UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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RISK COMMUNICATION ADVISORY COMMITTEE

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February 16, 2016
1:00 p.m.

FDA White Oak Campus
10903 New Hampshire Avenue
Building 31, the Great Room
White Oak Conference Center (Room 1503)
Silver Spring, Maryland

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PAUL G. HARWOOD, Ph.D., M.A.	Member
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M E E T I N G

(1:00 p.m.)

DR. BLALOCK: I would like to call this 22nd meeting of the Risk Communication Advisory Committee to order. And for the record, we're starting today's meeting at 1 p.m. due to inclement weather.

I'm Dr. Susan Blalock, the Acting Chair for the Committee. I am a Professor and Vice Chair in the Eshelman School of Pharmacy at the University of North Carolina in Chapel Hill. My area of expertise is behavior change and medication risk-benefit communication.

And I also want to sidestep just a little bit from the script to just thank everyone for the extra effort that it took to get here for those who, you know, came from out of town, and also the extra effort that was required by the FDA staff including in the early morning hours today to keep the ship on course.

So I note for the record that the members present constitute a quorum as required by 21 C.F.R. Part 14. I would also like to add that the Committee members participating in today's meeting have received training in FDA laws and regulations.

For today's agenda, the Committee will discuss recent developments in risk communication and related sciences and possible approaches and applications in the context of FDA communications. Before I begin, I would like to ask the distinguished Committee members and FDA staff seated around the table to introduce yourselves. Please state your name, your area of expertise, your position, and affiliation.

Would you like to start?

DR. PLEASANT: Sure. I'm Andrew Pleasant. I'm by title Senior Director for Health Literacy and Research at a nonprofit based in Tucson, Arizona called Canyon Ranch Institute. For these purposes, it's probably also worth saying, I am a member of the scientific committee of the Public Communication of Science and Technology Network, which is an international network of scholars like ourselves. And the conference is in Istanbul in April. I hope to see you all there. And I'm also a member of the Institute of Medicine Roundtable on Health Literacy. Thank you.

DR. ZAVALA: Hi, my name is Mirian Zavala. I'm an Assistant Professor at the College of Mount Saint Vincent. And my area of expertise is health disparities.

DR. KREPS: Hi, my name is Gary Kreps. I am a University Distinguished Professor of Communication at George Mason University, where I direct the Center for Health and Risk Communication. And my work focuses on the reduction of health inequities through dissemination of relevant health information.

DR. LIU: Hi, my name is Brooke Liu. I'm an Associate Professor of Communication at University of Maryland. And my area of expertise is risk and disaster communication.

DR. SNEED: I'm Jeannie Sneed. And I recently retired as a professor from Kansas State University. And I'm now doing some private consulting. My area of expertise is food safety.

DR. KRISHNAMURTHY: Hi. I'm Partha Krishnamurthy from the

University of Houston, Bauer College of Business. I do research on decision making. I also hold joint appointments at Baylor College of Medicine and the University of Texas Medical Branch.

MS. DUCKHORN: Good morning. My name is Jodi Duckhorn. I'm the Director of Risk Communication here at the FDA.

DR. RIMAL: Good morning. My name is Rajiv Rimal. I am the Chair of the Department of Prevention and Community Health at George Washington University, up the street. My work is in social behavior change communication, most of that in Africa. Currently, I'm working in Ethiopia.

DR. YIN: Hi, everyone. I'm Shonna Yin. I'm an Assistant Professor of Pediatrics and Population Health at the NYU School of Medicine. And my area of expertise is health literacy, with a particular focus on medication safety.

DR. DILLARD: Hi, my name is James Dillard. I'm a Professor of Communication Arts and Sciences at Penn State. My research interest is the role of emotion in persuasion.

DR. COHEN SILVER: Hi, I'm Roxane Cohen Silver. I'm Professor of Psychology and Social Behavior, Medicine, and Public Health at the University of California, Irvine, where I study how individuals and communities cope with disaster.

DR. HARWOOD: I'm Paul Harwood. I'm the Market Research Lead at Twitter. And my specialization is overseas social media.

MS. FACEY: Natasha Facey, Acting Designated Federal Officer for the Risk Communication Advisory Committee, FDA.

DR. BLALOCK: And next, Ms. Facey, the Designated Federal Officer of the Committee, will make some introductory remarks.

MS. FACEY: Good morning. I will now read the FDA Conflict of Interest disclosure statement.

The Food and Drug Administration (FDA) is convening today's meeting of the Risk Communication Advisory Committee under the authority of the Federal Advisory Committee Act of 1972. All members and consultants of the Committee are special government employees and are subject to federal conflict of interest laws and regulations.

The following information on the status of this Committee's compliance with federal ethics and conflict of interest laws covered by, but not limited to, those found at 18 United States Code Section 208 are being provided to participants in today's meeting and to the public.

FDA has determined that members and consultants of this Committee are in compliance with federal ethics, conflict of interest laws. Under 18 U.S.C. Section 208, Congress has authorized FDA to grant waivers to special government employees who have financial conflicts when it is determined that the Agency's need for a particular individual's services outweighs his or her potential financial conflict of interest.

Related to the discussions of today's meeting, members and consultants of this Committee who are special government employees have been screened for potential financial conflicts of interest of their own as well as those imputed to them, including those of their spouses or minor children and, for purposes of 18 U.S.C. Section 208, their

employers. These interests may include investments; consulting; expert witness testimony; contracts/grants/CRADAs; teaching/speaking/writing; patents and royalties; and primary employment.

At this meeting, the Risk Communication Advisory Committee will discuss recent developments in risk communication and related sciences and possible approaches and applications in the context of FDA communications.

Based on the agenda for today's meeting and all financial interests reported by the Committee members and consultants, no conflict of interest waivers have been issued in accordance to 18 U.S.C. Section 208.

We would like to remind members and consultants that if the discussions involve any other products or firms not already on the agenda for which an FDA participant has a personal or imputed financial interest, the participants need to exclude themselves from such involvement and their exclusion will be noted for the record. FDA encourages all other participants to advise the Committee of any financial interests, financial relationships that they may have with any firms at issue.

Before I turn the meeting back over to Dr. Blalock, I would like to make a few general announcements.

Guest speakers were invited by the FDA to provide presentations in today's meeting. Each invited speaker's views and opinions do not necessarily represent the views of the FDA. Handouts for today's

presentations are available at the registration table outside the meeting room.

The FDA press contact for today's meeting is Angela Stark. Members of the press, please sign the sign-in sheets located at the registration table. I would like to remind everyone that members of the public and press are not permitted in the Committee panel area, which is the area beyond the speaker's podium. I request that all reporters wait to speak to FDA officials until after the panel meeting has concluded.

To help the transcriptionist identify who is speaking, please be sure to identify yourself each and every time that you speak.

Finally, please silence your cell phones and other electronic devices at this time.

Thank you. Dr. Blalock?

DR. BLALOCK: Next, I'd like to invite Ms. Jodi Duckhorn to provide introductory comments.

MS. DUCKHORN: Welcome Committee members and consultants, guest speakers, and members of the public to the Risk Communication Advisory Committee. I am truly thrilled to say that despite the weather, everyone has arrived safely. Thank you for your commitment and your flexibility. It has been a challenging past couple of days.

Having said that, Malcolm Bertoni, the Associate Commissioner for Planning, was scheduled to provide opening remarks. Ironically, he is stuck out of state due to weather-related travel issues. I am Jodi

Duckhorn. I am the Director of the Risk Communication Staff responsible for coordinating this meeting.

The purpose of this meeting is to present and discuss recent research in the field of risk communication to determine how it can be applied to FDA's communications. As an agency that is charged with regulating many U.S. consumer products, it is beneficial to consider the latest research in risk communication.

Over the course of this two-day meeting, you will hear presentations from guest speakers. These speakers were invited by the Agency to present the latest science in risk communication. We contacted numerous national experts in the field of risk communication and related sciences to participate in this meeting. These experts were suggested by many of FDA's social scientists and health communicators.

We are pleased that of those contacted, twelve national experts were available to participate in this two-day meeting. Each guest speaker will present on state of the science research in risk communication and related disciplines.

After a series of presentations, the Committee will be asked a very important question. How can the FDA apply the research presented within the context of FDA communications? The Committee's discussion and recommendations from this question will help the Agency develop communications that are effective in reaching consumers of FDA-regulated products. FDA is here to listen to the Committee's prolific discussions.

Please note: This meeting is structured in a way that we cannot

respond immediately to the Committee's discussion and recommendations. After the meeting, we will do our best to implement recommendations within our regulatory authority.

A special thank you to Dr. Blalock for serving as Acting Chair and Ms. Facey for serving as our Acting Designated Federal Officer. Thank you to all of the guest speakers for taking the time to share your important research with us. And thank you to the Advisory Committee members and consultants for taking the time to discuss how FDA could utilize this important research.

DR. BLALOCK: Thank you. We'll now move to the first session on Strategies and Tactics for Effective Communication about Risks and Health. We'll hear presentations from Dr. Benjamin Chapman followed by Dr. Timothy Coombs. At the conclusion of each presentation today, we'll take clarifying questions from Committee members.

And I do need to remind public observers at this meeting that while the meeting is open for public observation, public attendees may not participate except at the specific request of the Committee Chair.

Dr. Chapman, you may approach the podium and begin your presentation.

DR. CHAPMAN: Thank you so much for the invitation to share some of the work that my group is working on and some of the insights that I guess we've gained over the last 8 or so years as we've looked at social media. A little bit of background, just on me, to give you a frame of where I'm coming from from my presentation today.

I have an undergraduate degree in molecular biology and then

two -- a master's degree and a Ph.D. in plant agriculture, although I did very little with plants. I've worked only in food safety for the past 15 years, microbial food safety specifically, really from farm to fork, and with a focus in the risk analysis paradigm around communication and management.

For the past -- well, for the past 11 years, I've co-published a blog called barfblog. And if you're not familiar with it, it's a place where a colleague and I curate information around food safety, and really it's to guide or engage people around food safety. And, in fact, that's where a lot of our research comes from is in the on-the-ground aspect of risk communication.

As far as financial disclosure, I've listed some projects here. Most of the work that you'll see today comes from two federally funded USDA grants, although I have received funds from other entities.

I really wanted to start off my presentation today with a short discussion around certain issues that happen and pop up. And I'll provide an example that's very pertinent, I guess, within the public realm, and it's around an outbreak or multiple outbreaks of foodborne illness that have been linked to one specific business. Really, if you look at how the social media aspect of this outbreak or these set of outbreaks have played out, there is a really interesting risk communication situation arising. We have sort of a high-risk type of product, very trusted type of brand, and over the course of a 6-month period, six incidents leading to a few hundred illnesses. As part of the recovery, the brand went to offer free items. And the conversations in

social media, you can see a screenshot from Facebook here, really do impact the -- or at least the self-reported choices -- but do get into what some of the public perception is. So as you can see, the company provides a free burrito. And there's information about isn't that the place that everyone's getting sick at?

Can also see other just -- and this is a quick look at some of this discussion -- really the focus has been around the risk of *E. coli* and the individual brand. So even in the recovery aspect of things, we see calling back to public perception.

A more interesting situation is some of the missteps that can happen when it comes to recovery. And there was a large string of social media looking at a mistake because the company had provided someone's number. And those numbers were misdialed, and texts were sent to the wrong person. And that went into a whole other conversation. The last one that I show you here is really just a screenshot of Twitter feed over 2 minutes in recovery, where you can just see the vast amount of conversations that are happening around this brand.

And I only use this example to highlight some of the work that we've published around, which is how quickly messages and conversations happen, how much information and misinformation is shared, and how that really can shape the public discussion and engagement.

There is some work done a couple of years ago by a public relations firm. And that firm published the information, termed a group

of online individuals, a subsection of those who were speaking online, as Food eVangelists, "e" being the operative portion of that because they're online; that's the joke. In this subsection, Ketchum, the public relations firm, felt that that subgroup generates over 1.7 billion conversations online about food weekly. And they don't see themselves as "activists," as being entrenched in ideals or beliefs around certain issues. What they are -- what they do see themselves as an interested public. They have expectations that food companies and regulators will engage with them and discuss food safety related issues. And they are, as we've seen in other studies, really have become nodes for social amplification.

And this working -- I do a lot of work with local regulators, state regulators, as well as the food industry, small businesses, all around from farm to fork. This aspect of food evangelism has shocked the individuals who are often tasked with responding to it. They just don't have the infrastructure or the focus to engage and respond.

So I'm not going to bore you too much with sort of the -- any of the theoretical frameworks around risk communication, but I will draw to something that we build a lot of our work on, which is this idea of the information vacuum, where we have a scientific assessment of risk and public perception of risk. And in a time of crisis or in a time of very quick conversations, that centerpiece gets filled very quickly by whomever is there. And I think that's one of the reasons why I wanted to use these examples and bring this to this group's attention is that information vacuum is being filled within seconds of events that are

happening in a social media framework. And that's a good thing, and that's a bad thing.

It's a very good thing from access to information and engagement. It's a bad thing when we're not prepared -- and I say "we," I mean sort of everyone who's involved in food safety -- prepared to be part of that information vacuum.

Some of the things that our work has really been based on is I guess some classic communication work looking at using stories and narratives which are better than statistics, putting food safety into context, generating dialogue in surprising messages. And it's really the narratives and the dialogue that I want to highlight as the 15 years that we've been following food safety social media, that really is the area that we see as the most effective way to engage.

And generating dialogue, I'll skip forward here to your sister agency's work around why CDC uses Twitter. The idea is to provide openness and transparency around what an agency is doing to get really into speaking the audience's language. And I think that if there's anything that we've seen in our work at looking at social media of what goes right and what goes wrong, it's when individual communicators or organizations that are communicating try to grab buzz words and engage in a way that seems like it's really cool and hip. It's important that as FDA goes forward with this area, that they engage with individuals who are already part of the social media world as part of their lifestyle so they understand where communication goes and how incidents play out.

I've heard a couple of the other speakers mention this. It is difficult to distill down some work into 20 minutes, so I'll attempt to do that in one slide here. Two years ago, my group published a paper looking at what we know about food safety and social media. And I can distill it down to these five words. It's really difficult to be part of the social media world if you're not creating either messages or material, and messages and material that are streamlined or specific to the social media paradigm.

It is also really impossible for communicators to be part of this world if they are not actively participating in it. And I'll give you an example of trying to address a situation through social media, and that situation, whether it be a crisis, whether it be an outbreak or a recall setting, being the individual communicator's or the individual agency's first hit on social media. They're not a trusted source. You have to participate all along. And so in non-crisis time and crisis time, but they've got to be there sort of all the time. And this is something that, as I work with regulators quite a bit, is something that isn't always within the mandate.

Engagement is the other -- in another step that we've pulled out of our work. The world of food safety is really good at creating things like brochures and fact sheets. But those are, as you all know and as the group knows, those are one-way communication tools. Here's some information; let's put it out there. The world of social media doesn't operate that way. It operates on a give-and-take dialogue, an engagement over time. And not having a really good answer to a

question, being able to go back, find out what those answers are, and going back to the social media world. It is a constant cycle of providing information, listening, and coming back and forth.

Moves into the next piece from our work, which is really listening. Social media is often seen as sort of the bane to many individuals' existence, as they've been tasked with having to monitor it. But it really had the opportunity to show and direct where public discussion is and where public perception is around certain items. So we can get ahead of things that may not be seen right now in surveys or in other mechanisms.

And the last piece is, it is pretty hard to do. It's not an easy world to get into.

I want to highlight one more example of where social media plays a large role in discussion. Some of you might be familiar with a situation that occurred in 2011 around lean, finely texturized beef. It is known affectionately on the Internet as pink slime. The issue wasn't around really what was being told. There was coverage of this type of product in 2009 in the *New York Times*, which is a pretty sizable media source. It was on ABC TV in 2011.

But the public outcry did not occur until it hit Facebook. And I share a screenshot here of one hour following a story on 20/20, where 63,000 shares on Facebook hit. And that really is what pushed things over the top. And the criticism that we've provided in our research is really for the industry and the communicating group to say, let's not forget where the issue happened and where the conversation

happened. It was on Facebook, but really it took three weeks for a response to go through social media. And by that time, the damage had been done.

I'm going to switch gears here a little bit and tell you a little bit about some other research that my group has conducted. So we'll move out of the social media and move into communication in restaurants. And I bring this to you as -- as you may know, the FDA, every 4 years, puts out something called the model Food Code. And that Food Code dictates -- well, sets out guidance which can be adopted by states on how restaurants and other food service entities should be regulated. In that guidance document, there is an area on consumer advisory. And so my group has looked at consumer advisories and looking at the communication both on menus and, more interestingly to us, the communication that occurs between a server and an orderer or a patron of a specific type of item.

So you can see here, at the top of my slide, a standard disclosure. And the Food Code talks about the disclosure of risk around eating undercooked foods as well as a reminder. And that reminder is largely done in this fashion. Here is a disclosure: "In compliance with new Food Code regulations, we remind you that consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness." And so there's our disclosure. Our reminder is in the form of this asterisk here that you might be able to see where my laser pointer is. Right beside where it says, "Order it RARE!"

And so what we did is engaged with secret shoppers throughout the United States to go and purchase and engage with servers in an actual setting. And we used colleagues who were working on a large food safety project on *E. coli* in beef to go to these restaurants. We went to 270 restaurants nationally, chains and independent. And we really sat down with a script of unprompted and some prompts on how do we gauge the risk communication ability of servers.

To give you a sense of what an undercooked hamburger looks like, there's one. The thing that's kind of interesting about this project for us is that undercooked has a very specific definition in the Food Code that has to do with temperatures. That's not very practical in restaurants, because when you order a burger, you order them usually medium rare, rare -- well, that's a very risky burger -- well done, medium. And so there aren't -- those correlations between temperature and doneness and quality aren't there. So that's a challenge for us. So this is a well done burger that was purchased.

Engaged with 30 secret shoppers at 265 restaurants in 7 locations. We ordered medium rare burgers at the end of a meal. So here's the -- set the stage for you. Our shoppers had lunch. At the end of that lunch, they said, oh, I'm going to order a burger to take home to my significant other, my spouse or my friend. In fact, actually, can you make that two? And I'd like one that's well done and one that's medium rare.

And we left it there as an unprompted, let's see what the responses are. If there was no prompt, we then -- or if there was no

response to that, we then prompted with, oh, you know what, is it a good idea that I order that burger undercooked? Is that -- is there any risk involved with that? To really gauge the conversation. And then the some of the limitations of our study was we couldn't record, we had to trust our secret shoppers that they could then go recall these conversations.

And what we found in this work is in review right now, so unfortunately I can't share the paper with you. But we saw some major gaps in server knowledge and risk communication. Here are some of the numbers. In the majority of servers -- the majority of servers indicated an unreliable method of doneness. So they said it's okay, you can order that medium rare because -- and we use -- we look at it, and if it's not pink, it's safe, which is not a scientifically based message. And we found statistically significant differences between chain and independent restaurants, with chains providing better communications.

And I won't bore you with too many of the details. But I will give you some qualitative data that we've included in this research to give you an example.

"Eating a medium rare burger is perfectly fine; it's not a problem." And then the server went on to tell our secret shoppers a story about her sister eating a barely browned beef, raw in the middle burger while she was pregnant, and she is fine.

"Medium rare is safe. It'll be cooked to about 135 degrees." And that is a well undercooked burger.

And, again, these are very striking. So what we saw was 70

percent of servers argued or were in conflict with their own menu risk disclosure.

"Ingredients used are good quality; it's not risky as long as the outside of the burger is cooked. It's safe because that's where most of the bad bacteria is," which is not correct.

And then we did -- you know, we do have in our research some positive results. "I was actually going to tell you about that." This is an unprompted one. "We have to remind you that there is a risk when you order an undercooked food. You can still get medium rare. I just need to let you know about that." So we did see some positive, but in the -- in our work, we really had about 70 percent.

And I wanted to share this with you, because it is all well and good that we have good disclosure of risk as a risk communication vehicle in the Food Code. Operationally, it doesn't work. And it's not practical because what we are requiring is this menu piece to tell people what happens. We don't require anything verbal. And then there's not a level of training for servers. And it may surprise none of you in the world of risk communication, but servers really aren't great risk communicators. They're really there to sell burgers.

And with that, and 29 seconds left, I will end my presentation. So thank you very much.

DR. BLALOCK: Thank you for your presentation, Dr. Chapman. Do any members of the Committee have a brief clarifying question for Dr. Chapman? And here, we're just looking for questions that would be specifically to clarify a point made by Dr. Chapman or any of the

materials that were read prior to the presentation. Dr. Zavala?

DR. ZAVALA: Yes, regarding the servers and their age as a way of looking at risk, and their reaction is consistent with Dr. Reyna's study in 2009 that they're looking at more of the odds of a risk occurring one time, two times, or three times. And their age of -- the brain development at that age, up to the age of 25, is not the same as an adult, so this behavior is sort of consistent with that study.

DR. CHAPMAN: Yes, I don't know if that's a question. It's a comment, yeah. I'll take the time. Yes, it is. We unfortunately, and it has to do with sort of the logistics of the study that we ran, we weren't able to get full demographic information about our servers. We did record gender, but age is difficult to judge for lots of reasons. But, yeah, we're familiar with the work that -- it's not, it's not surprising, but what we -- what my group, I guess, is all about is operationalizing some of the risk communication work that's out there and confirming or refuting some of that work. And so, yeah, in this case, I think you're -- we're familiar with that. Thank you.

