maybe that's a better way to say it, out of practice -- because of this gist-like thinking we are doing versus how much is the biological substrate just going down.

DR. CASTEL: It's a good question. I would put some caution in the training and so on. The older adults are still remembering fewer items. There is still a memory impairment. They are not remembering as much. But what's interesting is that they are being efficient, given how much they are remembering. That they learn quite quickly. In a memory task, they realize after the first trial that they didn't do as well as they could have done. So it's not that we have actually enhanced their memory or their memory is better, but it's almost like they are better calibrated in terms of focusing on the important information. Younger adults can remember more and also the important stuff.

But I think what's important is that experience, but also feedback, as Ellen mentioned. Getting feedback about score, realizing it's not quite as good as it could be or that it's negative -- that they are betting on too much -- like in a doctor's office. If you hear all the side effects, you think you will remember all of them. But it's only five minutes later that you remember that you can't remember all of them. Then you might realize, next

time I'm going to write it down, or next time I'm going to ask them to slow down and say the three most important things or something like that. So that sort of experience and the feedback if you have forgotten things is helpful, I think, especially for older adults. Even though they know their memory is not as good as it used to be, sometimes you need that kind of feedback and experience to realize that there are ways to focus on important things.

DR. PETERS: Great questions. Thank you for your response.

I want to pull back for just a moment and just sort of review where we are in the meeting. It's about 11:20 right now. Officially, our schedule is that we would take a lunch break and then meet until 2:00. Lee and I talked about the possibility of going through lunch and perhaps adjourning at about 1:00.

To be able to do that, however, we do have a couple of things that we promised FDA we would do, which is turning to the questions that FDA posed. I know we still have a couple of other people who have perhaps some clarifying questions. But what I would like to do is have us start leaning towards the questions, so that FDA can get out of this meeting some of the more concrete stuff that they would really like to get out of this meeting.

We have been talking a lot about the theoretical

issues, but I think maybe now we want to start to think a little bit more about the application, in order to provide some of the advice that we have as committee members to help out the FDA.

So if you can, in your questions, let's start to lean in that direction. What I have in terms of order at this point is Sokoya, Nan, Gavin, and then Kala.

MS. FINCH: First, I don't think my brain can work as fast as you request. I'm in that mode of the aged, mature person. Anyway, let me ask the question that I have down here and try to see if it's related to the six questions on our topic list.

First, let me say to Valerie, a very impressive presentation and very good data. I really appreciate all of that.

You talked about the barriers to getting the right gist. What I'm curious about is, what is the effectiveness of the gist when you talk about translation, that information translated through cultures and the subcultures of that culture -- a Hispanic population and the vast subcultures of that particular culture -- in terms of, just like one word can be transformed to many different meanings? So I was wondering about that. Does your research say anywhere that that translation maintains the intended value of the way you displayed it?

I have two other questions for two other individuals.

DR. REYNA: I will try to be brief. This is a topic that's near and dear to my heart. I think one of the fundamental differences between verbatim and gist is that gist is subjective. Therefore, it is definitely influenced by culture, by identity, by those kinds of factors. Two people can look at the same message, and if the backgrounds, experience, and knowledge are different, there are different bubbles over their heads for the gist. The verbatim is the same. The exact words are the same. But the gist is quite different. I think that's very important.

One of the concepts I want to throw out there -- it's not a concept from fuzzy-trace theory, but I think it's important to acknowledge -- is the idea of funds of knowledge. People from different backgrounds, even people who are of low numeracy, don't come without knowledge. They come with rich knowledge and experience that can be tapped into. So it's not that there isn't any gist in there. It's that getting there sometimes -- different words mean different things. The implications, the background knowledge about what's plausible, what's not plausible differ across subgroups, especially with respect to the medical establishment, and so on. But it's not as

though there isn't a rich background of experience and knowledge and life insight that can be drawn on from people from very different backgrounds. We just have to get the translation right, both literally and figuratively.

MS. FINCH: Just a follow-up. I think of something very simple, the Nike commercial, "Just Do It." I guess it can be translated based upon the intent of the ad, but something as simple as "Just Do It" is translated into different meanings when you look at different cultures. So I wondered about that.

I have a comment to Alan on your model where you talked about three different approaches to deal with the side effects. You have three margins or boxes. One box deals with the most to the least common side effects. The next box is the font size. The other box is the prevalence. I just want to say that I like that. It's very clear, to the point. The box with the percentage on it -- the dizziness, 53 percent, down to the rash, at 3 percent -- what it does for me as an average consumer is, it tells me -- I can choose what's important to me. Let's just say I'm working in the field where I'm around a lot of people, but I have to take this medication. I'm looking at the side effects, and one of the most important side effects to me may be diarrhea. That's at 11 percent, and not 53 percent. But it takes on a different level of

importance as it relates to me and my lifestyle and what I'm doing in that time period when I'm taking the medication. The three boxes really hold a lot of value visually, and are very simple and to the point. I just wanted to make that comment.

Then I have a question for Brian. You talked about the precision and the evaluability of the different risk concepts. I was wondering how that value transcends culture and diversity in terms of holding the meaning of the risk concept, as well as the level of that precision. Does it lose meaning or does it transcend?

DR. ZIKMUND-FISHER: Boy, that's a tough question. Part of my answer is to say that I think different people and people with different cultural backgrounds have different preferences about the degree to which they want a precise piece of information about risk. Some people -- I put myself in that pile -- have a general tendency to want greater degrees of precision. It's not enough for me to know in certain circumstances that something might happen. I need a greater sense of whether this is a 20 percent thing or this is a 15 percent thing or this is a 10 percent thing. That comes in part from my background as a scientist, somebody is highly numerate, who is comfortable with numbers and who draws meaning from them in my day-to-day existence.

In a different context -- I'll give a personal example, and I think this perhaps captures it -- I'm an academic. I read all day long. My vision is extremely important to me. I have had glasses for decades. I have considered the question of whether or not I wanted to get LASIK surgery or another kind of corrective surgical intervention. I never even looked at the percentages. The recognition that there was a potential for a major impact on my vision was enough. Once I connected that to my situation and my needs, I was unwilling to consider that potential therapy, because I knew that was not a risk I was willing to run. Whether that was a 10 percent risk or a 1-in-100 risk or a 1-in-1,000 risk did not matter.

While I can't say for sure what the particular context is that's going to matter, I do think that that relative importance is a function of our cultural background, our employment situation, what we need to be doing in a particular situation.

DR. PETERS: Thank you, Brian, and thank you for the questions, Sokoya.

At this point, Nan and then Gavin and then Kala.

DR. COL: This ties into, I think, gaps. I think that there's a tension, an inherent tension, that we may want to be aware of between gist, evidence-based medicine, and informed decision making. I'm just becoming

increasingly aware of this potential tension. I just think it's an area that, when we are thinking about how to use this -- this may well be how people process memories and remember things. But when we start to try to manipulate people's gist, we are, as you mentioned, predigesting information for them, and to the extent that we predigest, we are also coming to conclusions. If you take that sort of predigestion, ultimately, when the patient say, "Doc, what would you do?" what they are asking is, "Doc, what's your gist?" In many ways, they are asking for the ultimate predigestion -- I can't deal with this. So what we're trying to do is package little things, predigest things. We are trying to interpret data. We are taking that role of interpretation from the patient. We are assuming that we have the right interpretation and that there is a single -- this is good, this is bad.

I think that's where the tension with evidence-based medicine comes. If you have ever been on any of these panels, you can't get five of the top experts to agree on anything. So even coming up with a single gist for five literature reviews -- what is the bottom line? -- that's extraordinarily difficult, and you are going to find a good, credible scientist who will disagree with whatever gist you come up with.

How do you accurately get agreement among

scientists about what the accurate gist is? Then to what extent are we removing the right from patients to interpret data on their own?

Now, of course, the alternative is that you give them all this data. Most patients are not equipped to interpret it. But some are, and some will come to a legitimate different interpretation that may be better than what the experts may come to. So we have to be careful with how we digest information for patients. I think it's a real tension.

DR. REYNA: Thank you for highlighting the challenge here. I think it's very consistent with evidence-based medicine. I think there really will be situations in which we would say, look, there are three main ways people look at this. But then we have to separate -- this is why it's so important to know what the locus of the issues is. There is the nature of the options -- sometimes people who disagree vehemently on what we should do about those options agree that that's what the options boil down to -- versus values, where you can all agree this is what the options boil down to, but one person values one thing more than another.

