UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

+ + +

RISK COMMUNICATION ADVISORY COMMITTEE

+ + +

February 17, 2016
8:00 a.m.

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

COMMITTEE MEMBERS:

SUSAN J. BLALOCK, Ph.D., M.P.H.	Acting Chair
JAMES DILLARD, Ph.D.	Member
PAUL G. HARWOOD, Ph.D., M.A.	Member
PARTHASARATHY KRISHNAMURTHY, Ph.D., M.B.A.	Member
BROOKE FISHER LIU, Ph.D., M.A.	Member
RAJIV N. RIMAL, M.A., Ph.D.	Member
ROXANE COHEN SILVER, Ph.D.	Member
JEANNIE SNEED, Ph.D.	Member
H. SHONNA YIN, M.D., M.S.	Member
MIRIAN ZAVALA, D.N.S., R.N.	Member
GARY KREPS, Ph.D.	Temporary Member
NATASHA G. FACEY, M.S.W.	Acting Designated Federal Officer

Free State Reporting, Inc.
1378 Cape St. Claire Road
Annapolis, MD 21409
(410) 974-0947

FDA PARTICIPANT:

JODI DUCKHORN, M.A.
Director, Risk Communication Staff
Office of Planning
Office of the Commissioner

GUEST SPEAKERS:

CHRISTOPHER R. TRUDEAU, J.D.
Professor
Western Michigan University -
Thomas M. Cooley Law School

LAUREN McCORMACK, Ph.D., M.S.P.H.
Director
Center for Communication Science
RTI International

NATHAN DIECKMANN, Ph.D.
Assistant Professor
School of Nursing & School of Medicine
Oregon Health & Science University

TIMOTHY L. SELLNOW, Ph.D.
Professor
Nicholson School of Communication
University of Central Florida

K. "VISH" VISWANATH, Ph.D.
Professor
Department of Social and Behavioral Sciences
Harvard T.H. Chan School of Public Health
Department of Medical Oncology
Dana-Farber Cancer Institute

LINDA ALDOORY, Ph.D.
Associate Professor
Department of Communication
University of Maryland

INDEX

INDEX

M E E T I N G

(8:00 a.m.)

DR. BLALOCK: I'd like to call this meeting of the Risk Communication Advisory Committee to order. For the record, we're beginning today's meeting 1 hour earlier due to the inclement weather that we experienced yesterday.

I'm Dr. Susan Blalock, the Acting Chair of the Committee. I am a behavioral scientist. I am Professor and Vice Chair in the Division of Pharmaceutical Outcomes and Policy at the University of North Carolina, Chapel Hill, and my area of expertise is behavior change and medication, a risk-benefit communication.

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 Committee members participating in today's meeting 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.

So before we begin, I'd like to ask our distinguished Committee members and FDA staff seated around the table to introduce yourselves. Please state your name, area of expertise, position, and affiliation. And I'll start here.

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

DR. HARWOOD: Paul Harwood, Market Research Lead at

Twitter.

DR. SILVER: Roxanne Cohen Silver, Professor of Psychology and Social Behavior, Public Health and Medicine at the University of California, Irvine.

DR. DILLARD: My name is James Dillard. I'm a Professor of Communication Arts and Sciences at Penn State.

DR. YIN: Hi. I'm Shonna Yin. I'm an Assistant Professor of Pediatrics and Population Health at the NYU School of Medicine, and I have expertise in health literacy.

DR. RIMAL: Rajiv Rimal in the School of Public Health, Milken Institute, George Washington University.

MS. DUCKHORN: Jodi Duckhorn, Director, Risk Communications Staff, FDA.

DR. KRISHNAMURTHY: Dr. Krishnamurthy, University of Houston.

DR. SNEED: I'm Jeannie Sneed. I retired in June as a professor from Kansas State University and currently do a little bit of consulting. My research area is consumer and retail food safety.

DR. LIU: I'm Brooke Liu. I'm Associate Professor of Communication at University of Maryland, and my research area is risk in disaster communication.

DR. KREPS: My name is Gary Kreps. I am a Distinguished Professor of Communication and Director of the Center of Health and Risk Communication at George Mason University, and I study health communication.

DR. ZAVALA: Mirian Zavala, Assistant Professor at the College of Mount Saint Vincent, health disparities expertise.

DR. BLALOCK: And Ms. Facey will make some introductory remarks.

MS. FACEY: Good morning. I will read the FDA Conflict of Interest disclosure statement. It's the same statement that was read yesterday; however, to go on record, I will proceed with reading the Conflict of Interest disclosure statement.

The Food and Drug Administration 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 U.S.C. 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 and conflict of interest laws. Under 18 U.S.C. Section 208, Congress has authorized FDA to grant waivers to special government employees and regular federal employees who have financial conflict of interests 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 for 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 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 panel area, which is the area beyond the speaker's podium. I request that reporters wait to speak to FDA officials after the meeting has concluded.

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

And, finally, please silence your cell phones and electronic devices at this time. Thank you.

And I'll turn it back over to Dr. Blalock.

DR. BLALOCK: Thank you.

Before we begin today's presentations, Ms. Duckhorn, would you like to make some comments?

MS. DUCKHORN: Thank you. I wanted to acknowledge the request yesterday to be able to engage a little bit more with the guest speakers. Today the format will be such that the guest speakers will present and you will have an opportunity to again ask only clarifying questions to them. And then when the discussion portion begins, you can ask questions to the guest speakers. The guest speakers can return to the podium, and you may discuss -- you may have a discussion with

them or ask questions to them.

We do request that your questions try and stay within the framework of our discussion about how the FDA could best utilize or implement the research that was presented because of the limited time that we have for discussion. Thank you.

DR. BLALOCK: So we'll begin Session 4: Strategies for Making Messages More Effective. We'll hear presentations from Dr. Christopher Trudeau, followed by Dr. Lauren McCormack, and then at the conclusion of each presentation we'll take clarifying questions.

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

Dr. Trudeau.

DR. TRUDEAU: Thank you. Thank you all for having me today.

I'm a bit of a horse of a different color here in this meeting because I think I'm the only lawyer here. So I apologize for the language that needed to be read before we got started.

But what I want you to think about, and I was just thinking of this as the language was being read, what happened to your mind when that was being read? How much did you pay attention to, and did your consciousness go in and out as that was being read, and what brought it back?

Because that's really what my talk is about today is -- it's different from Dr. Botan's, which is the idea of how do we create or how should we create the message? This is really focused on now we

have this message that we need to deliver, either because there's some regulations that are involved or it's because our organization has decided that this is the message we want to get out to the patient or the public or the consumer, whoever it might be, how do we best deliver that message effectively so that we keep people's attention, with the risk being what we just went through is the in and outs of the long necessary reading of the disclosure requirements and things like that.

So to lay a bit of foundation, the FDA's mission is clearly related to effectively communicating the things that the FDA does. So this is from the 2011 to 2015 Strategic Priorities: "We recognize that effective communication is the foundation for successfully implementing the FDA's guiding principles." Because, I mean, it's great to have principles and regulations, but if people don't know about them and they don't know how to use them or what they even are, then we're not really serving mission. And from the more recent strategic plan, 2014 to 2018, Objective 3.3 is to "improve safety and health information provided to the public." So that's one of the current objectives of the FDA so -- and then from the broader parent organization, Department of Health and Human Services, you can see the underlined portion here, "using clear and productive communication strategies" and "integrating health literacy principles" to help communicate these goals to the broader public.

So that's kind of my goal here today, is to help provide this community -- or this Committee with a strategy to help achieve the

FDA's risk communication goals, at least, in some respect that you can do in 20 minutes.

So it was interesting to hear Dr. Blalock's comment yesterday that you've had a session on REMS recently, which is good, because that's what I was thinking about as I was preparing for today is, well, let's take one of the major or the high stakes FDA documents that really impact patients and providers and others. So I was thinking about REMS, so Risk Evaluation and Mitigation Strategies, which obviously has a legal bent, which I obviously like. But this could -- what I'm talking about today really can apply to any of the other documents that the FDA has to regularly issue or have other people write and then they approve.

So what are REMS? Just kind of as a reminder or to the audience, it's when the FDA determines that additional safety measures are needed beyond the professional labeling of a drug, or whatever it might be, to ensure that a drug's benefits outweigh its risks.

So one of the main points of a REMS is to communicate risk to patients and providers. That's the goal, right? And so highlight that: The main point of a REMS is to communicate risk.

Now, let's take a look -- or, first, let's think about the mindset of those creating the REMS because, again, it's -- they're created by folks at the drug company and then submitted to the FDA, and then the FDA will allow them and put them on the website, which is where I found some of the examples for today.

So consider the mindset of those creating REMS. Their goal is to

get the food, drug, cosmetic approved. Their lawyer's main goal or legal team's main goal, whatever you want to call it, is to protect the organization. We want to get this approved -- the organization tells their lawyers this is what we want to do; now you need to get this done. And one of your goals as a lawyer is always to protect your clients, who within the organizational situation is to protect their organization. So patients and consumers are secondary in this mindset. You know, that might be the point of the REMS, remember, is to convey this risk information clearly to providers or patients or whoever it might be, but yet there's these -- there are these competing interests by those that are creating these.

So let's take a look at a particularly horrible REMS, which it's hard to get it on the screen, but I did the best I could here. So, again, look at the top. It says Patient Agreement. So this is meant to be going to a patient. There are REMS documents that go to providers, but this one -- I wanted to focus on the patient agreements for this particular presentation.

So you're starting out with this. Now, realize, this is required by the FDA because this is a particularly risky drug. So let's start out with something that's very obvious to the patient, right, information disclosure. We're so concerned about this drug but yet we're going to start out with we're going to collect and use your information in the following ways. And then spend -- and I cut the last portion of the document out so I could fit it up here. So it's really about the first third of the page talking about, you know, what your doctor will provide, the

information that'll happen. Your information will be stored. The information will be used to help learn more about the safety. The information from the patients will be reviewed, but they won't identify you, but we can share this with the regulatory agencies, all of that. That's clearly what's important to the patient, I'm sure. That's what we're all thinking.

If that's not bad enough, spending the first third of a page talking about information disclosure, if you really want to make sure somebody doesn't know everything about information disclosure, then put some more things at the bottom. You know, there's something in the middle that I want you to read, but then I'm going to get back to information disclosure at the bottom: "Your doctor will no longer provide any of your information" if you opt out of this program -- so it's not all -- it's not well organized.

But where's the risk information? Well, it's right here. It's right in the -- you know, right after the -- which would be about the bottom half of the page is where that first line is: "My doctor has explained the risks and benefits of treatment." "I received a copy of the Medication Guide." "I understand that I will be observed at the clinic for 3 hours after each injection."

And by the way, I took a look at the information guide or the medication guide too. It's a little better than this. It doesn't really -- you know, it's not as -- it doesn't follow all the health literate principles that we would normally like, but it's better than this in some ways. So hopefully this would be a secondary thing that the person would get.

But think about this. This particular drug is used for schizophrenia or for bipolar disorder. And let's say you just were diagnosed with that or your medication didn't work and they had to switch over to this one. You may have gotten this medication guide, and the doctor left the room and you're looking at it with your family, and then you get this. Unless there's some delay, so you can take it home and read and really decipher what's going on, you're going to be getting this probably all in one appointment or at least -- maybe one or perhaps two appointments; maybe there's a follow-up appointment there. So the way we organize information really matters.

So taking a closer look at the risk portion of this, do we really need more information, more disclosure of information info right here after you've just had it in the first half of the page? But just in case you didn't see all of that, I want you to agree to have my information entered into the Patient Care Program registry. And then it gets into the risk stuff, and I've received a copy of the medication guide, I understand I will be observed. And just -- I can't help -- I'm kind of a compulsive when it comes to pointing out problems in documents, but here's a problem. So I agree to seek Medicare right away -- or medical care right away if I have a reaction such as -- and let's list everything, but let's not list everything on the next one. "I agree to contact my doctor if I have a reaction," and so forth. Okay. So I don't know what people are thinking when they're drafting this.

And by the way, caregiver -- "I or my caregiver have discussed any questions." Caregiver is not mentioned in this document at all until

right here. So I don't know why somebody would put that in there unless they're going to keep doing that. But I digress.

So when it comes to the ordering of information, why would anybody order the information this way? Well, because you just don't understand what is important to patients; that's one possibility. It's probably a combination of all of these. Because you needed to get this done quickly to comply with FDA regulations and meet company objectives; that's probably a factor in it. And because you're more worried about complaints over information disclosure than you are about the risks of the treatment. So this is the lawyer's worry, you know; well, I'm worried about -- HIPAA's a big thing, and I want to make sure that people are aware that we're going to disclose this information to various entities, so I want to make sure we highlight that. But that's not what's important to patients. We all kind of intuitively know that.

So there are competing interests, and that's why I think the FDA, probably through this Committee, should further guide the way or the manner that the information is organized. So this is what I -- you know, if you think about a general formula for clarity, you have the clear content and user-focused design and clarity. I mean, that equals clarity. You can't just have -- you can't just use sixth or seventh grade writing and then just put a whole block of text with no paragraphs in there. Nobody's going to read it. Nobody's going to be invited to get into that particular document. So you need to mix the worlds from clear writing, plain language, but also user-focused design, which is critical to getting folks into the document to get you started on reading something.

But along with document design, and this is not new, but the way information is organized within the document is important as well, and document designers know this, but lawyers and regulators don't really consider this much. They consider first what I need to disclose and then maybe a little bit about how I should disclose it but not necessarily the order.

So this is where I think prioritizing risk information becomes something that we should look at further. So creating functional risk hierarchies, as I call this, is really something that we should do to guide future drafters of documents that have a legal bent or at least high stake documents where you have certain things that you must disclose.

So what's a functional risk hierarchy? It's simply a way or a guide to prioritizing and ordering information based on the needs of the audience, document's intended audience. There's a lot of other audiences, but the intended audience is who you have to focus on. So for patient-focused documents, this means prioritizing what's important to patients first and then putting in whatever else you feel needs to be disclosed because of certain regulations or laws or company objectives, whatever you want to do, because, again, that way when you start getting into the litany of things you need to talk about, the important things are highlighted and put hopefully up front in a user-friendly way.

So how would you create a functional risk hierarchy? Well, the first thing that somebody needs to do is to focus -- you know, consider the intended users and learn about their needs. So whether this is user testing afterwards, whether this is focus groups beforehand, whatever,

you have to gather the information about your intended users. And I've got some thoughts on this here in a future slide.

So you consider -- you gather information about your intended users, and then you write down information that you're -- you know, this is the planning part of the document, not the drafting part of the document. So you write down the information that your intended users would want to know, and then you rank or organize that information from most important to that person to least important. So the idea is kind of getting in the mindset of who your intended user is and then kind of ranking what is important in going down the road.

And then if you feel like or the legal team feels like, well, there's other things we must disclose by law or that we want to disclose to make sure we cover all of our bases, fine. But that's relegated to its position kind of at the end. Then if people want to zone out when they get to that point, well, hopefully they've used their energy beforehand on the important things, and that's kind of the goal. And then you add those to the bottom of the list, and you only move it up if there's some legitimate reason for doing so, like the law requires it to be conspicuously noted on the top of the document or something like that, which is very rare by the way.

So what do we know about users of health documents, because that's the next step in this, is trying to figure out how to organize or how to come up with these -- you know, with a useable functional risk hierarchy. Well, we know that people decide for themselves how much attention to pay to a document based on its importance to them. We

might think it's really important, if you're a provider or you're the lawyer drafting this, this is really important, but it might not be for them. We cannot assume that people will think the same thing that we think and think it's important, so I'm going to spend a half hour on this document. That's just not how it works.

These documents are tools that are meant to be used for a purpose. I always tell this to my legal writing students when we're talking about contract drafting, is you don't go home and read your lease from cover to cover. At least I hope you don't do that. It's not *Moby Dick*. It's not a novel meant to be read from cover to cover. These are tools that we look at for various questions that we might have.

So when we think about how people use these type of documents, we need to think about that when we're creating these hierarchies. What would somebody want to know right away? What would they want to know next? You know, that type of thing, and that can help us create these hierarchies.