DR. BLALOCK: Dr. Krishnamurthy?

DR. KRISHNAMURTHY: I was curious about one element of your study which I thought was very interesting that you said, after ordering and having your food, then you kind of said that you want to take it to go. How do you think that would have changed the dynamics if you had done it at the very beginning?

DR. CHAPMAN: It's a great question. It's one that we wrestled with early in our study, in our study design. And it had to do -- and I'll

come back to the risk calculation -- what I wanted to not do, as the PI in this study, was expose any of our secret shoppers to something that may be risky just by being a data collector. And so I -- it's a limitation that we've talked about because it doesn't fully simulate what that ordering process and eating it on site does. But it was sort of the best that we could do.

We did have some qualitative results that the servers, especially at the non-chain restaurants, felt that the quality of the product would be poor if it was taken home, if it was take-out. So they, in fact, tried to talk us out -- it had nothing to do with safety, but they were like, that bun is going to get soggy, so you know, just want to remind you of -- that the quality is going to go down. So even the servers were, in those cases, were aware of a difference in just a standard ordering. It's a great point.

DR. BLALOCK: Thank you very much.

DR. CHAPMAN: Thank you.

DR. BLALOCK: Dr. Yin, one final question.

DR. YIN: Hi. I was struck by a point you made that organizations like the FDA would need to participate in social media all along, both in crisis and non-crisis times. I wonder if you have an example of this being done successfully, where an organization was able to kind of embed themselves in social media and then were able to effectively act during a crisis time.

DR. CHAPMAN: Sure. Yeah, no, it's a great question. I would go back to the example of CDC. Really -- and their use of Twitter over the

past 6 years. There's been an encouragement within that agency to allow for individuals working to write blog posts and to engage with individuals on Twitter specifically around what CDC is doing. And not in a, hey, there's an outbreak going on, but here's a day in the life of what happens at CDC. These are the things that are going on.

Those individuals and those groups that have been successful -- and I can only sort of look at it in the sense of the food safety community -- they've become trusted individuals that become go-to when media have questions and when individuals are asking questions online. So they have a level of accessibility, and I think it's been done very, very well at CDC.

DR. YIN: Great, so you envision it kind of coming from the CDC versus identifying people out there in social media currently --

DR. CHAPMAN: Correct.

DR. YIN: -- to become liaisons.

DR. CHAPMAN: Yeah, yeah, yeah. And so please let me clarify that. Yes, exactly, I think that -- and I made the point, but I might not have articulated it very well that it's important to have those who are engaging as risk communicators on social media on behalf of FDA, that they are in the lifestyle of social media, that they have an individual -- I don't know -- persona already there and that they are able to navigate the system. So no, not going outside and finding individuals that are already really good at social media and saying here's an FDA message, but in fact, using employees that are already good at social media. Thank you.

DR. YIN: Thank you, Dr. Chapman.

DR. CHAPMAN: Thank you.

DR. BLALOCK: So now we'll turn to our second presentation, Dr. Timothy Coombs. Dr. Coombs, you may approach the podium and begin your presentation.

DR. COOMBS: I'd like to thank the Committee for giving me a chance to talk about our little study. This is a situation where 20 minutes is actually a lot of time because it's fairly short in terms of what we did.

My background, I come from crisis communication, primarily from the corporate side. So I'm interested in looking at how organizations talk and what sort of channels they use during crisis situations. And a product harm situation involving food tends to rise pretty high because there's really an important threat there to public safety as well.

And just kind of a little bit of background about where we started with this study. What I have up here is the idea of, well, who recommends that social media should be used during food product recalls? In public relations, which is an area I teach in, there seems to be an obsession with social media at times. And everyone should be out there saying everything on social media. No, that's not really the answer to everything.

But if you look at first the food industry white papers, they are recommending the use to their own members, social media during a food crisis, food recall situation. Also the U.S. Consumer Product Safety

Commission recommends its use as well. So if you read through these documents, you'll find a lot of groups saying you should be using social media during food recalls.

I thought, well, do they actually use that, because I would check every so often. You know, I get the alerts on my phone when something's been recalled. So I'd go out to Facebook, see if the company had a Facebook page. But that was kind of anecdotal. Then I ran across a study that said that how companies had just really embraced the use of social media during their recalls. I thought that doesn't seem right. Anecdotally, that's not what I was finding.

So I was able to put together a small team, and we did some research studying this. And give you kind of just a little bit of structure how it is. This is primarily a tactical approach that we were using, setting the tactics, but we'll come back to the strategy that's related to those tactics at the end.

The basis of the study is we looked from October 2014 to February 2015 at food recalls. And we were looking at ones that had been publicly announced, so using a variety of sources, when they were announced and they were looked at. During that time period, we found 69 food recalls. And they were coded for an announcement on websites, Facebook, or Twitter.

So when the announcement was made that the company had a recall, then went out and searched. Do they have a website? All right. Did they mention the announcement or not? Do they have a Facebook page? Mention or not? Pretty basic coding. And the same thing for

Twitter. Do they have an account? Did they mention it or not? And what we did is we looked for a 48-hour time period because that's when you would expect it to appear and for it to have its most impact was within that time frame. And also, when I come back to the strategic part of it, the 48 hours also make a little bit more sense for it.

So this was a coding process, and it sounds quite simple, but it actually gets, as my one honors undergraduate student who was working on the project found out, it takes a lot of time because you're looking through a lot of stuff trying to find it. The hard part is oftentimes companies will use their websites, but they embed it somewhere that you would never expect to find it. And she had to look very carefully oftentimes for that.

The usage from the 69 that we found, so you can see about 53 percent actually posted it to their website, and of those 48 percent would put it on their homepage. So you would go to the site, right there on the homepage, there's a link talking about it. If they weren't there, in most other cases, it was in their section on news releases. That's fairly common instructions for organizations to have. They have a news release section, and they would drop it into there as a result. There were a few other random places companies put it, but mostly homepage or in the news release section.

We looked at Twitter. This was not overwhelming, as contrary to the researchers that said was widely used in recalls. We only found three that used it on their Twitter page that mentioned they were having a recall. Facebook page, a little bit better, four. So from 9 to 10

percent, but really not really that big of a difference. And then if they had all three digital channels, did they use all three digital channels? Only three companies did. There was a case where a company used its Facebook page but didn't use it on its Twitter page for a result.

Tried to extend this study and kind of updated it. Now, we have a little over 100 there. We've actually found it's starting to drop in terms of the website, but that could just be that during January and February this year, companies weren't using their websites as much. We're seeing about the same rate of usage in terms of Twitter, still about 11 percent. Facebook, 6 percent -- 9 percent. And then all three digital channels, 9 percent is that as well. But it's a very small number.

So we can't really, at this point, look at the data and say is there something going on here? Is there a pattern in those who use it and don't use it in terms of the industry, in terms of the type of recalls being done? We can't do that. There's not enough data for that yet, unfortunately. And we have pulled them out, and even at 6, nothing is clear. They're all over the board. It could be a level 1; it could be a level 3. And the industry, they could just be selling nuts mostly online versus a large chain. It just -- there's no pattern emerging yet from what's going on there.

And this led us to start thinking. Well, gee, why are companies so reluctant to use their social media to get the message out? In particular, what you find is a number of these companies, when you go to their websites and you see their Facebook pages, they are talking about how much they care about the health of their customers and how

important health food is to them. Some of these companies are specialized in healthier types of foods. Yet, it's striking. They don't tell their customers, who are going to their sites, that they had a recall, something that actually could threaten their health in a different way, but it threatens their health. And, again, I want to come back to some very recent research that can add to sort of more of an urgency for food companies to talk about this. So not much is going on.

If you look to the data from marketing. When marketing looks at product recalls and they talk about sort of what you would do if you're going to be a proactive communicator, sometimes called a super effort in a recall, what they find is that has a negative effect upon stock prices, whether it's a general recall, there's some data on that, and one just on food recalls relating only to foodborne illnesses, that the more you talk about it, the more that can harm your stock prices. So that would be a motivator not to do this.

So if your company's saying, oh, if we don't talk about it, maybe people don't find out about it, and then they don't get upset about it, of course, you're hoping, then, that no one gets sick or dies from your product because you weren't more actively involved in trying to get it recalled, because at the same time, the idea of going out and being very proactive can have a short-term negative effect on your stock prices. It can have a very positive effect upon your reputation when you do this and your relationship with your customers. So that's what we find.

So why use it? Well, the obvious one is customer safety. If I can make just one more person aware because I put it on Twitter or

Facebook that they should not eat this product and not get ill, I think that's important. But there's also the idea of corporate reputation protection. And what we're finding both from academic research and from industry research, that companies that go out and are very proactive in their crisis communication see their reputation come back faster and come back stronger.

And a very important feature of that is the concept of stealing thunder. And we'll be hearing from legal later on, or actually first thing tomorrow morning. This is a legal concept, stealing thunder, and it comes from the idea of, well, if I have a case and I'm defending my client and I know there's a weakness in my case, I want to be the first one to present that weakness because it'll do me less damage than during the trial. And that's where this concept comes from.

And crisis researchers have examined that in terms of who releases the crisis information. And what they find is that a crisis inflicts less reputational damage when the organization is the first source to report the crisis. And this is a very robust finding. And if you look across the crisis literature, I think probably stealing thunder has the strongest effect and is the most reliable effect that we have with crisis communication. And the research has been done here in the United States. There's been some done in Asia, some done in Europe as well, fairly extensively on this. Stealing thunder has been used in a variety of different crises, including food safety recall situations, where the stimulus was the recall of, in this case, bagged lettuce by a company that actually had had a crisis as a result of it. And the findings are there.

It does have a benefit for the reputation.

And the reason this is important is this can be an encouragement to an organization. Because you can say, well, if you're worried about your stock prices, aren't you really worried about your reputation and also your relationships, because those are intangible assets but they're very important assets now in the corporate world? So need to kind of give them a push in that direction. Stealing thunder can take a tactic, using social media, and turn it into a strategy.

And the reason that's the case is, if you look at the data that's been generated from social media users and news media use over the past few years, somewhere around 30 percent of the people who are either following an organization on Twitter or like them on Facebook get most of their news from that social media source. So the odds are great if the organization has had a product harm recall with their food situation, and they put it out on their social media, the people who are following them closely on social media, they're going to see that as a first source, even if the news -- Even if they've already officially posted it by the government or the media have reported it, 30 percent are likely to have found it there on social media. So the organization, by using social media, has an inherent chance to steal thunder in that even.

And that's why I say you take a tactic and you turn it into a strategy, because I'm using something that's basically tactical, my social media channels, and I'm using it now as a strategy to try and steal thunder and get out in front of the situation.

And, again, that's another reason we limited to 48 hours because of the stealing thunder effect. Once you get past that time period, people are less likely to find the organization as the original source for all of this.

And I just wanted to add one additional piece of information that came in recently. Deloitte, which is a strategic communication company, recently released a report about what drives food purchases. And it said, yeah, there are still the old drivers such as price, quality, and so forth. But what Deloitte identified were some new drivers that were emerging, and particularly, they didn't give the percentages, but they're saying it's a growing percentage of customers who were in this category, these new drivers.

Among the new drivers, two are, I think, are related to what we're talking about here today. One is transparency. They want transparency from organizations. And what they mean by that is that they provide a lot of information about their products across all communication channels. So if I'm an organization and I don't communicate about my recall through all my channels, it's a violation of transparency. And for some of those consumers who are not driven by these new drivers, that could be a mark against me. So, again, this might damage my relationship.

Another driver is safety, and they define safety very broadly in this category. And, again, if I'm not talking about safety in all my situations, is that not then problematic for my relationship with my consumers? And I think particularly of those companies that talk about

their concern for the health of their consumers and the healthy food they're producing, then not telling them that there's a threat to their health through the product that's being recalled that's out there.

So I think these coming together with what we've just heard previously, there's this ongoing conversation about food that's very active out there that organizations are at risk if they don't start thinking more about food safety and how they can present that during a food recall with the use of social media, because while it might help them short term protect stock prices, long term there can be damage to the reputation and the relationship with stakeholders that could be far more harmful to the organization than just a short term drop in stock prices.

As I said, it's a short study, so I can stop there.

DR. BLALOCK: Thank you, again, Dr. Coombs. Again, does anyone on the Committee have a brief clarifying question for Dr. Coombs?

DR. PLEASANT: Sure. So I just want to expand a little bit, because this evidence has been out there for quite a while that it might be a good thing to do but yet corporation after corporation continues to not do it. Could you touch on the why?

DR. COOMBS: That's the hard question to answer, why. One of the things we're looking at is the fact that -- we want to go back but take a longer process of going back and coding the social media -- that many of these companies are only seeing their social media as a marketing tool. It's a one-way marketing tool. So they don't think at all

to add that into their thinking when they're doing the recall situations.

And that might be probably a pattern that, when you're talking about trying to engage them, I think the companies that are actually effectively out there doing engagement through social media -- and that's very rare; we have other data shows companies generally don't engage through social media -- but those are the companies who are then putting the information out there. The ones who are just seeing it as marketing, it's just not part of their thought process when they're doing their recalls.

DR. KRISHNAMURTHY: Following up on that thought, I think it is -- you're absolutely right, and I think the findings are quite fascinating that -- and your thought that marketing should actually take a long-term view of the brand and they would actually jump on the social media and advertise or kind of make -- show their concern for their customers.

I have a question. Is there a policy on the part of the FDA, you think, like when there is a food recall, does it require what kind of communication a firm ought to engage in?

DR. COOMBS: No, it's not -- social media is not specified, that it has to be used.

DR. BLALOCK: And just for the record, for the transcriptionist, that was Dr. Krishnamurthy who asked the question.

And Dr. Sneed.

DR. SNEED: Thank you. I know you mentioned that you don't have enough data yet to really look at size of recall, type of recall, classification of recall.

DR. COOMBS: That's right.

DR. SNEED: Another explanation might be that there are -- recalls can be very general, but they can also be fairly specific. And so there are mechanisms in place where they can trace who their customers are that bought that product. And companies like Costco and that sort of thing are very good at doing that because of the receipts and the computerization. So they may not feel it's as necessary because they can really target the customers who bought the product as opposed to something that's really broad and brings a lot of attention to their company.

DR. COOMBS: Right.

DR. SNEED: So --

DR. BLALOCK: And if folks could say their name when they ask a question.

DR. RIMAL: Say our name? Rajiv Rimal. I was wondering. If I understood your study correctly, this was limited to food recall --

DR. COOMBS: Yes.

DR. RIMAL: -- right? I'm wondering if the practice in this industry differs any from other consumer industries like automobile recalls and so forth. Is there anything to learn from sort of that kind of a comparison?

DR. COOMBS: Yeah, I think there would be. We just -- we focused on food. And that would be the starting point but would be to compare it out. One of the challenges with the -- in getting back to your point about other channels to reach -- the automobile industry has

other channels to reach pretty easy, and appliances. I need to find sort of an equivalent type of industry where you don't necessarily register your products so much.

One -- actually probably one to compare it to would actually be children's toys because you don't necessarily register your children's toys. And, again, when they're -- there's a huge risk there, because if you don't get those off the market and you injure or kill a child, that's a very terrible situation to be involved in. So that, I think that would be the one to compare it to. Although typically the people involved in the toy industry with children tend to be some of the most proactive communicators, but that would be interesting to compare it with.

DR. BLALOCK: Thank you, Dr. Coombs.

DR. COOMBS: Thank you.

DR. BLALOCK: So I want to turn now to the first discussion question. And our task here is to answer the question based on the background readings, the presentations that we just heard, as well as the expertise around the table. And with that, I would like for each Committee member to identify him or herself. And that's for the transcriptionist, so that we can make sure that we have an accurate transcript of the meeting.

(Off microphone comment.)

DR. BLALOCK: So the question is how can FDA communicators apply the information just presented? How can FDA communicators apply the information just presented?

Dr. Krishnamurthy.

DR. KRISHNAMURTHY: I think one question that I brought up with Dr. Coombs was whether the FDA does or should have some policy regarding how food recall information must be disseminated and the channels that must be used, especially given the discrepancy between the number of people who have a website and those who post and make it accessible. Should there be standards of that nature at all? Is there any standard of that nature?

DR. BLALOCK: Dr. Kreps.

DR. KREPS: I thought there were implications for FDA from both of the presentations. From Ben Chapman's presentation, I thought it was really important to think about ways that the FDA can provide training to people who deliver health information, like pharmacists and physicians and nurses, to make sure that they could do a good job of risk communication, because I suspect the same kinds of issues that occur with food servers are happening in the delivery of health information, that the providers are not really doing a good job of explaining the risk. They seem to be more focused on the instrumental focus of getting the information across about the therapy or the drugs that they're giving rather than the risks and benefits.

And then for Tim's presentation about recall and social media, I think that the implication here is also for the FDA. The FDA provides online information about drug risks and medication risks on a pretty -- how do I say this nicely -- bland online database that is not very consumer friendly. And I suspect that most consumers don't come to that website to find out when drugs are -- there are warnings for the

use of different medications. And so I think the implication here is that maybe the FDA can become more proactive about providing online social media coverage about these different medications, particularly if it's targeted to the people they know who are using these drugs or the groups of people.

DR. BLALOCK: Dr. Harwood.

DR. HARWOOD: I think that the FDA can look at the social media sort of activity across all their multiple accounts that they have, both in terms of Facebook and in terms of Twitter, and think of them in terms of what message they're trying to send a specific audience of each particular account so the end user who follows an account that just deals with a recall is using that account for a particular utility. A user who is using another account to find out general information about FDA information is obviously having a different utility. And working out what level information from one needs to be shared on another should be something I think the FDA should look at.

Also I think that it's interesting from what we saw today that some attention needs to be paid to actually the messaging that goes within a social media post. So a post on Facebook must be very different than a post on Pinterest or, we didn't hear it mentioned today, but if we're trying to reach the younger users, the college students who buy the burritos, Snapchat. So how will the FDA be able to utilize these other social media as well?

DR. BLALOCK: Dr. Zavala.

DR. ZAVALA: Yes. Adding to what Dr. Harwood said and

Dr. Kreps regarding the message and the information being put on the FDA website is the language that's being used. If the terms of, regarding medication information, noncompliance is not a very friendly word, we may want to consider another terminology that will make it more friendlier to the end user as congruence and helping them with their decision making.

DR. BLALOCK: Dr. Rimal.

DR. RIMAL: In addition, it might be good to think of who the target audience is, that if FDA wants to communicate information about some recall, reaching the consumers directly may be one way to do it, and I think that's the way we've been talking about through social media and so forth. But oftentimes that information is sort of reached -- it reaches the consumer through like a two-step flow that target audience of the FDA may be media outlets, for example, who then, in turn, distill that information and sort of disseminate that information to their audiences.

So I think one way to sort of grapple with this might be to think about who the potential audiences are of the FDA. And it may be more than just reaching the consumers directly, so there may be media outlets, there may be other public health agencies, or sometimes public schools and so forth. So there are probably many other entities that would enter that picture as well.

DR. BLALOCK: Dr. Kreps.

DR. KREPS: I really like what you said just now, Rajiv, about the two-step process. And I think there's a application in social media that

I've been studying for the last year or so with the use of bloggers who have a audience and have established credibility. For example, we've been using mommy bloggers to give vaccination information or breast cancer risk information to mothers and daughters. And because they have established credibility with those groups and have followers, they're a very rich source to use.

The government typically is not -- the federal government is not typically a really favored source for a lot of at-risk consumers to get information. In fact, that's one of the last places they want to go. So it's a really good idea, I think, to identify credible sources, particularly in the blogosphere and on other social media, to carry that message for the FDA.

DR. BLALOCK: Dr. Zavala.

DR. ZAVALA: Yes. I would like to add when using organizations, as you mentioned, that are credible, nurses -- I'm a nurse -- we are seen by the public, the American people, as a trusted organization. And using our Facebook pages and other outlets that we have would be a good source.

DR. BLALOCK: Dr. Rimal.

DR. RIMAL: I'll just add to that, after the H1N1 scare a few years ago, we looked at the information that the CDC provided on that issue. And what was quite remarkable was that they actually had five or six different audiences for that information, one of which was media, one of which was public health agencies, and so forth. And what that allowed the CDC to do was use language appropriate to the target

audience.

So, for example, when they were communicating with other scientists about H1N1, the language was very technical. They used the right sort of jargon. And when they were communicating with media outlets, the literacy level of that was the lowest, which was, I thought, really a beautiful way of segmenting your message according to your audience.

DR. BLALOCK: Dr. Liu.

DR. LIU: We've talked a lot on this Committee in the past about kind of atypical risk communicators. And we've talked about doctors and nurses. And I was really struck by these waiters. We never even considered that, and that just seems like a "no duh" moment. So I would think maybe for other types of risk thinking about who are the actual people out there interfacing with these populations, and maybe think widely just beyond healthcare practitioners or social media or traditional media and just think more outside the box with different crisis types.

DR. BLALOCK: And Dr. Pleasant.

DR. PLEASANT: Thank you. So from a hopefully useful angle, the question is, I think, not how at this point but whether the FDA should include social media in its requirement of announcing recalls, and do we have enough data on the effectiveness of social media and how to actually formulate a message. And based on today, I'd have to say that we don't yet have that.