I call this the "Sammy Davis, Jr. effect," because Sammy Davis, Jr. -- hopefully, I have the facts here right -- had a kind of cancer, throat cancer or

something like that, that would eliminate his ability to sing. He said, "I am who I am. I want to be a singer. I want to go out singing, even though I know I'm going to die sooner."

He may have agreed with his physicians on what the options were, but based on his values, he made a different choice.

Finally, there's a difference in risk threshold, which is yet a separate effect. You can agree on what the level of risk is. You might say, yes, it's very low. You might agree on your values. But you still might set your threshold in a different spot than the person next to you.

So again, I think this is very consistent with evidence-based medicine. It's not that there is only one answer, one message, and that's it and we're done. There may be three or four legitimate -- people who have experience and insight might differ on the bottom line. I just don't think there are 1,000 or even 100 different takes on the same set of facts.

At the end of the day, if we don't know what we mean, how can the patients know what we mean by the nature of the evidence?

DR. COL: I agree. And I think that in many, many -- it's not always, but in many cases, that's the case. But I'm thinking about prostate cancer. One of the

key tensions is whether or not screening saves lives. There is a good trial in Sweden that shows that it does and there's another good trial done here that shows that it doesn't. That is a critical piece of evidence, an absolutely critical piece of evidence. A lot of the debate really, from a logical point of view, comes to whether you think it does or it doesn't. If you do, then -- that also goes for screening. It goes for treatment. There's a whole other set of things that come with this one fundamental, key fact that is not widely agreed upon.

So I think there are many cases where if the gist depends upon a critical fact where there's not agreement -- and often these preference-based decisions are based in areas where there are key areas of uncertainty. In many areas there's not, but in many of the areas that decision scientists tend to focus on, there is fundamental disagreement about core facts.

DR. REYNA: My response to that is, the gist is not "therefore, ignore half the facts." That's the whole -- to me, the bottom line then would be, there are two good studies. People on this side say that one study is better than the other because it has more people in it and they are more representative, and it shows this is efficacious. This other study shows the opposite, but it's a smaller study. The bottom-line gist there is that there

is uncertainty. Sometimes the fact that there is ambiguity about the evidence is the core gist that you are trying to communicate.

DR. PETERS: I think that's a very important point -- and we ran into this yesterday as well -- this idea that sometimes ambiguity is the information.

Gavin, Kala, and then Noel.

DR. HUNTLEY-FENNER: I just want to pick up again -- and I think it's related to Nan's point -- that there are these tensions. I want to make sure that I understand the gist theory. One of the features of gists is that they are durable. They are robust under, let's say, emotional influence. Yesterday we were talking about side effects and the European Union approach to categorizing them as rare versus serious, based on proportions, or rare versus common, for example. It seems like those sorts of categories are the kinds of things that might influence a gist, maybe distort or anchor a gist. I'm wondering if there are implications, then, for us if we are trying to communicate something, that maybe it's not a good thing to do, to categorize numbers that way. Potentially you might miss the most important gist, which is why this particular side effect is important to me or this side effect is important to me. It might be masked by these labels.

I'm throwing that out there.

DR. REYNA: I completely agree. That's exactly what I'm wrestling with right now. When we all agree that certain literal numbers map onto words, we are ignoring that contextual effect I was trying to underline, that notion that a 15 percent chance of rain is not the same thing as a 15 percent chance of immediate heart attack. If we do this literal mapping, where 15 is always low and 50 is always middle and 80 is always high, which is which people tried to do in the 1980s -- they tried to decide, let's map these words onto literal numbers, and that way we'll be consistent -- that misses this whole human ability to interpret in context, which again can have its pitfalls, because we are literally biased by context. But you miss the point when you are not biased by context.

Indeed, we know from Ellen's work and other work that when we give people labels, we are sending a message. They think we are trying to tell them something -- namely, that it's low. They believe us. Then that does skew the perception. But if their own perception of this particular thing -- like the grandfather who said a 1 percent chance of cystic fibrosis, since I have been through this experience, is high to me -- then you're right, we are going to obfuscate that particular gist for that individual. So I think we have to tread lightly.

Sometimes, ironically, giving the numbers is important, so that people can extract their own gist. It's not that the number is important. It's that the person has to decide for themselves what the interpretation of that number is.

DR. PETERS: Just to follow up on that a little bit, I agree, actually, that labels can cause you to sort of miss what's important, on occasion. Sometimes people don't know what's important, though, and labels can actually help them perhaps to identify what's important. I think it depends on the context a little bit.

I think also that if you didn't want to give this kind of predigested information -- I think that's the label you were giving it before -- some of the ways that you can help people to gather their own gist -- and I know Valerie has done some testing on this -- would be to use thinks pictographs. And Brian talked quite a bit about this, too. But then you run into pragmatic issues. Think about it in terms of consumer medication information, some kind of a PMI or something like that. There are 10 side effects of this thing. Are you going to put 10 pictographs in, and are people going to be able to consume that? Or is that actually going to keep people from really, in the end, getting the gist of what's going on, and so they actually miss the values, for that reason, instead?

I think there is a really interesting tension here that Nan brought up originally, but that also exists within the question that you are asking, too.

DR. HUNTLEY-FENNER: Yes. I guess the issue I was trying to raise is that it poses a challenge to the notion that we can standardize presentation without, quote, standardizing the interpretation in a way that's misleading.

DR. PETERS: Thank you. I have Kala and then Noel and then Moshe.

DR. PAUL: I'll pass.

DR. PETERS: Okay. Noel and then Moshe.

DR. ANDREWS: What Gavin was saying -- this is really important, to take what we have known right here and translate it into some action on what our mission is in a brief summary, if we are able to do that. I'm struggling with this, because if we do have a label or a box, you just can't throw the numbers out there. There's relative information. You have to provide some meaning. Then you have value-based issues. Who is going to make that decision? Is it the Office of Drugs? But that may not be the same as a person's gist. If you do that, do you give this as a typical person and then bounce it back to online, where you have different options, like Bill was talking about before?

I don't know. Maybe these are all empirical questions. You are rushing ahead with this. Will people even read this? We were talking to Mike earlier today about the UK experience -- he might talk a little bit about that -- with the different descriptors. I know he has research on that as well, whether or not that can work.

These are all very tough questions, I think. It would be great to have some research evidence on exactly what consumers are taking from all this.

I don't know if I added anything, but thank you, Noel.

DR. HUNTLEY-FENNER: By the way, my comment was to number 3.

DR. PETERS: Thank you. I would like to go on record as saying thank you for hitting number 3.

Why don't we go on with Moshe, Bill, then back to Noel?

DR. ENGELBERG: I want to bring up I guess what I would call a potential reframing, at the risk of offending everybody. I hope it will be equal-opportunity offending if I do.

In my experience working in public health for a long time, sometimes we can be quite paternalistic and tell people, you should do this, you should do that, so you'll live longer, and things like that. I want to come back to

Brian's point. Step one is the patient need, instead of our need as fixers of things. If that's a starting point, FDA has asked for help about informed decision making. As I think about it, that's a process -- making a decision with information -- versus an outcome focus -- and this is the reframe part -- that the outcome is really a good decision. I wonder if that shift would affect our thinking some. For example, it brings up in my mind the question, do people need to make an informed decision? In research we have done with older adults, especially the 70-plus cohorts, there are a lot of people who say, "I'll do what my doctor says, who has been my doctor for 30 years. I trust him or her. I just want to do what they say, and it bothers me when you give me all this information and tell me to decide. I don't want to be empowered." They may not say that explicitly, but their empowerment is handing off responsibility to the doctor.

I wonder if we are being a bit myopic with respect to the patient desire for making informed decisions, and thereby our task.

DR. PETERS: I think it's a really interesting reframe into what I would call the burden of choice. Some people would choose not to have that burden of information and choice.

I had a feeling Nan was going to have a comment

on this.

DR. COL: I think it's a great point. I think we have to respect that. But I think there is data out there -- and, of course, it depends on the decision and the context and all sorts of stuff. But most people do want that. I think it's viewed as patients have a right to be involved when they want to. The majority of patients do want to be involved in decisions that pertain to their health. There are several also who initially say they don't want to be involved, and it's only because they don't really understand what it means to be involved. So you have to also -- the answer depends on how you ask it.