People actively interpret as they read. Let's say you get a patient agreement like the one we just saw. You know you're going to be on -- the doctor wants you on this particular drug or else they wouldn't have suggested it. So you're kind of interpreting, all right, well, this is something I want to do; this is something I want to engage in. And so you're -- as you go through and you're reading each paragraph and each sentence and all that, you're starting to interpret, well, maybe I want to do this. You might already have your decision made by the time you get

to something really important, which is at the bottom third of the page because of whatever else was stated.

So what we put up front really matters. And so does the way we draw a user's attention to it, by the way. You know, text walls won't work. There's a lot of different things that we could talk about for hours. But in terms of the organization, what we put up front really does matter.

And then, again, users interpret their documents based on their own knowledge and expectations. So this is really why user testing and kind of gathering some research about what patients and providers, for that matter, want to see in a particular document makes a lot of sense because we're already -- people are bringing something to the table, whether it's the provider or whether it's the patient who has bipolar or whatever, they're bringing their own experiences to the table, so we'd like to know what those are because that can help us better figure out how to organize things.

So regarding the first REMS we looked at, I mean, you don't have to be able to read the whole side, but how was the information ordered? Here are the operators of the patient care program. Then one third of the page on information disclosure. A reminder that the patient must enroll in the program to get the drug, just in case you didn't see it from the first part. Then the risks and benefits acknowledgment. Post-injection recovery statements.

By the way, we often forget about that as lawyers, is the way that you recover, and what happens to you when you recover from

something is probably as important as the risk, because if you don't know that the recovery is going to be particularly difficult because you weren't disclosed of that information, that might plant the seed that I wasn't really told about this, let me go -- you know, this is not right, I should have been told about that. And maybe you were but it just wasn't explained to you in a good way.

Allergic reaction statements was next. Acknowledgment that the patient has asked all questions. And finally the right to stop taking the drug. So this information organization, when you break it out by topic like this, doesn't make much sense. And so that's what I'm talking about is creating these hierarchies that kind of better organize this information.

Now, here's a better one. Again, I mean, there's some issues obviously with some of the language or whatever, but even the design is much better than this. But on the left side, you see on the left side here -- let me see where my pointer button is -- are all the risks. "My doctor has reviewed with me the benefits and risks." I am aware of the serious risks including these things. "I understand the need to have blood and urine tests."

So, again, here are the risks that we talked about, but here are also the problems -- or the requirements of taking this drug is that I need to have these blood and urine tests. I understand that I have to have these thyroid tests, because these are all factors that should go into the patient's decision, not only the risks but also what you have to endure in order to take this drug.

And then over on the right side is the information disclosure stuff, because that's what you really think about when you think about REMS is two big things, is information disclosure so that way you can kind of study the risk and things like that, but also the fact that these are very risky things and it's going to require extra knowledge and extra treatment options or extra testing options after you start taking the drug. So much better organized. But that's the problem; if we don't provide any guidance on this, then you get hit or miss type REMS.

So what can the FDA do to fix this for REMS? Well, this is where -- you know, I was just talking about we need to know what patients think. Well, this is where studies can come in to create an evidence base to better determine the order that patients prefer to receive risk information.

REMS are all relatively the same. The drugs might be different, but the way that the risk information is conveyed is likely to be very similar regardless of the drug. So studies on one drug, various REMS that are out there, if they yield certain results, it likely can be replicated for other drugs. And this can be done for providers too because there are provider-specific REMS documents. And so we expect that provider preferences differ from patient preferences, but evidence would further refine this. Would providers expect -- want to see the risk information and then what extra testing needs to happen first, or are they more concerned about the information disclosure and what they have to do as providers in order to get somebody in this program? So that's where we can really make some gains on this.

So with this data or with this evidence, the FDA can then create a style guide or at least -- maybe not -- I hate to say a mandate, but a guide for those creating REMS so that way they can create these that are in ways that are more effective to their intended audience. And then you can obviously, in a guide, include other things like plain language document design principles, any number of topics that you want to guide them on. That's why they call it a guide.

But so in 20 minutes, that's my principles. It's something that really, I think, we don't cover enough when we think about communicating risk, is how do we do this. And particularly from a legal perspective, it's something that we should think about but we don't because we have these competing interests. Thank you.

DR. BLALOCK: Brief clarifying questions?

Dr. Zavala.

DR. ZAVALA: Yes. Hi. You mentioned that the FDA should have more usability studies to create evidence. Are there any out there?

DR. TRUDEAU: I don't think there are. I mean, but that's where -- and that's -- as Dr. Blalock was mentioning yesterday, they're not required. People who are creating these REMS are not required to test these in any way. So this is where -- I mean, there are usability studies that are done on various things. I don't know of any on REMS specifically. So there may be something out there I'm just not aware of.

DR. KREPS: You focused on the use of text-based materials. Are there other types of delivery systems that you examined, such as digital delivery or interpersonal delivery?

DR. TRUDEAU: Well, that would be -- that, I think, is the next best step as well is, okay, well, let's first -- since we know we have to create these REMS, which are mostly text based, let's deliver that and then build off of that and start thinking about, okay, how do we deliver that digitally? What do we know about the digital user? Or is the particular provider's office using iPads or whatever, and how will that differ in terms of the way that we give this information?

Now, again, one of the other things I talk a lot about is kind of informed consent as a process rather than just a form. So that kind of hits right on what you're talking about, is there's a broader spectrum to this than just what I'm talking about today. Designing the way that this is communicated to the patient is important. It's, again, one of those things where something that's life changing shouldn't be done in one 12-minute appointment where you're learning you need this drug for bipolar disorder or whatever and you're still trying to deal with that in your mind. So designing that process, that's more -- that kind of combines the media, from the verbal communication to here's the document to maybe here's the educational video that I want you to look on the -- that's a much broader spectrum but, yeah, that's definitely something to that.

DR. BLALOCK: Thank you.

And for the transcript, that was Dr. Kreps who asked the question.

So hearing no more questions, we'll proceed to the second speaker. Thank you very much.

Dr. McCormack.

DR. McCORMACK: Good morning, everyone. My name is Lauren McCormack, and I direct the Center for Communication Science at RTI International. For those of you not familiar with RTI, we're a nonprofit research institute based in Research Triangle Park, and we do a lot of work for the federal government, grants and contracts. We also work for states, foundations, and international clients.

And folks in my center, the researchers and I, have had the opportunity to work with FDA over the last several years. For the last 6 years we've conducted over 20 studies funded by FDA looking at things related to direct-to-consumer advertising in particular, although I'm actually not going to be talking about that today, although I may mention a little bit of the research here and there.

So I'll be focusing on best practices in risk communication. And then I'll also be thinking about how to apply these, how FDA can apply these, knowing that FDA is a regulatory agency and they have a unique position of also having responsibilities with respect to communication and dissemination, and that presents an interesting position for the Agency. So I'll talk, my second half of my presentation, in terms of strategies for overcoming some of those challenges given that unique position.

So FDA's regulatory mission is quite broad, covering food, drugs, biologics, and medical devices, and lots of different products in each of those areas. And then the list goes on in terms of also a number of other products, and consumers may not realize that FDA actually

oversees and regulates things like lasers, nail polish, pet foods, so they may not think about FDA as a source of information for these kinds of products. And very few, in fact, only 6% of people have gone to the FDA website for information, based on a national survey. So one thing that FDA could do is help the public understand what their role is and what they do oversee, to lay the foundation for the messaging that comes to follow that.

So, as we all know, risks and benefits are part of a lot of what we do in life. And what's really key is communicating about the risks and benefits in a factual way that's clear to consumers, patients, healthcare providers, and also providing information that they can act upon; what is the main message that you want to communicate to people? And then they can take that information, consider their preferences, their values, and then make an as informed decision as possible with that information. That's the overall goal.

So that brings me to my question of how does FDA apply risk communication best practices given real-world limitations?

So it is ideal for the Agency, I would think, to create a strategic communication plan. The plan should be science based and have clear implementation steps.

Having input from individuals across the Agency, across all the different centers into this communication plan would be advantageous in terms of fostering collaboration across the centers. In large organizations, sometimes people may not be aware what other parts of the organization are doing, so fostering that collaboration. And when

you bring people together who have different backgrounds and areas of expertise and perspectives, that's where innovation can happen. It also can create efficiencies. But also making sure that the plan is well supported at all levels of the Agency, including agency leadership, because that can send a message that the Agency views the communication function and responsibilities as an important part of its overall mission.

The plan doesn't need to be 1-inch thick. It doesn't need to take 2 years to develop. It actually can be done pretty quickly if you've got the right expertise in-house. But what it can do is put together things like, hey, these are our three major activities that we want to focus on in 2016-17, and here's maybe one campaign that we want to have, here's where we're going to get the resources for it. Maybe agencies pool resources and have an integrated campaign that covers a lot of topics for the agency.

Another best practice -- we touched on this a little bit yesterday -- was using audience segmentation. Not all stakeholders behave in the same way. Nor do they have the same information needs or react the same way to different channels and messages. So audience segmentation, I know you're very familiar with that, but for the record, it's dividing audiences into discrete segments, people with similar beliefs, particularly dividing them up into factors that influence decision making.

And while the Agency is charged with communicating with the public at large, we all know that there are many different publics. So

once you have these segments, well, what do you do with them?

There's a number of different things you could do with them. You could create messages for each of the segments. Of course, that is the most resource intensive and time-consuming approach, but in some cases it's necessary. You could prioritize the most important audience that you've really got to reach based on whatever the particular message is. You could also choose the lowest hanging fruit, who are the easiest to reach, who's the largest segment. There's a lot of different ways to go, but these kind of conversations can help think through what strategically do we want to do and who do we want to reach. But trying to communicate with the whole public with one message generally does not work.

And just to drive that point home a little bit further, there's a great website, usability.gov, for those of you not familiar with it, with great practices and guidance in terms of communicating and particularly with web-based communications. And they talk about the thing that using nondescript general public isn't helpful because it doesn't exist. And therefore when teams get together and think about who do we want to reach, they need to get more specific than the general public.

This is an example of a persona based on some work that I've done in collaboration with the FDA Center for Drug Evaluation Research, Office of Communications. And we developed these personas to really bring your audience segment to life. You have understanding not just of demographic but psychographic characteristics, knowing about them and having this information before you sit down to write a message. So

this can help define who that audience is.

Yesterday we heard a presentation about the role of emotions in decision making, and they certainly do play a significant role. Knowing that decisions actually are not made rationally all the time, so I want to take just a moment to comment about a nice report that was done for the IOM in 2014, trying to channel Baruch Fischhoff here as the lead author of that report, talks about the role of emotions and the importance of communicating particularly with uncertainty, which is a lot of what FDA has to communicate about is uncertainty. And the report comments that the job of a communicator is to find out which uncertainties are important to the individual and deliver scientifically grounded messages that provide that information.

Poor communication related to uncertainty can cause a few things. First, needless hesitation, unwarranted confidence, inappropriate choices, personal regret, and interpersonal resentment. So those are all not so good unintended consequences.

And then just lastly on that, he explained there's three concerns that experts often can hamper taking a scientific approach to communicating uncertainty, three things. The first, experts might be reluctant to express uncertainty, which they perceive as misplaced imprecision. Second, experts might have such a poor opinion of lay audiences they don't expect them -- they expect to be misunderstood when communicating uncertainty. And, finally, experts might be concerned about being punished for sharing the uncertainty.

So moving on to another best practice, using clear

communication. Our last speaker also addressed this topic. It's very common and very popular in the health literacy world. The last decade there's been a number of principles focused on clear language and leading to greater audience understanding.

It's not that you want to be informal in your conversation, but you really want to be thinking about communicating in a way that people can understand. So taking this example of a somewhat complex statement related to dietary guidelines, reworking that to a shorter, simpler, action-oriented message can go a long way. And plain language happens to be the law signed in the Plain Writing Act in 2010 and subsequent regulations.

So this is some work that I've also done with CDER. We did an experimental study of drug safety communication. So you can see this message on the left is a drug safety message related to a fictitious drug, and we took the original message and applied some plain language principles to it, including decreasing the reading level from 11th to 8th grade, took out passive voice. We chunked it. You can see there's a visual. There's motivational questions. There's bullets. So these are easy changes to make if you understand how to make them and apply them, and they're really fairly small.

So after showing these two visuals to over 1,000 people, we found that knowledge was greater for those who received the revised drug safety message. And this is based on a multivariate model with a five-item index as the dependent variable.

So the last best practice that I'll mention is the importance of

conducting ongoing research and evaluation of communication. It really completes the communication lifecycle, from planning to testing to implementing to research.

And three different types of research to mention: Formative research, really understanding that stakeholder audience. What's going on inside their mind? What's important to them? What are their beliefs and behaviors? With pilot testing, there's a range of different kinds of pilot testing to be done, easy, quick turnaround as well as more rigorous pilot testing. And then lastly, various kinds of evaluation from process to impact, but you really are -- what you want to do is assess is it working? Are your communications having an impact?

So with those best practices in mind, I'll now move to some challenges in implementing them, because it's easy to say, well, here's the best practices, but it's yet another thing to actually implement them.

So I've already touched on multiple audiences, so I'll move to the second box at the top, legal reviews and language, which was also just addressed. But there can be pressure to use precise technical language, particularly when you want to do -- you have a lot of challenging and complicated information to convey. One thing that can be done is that training those at all levels of the review process in these plain language and clear communication principles to ensure that everyone is aware of their importance. Language is extremely important in communication, and every word can matter.

Balanced summaries of product risks and benefits. There is an

interest in making sure that they're balanced without endorsing the product, but we also have to make sure we don't overcorrect and present too many of the risks.

And then also this regulatory dual function that I talked about and the need for research.

So strategies to overcome and adapt to some of these challenges. First, creating message maps. And I understand that Vince Covello is a really well-known speaker on this issue and can provide very good guidance for all parts of the Agency in message mapping, and there are others out there with expertise in this area as well. But what it really does is provides a roadmap for detailed displayed responses to anticipated questions of a stakeholder.

So, first of all, you ask, well, who are my stakeholders for this particular message? What are their questions? And then knowing that before launching into message development.

Another strategy, engaging in social media active listening. Yesterday we talked about using social media as a way to put information out. Social media can also be a way to, with media monitoring, listen to what the conversations are and use that as you're thinking through your strategic communication. But also not just lurking, but also -- that's the term for -- but active listening and telling folks, hey, we acknowledge, we the FDA acknowledge, we're aware of your concerns and your information needs, and that way people feel heard. Even if FDA cannot address the concerns right now, periodically letting people know that they feel -- they've been heard.

Next, acknowledging uncertainty. I touched on this a little bit, but oftentimes with uncertainty, the instinct is to wait until we have all the answers, but this can breed mistrust because of the length of time that it takes to get all the answers, a long time. And sometimes with uncertainty, people avoid subjects altogether. So, in this case, a best practice is to clarify what is known and unknown at the time of the communication, let folks know what you're working on to try to get the rest of the answers, and that you're going to be back in touch with them soon with an update.

This is a tool, and there are a number of tools out there. This is just one example that the CDC has developed, the Clear Communication Index. It is a way to score documents. Can be done at web-based communications, where this was developed for. Twenty-two items, you get to the end of your tool, and you say, yes, we've done this; yes, we have the main message at the top; yes, we've done this or we haven't. And you come up with a quantitative score to say if we haven't crossed a certain, say, threshold, then you need to go back and take another look at the message. And everyone could be trained in a tool like this.

Conducting rapid prototyping. So this is quick turnaround iterative testing refining messages as opposed to waiting till they're perfect. And these can be small subjects, six to nine individuals, for example, getting some quick feedback. Understandably not all messages can go out before they're tested, but certainly some can. Just a thought there. Again, it doesn't really have to be a nationally representative sample; they can be small.

User-centered design. What that means is involving the users in the product development. As opposed to developing a message for someone, engaging them in the development process from the ground floor. These are some usability principles and factors that affect the user experience. Do users -- first of all, can they find the information? Do they find it accessible, including individuals with disabilities? Is it credible? Is it valuable? Is it useable? Is it useful? And is it desirable? If you can answer yes to all those, then you're in good shape.