And that would be the next step, right, whether it's a forced or

voluntary recall. What are you going to require the company to do, because it's highly unlikely, given the current climate, that the FDA is going to have the resources to put all the communication out on social media channels themselves. So it's going to have to fall back on the industry.

And then how do those regulations need to be prepared and written? And that's where I think we could probably be useful as well, right, through some sort of a participatory regime involving the best scientists in the field today as well as public input and come up with those guidelines. That, I think, I can see the FDA making progress in that direction, personally.

DR. BLALOCK: Let me just ask a question, to ask you to elaborate just a little bit. You know, you said that there was still sort of a lack of data, that we needed empirical data on the effect of different kinds of messages put out through different channels. And you did talk about guidelines. But I'm just wondering if you can elaborate maybe just a little bit more on what kind of data or what kind of studies you might envision.

DR. PLEASANT: Sure. Happy to. So let's just look at the data that we had presented today. If we have between 9 and 11 percent of firms involved in a recall that are actually posting something about the recall via Twitter or Facebook or all three of the digital channels studied -- and I think it is really important to also keep in mind Pinterest and the other ones that haven't come up today that's not a big enough sample size to draw any conclusions on whatsoever. But there's really been no

study on the effect of what the messages posted had, if any, on users.

So it's about media effects. So the very first thing you want to find out is if we post on Twitter, Facebook, Pinterest, etc., in what fashion, then what effect will that have on the audience that actually received it, and is that audience the one that we really wanted to receive the information? Because that might not be the case at all. All right. So there's just a host of traditional media effect studies that haven't been done on social media yet.

DR. BLALOCK: Thank you. Dr. Krishnamurthy.

DR. KRISHNAMURTHY: I think following up on what Dr. Pleasant mentioned, right now I think it is a good time to audit the communication policy of the FDA as it relates to crisis-related recalls and see whether it reflects a social media component. I agree that the data is not nearly as robust as it -- as we would like it to be, but from what little we have seen, especially from Dr. Chapman's presentation, that information moves rather rapidly when it is posted on Facebook and Twitter, I assume, compared to when it is on regular mainstream media like print and TV.

If that is the case, then, and if there is any policy at all regarding communication of food-related crisis, then it needs to reflect what the social media angle should be because that does not make sense that the most effective medium of communication is not being reflected in FDA's policy regarding communication of food crisis.

DR. BLALOCK: Dr. Kreps.

DR. KREPS: I liked Andrew's idea about requiring the companies

to come up with a communication plan. It reminded me of what NIH has been doing recently with people who apply for R01 grants, where they ask them to come up with a diffusion and dissemination plan. And so I think that using that kind of guidelines that are already established by NIH, when there is a food recall or a product recall or a drug recall, the FDA might request that the company that produces those products come up with a communication plan, a dissemination plan that would be targeted to the audiences that are most at risk to get that information out.

And that could be reviewed and recommendations could be made. So it wouldn't necessarily have to be social media. It could be a range of different strategies that would be appropriate to that product, the risk and the audience. But there would be an attention made to that process that I think may be lacking right now.

DR. BLALOCK: Dr. Yin.

DR. YIN: Hi. I also wanted to agree with what Dr. Pleasant and Dr. Krishnamurthy were saying, that we don't know enough about what the most effective strategies are to reach people and the role of social media. And I think it's important that there's more research that's done, whether it's done retrospectively, where you look at and identify specifically very successful campaigns in the past and what are the key pieces of information, what to learn from that, and potentially prospective studies on what different strategies you might be able to try with social media.

I agree that even if a company does post on their Twitter, that

might not be the most effective way for it to get out there. Maybe other sources of information would be more effective to reach the population we want.

DR. BLALOCK: Dr. Krishnamurthy.

DR. KRISHNAMURTHY: Just following up a little bit on that. I just looked up the FDA guidance regarding what the industry needs to do when there is a recall. The words "social media" appears zero times. The word "communication" appears once in a fairly lengthy website. I think that is necessarily a call for action right there, to go and look at exactly what should we expect of the industry participants when there is a crisis.

And I also want to pick up on what Dr. Coombs mentioned. If it is -- if there is a crisis and if the firm benefits by being the first to mention it rather than when it is featured on the FDA's website or someplace else, then perhaps the business community needs to be educated on the importance of communicating information even if they take a short term hit in terms of reputation.

DR. BLALOCK: Other comments. Dr. Rimal.

DR. RIMAL: I'm sort of wondering out loud, I guess. Recall is something that happens when something has gone bad. And in many instances, I would assume and I don't know, I'm assuming that it would be a step taken as almost a last resort, that, I would guess, that between when something goes awry and the recall happens, that there are probably many other things that are happening in the interim. So I just wonder out loud whether imposing guidelines at the recall stage

may be, in a sense, a little too late, that there may be other opportunities before one actually hits the recall stage when there might be opportunities for communication? I don't know. I don't know how that process works.

DR. BLALOCK: Dr. Harwood.

DR. HARWOOD: So I think in terms of any research that's conducted, it would be good to also include the social element of social media. So research looks at the number of interactions that the firms have on social media, answering questions that people have asked in response to the initial posting of the information.

And I think also when we look at the use of FDA, it's not necessarily just putting out information as the FDA; it's also re-sharing information that's already out there, whether that be information from the Department of Agriculture, whether it be sharing information from the actual companies themselves. So looking at whether the FDA can actually share other people's information may be applicable.

DR. BLALOCK: Dr. Pleasant, did you have a question?

DR. PLEASANT: No.

DR. BLALOCK: Comment. Dr. Kreps.

DR. KREPS: I just want to respond to what Rajiv was saying. I think there are some steps before recall. There are like advisories about drug risks, and there are recommendations about best practices for using medications. And the same thing for other health-related products, and I suspect for food as well. And I think that these guidelines probably can be used at each of those steps, not just waiting

for recall. I think that's a really good recommendation.

DR. BLALOCK: Dr. Sneed.

DR. SNEED: As I understand the food recall process, there's a lot of legal implications on that. And I think until a food recall is actually decided upon, there's probably not anything that can be done that FDA can require the company to do. So I know that USDA and FDA both, when they're working on recall situations, there's a lot of things that they can and cannot say. So there's probably not -- it's probably at that point where a recall happens. And most recalls for food are voluntary recalls.

DR. BLALOCK: Other comments? Dr. Liu.

DR. LIU: Just wanted to note that there has been some research on this topic, so we're not just totally shooting at the hip. I mean I can name one study I know. I just looked it up to verify it. Karen Freebird did her dissertation topic on food recalls, compared social media to official sources. And she found that people were more likely to comply with the recall when they got the news from their friends and social media than from other sources of information.

So there is research on this topic that we can go to. I'm always a fan of new funding for new research as well. But, you know, we've had social media now since 2006 for Twitter and Facebook, so we do have a body of scholarship here we can use.

DR. BLALOCK: Dr. Krishnamurthy.

DR. KRISHNAMURTHY: Following up on Dr. Sneed's point, I think it is a great one that some of them are voluntary recalls and some of

them are mandatory. But the guidance does talk about the fact that you must promptly inform your customers. And if the firm does not initiate the communication, that FDA will do that. In fact, it goes into great detail in terms of what needs to be communicated, what are the batch numbers involved and so on and so forth. It's fairly detailed in terms of what.

But there is very little information on the how it needs to be communicated, which I thought was the two presentations' focal point. And I think like FDA could use a little bit more updating of the how part of the communication of the recall as much as the what part.

DR. BLALOCK: Other comments. Dr. Pleasant.

DR. PLEASANT: I'm not entirely changing gears, but you're absolutely right. There is some research out there, but it's nothing compared to what we've looked at in terms of print, for example, and the effects, or broadcast. But one thing that was mentioned, and I just want to highlight it to hopefully be useful. And it was in the first presentation about using stories and narratives, and it was in the backup reading.

The one thing that didn't mention is why it is really useful to use stories and narratives as the context for when you're trying to convey risk information. And there are several. But the one that was not highlighted, which is probably the most important in my view, is that to be a narrative, a story, it has to have a moment of change. That's the definition of a narrative.

And what do we generally want people to do when we're trying

to communicate about risk? We're trying to get them to change. So what's useful about narratives, just beyond presenting statistics and risk calculations and cost-benefit equations, is that it embraces change; it can illustrate what the change can be and how people can go about making that change in an informed way.

So, and this is true across media. It's as true on Twitter as it is in the *New York Times*. That if you include your risk information, whether it's about a recall or something else, because the FDA has a very large mandate, the power of the story is going to help you get the response from people that you want. So don't forget that as a very important strategic tool.

DR. BLALOCK: I think that -- are there any more comments? I think that part of what I've been asked to do towards the end of the discussion is to kind of summarize what I've heard, some of the major points, probably give people another opportunity to interject and also correct me when I'm sure I'll be wrong about some things.

But one of the, I guess, and there were definitely many, many good points, and I'm not going to be able to elaborate on all of them, but I think one of the things that I heard a lot was clearly we live in sort of an information age. And this social media and all the different types of social media is out there, and we need to be capitalizing on that and using that to reach audiences.

I think one of the big things that I heard was that there really needs to be a coordinated approach that involves identifying the target audience, whether it's the ultimate consumer or whether it's different

sort of partners, whether it's companies involved in food recalls, whether it's nurses, other types of health professionals, but really differ -- and that they can echo the message and repeat the message with those partners. So there really needs a coordinated approach that takes into consideration what we're currently doing now, the audit that Dr. Krishnamurthy mentioned, I think, towards the beginning.

And then no one really said this, but I often say this. It's a lot easier to hurt people than it is to help them. And so this really is kind of a new game. And so we do need to do a lot of research on the processes. It's not just enough that -- you know, whether people are putting the messages out there. But what exactly is the effect of the messages?

And then I also heard training -- this is kind of different -- you know, training different people to be risk communicators. And the reason I struggled for the word "people" was to include people like waiters at restaurants where we go for food and then as well as healthcare providers.

So those were the main things that I heard. So with that said, let me just -- I think we've got time for me to open it up to questions. Is there something important that I missed that you really want to make sure gets highlighted?

And if not, do you have any follow-up questions, Ms. Duckhorn?

MS. DUCKHORN: No, I think that Dr. Krishnamurthy really summed up a lot of the discussion by saying that the FDA needs to provide more guidance about how to communicate in addition to what

needs to be communicated. I think that really summed it up into one statement. Thank you.

DR. BLALOCK: Dr. Sneed.

DR. SNEED: Just one other observation. From Ben's presentation, he had the blog up about Chipotle. And the one person said isn't that the restaurant that made a lot of people sick? And the next person said, yes, but it tastes yummy.

(Laughter.)

DR. SNEED: I think in a nutshell that sums up a lot of our problems that we have to address is how do we help them understand that just because it tastes yummy doesn't mean it can't make you really, really sick or potentially even kill you.

And so I think that we need to keep that as a little bit of a focus that we do -- but it didn't surprise me, because I have to admit, I went to Chipotle not too long ago, because a friend was visiting from Ohio where they didn't have a Chipotle, and she loves the place. And so she had to go there. But the risk is still there. So it's kind of an interesting phenomena.

DR. BLALOCK: Any other final comments? Was everybody able to get their opinion in?

Okay, well, then I think that we're ready for the break. So, we'll take a 15-minute break. And do I have 3:30, about 3:30. So reconvene --

(Off microphone comment.)

DR. BLALOCK: Oh, 2:30. Okay. So reconvene at 2:45? Is that

right? Okay. So reconvene at 2:45. And I do need to ask Committee members, please don't discuss the meeting topic during the break amongst yourselves or with any members inside or outside of the audience. So we'll resume at 2:45.

(Off the record at 2:27 p.m.)

(On the record at 2:45 p.m.)

DR. BLALOCK: We'll resume with the second session. Effective Risk Communication - Audience Engagement for Change. We'll hear presentations from Dr. Lipkus followed by Dr. Broniatowski. Dr. Lipkus, you may approach the podium and begin your presentation. You're there.

DR. LIPKUS: Yes, I'm raring to go.

DR. BLALOCK: I should have looked up.

DR. LIPKUS: Well, I want to thank, first of all, the FDA and the Committee for having me here. What I want to do today is present an overview on a topic that I find very dear to my heart, which is to what extent can we use physiological data as a risk communication tool to try to motivate people to change their health behaviors in a way that's hopefully beneficial for them.

So what I'm going to do is present a -- first a definition of what I mean by physiological data with respect to biomarkers, give you an idea of what the challenge is, understand why we might want to use biomarkers, and then present kind of a general overview of what the data seem to suggest with respect to the use of biomarkers, primarily in the area of smoking.

So what are biomarkers? Well, basically, what they are are physiological indicators of something. And what they indicate are these three main categories. One of them is indicators of either harm or abnormality. For example, you go through a spirometry, and the spirometer tells you that you have some form of lung damage. It could be susceptibility to the future of a disease. So it could be, for example, your future risk for lung cancer, given some genetic or genomic test. And it's also to what extent might you be exposed to some harmful chemicals. And an example here might be to what extent, as a smoker, for example, do you have CO levels given a breath test.

In terms of the risk communication challenge, the main challenge is the following. To what extent will giving people this information in one of these three areas or in combination actually influence what we consider to be beneficial lifestyle changes? So, for example, does presenting people with biomarker information get people to quit smoking? Do we get them to exercise more? Do we get them to diet? Or even maybe use less alcohol? And certainly the best data is to suggest that the presentation of these data is more affecting than when no data are presented.

So we could change lifestyle behaviors through a multitude of different ways. So why should we spend any attention on the use of biomarkers? I have here a whole slew of reasons why I think biomarkers are important to study. One of them is these biological foundations really give us evidence of why diseases evolve. And once we have that knowledge, there's several ways we could use it. One of

them is certainly how do we educate the public about the disease and the various risk factors, of which the biology is very important. And the idea is if you give people a biological underpinning of disease, they have a better mental mindset of what their actions might do to affect these biological mechanisms.

The second thing is if we know what the biological mechanisms are, we could do an intervention and actually look at changes in those biological mechanisms to see whether or not our interventions are effective. Another reason is we use these biomarkers in clinical settings almost every day. You go to a doctor's visit, we often go ahead and do blood tests, we often conduct screening. So it's something that the audience, the public, and the patients already are faced and they're presented with this information. The question is, well, what will they do with that information?

The other reason, which is similar to the second one, is there are already various mechanisms through which people could go get some of these physiological indicators. The classic ones are direct to consumer tests that involve, for example, genetics, such as offered by such companies as 23andme.

And I think the fourth one is the theoretical plausibility for using biomarkers. One of them is they present a teachable moment. In other words, situations where people could actually can have "an epiphany" that could somehow make them more open-minded to change. And certainly the last one, which most of us talk about, is this whole issue of changing risk appraisals.

Here's just a theoretical framework that does suggest that if you think about risk appraisals as consisting of a variety of different constructs, such as perceived risk, perceived severity, how you feel at the moment of getting feedback as well as how you anticipate your feelings might be when you get feedback, all these as a group are risk appraisals. What the literature seems to suggest, based on some meta-analysis, is that they do actually affect intentions to change, and they actually do lead to behavior change.

So let me go ahead and then switch to some of the empirical data. I'm going to present data on smoking. The reason for this is because smoking is probably the most commonly used area to understand biomarker feedback. There's over 30 years of evidence that suggests this. And there's been various biomarkers that have been used in this particular category, some of which I actually have listed up here.

So just to set the groundwork, I'm going to go ahead and just lay out what the typical design is for the use of biomarkers. This is a study that we've just recently completed, and hopefully we'll submit the data in about 2 to 3 months. We will be double-checking these data. But the basic idea of this study was can we actually get college smokers to quit, smokers to quit smoking if we present them with data, genetic data about their susceptibility to getting lung cancer through this gene called GSTM1?

The basic idea is if you're missing this gene, you're at a higher risk for lung cancer. If you have this gene present, you're at actually lower risk for lung cancer. So the basic design is, people get tested,

which are people who have GSTM1 missing or present or no feedback, and this is the pattern that we've gotten in terms of cessation rates at one month.

These are not statistically significantly different. But this pattern here is very common in the various other studies that's been done. And it also mimics a study that we've just recently completed giving college smokers susceptibility feedback for nicotine dependence.

So what does the literature then suggest about using genetics and smoking? These are three meta-analyses that have been done that involve anywhere between three to four studies. In general, what you find is that if we do get any effects for genetic feedback about susceptibility to smoking related diseases, primarily lung cancer, two of the meta-analyses show some weak overall effect either as an odds ratio or relative risk at 1.55 or 1.87. And there's one meta-analysis that shows a 1.35 overall effect, when you look at people who have been tested versus not tested.

So the general trend and the most favorable outlook is if you give people this genetic feedback, it seems to promote short-term cessation. It does not promote long-term cessation. If you look at the individual studies, with the exception of McBride et al., of which I was actually fortunately one of the investigators there, you don't get usually any effects for single studies. So this is really pulling over all these various investigations.

Well, what about when we start looking at biomarkers of harm and exposure, primarily those that look at the use of spirometry and

carbon monoxide? Well, we get again very mixed effects. I'm not going to go through these various studies, but this is just to give you a sense of what the designs are for these various studies. The general understanding of these is that they tend to be relatively complex. They are usually involve a lot of multi-component parts to them, and therefore it's relatively hard to sometimes tease the unique effects from a specific biomarker.

So if we look at just the use of spirometry as a form of harm, based on one analysis, the basic idea is there's not enough evidence or good evidence to suggest that actually giving people evidence of harm through spirometry, in other words abnormal lung functioning, actually does anything to promote smoking cessation.

Well, those have been when you give people feedback of some sort, with the risks and so forth. What happens when you give people actually pictures of harm? Do you find any differences when people can actually see the harm that they are experiencing? So here's what -- an example, I'm going to deviate from smoking. But there's been some really nice research looking at exposure to sun and especially looking at how the sun harms the skin.

So what these studies really include is giving people a snapshot of their face with just a normal face you would look at every day versus looking at UV photography that actually shows underlying damage. So if you look at these first top pictures, what you find up here is that this is the normal face, and then this one is the damaged face. I'm sorry, it's a little dark, but if you were to actually look closely, what you see if a

whole bunch of pigmentations of grayness. And that suggests harm due to sun exposure.

And people clearly get these ideas of what's being expressed. And what we find is that there are some actual positive effects of giving people UV exposure photography as in this up here, through, for example, with Gibbon's, looking at tanning; what they find is when you give people images of harm to their face, they actually do spend less time tanning. And similarly for skin examinations, there's some effects. Now, when you show the entire body and looking at where there might be some damage, that that actually does promote self skin exams.

Okay. So this is a picture of deposits of calcium in the arteries. There has been some work looking at CT tomography -- I think that's what it's called. And the question is consider yourself going through a screening program where you want to see if you're at heightened risk for cardiovascular disease and your radiologist or your primary care physician comes up to you and says here's a picture. And you're looking at this picture. And the question is what does this picture really mean to you? And how does it really affect your own impressions of getting coronary disease? So imagine you're an actual patient that sees these calcium deposits that are actually in white. What would be your reactions to that?

Well, there's been one study -- there's been several, but one study in particular which has suggested that if you actually give smokers images of plaque, that that actually motivates cessation. So this is the study that was done by Bovet. It was actually a unique study because it

was done in one of the islands in the Indian Ocean. As a caveat, the smokers that were here were actually light smokers; they weren't very addicted. And there was no actual formal biomarker taken like CO to make sure that they actually quit.

But, nonetheless, the data are suggestive to suggest what? That giving smokers evidence of harm compared to when you don't give them evidence of harm, you either don't take picture or those people who had pictures but there wasn't evidence of harm, that it seems to be a motivational kind of tool.

So this seems to be kind of a promising kind of finding. Well, what does the other literature seem to suggest? Well, if you look at various cardiovascular imaging studies that look at computer tomography or ultrasonography and you look at their overall effects and you look at them in settings that we care about such as primary care, what you find is there's no significant effects overall for smoking cessation, even though it's approaching statistical significance.

I will add, as a caveat, if you look at another meta-analysis done by Hollands, you actually do get a significant effect overall -- it doesn't necessarily mean because it's primary care -- of a 2.84. So there is some good suggestive evidence that showing pictures of cardiovascular disease through calcium buildup and so forth might be another one.

In terms of other particular types of behaviors, and they report here only one study in the primary care arena, that there's actually no significant effects of presenting calcium deposits.

Okay. So what's kind of the summary then of using visuals to

present harm of some biological process? There was a Cochrane review that was done not too long ago that seems to suggest that nothing could be made as far as a real strong statement that they work. However, if anything, and if you take it with some level of caution, it could be the case that actually presenting visual information to people might be a useful way to go ahead and motivate them to actually change some behavior at least, and most of this has been again in the area of smoking.

Okay. So what does the overall consensus then seem to suggest about using biomarkers? And, again, even though the heavy emphasis is on smoking, these commentaries are for other kinds of disease areas -- or not disease areas, but lifestyle areas such as diet and exercise and so forth. Well, one of them, and this is a real big conclusion that lots of different people reach, is that as yet there's inconclusive data to suggest biomarkers are really an effective tool to motivate behavior change. And part of the reason for that is there aren't really a lot of well done studies. And I'm going to look at why we get inconsistent finding in the next slide.