But I think that just because there are a significant minority of patients who do not want to -- and again, as patients get older and are less educated, they also want to be less involved in decision making -- we respect that desire. But I think we have to also respect the majority of people for whom we have a moral obligation to help them make informed choices that are consistent with their values.

DR. PETERS: Kala, this is directly on this point?

DR. PAUL: Yes. I was just thinking in terms of how we communicate this information and how much of people not wanting to be involved in just what Nan said, that they

don't understand it. So the failure is ours, in many respects, because we haven't figured out a way to make them able to become involved, because they don't understand what it is that they are deciding. I'll take the drug or I'll not take the drug. Doctor, you tell me, because I just don't know how to sift through this information.

So it's either what we present or how we present, assuming, of course, that there is a way to present it to get them able to understand it and at least participate. But I think a lot of people, particularly, as you said, lower socioeconomic groups and lower literacy, don't want to, simply because we haven't been able to figure out a way to give them that opportunity.

DR. PETERS: I have to admit, while I do a lot of work on information presentation and how to help people who are less numerate, who are older to better understand information so that they are empowered and they can take charge of their health. I would have to say the question -- and I think it's a very important question -- that Moshe is bringing up is actually an empirical question. It's the kind of question that maybe in some of our research we should start to think about and look at. Let's say we do make it as understandable as we can. Let's say we make it as consumable, as comprehensible, as usable. Is it the case that the people who didn't want choice before

now actually do want choice? Or is it the case that they are there, that they really don't want the choice? There are older adults, at least with this cohort of older adults, who grew up not taking part in these kinds of processes. It may be that with the inflexibility of cognitive processes that happen with age, this particular cohort may not desire that kind of choice even with more comprehensible information.

At the same time, we have this huge baby boom generation of free choice coming, steamrolling down the health train, who are actually much more accustomed to information and choice. Things may be very different with them. It may be that the empiric results would say something different with them than they would perhaps with the older adults that you are talking about now.

Nan?

DR. COL: Just a follow-up to that. I think the other key party to look at this empirical question is the impact on providers. Throughout my training, whenever there is a whole slew of drug choices treat, which is increasing -- there are increasingly larger varieties of things to treat common conditions -- the mantra that I was taught, that was being taught to most doctors, is, don't learn how to master every single statin; be comfortable with a couple. Really know a couple of drugs in each

class. Know those drugs really, really well, be comfortable, know all the side effects, and stick to those. That's how we learn. We don't know every treatment for these things. We just know a couple that we are really good at and we're comfortable prescribing.

What's going to be the impact when now we have more drugs out there and now patients are saying, I want drug number four and the doctor is saying -- well, they are not saying it, but I'm only comfortable with -- I have never really prescribed that drug, because I -- but that's what's going on in the doctor's head.

I just wonder what this -- if we're really trying to -- it's going to result in a shift, and there may actually be more errors on the providers, because if they do venture into new territory, they may forget to disclose more side effects or they may not know about how you initiate drugs or what to watch for.

It's just, I think, empirical evidence on what the providers -- how that shifts. It is very different from how we have been trained.

DR. PETERS: Very interesting point.

Bill and then Noel.

DR. HALLMAN: I would like to address 1 and 2, because we're supposed to be doing that --

DR. PETERS: Again, may I applaud you for doing

this?

DR. HALLMAN: -- and point out that these are really good questions. One of the things that I do is look at how to motivate people to respond to contaminated food product recalls. One of the problems that we have there is that in the warnings the information that gets put out is very general information. There is a tendency for people to think that it applies to other people and not to themselves. So when we ask, are food recalls important, everybody says yes. We ask, do you share this information, and everybody says yes. And "everybody" is, like, 90 percent. Then we ask, have you ever looked for a recalled food product in your own house? It's about 60 percent. So people think it's important, but it's information that applies to other people.

So we see these kinds of perceptual biases. With 1 and 2 here, with drugs, my sense -- and I don't have good empirical data -- is that people want to believe that they will be one of those people whom the drug will help and discount the fact that they will be one of those people who could suffer side effects. So getting this issue is really, really important. When we think about it in terms of drug advertisements, the lead story is, this could improve your sex life or this could improve your depression symptoms. There is a kind of certainty in the language

that is put out there about the benefits, which is then followed by this list of very rare side effects.

I wonder if we could talk about those issues very specifically.

DR. PETERS: I wonder if we could even go back to what you started with, with number 1. If people have the sense that this is important but it's not about me, what would you do? What would you want FDA to tell people to try to get them to take the appropriate actions?

DR. HALLMAN: One of the things that we have suggested around food recalls is that the information become more personalized. There are a number of supermarkets that are using their shopper loyalty cards to specifically let consumers who have purchased the product know that they are at risk. That can be very, very effective. It's one thing to get a phone call from your local supermarket saying, "We noted that you bought pistachios that are recalled. Please check. Don't eat." That's very specific advice -- it's difficult to ignore that -- versus one line that you may see in a newspaper or on television that says this particular brand was recalled.

DR. PETERS: That's actually very cool. Is that pragmatically possible?

DR. HALLMAN: We could have a very long discussion and a whole session on food recalls. At some

point I hope we will. There are lots of issues related to it. One is that people often give false information when they sign up for the loyalty cards. So there are an awful lot of people whose address is the local stadium, because they are afraid that they are going to get coupons and things. They didn't sign up for the loyalty card with the thought that that would be a benefit in mind.

There are also some potential liability issues. If you fail to inform somebody, are you liable for that?

But in general, yes, it's really possible.

DR. PETERS: I think Michael has something on this point.

DR. WOLF: I didn't mean to jump up in line, but this also works well. This also answers number 4 as far as what other literature should be going into it. There is work right now -- I mentioned this; sometimes I feel like I'm saying thing over again -- electronic health records and pharmacy software systems, where you can -- for instance, when you find out about a medication that has a new warning, it's easy now to be able to isolate and target the patients who have received prescriptions through the orders, to identify patients who are in your particular practice -- the 4,000 patients on this medication that you need to contact. So those systems in place are already being built up very, very well in some of these EHR

platforms.

What the pharmacies could also equally identify and take on that role, especially with some of these larger new medication therapy management kind of mandates that are being called -- I think at least those two points of care for prescription products, medication products -- you could have that kind of loyalty card -- I know who has the medication.

Also the other thing I would just say -- one of the things through AHRQ, where they are leveraging health technologies for medication reconciliation, education, insurance -- some of the initial projects -- I know we were one of them, but several others -- were looking at how you could tailor information so moving upstream, generating PMI at the point of prescribing rather than dispensing -- that would dynamic forms created with the prescription, so there are algorithms knowing that if you are male, you are not going to get the "do not use if you're pregnant, think you're pregnant, or breastfeeding." There will be things that will be taken off based on the very fact that we know who you are a little bit more than had you just been patient X.

They are working with that. To finalize my point to number 4, thinking about what literature, who else should be at the table, or ways you could be thinking about

it, either reaching out to the Office of the National Coordinator, where they are doing large build-outs on how you can leverage electronic health record technology for patient education benefits -- I think this is somehow another -- I don't know how the FDA or this committee specifically could be helping to guide some of that work, especially when it talks about -- one of the biggest things, the 300-pound gorilla, in EHR systems is the medication-related content. That would be a group definitely to tap into.

The final thing is, AHRQ also has a contract with Apps Associates right now to create a central repository and a way of rating publicly available patient education products that could be leveraged into the electronic health record right now. They are trying to come up with some way of saying this is good content, bad content, and create a repository on the AHRQ Web site. That, I can tell right now, would be heavily guided or could be influenced and could require assistance from, like, this committee in thinking about what good information is, what good risk communication is, since a lot of these products they are talking are not just, this is asthma, but also decision aids, et cetera.

DR. PETERS: Thank you.

We have Noel and then possibly back to Michael

again. I'm not sure.

DR. BREWER: There are a couple of things that I want to mention now that I have heard some of the recent comments.

One of them is, Bill, your comment that people don't always get it when it comes to risk. But there's also benefit. You and I have this paper -- Brewer and Hallman -- this was during the flu vaccine shortage in 2004-2005. What we found was that a third of Americans that we studied were at high risk and knew it and got the vaccine, for the most part. A third of them were at low risk and knew it -- risk meaning risk category, people most likely to benefit from the vaccine. They were in a low-risk category and didn't get vaccine, for the most part. But a third of the people were in a high-risk category, didn't know it, and didn't get vaccinated as a result.