Testing in virtual environments is another methodology that could be used for quick turnaround testing. This is one example that RTI has developed. It's something called iShoppe. It allows researchers to immerse participants in a simulated environment and study their behavioral responses. So on the left here you've got tobacco products and testing how product placement affects teenagers' use of and selection of products. You could also do food labeling studies, as shown here on the right. Virtual reality could be one of the strategies used for some of that product testing.

You want to make sure people can find the information when they do come to the FDA website, but you, of course, don't want to rely only on web-based -- a website as the source of information. You want to enhance your digital strategy channels and partnerships. Partnerships are critical for promoting trust, getting people to the website and promoting awareness of these resources. So driving your online traffic to where you want people to see it and optimizing your search engine so that when they do come to the FDA website, they plug

in a word, they're going to go to where you think they need to go. And monitoring how easily people can find the content there.

For those of you who may not be familiar, there is a group called 18F. It's a consulting organization within the federal government that helps federal agencies adopt modern practices to managing and delivering digital services. So they are federal employees, as they say here, like you, but we're a team of designers, product strategists, architects, and acquisition specialists. So they offer that consulting services, and that could be at FDA's disposal.

Testing messages with federal employees. There are 2.5 million or so of them out there, and most of them are not scientists. They are also not subject to the Paperwork Reduction Act, which means that we don't have to go through OMB clearance to reach these folks. But what you could do -- FDA could do is include folks that represent most of the audience segments -- patients, smokers, consumers of a certain product -- and do some product testing quick turnaround on them, and they don't even need to be paid incentives.

When you do talk to more than nine people who are not federal employees, you have to go through OMB clearance under our contract. So FDA centers have access to expedited OMB review process for research. OMB process can take somewhere between 3 to 6 months, up to 9 months sometimes, depending on what's going on. The OMB expedited process takes 4 to 8 weeks; however, there are a limited number of slots to get through. And if there are two studies are already in the queue and you come in with yours, you're going to have to wait.

So one good idea would be to increase the number of slots for doing this kind of research.

So once you've done all that, you've overcome these challenges, you apply these best practices, you ask yourself, how do we know if we've done a good job? How do we measure success? Well, we've talked about some thinking in that strategic plan; it should start with goals. Then you can measure whether these goals are met. You have metrics associated with each goal. You may not meet all the metrics, but maybe you meet some of them.

And the bottom line is, are people making informed decisions? And there's actually a lot of discussion right now in the shared and informed decision-making literature about how one conceptualizes and defines informed decision making. But suffice it to say that are people aware of their choices; do they understand the pros and the cons? Have they been involved in the decision-making process? Have they considered their values and preferences? And then you've got some metrics here, like cessation for smokers, safety of some products. Are people talking to their doctors, if that's what a message advised?

And then some areas for future investigation. A big one is who are FDA's primary audiences? What are the best strategies for reaching them? What are the best methods from translating new communication research into FDA practices? As we touched on earlier, how does FDA best utilize social media for both push and pull messaging and not just that one-way communication? What do audiences expect and desire from FDA on social media? Have we asked

them that? How can FDA establish a process for quickly developing cross-agency consensus during outbreaks in emergent issues?

And these, with about 9 seconds left, are some resources for consideration. Some really good resources out there on plain and clear language.

So with that, I thank you and acknowledge those who assisted with the presentation, including Ji Sun Lee and Doug Rupert at RTI. So thank you very much.

DR. BLALOCK: Thank you, Dr. McCormack.

Any brief clarifying questions?

Okay. Hearing none, we'll -- thank you, Dr. McCormack. We will turn our question to the general question for discussion, which is how FDA communicators can apply the information that was just presented.

Dr. Zavala.

DR. ZAVALA: Thank you for a very informative presentation. The only thing else I'm thinking about is partnering with other organizations to disseminate the information.

DR. BLALOCK: Dr. Dillard. Oh, I'm sorry. Dr. Harwood. Sorry.

DR. HARWOOD: I liked both of the presentations. I really like the idea of the audience segmentation. I think one thing that would be really useful in terms of the questions that were raised in the final slide would be adding technographics to the demographics and psychographics within the actual segmentation because then you would actually know and be able to overcome some of the barriers for actually reaching the segments that you've identified.

I also think once you've got your audience segmentation, it's important that you share that within the Agency itself so everyone knows the face of the different segments, so when you have meetings, everyone is aware of who Jane or whatever the woman's name was on the mock-up on the slide.

DR. BLALOCK: Dr. Kreps?

DR. KREPS: Yeah, both presentations really illustrated to me how complex it is to provide comprehensive risk and benefit information to diverse publics. And it illustrated to me also how often we end up violating the complexity by providing information in very routine simplistic ways that end up making the information even more complicated and less accessible rather than more. And so I particularly liked in Lauren's presentation the comprehensive approach to thinking about a variety of different ways of addressing this issue.

Now, clearly the implications are that there needs to be greater investment in the communication of this information through a variety of different means, more background research, more use of a variety of different channels, more feedback systems, more evaluation refinement. And so I think that the implication for me is that this may be a good time to consider a larger investment in the communication process by FDA in terms of addressing these issues.

You know, and I think this actually kind of summarizes a number of the presentations, that it appears to me that we're not doing as good a job as we might in getting the right information out to people in ways that they can use it, and we really need to rethink how we do that. I

think we've had this kind of an old notion of if you build it, people will come; you just put the information out and that's enough. But clearly it's not. It's a more complex process, especially because of the dire implications of this risk information for making good health decisions. Just my point of view.

DR. BLALOCK: Dr. Krishnamurthy and then Dr. Sneed.

DR. KRISHNAMURTHY: I'm not sure whether to frame this as a comment or a question. Especially Dr. McCormack's presentation, I want to take something away from it which I think might be very useful.

We all know that FDA invests a lot of energy in communicating and producing communication materials, but also understand that there are certain limitations in terms of their ability to test the messages and their effectiveness. And the particular slide that interested me was the strategy of testing messages with federal employees. And the reason why I bring it up is there are lots of university-based researchers that could partner with FDA, and I've mentioned this before in our previous meetings. If there is some mechanism that can be brought to bear where researchers who are eager to be of use can also get access to data sources, that way it can be a win-win-win for everybody, especially for the public. I think the FDA can get its materials and communications tested out, and I believe the researchers can get access to good quality data sources that will allow better quality conclusions and the public at large will be served better when a good quality goes out. So I do not know if that is something that can be discussed or something that needs to be brought up.

DR. SNEED: It seems like there's a real conflict between the legal aspects and the consumer communication, and I think it's a real quandary for FDA because they're concerned about both. But speaking as a consumer, you get a medication and you open up the information about it, and first of all, you have to get a magnifying glass to read it, and there's so much information about risks, I'm always curious about what the probability, because I would imagine that the probability of most of things is so small and so remote, but legally they have to be covered.

It seems like what we need to focus on are what are the most important risks that affect consumers as opposed to giving them all of this information. Most consumers don't want or can't consume all of that information. And so is there a condensed version, and then for that really -- that one that wants to read the novel, if they can go to a website and download all of that. But I think I'm a relatively well-educated consumer. All of that stuff goes in the trash at my house.

So I think FDA needs to kind of struggle with how do you balance the legal aspects with making it useful by consumers?

DR. BLALOCK: And I'll just echo what you said about the information that comes into your house, because I've actually done studies with a variety of people and focus groups, and most of them aren't aware of the information or never look at it. So that's not just in your house.

Dr. Dillard and then Dr. Yin.

DR. DILLARD: Although this meeting's a little bit different in

terms of structure, in every prior meeting that I've attended, this group has been confronted and charged with looking at a very specific problem, and in every one of those meetings we have concluded that really we need to do some research on this, preferably very quickly. So I was taken with Dr. McCormack's suggestion that the federal employees could be used as a survey panel essentially. That seems to me to be a beautiful solution to the policy problems that have kept FDA thus far from doing immediate field-based research. And so as enamored as I am of that conclusion, I wanted to ask Ms. Duckhorn if there's some barrier to implementing that? Could it be done -- could it be done?

MS. DUCKHORN: Yes, it can be done, and it is done. We currently use federal employees in our Risk Communication Staff to test -- to do usability testing or message testing on specific documents. We aren't doing testing on REMS or on medication guides, but we can. That is something we can do. We haven't been approached by those particular groups to do that kind of message testing.

DR. DILLARD: I had something in mind a little bit more grand. If there's 2½ million federal employees, that in theory constitutes a large number of people that could be considered as an ongoing panel in an opt-in process, of course. But it would allow -- if you had a technographic, demographic, psychographic information, whatever people are willing to provide, you could identify those -- a subset of the 2.5 million that have some connection to whatever problem is immediately of interest. So it's not necessarily just a within FDA

solution. It requires some resources to maintain a panel like that, but I could imagine that the payoffs would be enormous in terms of real-time information.

MS. DUCKHORN: This is Jodi Duckhorn. There are limitations to how we can use federal employees. So I want to clarify the point that Dr. McCormack made about using federal employees.

The Office of Management and Budget says that you can survey federal employees as it relates to their job. There is some gray area in there, and that's why we are able to use FDA employees when we're asking about our internal message testing. But it's hard to expand beyond FDA employees because of that limitation. I understand exactly what you're saying, that it would be fantastic to be able to have all federal employees at our disposal as an opt-in kind of panel, but that isn't an option for us at this point. We are, I will tell you honestly, we are exploring an option of working with OMB to get a regular panel of the kind that people -- you know, a public panel.

DR. BLALOCK: Dr. Yin.

DR. YIN: It seems to me that the FDA is interested in establishing standards for communication materials, and I wondered about some of the barriers to doing so. It sounded like, for example, there are these tools that exist to assess readability, suitability, usability, and that certain cutoffs could be used to evaluate materials, and it seems like there could be standards that could be developed in terms of user testing.

Could the FDA say that you have to test all the REMS with a

certain number of patients from certain health literacy levels, etc.? What are some of the barriers to doing that? Is it about enforcement? Is it about -- what are some of the reasons why that hasn't happened yet? Or has it happened?

MS. DUCKHORN: So let me just start by saying I'm really supposed to be in listening mode. I will address it.

DR. YIN: Sorry.

MS. DUCKHORN: That's okay. When it comes to REMS, they are -- while they are primarily and initially developed by the drug manufacturers, they are given to FDA for review and approval. So the FDA does review and approve them. Before they are posted on the Internet or implemented, we have health communication specialists and REMS analysts who actually review these things and provide their expertise.

We are under timelines because of PDUFA user fees, and so that is a big factor in -- I know at least with medication guides and things like that, with why not everything goes through usability testing. To be honest, I don't know why. It could be that there's sort of a thinking that everyone knows how to write to a plain audience, everyone's a social scientist, everyone's a great writer. I honestly -- I don't know, and I can't speak for the Agency.

We are -- I think Lauren -- Dr. McCormack also mentioned something about CDC's Clear Communications Index. We have piloted that in our Center for Foods, and we are under discussion about utilizing it more across the Agency. You know, it's preaching to the choir. I

believe that it should be used more also.

DR. BLALOCK: Dr. Sneed. No? Dr. Liu.

Okay. Dr. Cohen Silver.

DR. COHEN SILVER: Yes. I think I heard this properly. I think that Dr. McCormack said that 6% of the general public has been to the FDA website. Did I -- is that the right statistic?

So, to me, that was actually the most profound comment I've heard over the years or the -- I guess it's 2 years that I've been attending these meetings, because there's so much discussion about putting information on the FDA website and 95% of the public has never been there. So I think I just want to sit back and take that in and think about how we can go from there, to moving beyond using the FDA website to communicate information.

I think yesterday Dr. Kreps talked about thinking about working with people who have blogs. I know yesterday I commented about working with the traditional media sources. So I just would like to point out that that is a very, very important piece of information that we need to recognize. All this attention on how this information is communicated on the website is just not reaching the consumer.

DR. BLALOCK: Dr. Liu.

DR. LIU: You said almost exactly what I was going to say, so -- I was also very struck by that 6%. And I think that obviously that's a huge challenge. I think part of it is it's very static communication too, and so I'm also a huge fan of the Clear Communication Index. And I think the part that's most compelling in the testing we've done in my research lab

is the call to question, the call to action, so bringing it more to a dialogue instead of just a piece of information.

And we know the way people make decisions is through information seeking and sharing and making meaning through their social network of information. So to the extent that we can at least create documents, if they're still going to be static, that they provide informed information seeking and sharing, have those questions, even maybe provide toolkits for having the conversation with their caregiver or their doctor, I think that would be a step in the right direction.

DR. BLALOCK: Dr. Rimal and then Dr. Sneed.

DR. RIMAL: I wanted to make two comments. One, that the fact that 95% of the people are not coming to the website may mean that they don't see a need to do so; that when you talk about REMS and other things like that, it may in fact be relevant to only a very small proportion of people out there, which seems fine. And I think we should also get away from the belief that FDA is the holder of all the knowledge and information. I mean, there are lots of places where people can go to for information.

The second thing I wanted to mention was, I think going back to what Dr. Sneed was saying, that perhaps we need to prioritize the information that's presented and get away from thinking that all the information has to be presented in one venue in one channel through one modality. And if we prioritize the information to say, okay, here is the most, you know, five critical things you need to know for this particular situation, and present that graphically, present that in a very

visually appealing kind of way, and then say for all the other stuff you can go to this website. Maybe you can even have other inserts that are included in the same package, but it's clearly prioritized so that we're leading the audience in terms of how to read that information and how to make sense of it.

DR. SNEED: A follow-up on Dr. Cohen Silver and Dr. Liu's statement. Yesterday we kept coming up with the server, and someone used the term the frontline person. Maybe that's our target rather than the whole public, and how do you focus on the person that's going to interact with the person that has the question or the patient who has a problem. And so maybe that would affect our thinking in terms of target audience.

DR. BLALOCK: Dr. Kreps.

DR. KREPS: Chris' discussion of the legal aspects got me thinking a lot about the legalistic way that we present health information. This semester I'm teaching a graduate seminar on interpersonal communication and I'm -- the first time I've taught this in many years, and so I've been thinking a lot about the relational aspects of communication, that every time we communicate, we provide both content information and also relational information about how people feel about each other, what they think, what their emotions are. And there's a tremendous bias in the biomedical world towards the content, and then adding the legal dimension onto it even exacerbates this much further.

And so I'm thinking are there ways that we can expand the focus

of communication to be more personal, to be more relevant, to be more humanizing, to be more interactive to help people identify how this information is personally useful.

Rajiv was saying before that maybe the reason that there's so many few people going is that maybe that many people need that information. Yet, I think that the vast majority of people, especially older Americans, are taking some form of medication, and they probably do need this information. They may not be aware they need the information, but they probably do need the information, and they're not seeking it because they don't recognize it or the information does not appear to be particularly relevant to them.

So I'm thinking if there are ways of trying to enrich the delivery of information in a number of different ways by using a range of different channels, by identifying a variety of different sources, by designing the messages so that they are more appealing, both verbally and nonverbally, by making them more targeted and tailored to the individual and their needs, by engaging people in a larger interaction and process of communications so there's more feedback and adaptation over time so that people actually know how to utilize the information, I think that we can enrich and expand the process of communicating risk information.

And while, you know, the focus here is on risk and benefit communication, I think this is kind of an issue that addresses the larger frailty of scientific communication in general and medical communication, is that we're focusing so much on the data that we're

not really reaching the people with information that makes sense to them and that they can use. And I think we can start doing this in little ways so that it's incremental. I mean, there's a big plan of doing this, but I think there's a lot of different ways that we can make the information more interesting, more relevant, more usable, more accessible, and more interactive.

DR. BLALOCK: And part of what I hear is presenting the information in such a way that people are motivated to engage with it.

Dr. Dillard. Dr. Harwood.

DR. HARWOOD: So I think both presentations sort of illustrate that when we're looking at usability, we need to sort of at least stay out with the curve, and when we do usability, we really are looking at user experience in terms of the platform in which the communication is actually going to be disseminated, so it's not just the message. And also there are many opportunities that we gain when we add in the platform component so that we can have information that will pop out. We can utilize card sorts so the person who wants to look at the risk can look at the risk; the person who wants to look at legal can look legal. So I think there's lots of opportunities there.