But the other one that I think is extremely important, when you look across all these studies, in that with few exceptions, when you tell people that they are not at harm's way, so when you tell people that they are at low risk or you don't provide them any evidence of physical harm, it doesn't dissuade them. There's no negative impact. And why is this such a big issue? Because one of the things we always think about when we think about risk communication is it's only when you give

people evidence that they are at harm's way that the probabilities are higher that they're going to change.

In fact, there's very little data to suggest out there that giving people evidence of low risk is actually detrimental. There isn't any. And, in fact, if you look at the slide that I present with our GSTM1 study, what you find is telling people they're at lower risk, if anything, motivated cessation more than what, people who didn't get any feedback whatsoever. And this is a point I'm going to get to a little bit later.

And the other thing that all these trials and summaries seem to suggest is that we need to go ahead and design better well randomized control trials.

Okay. So I said there was inconsistent findings. Well, what are the various factors that go into this? I think there's a variety of different reasons why we get inconsistent findings in admittedly small literature, per se. One of them we talk about different diseases. We talk about cancer, we talk about coronary disease, sometimes we talk about diabetes, sometimes we talk about obesity, etc., Alzheimer's disease. So different diseases.

In general, what you find from these studies is that the sample sizes are small. And it's only -- you pick up effects sometimes when you do these meta-analytic kinds of analyses. The other thing is there's inconsistency in measures and when we actually assess our outcomes, different populations with different motivations in terms of actually changing.

A lot of these studies manipulate other variables other than the biomarkers, and they're not necessarily done in a way that you can tease apart the effects very well. So, for example, they don't necessarily do factorial designs; if anything, they do more additive designs where you can't actually test interactions very well.

They use varying biomarkers. There's not always consistency in the type of biomarkers that they use. So, for example, if you use genomic testing, sometimes they'll include up to 5, sometimes up to 23 biomarkers. So it's difficult. And also how the feedback is actually delivered may vary in terms of who does it, what information is presented, and how it's presented.

So I think that one of the things that we need to be very mindful of is are we asking the right question? The questions that people have been asking is do biomarkers affect behavior change? I think that's the wrong question to ask. I think that the right question to ask -- and admittedly I'm biased here and maybe speaking as a social psychologist now -- is that we need to understand for whom biomarkers work for, under what conditions do they actually work, for which outcomes are we talking about, and why.

And in particular points 3 and 4, I just want to say a little bit about. We always think that the behavior is the most important outcome, yet we need to always appreciate that behavior change is a multi-step process that involves a lot of different variables. So we really need to be asking the questions to what extent do biomarkers affect the various principles that theoretically we know and empirically we know

seem to affect behavior change. And that means we need to understand the whys much better. A lot of these studies don't actually include measures and mediators. For example, the most classic mediators you should assess is things like risk perceptions and desire to change. A lot of these studies don't actually even assess those very basic items.

Okay. So what are then some of the future "promises" that the use of biomarkers may give us? Well, one of the things that I think is important to investigate further is we need to understand how the process of testing actually can fulfill the promise of behavior change. Maybe the process of testing gets people to really think about their own behaviors and reflect on it in a way, both the good and the bad, in terms of what would happen if I don't change my behaviors, what would happen if I do? So we really need to think about what is it in the testing process itself that could evoke some mechanisms that get people to really think about making a behavior change?

I think the other thing that we need to capitalize a little bit more on is how do we empower change with low risk feedback? In fact, there's almost no data that I know of that talks about how do we tell people you're at low risk or you show no abnormalities. What we seem to focus on is always the high-risk group, but on average, what you find is generally speaking people aren't going to be at high risk, and most of the population are going to be at lower risk or average risk. What do we do in terms of our messaging to use that as a persuasive tool to get people to change?

I think the third one, and this is one that I'm glad to see is being used in, for example, in the graphics labeling and graphic warnings in cigarettes, is we needed to see how we could use graphics and images much more forcefully to go ahead and motivate people to change and understand what's going on. In particular, images and graphics might be very useful in trying to get people to understand the mechanisms that are going on, and in particular, given the technology we have these days, it's really great to go ahead and see how your diseases change from an image perspective or to actually use images to be a source of feedback, saying here you were at a certain time point; now let's look at your feedback in another time point and see how changes or no changes using graphics and images may actually go ahead and modify behaviors.

The fourth area here is communal effects of biomarker feedback. What is this all about? We typically give biomarker feedback to see how it affects a given individual. Yet, there are some ways of using biomarkers to go ahead and say, hey, this how other people in your network or in your family are actually being affected by certain kinds of behaviors. The classic example of this is secondhand smoke. There are some limited research, and admittedly a lot of it is nonsignificant, where you tell parents who smoke, look, your child is exposed to so much levels of CO, thirdhand smoke, secondhand smoke, particulates in your air and so forth.

And what you find is that actually does seem to motivate parents to make a change. Not necessarily quit smoking, but it could be more

such things as smoking outside, all right, or making it so there's zones for smoking where the infant or the child is not exposed to.

And then the final thing I just want to say is we should be able to capitalize on the newer designs that are being created these days and used these days. One of them are adaptive designs. We typically think of studies as you do an intervention, and you see whether or not it works. Well, what adaptive designs are all about is saying what happens when people don't work -- when a particular intervention doesn't work. Do you stop there? No, purpose of the adaptive design is let's build upon what we know didn't work for the first step. What sequential types of interventions can we give people to go ahead and achieve the ultimate goals of behavior change?

So I think we need to start thinking a little bit more creatively in terms of the designs we use. Like, for example, we have now microtailored designs and so forth and so on. And I think we need to use better technologies. For example, we typically ask people the questions 3 months, 6 months, 12 months. For the life of me, I don't know why those time points are always the most critical. I'm totally confused about that.

But we could capitalize on, for example, ecological momentary assessments, where you could actually look at data in real life, texting. You know, we could go ahead and use our iPhones, computers. There's a whole way of using technology in a way that better captures not only the behaviors but also how we could actually disseminate the information itself.

And with that final note, I want to acknowledge the various people who actually gave me their viewpoints on this whole topic of biomarkers. Thank you.

DR. BLALOCK: Thank you, Dr. Lipkus. It looks like we have a clarifying question. Dr. Kreps.

DR. KREPS: Thank you, Isaac. That was a very nice presentation. I know it's probably frustrating for you that there's not more powerful behavioral outcome data from the use of biomarkers. But I think it has a lot to do with the complexity of behavior changes you mentioned.

My personal feeling is that we need to be focusing more on giving people information about how they can use biomarker information and so they have a sense of a goal, a path, an efficacy to achieve those goals. There's a good theoretical validation for that with the extended parallel process model. And I, and I think this is an issue not just for biomarkers but I think for genetic testing and genetic counseling and for screening. When people are given the results, they're not often given good information about what do you do with that and what does it mean for me. And so I think it means that we need to enrich the communication process.

Obviously this is an empirical question, and I think this is an area where I would encourage you to examine further. How can we communicate this biomarker information and the other kinds of genetic information and screening information in ways that people can really use so that they are more likely to utilize that information?

DR. LIPKUS: Yeah, I think you bring up an excellent point. In

fact, if you look at Martina Marteau (ph.), one of the comments she makes about genetics in particular is there's this whole notion of illness perceptions, where there's these five dimensions of illness perceptions. And one of the things we need to do a better job of is when we give people genetic or genomic feedback, how do we use that information to get them a better appreciation of how this plays a role in illness perceptions, which in turn may actually influence various behaviors?

But the unfortunate thing about these studies is you really don't get a sense of how people are using the information at all. In fact, one of the weaknesses is you don't even get a lot of information about how the information was presented, let alone how it was used.

DR. BLALOCK: Dr. Zavala.

DR. ZAVALA: Yes, I have a question. When you spoke about the lung -- I'm sorry -- smoking and the connection with the biomarker to lung cancer, you were mentioning their success with short-term cessation. And I have a question as to why long-term cessation is not as successful.

DR. LIPKUS: With the use of biomarkers?

DR. ZAVALA: Yes.

DR. LIPKUS: Well, we don't particularly know that. My guess would be there is probably different mechanisms in terms of getting people to first quit and then the processes of maintenance. And if you look at the various theories of health behavior change, we know a fair amount of what gets people to change. You know, there's all these theories. We don't really know very much about processes of relapse.

So my argument would probably be such things as, if you look at, particularly for smokers, to what extent do they use smoking as a crutch to reduce stress? To what extent are they actually influenced by being around other smokers? To what extent do they actually miss some of the positives that smoking would give them? The other one could also be, and it wasn't clear in our particular study if you want to look at processes of nicotine addiction and so forth, to what extent, when they start feeling there is high-risk scenarios, do they go ahead and reuse some of the skills that they've learned earlier to deal with high relapse, challenging situations?

But in terms of the actual predictors, with respect to interactions with biomarkers, we really don't know that. And it's typically very -- pretty rare in these studies to actually assess things past 6 months.

DR. BLALOCK: Dr. Krishnamurthy.

DR. KRISHNAMURTHY: First I want to thank you for a really fascinating presentation. I learned a lot. I do have a question about what happens if I know that my doctor is going to give me detailed information about my health or my -- kind of various levels and so on and so forth? Is it going to reduce the likelihood that I will have my preventive screens to begin with? Because I do see that there is some evidence that people look at screening tests as being somewhat risky. And they just don't want to deal with the bad news, and they don't go to the physician in the first place. Now, if you're going to make it even more high-definition bad news, like you know, that you're going to tell

me all levels and so on and so forth, is it going to create even greater avoidance of the preventive service in the first place?

DR. LIPKUS: Yeah. So, and specifically -- first of all, thank you for the compliment. If you look at screening behaviors in particular, like cancer screening, for example, what you find is the reasons for not getting screened, the issue of fear of finding cancer is not a high prevalent reason to begin with. You know, common reasons are, for example, I don't like the preparation procedure; it's painful; I don't have the time to do it; my doctor didn't tell me I needed to get this done; and so forth and so on.

Now, in terms of what you're saying, do people think about the high risk or the low risk? I think it all depends on how you construe the behavior. All right. For some people, screening is actually a way of identifying am I at higher risk for a disease, and therefore that's useful information because then I could act upon that. For some people, they might want to get screening for saying I'm perfectly fine; therefore, whatever I'm doing, I'm the right road and I should continue to be on that road.

So I think the answer to your question is really the issue of how do people construe the actual screening process itself. And, in fact, there's really nice work by John Updegraff that actually shows, if you look at framing effects, that whether or not people act on screening and the results of that and want to do it is really a function of do they view screening as a way of promoting positive effects versus negative effects. And what you find is high risk is good with loss framing, right? But gain

frame is good for low risk.

Now, those are co-relational. We're actually doing a study to test that, and I hopefully will have the answer to that in about a couple of weeks, if my statistician is not too busy. Thank you for the question.

DR. BLALOCK: Thank you, Dr. Lipkus. We'll continue with the second guess speaker for this session, Dr. Broniatowski.
Dr. Broniatowski, you can now approach the podium and begin your presentation.

DR. BRONIATOWSKI: Okay, well, thank you very much for having me here. This is joint work that is with my colleagues Eili Klein at Johns Hopkins University and Valerie Reyna at Cornell. And what we're going to talk about today are patients' expectations for antibiotics.

So just start off briefly with a conflict of interest statement. I have a financial interest in Eli Lilly and Company, which is a manufacturer of antibiotics, and that's a topic under discussion today.

Just a brief overview of what we're going to cover today, just a little bit of background on antibiotic resistance. Obviously that's a topic that we've all heard about. But really, ultimately, we're going to get to this issue of patients' expectations and how patients understand the meaning of antibiotics. And so from there, we're going to go into Fuzzy-Trace Theory, which is a theory that discusses how patients construe the meaning of things like antibiotics. That leads us to two hypotheses that we'll consider.

The specific methods we use to test these hypotheses are a survey of patients in the Hopkins Emergency Department. And that has

some results and implications for how we should communicate with those patients, which is really what we're going to touch on.

So, very briefly, we've all heard about the issue of antibiotic resistance. It's really an increasing threat. According to the CDC, as of 2013, at least 2 million illnesses and 23,000 deaths are attributable to antibiotic resistance, leading to a societal cost of up to $20 billion direct costs and maybe as high as $35 billion in indirect costs.

So the question is where is the source of this problem, and why is it that essentially we are seeing what amounts to an overprescription of antibiotics? And in many cases, the literature attributes this to an issue of patient satisfaction. Patient satisfaction seems to drive prescribing. In a sense, there's this idea that doctors prescribe because they think this is what patients want.

And, in fact, the literature seems to indicate that patients will generally come in with some sorts of expectations. The physicians will have some expectations about what the patients want. These may not necessarily be lined up. But as long as the doctor thinks that the patient wants antibiotics, the doctor is more likely to prescribe. And so, you know, at the same time, we know that the patients are more likely to be satisfied and the diagnosis are also more likely to be accurate when the expectations are clear and then the physicians address them.

So ultimately it's in everyone's best interest to have this clear line of communications between the patients and the physicians. And ultimately what we're trying to do is figure out how can we get that line of communication to be as clear as possible.

So this leads us to ask, well, how are these patients' expectations formed? And ultimately this comes down to a question of, well, what is it that patients mean when they say antibiotics? What is it that they expect ultimately from antibiotics? And so there are some ideas out there in the literature. For example, some people suggest that antibiotics may be conflated with treatment in general. There's an idea that antibiotics make it worth the time and the effort of going to the hospital.

And so there are a number of ideas out there, and ultimately, we would like to determine what is it that antibiotics mean to the patient. And so this leads us to draw on Fuzzy-Trace Theory, which is a theory of medical decision making under risk that focuses on how meanings are derived from the data that are given.

Okay. So a little bit of a background here on Fuzzy-Trace Theory. The key concept is that people encode multiple types of mental representations in parallel. And Fuzzy-Trace Theory distinguishes between two key types. The first is called verbatim. So, for example, if I were to tell you if I take antibiotics, there's a 0.1 percent chance of negative side effects, then the verbatim representation mirrors that. It's a detailed representation of the stimulus itself, 0.1 percent chance of negative side effects.

On the other hand, we might talk about the gist representation, which is what is it that that stimulus means to that patient. Okay. So the gist may be if I take antibiotics, mostly nothing bad will happen. Now, at the same time, gists are culturally rooted so for one person it

may be mostly nothing bad will happen. Depending on what your base rate is, the gist may be different. Ultimately, we want to understand what is the bottom-line meaning to the patient.

And whenever possible, according to Fuzzy-Trace Theory and its essentially empirical backing, patients will prefer to rely on the gist rather than the verbatim representation when they make their decisions. So they're going to make decisions in a manner that is consistent with their understanding of the meaning of the data, even if that meaning may or may not be consistent with the actual data themselves.

Okay. So this leads us to our first hypothesis here. The first gist that we consider is called "Germs are Germs." And this is ultimately the idea that patients don't know the differences between bacteria and viruses. And this is something that we see a lot in current public health communications campaigns, specifically the CDC's Get Smart program, which is focused on trying to educate patients about the differences between these two different kinds of microbes, between bacteria and viruses. And so if "Germs are Germs" is true, then it suggests that educating patients about the differences between bacteria and viruses should reduce their expectations for antibiotics.

On the other hand, we may consider a hypothesis that is motivated by risk perception and specifically by Fuzzy-Trace Theory. And the idea here is that we start with a certain status quo. The patient is already sick. They're not feeling good when they show up, and they want antibiotics. Okay. And so they have really two options. Either

they can avoid antibiotics, in which case they stay sick for sure. Or they take antibiotics, and if they think antibiotics are effective, then maybe they'll stay sick or maybe they'll get better. All right. And so given that getting better is preferred to staying sick, they'll choose option two; they'll choose to take antibiotics.

And so there are obviously some underlying assumptions over here. First of all, if you adhere to this gist, if you hold by this, then you have to believe on some level that antibiotics at least might make you feel better, which is interesting given that there's recent sort of emerging evidence that some antibiotics may have anti-inflammatory properties and may make people feel better regardless of whether it treats the illness. At the same time, people have to believe that antibiotics are essentially harmless to the individual.

So we're really looking at this sort of double-pronged thing where, on one hand, antibiotics can help, and on the other hand, they can't hurt. Okay. Now, if you have a viral infection, neither of these are true.

Okay. So how did we go about testing this? Well, we administered a paper survey between January and April 2013 at Johns Hopkins Hospital in Baltimore, predominantly an African-American community. And the survey was administered anonymously to patients. So this is after patients were seen by their physician and they were essentially waiting for discharge. We included patients if they were 18 years or older. They had to be capable of responding, which is to say they could understand English; although literacy was not necessarily

one of our criteria, they had to be able to at least understand English. And they had to be lucid, which is to say that they were not in such pain that they couldn't respond or they weren't unconscious, for example.

And so as far as the specific content of the survey, we asked them 17 questions. These were all rated on 5 point Likert scales, which is to say from strongly disagree to strongly agree. And we tested a number of different gists. The first thing we tested for was essentially correct knowledge. We wanted to know if we asked them, for example, do antibiotics work against bacteria, would they say yes? But then we also asked them items consistent with "Germs are Germs." So, for example, do antibiotics work against viruses?

We tested a number of items associated with "Why Not Take a Risk?" And so these might be things like, well, I don't know if antibiotics will make me better, but it's better to be safe than sorry, so I should take them. We tested items consistent with the notion of side effects associated with antibiotics, so this idea of downside risk. Antibiotics might have side effects, so I should only take them when I know they will work. And then we also tested a number of other hypotheses such as the ones that I mentioned earlier. We analyzed our results with an exploratory factor analysis and then asked also two free response questions.

Okay. So the patients that we enrolled were roughly uniformly distributed in age. And, again, these were a largely African-American sample. Over 60 percent of our sample was African-American. And over 60 percent of our sample had at most a high school diploma.

Okay.

And so what were the results that we found? Ultimately, we found that about 3/4 of the patients that we surveyed did display some correct knowledge, which is to say they knew that antibiotics would work against bacteria. But there were several widespread misconceptions. About 42 percent, which is to say less than half but still a sizable amount of patients, agreed that antibiotics work against viruses.

And if we asked them for a free response question, what's the different between bacteria and viruses, about a similar proportion, 40 percent, said that they didn't know the different between bacteria and viruses, and 29 percent reported -- spontaneously reported factual inaccuracies. So, for example, somebody might say that one type gets in the body whereas the other one grows in the body.

There were no differences among these responses between patients who had flu-like symptoms and patients who showed up, for example, with trauma or other sorts of things that were not necessarily related to reasons why they might expect antibiotics. And this is consistent with the way in which we asked our questions, which is to say not specifically related to the reasons that they showed up in the ED.

Okay. So our major findings here. More than 3/4 of our sample endorsed at least one item supporting this idea of "Why Not Take a Risk?" And these items did capture a unique variance in our factor analysis, which means that they're not strictly related to "Germs are

Germs." On the other hand, less than half of our sample endorsed at least one item in "Germs are Germs." Whereas "Why Not Take a Risk?" was not associated with education, "Germs are Germs" was. So the more educated people were, the less likely they were to say that antibiotics would work against viruses.

On the other hand, if we look at the patients that disagreed with "Germs are Germs," which is to say they knew that antibiotics did not work against viruses, they still agreed -- 3/4 of them still agreed with at least one item endorsing "Why Not Take a Risk?"

So what are some of the implications of this? Well, current public health campaigns that focus on "Germs are Germs" may not actually be addressing a rather widespread rationale for antibiotic use, which is this notion of the absence of a downside risk with a presence of an upside gain or "Why Not Take a Risk?"

Okay. What about side effects? Well, one of the things that we tested for was how do people perceive side effects? And about 2/3 of our patients did agree that antibiotics might have harmful side effects. Of these, about 70 percent agreed with at least one item endorsing "Why Not Take a Risk?" And these two gists were also relatively weakly correlated. So that suggests again that we have these two separate dimensions, one of which really focuses on the perception of the downside and the other one addresses the perception of the upside. And these two are not necessarily in lock step.

Okay. So what does all of this mean for the sorts of educational interventions that we might draw on? First of all, in some, a number of

patients seemed to endorse a strategy that treats risk categorically, and that categorical risk perception promotes antibiotic use. So ultimately antibiotic use will boil down to a choice between on one had avoiding antibiotics and staying sick for sure, and on the other hand taking antibiotics, which may make you get better but you may stay sick. And given this representation, which is essentially a risky choice framing, it's a loss-framed way of looking at the problem, option two is more likely to be chosen.

Germs are Germs is an important and widespread misconception. Okay. This is clearly something that a number of the patients in our sample showed. However, fewer than half of those patients agreed that antibiotics work against viruses, and a large majority of the patients that reject "Germs are Germs" still endorsed "Why Not Take a Risk?" And so this suggests that conveying the differences between bacteria and viruses, focusing on the "Germs are Germs" hypothesis, may not be perceived as relevant to patients' decision.

So, for example, a patient may think to him or herself, well, okay, I understand that viruses will -- antibiotics may not work against viruses, but you know, there's just this little chance that it might be bacterial, so you know, why not give it a shot? Right? And so this suggests that on one hand educating patients about the side effects may actually contribute to behavior change. So emphasizing this downside risk may have a helpful effect.