So people can misunderstand not only the potential harm to them, but they can also misunderstand the potential benefit and seem to be somewhat reluctant to embrace some of those ideas. Challenging, definitely very challenging.

The other thing I want to pick up on, based on Michael's comment, is that he and I have the same role on different center grants. AHRQ just funded three different center grants. He is the collaborative scientific lead on

his grant and I'm on one that UNC got around patient harms. We are studying how to get people to stop using potentially harmful preventive services. I think the thing that is particularly generalizable here is that there may be drugs or other medications that, for whatever reason, change in status, and trying to get people to stop doing something they have been doing, and the potential to pick it up again later -- that's an example in food recall -- it's a challenging, challenging issue. We're just at the beginning of trying to think that through, but one of the things we have come to realize is that it probably depends on what kind of information you are giving and whether the kinds of harms you are talking about are congruent with how people think about the problem, essentially. Some things really resonate with them and others just don't every really settle in or take on meaning or get really incorporated.

So those are my general comments. That was question 6, that last comment.

Question 1: What should you do if you know what the behavior is that you want people to engage in? Here's my controversial comment: Don't communicate about risk. Just get rid of the opportunity for the behavior. Regulate it away. Take the product off the market. Remove the environment in which people will be in the risky situation.

That's where I would start. If you have a dangerous situation that people might be in, get rid of the danger. That's where I would start. Then, when all else fails, if there are products still out there, if there are still situations that you can't remediate, think about risk communication as a backup effort, when things fail.

That's my opinion about number 1.

I know it's a lot to squeeze in, but I have a question for Valerie. Valerie, picking up on a conversation last night -- a sort of high-energy conversation -- if we want to understand the gists that people have around, say, a medication, I'm curious how we study that. I guess we would have to ask people, right?

DR. REYNA: Great question, Noel. How do you measure gist?

DR. BREWER: No, I'm saying -- you have a theory, for example, that there are a limited number of gists. That's your working hypothesis. You have some data to that effect. I guess you found that out by asking people some open-ended questions and got some qualitative information, right?

DR. REYNA: Ah, I see where we're going. Not exactly. That's a really good question, because measurement is so important. It's fundamental to everything we have heard about. One way I have done it --

but I'm also building on -- when I say there are a limited number of gists for most people most of the time, it's not just based on my own work. It really stretches all the way back through psycholinguistics and people's memory for narrative and text in a variety of circumstances. So it's not just my work that I base that on.

There are converging operations. It isn't just asking -- you can ask people, certainly, what is the gist of this, or what are the important ideas of a narrative? But also there are a number of other converging operations that you need to do. Some things that people can talk about, they have conscious access to, they can give you a judgment that actually predicts their behavior. There are some domains. We know about that. For example, if you ask people how similar two things are, they can give you a rating that does predict their behavior. If you say, why did you say that A is similar to B, what they typically say is not necessarily predictive of much. It's about a talking thing.

So those are some fine points about methodology.

On gist, there are multiple converging operations. We don't just ask people and just leave it at that. We also have a variety of different kinds of instructional conditions from which we derive mathematical models that predict actual behavior. What are you going to

recall? Where are you going to recall that word on the list? Are you going to recall it at position 6, 7, or 8? We can actually predict that based on the nature of the memory. How long are you going to remember it? What types of factors are going to increase your recall or decrease your recall? I could go on and on.

It's a question not only of converging operations. So we have math models and special techniques to get at the underlying gist, as well as a variety of different kinds of measures, including forgetting, summarization of the main points, and then some of these more specialized techniques to get at the gist.

The good news is that those measures converge, not only in my work, but in prior psycholinguistic research as well.

DR. BREWER: I guess I'm wondering -- there are some of these gists like you described in your talk, where you give a quick summary, and they are very pithy and insightful, and they reflect, in many ways, your own intuition for what other people might be thinking. They are persuasive. They are powerful.

I guess, in the way that you are introspecting, you would also ask people to introspect. That might be at least some piece of the work that you do, asking for that introspection -- some piece. I'm not saying it's all, or

maybe even central. But is it at least a contribution?

DR. REYNA: I'm actually trying to summarize a lot of techniques when I get to those. I was sort of trying to give rules of thumb for how you might end up with that kind of summarization. I compressed a lot into that 25 minutes. It's not just arbitrary, like I come up with a pithy summarization. There is usually, for numbers, a nominal gist -- none or some. There is an ordinal gist. These are questions you can always ask about numbers. Is there a linear trend? These are things that you can look for ahead of time, rather than just say, okay, tell me what you introspect.

Introspection is fraught with errors. As psychologists, we had a whole period of time in which our initial methodologies were all based on introspection. We had trained introspectors -- not just random people, but people trained to become really good introspectors. There were tremendous pitfalls from that that are known in the history of psychology.

Is it that you can ask people questions, get useful answers, and make predictions about the behavior? Yes. But the predictions-about-the-behavior part is an essential component of that. You can't just stop with people's musings about why they might do what they are doing. I think that methodology -- we tried that, and it

didn't quite pay off.

DR. PETERS: And I think there's an interesting analogy in how people have gone about trying to come up with information formats that work better for people who are less numerate, for example. As highly numerate people, we use our intuitions to come up with formats that will work better for people who are different from us, but we don't always know how their minds work, and perhaps not even how our own minds work, as you are suggesting. So in the end, you have to empirically test. Sometimes in our own lab group, for example, we have discovered we weren't quite right on that one, but because we did the empirical testing, and we'll often do follow-up testing, you can start to improve on your intuitions with some data at that point.

Why don't we go on to Bill and then Vicki. Then what I would like to do after that is go ahead and get some last comments from people on each of the questions, if there is something we haven't gotten to yet. I would like to make sure, by the way, that we are including Brian in on this. Maybe when we get to that section, Brian, you might consider, if you have some comments, going up to the stand.

For now, let's start with Bill and then Vicki.

DR. HALLMAN: I have two comments on number 4, trying to get people to pay attention to the verbatims

related to quantitative directions. I think the idea of some standardized icons would actually work very well there. I'm a little concerned about using icons for side effects because I'm not sure exactly what it would look like for nausea and diarrhea and vomiting. I'm not sure I want to be involved in making those icons up. But I do think for twice-a-day, two pills, for children, that makes a lot of sense.

The other thing that I want to say, at least for the record, even though it's not under FDA's purview, related to product advertisements -- we are talking about risks and benefits and side effects. One of the things we have not actually talked about is the cost of the drug. When people are making a decision or talking with their doctors about what drug to adopt, that is a big deal for people, especially people paying for their own drugs. There needs to be some way to communicate, above existing drugs, for example -- this drug may cost 50 percent more than existing drugs. What is the payoff in terms of additional benefit? What is the payoff in terms of reduced side effects or reduced risks? For me that, would be an important gist to try to get to people. This is really expensive, but it's really worth it, or it's really expensive, and not so much better than existing drugs.

Again, that's not the FDA's responsibility, but

that's really kind of how people will want to think about this. Let's not divorce ourselves from the cost of the drug. That really is kind of a side effect of taking it, in a way.

DR. PETERS: Yes, there are actually two different levels of cost. One is for the individual patient, as you are suggesting, but there's also what ends up becoming a societal cost that goes to the health insurance companies and to the government when it comes to Medicare. Probably not an FDA issue, however.

DR. HALLMAN: Agreed, but if we were to think about putting together something on the Internet, for example, that allowed people to explore their own risks, their own benefits, given their profiles, given their preferences, you would want to include cost as a variable in their calculations there, I would think.

DR. COL: I agree entirely. I think one way -- one of the big distinctions is whether it's generic or not, so potentially just identifying effective treatments that are generic may really help patients steer their --

DR. PETERS: Vicki.

DR. FREIMUTH: I want to go back to question number 1 and suggest that there may be some situations in which we have a different objective than we have been talking about up to this point. Most of us have been

talking about informed decision making as an objective. But I think FDA should consider that there are times when their objective is just straight persuasion. In emergency situations and in food recall -- I sort of feel that way about tobacco, but that might be more controversial -- I think you can't always remove the product, which would be the ideal. When you cannot, I think there are some situations where it's not informed decision making, but it's just going back to persuasion. That may change the techniques, the kinds of messages, et cetera. I wanted to put that on the table.