In terms of the 6%, I don't think it's so bad if we think of it in terms of at the moment the FDA website is aimed at the public. If we think of 6% as a part of a segment, it's not as bad since the information really isn't targeted to one segment. So there are obviously ways that the FDA could utilize data from companies so that when a consumer touched the FDA website, you already have some inclination as to what

audience segment they would be in, and the page that then is delivered is delivered in the format that is most receptive to that particular audience segment.

DR. BLALOCK: Dr. Krishnamurthy.

DR. KRISHNAMURTHY: Yes, I would like to follow up on the question of how many people access the FDA website. And I go back to the basic question of why do people want to come to the FDA's website? What kind of expectations do they have of the FDA? It is one thing that the FDA's mission is to communicate; it's quite another thing as to whether the public perceives the FDA's mission as one of communicating, or they look at the FDA strictly as a regulating agency in the sense that they will approve medications or change the approval levels, and after that they're sort of hands off.

So I think it is very important given the role of communication in the FDA's mission, it's worthwhile doing an audit of or at least a survey of what the public expectations are in terms of what do they want from the FDA; what do they look to the FDA for?

And a second question is we are moving away from a computer-based access of internet resources to a mobile platform. So is the 6%, does it include all the platforms, all the different ways in which the information is communicated? And I also think of the FDA not as a retailer of information but as a wholesaler of information, in the sense that FDA populates other media with their communication material; therefore, that 6% or whatever percentage that might be is not quite the full story in terms of what the FDA does in terms of influencing the

information landscape.

DR. BLALOCK: Dr. Zavala.

DR. ZAVALA: It was just a question regarding when Jodi was speaking about the usability regarding REM. Have you gotten any results back? Earlier you were speaking about the use of studies regarding REM and the usability when you were answering Dr. Yin's question. I was wondering if you got any results back?

MS. DUCKHORN: I'm not aware. I'm sorry. As far as I know, I don't think any usability studies have been done internally on REMS or medication guides. That's, I think, what I was saying.

DR. ZAVALA: Oh, okay. Because Dr. Trudeau said he -- there wasn't any that he knew of, but I thought you were addressing that. Okay.

DR. BLALOCK: Dr. Sneed.

DR. SNEED: I wonder what percentage of the public even knows what FDA is, much less to go out and seek them out. You see these interviews of people on the street, and they don't even know who the president is, so they probably don't know who FDA is.

DR. BLALOCK: Dr. Cohen Silver.

DR. COHEN SILVER: Just to follow up. I'm looking again at the slides that Dr. McCormack showed and the -- it went onto two slides of the regulatory mission. So it's food, drugs, biologic, medical devices, electronic products, cosmetics, veterinary products, and tobacco. I bet that it touches everybody. And so it's not just people who take drugs, and it's over-the-counter as well as prescription drugs. So I completely

agree with Dr. Sneed. I don't -- I bet most people don't have any idea what is covered, and therefore, you wouldn't know to go to the website to even check on these things. All this means to me is that the website, the FDA website cannot be the tool by which FDA communicates information.

DR. BLALOCK: Dr. Harwood.

DR. HARWOOD: So I think that just brings out the necessity that there should be a different segmentation for each aspect, that there's not one FDA segmentation, but you have a segmentation that deals with the food and for the drug, etc. I just wanted to clarify.

DR. BLALOCK: And I will take just a second to try to sort of summarize what I've heard as some of the main things, and I think we'll probably still have a couple of minutes after that if other folks want to chime in and say that no, no, no, you missed something that is really important.

One of the things I heard as a suggestion in one of the presentations was the need to develop a strategic plan for risk communication, and I think that that sort of ties in with some of the things that we talked about yesterday, because you can get overwhelmed with the scope of things and so having a strategic plan that probably lays out the big picture long term but then also chunks it up into maybe for the next couple of years so that you don't get overwhelmed by the larger scope of the task at hand.

One of the other things I really like from Dr. Trudeau's presentation, and I had not heard the term before, was the functional

risk hierarchy. And my bias is towards thinking about medications because that's just what I do work in, so it may not apply to other areas as much as it does to medications. But for medications, these REMS programs are developed by the industry, the person who is creating the -- who has developed the medication and is applying to have the medication approved. And so providing them guidance, more guidance on this type of functional risk hierarchy that Dr. Trudeau talked about and really putting it into the patient perspective, not what is most important to the attorneys but what is most important to the patient, and that requires -- in some ways I think it almost does require a sort of shift in how we think about this.

And, you know, one of the terms that I've heard used -- and actually it was a patient that was in a study of mine that used this term -- I had never heard it before. And I was asking them to look at -- and this was not a medication guide. It was just other written information that's often stapled to your prescription bag. And he said, oh, you really want me to look at that? That's just CYA. And I won't say what CYA is here on microphone. But for anybody during the break, I will reveal the code. But I do think that when you look -- and especially when you look at the information that's disseminated about medication, it really is focused on legal concerns rather than on consumer concerns. And that almost requires sort of a shift in how we think about how we develop these things.

I heard a lot of talk about user testing and usability testing, and I imagine different people define those terms a little differently.

Usability testing, as I understand the tool from CDC, might be done without consumer input. It could be done by the person developing the message and just looking at the checklist. And someone correct me if I'm wrong about that. And certainly that's important, but also it doesn't forgo the need to do user testing, because it's one thing to have people who are developing the material think that it meets the plain language guidelines and everything; it's another thing for patients to really say, yes, I understand and I understand -- I comprehend the message that you're trying to communicate.

The other issue that I heard a lot was user testing, and just in terms of, you know, even more broadly than what I usually think about it when we talk, and this ties in a little bit yesterday to the channels of communication, because one of the tests that any communication has to meet is that people have to attend to it, people have to find it, people have to be aware of it. People can't possibly understand or use it unless they can find it. And so when you think about Tweeting and Facebook, maybe people can find things better there than on the website. So it just ties into, I think -- you know, raises some other issues.

Let's see. And then I did hear a lot about -- I heard Dr. Kreps talking about the need for investment, greater investment in communication, and I think that's just a challenge to the FDA because there is the regulations concerning what you can and cannot do. And even when we talked about the federal employees, what you can -- with the types of research that you can and cannot do with them. But I think

that some of the ideas that we've talked about just in terms of greater user testing, they really do require more resources, and maybe in a strategic plan there could even be an initiative of how do you fund these initiatives that everyone is saying that we need.

So let me stop there and -- is there more discussion or reactions to what I've just said, either to enhance or contradict?

Dr. Rimal.

DR. RIMAL: Pardon me for being very naïve, but I'm struggling to figure out what is the problem we're trying to solve. Is the problem we're trying to solve that we want more traffic to the FDA website? That seems kind of odd to me that -- you know, in a perfect world, if everything is working as the way it should and consumers are getting the information from their physicians and they're using the drugs in the ways they were meant to be used, you would have no traffic to the FDA website, right? Because I think -- maybe it's my misunderstanding, but I'm sort of getting the sense that the REM communication and so forth are things done when something goes awry, when something does not go according to plan. So if that is being captured by 6% of the population going to the website, maybe it's not such a bad thing. I'm probably missing the boat here.

DR. BLALOCK: I'll just respond to that. That's not my understanding of the REMS program, and Ms. Duckhorn can chime in as well. My understanding of the REMS programs is that these are medications that do have serious risks, and the FDA, as part of the approval process, wants to make sure that patients are aware of these

risks before they take the medication. And so therefore there will be different REMS strategies used just to ensure essentially informed consent. So really trying to be proactive rather than reactive to a problem.

But with that said, medication guides -- and, you know, one medication guide -- and I know that we're getting close to the break, so I'll try to be short. One medication guide for -- am I allowed to say drug names? Probably not. One medication used to treat osteoporosis has in the medication guide -- medication guides, for those of you who don't know, often say what is the most important thing that you should know about this medication? And I think that there are probably -- there's a class of medications that probably have this warning on there.

So what is the most important thing that you should know about this medication? It may increase the risk of atypical thigh fractures. Okay. And I actually had a colleague recently talk to me who was recently diagnosed with osteoporosis and this medication, and she said, well, what's this all about? You know, I'm taking this medication, and it can increase my risk of thigh fracture? So -- and, again, because we're approaching the break, one of my sort of pet concerns is that when patients are thinking about starting a new medication, probably one of the most important things that they need to know is why should I take this medication? That probably should be at the very top of the box, not the list of risks. And then the list of risks clearly for informed consent needs to be there, but not so -- not in the order that it's presented now. And I think that that's an example of a document that's

written with the lawyers' concerns in mind. You know, they're not going to miss that, but it also has the potential to cause undue alarm.

And I speak to rheumatologists who spend a lot of their time convincing people who really need this medication that this risk is pretty unlikely. So at any rate -- and I think that that's an example of, again, information that's really sort of geared towards concerns, legal concerns rather than consumer concerns, and that's something that we need to shift.

So I know we're -- oh, she says I have no need to rush. But so I think that was the point that I wanted to make. But again, let me allow other people to sort of chime in on that.

Ms. Duckhorn, did you want to say anything in sort of response to that, if I've misrepresented anything?

MS. DUCKHORN: I guess the only thing that I do want to point out is a couple times we've talked about the information that's disseminated at the pharmacy. Usually the paper that is stapled to the bag or shoved inside the bag, unless it says medication guide, it's actually not regulated by the FDA. So that is something to consider, that we don't regulate that, we don't write it. And so those big, long, run-on sentences that you need your magnifying glass to read, that's not us.

MS. BLALOCK: Other comments before we take our break?

Okay. So I think that we are ready for a 15-minute break. What time is it? 9:40? So we'll come back at 9:55. Have I done the math right? 9:55. Thank you.

(Off the record at 9:40 a.m.)

(On the record at 9:55 a.m.)

MS. BLALOCK: Session 5 on How Audiences Negotiate Multiple Messages. We'll hear presentations from Dr. Nathan Dieckmann followed by Dr. Timothy Sellnow.

Dr. Dieckmann.

DR. DIECKMANN: Thank you. Make sure I know how to fly the plane here. Okay.

Thank you very much for inviting me to talk today. I think Dr. McCormack actually did a great job of outlining a general risk communication approach, and I just wanted to talk about some additional issues to consider when thinking about risk communication and try to make this problem even a little bit more complicated for you, if it's not complicated enough as it is.

So what I'm going to talk today is about some experiments that we've done looking at how the public reacts to expert disagreements or expert disputes about matters of fact or forecasts into the future. And we all know that there is expert disputes, either from individual experts or from expert organizations are common in many domains. We can think of climate change forecasts, economic forecasts, forecasts in statement of facts about sociopolitical events, and we've probably all had kind of personal interaction with some kind of conflicting health information in some way, whether it be dietary recommendations or the amount of salt that we should be taking in or the amount of exercise that we should be getting. These recommendations seem to

change and seem to be in conflict with each other.

We were kind of interested in how the public actually perceives these types of apparent conflicting health information. So it's important that we actually understand how the public reacts to these things just so we can design better communication strategies between public and expert organizations or individual experts.

So the first question is why the experts disagree in the first place. And from a kind of traditional view of this, if you think of expert consensus as a necessary feature of expertise itself, there's only two options basically why expert organizations would disagree with each other. It's basically that they're either incompetent, one or more experts are incompetent in some way, or that there's some kind of intentional or unintentional bias going on due to ideology or world views or private interests or something like that.

However, there's another perspective here, that disagreement and disputes about matters of fact or about forecasts is a normal part of science. Right? That's part of the scientific process. Just when you're dealing with complex, dynamic, uncertain real-world problems, by definition, some experts are going to think about things differently. They're going to come to different conclusions, and that's okay. All right, so even the most competent and unbiased experts are going to be expected to disagree, particularly at the beginning of an inquiry before a lot of work has been done on a particular issue.

The lay public, when interacting with conflicting health information, is at a distinct disadvantage in trying to understand what's

going on. They basically have no way of knowing the actual causes or the magnitudes of the disputes. Now, years of psychological research shows that just because people don't have all the facts, it doesn't mean that they're going to withhold judgment in some way when they actually see an apparent dispute between experts. And this is what we're actually interested in here; what does the public perceive of the organizations or of the experts when they actually perceive that there's some expert disagreement there, which is rife in the health domain?

So there's a number of possible kind of causal attributions that a layperson could make as to why there's expert disagreement, why all the experts aren't saying the exact same thing. I'm going to call these first two causes basically the problem is with the world, not with the scientists. This is basically that there's too much complexity in a particular domain, there's too much kind of inherent uncertainty that, of course, scientists are going to come up with different answers until there has been enough time to go through the inquiry before you can kind of converge on a single answer to a question.

Points 3 through 5 are causal attributions that are more about the problem is with the scientist, not with the world. So science is objective and certain; we should have a correct answer, but the experts lack knowledge. Either they haven't just spent enough time getting the knowledge about the causes of an event, or the experts are just straight incompetent; in other words, they aren't experts at all. Or the experts are biased in some way. So it might be a particular organization is biasing their conclusions for some other purpose other than to

communicate the true risks and benefits or true matter of fact about something.

This sixth point here is something that came out in some focus groups that we had done, and it's one attribution that maybe a lot of these apparent conflicts between experts have more to do with their unwillingness to admit uncertainty; that a lot of organizations and experts are kind of forced into a position of making a deterministic claim about how things are, and therefore, when multiple organizations do this, things appear to be in conflict. But if they were more willing to admit the uncertainty that they have about these things, you might see more overlap.

So our question again is what is the public going to think when they perceive expert disagreements? Which of these possible attributions will they make?

There's been surprising little research actually on how the public perceives expert disagreements. There's been some work by Brandon Johnson and Paul Slovic in the late '90s, early 2000s, and some other interview studies, but all of these have been on kind of very specific topics within the environmental domain and one study on food additives. And what we wanted to do -- so I'm just going to show you an example of kind of one of the studies that we've done along these lines, some of the conclusions that we've drawn from them.

This is from a recent paper in the public understanding of science. Here what we wanted to do is look across kind of a diverse sample of forecasting topics from various domains and try to get a

sense of how people were perceiving expert disagreement in these domains and what they attributed that expert disagreement to. So we used a psychometrics approach.

We were also interested in stratifying the public group by education level, with the idea that people with more formal education may be more exposed to scientific concepts and might be more likely to attribute any disagreements to just a normal process of science as opposed to incompetence and so on.

And we also wanted to look specifically at people's self-reported knowledge about a particular domain, so whether they felt that they knew what scientists did and they understood the domain, or if they were dealing with a situation where they really didn't know what scientists do and they were kind of blind to it.

So we generated 56 different forecast topics from 8 topics from 7 different domains. Within each of the domain we varied a few things, time horizon and whether the forecast was binary or continuous. I'm not going to talk about these manipulations much because the public participants weren't very sensitive to these. I'm going to focus on some other aspects of the work.

So here's an example. We had 56 different forecasts here, but here are some examples of some of the forecasts or the kind of forecast topics that we used in these different domains, some in the health domain, politics, terrorism, climate change, economics, crime, and some other environmental ones.

So we recruited 342 people from an online subject panel. About

half were female. The age ranged from 22 to 76, and we tried to get a broad range of educational attainment. About a quarter of the sample had completed high school or less, all the way up to 16% having some advanced degree.

And the basic procedure, I won't kind of dwell on the details here, but basically each participant was presented with seven randomly presented forecasts of which then we had them make a series of ratings on them. So we had them look at the forecast topic, make some ratings about how much they thought that experts disagreed for these type of forecast topics. We had them then make a number of ratings that tried to get at those six different causal attributions that I showed you on the previous slide: the extent to which that they thought the domain was very complex and random, the extent to which they thought experts knew what they were doing in that domain, whether they were competent, whether they were willing to admit uncertainty, and whether the experts were biased or not.

We actually got a whole battery of other measures of cognitive ability, education, income, and also, like I said, self-reported knowledge of each of the individual forecast topics.

And, again, the general idea here is to look at how ratings of expert disagreement can be explained by these different causal attributions to try to get a sense of which of these causal attributions are being used by the lay public.

This is a little bit of detail about the analytic approach. But basically what we did is calculated a mean or an average score across

the group on each of those different measures and did the analysis at the forecast level. So the sample size here was 56. I won't dwell on the details here and just get to some of the results.