However, our findings suggest that a two-pronged approach may

actually be even more effective. And so on one hand we might want to communicate that the risks associated with antibiotic use are qualitatively worse than being sick. On the other hand, we should also communicate that there are virtually no benefits associated with antibiotic use.

And I really want to emphasize, these are categorical statements. Right? We're not giving them the numbers. We're not giving them statistical information. We're communicating the categorical gist, the meaning. And obviously this has to be done within the context of a doctor-patient relationship where the doctor has made the assessment that the patient does not need antibiotics. Ultimately, the implication here is that the communications are most likely to be effective if they are categorical in nature.

Okay. So some limitations of our work. Our study is representative of an urban, low socioeconomic status patient population, but it's not nationally representative. And we're currently in the process of testing this on a much larger sample. The sickest patients and those that were experiencing the most pain were less likely to be responsive and therefore couldn't be included in our sample because they couldn't respond to the survey.

The analysis itself was not limited to those that were most likely to expect antibiotics, which is to say people, for example, with flu-like symptoms. Now, this being said, most patients expressed some level of support for antibiotic use regardless of their complaint, and the way that our questions were phrased were not specific to their

illness -- their specific reason for showing up in the ED at that time.

And ultimately we measured people's beliefs and attitudes. We didn't directly measure their changes in behavior. Now, beliefs and attitudes are known to predict behavior. And we're currently in the process of testing actual patient behavior changes, and so that's also currently in the works.

So some conclusions. Ultimately, patient educational interventions may be more effective if they explicitly address this "Why Not Take a Risk?" gist. And so, again, I really want to underline this point. When healthcare providers have made the determination that antibiotics are not indicated, right, so assuming that antibiotics are not indicated, then if that is something that -- if it's clear that antibiotics are not indicated, then the communication associated with that should be that antibiotics can hurt. You know, again, emphasize that the side effects are worse than the status quo or can be worse than the status quo. And also communicate that they will not help, again under the assumption that they actually will not help, that the physician has made that determination.

All right. Well, thank you very much.

DR. BLALOCK: Thank you, Dr. Broniatowski. And let me -- do any members of the Committee have any brief clarifying questions? Let me emphasize that what we're looking for here are questions really to clarify what the presenter -- any points that the presenter made. And then we'll have obviously more discussion after this.

DR. DILLARD: Thank you for your presentation. I was struck by

the parallels with Dr. Chapman's work because it seems that the servers in your study, that is, the physicians are saying have it rare -- order it rare, and by the way would you like some antibiotics with that?

And it made me wonder if the same solution is also in place or could be in place, which would be to have that risk statement on the wall in a doctor's office. Is it there now? I don't know.

DR. BRONIATOWSKI: Yeah, to my knowledge, the "Why Not Take a Risk?" gist does not form the basis for any existing health communications that are widespread. Now, this being said, one of the points that you mentioned is, well, maybe the physicians themselves may share this gist under some circumstances. And that's actually also something that we're currently in the process of testing.

DR. BLALOCK: And just for the transcript, I think I inadvertently cut off the mike before I said that question was from Dr. Dillard. So Dr. Yin.

DR. YIN: Hi, I'm Dr. Yin. I had a clarifying question. You focused a lot in this experiment with the benefits and risks to the individual. And I wondered about -- you mentioned this idea that we need to educate patients about the side effects and adverse events. Do you mean that in terms of an individual perspective or also the global implications of antibiotic resistance, etc., how does that resonate?

DR. BRONIATOWSKI: Right. Great question. We didn't focus on the specific issue of the patient's perception of antibiotic resistance in this study. We focused only on the individual. And that actually draws on literature that suggests that it's really the individual risks and the

individual perception that the patient draws on. Now, again, this being said, this is an area that we're also looking into in future work.

DR. BLALOCK: Dr. Krishnamurthy.

DR. KRISHNAMURTHY: I had a question about the framing of the gist itself. You framed it as why not take the risk. I believe of the side effects or of the medication, could it not be also thought of as the patient is looking as why take the risk that it is a bacterial infection and by not taking the antibiotic, I'm kind of now foreclosing on that option. So is it possible, because I don't see patients as embracing risk as much as wanting to not take the risk of it being a bacterial infection and not taking the medication.

DR. BRONIATOWSKI: Yeah, so, and again, ultimately what we really want to emphasize here is that they see the possibility of an upside gain from taking antibiotics, and they see the absence or the lack of any downside. So, you know, to directly address your question, which is, well, are they really risk takers, you know, given the framing that I just mentioned, which is consistent with the sort of a loss framing, they're more likely to choose the risky option. And that's why we chose why not take risk as a way of describing that.

DR. KRISHNAMURTHY: I just have a follow-up to that. Does that also mean that giving them information on the likelihood that it'll be a bacterial infection, given that the doctor say it's a viral infection, would that change people's behavior if that is the -- is that an implication that we can take from it? Let's say, for example, the physician says that it's less than 1 percent or 1 in 1,000 chance of this being a bacterial

infection; would that alter the likelihood that they would want to take the antibiotic?

DR. BRONIATOWSKI: Right, so providing that kind of likelihood, a sort of numerical likelihood is in a sense a verbatim representation, right? And that may be interpreted as oh, wow, that's a really small likelihood; I don't need it. Or it may be interpreted, you know what, I may be that guy. I may be that one person that they misdiagnosed. And so that's really sort of where there's some of this flexibility here in communicating the gist -- communicating the verbatim with the gist could also be effective, right? But really making sure that it's the gist that comes across is what we're focused on here.

DR. BLALOCK: Dr. Pleasant.

DR. PLEASANT: Thanks. I just want to dig into that very question a little bit more. So I don't know how to characterize this, so I'm just going to throw it out as a hypothesis, I suppose, and you can agree or disagree. Is your notion of verbatim information versus gist as knowledge?

DR. BRONIATOWSKI: Okay, so there's relatively specific definitions of what we mean by verbatim versus gist. A verbatim is a very precise yet symbolic representation of the stimulus itself. Okay, so if I were to give you a stimulus that says, for example, 5 percent of the people who take antibiotics actually need it, then the verbatim representation is 5 percent of the people who take antibiotics actually need it, whereas the gist representation is the meaning of that stimulus to the patient. Now, a patient may look at that 5 percent number, and

they may say 5 percent, that's really low, or 5 percent, that's essentially nothing, or 5 percent, that's actually really high, depending on where they're coming from and what their base rate is, okay?

And so the gist is -- it's not derived in the deterministic fashion from the verbatim. The two are encoded in parallel.

DR. PLEASANT: So you actually then have no idea whether people understand the verbatim information at all.

DR. BRONIATOWSKI: Right. So you can actually -- and, again, we didn't do this specifically in the context of this experiment because we didn't provide verbatim statistics regarding antibiotics. But in multiple other previous experiments testing Fuzzy-Trace Theory, you can test people for are they aware of the verbatim information. You say, well, you provide them with the verbatim information, and can they recover it. And then in most cases they are.

DR. PLEASANT: One more quick follow-up on that. So that means that you're just sort of creating a category of this verbatim information, but you don't know if people have actual knowledge, that they're informed, that they know what it means, whereas gist, it's what they're informed about. So all you're really arguing is for an informed decision, but you've characterized it in a way that the verbatim is inappropriate because it's verbatim and complex.

DR. BRONIATOWSKI: Well, and I think that's -- there's a lot of truth in that statement, and in many cases, we communicate the verbatim information to the patient. But ultimately it's not clear that the patient understands the meaning of that information. And so what

we're saying here is that communicating the meaning of the information is what is more likely to lead to behavior change as opposed to simply communicating the raw numbers, which seems to be what underlies a lot of modern communications.

DR. BLALOCK: And I think we might be moving just a little bit beyond simple clarifying questions, so -- but, Dr. Cohen Silver, did you have a clarifying question?

DR. COHEN SILVER: Yes, I did. You indicate that you mostly used a relatively uneducated, urban sample. Do you think that's the worst-case scenario? I mean are these the -- is this -- if we went to a more educated population, do you think you would see the same sorts of numbers, percentages? I know you say you're going to do --

DR. BRONIATOWSKI: Yeah.

DR. COHEN SILVER: -- more nationally representative samples, but I'm just curious as to why you chose this particular sample.

DR. BRONIATOWSKI: Right. So a couple of reasons. So, first of all, we haven't published it yet, but we have tested the same questions, the same survey in a number of different contexts, including other cities, other hospitals, also online. And we find that "Why Not Take a Risk?" does replicate, and in pretty much the same proportions.

So, again, even within this study we found that "Why Not Take a Risk?" was not associated with education, whereas "Germs are Germs," again, the idea that people don't know the difference between bacteria and viruses, that is associated with education. Now, if "Why Not Take a Risk?" is driving people's behavior, then it suggests that education on its

own may not be sufficient.

DR. BLALOCK: And one final -- I'm sorry.

DR. COHEN SILVER: So does that mean that educating people won't help?

DR. BRONIATOWSKI: Well, it means that educating them specifically about the differences between bacteria and viruses may not be addressing their rationales for taking antibiotics.

DR. BLALOCK: And one final clarifying question?

DR. KREPS: Clarified for me anyhow. One of the things I think is going on is I don't think this is just a misinformation issue. I think it has a lot to do with deep cultural beliefs about the power of antibiotics and the power of medicine that I think cuts across different socioeconomic and educational levels. And so I don't think that the intervention just to clarify the information is enough. I think it has to address those strong cultural beliefs that antibiotics are a miracle drug that can solve any problem; the more you get, the better; and the great belief we have in medication as a panacea for all ills. And so I think so more psychologically detailed approach it gets into, deep meanings, not just information, may be needed to shift the needle on this issue.

DR. BRONIATOWSKI: Yeah. I would certainly agree that there is a cultural component in that that does underlie the gist. Now, we did test for a number of things like people's conflation of antibiotics with treatment in general, which seems to be consistent with what you're saying. That was not -- that was not a -- that didn't capture a significant variance in our study, whereas the specific categorical representation

did.

Now, this being said, there are, I'm sure, multiple cultural factors that may influence how somebody derives a gist representation from a given stimulus. And ultimately, again, that underlies why we may want to communicate the gist very clearly.

DR. BLALOCK: Thank you very much, Dr. Broniatowski.

So we'll now turn our attention to the discussion question, and it's the same discussion question that we had after the first set of presentations. So how can FDA communicators apply the information from these two presentations?

Dr. Pleasant.

DR. PLEASANT: Somebody had to.

So since we can just discuss now. Cautionary tale: It's happened in the field of health literacy historically, unfortunately, and it could be a takeaway people, I hope, don't take from these two presentations, which were very good. But it's very easy to beat up on knowledge, and it's very easy to beat up on technical information. But I think the biggest evidence we have out there is that knowledge, while not sufficient, is required. And to take a position that takes the science out of the communication altogether can lead to an uninformed decision. You might gain compliance with some people. But perhaps compliance isn't the right bar. Perhaps what we should have as a bar in this area of study is just did people make an informed decision or not?

Now, what that decision was, whether it was quote/unquote "in compliance" with the evidence base at that point in time in history,

maybe that's not actually the most important variable. Maybe what we can shoot for is to reach and help people through their health literacy, make an informed decision about their lifestyle. And if that decision happens to agree with the evidence base in place that day, we might just have to accept that.

Now, I completely hypothesize and I've seen it true in some studies, that if you do that, the majority of people will make a decision that is in line with the evidence. But is our bar compliance, or is our bar informed behavior change, whatever that behavior may be?

DR. BLALOCK: Others? Dr. Kreps.

DR. KREPS: I had two application suggestions based on the presentations by Isaac and David, one based on Isaac's presentation. It seems to me that if we're going to communicate risks to publics, we need to really make it clear to them how they can use that information and how to apply it. Just understanding that there is a risk or a connection is not enough.

And so I think we need to figure out ways to enrich the depth of our risk communication so the people would know how they can apply that information and have a sense of efficacy that they can do something about it, because I think what happens is that people will hear the information about the risk, but because they don't know what to do about it, it just kind of rolls off their shoulders, and they say, okay, now I know about that, good, but they don't do anything.

And then with the David's presentation about the antibiotic resistance, I think it suggests to me that we need to understand more

deeply why it is that people have strongly felt beliefs and feelings about different products, services, or medications so that we can provide information that not only gives them basic information but helps them to reassess those beliefs. And as we know about making changes that are culturally based, we need to involve other members of that cultural group as a way of reinforcing that change over time.

So I guess the overall implication for both is that to do effective risk communication, we need to really enrich the communication. It's not just providing information about the risk, but enriching it in a way that people can use and understand it.

DR. BLALOCK: Dr. Krishnamurthy.

DR. KRISHNAMURTHY: I think both these presentations were very insightful. But there is one countervailing force that I want to draw attention to. And the idea is that all patients are somehow equal in their preference for information. And that may not necessarily be the case. Shared decision making is -- should be the goal, giving as much information as always a priority.

But the question is helping patients navigate the information landscape is part of the physician's role as well, and I have come across research recently, like know that there is patients, not all of them necessarily want more information. And that might actually be detrimental to their continued engagement with the medical community.

And I do not know how necessarily this changes the way FDA should learn anything or kind of communicate that to its principals, but I

just want to make a point that it is not always that more information is desired by the people whose behavior we want to change.

DR. BLALOCK: Dr. Rimal.

DR. RIMAL: A couple of things I wanted to mention, I think, sort of as takeaways. One, risk assessment in real time may look and feel very different than after some time has lapsed. So, you know, if a doctor gives me a really horrible diagnosis in the clinic, that information may mean something to me at that time, which over time will likely look and feel quite different given I've had some chance to ruminate, to talk about it with others and so forth. So I think the expectation that providing that information will result in behavior change is -- assumes a lot. And so in some sense, I think I'm not surprised that the evidence is rather weak in seeing that link.

Second, I think from the second presentation, one of the things that I took away was that perhaps our target audience should also be physicians in how we ask them to communicate with their patients. And I meant to ask, and I was not able to ask of David whether in the assessment of knowledge, whether people knew about the antibiotic resistance, that phenomenon, and whether any patients were acting on that belief or not.

And then lastly I think this is going back to what Dr. Pleasant was saying; I found that missing from both presentations was a statement about patient values. And I think this also what Dr. Krishnamurthy is talking about. Some patients may value more information; others may not. Some patients -- the discussion about what does the patient value

is consistent with their value system, with their beliefs, with their cultural background and so forth.

I think all these are really important variables that we do need to take into account. And I think if taken into account, we will probably see stronger effects.

DR. BLALOCK: I'll just interject a comment as well. I mean I think that one of the things -- you know, the results presented by Dr. Lipkus didn't really surprise me either, you know, and I think largely because the process of behavior change is incredibly complex. And we all in a variety of ways know the things that we should be doing to be healthier. And everyone in this room, I'm sure, is aware of something that they could be doing to be healthier, and they're not doing it.

You know, and I guess I like expressions, and when I was in probably in training we used to say the road to hell is paved with good intentions. You know, we all intend to lose weight tomorrow or get that annual checkup tomorrow. And the reason, I guess, for making this point here is that often we present information, including the types of information that Dr. Lipkus presented, as though everyone were in the same stage of change.

And one of the things that I think is important to recognize is that -- you know, and people in different stages of change, people who aren't aware of a particular risk factor, they may need a certain type of intervention including information. People in another stage of change who, oh, yeah, I know that my cholesterol is up and I know that I need to do this, in order to facilitate them moving forward in change, they

need a different type of intervention.

So to see main effects based on one simple intervention of for sort of one size fits all just isn't surprising. And Dr. Lipkus alluded to some of that in his presentation.

I think that's all for right now. So other comments. Do I have a list? Dr. Cohen Silver.

DR. COHEN SILVER: I thought the presentations were excellent, and I've just been trying to think about how to scale them up so that the FDA could use them. And the only thing that I can think of is we had a meeting a long time ago about how the FDA communicates to physicians. That's one whole problem.

I think we have to think about communicating to the public -- you know, there's many publics -- so the public, and I keep thinking about trying to figure out how to work through the media to address some of these, the issues that we saw today and how -- think about the different targets. I think it's been spoken earlier today as well, thinking about how to communicate to different targets with the ultimate goal of getting to the end user.

But if we -- I think we really need to think about different ways of working with either the physicians or the pharmacists or the -- in the schools. We've talked about many over the months, many different places in which we might want to intervene. And I think that if we're talking about scaling up from the FDA on down, we really need to think about working with the media, working with physicians, working with schools, working with nurses, working with pharmacists.

DR. BLALOCK: And I'll just echo one thing in relation to that, and that sort of ties it back to what I said as well, that, you know, when you start to recognize that people can be in different stages of change, it makes that process very complex. And dealing with it in a lot of venues is probably likely to be not as effective as where you can have that interactive capability that you do when it's the physician talking to the patient and can assess barriers to change, can assess stage of change, can assess things that motivate change. So I'm just echoing sort of your call for things that focus on healthcare providers as well.

Ms. Duckhorn.

MS. DUCKHORN: Thank you. I would like to hear a little bit more discussion about how -- more than just the call to communicate with different target audiences but how to communicate to those target audiences, specifically because FDA communicates with the masses, and we tend, as much as we can, to target our messages to what I call the least common denominator as much as we possibly can.

But what I hear around the table is everyone saying people have preferences. So I'd like to hear more discussion about how the FDA specifically can target more specifically. Thank you.

DR. BLALOCK: Dr. Dillard.

DR. DILLARD: It seems to me that the notion that doctors should communicate directly with patients and patients should themselves seek out information is a valuable one. But I, in addition to that, I think there's the obvious routes through which you're probably already channeling information, which is directly to the media. It seems like the

media campaign or perhaps FDA-initiated campaign to alert people to the dangers of antibiotic use has made that an issue that's in play in the media now. And the media are always looking for the second act to that. And if the act is there are risks to taking antibiotics, that's a pretty simple message that the structure's in place to disseminate.

DR. BLALOCK: Dr. Krishnamurthy.

DR. KRISHNAMURTHY: I'm glad that Dr. Cohen sort of brought up the discussion that we had some time back about patient-physician communication. And I -- again, this is a question about broad policy as to how does FDA communicate to physicians? I don't think necessarily some of the interesting research that we saw today scales directly to how can FDA have long-form interaction with patients. I just don't think it is a practical question there.

However, if there is a new way and novel method of delivering information to physicians -- because these things are at the junction of the physician-patient interaction. Right now, I do not know if there is a particular channel that is being adopted for direct communication to physicians. And I think there must be some research initiated on what could be a useful method of communicating to physicians, which in turn would allow you to channel a lot of information that you are gleaning through the various committees and the reports that you are getting and be more efficient.

I know this is an unpopular demand -- not a demand -- request that the FDA needs far more resources to be able to kind of do or conduct or guide such research that it'll be more efficient than what

they are doing. I think it's already a very challenging job that what you're being asked to do. And here we are giving more and more suggestions without necessarily opening your bandwidth there, so --

DR. BLALOCK: Dr. Rimal.

DR. RIMAL: I think going back to Dr. Lipkus' findings, I think it's incredibly invaluable that there is now this body of work that shows that we, in fact, don't have a magic bullet, that just showing patients here's a picture of your dirty lungs or, you know, here's what the biomarker says, that's not going to all of a sudden result in changes in behaviors. And so I think the next generation of research in that area does need to ask questions pertaining to I think what Dr. Lipkus was already alluding to, which is works under what conditions, among whom, and what kinds of situations.

And coming back to things like the stage of change or the particular value preferences of the patients and directing the communication -- directing physicians to be mindful of those things may be a very easy first step.

DR. BLALOCK: Dr. Pleasant.

DR. PLEASANT: Thanks. So I think what we're all trying to say is tailoring information is incredibly important to be effective to move people to an informed decision and hopefully a behavior change that leads to healthier and also more cost efficient outcomes, I might add. There's nothing wrong with a triple bottom line. But at the mass scale, right, tailoring is expensive, and it's time consuming, and a lot of people can't do it very well still yet, because why? You have to ask a lot of

questions to tailor.

And the systems that -- and this is not solely an FDA problem, but it is also an FDA problem -- the systems aren't aligned to create incentives for people in the trenches; if you want to just go with physicians, we'll go with physicians. You have this conversation with a physician, 8 out of 10 times they're going to tell you I don't have time. All right, I need to see X number of patients to financially survive every day, and that does not include me having a half an hour long conversation with each patient about their perceptions of antibiotics.

So how do you -- you know, what we'd need then is, in fact, a system change. But the only way to leverage that is through data. So what the FDA, I believe, has the resources to do is to launch some really targeted intervention case study campaigns to prove that there is a way that you can create at least a sufficient amount of tailoring in the communication process so that people can evaluate that information in the context of their own lives and then use it to make an informed decision.

I've seen it happen. I've led some myself. It can be really effective. But it does need to be launched from a system of we are creating space inside the system to change the way that we do everything and try to tailor it a little bit more, bring people into the decision-making process, and then demonstrate to the funding sources that this really can work and can be scaled up, because scalability is the challenge.

DR. BLALOCK: Dr. Krishnamurthy.

DR. KRISHNAMURTHY: In the world of EMR that is now becoming more and more common, I really believe this is just some broad philosophical question. I think the FDA should look at an alternative information platform where like it is not disease specific, it is not -- it should not be like that every time you get new information, you have to find a way of communicating it to the physician. Just inefficient, I think.