DR. PETERS: Craig.

DR. ANDREWS: If I could jump in here, I totally agree with that. In fact, I was thinking about that and I was agreeing with what Noel said. Some products are inherently risky, with liability issues. There are some here that I wish were, but that may not happen. A great example of this, I think, is with the FDA with the graphic warnings, where they have added -- we pushed to have the 1-800-Quit-Now number on there. The reason is that consumers need to have a clear, viable solution. As most of you know, self-efficacy is really important. If you are just creating fear -- and a lot of people have this fatalistic view of risk information -- where it just causes all sorts of emotional issues -- a lot of you know about the parallel

response model and all of those. If you are just doing that, that's going to create more anxiety rather than having a clear solution as a way out for people that is bold.

I don't know how you do this with a brief summary or other print material. But in general, communication has to be, I think, bolded -- health-care professional, Web sites, other sorts of key information as a way out for people.

DR. PETERS: Kala and then Nan.

DR. PAUL: I was looking at number 2, if I may speak to that one. The question is, what do you do when you have different categories of patients and different categories of risk for those different categories of patients? I was thinking, given some of the stuff that we have heard about gestalt or gist, it would make sense in much of what we were saying earlier to try to communicate this as chunks. If you are a patient with X, this is what you need to do know or this is what you should tell your doctor, as Gavin was saying. This is a risk factor. If you are a patient with Y, either an indication or a particular precondition, then this is applying to you. I think it's something we were talking about. Even when you are writing sentences, if you have a clause, you are setting up a context in which the patient can then

recognize their brand. I think these are all the commonalities that we have talked about. Whether you use the word "you" to personalize it or you -- you still have to bring the patient and the material together and find a way to bond them so that there's a better chance that they will actually read it and retain it and use it.

DR. PETERS: With some of the drugs, the side effects become more important as we age. So you can even see trying to communicate the gist of this increasing risk with age through some kind of graphical technique, so that someone who is 50 will know, okay, this is okay for now, but as I get older, I'm going to want to start to pay a little more attention to this and perhaps stop that drug.

DR. PAUL: That's a really interesting potential. Again, I'm thinking in the context of the medication guides and the patient package inserts. I don't think that has come up for anything I have worked on. Just the concept, not just that older patients have a higher risk, which is a statement we would normally make, but that the risk increases as you get older is a visual that has a dynamic component to it that I would think makes a bigger impact. As I have said before, you can put an icon in and it tells exactly the opposite story of what you thought.

I'll tell one I did. I put drinking water, and I had a tap, a glass of water. I thought it was great, until

I found out that I had made it black, which meant that the water is not potable. So you have to be careful with icons.

DR. HUNTLEY-FENNER: The other benefit to having a graphic like that is that you may not think of yourself as old, unless you're a 45-year-old losing your memory, but you may pay attention to the relationship with age. That's the point.

DR. PAUL: Yes, and I think also maybe there is something to think about there in terms of severity of disease.

Just thinking about communicating, a spectacularly good example of global communication is these international road sign icons. They have been vetted. They work. Everybody knows what a person lying in a bed means. Everybody knows what a round circle with a fork and a knife on either side of it means. So there may be some -- even though I don't even want to go where we have an icon for diarrhea. There are international signs for bathrooms that would help. But it's possible that there are -- one of the things that the FDA has been very good about is trying to standardize some of the terminology. If we have the term "flatulence," it's almost always reported as gas when the patient is reading it. So that becomes known. So that's the kind of thing where, when you think

about some of these categories and a gestalt, and you give a picture, the picture is always one that can elicit a certain set of cognitive responses or thoughts or maybe even emotions, I'm not sure. But it's something to consider in terms of communication.

DR. HUNTLEY-FENNER: Just a word of caution. There are studies that show literacy effects for interpretation of symbols. It turns out that there are linguistic qualities to these graphics.

DR. PETERS: Nan and the Moshe. Then I think I would like to turn to some last comments on each of the questions.

DR. COL: I want to first comment on Kala's -- I thought it was great. I think tying in what Bill said before -- it's always, this doesn't pertain to me. As soon as you mention older, it's always somebody else, not them. Some with comorbidities -- oh, I may have that, but I'm strong or I'm -- it doesn't pertain to me. Or I'm not obese, I'm just robust.

I think that people always do this. This is how we adapt to our health situations. We deny any problems that we have. It's always other people who have these problems. So I think we have to be really careful, because if we are trying to put these labels that people attach not to them, it won't be effective.

I think, in responding to 1 and 2, what's really needed is a spokesperson who people can trust. It's something -- like there's a Dr. Oz. It could be an actor who is a face that people can trust. That person could then speak. Then I think if they want to bring in an older person, bring in a healthy-looking 55-year-old person, if that's who they are trying to target. Don't bring in a 90-year-old. But actually, I think, visuals and that narrative -- because I agree, we do want to persuade on these things. I think the best way to persuade is with a trusted person and developing somebody charismatic, and give them good film training and good scripts. This is not that hard to do. Everybody else does it.

DR. ANDREWS: I just want to interject, that's the legacy of this committee. I think that has been recommended all four years that I have been here. I believe in one of the videos they had a dermatologist that they were talking about. I just thought I would get that out there. If you go back into the history of this committee, that was loud and clear.

DR. PETERS: Moshe.

DR. ENGELBERG: I would like to put on the table a crude idea. By crude, I mean not fully developed. Maybe this already exists and it's done, but I don't know about it. I'm looking at Brian's taxonomy about the types of

risk knowledge. When I count them, there are about eight -- possibility, relative and comparative possibility, and so on.

With that, I'm trying to address all six questions at one time. I'm wondering if we can connect -- FDA starts with situations like this. The endpoint, I'm thinking, will be a recommendation for some kind of risk knowledge. We will say, in this situation, you should show categorical possibility, or whatever it is. So an endpoint is a type of risk knowledge. The beginning point for FDA is the situation. In between each situation can translate into maybe a top two or three patient needs.

I'm making this up. I don't know if that's accurate.

If that's the case, then maybe we can be prescriptive and say, here's a situation, here are the likely patient needs, which translates into information needs, and then to meet each of these information needs, here's the type of risk knowledge that would be useful.

If it doesn't exist, a taxonomy like that, I think, would be very useful and kind of pull everything together. Maybe it's something this committee could produce. That's the other half of the idea.

DR. PETERS: I think that's a great idea. Let me ask you a question. Do you think we have enough empirical

support? If we were to identify a particular situation and we knew what the patient needs were, could we give specific advice at that point where we know for sure that that's the level of precision that's needed across all populations?

DR. ENGELBERG: Two things. Instead of being across all populations, I would pull out different populations -- represent that by different needs. But I don't think that's what you mean by "across all populations." So my answer is, probably not. But I think even an attempt in that direction would be better than nothing. If the baseline is that no one has created that, then we could say, with the current state of knowledge, this is what we think is best.

DR. PETERS: Brian, would you like to comment?

DR. ZIKMUND-FISHER: I would. I think both that comment and Dr. Col's earlier comment about the tension between the goals of informed consent and the challenges that we face in terms of developing some more simplified representations that lead people towards specific gists -- it's always going to be a challenge. Whether we have the evidence base now, whether we will ever have a complete evidence base for every type of situation is always going to be a challenge. Yet I think there is a pathway in front of us that can be useful.

I would like to take us all back to one of the

themes that I brought up in my talk, which is the idea of sequencing information as much shaping what information we provide. The question isn't always what to show as much as it is under what sequence to show it. In the initial representation, the first thing that somebody might be presented with could have certain characteristics, and that might then lead them to know, these are the things that I see as more important. Dr. Castel talked about older adults having prior knowledge about what's important to them, and they will use that information when they can connect it to meaning. If we guide that meaning-search process initially, then perhaps we can present additional information at whatever depth and process that somebody sees congruent with their particular needs. One person might look for particular numerical details about how likely a particular side effect might be. Another person might be happy. They know that that's not something that's meaningful to them in their situation.

I would like to put forward the idea that it isn't necessarily about picking -- this is the level of representation that's the right choice for a particular task -- as much as potentially allowing a learning process to unfold, so that one can first explore, why am I interested in this, and what are my needs, and then get the information appropriate to that. That's going to be

somewhat different in different contexts. But what we might be able to do is to specify the types of information that will be most useful for that first stage. That may then be the most useful thing we can do to help get people thinking productively about their particular situations.