So it turns out there was quite a bit of variability across the group in terms of their perceptions of the expert disagreement across all of these different forecast topics, but that variance wasn't explained by the time horizon. So, for instance, if the forecast said that experts were disagreeing about something that would happen in 6 months versus they were disagreeing about something that would happen in 50 years, the public didn't seem very sensitive to, what we might expect, to be more disagreement for the people when they're making a long-range forecast.

And the domain was surprisingly not a really strong predictor either. So this is whether the forecast was in climate change or economics or health or something. Although there was a trend for forecasts in the health domain to elicit slightly lower ratings of expected expert disagreement, such that they expected health researchers to do a little bit better job than climatologists or people -- or economists and so on.

So what I'm going to report here is the results, just some simple results broken down by different subgroups. I'm going to show just a series of simple graphs here that's basically showing the strength of each of the causal attribution predictors.

Here is for the subsample of the group that had lower educational attainment. For them, by far the strongest attribution here

was that the experts were incompetent. So what this means is that when they perceive particular forecasts to have experts that have a lot of disagreement, they also perceive those forecasts to have incompetent experts. They didn't necessarily think that they were biased or that this was a part of normal science. They basically thought the fault was with the experts, and the experts are incompetent.

We find basically the same results for people with lower self-reported knowledge. So for people that say that they don't really know very much about a domain or how scientists work in a particular domain, they also attributed expert disagreement to incompetence of the experts.

For those folks with higher educational attainment that scored higher on some of the cognitive ability tests and so on, there was a little bit more of an nuanced attribution as to why experts are disagreeing, that some of it has to do with the difficulties of normal science, that we're dealing with complex things that are changing over time, there's some inherent randomness there that's difficult to predict. But there was also a co-attribution here of bias such that although they did think that science was hard, they also thought that some of this expert disagreement was due to experts intentionally or unintentionally biasing their conclusions or communications for some kind of an end.

And then finally we wanted to look specifically -- this result was somewhat surprising too. We wanted to look specifically at people who claimed that they knew a lot about a particular domain and they knew how scientists worked and they knew what -- or how forecasts would be

potentially made in that particular domain. And for them, the strongest attribution was just bias. And this was kind of an overwhelming representation. We may have expected that people that knew more about the science may be more likely to say that expert disagreement is due to normal scientific issues, but really what they did is they attributed it to the experts being biased.

So what does this all mean here? What we basically found is that people lower in education and with lower self-reported knowledge about a domain appeared to most strongly attribute expert disputes to expert incompetence. And this is kind of an interesting claim here. So this means that if there is some kind of dispute and a member of the public is perceiving that experts are disagreeing with each other -- that could be an organization like the FDA -- the most common attribution as to why that's happening is that the organization is incompetent; they're not doing their job, they're not doing it right. And the implication would be that organization would lose source credibility, and there would be a number of downstream judgment and decision-making issues that would come from that.

And this may generally just relate to kind of a more simple view of science as objective and certain, and what scientists are doing are like archeology, just finding the fossils in there, and when you find them, you show them and that's fact, right? But people that work in the field know that's not really how science works, of course.

People with the highest self-reported knowledge about a particular domain appeared to overwhelmingly attribute disputes to

bias. And in some ways this actually implies a more sophisticated view of science as being socially constructed in some way, right? That it's not just archeologists uncovering things and showing them, that it's a social process.

And it was only those folks with the most formal education, which was about one-third of the sample, about, that attributed any expert disagreements to actually the normal process of science, basically not blaming the scientists for being incompetent.

So what we've basically done so far, and we have some other studies kind of in the works along these same lines, is try to just get a general sense of what people think when they are seeing conflicting health information. And this is a big problem now. We actually wrote a thought piece in *Health Expectations* recently on ways to go for future research here in trying to determine how people are responding to conflicting health information, which is extremely present with Twitter and other online resources for finding information as well as more traditional organizations presenting risk information as well.

And one kind of open question is how exactly do people perceive expert disagreement on kind of the individual issue level? So it's quite possible that there might be particular issues that the FDA deals with that are going to be more amenable, and people are more likely going to seek out other information and potentially see some conflict between the FDA message and some other information.

It might have to do with what we're calling multiplicity here, too, which how many sources are actually disagreeing? Are we just talking

about two well-respected organizations that have a different opinion about a matter of fact, or are we talking about 20 different things that someone could find online that all disagree with each other, and how is the public actually going to react to that?

There's other questions about the evidence's heterogeneity too, which is the question of what types of evidence are actually conflicting? Are we talking about two scientific studies that are showing a different result, or are we talking about someone perceiving conflict between a message from the FDA, a scientific study, and a personal anecdote from their neighbor or something like that? All of this has not really been investigated fully as to how the public is really navigating the tons of conflicting health messages that are coming toward them.

And temporal inconsistency is another one I thought might be somewhat relevant to the FDA too in terms of how the warnings for particular products come out. So you can go on the FDA website and see particular warnings for products. Those warnings can actually change over time as well. And it's an open question as to whether some members of the public are going to perceive that as some kind of conflict, right? If they don't think about the fact that maybe the science has converged on a different answer or there's some more evidence now, and if it's not clear on the website or the FDA doesn't make that clear, it's possible that the perception could be there's inconsistencies there. There is conflicting health information coming from a single organization; they must be incompetent. I don't know why they're changing their messages so much.

Some other open questions are exactly how -- the perception of conflicting health information and its perceived cause. So if they're saying they think that a particular organization is incompetent because there is conflicting information coming from them, how exactly is that going to affect judgment and decision making?

And here there's kind of a litany of possible psychological consequences of the perceptions of conflicting health information, from people ignoring information or potentially being motivated to seek more information, of which they may find more conflict potentially. They may weigh information less or see the conflict as an opportunity to only use the information that confirms what they wanted to believe anyway in the first place. We have some other experimental evidence of that as well.

They might just end up in a decision paralysis situation where information overload, too much conflict, and they just don't do anything. There's been other research showing that when there is some kind of perception of conflict in terms of a message, it's lowered the behavioral intentions of people to actually follow through on whatever that recommendation is, whether it's decreasing salt in your diet or something like that. And also there is other kind of emotional effects of increased anxiety, heightened risk perception, and so on.

And a kind of fundamental question for me is if in the additional research that we and others are doing we show that -- well, first I should say, some type of conflict is going to happen no matter what. There's no possible way that any organization or expert could always

put out consistent messages that are not going to conflict with anything else that someone might see, right? The only thing that you can do is somehow try to communicate that message in a way to decrease any of the ill effects of these perceptions of conflict in terms of them thinking that the organization is incompetent or something.

So my kind of general question is how we can potentially nudge people to be more accepting of disagreement as a natural part of the scientific process as opposed to making attributions about incompetence or bias and so on? So we're just beginning some of this work, but there is ideas to perhaps embed, to the extent possible, depending on the medium, kind of simple educational messages within communications to reinforce the idea that conflict is normal, this is a normal part of science, this is how we actually reach some kind of agreement as to what a matter of fact or a forecast actually is.

And as some previous presenters have discussed too, it may suggest also a need for audience segmentation in some way. At least some of our results here, that if there's segment of the population that are going to perceive this risk information and potential conflict in much different ways, it's possible that they need to receive different messages. Unfortunately, I can't end with a slide to just tell you how to do it all and it'll be all fixed and you won't have to worry about it, but I'm just trying to give you something else to think about, like I said in the beginning, just to make this even more complicated than it already was from the previous speakers.

And I'm ending with 5 seconds, so I'm pretty proud of myself.

Thank you.

DR. BLALOCK: I actually have a quick clarifying question.

DR. DIECKMANN: Yes.

DR. BLALOCK: And I may have just missed it.

DR. DIECKMANN: Yes.

DR. BLALOCK: How did you assess perceived disagreements? How was it operationalized?

DR. DIECKMANN: Yeah. So we just asked them a series of three questions about the extent to which they thought that scientists that work in this particular domain disagreed with each other, the extent to which they had actually perceived or have seen experts disagree in this particular domain. So it was three questions which were highly correlated, and we averaged them.

DR. BLALOCK: Thank you.

Dr. Kreps.

DR. KREPS: While I'm sure there's different levels of evidence, different positions on a lot of the issues that FDA covers, I wonder how controversial those different issues are? You know, I don't know for sure, but it seems to me that most of the evidence that FDA presents is not tremendously controversial.

DR. DIECKMANN: Yeah.

DR. KREPS: So there wouldn't be a lot of issues. But then there are a few things like the cancer screening guidelines and food recommendations that are controversial probably because there are commercial stakes involved.

DR. DIECKMANN: Right.

DR. KREPS: But I'm wondering -- the clarifying question is what percentage of these or how much of the issues that FDA covers would be in the controversial range?

DR. DIECKMANN: Yeah. So that would be difficult for me to assess, not having a lot of knowledge about the FDA and all of the missions involved. Actually, one of the previous speakers, when I saw actually the number of products that were actually being regulated in some way, I was surprised. So it may actually be more than I thought.

But I think one thing that you have to think about too is although we as scientists who actually look at these things might not perceive things to be controversial at all, but in focus groups and with talking with members of the public, sometimes they perceive conflict in places that you might not expect. I've been continually surprised. And I think that's what's great about doing this type of research as to where the conflict arises and the type of sources of information that they're actually going to. So it's possible that there might not be any disagreement within the messages coming from the FDA, but members of the public can get information from all over the Internet and so -- and could potentially find some disagreement there, although I can't say what percentage it would be.

DR. BLALOCK: Thank you, Dr. Dieckmann.

DR. DIECKMANN: Thank you.

DR. BLALOCK: So we'll continue on with Dr. Sellnow.

DR. SELLNOW: I want to thank the Committee for inviting me to

participate. It's an honor to share my research here today. I need to give credit where credit is due. I've worked with a research team. These are some of the people that have helped put together this study, and particularly this work has been sponsored by the National Center for Food Protection and Defense and the CREATE Center for Risk Studies at the University of Southern California. And, of course, although this has been funded by the Department of Homeland Security and others, these opinions are mine.

So we'll talk about the process of looking at different messages, competing messages to try to -- as we watch audiences and publics try to ascertain the actual danger that faces them. Much of the work that I've done, given the sponsorship for this research, relates to food.

Came up with a whole set of best practices, studied those, and advanced from that process to get into the whole understanding of competing messages and message divergence and convergence, and that's what I'll talk about today as a form of competing messages for risk communication.

So today this is my journey. We'll talk about the foundations of message convergence and convergence theory, some recent studies, and future directions for the FDA. But I thought, just to make things interesting, I'd switch from an inductive approach and go deductive. And so I'll give you my recommendations now, and you can watch these manifest in my presentation, just to be different.

So here's my recommendations for FDA risk communication. First of all, realize that cocreation or message convergence occurs

among agencies and their publics, as Dr. Botan and Dr. Coombs talked about yesterday, but also among agencies and agency-to-agency-to-agency interaction. So I'll talk about that. Secondly, the FDA would be well off to recognize, emphasize, and coordinate favorable convergence among messages as multiple messages appear on a subject. And, third, the FDA would be well advised to justify and explain points of divergence among their message and other messages. So let's see if I can make these manifest in this presentation.

So convergence theory is not mine. This comes from the 1969 text, Perelman and Olbrechts-Tyteca, looking at a new rhetoric. And a new rhetoric looks at arguments in a realistic setting, and I'll talk a lot about how arguments interact in a public setting.

The primary author that extended this work is Chaim Perelman. Now, as a Jewish citizen in France during World War II, he had reason to want to understand post-war the process by which arguments are made and publics condone different activities. And so the two primary concerns that he had were pluralistic values so that all sides are heard. Also, he recognized that people don't make decisions with formal logic, but rather that there is an informal nature to it, and he set about understanding that, part of which is convergence theory. Put simply, multiple sources contribute multiple messages on the same topic, but these messages interact; in other words, there are overlapping components of these messages.

So I've got three general propositions. First of all, although there are competing messages, they're rarely completely distinct; in other

words, there are always going to be points of overlap. Those are the strongest points of influence. Secondly, audiences recognize this plurality and actively seek an understanding of points of overlap among multiple messages when those issues concern them. Third, as discussion continues, points of convergence can deteriorate as new information is released.

I've done a project with the World Health Organization on vaccines, and the whole goal of that project was to try to understand how we lost message convergence in vaccination in some parts of the world.

Here are some studies that have contributed to this process. I did some work with bovine spongiform encephalopathy trying to understand the competing messages. When we believed the food supply was safe, there was a continued resistance and consumers lacked confidence in the food supply.

A fascinating study that one of my doctoral students completed several years ago is published in several different locations now, looking at complex pregnancies and how doctors communicate among each other to get information from the agencies and organizations that they follow, from each other and with interaction with the patient. Fascinating study.

And then what I'll talk about today is a simulation looking at school lunch programs, and then we've done some work for the USGS on earthquake early warning, trying to understand and come up with coordinated messages there.

It's important for me to explain the simulation. I didn't have time here today to show -- it's a series of news stories that were broadcast; we chose television considering that it could also appear on YouTube -- a series of stories where convergence appears. And so just to give you the details of that simulation I don't have time to show is that initially there is a *Salmonella* outbreak in the public school lunch program, and we buried this by the site with which group with which we -- where we were talking to focus groups. A letter is sent claiming that this is a terrorist intentional contamination, using the word "terrorist." And then throughout the series of messages, the Poultry Association, the CDC, and the FDA are quoted refuting the claims of the letter so that it's revealed as a hoax, but this takes a series of stories.

So multiple sources, multiple information are shared for the audience, and then we asked them a series of questions in a focus group format. And we did that in a variety of states -- we were well funded for this project -- so that we could accommodate diversity in location and other characteristics.

So this is a multiple city approach. And when we identified points of convergence among the audience, we asked them to talk about where they saw messages of different audiences converging, where they found those converging messages influential, and how they use convergence and perceive convergence in their daily lives. And then points of divergence in the stories and how that influences their decision making.

We transcribed everything, and then we allowed for both a priori

as well as emergent concepts to appear in our interpretation. So enough of that.

What did we find? Well, participants explained that they were exposed to multiple messages, and when they did so, they sought additional messages. How many of you now when you watch a television program have another source of information handy, a tablet, a laptop, where you hear something interesting; I want to hear more about that. I just -- I don't know if I can watch television without my iPad anymore. I may have lost that capacity.

But also keep in mind that traditional forms -- I know Dr. Kreps mentioned he's teaching an interpersonal communication class. We know interpersonal communication plays a major role in all these kinds of interactions to make decisions. We have a variety of contacts, and those interpersonal dynamics are very important.

But dealing with that first proposition, a distinct source preference, participants generally preferred federal regulatory agencies and other types of information. Now, I didn't put this in here just because I'm presenting to the FDA. But this is -- the FDA did get a shout-out here. "I would believe the FDA, whatever they say, before I would believe the poultry people. Just because they're the FDA. That's the way my mind thinks." And so -- and this was not the only person who made that kind of a comment. The CDC was referred to favorably as well.

Also, participants were skeptical of information shared by agencies they perceived as having a vested interest. And we did quote

the Poultry Association, which was highly credible, an independent agency. But that simply did not bear the kind of impact that the more objective government agency groups did have or agencies did have.

Participants are more likely to take action when they perceive significance among multiple convergent arguments. I like this quotation, although it's a bit awkward. "I'm going to listen to what I'm hearing the most. You know, like what is common between what everyone is saying. So if I'm watching ten different things and eight people are saying 'Wash your hands every five minutes,' then I would probably be more prone to wash my hands every five minutes." Now, this is a simplistic statement, but it goes to show how people are aware that that overlap is vital. And that gets back to my emphasis on looking for and recognizing, emphasizing, and coordinating those favorable messages because they are influential.

Proposition 2. Participants see convergence via messages they find on multiple social media sites. I like this. This the life of my students. "On YouTube, everyone's a reporter now. So if I go on YouTube and I'm seeing these videos popping up, I might watch one and pay attention to where they're getting their information from. And then...get on Facebook or Twitter, and usually you'll see something that correlates to what you saw on YouTube. And then go to the headlines and you'll see a headline that correlates with all three."