I almost envision a world in which if somebody is about to prescribe an antibiotic, there is a message that kind of triggers in Epic, or whatever the EMR format that might be -- and I say this with full recognition that there is going to be tremendous resistance on the part of various principals, oh, why should we change our behaviors? But I think like it is -- it's not efficient to not have a way of directly injecting FDA's recommendations at the time of interaction between the patient and the physician.

And I do not know what will produce a change of that magnitude. For example, if there is a risk that has changed for a particular medication, why should the physician wait until one year before they get that dear healthcare provider letter, which I don't even think they are probably reading it or something like that, when you want to affect the risk calculus at the point of contact with the patient.

So I do believe that the FDA and the communication community in general should investigate the feasibility of a platform that allows the FDA to more easily communicate any intelligence and knowledge that they are developing on a routine basis rather than one-off

communication.

DR. BLALOCK: Dr. Zavala.

DR. ZAVALA: Yes, I think that using public service announcements as being cost effective to disseminate the case studies that Dr. Pleasant was stating, talking about would be a good strategy to put out the information.

DR. BLALOCK: Other comments. Dr. Yin.

DR. YIN: I love the idea of leveraging the electronic medical record systems and trying to push out information to patients at the point at which medications are being prescribed and other things. I wonder how we can incorporate some of the questions around tailoring in those situations, however. You know, how do we take into account these value preferences or where people are at in terms of the stages of change in those situations? I'm not sure how that would be tackled.

DR. KRISHNAMURTHY: For instance, like if you take the biomarker studies, like if after randomized controlled trials we do find that there is strong effect of tailoring biomarker information to the patient, then when your EMR kind of involves testing, then you can prompt the physician to have a conversation about the biomarkers. That way the idea that discussing biomarkers produces salutary, self-regulatory changes can actually be implemented in the real world, if there is such base data out. That is just an example of what I'm thinking.

So if we find that there is a good effect of a particular communication modality or a particular point that we want to

communicate, then if that pops up or if there is a prompt or a cue for the physician, I know it's additional tax on their time, I'm not disputing that, but if it's going to be net beneficial, then why not have the conversation? Likewise for the antibiotics, if the physician is about to prescribe an antibiotic, then the question is, hey, did you have a conversation about viruses versus bacteria and -- something of that particular nature.

DR. BLALOCK: Other comments. You know, one thing that I thought about as other folks were talking, there is a limit to what any single person or agency can do. And so I think that one important part of this is really working through what the goals of different communication programs are.

And I think for one -- and I've done work on the stages of change before. And stages of change can be applied both at the individual level as well as the population level. If you think about smoking these days, messages to tell people that -- messages telling people that cigarettes kill probably isn't new news to anybody. You know, in the 1960s I can -- I hate to admit it, but I can remember when those labels came on, and probably a lot of the change that we see in smoking over, what is it, the last 50 years started there, you know. And the first step to behavior change, you sort of pooh-pooh knowledge, and I do that a lot. But that's the first step in behavior change.

And when you think about the complexities of behavior change and maybe even informed decision making, at what point -- I think from the FDA's perspective is, what part does -- what role does the FDA want

to play in facilitating that and really taking it from again considering each behavior uniquely, because I know there's a lot of products that you regulate, food -- you know, I think of medications, but food -- a lot of products, and it's just going to differ. So I think if you step back and say, okay, what do we want to accomplish? Do we want every physician in the United States to be aware of X, Y, and Z? Do we want them to do X, Y, and Z? That that's at least, I think, a step in the right direction.

Did I see other comments? Usually when I talk, people want to rebut. Dr. Kreps.

DR. KREPS: I don't want to rebut, but I'm intrigued by the discussion about the tailored information systems and risk communication. One of the lines of research I've been working on for the last few years is the use of online patient portals that different healthcare systems provide. And typically they provide information about medications, but it's very, very basic, and it's mostly focused on ordering new medications and refills and not very much about the decisions about those medications.

So one of the things I've been working on with some different healthcare systems is to provide more opportunities for questioning and answering about different types of medications, healthcare services, risk factors. And I think that we have the technology now, with tailored information systems, to build pretty robust interactive systems to enrich and flesh out the interaction, not just providing information about the risks of antibiotic resistance but allowing people to explore and discuss those issues. But I think there needs to be a will within the

healthcare delivery system to build these more robust systems.

Now, I'm not sure what kind of role the FDA can play. One of the things that the National Cancer Institute had done was to make their data about cancer risks, cancer treatments, cancer outcomes available open source to any system that wanted to use that information. They learned pretty quickly that most consumers were not going to the NCI website for cancer information, even though there was good information there. So what they wanted to do was make sure that the good information they had there was more readily available on the sites like WebMD or even better local portals that are part of the healthcare system that you belong to.

So maybe there can be some kind of a licensing agreement that the FDA can provide about providing the latest information about medication risks, medication advisories, food risks, food advisories to the different sites. And maybe we need to think even more broadly than just the patient portals. Maybe the different social media sites as well, where people may want to go more informally to get that information.

One of the big fears about social media is that consumers don't get good information or full information or state-of-the-art information. Maybe we can short cut that by allowing the FDA and maybe other agencies that have the latest information to provide that information to these groups. At least that could be a recommendation we could make.

DR. BLALOCK: And that kind of goes back to the first set of presentations as well. And I do -- you know, Dr. Krishnamurthy also

talked about electronic medical records. And I really -- I would echo that as well, that at least when you've got simple behaviors that you're trying to change, providing information at the point of decision is going to be a lot better than something that is sitting on the physician's desk waiting to be opened. So if efforts could be made to integrate these things into decision applications and electronic medical records, I echo that idea.

Other comments. Dr. Pleasant.

DR. PLEASANT: Not to be a naysayer, but --

(Laughter.)

DR. PLEASANT: -- a truism does exist in the world. A good EHR in a bad system is still going to be ineffective. You can have the best electronic health record, but if your healthcare system is still treating diseases and not people, it's not going to make a difference.

DR. BLALOCK: And just to get some dialogue going, the only thing that I would say in sort of response to that is, okay, but can the FDA affect that? You know, it goes back to that question that I raised. What can the FDA affect? And I don't know if you can affect the quality of that in the healthcare system; that's one thing. But I'm not sure that -- I'm not sure that that is something that the FDA can affect. But maybe I'm being too narrow-minded.

(Off microphone comment.)

DR. PLEASANT: Yeah, just checking first. Yeah, actually, I think they can. It comes down to incentives. What are healthcare professionals rewarded for at the end of the day? Is it seeing how many

patients or reducing the disease burden in a community by X percent. That's -- both of those are very valid incentives, but they will change the way that healthcare professionals interact with the people that they serve.

What do you get paid for? A patient who complies and shows up and takes the prescription medication out of the pharmacy, but then you don't know if they actually take it? Or for the health outcomes, because you fully explain the why, how, and when a person needs to take the prescription medication? All of those fully can lie within the FDA purview. So it's really about how you want to set up incentives that can realign a system to move upstream and also into prevention instead of treatment of disease.

DR. BLALOCK: Other thoughts. Dr. Zavala.

DR. ZAVALA: Just to add to Dr. Pleasant's statement. The healthcare system is changing. Not as fast as we like to see, but we are seeing the paradigm shift from volume to value care. And that's what we, I guess, we all want.

DR. BLALOCK: Other comments. Has everybody had a chance to express their views, opinions? Okay. Well, I know that this is the point at which I sort of summed up, after the first set of presentations, but this was so varied that I think I'd be challenged to really sum up.

Do you feel like you've gotten what you need out of it, or any follow-up questions for us?

MS. DUCKHORN: No, I think this is good. Thank you.

DR. BLALOCK: Okay. So I think, looking at the agenda, we're

moving to the open hearing session. So we'll now proceed to the open hearing portion of the meeting.

Public attendees are given an opportunity to address the panel, to present data, information, or views relevant to the agenda.
Ms. Facey will now read the Open Public Hearing disclosure process statement.

MS. FACEY: Both the Food and Drug Administration and the public believe in a transparent process for information gathering and decision making. To ensure such transparency at the Open Public Hearing session of the Advisory Committee meeting, FDA believes that it is important to understand the context of an individual's presentation. For this reason, FDA encourages you, the Open Public Hearing speaker, at the beginning of your written or oral statement, to advise the Committee of any financial relationship that you may have with any company or group that may be affected by the topic of this meeting. For example, this financial information may include a company's or group's payment of your travel, lodging, or other expenses in connection with your attendance at the meeting. Likewise, FDA encourages you, at the beginning of your statement, to advise the Committee if you do not have any such financial relationships. If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

DR. BLALOCK: For today's public hearing, we received no requests to speak. Does anyone in the audience like to address the Committee at this time, and if so, please come forward to the podium,

and you will have 5 minutes.

Okay, it looks like we have none. So I now pronounce the Open Public Hearing to be officially closed. And we won't take additional speakers for the day, and we'll proceed with the rest of the agenda.

So we'll now take a 15-minute break; is that right? So what time is it?

MS. FACEY: 4:18.

DR. BLALOCK: 4:18, let's call it 20. So come -- so we'll take a 15-minute break and come back at 4:35. So, and again, I need to remind Committee members not to discuss the topic of the meeting outside of the room. And we'll resume at --

MS. FACEY: 4:35.

DR. BLALOCK: Thank you. 4:35.

(Off the record at 4:19 p.m.)

(On the record at 4:37 p.m.)

DR. BLALOCK: So we're now entering the third session of the meeting today, Communicating for Public Health - Public Service Announcements. And we'll hear presentations from Dr. Jennifer Lerner, followed by Dr. Carl Botan.

So, Dr. Lerner, you may begin your presentation.

DR. LERNER: Thank you. Thank you for having me. It's a pleasure to be here. And I have an ambitious agenda for the number of studies I plan to cover. I'm happy to slow down or speed up. You can just give me the word. And now we have a heterogeneous group here. And so I've made some assumptions about what you might be familiar

with and what you might not, but if I'm wrong, again, I welcome your questions after for clarification.

Okay. So the title of my talk, my wordy title, Beyond Valence: Emotion-Specific Influences on Citizens' Perceptions of Risk and Implication for the Design of Effective Risk Communication. What that means, "Beyond Valence," is moving toward a more specific focus on discrete emotions rather than just focusing on positive or negative valance when we talk about emotion. And that will be a theme that runs through all of the research that I present today.

So a very quick history that many of you will be extremely familiar with, for the field of psychology's focus on risk perception and communication you might say begins in around the 1950s and for most of the mid-20th century, behaviorism was the dominant paradigm, where we focused on stimulus leading to response, and research was absolutely silent about what people think or hear about risks.

The latter half of the 20th century began the cognitive revolution. And then the shorthand nomenclature was to insert cognition or C between stimulus and response. And a very exciting set of research and experiments grew during this time, particularly examining the role of heuristics and biases in explaining departures from rationality. In other words, why don't people perceive risk in line with the base rates for events, but instead overweight some risks and underweight others?

The work of Paul Slovic is a beautiful example of that kind of research, and many of you will be familiar with this two dimensional

chart that he developed where on the horizontal [sic] axis you have a dimension of uncertainty or what he referred to as unknown risk, and on the horizontal axis, you have the controllability or dread risk dimension. And it turns out that this is a very useful two-dimensional plot for understanding the cognitive predictors of risk perception.

And so you have things like bicycles, which are in this lower left-hand quadrant, and this is from his paper in *Science*, where bicycles are perceived as relatively controllable, so they're on the left side of this horizontal axis, and relatively observable, predictable. And so this quadrant right here are things that people tend to perceive as not so risky, despite the fact that bicycles are quite risky in terms of the number of deaths.

And up here, this is the very high perceived risk quadrant, things like DNA technology, and that's explained, of course, in his framework by the fact that these things are perceived as uncertain and uncontrollable. And he has mapped the space in a really useful way. I'm circling here a few things that are especially relevant to FDA.

So this literature has been nicely summarized in terms of a certainty heuristic, which is that we humans tend to reject options that are associated with uncertainty, and we see them as more risky, regardless of what the base rates for death are and a controllability heuristic, otherwise known as dread risk. And I think most people here are familiar with this paradigm. I present it because it's very important background for understanding the role of emotion on risk perception.

So moving into 2000 onward, after the cognitive revolution has

come an affective revolution. And affect being a global superordinate term for emotion, moods, dispositions, etc. And so the nomenclature, stimulus and then both emotion and cognition leading to response. My colleagues and I recently wrote the first chapter that's ever been featured in the Annual Review of Psychology on emotion and decision making.

And here you can see in our graph the number of papers on emotion or affect, mood, and decision making has been increasing exponentially in recent years. And it's not just increasing because all research on decision making is increasing. It's also increasing as a percentage of decision making research. I have an arrow here pointing to 1983, because that is really a landmark year in research on emotion and decision making because some very key papers came out that year, one of which, I'm going to describe to you.

I should say, by the way, that because I am a compulsive perfectionist, I re-ordered a couple of the slides. And so if you have any confusion on your handouts, I refer you to the screen.

Okay, so a key idea that came about in 1983 in these landmark papers is the idea of mood-congruent processing. So following the information processing, cognitive science revolution affect has sort of overlaid on that model, and a lot of the early predictions took the form of if you're in a negative mood, you're going to see things more negatively, and you'll have pessimistic risk perceptions, whereas if you're in a positive mood, you'll see things as more -- as less risky.

And here, one of those landmark studies that I mentioned,

Johnson and Tversky published a paper called, "Affect, Generalization, and the Perception of Risk." The generalization is very important. They are brilliant multi-dimensional scalers who tried very hard to show that the cognitive content in an affective prime would predict the degree to which it carries over and colors perceptions of risk. If there's similarity between the content of the prime and the content of the target risk, there would be more carryover. But they did not find that.

Instead, they found this global generalizing effect, where once affect is triggered in the system, it becomes a perceptual lens that colors perception of everything. And there you see fatal risks, non-fatal risks, and life problems, negative affect in the black bars, positive affect in the white bars. So that in this particular case, the negative affect they induced was really sadness, so people would read a story, for example, about a girl dying of cancer, and then they'd rate the likelihood of all those risks. And if they were in that sad mood evoked by that news story, they saw all risks as more likely; conversely for the positive affect.

So when I came into the field, my colleagues and I were very struck by this carryover effect that emotion becomes this crucial perceptual lens, that it has such widespread effects. And we also were struck by the lack of specificity. And we were struck by that because we were students of the scholarly cognitive literature, which said that perceived certainty and controllability mattered enormously for the perception of risk.

So we started working on seeing whether it made sense to come

up with a theory of specific emotions rather than global valence, positive versus negative. And Dacher Keltner and I came up with what we call the appraisal tendency framework, which is to consider valance, positivity versus negativity, as only one appraisal dimension of emotion. Scholars, emotion scholars around the world, I've identified and actually converged, a rare moment of convergence in behavioral science, on the idea that there are approximately six key appraisal dimensions. And one of them happens to be control. Are things under individual control versus situational control? Another happens to be certainty.

So the research strategy that falls out of our theoretical framework is that you want to compare emotions that are highly differentiated in their appraisal themes on judgments or decisions that relate to that appraisal theme. And, of course, we know, from the work of Slovic and others that control and certainty relate to judgments of risk.

So we took this approach, and we chose as our target emotions fear and anger. They're both negative emotions. And so by all theoretical and empirical accounts up to this point, they should both increase perception of risk and lead to pessimistic outlook. However, fear and anger happen to fall on opposite ends of the dimension on control. Anger tends to make people feel that individuals rather than situations are in control, whereas fear is the opposite. And anger makes people feel a sense of certainty, whereas fear is defined by a sense of uncertainty. It's the quintessential experience of fear that you just don't know what's going to happen.

So they are opposed on these dimensions, and if control and certainty are the most important predictors of perceived risk, then fear and anger should actually have opposite effects from each other, not similar, despite the fact that they share a negative valence.

So here, if you want to see what these predictions look like in a pictorial form, there's a grid, and you can see that researchers who follow a mood congruent or valence perspective would predict that, if you're in a fearful state, you'll perceive more risk; if you're in an angry state, you'll perceive more risk. If you follow this appraisal tendency framework that we're developing, you would predict the same thing for fear, but you would predict the opposite for anger.

So we have tested this many times. I'll fly through some evidence. Here this -- we go back and forth between using emotion states and emotion traits, because they're really two sides of the same coins. And they have different methodological advantages. States obviously giving us the ability to test causal effects. In this case, these are emotion tendencies or affective dispositions toward anger. There are definitely trait angry people -- you may know some of them -- and trait fearful people. And what you see on the vertical or y-axis is perceived risk. And that's, of course, collapsing across a wide array of risks, because as we saw in the Johnson and Tversky classic work, they all collapse together regardless of whether they are fatal risks, non-fatal risks, personal risks, etc.

So here we see the opposing influences. That's in terms of risk perception. We also wanted to look at actual risky choice -- real

behavior -- and where people are choosing between a gamble and a sure thing. Many of you will be familiar with Kahneman and Tversky's prospect theory. And a key prediction that falls out of prospect theory and their Nobel Prize winning work is that when outcomes are framed in terms of losses, people tend to be more risk seeking in order to avoid the loss, as opposed to risk averse, taking the sure thing. And that behavior flips if you frame the same outcomes in terms of gains.

So here this is what we're calling the new influenza problem, which is a spin on their classic work, Kahneman and Tversky, where you imagine the U.S. is preparing plans for the outbreak of a new strain of the flu, which is expected to kill 600 people. That information remains constant. And there's two alternative programs. If A is adopted, 200 people will be saved; if B, 1/3 probability that all 600 will be saved, 2/3 that no one will be saved.

So what you see is that A and B have equal expected value. The -- we're just calling attention here to the fact that there's a certain thing here and probabilistic outcome there. Now, you can change that problem by Version L, which is calling attention to the losses. We hold constant the fact that it's going to kill 600 people. And instead of saying that 200 people will be saved in the gain frame, we say 400 people will die.

So you get the idea, and people have to choose between a sure thing or a gamble. And here's the classic finding, which is that people choose the sure thing when outcomes are terms of gains, and they switch and choose the gamble when outcomes are framed in terms of

losses, even though it's equal expected value. And that's true regardless of whether you do within subject or between subject manipulations.

So that's the backdrop to our investigation of emotion. And what we wanted to know is how robust is this phenomenon? We've just seen, in the study I showed you a minute ago, that fearful people are risk averse. And angry people tend to be risk seeking because we hypothesize of their underlying differences in perceived control and certainty. Is it possible that emotion can moderate this pattern?

So I'll come back to that. So here our predictions are in terms -- we're predicting here whether they're going to choose the gamble, which again is the risky outcome. And if you follow the mood congruent valence approach, you say the same prediction for fear and anger, whereas with our new appraisal tendency framework, you predict that angry people are going to be more likely to choose the gamble than fearful people.

Okay. So first we look at the loss domain. And on the y-axis, you see as you go up it's more risk seeking. And the angrier a person is, the more likely they are to choose the gamble in the loss domain. The more fearful a person is, the less likely they are to choose the gamble.

So in other words, the fearful person is going against the dominant tendency to be risk seeking in the domain of losses, and they, although more weakly, maintain that same pattern across frames. In other words, emotion here is so powerful that it actually moderates what is otherwise a very reliable robust phenomenon cross-culturally.

One of the things that this points to is that risk communication matters enormously in terms of the framing of losses or gains. And we've known this for some time, thanks to Kahneman and Tversky because -- so a doctor can say 90 percent of patients are still alive when recommending a drug or a procedure, and that's the gain frame. Or a physician can say 10 percent of patients are dead, and that's the loss frame. And depending on which of those they say, it has huge implications, or a patient can use a neutral -- a doctor can use a neutral frame. It may be that people who are dispositionally fearful and anxious are much more susceptible to this kind of framing and need to be targeted in special ways, and likewise people who are dispositionally angry, or if they have, for some reason or another, been induced to one of those states.

A stronger test of the appraisal tendency framework comes in when you invoke the emotion of happiness, because happiness is of course a positive emotion. It just so happens that it's also, like anger, high in sense of controllability and high in sense of certainty. And so if you take -- if you are -- want to give a strong test of the appraisal tendencies perspective, then you hypothesize that the risk perceptions for happy people are going to more closely resemble those of angry people -- or sorry, the risk perceptions of angry people will more closely resemble those of happy people, even though happiness is positive valence, than they will of fearful people. And, of course, the mood congruent or valance perspective would say, no, happiness will be distinct from fear and anger.

So we've tested this with standard measures of life events, where people are -- where you can get a overall optimism measure. And some of them are risk perception items like the chance of having a heart attack before age 50. Others of them are just life events like enjoying post-graduation job. And what you see is that the happiness beta there is almost identical to the anger beta. These, when it comes to risk perceptions, angry people look like happy people, which can be quite dangerous.

We have worked to try to see whether certainty and controllability are, in fact, the underlying driving factors. And so if they are, then it should be that fear and anger are most different from each other when certainty and controllability are ambiguous. And so here's the prediction. And what you see is that, yes, when certainty and controllability are unambiguous, they look similar. It's only when they are ambiguous that they look different.

We also have shown -- and I'll skip quickly ahead -- that appraisals of control and certainty actually mediate the risk estimates. We've also sought to find out whether these perceptional differences matter for real life events. And so in a nationwide, nationally representative sample, we've conducted experiments, longitudinally in the aftermath of the 9/11 attacks, and we've induced fear and anger through media exposure to selected pre-screened media. For example, the fearful news stories were about anthrax.