DR. REYNA: Just a quick yes. I, of course, agree. In particular, I think often people do want to extract multiple gist representations, both the nominal categorical risk -- is this a significant risk or not, that fork in the road -- and then what's bigger than what. Those two things -- often they need to know both, and they tell you different things.

DR. PETERS: One thing that I wanted to bring up is that we do need to remember a little bit the context that we are in as a committee. We are placed within FDA. I think the comments that Brian is making and that Valerie has followed up on are great in terms of being able to personalize for the individual patient who is front of me if I'm a physician, let's say. It's a little harder -- not impossible, a little harder -- from an FDA standpoint, because they have to regulate. One of the things it points towards is something like providing tiered information on a Web site that's accessible, at least for those people who have access to computers. Not everybody does. I think maybe it was Gavin who brought this up earlier. I don't

remember the phrase that you used, the conversation starter idea. Maybe in that first tier of information, we want to make sure that that is what's going to really start the conversation with the learned intermediary , the health-care provider, that the person is inevitably going to go to, who then can maybe go through these more nuanced processes and provide tiered information as necessary, as needed by the patient.

Do you have another comment, Brian?

DR. ZIKMUND-FISHER: I would actually like to connect that exact theme to another one of the comments that I wanted to make, which is following up on the discussion of question number 1 and the situations in which perhaps we sometimes do need to be more persuasive and directive. We talk about goals. I was reflecting upon my experience, as somebody who is interested in risk, watching the outbreak of *Listeria* in cantaloupes unfold and the communications that were related to that. In many ways, what I wished had been more prevalent in the discussion were instructions at the level of what I should be doing. I didn't need to know that cantaloupes were contaminated. I needed to be not eating those cantaloupes. I needed to know whether the meal that I had four weeks ago mattered or not for what I should be thinking about. I needed to know whether, if I was sick to my stomach for one day, I needed

to be doing something, and if I was sick to my stomach for a week, I needed to be doing something.

The difference between knowledge that this is a problem area and what I as a community member need to do in response to that may be part of that tiered structure. If the first instruction is, don't eat any more cantaloupe and watch for this thing, maybe that's what we need to do at that first stage. If the second stage is a more nuanced exploration of that risk, more detail, then potentially we can steer people to providers, steer people to other kinds of Web-based resources, and things like that, to meet those other needs.

DR. PETERS: Bill and then Kala.

DR. HALLMAN: We're actually doing some research on exactly this issue, with the cantaloupe outbreak. We have found with other recalls that it's exactly this kind of information that's missing. It may be put out in press releases by FDA, but it's not getting picked up by the general press. So people get the sense that there is a problem, but they don't get a sense that it applies to them and they don't get a sense of what it is that they are supposed to be doing. Typically the follow-up stories are about how many people have been made ill, but not, here's what you can do. Getting to the gist of the information, people's mental models of what they should do for produce

in general -- I'll just wash it. You need to be saying very specifically, and don't wash it because that's a bad idea. That's not going to make this clean. Or I'll just cook it. You need to be saying very specifically, lots of people think cooking it would be okay, but it's not.

So very simple directive kinds of things are really what's important in these particular situations. Absolutely.

DR. PETERS: Val.

DR. REYNA: I think if we are in the communication business at FDA, we are in the gist business. If we say we can't communicate any bottom line to people, that we shouldn't even try, then we can't communicate. Meaning is going to be part of that for it to be useful. You just gave a good example.

I also want to make a quick distinction between persuasion and not being -- I think sometimes there is a bottom line to decisions. That's not necessarily persuasion. The ball is still in the court of the patient or the public to decide. But when we say that the evidence is 50/50 when the evidence is 90/10, that's biased, not balanced. It's biased to say it's different than it actually is.

DR. PETERS: Kala.

DR. PAUL: This is in relation to what Bill and

Brian said. You have gone from the realm of risk communication into the realm of usability, and that's information. In some respects, that is also the charge of the medication information, which is not only that you know the risk, but that we provide, in the context, usable information. I think this is something that Gavin is very familiar with. When you deal with instructions for people working with devices or working with toys or working with electronics, they may have a risk of getting shocked, but what they really want to know is, how do I use it? What do I do?

There is an element of that that is part and parcel of what we're talking about, but isn't exactly the same as the risk communication that we have been talking about in terms of how you let people know that there is a problem to start with. Certainly, once you have let them know, you have to let them know what to do about it. I think it's an extremely important part, but I would make that distinction.

DR. PETERS: I have to admit, I would just have a broader definition of risk communication that includes these usability kinds of issues. Anytime you are providing information, as FDA does, you do want to make sure that it is useful information and usable information. For myself at least, I would broaden that definition a bit.

I have Noel. Then I would like to see if people can make specifically some comments on question number 5, because we haven't discussed that very much. Noel first, please.

DR. BREWER: Vicki's and Valerie's comments are really standing out to me as being particularly important. Yes, certainly there are some times when we may want to persuade. But I really like this distinction that Valerie just made that there's a difference between having a point of view and trying to sell someone on your point of view, or at least having a point of view and being successful in selling someone on it. It is absolutely the case that there are times when the FDA should have a point of view and it should be unambiguous to the public that the FDA recommends or advocates or is in favor of some particular behavior or ceasing some activity. That part is achievable. I think that need not be a complex or difficult task.

The next task, though, of communicating that opinion in a way that changes what people do is a very tall order. Having effective, persuasive communication is a whole other thing. I don't think the FDA should shy away from it when it needs to happen, but I do think that it's important to realize that it's a difficult thing to do, that it requires special kinds of expertise, and that it's

going to take a game plan.

DR. PETERS: Thank you for that.

Does anyone have any comments on question number 5? Maybe we could start with our guest speaker.

Why don't I go ahead and read the question just so that everybody knows exactly what it is -- about product characteristics that could be more or less risky, depending on how and how much it is used, like fat or sodium or other food components, zinc in denture adhesives, or exposure to radiation in diagnostic procedures.

The question is, how do we communicate about the amount of risk or benefit related to product use when it comes to these product characteristics that could be more or less risky?

DR. ZIKMUND-FISHER: I think I would like to start by just noting that these types of problems tend to have the following characteristic: What we have available to us is a marker that is not risk, but is nonetheless quantitative, whether that be fat grams, whether that be zinc doses, whether that be radiation exposure levels, et cetera. The fundamental challenge often is helping people to understand the relationship between that marker, which they have available to them, and risk. That relationship is not always linear, the way they might think it is. That relationship may have a threshold that they need to be

paying attention to that they do not necessarily know.

If we conceptual those problems as all having similar kinds of characteristics, really what we are talking about is another information evaluability problem. They have information. It's just not very useful information. It's not very valuable information. So the same kinds of issues of what kinds of context we can provide to give people anchors, to allow them to understand this might be risky, this might not be so risky, are where the ballgame is.

To put an example on this, I have particularly followed in the past years the communications related to radiation exposure as the Fukushima plant began to leak radiation and was very intrigued by some of the visual displays and other kinds of things that were circulating. There was one in particular that compared different levels of radiation leakage from Fukushima and from Chernobyl to everyday life events, like taking an airplane flight across the US or eating a banana or living in a brick house or having a dental x-ray. By putting those things into context -- oh, I eat lots of bananas, I flew back and forth -- that at least puts some context on the sense of whether this is an exposure level that, to me, means something at that gist level that is a risky thing or is it associating with things that I don't associate as risk.

That then at least gives us some kind of an ordering and allows us to put this unfamiliar piece of data into that ordering.

DR. PETERS: Thank you. I hope I'm not supposed to be afraid of eating bananas now.

Craig and then Kala and then Bill.

DR. ANDREWS: I agree with what Brian was saying. Sometimes it's nonlinear. In fact, we found that in some of our studies on reduced-calorie/reduced-fat claims. We call them a nutrition elite. That's partly why you see these fixes with the front-of-package symbols and other things to get around that.