Well, what I'm talking about here is that this is how we're making decisions now. There is a shift in the landscape for our decision-making process, and interestingly, this is from a person with --

everybody who participated in a focus group had to make food choices for children, so it had to be something that children -- so it's not one of my students, even though it sounds like one. This has to be someone who's making food choices for children.

Proposition 3, on the reflection process. Participants actively assessed the significance of convergent and divergent arguments. "Somewhere between exaggeration and sensationalism, you'll find the truth." And I think these are people talking about extreme messages, trying to understand what the common ground is and being fully aware that although the messages compete, there's likely to be some overlap.

And then finally participants may change their minds as arguments evolve. "I seek out the information and look for a common thread, but with the knowledge that maybe the whole story isn't in yet. I would tend to be a little more careful until we know a little bit more."

I just have one more. Participants sense contrived convergence. So we have to proceed with caution if we're going to pursue convergence as a persuasive element and realizing that we have an environment of multiple messages, because if we get to the point of being perceived as contrived, our credibility is lost. And this comes from a -- when we were talking about terrorist response and trying to talk about the fortification that was in place, one of the individuals responded, "They want us to feel this way. They want us to feel like little sheep running back and forth, and I began to resent it." So talking about the fortification and the consistent patterns for response to terrorism, it became almost to the point where they perceived it as

contrived.

So discussion and implications. Well, we know that multiple messages come from multiple sources. This is our environment. We have to accept that, and we have to be able to respond to it. We also know that audiences can actively critique the credibility of those messages. It's not that we, as some of us feared, that with so many messages coming from the Internet, that there would be an inability of individuals to show the kind of media literacy to distinguish among those messages. Well, I think people can distinguish among those messages, at least in our measures.

Audiences consciously seek convergence among multiple sources. That was abundantly clear in this project. And audience assessment is ongoing and may change based on new information, arguments, and rebuttals. Much to the dismay of those of us who believe that we've reached convergence on important issues, it can deteriorate. We need to be vigilant so that areas when we believe that the science is right and the behavior matches the science, we have to understand that in areas in such as vaccines, we can lose that convergence.

Some of the research where we're going that -- we talk about the perils of congruence, where we go beyond convergence, that overlapping messages, to where there's one dominant message. This was the case in L'Aquila. I've done some work on that case in Italy where they had what we call a warning that was ignored supposedly by scientists to the point where then there was an earthquake. People felt

like they were not given the kind of information they needed. Again, pluralism was lacking. And so, you know, hundreds of people died in this earthquake. And I worked with a variety of agencies on this project for some time trying to understand what the line is between convergence and congruence. It's very important.

To the right is an app for warning messages. We're talking about converging messages among a campaign, like "Drop, Cover, Hold On," and an app that just gives an alert. Can we get that convergence where I get a short signal and then something I -- that converges with training that I've had to respond? So I don't need all the information; I can respond.

Then in the right-hand corner, lower corner, Ebola risk communication, we spent a lot of time -- we're still on this project wrapping it up with the CDC. You might recall the divergent messages that came out about how Ebola is spread, and it didn't help that this happened during a campaign year. But there was a lot of, I would call, bad science reported. It was diverging messages about Ebola, and we worked on that and looked at its impact and its frequency and the CDC's ability to counteract that. So that was very interesting.

And then a project that I'm involved with right now with the USDA is looking at the rapidly emerging diseases in the food industry, particularly with livestock, so that there can be almost an effort to develop pre-convergence, where we try to find out what parties need to talk to each other, so that if we have some sort of rapidly emerging disease hit our food supply, how can we get together and get a

consistent message, as consistent as is possible allowing for pluralism, to deal with that process. So it's a rapid response grant. We're preparing for that and trying to build an infrastructure for that process.

Again, I want to talk about the -- I want to reiterate these recommendations that I have. And that is that we ought to at FDA, I think, realize that cocreation of messages occurs, and it's convergent. It's not just us speaking with our publics and listening to our publics. There's also this second step or this additional step that there are other agencies or entities competing for our public's attention, and that competition, that convergence/divergence also is a cocreating activity. So we've got to account for that. It's not -- we can't just focus on us and our publics; we've got to take into account these other agencies competing.

Secondly, we need to recognize, emphasize, and coordinate favorable convergence. If we can build that convergence, we have to realize that this is highly persuasive information. So if people perceive convergence, this can be highly persuasive.

And then, finally, if we can experience -- when we experience points of divergence, as CDC did with their Ebola communication, we need to justify or explain those points of divergence. We can't expect that we've stated our case, there's a diverging argument, well, work it out. I think we need to actively explain why we diverge and then try to look for convergence beyond that process.

So these are my recommendations. This is based on convergence theory, which I am convinced is an effective means for

managing multiple messages in our communication environment. Thank you.

DR. BLALOCK: Thank you very much.

Clarifying questions for Dr. Sellnow?

Dr. Yin.

DR. YIN: I had a clarifying question. I was wondering in your study if there were any differences in terms of literacy or income or racial/ethnic group in terms of the way people approached message convergence in terms of actively critiquing source credibility or consciously seeking convergence? It seems like some people may be more activated in that sector.

DR. SELLNOW: There was two. When we did our focus group in a predominantly Arab-American community, there was considerable resistance to each mention of terrorism and the response. And that's where some of our resistant messages came in, and that's understandable, although we did not specify the background of the terrorist agent at all. Still, that word is something that we would consider replacing.

And then, secondly, in our South Central sample with our focus groups, we had the lowest level of education and income and -- well, and it was similar to a sample that we had in the Southeast, and in those cases we found that they could recognize convergence. We were pleased with that. The complexity of the answers and the critiquing of the credibility of the various agencies was less.

Good question.

DR. BLALOCK: Dr. Kreps and then Dr. Krishnamurthy.

DR. KREPS: I had some of the same reactions to your presentation, Tim, that I had to Nathan's about -- when he was talking about disagreement and you're talking about convergence, about whether or not the -- how controversial the issue is has a huge factor in terms of attention to converging messages and the need to develop redundancy and reinforcement across messages. So I'm asking you whether that's the case?

DR. SELLNOW: Well, I -- you know, I think most of the time that there's not a lot of controversy, but sometimes if we start to -- for example, with divergence, if we start to lose convergence on good science by claims that I would argue -- and forgive my simplistic terms of bad science and good science. It's just -- it's a habit of mine that I picked up from dealing with scientists. But the point is that if we're into a point where our message is threatened, I think it does become controversial. I think it did with Ebola. I think it does when we look at intentional contaminations of the food supply, those kinds of things.

But, by and large, no. We did a very extensive study with *Salmonella*, the contamination -- the *Salmonella* contamination of peanut paste coming from Peanut Corporation of America. And the FDA was very active in that process, put up a website with 200 products that were contaminated, and it was a go-to source.

So, in essence, the -- what we called it is the FDA being thrust into position of proxy communication. Because here's a controversial issue, you've got someone who shipped -- knowingly shipped a

contaminated product that then was sold and broken up and sold again and again from ingredients, and then stopped communicating and then just shut down. Those individuals are in prison now, but the point is that FDA had to step forward and figure out where this paste came from, who had it, and list those processes -- list that. So that was an example that really stuck in my mind.

DR. KREPS: You know, maybe controversy is not the right descriptor. Maybe it's more like equivocality.

DR. SELLNOW: Yeah.

DR. KREPS: I'm really fond of Weick's model of organizing. I use it to guide a lot of my work. And so he talks --

DR. SELLNOW: Yeah, I've read your book.

DR. KREPS: -- about equivocality in terms of predictability, complexity, uncertainty. And so I think that maybe the more equivocal the issues are, the more the convergence of messages comes to play, the more they probably butt against each other because there are different takes on these issues. So that might be a really interesting way to frame it to look at these issues based on how equivocal they are to different audiences and then how we can utilize message convergence theory to reduce equivocality.

DR. SELLNOW: Yeah, I'm going to take that as a good helpful suggestion. Because I've been framing this as competing messages, and it may well indeed be that what I'm really looking at are equivocal messages. So I take that as a recommendation I might -- that might appear in my work with your permission. Thanks.

DR. BLALOCK: Dr. Krishnamurthy.

DR. KRISHNAMURTHY: Just a question regarding two different kinds of convergence that I sense here in the procedures. You had a focus group methodology which creates its own social dynamic, where not only are they considering the convergence or divergence of the sources of information, but they're also looking at the convergence or divergence of the opinions of the people in the focus group itself. And some people might be more prone to social influence than others are by listening to others. So I was just curious to know why the focus group methodology rather than a straight experimental methodology where you looked at how individuals react to convergence and divergence among the sources of information?

DR. SELLNOW: No, that's a valid question. The reason we started with focus groups is because we were still teasing out key variables in the theory. And then when we moved on to our research with the USGS, for example, where we're looking at earthquake applications, then that is an experimental design with various -- the treatment conditions are various exposures to the campaign and various exposure to different types of warnings. So we've moved into an experimental design. But when we get new variables, I'll back up again and do focus groups.

I just thought it was really interesting to hear the talk. That's why I picked this one to share here.

DR. KRISHNAMURTHY: This is a follow-up. I really thought it was an interesting methodology, so it is not that. And perhaps --

DR. SELLNOW: It's time consuming and expensive, but yeah.

DR. KRISHNAMURTHY: Right. But it also can be used to understand how the interplay of the dynamics between information that we get and how we share them with other people as well, I think.

DR. SELLNOW: Right.

DR. BLALOCK: Thank you very much.

DR. SELLNOW: Thanks.

DR. BLALOCK: So let's move on to our discussion question, which is how the FDA communicators can apply the information just presented. Reactions?

Dr. Yin.

DR. YIN: I really liked what the last speaker said about the FDA taking a proactive stance, so in a pre-crisis situation to be thinking about who -- the pre-convergence messaging, who needs to be at the table so that -- you know, anticipating when there's going to be some sort of issue with the food supply or whatever the crisis is, how we can get to convergence quickly. I really like that idea of planning in advance and trying to develop some sort of infrastructure to support that.

DR. BLALOCK: Dr. Krishnamurthy.

DR. KRISHNAMURTHY: I think both the presentations underscore the importance of having multiple channels for getting the information out so that it is not seen only as coming from one website or one source. And if it is important enough and it comes from multiple agencies, multiple modalities and multiple types of outlets, like federal agencies versus the media at large or physicians or other consumers,

Facebook and so on, I think that convergence should be looked at as a tool for amplifying the effect of the message that FDA tries to put out. And there are other people who can speak to that also, but this notion of convergence as an amplifier of the effect is something that should be taken into consideration when looking at channels of communication.

DR. BLALOCK: Dr. Kreps.

DR. KREPS: I like that idea about the use of multiple channels. And I want to expand that also to look at multiple overlapping messages as well. And also different sources so that -- I think when one source, like a government source, presents a case, it gets certain attention, but if you get also from industry, from consumer groups, from other sources, perhaps credible sources, local sources, it enriches the belief in that message. And so I think the idea that building collaborations and seeding different sources of messages and also maybe building in more interaction where people can have discussions maybe on social media, blogs, for example, or on Twitter or on Facebook or on other places where we have an opportunity not just to hear the message but to discuss it, I have a feeling it's that interaction that's really powerful in reaching conclusions.

Just hearing the message is enough to raise attention but not really enough to really move people to action. And if we can get more interaction going on about it -- you know, to go back to my discussion about Weick's model. Weick says that there's a principle of requisite variety that guides response to different situations. The more complicated or equivocal the situation is, the more we need to build a

complex, multifaceted response.

And one of the big problems in a lot of organizational response is that we do a relatively simple response that doesn't really match the complexity of the problem. And a lot of the issues, particularly these controversial ones or difficult ones where there are different stakeholders, may need some interaction. So he says the best way to deal with the equivocality and to build in requisite variety is to build in communication cycles or interactions between people, especially knowledgeable people or people who have certain types of expertise, personal expertise, scientific expertise, relational expertise that can bring different positions to bear on the situation.

So every time you have one of these rich cycles with people with different kinds of expertise, it reduces some of the equivocality, and it moves people towards building responses like -- we call that rules for dealing with the issue. And I think that we can use that as kind of a template for building in decision-making and action-taking responses to important health and welfare related issues. Recognize the ones that are most equivocal and then building in or encouraging more interaction.

There's always, it seems, there's a focus on like the magic bullet; promotions are going to have that magic message, that one channel, you're going to do this one PSA, it's going to do it all, one great pamphlet. But the truth of the matter is that you need a lot of different messages, and you need to have them moving and evolving over time through active interaction.

DR. BLALOCK: Other comments?

I'll just summarize a little bit of what I've heard. And, you know, one of the things that I meant to highlight during the last session, and it jogged my memory because it's relevant to this session as well, the presentations, but I think it was Dr. McCormack who recommended engaged listening via social media. And I think that that is an important thing if it could be done because -- and, again, I think some about vaccines and how much misinformation there is about vaccine safety, especially in kids. And knowing about what are the messages that are being communicated via various social media channels I think puts the FDA in a position to be able to respond.

I also liked the comment -- I'm not quite sure -- and Dr. Sellnow, you know, sort of mentioned that as well, and that's what jogged my memory.

Someone else -- I think it was someone on the Committee but I'm not exactly sure who it was, mentioned taking a proactive stance, identifying -- Dr. Yin -- identifying early warning signals or signs. And the idea, the thing that I think connects this with the discussion that we just had was so that we can identify what kind of mixed messages people may be getting and having that kind of a proactive strategy to identify early warning signs before a problem emerges or when there's misinformation being communicated to provide a response, I think, is really important.

And it sort of reminds me of the Sentinel Initiative, and the Sentinel Initiative is focused on identifying early warns of drug safety.

And this is communication safety, and when there are things out there that -- you know, words and messages can harm. And so if you think about ensuring accurate communication, I think those kinds of proactive strategies, that's an excellent idea if it could be implemented.

And then just reiterating things that Dr. Krishnamurthy and Dr. Kreps said, that collaborating with various agencies to ensure that everybody is communicating messages that at least don't conflict with one another and that have the potential to amplify the message. And the sort of phrase that I thought about as people were talking was "designing for convergence," so actually designing communication strategies for convergence.

So those were sort of the ideas that I had as we were talking. Other comments?

Dr. Krishnamurthy.

DR. KRISHNAMURTHY: I just want to kind of pick up on one phrase that you used, designing for convergence. I think that is the takeaway as far as I was concerned from this particular thing. Thank you for that phrase.

DR. BLALOCK: Dr. Harwood.

DR. HARWOOD: I think it's just going back to previous discussions that if you are using social media and you're going to try and combat the mal-information, it's just remembering that it's bi-directional communication, and sometimes maybe the FDA needs to step in when there isn't a risk so that it can have a voice to clarify that mal-information when the public believes there is a risk when there is

no risk.

DR. BLALOCK: Dr. Zavala.

DR. ZAVALA: Expanding on what Dr. Harwood said, it's very important because as Dr. Lerner mentioned yesterday, when the message becomes part of an integral emotion, it's going to be hard to change that behavior, so intervening would be very important.

DR. BLALOCK: Other comments?

Dr. Rimal.

DR. RIMAL: I have a question maybe if the prior speakers want to address this. I was wondering what would happen if, when there is divergence and then there's a second attempt to bring the divergence to convergence, whether that is counterproductive because it adds to the noise or does it sort of have some ameliorating outcome?

DR. BLALOCK: Dr. Sellnow or Dieckmann, would you like to offer a response? And both of you can come up forward if you'd like.

DR. SELLNOW: So that's a very good -- very important question because if we're -- if a diverging argument does not have traction, in other words, people are paying little attention to it, for the FDA or another agency to make a very public and a very attentive response for its publics would really be unnecessary.

I think another person here who could talk about this is Dr. Coombs, talking about the concept of para-crisis, where sometimes divergence does not, it's not a fault -- it doesn't really threaten it's -- it is a message. But there is a threshold here -- and I don't know, Tim, if you want to talk about that -- but the threshold appears when more

people start to pay attention to that divergent message than makes the Agency comfortable. So, but on the other side, to simply state your case and let it stand, I don't think is good advice. I think there's too much communication. I think people come to the issue at various points, and if they come in and your case is old news that you originally stated, then I think we need to be active participants.

DR. BLALOCK: Dr. Dieckmann.

DR. DIECKMANN: No, I don't have any --

DR. BLALOCK: No. Dr. Coombs, did you want to take an opportunity to add?