The anger-inducing news stories were about celebrations in the Middle East saying Osama is our hero. And even in nationwide samples,

you see that fear and anger have different effects regardless of whether people are predicting for the self or for the average American, regardless of whether you have them use probability scales or Likert scales. In fact, 80 percent of the variance associated with risk perception differences in gender is explained by emotion.

DR. BLALOCK: And I need -- just in terms of being the timekeeper, we're pretty much out of time.

DR. LERNER: Okay.

DR. BLALOCK: So maybe a minute?

DR. LERNER: Yep.

DR. BLALOCK: Okay.

DR. LERNER: So there's lots more in our research there. And so implications for risk communication: First, emotions, both state and trait, have highly specific effects on the perception of risk. And so public service announcements, and there are many that evoke emotion, need to, rather than arbitrarily invoking -- evoking a wide array of negative emotions, very carefully and with a theoretical and empirical grounding, design carefully which emotions to evoke because some responses will backfire.

We have a program of research showing, for example, that when you induce sadness, people become impatient for financial and other kinds of rewards, and they make very poor decisions. And it just so happens that lots of anti-smoking PSAs evoke sadness, which we think will backfire. So, in sum, risk communication needs to be designed with a comprehensive understanding of affective science. Thank you.

DR. BLALOCK: Thank you very much, Dr. Lerner. Do we have any clarifying questions of a brief clarifying question from the Committee?

DR. PLEASANT: Thanks. This is very interesting. What I'd like to learn more about is the temporality of affect and how that plays into this, because at one point in time you talked about people who were generally happy or generally angry, but we all know that some of us go back and forth all the time. So if you're planning a risk communication event, how do you take a sustainable approach to affect when it can change quite rapidly?

DR. LERNER: Um-hum. So state and trait are both very important. We measured trait affect immediately after the attacks and found that it predicted risk perceptions 2 months later by measuring the affective dispositions. And there's very good evidence that affective dispositions are stable over time. My colleague at Harvard, Jerome Kagan, measures salivary cortisol immediately after birth as a marker for anxiety and can predict dispositional anxiety via amygdalar activation up to 21 years later. So it is possible to identify individuals and target that way.

And then in terms of state affect, state is much more fleeting. However, it's currently being used all the time in PSAs. It's just being used without an empirical and theoretical grounding. I hope -- does that answer your question a bit?

(Off microphone comment.)

DR. PLEASANT: I mean I am aware of cortisol and its function, but I don't know if that's comparable to a self-report status.

DR. LERNER: Of anxiety?

DR. PLEASANT: Well, of an emotional state. Period. Right, do you use a biomarker? Because you can't for all of these. And you could argue some emotions are going to last longer than others, perhaps love for some people or hope for others, but not anger for some.

DR. LERNER: Yeah, so there's definitely different temporal characteristics of different emotions. Anger is much more protracted than is fear, for example. I'd be happy to share some papers with you on -- showing the correspondence between self-report of anxiety and cortisol secretion, taking into account the fact that you have to wait at least 25 minutes post event for the cortisol, the HPA axis system to respond.

DR. BLALOCK: Dr. Krishnamurthy.

DR. KRISHNAMURTHY: Dr. Lerner, I just have a quick clarifying question on your charts. The emotion tendency Z scores, what do they actually refer to? I was not able to --

DR. LERNER: So that's one standard deviation above the mean on the trait and one standard deviation below the mean. And in the complete papers, we actually have the scales that they came from.

DR. BLALOCK: Thank you very much.

DR. LERNER: Um-hum.

DR. BLALOCK: So we'll continue Session 3 and hear from our second speaker, Dr. Botan.

DR. BOTAN: Thank you. And please excuse any hacking I do up here. Thank you for having me here today. I wanted to talk a little bit

about an evolving understanding of difference between message-centered health risk communications and publics-centered health risk communication and what I call a cocreational view, which is an evolving model that might be helpful in mediating this difference and lead us to some decisions about how to handle things.

Before I start, I just want to make very clear that there's nothing intended in my comments today to question the intentions of folks involved in health risk communication. I don't think anyone's involved for the glory of it, and certainly no one's involved for the pay. So that the -- I'm accepting -- I accept that the intentions are good.

And the underlying message, and I'll divulge it right now, that I'll get to is that the best available science is necessary but seldom sufficient for effective health risk communication and that we may be focusing far too much on the best available science, which I will in some respects liken to the technical aspect of risk communication, and not enough to the subjective side.

So I'll be making basically three points. Talk a little bit about what I perceive to be the current model or models and in terms of what they teach us we should be saying. Then talk a little bit about the old traditional two aspects of communication, which have been around forever. This goes back to Watzlawick, Beavin, and Jackson or whoever -- Watzlawick certainly. And then I'll just introduce briefly a tool that I've been working on that's the subject of a new book I have coming out at the end of this year that I call the cocreational model or the cocreational approach.

And certainly the history of the success rate of health risk communication campaigns have had varying degrees of success, and they've been reported all kinds of times in the literature. Recently the CDC's Community Guide from a little over a year ago kind of summarized that health promotion behaviors have demonstrated an absolute median change of about 8.4 percentage points. But that can be broken down very easily in the literature.

One of my favorite articles is from -- a little older, it's '07. And it's by Snyder, and many of the members of the Committee may already be familiar with that, of course, which was a meta-analysis over 9 articles that covered 440 campaigns. And that article reported that the effect size for, for instance, seat belt campaigns were about a 0.15, and that was the highest level of success rate covered in that article, whereas youth drug campaigns and marijuana campaigns were coming in in the very low single digits, around 0.01 or 0.02 on effect size. And I am aware that normally when we talk about effect size we'd be talking about a number like R squared or AR squared, but the author has specifically indicated our representative effect size in this particular study.

The problem is that even if we were to settle for these levels of effectiveness, most folks I think that are involved in health risk communication and most involved in strategic communication in its other forms, so that includes marketing communication, print advertising sorts, broadcast advertising, e-mail, and some other forms, all will generally report things in the single digits in terms of their

effects.

But it seems to me that there are growing challenges that we're facing, and this might just be me, and certainly if members of the Committee disagree, I'll be happy to hear that disagreement, but it seems to me that there are some growing challenges that are sort of coming down the track towards us, sort of the old stereotype of you're in a tunnel and you see the large single headlight coming at you.

There are some health challenges, and I don't just mean Zika, but other things that have been going on for a long time, like obesity, and I'm sure members of the Committee are better versed in that one than I am, but between 1980 and 2016, adult obesity roughly doubled, and childhood obesity roughly tripled. And with that, as we know, will come increase in diabetes and a number of other health challenges.

But maybe more important and closer to my own work is the fact that I think our publics are changing. And, in fact, I think and have said many times that publics are always changing. Publics are in a constant state of change. So there's no great disclosure in this statement, but I think our publics are changing in very fundamental ways in health risk communication. Certainly, I think our publics are not the same as they were 40 years ago or 30 years ago, probably not 20 years ago, and maybe not even 10 years ago. Publics are better educated today. Publics -- there are larger publics. There are more people. Publics are better embedded in various kinds of networks, both social media and otherwise, for getting information and for exchanging views with one another. So there is more consensual response to not only media

development but to health development and health issues.

There are other ways that publics are changing that might actually be more challenging. And there was an article, came out in 2010, as far back as 2010, which indicated that, at least from the view of this author in this article, about 80 percent of the public distrusts government, which is where, of course, a lot of health risk communication is generated.

Then Gallup, this past year, back in September, had reported that only about 40 percent of our publics have a "great deal" of trust in the media. That could be flipped around to say that 60 percent don't have a great deal of trust. And as we've already heard here today, and as we all know from practice, many health communication campaigns depend on the mass media, and many are sponsored by government bodies. So we face a whole raft of challenges kind of coming down the road. And it seems to me that how we communicate about health communication, about health issues may be a part of that problem and may exacerbate what I think is sort of a train coming down the tracks.

Let me go back to one of my favorites, which is CDC's Community Guide. And they said -- their definition of health communication, and this was in 2015, the early part of 2015, that "Health communication campaigns apply integrated strategies to deliver messages designed, directly or indirectly, to influence health behaviors of target audiences." And note the message-centeredness of this definition. That the function of health communication campaigns is to engage in delivering messages, that that's the business we're in. And I think that's fairly

representative of a lot of folks and a lot of practices in health communication.

And I'm not here today because I have any really bright or new insights into this, but what I am going to argue for is a change of emphasis or a change of worldview in what we ought to be thinking health communication campaigns exist for. And I will respectfully disagree directly with the CDC definition of health communication campaigns, and that in spite of having taught down at CDC most of the last 8 or 10 years. And I have a high regard for those folks. I just don't accept this definition.

Note also that this definition of health communication is very one way, and I know that members of this Committee have already, in your questions today, showed a sensitivity to the need to be two way, certainly Dr. Pleasant in particular but others. And I understand that I'm sort of talking to the choir here, but this sort of approach from arguably the most prestigious organization in health risk communication is pretty one way in its orientation.

Now, admittedly we all do some two-way practice when we're engaged in health risk communication, but how frequently is that two-way practice really researched to find out how best to modify our campaigns to achieve the results we want and kind of putting -- kind of twisting that a little bit, but only a little, to one of Dr. Rimal's comments earlier today about the silver bullet, too often I think we use research in health risk communication to try to refine things we have already decided we're going to say so that they have a better chance of

qualifying as a magic bullet.

And I see this as an instrumental sort of approach. It's also, going back to the last speaker, got some behaviorist underpinnings to it because we're looking to come up with the things we can say or the ways that we can say them that will get the desired response. And the more we look for that, the more we focus on the message, I think, the more we may be contributing to these challenges that I see kind of coming down the track.

And what I'm going to do is counterpoise what I'm calling a cocreationalist perspective or cocreational view on the relationship between sponsoring organizations and publics in health risk communication. Let me, before I do that, step just to the side a little bit for a couple of ideas.

And the first one is -- and this has also come out in comments both from the speakers and from the Committee today. I know that this is not a new idea for this group at all. But it has to do with the subjective versus more "objective" or technical side of risk communication. And one of my favorite sources for that was Peter Sandman's work some years ago. Peter was a colleague of mine at a previous university. And he referred to the subjective side -- or he referred to the technical side as hazard, that was his term "hazard," and he referred to the subjective side with the somewhat unfortunate term of "outrage." And that probably needs to be replaced these days, but the idea was there, that there's a subjective component to perception of risk that I think probably all of us agree with today.

Let's imagine, for a moment, that we could measure risk on, hypothetically in some abstract situation, a 1 to 10 scale and that it would be made up of two components to get a total score. And the first component would be the more technical. It's what Sandman called hazard, what I'll call technical today, and it's the old risk magnitude -- oops, that's an R, it's supposed to be an M, sorry -- magnitude times probability is the technical side of risk, the classical technical side of risk. And the subjective side is measured also as a part of that 1 to 10 scale. If we did that, what we might find is that experts, whether in health communication or other aspects of risk communication, might lean something like 8 to 2 or 9 to 1 balance in focus on the technical aspect of risk communication as opposed to the subjective.

Publics, in my opinion and from what I've found throughout the literature and in my own practice over the years, is that publics actually want both technical and subjective components in successful risk communication campaigns. So let's just for a moment say that publics may be in the 5-5 range or the 4-6 range, balancing probably better than we do in many cases the technical and subjective aspects of risk, in which case I think the challenge facing us today is not to justify sort of a 9-1 emphasis on the more technical aspects or to jump off into some other subjective extreme but rather to work to develop more of a balance between the technical and subjective aspects of risk.

The second kind of background thought I want to put in has to do with the two aspects of all communication campaigns and in this

case health risk communication. And those are, again, probably not new to anyone on the Committee or in the audience, are the content and relational aspects. So another way of saying what I've been saying and what I'm going to say is that we may be focusing too much on the content aspect and not enough on the relational aspect. And the reason that's a threat -- Coats said it much better than I could, so I'm just going to mooch from him -- that "Each person responds to the content of communication in the context of the relationship between the communicators. The word meta-communication is used in various ways, but Watzlawick uses it to mean the exchange of information about how to interpret other information." So when we engage in risk communication campaigns -- if Pearson and Watzlawick, Beavin and Jackson and others are correct -- when we engage in risk communication campaigns that focus too much on the technical side, we are not only communicating the content of that message but also a lot of commentary on the relational aspect -- on the relation that we have or perceive ourselves as having with the publics. So our sponsoring organization and the publics have a relationship, and that's disclosed -- I'm sorry, what we think of that relationship is disclosed to many publics by the relational aspect of the communication regardless of the content.

Now, let me remind you what I had up in red in the first place. The best available science has to be there, and it has to be right. It's a precondition to doing successful health risk communication. It is not however typically sufficient in my view.

So by leaning -- and what I'm arguing for today is to treat the relationships, to treat the relationship between sponsoring organizations and publics as being equally dependent on both the content and relational aspects of what we do. Excuse me, I'm still getting over this. And I've got a little model here that I've adapted a little bit for today's discussion. It's actually intended to be a broader model. It's called the cocreational perspective, and it does require a little bit of a change in assumptions because this model is publics-centered. It is not message-centered. And it avoids instrumentalizing publics even when our motives are good. And remember the other thing I had in red at the beginning about the motives being good.

So this is a diagram of what I call the cocreational molecule. And the reason for calling it a molecule is that it's the smallest unit that I can think of that basically depicts the relationship between organizations and our publics in health risk communication. There can be much bigger and more involved models, but this is the minimum one that I can think of that basically depicts that relationship.

And the important thing to look at here is -- I'm sorry, let me skip back. The circles here represent the role of publics in that relationship. The boxes, the rectangles represent the role of the organization. And the boxes inside the rectangle here are the actual campaigns. These are health risk communication campaigns, or any other strategic communication campaigns occur in this area.

So back to publics. For me, and I hope for many of us, publics are not only the most important part of the health risk communication

relationship but also probably the most independent. Publics come to any communicational relationship with us with a lot of their own meanings, goals, values, views of the relationship, history, culture, all kinds of things that they bring to that relationship. Some of us do good research and find out about them, but some don't. That's why that line is dashed.

As we plan out our campaigns, we research our information, and we use an inflow of information to us in order to move to the strategic level or planning level of the campaign. Part of what flows in to us is the policies of the organizations that are sponsoring the campaign or sponsoring us. And that operates at the grand strategic level. I'm not going to go into all that today, but that's grand strategy -- policy level is grand strategy, whereas strategy, the strategic level is the level of the campaign, it's the level of campaign planning, and tactics are the specific steps, the units of work taken to implement the campaign. So they are subordinate to a campaign.

Remembering that this is the boundary of the campaign, sometimes our campaigns, if we do good work, can send out strategic information to the organization, somewhat in exchange for the information that we got, often with respect to policies and that sort of thing.

Now, the complicating step in this is up here with this little arrow, and that's to depict the role of channel. And channel operates both at the strategic and the tactical level. It has strategic aspects and tactical aspects. It's always tactical; it can be strategic as well. But even

if you go back to the old communication models -- this is 1960s or '50s, Shannon and Weaver for example, the original models that had interference coming into the model.

The channel that we adopt always has some effect on the message. It's receives and retransmits, so it has some effect on the message. And that can be a confounding effect. It often -- we often hear health professionals complaining that the media dumbed down the message, for example. And other times we say -- you know, if you're a reader, sometimes you think, well, they made it too technical. But the channel has some influence on the message that gets out to publics, so the first complication is that no matter how carefully we do our research, how well we plan out the strategy of the campaign, and how well we implement it, what gets out to the publics isn't exactly what we did in those steps.

And as it gets out to the publics, it is in a soup of all kinds of messages. It has to compete for attention. And publics, of course, choose which campaigns they're going to interpret. At that point, the publics take the content of our campaign and what they started with, and they create new meanings. This is that 5-5 from a minute ago. So the publics are taking where they started and combining what we did and create for themselves new meanings. This is my definition of progress, by the way, although that's a different topic.

Note the size of this arrow versus the size of this arrow. And I'm not prepared to defend on the basis of research what size those two arrows should be except to say that what publics decide our campaigns

mean is much more influenced by what they started off thinking than it is by what we say in our campaigns. If you were to be maybe just slightly cynical about it, you might go back to my earlier slide. It talked about single digit effect sizes. If we were in single digit effect sizes, then this arrow, well, it might be representing something like 90 percent of the decision making in the cocreation, and this might be representing about 10 percent.

But whatever it is, we have to be focused primarily on the publics and how they go about cocreating me. Now, out of that then comes health behaviors, which we often seek to evaluate, and that then feeds back into 1 and 2 again. All this model's attempting to do is to put publics at the center of the process. And note that we have all kinds of influences coming in on us. Compared to us, publics are pretty much sovereign in this relationship. Now, publics have lots of influences, but they're not contained within the health communication relationship typically.

Let's see, I've -- and I said I was going to try to hurry. So let me just conclude quickly. For me, then, scientific content has to be right, and it has to be present. But good intentions and good content are not enough because publics hear the technical content of our messages, but they also hear the relational aspect of our messages. And sometimes what they interpret is that we are positioning ourselves as information gods, to use an old term, or that we are not paying attention to their concerns.

If they have a subjective component and all we do is respond

with magnitude times probability, that might be understood as saying that their subjective concerns, their fears, their emotions are not a legitimate enough issue for us to be responding to, for example. We may have other fairly legitimate reasons for not responding, but they're not necessarily understood that way. The meaning of our not responding to their subjective concerns is part of what they cocreate is that meaning.

So, ironically, if we do health communication campaigns in which we focus too much on content and not enough on the relational aspect, and then publics cocreate the meaning of those campaigns thinking both about the content and the relational aspect, it is entirely possible that our publics can actually understand our campaigns more fully than we do. Doesn't mean that they understand the technical aspects better than we do, but they might actually understand the whole campaign better than we do because our publics cocreate the real meanings of our campaigns.

Thank you.

DR. BLALOCK: Thank you, Dr. Botan. Do any members of the Committee have any -- a brief clarifying question? Okay, thank you, Dr. Botan. Oops, Dr. Sneed.

DR. SNEED: I was just wondering if you have any examples of health campaigns that have actually used this approach, and then practically how you would go about it.

DR. BOTAN: Well, those are two separate questions. And no, I don't have examples. This is fairly new. I have been talking about it and

using it in training for some time. And I know it has been used in a number. But I don't have that data. It's been used actually, not specifically in health communication, because I deal with this for all of strategic communication, which for me includes health communication, marketing, and advertising communication and all of public relations. The fields that exist to conduct strategic communication campaigns are, for me, what constitutes strategic. So it's been used in a lot of places, including some in business. It's actually been used more in Europe than here. And no, I don't yet, and that's a weakness. As soon as I get the revisions of the manuscript done, that's next.

And your second question was how to do it. That's going to come out of my getting more of the data.

DR. BLALOCK: Dr. Cohen Silver.

DR. COHEN SILVER: By using the term "publics" plural, I'm assuming that you mean that it could be the public -- one public could be healthcare professionals --

DR. BOTAN: Um-hum.

DR. COHEN SILVER: -- that come from the government to the -- and the other could be the general public, and that would be the communication from the healthcare professional to the --

DR. BOTAN: Yeah, except it wouldn't be -- I wouldn't think of it as a general public. There are multiple publics --

DR. COHEN SILVER: Right, but --

DR. BOTAN: -- in the general. But yes, you're correct, for FDA --

DR. COHEN SILVER: The FDA could -- one public, for the FDA,

could be healthcare professionals.

DR. BOTAN: Absolutely.

DR. COHEN SILVER: Another could be nurses. Another could be let's say physicians versus nurses versus pharmacists. And then -- so, would it be appropriate then to think about the FDA communicate -- thinking about how to target these various publics, both the general publics as well as healthcare professional public?

DR. BOTAN: I think so. I basically have in mind, when I'm talking about this, the general publics. And without getting into a question of segmentation, which is a sore spot for many folks, I have no difficulty with it being used within the health professions, but also within the health industries, so that a communication by FDA to various device providers or the major contractors, the HMOs and stuff like that, I think all of that would fall well within the bounds of what I'm talking about, yes.

DR. BLALOCK: And Dr. Harwood.

DR. HARWOOD: In terms of the publics -- sorry -- in terms of the publics, we've got new meanings coming out of those --

DR. BOTAN: I'm sorry, I didn't hear that part.

DR. HARWOOD: You've got new meanings being cocreated by the publics. Why not also --

DR. BOTAN: Yeah, cocreated.

DR. HARWOOD: Why not also reexamine new publics? So it seems as though there's a suggestion that we already understand how we segment healthcare providers and how we segment the population.

How do we know we've got that right?

DR. BOTAN: I'm sorry, I didn't mean to imply that I thought we already know how we segment them. That's part of why I said there's a bit of a sore spot with segmentation. You can segment by industry or by specialization or something, but I would not think to do it that way. I'm sorry, what was the first part of your question?

DR. HARWOOD: If we've got new meanings in terms of cocreated by these publics, and we're going to push out a campaign to publics, how do we sort of measure that we're actually getting an effect if we don't really understand that the segmentation is actually correct and the most appropriate segmentation?