I think everybody can't be categorized together on how this works, and sometimes there are surprises. As researchers, we were surprised that -- and this was not the case in products that were viewed as less healthy, but it was the soup example I was giving before. We thought that maybe disclosure that it was one-third less sodium and disclosure that it actually had 500 milligrams, which is high -- that didn't work. We also disclosed it relatively, that it was 22 percent of the daily value. That didn't work as well. But we really needed evaluative information, meaningful information tied onto the number. It was only for those with high nutrition knowledge. I guess you could also talk about numeracy people.

People come in with a lot of baggage, I think, on the different levels. One size doesn't fit all, especially for situations that are a little more challenging in an advertising environment, where you do have the positive benefits out there and some of the gists that are taken from that.

DR. PETERS: Just a quick follow-up question on your comment. If one size doesn't fit all, given that FDA has to regulate, is there a format that does better by some criteria? It could be that it hits more people than not. It could be that it doesn't further disadvantage disadvantaged populations. I'm not sure what the right criteria are. Any comments on that?

DR. ANDREWS: That's very difficult. We have had discussions on that already. I think it was Shonna who was talking about the typical patient, and if you had some sort of facts box with UK interpretations, and then you have value issues and then you bounce away from that with a huge disclosure. with a Web site to have different tiered issues. I don't know how that would all work. It's kind of scary. I think you would need, certainly, empirical evidence to take a look at how consumers actually do it.

I don't know. It's difficult for the FDA, because they probably have a time mandate with all of this.

DR. HUNTLEY-FENNER: Could I ask just a question

of information? Are we talking about persuasive messages or just simple disclosures?

DR. PETERS: I was talking about simple disclosures.

DR. ANDREWS: The other aspect is, too, that a lot of times the stimuli are important. Disclosures and warnings can work with the right stimuli. Quite often a lot of the studies I see are in the context of the brief summary type of thing, where it's information overload, maybe in 5-point font, where it's not clear and conspicuous. That's a caution.

DR. PETERS: I have Kala, Bill, and then Nan.

DR. PAUL: I was thinking of something very simplistic until I was listening to Brian talk about some of the relative things. But let's say we have something, whether it's linear or not -- let's say zinc exposure. If we know that the zinc exposure has a downside, whatever it might be -- let's say it's marrow suppression -- you would have a visual that shows that increasing use or use over time, whatever your two-dimensional characteristics are, results in a higher rate of X. I'm just wondering, is it possible to show this -- we were talking about something increasing with age. Not that the zinc exposure goes up, but it would be something secondary to zinc exposure that goes up. So you have whatever that line would be, but you

have a visual.

You are doing something else with the plane flight. You are giving them the context in which to judge whether that risk is significant. I interpreted this that somebody has already made the distinction that that risk is something to worry about after you get to a certain point.

I'm just asking about the potential for using something visual, in the same way we were talking earlier, to indicate to a person that if they are going to use this product for 10 years, their risk goes up for X. You are not actually telling them not to use it. You are not really giving them a different amount of information. You are just disclosing.

DR. ZIKMUND-FISHER: You're touching upon a challenging issue. Part of my hesitation here is that I think visuals, particularly multidimensional visuals, have potential to show complex relationships, but they also have the potential to draw our attention away from the message that we most want to be focused upon. I think the question has to come down to, which message becomes preeminent in our thinking about what the person needs to understand? Is it that relationship? Is it the level? A representation that does a good job of showing one is less likely to be effective in doing the other. At a minimum, just simply the cognitive demands of focusing your attention on that

relationship may make you less likely to pay attention to some of the other aspects of it that you might want to do.

There are certainly times in which what we really want is to ground people in a mental model's understanding of the relationships that matter to them in their lives. Let's take smoking, for example. It's not just that smoking has potential effects, but duration of smoking matters in a way such that even if you have been a long-term smoker, can stopping after 20 years still provide you with significant benefits? Understanding that relationship, even if you don't understand anything about the levels, may be a very powerful motivator for someone to say, yes, even though I have been a smoker for a very long time, I might be willing to change now, because I recognize that there is a benefit from that action.

I keep going back to what I started with. I think it depends upon goals. In one context I'm being told I have been exposed to some level of radiation or some level of zinc. Should I be worried about this, in the sense of whether this is different than my background levels of exposure? Then comparison against some kind of everyday standard might be really useful to help me know, is this a lot larger, is it a lot smaller, or is it about the same? But if you want to talk about those kinds of behavior relationships, then you're right, that's not what

we need.

DR. PAUL: I think you point up one of the issues that makes this very difficult. If I have been exposed to a level of radiation, it's a static piece of information. If I'm using a zinc product, over time I will have a greater exposure. So the exposure changes. Or if I overdose my child because I can't read a bottle label, or for whatever reason, then the exposure is actually changing.

So there are two different pieces of information. One is, how do you take an exposure that may vary, but at any one time may be static, and give that information and put it in context, versus how do I tell someone that a relationship exists between the length of time they use something, the amount that they use, the amount of ingest -- the sodium in six containers of soup as opposed to one serving?

That was the question. I think I interpreted this as meaning, how do you show that there is something relational about time or extent of exposure and the risk or the chance that some untoward event will happen. That's why I was looking at a simple flat graph kind of representation.

DR. ZIKMUND-FISHER: I think that's a very important empirical question. It's one I do not believe we

have the evidence base for at this point to really answer -- as well, at least, as I would like to be able to answer.

DR. PETERS: Thank you.

We have Bill and then Nan. Then at that point, unless there are some pressing critical issues, I think we may go ahead and adjourn.

DR. HALLMAN: Let me follow up directly on that point and then make one additional point. I think we need to be careful in trying to display this increased risk over time or cumulative risk versus scaring people that any exposure is a bad exposure. We don't want to scare people away from using denture adhesives because they feel like any additional exposure to zinc is a bad exposure. So there is certainly a balance there.

On the issue of trying to put new risks into context, the Fukushima example that you gave, where perhaps the lowest risk is eating a banana -- we have done a little bit of work with that, on trying to communicate the risks of radon, for example. What we found was that we scared the hell out of people about things that they had no idea had radiation related to them. So they learned more about a bunch of radiation exposures that they knew nothing about, and didn't focus on the radon exposure at all.

Which brings me to the point that -- well, two

things. One is that people generally don't walk around with these kinds of scales in their heads. They don't know how much radiation is a banana. People don't walk around with these scales in their heads in which they can put a new risk into context, in general.

Secondly, in choosing the kinds of things to put on that scale, you are also making some value judgments. Perhaps people could take from this that if eating one banana gives you this amount of risk, then, in comparison, exposure to Fukushima is X times this number of bananas. So choosing which exemplars to use -- there is sort of a metacognition that's going on here that we need to be really, really careful of. I'll sort of leave it at that.

DR. PETERS: Very interesting. I wonder to what extent having government standards as the comparison object, as opposed to or in addition to the number of bananas, might be more helpful, perhaps.

DR. HALLMAN: There's certainly a lot of research on risk comparisons. We could talk at length about that. I just wanted to throw that one caution in.

DR. PETERS: Nan.

DR. COL: I agree, I think this is a really different beast, because you are trying to get the concept that this is okay, but there really is sort of a threshold effect when it's not okay.

I was thinking that a nice way of communicating that, and one that seems to be effective, is in the Weight Watchers area, where food is good and starvation is bad, but too much is not good. They have that little, two of this, three of this is okay. But they do little quantiles of when you are exceeding your threshold.

I'm wondering, for things such as radiation exposure -- because people have no idea how much is in anything -- coming up with at what point you start approaching that threshold -- it could be two CAT scans, three x-rays, three chest x-rays -- where you could just sort of add up -- so people could have an idea about whether they were anywhere near that threshold or not, just by converting it. There are only, probably, 10 types of major radiation sources that people have. You could put them in a scale.

But I think other things like that -- some way of saying, if you use denture adhesives, if this amount -- making a clear thing: This is safe and this is when you have to start to worry. But I think making that incredibly simple, again using the way Weight Watchers does it, is a great way, because it works.

DR. PETERS: I think it's a really interesting point. What we require right now around things like, just as an example, acetaminophen is that we expect people to be

able to count up and calculate across different sources. What you are suggesting is that coming up with some sort of simple counting rule --

DR. COL: Exactly, using groups, CAT scans and whatever else might fall into that level of radiation exposure, things that are really minor -- I'm making this stuff up because I don't know how much radiation is in -- but a chest x-ray and dental exposures and whatever others might be -- flying cross-country if you do it -- but the fact is saying that 1,000 of these, 2 of these, 1 of these would put you towards the limit, but simplifying it into really simple categories that people could relate to.