DR. COOMBS: Yeah. One of the problems we find, particularly when I work with managers and CEOs, is they're concerned that -- they know social media's important, but they don't know how important. And we can extend that to all messages when they occur, because some are really going to lead to a crisis and some are just kind of remotely out there.

And that's where going back to the idea of scanning is really important, because when you map your scanning, you can see where it's going. And particularly if you use a visual representation of the data, you can see if a node dead-ends, like Dr. Sellnow said, and then you don't worry about that, versus a node that spreads out and also is going to large nodes, because there's also -- if it's spreading but among people who hardly matter -- I hate to say that, but they're just a small amount versus they're going to large -- and I'm using large and small because that's how it's represented visually in the data -- that can give

you a better idea of when you're really going to need to jump in and you know something bad is about to happen.

DR. BLALOCK: Dr. Dillard.

DR. DILLARD: On the question of message divergence, I wanted to say that there are several meta-analyses of what are called one- and two-sided messages that have been conducted in areas including advertising and sociopolitical issues. They distinguish between messages that just advocate a particular point versus those that acknowledge that there is another point of view and then they rebut that point of view.

And those meta-analyses are uniformly clear in showing that a two-sided message, one that acknowledges the presence of an alternative, of divergence, and explicitly refutes that form of divergence, enhances the credibility of the communicator and enhances message acceptance. So I think the data, for once, are really clear on that point and that you can take that one, that particular issue to the bank.

DR. BLALOCK: Other comments?

Dr. Duckhorn, have you -- do you think that you have the information that you need or follow-up questions for us?

MS. DUCKHORN: No, I think this was sufficient discussion. Thank you.

DR. BLALOCK: Okay. Well, I think we're ending up just a little bit early for lunch. And let's see, we're due back from lunch at 12:15? Is that right? And do we want to keep it at 12:15?

(Off microphone comments.)

DR. BLALOCK: Okay. So -- we'll come back at 12. Okay, so we'll adjourn, and I do ask that folks not talk about the topic of the meeting during lunch with each other. And we'll come back at 12. Thank you.

(Whereupon, at 11:02 a.m., a lunch recess was taken.)

A F T E R N O O N S E S S I O N

(12:03 p.m.)

DR. BLALOCK: Session on Techniques for Reaching Underserved Populations. We'll hear presentations from Dr. K. Viswanath followed by Dr. Linda Aldoory.

Dr. Viswanath, you can approach the podium and begin your presentation.

DR. VISWANATH: Good afternoon. Let me first start by thanking the FDA staff and the Committee for having me here and giving me an opportunity to share my piece of wisdom, so to speak, with you.

I want to make three points before I start going to my presentation. Number one, I apologize. I thought I had my disclosure slide. Just to -- I'm going to send you an amended slide. My funding comes from the Centers for Disease Control, National Institutes of Health, and FDA through NIH and some foundations. And so I will -- so I just want to -- but obviously these ideas and the data on the slides represent my own views and no one else's. So I take all the blame and the credit.

Second, I am not a psychologist. Individual is a unit of observation for me but not a unit of analysis. I focus on social context, much of what you have been hearing, and I think there are wonderful models, mental models and mechanisms. You don't hear a lot of that from me. And so I'm actually barely learning to spell psychology, so you won't -- you will mostly get discussions about social context with me.

The third and the final point I want to make is that I am not a

leadite. I might come across as a leadite based on my presentation, but actually I'm not against new technologies. In fact, I'm also learning to spell Twitter. So I think, you know, you will see some of that reflected in the presentation.

So I think the conversations -- and I'm sorry I missed yesterday as I was teaching, but the conversations began this morning talking about FDA should use blogs and social networks, social media and web-based platforms to deliver some of the information. And I think that's a great idea. But I want to provide a context in which when we talk about communications revolution, such as these information and communication technologies, I want to provide a particular context to that, right?

So there are tremendous advantages. You know, people said they are using multiple media at the same time on multiple formats. I think we are all used to that. People are reading their e-mails while -- you know, my students always -- I always thought they are taking notes diligently. I never realized that they are posting maybe updates on Twitter, on Facebook, on whatever they do with computers in their hands.

But there's no question about it that there is -- there is a term that's broad and wide penetration of these technologies, which provide us an amazing ability to synchronize that and integrate that in many ways. We talk about big data. Now, there is a new position, data scientist and all that, and it's a hot market for them, if you call yourself a data scientist. And there are tremendous opportunities to educate

people, I think, through these processes and through these platforms. It's a so-called teachable moment.

And one of the more fascinating things to me, especially with the ICTs, is that this integration of public and private sector, I think, and also where we can actually work together in the interest of promoting public health. That has not always been the case. I think we have always been antagonists in some ways. But I think while private sector plays a tremendous role in public health, both for good and ill, I think there are some great opportunities here in this case.

But I think, you know, that we have to understand the dysfunctional context of it. The context in which these ICTs are introduced matters quite a bit, and I'm one of those -- I think I'm one of those people who focuses on issues of race, class, and place, and what roles they play in actually providing access to people for these ICTs and actually their usage of how they use these technologies and then what they do with it.

Now, so what I'm going to do, I think, in the first couple of minutes, to introduce you to this idea of communication inequalities and relate them to this issue of health inequalities or so-called health disparities. And then give you, depending on the time we have, give you two stories or case studies to elaborate on the arguments I am making here.

So I think one of the challenges with, I think, in talking about, whether it's risk information and very complicated esoteric issues or even simple things, is the context, especially around issues of poverty,

right. And think about it. Living conditions matter a lot, and people who are living in very poor conditions and challenging conditions with this day-to-day insults, as we call them, and social determinants and micro-humiliations that they go through in their lives, really pose a tremendous challenge in both accessing information and using it.

It's very appropriate to start to illustrate my arguments with this example. Last year, we celebrated -- in 2014 actually, we celebrated the 50th year of the Surgeon General's Report starting in 1964. So one of the greatest public health success stories of our times, right, vaccination, where I spent some of my life on, and tobacco are two areas where we can really celebrate, right? So about half the American adult population smoked in 1964; now it's about 19, 20, 21, 22 percent, depending upon who is counting. So one of the greatest public health success stories.

Yet, if you look at who is continuing to smoke and the smoking trajectories over time, and this is a very clear picture, right, what it clearly demonstrates is that despite our best efforts, the benefits are not accruing equally across population groups, right. So using education as a stratifier here -- we can use income, we can use other kinds of stratifiers -- what it clearly shows is that smoking still remains a big issue in certain sections of the population, right, despite one of the greatest public health success we have.

And, in fact, if you dig deeper, poverty is a really big problem -- 29% of the people below the poverty level smoke compared with 18% above the poverty level. And, in fact, you can look at these numbers in

a variety of ways, and they show the same picture, right. And people start -- in different racial groups, they start at different levels when they are young, but by the time they reach in the young adulthood, the smoking grades are virtually the same, I think. And I think -- this is one example, and I can show this to you, these data for diabetes, for cardiovascular disease, for cancer, and for a variety of other things. And so that's -- I'm using tobacco as an exemplar to make this larger argument about inequalities, particularly certain sections of the population that are in poverty, right.

And many of you know, some of you in this room know that I think people have been looking at this and identified a set of factors called social determinants, a phrase I don't like personally, but I think, you know, that's what people use, social determinants of health. I feel that it's too deterministic, and it characterizes, somehow communicates that they're immutable, but they are mutable. So race, ethnicity, living conditions, socioeconomic position, and a number of other factors have been identified as leading to these inequalities and affecting those who are poor.

But the challenge with social determinants framework is that, as I said, it communicates certain amount that the whole idea -- the word determinism, deterministic, you know, communicates immutability, right. These are difficult to address, and I think, you know, these are very difficult to address despite the national policies we have to address them.

So from our perspective, in our own lab, we have been using

from a communication-centric perspective, we have introduced this idea called communication inequalities. What we mean by communication inequalities actually manifests at two levels. One is -- you know, these are differences among social classes and collective institutions in the manipulation and distribution of information. So this is at the group level or institutional level. And at the individual level, these are differences in access to and ability or capability to take advantage of information.

So these are the two levels at which communication inequalities manifest. And what we have been doing over the last 15 years is to really document that these inequalities exist, number one; number two, that these inequalities in communication are indeed related to health inequalities; and, number three, we have actually developed some exemplar interventions to see if we can address these communication inequalities, with the hope that if we can address communication inequalities, which we think is one of the more readily addressable social determinants, maybe we should be able to address health inequalities. Again, that's one argument. It's not the most important one for social determinants perspective, but it is from our perspective a very critical one, I think.

And we have demonstrated in a number of papers that these inequalities exist, whether it is usage of newspapers, seeking health information using Internet, etc., etc. I think we have actually documented -- except for television. Except for television viewing, I think, you know, in virtually every other medium and platform, you see

these inequalities between different income groups, different racial and ethnic groups, different educational groups using these platforms or spending time on these platforms or learning from these platforms.

So these inequalities do exist, and I won't have time to go through all of them, but I want to illustrate with the Internet because that has come up today, and we have been doing some interesting work on this area. So if you look at broadband penetration globally -- and these data are from International Telecommunications Union, which collects this data. So as you can see, and I don't like the word developing and developed because they mask a lot of nuances, but the point remains that despite this great penetration, that there are tremendous differences in who is able to access these broadband platforms and who's not able to.

This is from a Pew survey which clearly shows that in certain -- depending upon the country, again, the number of -- the proportion of people who are using Internet varies considerably, right. So we take the countries -- in fact, I don't remember if I have the slide -- I do have the slide. If you look at per capita income, it is closely related to whether, you know, a proportion of people, a greater proportion of people use Internet or not.

So this actually can be shown even in the United States. You know, despite all the talk and the celebratory discourse we see in public about the great penetration of Internet, actually if you start looking at the numbers -- these numbers are from the National Telecommunications Infrastructure Administration -- what you see is

clear differences across different racial, ethnic, urban, rural, and educational groups. In fact, this particular slide -- and there are more recent slides too; I will be happy to share those slides too -- show in fact the idea of intersectionality, which means it is not just race or ethnicity or education or gender or urbanicity, but it's a combination of these things. It's an intersection of these things that can really matter.

And the reason we are paying attention to this is because these things eventually lead to issues such as access to information, how people use information on these platforms, and how they process this information. And then we have published a number of papers demonstrating that.

And some people are -- the reason I have enclosed this slide is because some people have always said, well, cell phones can solve the problem, right. And the mobile revolution actually is one of the most fascinating revolutions. You go to some other -- deepest and remotest parts of Africa or India, you actually see people using cell phones in great numbers. So one solitary argument and a feature of this is that this can mute the differences among people.

I don't have the data -- actually, I think I took out the slides because I didn't have the time; in 20 minutes I cannot do it. But we actually have data which show that people from a lower socioeconomic position lose connections to cell phones. They have cell phones for a few months. They cannot pay the bills; they lose the connection. They wait for a few months. Then they pay the bills, and they get the connection back. That is, they go on and off the grid. So we have a

paper and review actually showing those data. So and they have data plans. These data plans are actually very -- they are very positive about these data plans and make -- and they use it in a very measured way, I think.

So I think these inequalities continue to persist. And I can tell you -- let me, before I go to the stories, let me say this. The usual numbers you see, the figures, 70% have access to Internet, or 80% have access to Internet, which means about 20 to 30% do not go online or do not have access to Internet actually is -- these are an overestimate. The reason we contend that these are overestimates is because in a number of national surveys, we do not include sufficient number of people from a lower socioeconomic position. You can compare. I think I may have a slide actually -- I will show the slide showing national data and our data to show how a number of these national surveys do not collect data from those from a lower socioeconomic position. And that's the reason we see these overestimates about access to information among these people, right.

And we have also shown that mere access is not enough. We have shown data on how they process this information and what are the best and preferred topics and preferred styles through which people are exposed to this information, right. It's just not access. I have -- the first -- I just covered access.

On the other hand, if I stop here, this could be very depressing, right. I mean, this is a very bleak picture at a time in 21st century when we are all so saturated with these technologies. So I want to end with

two stories, hopefully hopeful stories, to show that we can -- if we think about it strategically, tactically, we can actually overcome these inequalities and make a difference, right.

So the first story comes from a randomized controlled trial we have conducted on digital divide. We actually gave out, with the funding from NIH, gave out free computers, free Internet to a group of people and compared what they do with another group of people who did not have access or don't have regular access to Internet.

And the group, intervention group did not get a lot more things that you and I take for granted. That is, they got a free computer, they got Internet, and they got technical support and some classes on how to, right. And so we looked at if we have done all that, it should solve the problem. They should be able to use Internet very well now, right? We have solved all the problems of their access; they have technical assistance, everything.

And what we found is that despite all that, despite all that, they face difficult barriers. If you look at it, 70% had no free time to use computers. These are urban poor, by the way. These are people who have been recruited from adult education centers, and we randomized them into two groups. Fifty-four percent were concerned with information quality; 43% said despite our efforts, it takes a lot of effort to health information; 30% were frustrated in search for information, right.

So there are challenges that -- there are day-to-day challenges that this group of people face, and there are technology barriers. You

know, it's very interesting. To me, if you have a problem, you call your technical IT support and they will walk you through, right. This group of people don't have the technical support. We were providing the technical support. And the problems they faced in doing this, right, you know, a variety of issues such as computer wires or other kinds of issue, connectivity issues, they all impact upon whether they have continuing access to Internet or not. This is a huge, huge problem for them, I think. Even though we took care of -- we thought we took care of all those things.

But the other thing is how do they use the Internet, right. What we did, just to FYI, we not only did pre and post self-reported surveys, but we tracked for 9 months every second, every minute what they have done on Internet. So we have something like 7 or 8 million records of data. So we know all their browsing behavior, right. So we are now able to classify, and I wanted -- we wanted to do -- we are doing analysis.

One of the analysis stems from this report from the *New York Times*. A *New York Times* reporter called me and said I heard that you are doing this randomized controlled trial with urban poor. I have a hypothesis. My hypothesis is that urban poor don't know how to use the Internet; they waste their time and they waste their time by doing all kinds of things with entertainment. So I had to explain to him why his hypothesis is wrong. Our data do not show that; that once you provide access, that anybody can use it just like you and I. He didn't buy it. He went ahead and published this paper. But, you know, we

actually have data to actually show why he is wrong. Our browser data actually show -- these are the data, browsing data. Of course they use Internet for health, but they also use it for a variety of other functions. That should not be a surprise to anybody, right? Of course they use it like anybody else. Once you provide them with access and training -- and, in fact, in our test it showed that the more you use the -- they used a site, for example, if they used a site -- if you go use the Internet for news, you also use it for health. If you use it for education, you use it for health. If you use Internet for garment information, you also use it for health. Basically this is what we call capital enhancing information, you know, including health.

And so I think this argument that "the poor," quote/unquote, don't know how to use the Internet is completely false, which actually, I think -- especially for some of us who have been making the point that it should be an essential service for them. So let me -- and entertainment use was positively used in Internet too.

The last point I want to make in the 40 seconds or so I have is on the second story on what is the best way to communicate. And one of the stories which is very relevant is from our project CLEAR where we looked at -- at one time until the court intervened, FDA was supposed to have this very graphic health warning on cigarette packs. And so we got funding from FDA to test what happens. Especially we were interested in do graphic health warnings placed on cigarette packs are the best way to communicate risk, right. That was the question we asked.

So went out and collected data. We did a field experiment with 1,200 people. We did a lot of focus groups. After that we did a field experiment with 1,200 people who are either African American, white, or Latino, between 18 and 70, but focused on also blue collar workers, so we went out and aggressively recruited those from lower socioeconomic position. Here is a table I wanted to show you. Look at Project CLEAR and look at U.S. Census or the Health Information National Trends Survey and the Pew Internet. We actually went out and recruited a larger proportion of poorer people with a lower income and lower education to see how does risk information work among them.

And I just have one slide. Actually we are doing analyses, even last night I was looking at some tables. So I can't give you all the data, but it clearly shows -- we have published two papers so far; one is the national data, one with this experiment -- which clearly show that communicating risk information through graphic health warnings could be very effective. In fact, exposure -- even one-time exposure, even one-time exposure to a graphic health warning leads to increase in intentions to quit. We are just looking at some data. I cannot share that with you yet. We are analyzing. They also lead to conversations among them and conversations with their physicians, even one-time exposure, right.