DR. BLALOCK: I guess I'm not quite seeing the whole question, but let me try. I'm not sure that segmentation has to be correct before we can go out and do assessment. It certainly helps because we're targeting assessment, and if we do a lot of targeting the campaign, then using segmentation to target the assessments makes a certain level of sense. There are all kinds of approaches, including more qualitative ones that I tend to favor, having to do with, I don't know, longitudinal sort of focus groups, that sort of thing that don't require, I think, a lot of segmentation to begin with. Is that what you were asking? Did I misunderstand?

DR. HARWOOD: Well, I guess mine was more if the campaign is targeting say pregnant women, and that is the public that we originally begin with --

DR. BOTAN: Okay.

DR. HARWOOD: -- how will we know that a better public would have been women with another variable as opposed to the fact that they're pregnant? It seems as though we've pre-defined the public.

DR. BOTAN: Yes, in that campaigns can be targeted to meet the needs of specific publics, we have pre-defined the public, yes. But we haven't pre-defined how they're going to cocreate meanings or what meanings they're going to cocreate out of that. There'll still be tremendous variance within that public.

DR. BLALOCK: Maybe we can come back to this later in the broader discussion. Dr. Yin.

DR. YIN: Hi. I had a clarifying question. You expressed concern about the mostly one-way messages are presented and about the CDC definition. Is that because the one-way message comes from like a top down approach, whereas if the one-way message came out of this cocreational approach with the publics, that that would be okay that it's a one-sided message?

DR. BOTAN: No. If we did some research -- remember the last circle and the little arrow out the bottom -- so if we had taken the data from previous campaigns, it's a cyclical model of the campaigns, and we then created more one-way messages based on a better understanding of how the previous message -- what kind of meanings were cocreated as a result of that or in combination with that previous message -- not necessarily as a result of it -- we might make slightly better one-way messages.

But my concern is still that the focus on one-way messages puts

too much focus on the message and doesn't put it on the publics. And the purpose of this whole discussion is to move the focus to publics. So I'm generally not leaning toward one-way messages.

Now, that's not an absolute statement. There are times and situations and kinds of content and a number of things that we could imagine in which we really have to do one-way messages at least for a short time. But those need to be -- the evaluation of those need to be embedded in the context of have we been doing one-way messages all along, or as you're suggesting, have we been doing some kind of research on the cocreational process that a public we have an ongoing relationship with -- I don't know if this is touching back on where you were or not, that a public that we may have an ongoing relationship with, what they have done in creating meanings based out of their own backgrounds and the things we have put in previous messages.

So all of this stuff -- and I like to resist doing this, but I can't -- all of this stuff goes on a continuum. There's no finite categories. I would never say we can't do one-way messages or we can't do two-way messages. The qualitative difference in these things, in my mind, is that one-way messages focus on the message almost always, and what we need to be doing is focusing more on the publics. Understanding that the publics are the freest agent in that molecule, the freest agent in our relationship, they're going to be the ones that primarily determine the outcome. So if we are not concentrating on them, not focusing on them all along, we greatly reduce our chance of having the kind of outcome we're seeking and the kind of outcome that the publics are seeking.

DR. BLALOCK: Dr. Pleasant.

DR. PLEASANT: Thank you. I started with one, but now I have two quick ones. I'm going to slide it in. If you really take this literally, you're saying that there might not ever be any such thing as a one-way message, except for perhaps the one that everybody ignores?

DR. BOTAN: No, no. It -- there's -- it's still going to have some role. Remember that I said publics are always looking -- in my experience at least -- both for technical content, which can be one-way, and relational content, which implies at least an awareness of the two-way aspect of the relationship. So it's not going to -- it's not necessarily going to be completely ignored because it's a one-way message, but it is -- the chance of it being ignored are greatly enhanced over a two-way.

DR. PLEASANT: Okay. Well, if it's always cocreated, though --

DR. BOTAN: Pardon me?

DR. PLEASANT: If it's always cocreated --

DR. BOTAN: The meaning of it -- it's cocreated by publics, yes.

DR. PLEASANT: So thus it's inherently two-way at the end of the day --

DR. BOTAN: Well, it --

DR. PLEASANT: -- whether it was intended that way or not.

DR. BOTAN: It is for them, but it may not be for us if we ignore what they cocreate.

DR. PLEASANT: Okay. My second one, quick, is from a health literacy perspective. The one thing that I see missing or just no

reference to is skills. Skills. People's ability to read, write, numeracy --

DR. BOTAN: Yep.

DR. PLEASANT: -- it's not referred to as part of this cocreation process.

DR. BOTAN: No, it's not directly referred to, and that's a good catch. My answer would be that it's a part of circle one. It's a part of that background that is brought to the process. But I think you're right. Maybe I should address that a little more directly. I like that.

DR. BLALOCK: And one final clarifying question. Dr. Krishnamurthy.

DR. KRISHNAMURTHY: Perhaps I'm not fully understanding the one-way versus two-way, but I see all communication at an atomic level as -- it is one-way communication after taking into account who it is you are talking to. And the CDC definition makes it very clear that it is intended to kind of influence health behavior.

So if target audiences, by definition, means an understanding of who the target is, what they like, what they understand, what are the kind of meanings that they bring to the table, and of course you also have this idea of message testing to see whether the message makes a difference or not and be informed by the responses, in which case the cocreators of the meaning are telling you as to whether this is having the intended effect or not.

So I mean, in that interplay, at the end of the day, would we not be served by having communication and message testing as a continuous process by which we refine and incorporate the publics?

DR. BOTAN: In part. I like that. That's a good analysis. The assessment of what the public -- the assessment of the publics' responses provides at least the start of a two-way communication exchange. One of the practical difficulties is that when we start doing that, we tend to assess primarily what it was we intended to get in the first place and often don't put enough time and effort into delving into all of the meanings that the publics cocreated out of that original campaign. So we may get a good measurement about whether we achieved objective A or objective B, and we can even do that quantitatively, but we may well miss other things that sometimes can be more important that weren't even in that -- that weren't thought of in that research.

The other thing that I would say, I think, is that the question of two-way communication is primarily not a question of is the channel there and do we use it. It's a stance a coming out of the history of where the idea of two-way came from, if we kind of stretch things a little bit, goes back to rhetoric, goes back a very long time -- to Aristotle and the like -- and one of the things that many scholars that address the whole idea of two-way communication, the term that they have used is the idea of dialogue. And the dialogue is a stance, an attitude towards the partners in that exchange. So Habermas and a lot of others in communication, we've had Kent and Taylor and others recently doing that.

So what you're saying, I think, I agree with, but it's a minimal standard for it; it's not a maximal standard by any means. And it will

help us with campaigns that we've already conceived. I'm not sure how much it would help us with that light coming down the track.

DR. BLALOCK: Thank you, Dr. Botan. So we'll turn now to the more general discussion with the question how can FDA communicators apply the information just presented? And Dr. Zavala has a general comment that she wanted to make at the beginning of this session.

DR. ZAVALA: Thank you. What I would like to share is my observation on what's being shared by the expert opinions complementing the presenters, the studies, and although it's been established, we need more information. But what I gathered is this is a great opportunity to gather evidence-based practice, best practices, and assisting the FDA in being effective in risk communication.

And I'm noticing some commonalities between the studies like Dr. Botan. This is my understanding about the not having a one direction approach is similar to Dr. Chapman's study of engagement multi-directional. And I'm looking at it what else -- what are the commonalities amongst all the studies and the differences in coming up with the best strategies to effectively communicate risk.

Thank you for the opportunity. Thank you for your studies, sharing the information.

DR. BLALOCK: Dr. Krishnamurthy.

DR. KRISHNAMURTHY: First, I also want to echo that sentiment. We really learned quite a bit from both the presenters today. From Dr. Lerner's presentation, I mean, she summed it up very neatly in the last sentence of her presentation, that communications that involve any

kind of emotional appeal, you need to be informed by affective signs. I don't know if there is a way to put it more nicely than what she has done.

And I think of -- in regards to Dr. Botan's presentation, I got the sense that you were trying to impress us that the producers of communication need to be consumers even as they are producing it so that they can have an internal dialogue going so that the publics are taken into account while the communication is being produced.

DR. BLALOCK: Dr. Rimal.

DR. RIMAL: Before getting into the, I think, specific answer to the question that you have posed, I want to -- this is just my personal take on our exchanges today, which is that I found the presentations by the individual scholars to be really informative. And I wished that the structure of this discussion allowed for more questions and more engagement with the researchers rather than just limiting it to the clarifying questions, because I had lots of questions and comments that I think had the opportunity arisen, I would have really loved to engage the researchers about.

So I felt that that was a missed opportunity, because I think it's in those discussions, through those discussions that the answer to the following question that we're going to address now, which is the applicability for FDA, that those answers would emerge in a much more organic way rather than sort of saying now that we've heard, now let's put a different hat on. Now how does this apply? And that seems much more trite and artificial. So that's just a general comment that I have.

I think just reflecting on the two presentations, I really loved both of them. And to me the big message that -- sort of the commonality between both of those was that message as sent is almost never message as received, that what we think we are communicating is refracted, just like light is bent by water. And it's bent, our messages, what we say are bent by what consumers bring to the interaction, their history, their perceptions, the moods that they are in, whether they are in an angry mood or a happy mood or a fearful mood. So all these things matter much more than perhaps we have given credence to up to this point and sort of going back, which is perhaps why the effect sizes are so small, because we haven't taken all those other factors into account.

So I just wanted to say I really appreciated the -- what to me feels like the kernel of truth about our role in how we disseminate messages and the need to put relationships at the front and center of what we do.

DR. BLALOCK: Dr. Zavala.

DR. ZAVALA: Yes, I would like to add what Dr. Rimal was saying. I wish I had more -- I'm looking for -- well, more opportunity to ask questions, and I'm looking forward to the results of the study by Dr. Broniatowski. And the other nicely said by Dr. Chapman, which is healthcare providers cannot ignore the changing behaviors of the clients of accessing information, just like the FDA with the use of the social media. So it's like how can we effectively use it in a way that the basic information is communicated in a manner that can be understood

by the end users with stories. I will never forget what Dr. Pleasant said. We need the stories.

DR. BLALOCK: Other comments from the Committee?

DR. PLEASANT: I have a small one.

DR. BLALOCK: Dr. Pleasant.

DR. PLEASANT: Small scary one, perhaps.

(Laughter.)

DR. PLEASANT: If we take your argument for granted that, in fact, the recipients of a message are always involved in the creation of meaning, which I clearly have no problem with, we should actually probably say that that has lessons for even the way we conduct our statistics when we analyze change in particular. And we've talked a lot about change score here and low effect of health communication on change of various types, but while it's probably been hidden from view, just because it's a 20-minute presentation, nobody talked about how they actually analyze that change.

So we've all probably assumed it was a straight pre/post calculation. But if the starting point of an audience is one of, if not the most important predictor of the outcomes, then we all need to redo the way we calculate change to take that starting point into account. For example, people who have the most weight to lose will probably lose the most weight in intervention. But most often we as a field don't take that starting point into account when we calculate the change score.

And if we do that, that means that all of these small effect sizes that we're talking about today are going to even be smaller for the most

part. So it's not just a conceptual discussion that we're having here. There's some real practical value to some of this taking the audience into account and taking it fully into account. A lot of studies might lose significance if they did that. We have no idea.

But from an FDA perspective, if that is a message and an approach that the FDA wants to take, then I think they should consider taking it fully and embracing it all the way into even the methodological approaches for analyzing change that you're conducting. It would be a stalwart move and in a rigorous direction.

DR. BLALOCK: I'll just interject, I guess, a couple of comments. You know, the first was something that I thought about when Dr. Botan was speaking. And one of the things that I learned over the summer at another meeting was that in -- with medication guides that are mandated for certain medications as part of REMS programs, there's not a requirement that those be user tested, at least that's what I was told, that there's not an absolute requirement that those be user tested. And it seems like in terms of bringing the consumer perception into things, that that really is something that we should think about doing, the FDA should think about doing. And it is something that's done in the European Union.

And then, you know, in relation to the -- Dr. Lerner's presentation on emotion, it's really, really interesting and I -- and some of my work actually focuses on emotion as well, not at the level of sophistication that Dr. Lerner presented, by far. But I guess I still have to question when you look at it from a public health perspective, how

do you know what affective state your target audience is or the members of the target audience are in when they receive the message?

And I don't know maybe at least at a group level maybe there's a way to capture that. Certainly I think there's -- and other people probably know more than I do about this -- you know, people are so opposed to the childhood vaccines. I think that that may be driven more by anger -- really even as I talk, I'm not really sure. But even as I talk, it would be a good question to answer to know what's driving the reluctance. Is it anger, or is it fear? So that's all.

Do I have a list?

DR. COHEN SILVER: Just let me -- can I just respond to that point. There's some really interesting brand new research that's not yet published going on showing that a lot of it has to do with mistrust. So that whole issue that we were -- that one of the speakers talked about about trust in the messenger, and there's a great deal of mistrust. And there's -- it's really fascinating research now looking specifically at vaccines.

DR. BLALOCK: I've got -- Dr. Dillard.

DR. DILLARD: Thank you. I wanted to give a partial response for your question. It seems to me that in response to the issue raised with regard to affective states, affective states that exist prior to a message that's presented, that there are domains of life in which we might have a pretty plausible reason to infer that people would be in a particular state. A trip to the dentist or a trip to the oncologist, we could probably -- a pretty scary thing. Women experience postpartum

depression with a pretty high degree of regularity.

That's not a solution, but there are a lot of instances in healthcare delivery in which we might be able to make some broad stroke predictions about existing affective states. And that's really important, I think, because there is evidence showing that, for example, stylistic elements like gain and loss framing, gain framing works better when people are angry or happy. They're more persuaded. They take action more readily. Loss framing is more effective when people are sad. So there is room, I think, for a science of message matching to affective -- naturally occurring affective states, although it's certainly not the whole answer.

DR. BLALOCK: Let me just take a little bit of liberty here, and since it did come up as an issue of wanting more interaction with some of the presenters. You know, the question that the Committee members have been asked is to how can FDA communicators apply the information just presented?

Do any one of the presenters earlier in the day, at any point, would they -- do they have any response to that or any comments that they would like to make?

And, Dr. Botan, I'll need to have you to come up to the podium, and then Dr. Lipkus.

(Off microphone comments.)

DR. BOTAN: I just thought of this in response, mostly to a question from Dr. Pleasant, about what would happen with our effect sizes, and some other questions about message testing and so on.

Remember on the model the large arrow from publics -- what the publics bring with them to the relationship and the smaller arrow for message. If we wanted to do message testing -- when we do message testing, I'm not sure how frequently we pay attention to all of the things that may make up 90 percent of the response that we're actually measuring. In other words, when we do message testing, we think we're testing the message, and what we're actually testing is the meanings cocreated by publics when they integrated that message with their own background, and it was their own background that was the primary determinant of how they were going to respond.

So maybe what we need to do when we're doing message testing is learn to take into account some of that background. And if we did that, well, you may be right, sometimes about the reduced effect size. What we may actually get is a greater effect size or a more accurate assessment of our messages.

DR. BLALOCK: And Dr. Lipkus.

DR. LIPKUS: So I have some general comments. One of the comments that appears fairly often is we get small effect sizes. And it almost comes across as that's bad when, in fact, we should appreciate small effect sizes because it's through the morass of all the various elements that are out there in people's lives. So when you think of a campaign having a small effect size, compared to no campaign, what you're really doing is cutting through a whole bunch to get at least a small effect.

But the thing to also consider is that a small effect, over time,

can accumulate to become a significant effect, and particularly for some of the behaviors that we're talking about which are very difficult to change. Getting people to exercise, getting people to screen, quit smoking, what have you, these are very complex behaviors. So to say we could have a small effect size in changing some of these very difficult behaviors and thinking of it as an accumulation over time, I think, is very meaningful.

And also maybe to get a different perspective of not just thinking of a campaign but a sequence of campaigns to strategize for whom and when we could target follow-up campaigns. And I know that's difficult to think when we're just thinking about the resources to do one campaign, but if we think of it strategically as a set of steps rather than just one, I think that might be effective.

The other one is in, at least in terms of the talk I gave on biomarkers, I do think that -- a couple of things. One is we got to do a better job in general to give the people who are communicating the messages a better understanding of the perspective of the people they're interacting with. So if you think about the relational aspects that have been brought up today, we do need to have a better perspective of how the physicians view the patients' behaviors and vice versa and how they're seeing it, to come to some sort of informed decision or some consensus in understanding. I think that's important.

But the other thing is we also need to think of the infrastructures that currently exist, that there shouldn't necessarily only be one point of contact in a clinical encounter or a public health encounter, that we

need to create systems of follow-up that could afterwards get a sense of what the patients, the clients really got out of those conversations, because one of the things that we do really poorly at -- and if you think of the 5 A's for example -- is we do fine occasionally in asking the question, great at sometimes giving advice, somewhat okay at providing assistance, but the things that we're really lacking is being able to do the follow-ups, and part of that is because we have an infrastructure that doesn't allow a lot of resources to be able to do that.

So I think when you think about these messaging campaigns, the question should be -- and even in the clinic settings -- what can we do to better follow up on the people that we're really targeting to send, to get a sense of what's working and what's not, and then making some adjustments accordingly. Thank you.

DR. BLALOCK: Thank you. Dr. Lerner.

DR. LERNER: Thanks for this opportunity. I have two suggestions. The first is following up on my recommendation that public service announcements in particular are -- become better grounded in the emerging field of affective science. One way to follow up on that is to, when there is, for example, tobacco settlement money and vast amounts of money is being spent on the creation of public service announcements, that there be some kind of guideline that needs to be tied to foundational science. The same is true for other kinds of drugs, certainly alcohol.

And so there's just a huge array of media communication that is taking place, and funding is flowing to it totally apart from affective

science. And part of that is, as I tried to reveal in that brief history, that there was a dearth of affective science for most of the 20th century, but there is an explosion in the field, and now a lot is known. So that's one suggestion is to really tie it to those campaigns, particularly in the case of settlement money.

The other is to strategically establish links to the field of decision science for health service practitioners. All the physicians I see say I wish I could take your course in decision science, because they're not in any way trained in understanding probability. And so as frontline people, they're not able to accurately communicate uncertainty. And then that plays into lack of knowledge in laypeople about how to avoid really common errors and biases. And because the field is out of place in behavioral decision research or decision science where the most common errors in biases are well identified, we can easily teach people how to avoid them.

Things like how to calculate expected value. There's good evidence that that can be taught, and it's easy to understand, and then people are much less led astray. So if there can be a public information campaign that takes advantage of that body of literature, both for healthcare professionals and for patients and consumers alike, that would be wonderful. Right now, it's being taught at lots of places, but it needs to really get out into the public.

DR. BLALOCK: Thank you very much. Any others? And let me pull it back to the Committee then. Any other comments? Dr. Rimal.

DR. RIMAL: I wanted to mention that I think it's also important

for FDA, for all of us, when we're engaged in a communication, that we adopt a more horizontal posture than a vertical one. And the discussion earlier about physicians being one audience and the public being the other audience, I kind of take issue with that because I think even physicians are consumers of something. And indeed, the original Tversky study on framing effects found much larger framing effects among surgeons than among students. And I think there is a lot of -- there are reasons to believe that experts are more biased because of their expertise, and there's a lot of literature to show that.

So I think -- I don't think we should separate providers from consumers because providers themselves are consumers as well. And the need to have this horizontal dialogue, I think that's what emerges for me from the second talk this afternoon, then I think we're much more used to a one-way or a more vertical kind of communication. And thus more creative ways we can find to make that more horizontal, I think the more effective we are going to be.

DR. BLALOCK: And I absolutely agree. I mean I think that one thing that we've heard a lot here today is efforts to educate different kinds of clinicians and other people who are passing on the messages from the FDA that better equip them to be able to communicate those.

I think we're out of discussion. And I'm not really going to try to summarize, but I do think that I -- the common thread that I hear through a lot of our discussion today really just is the need for more evidence-based research on so many different issues. We've highlighted the complexity of just a lot of different issues from behavior

change to the role of emotion in decision making. And there's such a need for evidence-based research in this area. And I think Dr. Lerner gave a good suggestion on a possible funding mechanism, because often it is kind of difficult to get this type of research funded.

So, Ms. Duckhorn, do you feel like you've gotten what you need, or is there anything else that you would like to throw out to the Committee?

MS. DUCKHORN: I got what I needed from this discussion. I also want to acknowledge that I hear you that you haven't -- you don't feel like you've had enough organic way of getting to the question and that you want to have a larger discussion or more of a discussion with the guest speakers. We will take that back and consider that this evening. You have to understand we're on a tight schedule because of the changes that were made. So we'll see what we can do about making some revisions for tomorrow. But I just want to acknowledge that I hear you.

DR. BLALOCK: So I'd like to thank the Committee, the FDA invited speakers for contributions to today's meeting. And the February 16, 2016 meeting of the Risk Communication Advisory Committee is adjourned for the day. And please note that we will begin tomorrow at 8 a.m.

So thank you.

(Whereupon, at 6:08 p.m., the meeting was continued, to resume the next day, Wednesday, February 18, 2016, at 8:00 a.m.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

RISK COMMUNICATION ADVISORY COMMITTEE

February 16, 2016

Silver Spring, Maryland

were held as herein appears, and that this is the original transcription thereof for the files of the Food and Drug Administration.

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TIMOTHY J. ATKINSON, JR.
Official Reporter