DR. PETERS: Yes, so at least you would have to know, in the example you are using, that radiation exists. First you have to be able to identify the sources and then have some sort of simple counting scheme after that.

DR. COL: And then you could have the bananas as a category. You could say, if you ate 3 trillion bananas --

DR. PETERS: I'm not putting my bananas in that category.

DR. HALLMAN: On behalf of the banana growers, could we stop talking about radiation in bananas?

DR. PETERS: Yes.

Moshe has one more comment.

DR. ENGELBERG: I apologize to this fine committee if I'm being pushy on this. I wasn't clear about the answer. My question is this: Do we have as a committee want to take on the risk, should I say, of creating some kind of taxonomy or story or something that ties together the FDA's situation, the population needs and the corresponding gists, and some kind of diagnostic or prescriptive piece that says, here's the first step in the sequence, or here's a type of risk information -- something that pulls it together, even with our lack of total knowledge and mixed evidence base?

DR. ZWANZIGER: I just wanted to let you all know that I could imagine the committee having that discussion around, say, the table that Brian presented and suggesting, not a decision aid, but a communication-generating aid. There are still going to be exceptions, probably. One way to do that would be to consider it for a future meeting. Another way to do it would be to formally form a subcommittee and have the subcommittee work on it and then bring it to the committee as a whole. Another way to do it is to just tell us today that FDA ought to consider that and then figure out whether we can roll that into our own practices. So there are different options that you could pursue to get us the idea that maybe we ought to think about whether this is a tool we can use.

DR. ENGELBERG: The thing I'm not sure of is if others agree that this is a tool that FDA ought to use. I say yes on any of those three, but I don't know what others think.

DR. REYNA: I think there certainly are data now, and we could begin to build a taxonomy and make some decisions about that. But also Ellen mentioned a possibility that I think is important here to recall, and that is to think about research. FDA is doing some research. To get out some worked examples with some empirical evidence -- we could certainly formulate hypotheses and connect the data we currently have. I have some data, Brian has some data, and various people have data on clinical conditions and risks and so on.

But that's only a beginning and certainly would form a framework for a taxonomy, but then some initial evidence, I think, might be very, very useful.

DR. PETERS: And I think some of that initial evidence does exist. Probably some more would be needed before any kind of a committee recommendation, I think, could come out.

What is people's sense of this in terms of interest? Craig and then Noel.

DR. ANDREWS: I was going to ask Lee, do you know the timeframe that the FDA is under? Is there a mandate

that by a certain time they need to have something back to Congress on this?

DR. ZWANZIGER: The whole topic today is something that is sort of chronically of interest to us. There is no congressional pressure on this particular set of questions.

DR. ANDREWS: Those chronic side effects are pains.

There are a lot of pieces here -- research. I think certainly FDA has to get back to us based on all of our information. I think maybe another meeting, but that's my -- I think it might be done, but I'm worried about the context in a brief summary. I'm very worried about that.

DR. PETERS: Noel.

DR. BREWER: I guess I have a couple of thoughts. I'm not convinced that it would actually work out, but it's interesting to think about and to think through. I'm very swayed by Valerie's comment that we would want to see what the evidence shows.

I can say it in a slightly different way. There are lots of normative standards for how things ought to be in the world. We can say that normatively one should communicate risk or that one should -- not "should," that's not technically normative. But from certain logical principles, you can get to a certain argument. The problem

is, that argument may not actually benefit you in any way in the real world. Without the actual empirical data to describe how the real world is, in response to some of those suggestions that we make, I'm reluctant to go too far down that road. I very much agree that we would want to have evidence behind it. That does, unfortunately, substantially up the ante for the scope of the activity.

DR. PETERS: It sounds like something that maybe Lee and I can discuss further in terms of what might be most useful to FDA. In part, we are an advisory committee. As much as we can, I would like to see us helping FDA meet their goals. Their goals have to do with helping people be healthier, through the communication of risks and benefits in part. So I think we'll take that under advisement and we'll talk about it a little bit further.

Lee had actually started talking to me about it a little bit earlier, but I was not able to listen to different sources at the same time.

It wasn't a suggestion that was ignored from earlier, by the way. We were sort of having a little side conversation about what to do with it. Now we have identified some options, possibly.

DR. ZWANZIGER: Let me just say for the record that what I did say offline was supposed to be what I was trying to put on the record.

DR. PETERS: At this point, unless there are any pressing issues, I want to just say a few brief words, just to get them on the record.

What we have been talking about today are some very, very important issues, but mostly theoretical issues that need empirical research in terms of bringing this theory to application. But some of them are just critical, and they are issues that we have talked about over time in this committee: What are the objectives of the communication? I think Vicki brought this out nicely before: Is it more about persuasion or more about an informed kind of choice? Both of those types of objectives have to take patient needs into account. There are different patient needs, and the communication may be quite different.

The issues that all three of our invited speakers brought up around gist versus verbatim processing of information and the importance of gist processing tells us a lot, in three different areas. It helps us to understand why patients are doing things. Why the heck are you doing that? It helps us to understand some of these things that are surprises to people who are experts.

But it goes beyond that. It also tells us something about how to facilitate helping patients do things better that will meet what their needs are better,

whether that's predigested information -- I think that was the term that Gavin was using -- or helping them get the gist of the information on their own.

In addition to this -- and I wanted to highlight this; I mentioned it earlier -- these kinds of discussions we have been having also help to inform FDA, in the research that they are doing, what should they be measuring in evaluation? These processes are important processes that help to let FDA know whether people are making informed and value-concordant kinds of decisions.

The third thing I wanted to say was just going back to the idea of older adults and the stereotypes that we have, whether we are younger adults or older adults, about older adults, in terms of these robust declines, perhaps, that happen across the lifespan, and this idea -- and I think maybe it was Noel that brought this up -- that older adults actually do pretty well in some contexts. There is this really interesting motivated and strategic processing of information that goes into decision making as well, by the way. We didn't talk about that evidence. But it's not just about memory, actually.

Older adults do have memory deficits. It's something that can be helped by memory aids, for example. People brought up some of those examples. But those memory deficits aren't as much about some information than other

information, or aren't as much in some contexts than others. Older adults can actually be pretty efficient processors of information, because, as Valerie pointed out, they are pretty expert in life and they have that expertise that they bring to bear with them in the decisions that they make, including in food-related kinds of decisions.

The last thing I wanted to say -- and this is something that we have hit on in FDA meetings over time, and I wanted to emphasize it here again -- is the idea of consistency, and consistency in risk and benefit communications that exist over time, in order to build understanding the population, but also to build trust in the FDA as a good information provider. It comes out in a couple of different ways. I believe Kala mentioned that FDA has gotten much better about using consistent labels. I think you were the one who brought up that point. In any event, that use of consistent labels is very important. The idea of using different formats perhaps across different venues -- or things that are nominally consistent at least -- across promotional materials, but also print advertising -- as much consistency that can be built into the overall system is really going to help facilitate that comprehension and use of information that we want patients to have. They are going to understand more over time.

Finally, I want to hit on something that, I

believe, Craig and maybe Nan talked about before, which is this idea of a consistent spokesperson. I realize we have been sort of hitting FDA over the head with it, but I would like to continue the tradition. A consistent spokesperson is going to build trust in FDA as an information provider. That's going to be something where people are going to say, oh, I have to listen to this person, and maybe they are going to increase the depth with which they process the information that that person is saying. So I wanted to emphasize that once again.

Just in closing, I want to thank you audience members for sticking with us even throughout lunch. We appreciate it. We wanted to try to get done a little bit early today, and we appreciate your doing that. We hope you got something from the conversation.

I would like to thank our three speakers, both the one on the panel and the two people who are off the panel, for taking the time to predigest some of this information for us and present it to us in a comprehensible form. I thought you guys, all three, did a terrific job.

I would like to thank the committee and also the FDA for allowing us to actually consider these really interested issues, to do a little brain candy science today, and to think about that, because it's fun and interesting, but also because it's important, and it's

important to what FDA does in terms of looking at some of the general communication issues that FDA faces.

So thank you guys very much. It was an enjoyable session.

DR. ENGELBERG: A thank you to Ellen, first time chairing. A great job.

(Whereupon, at 1:00 p.m., the meeting was adjourned.)