So there are ways to strategically place risk communication messages, assuming that we take these issues explicitly, inequalities and poverty, into consideration, I think.

So I'm sorry I went through this fast, but the point I want to

make is that if we are going to do risk communication, we should operate and understand how communication inequalities work and with a particular focus on poor and poorer regions, poorer countries. ICTs do show a tremendous promise, but we need policies and programs in place to utilize them. And last, I think there are opportunities to reach, engage lower SEP groups, but we should understand their communication behavior by getting the data from them, not ignoring them in these national surveys. But we still need to do a lot more work on understanding how the day-to-day context of their lives influences their communication behaviors.

Thank you.

DR. BLALOCK: Thank you very much.

Do we have any brief clarifying questions for Dr. Viswanath?

Okay. Thank you very much.

And we'll move on to our next speaker, Dr. Aldoory.

DR. ALDOORY: Thank you. Thank you very much. Welcome to your last presentation. I'm so glad to be the one that comes post-lunch at the end of two very long days. Yay me. And I'll really try to keep it upbeat and keep you all awake for this.

And I also want to thank you, like all the presenters have done, for letting me be here and talk to you for 20 minutes. And, in fact, I'm actually feeling quite humbled because everybody that -- all the experts that I draw from are either in the audience or on the Committee, so I really feel like my goal today is not necessarily to inform you but just to try to spark some discussion, some dialogue, some topics to further

analyze in later research.

And so with that, let me start by saying that my goal, like I said, is to talk about health literacy but specifically the use of text messaging in pilot studies to show it as a channel for communicating health risks to low health literate populations.

Health literacy. So health literacy, as I think many of you know, was traditionally in education and medicine looking at patients' inability to read and understand prescription labels, health forms, hospital discharge instructions, and note their barriers to treatment adherence and to staying out of the hospital basically. So originally health literacy was seen as skills based in reading and numeracy.

Today, researchers in public and health communication study health literacy more as a critical factor affecting not just patient-provider communication but also community-based health campaigns and mass media and social media and how people are understanding messages from those sources as well. And research has indicated that, of course, low health literacy is predominantly associated with low socioeconomic status, low formal education, but everybody can be affected by low health literacy at some point in their life.

I know when I had to take my father to healthcare because he was starting to decline, he had certain symptoms that led us to think he had Alzheimer's, we were sitting in front of a neurologist and my father's a doctor, and the neurologist was telling us with all these big words what was wrong with him -- he actually had normal pressure hydrocephaly. Anybody here know what that is? Some of you? And

how it affects the ventricles of the brain and the fluid and all this. And my father was nodding, and I thought, okay, I don't know what he's saying, but my father knows. And we leave, and I say, so dad, what did he say? And my father said, I don't have a clue.

So I think all of us may be able to share some examples of how even with our education and our background we are faced with intimidating information, or we think we're supposed to know something or we're supposed to understand, and we don't address it in the way we should. So with that, I think it's a good example of the different skills that are needed for health literacy.

The Institute of Medicine defines health literacy as the ability to access, understand, and use health information to make healthy decisions that improve our health outcomes. Specifically, the emphasis on access and use are very pertinent to a discussion about text messaging. But even more so, the number of skills that are used to build someone's health literacy is multiple and complex.

So this is a wheel of skills that I put together to show what today is needed when we look at the ability to understand and use health information. We have your reading and your numeracy, but we also have a variety of other communication skills: listening, speaking, of course self-efficacy we all know is very important. Now we have technology skills. So you actually need people who understand how to use the Internet, how to navigate a phone, how to understand their electronic medical records and their personal health records now. And then, of course, critical reasoning, what's good, what's bad health

information and where they're getting that information from.

In the context of health literacy and mobile health, let me share with you some cell phone and texting data. I think you've already been inundated with so many statistics. This really is going to be the only slide with a few statistics. Otherwise, I'll just be talking summaries, and then I'm here for questions if you want later.

But 91% of American adults own a cell phone today, and 81% of cell phone owners use their cell phone to send or receive text messages. And, of course, we often jump to say, well, these are young people like everybody here, right, young people. But actually the data show that in populations over 50, there's still 92% of cell phone owners who are texting.

Raise your hand if you have texted today. Come on, admit it. Okay. So -- and I don't see that many people under the age of 30, so yeah. So people are using their cell phones, and they're texting frequently.

Regarding health information, over a third of cell phone owners look for health information on their phone. And specifically pertinent to this group, those in a health risk situation are more likely to use their phone for health information than other channels.

Now, when we get into the research, nearly 400 text message interventions have been conducted. That's a very conservative estimate. Those are just the ones that have been published, talked about, studied, and brought to bear. This was from -- this data came from a meta-analysis of text message interventions. But there are

pockets of limited service. Certainly in the rural populations, we find only 76% have cell phones right now. But these kinds of gaps are decreasing with better and better technology moving forward.

So I wanted to quickly tell you where the information that I gathered is coming from. First, I've conducted several pilots of text message interventions for health risk communication for low health literate populations. I've considered how text messages can address their health literacy needs. And this is just a list of the examples of the pilot studies that I've been a part of.

So Text4baby, I've been part of a Maryland group for the national Text4baby campaign. Text4baby shares messages, text messages about prenatal care and baby care up to 1 year of age. I think most people know about it. And in the state of Maryland, I was part of a team that evaluated actually the production of the messages, looking at the theory and how effective that theory was played out in the messages in themselves. We did content analysis of the messages for National Healthy Mothers, Healthy Babies Coalition. And then we also did some effects research.

We've also worked on something called Healthy Futures text message library. So Healthy Futures focuses on physical activity for families of young children, those with children before school age. And this was a seed grant provided by the University of Maryland with a group of students that looked at building a library that can be standardized but yet tailored in certain respects based on research and feedback from families of young children who are not in school and

what ways text messages can not only trigger their knowledge but also their intent to behave.

HealthSmart text message pilot. So part of the extension at University of Maryland, we were funded some money to pilot a text message-based, community-based participatory research study, where with rural low income mothers across the state of Maryland, they actually worked with us to develop the best messages through text and when to provide the messages, and then we did an evaluation of those messages across the state to see how they were received. And the topics were physical activity, food and security, dental health, and health insurance enrollment.

And finally Primary Care Coalition of Montgomery County has a new program called Building Bridges to Coverage and Care. So with the enrollment campaigns out there, what Primary Care Coalition and others are noticing is that people are enrolling in health insurance now but they're not going for that first visit. They feel their job is done. They got their health insurance, but there's not really preventive care, preventive behaviors after that. So this is a text campaign. After people enroll, they register for the text messages, and it's to get them to remember to make that appointment and then go for the appointment.

So these pilot data informed what I'm going to talk about here. First of all, advantages to text messaging and how it impacts health literacy. And these you all know very well, right? Cues to action, we all know how important this is. In this vein, a lot of work has been done

with text messages, and they found it to be quite effective for cues to action reminders, that kind of thing.

Text messages reach people where they are. They have their phone with them. The messages are very accessible to them, and research has shown there's high efficacy with the cell phones as opposed to a lot of websites and computer using a mouse or one of those pads. People tend to know how to use their cell phone and use it well.

Of course, there's many tailoring options now. A lot of text message systems were one way -- are still one way, but now that a lot of technology has opened up the two-way forms of being able to gather data from participants and then tailor messages back to them based on that data.

And it can encourage feedback. How are we doing? What's going on? What can you tell us about what we're doing, as well as what you can tell us about yourself?

And it's actually low cost. Low cost on both ends. On the production level there are a lot of free text-based text message systems now. And on the receiver level, they're been finding more flexible payment plans, unlimited message plans, or campaigns like Text4baby had the funding to provide money to pay for any person who registers, their text minutes and their phone time.

And then finally it can be used as an evaluation tool itself as well as messaging. This is underutilized in text message campaigns oftentimes because of the limitation of one-way services. But if you can

get two-way services, you can actually get a lot of data back, and I'm going to talk about that a little bit.

On the primary consumer end you can, of course, find out things such -- you can collect data. We're doing this now with two of my pilot message -- two of our pilot studies, where we ask them did you read the message; did you do anything about the message; text 1, 2 -- it's sort of multiple choice questions, and they text back.

And also among community health workers, we're looking at text messaging systems for organizations to reach out to their community health workers and others on the ground, collecting how many patients, how many clients did you see today? How many clients did you not -- were you supposed to see and couldn't see today? So a lot of that paperwork is being eliminated because the data are coming in from the cell phone from the workers on the street.

Two particular trends that are very advantageous for health literacy in cell phone and texting. One is, of course, this notion of interactivity. So as -- right now Mobile Commons kind of holds the license in two-way messaging at a national level, but a lot of other systems are using two-way messaging. And that interactivity means we can actually text and say, do you understand this message? And if they say no, we can actually immediately text a different message. And then we can immediately text another message: Did you understand this? All those teach-back, clarifying type of procedures we could do one-on-one we can do through text messages.

And then the advantage of integration. So here we have now

healthcare systems, and doctors and patients can group text so that one patient or client can actually have their doctors all on their phone talking to them and answering questions.

So what are some lessons learned from the research that I've done? And these are areas of, I think, innovation that have not actually been addressed very often in published research. And the first is this community-based participatory approach to design.

So all of the pilot studies that I have been in except for one have the residents or the target population be at the table to design the messages themselves. So we've gone a little further than just focus groups, what did you think of these messages, to more of a workshop setting where we talk about what is the value of text messaging, what is health literacy, and then what's important to you? And then we teach them about appeals, fear appeal, voice, peer versus authoritative, short messaging versus long, one-sided versus two-sided. And then we get them to kind of work in groups to create the messages themselves.

And we have found that that buy-in also helps within those communities that we're working with because then they share that information with others. Tell the others to opt in; these are really great. You hear, you know, post-text message campaign they were sent too frequently. Well, we hear that ahead of time and be able to figure out timing.

Parasocial relationship. So we have found that with text messaging, most people use text messages for personal reasons. And even when you get a text message from somebody that's not personal,

some of the research has shown that there's a perceived personal involvement with that person that's texting you, even if it's not a personal friend. So we found this out to be really important in our pilot study with rural women where they wanted the texter to be just like them. Okay, hemophilia nature. They wanted it to be messages from a mom -- Miss Peg was the name they came up with -- who had kids, who lived in a rural area, and was texting them health facts, but they wanted Peg to get the messages from authority.

So they didn't want the FDA to say this. They wanted Miss Peg to say, "Guess what I heard from the FDA?" Because they had more validity and legitimacy for Peg, but they didn't think Peg had the information so they wanted the FDA. So it was this sort of twist between both authority and personal together, and then they built this parasocial relationship with Miss Peg.

Self-efficacy, of course. Perceived control. Very important, high self-efficacy -- higher self-efficacy with the text messages than other forms of other channels.

And then timing can be everything. So there's no perfect formula. In our pilots we actually found that two text messages per week didn't seem to be too little or too much for recall, retention, and attention. Other research has shown that decreasing frequency over time or allowing people to individually select how often worked very well at attention towards the messages.

So other research beyond mine also provided evidence that text messaging can benefit low health literate populations. Mobile giving

raises millions in aftermath of crises. So the Red Cross immediately launched the donate by text by campaign after the 2010 earthquake in Haiti, and they raised over $43 million because of how easy and accessible and understandable this campaign was through texting. The research in vaccines, a lot of it does show that even simple reminders increase the likelihood to be vaccinated and get vaccinated on time.

Message tailoring and personalization. So a meta-analysis of 19 randomized controlled trials in 13 countries showed that in fact tailoring and personalization through text messages increased intent to change behavior, not just knowledge. Some of these results have been situationally effective with different topics. Smoking cessation and physical activity tend to be the two topics that have shown greatest success with text message campaigns.

And, finally, from awareness to adherence. So theory-based, theory-driven text message campaigns has been able to go -- have populations go from just awareness about something through a text message to actual behavior change. Specifically, health belief model and theory of planned behavior have been used most frequently, and I'm not going to go into those since I know everybody here knows them well.

So my last slide suggests issues and maybe future work looking ahead. Like television, television became the thing, everybody jumped on the television bandwagon, right? And then the Internet, everybody jumped on the internet bandwagon. Well, I feel like we are jumping on the text message bandwagon. If we just text it, they will come. And I

think what we're learning is, like the other channels, we have a lot more work to do, a lot more evaluation to do. And in some -- some issues I think they've really not addressed well at all.

Privacy and security. So if text messaging does get used for health information and is on somebody's phone, how does that protect their health information from others who might see the text or might get the text inadvertently? I don't know if anybody else has accidentally texted their mother or something they didn't want to text. So how do we address that?

Retention rates and long-term engagement. So really, at this point, most of the studies have been short term. Ours were 6 weeks, 8 weeks, and 12 weeks. But like many studies, like, what are the long-term effects, if any, from text message campaigns, and can we keep it up over time?

I really like the idea of text message libraries. There's already a few libraries in different federal government agencies. Office of Women's Health, there's Text for Tots. The Healthy Futures one we actually shared with Office of Women's Health and others. But it allows this sense of shared messages for people. So you don't have the time or resources to do this, but you can gather texts from a library that's been tested, empirically driven, certified by certain organizations or the government, and use them for local efforts.

And last two things, tailored nature topic context and age-specific receptiveness. I think a lot more research needs to be around the ability to tailor. I was at a mobile health conference a couple years

ago, and I was really excited to go to this one session because they were going to say how they got amazing success rates from tailored text messages. I thought this is great; I'm going to learn a lot. So they did a survey ahead of time, and it was age, race, education level, and I think where they lived, and then they had four sets of messages based on those four groups, and that was the tailoring.

And I thought, okay, I don't know if that's like really what I was thinking tailoring was. So it may go back to the definition of tailoring, but I feel text messaging has the power to truly be an effective tailoring option where through dialogue of the text channel we gain more understanding about our audience and then be able to address barriers as they occur or in very small groups as they happen, and then actually monitor and see if changes happen through the channel itself. And I think a lot more work has to be in those ways.

So, with that, I want to end with two statements. The first, health literacy, as I mentioned, is comprised of multiple skills needed for access, understanding, and use. So access, we have text messaging is prevalent, accessible, right on everybody all the time, efficacious every day; it's accessible. Understanding: The format forces designers to think about simple plain language, simple steps to action. The feedback loop allows for self-efficacy to increase to check for understanding, check if it happened, and if not, what can we do to change the message right there to increase the understanding of the message. And use, we can monitor over time if these messages were used to change behavior or not, when it happened, when it didn't, and

even get feedback on what other barriers might have been towards use.

So I think current literature -- this is my second point. Current literature has been really focused on text messaging for cues. And I -- cues and short term, and I would really love to see this Committee and the FDA take on a broader look at long-term evaluations, randomized controlled trials, and other ways to really see how the value of text messaging can build for low health literate populations.

Thank you.

DR. BLALOCK: Thank you.

Do we have any clarifying questions for Dr. Aldoory?

Thank you.

So we'll move on to our discussion question, how can the FDA communicators apply the information that was just presented?

Dr. Krishnamurthy.

DR. KRISHNAMURTHY: First I want to thank both the presenters. I learned quite a bit, especially Dr. Viswanath in his discussion about the role of communication as we see for the poor and the urban poor and so on. I thought that was a hard-hitting presentation in the sense that we tend to see socioeconomic place or status as a segmentation variable and a way to tailor, but I get the impression from what he presented that the way they consume information itself is very different, their ability to consume information is different. And to the extent health status is a function of how easy and able they are to consume information, I think there has to be some renewed emphasis on how to communicate to this particular population that is both

vulnerable and not capable of necessarily getting the kind of information they need. I think it needs to be thought of as more than a segmentation variable, is the way I would like to describe.

DR. BLALOCK: Dr. Zavala.

DR. ZAVALA: Yes. Regarding this population that Dr. Viswanath's study looked at and what Dr. Krishnamurthy mentioned is, since they have the cell phone on/off because of economic reasons, that it's imperative that we use other organizations that these people find as trustworthy. I cannot say enough. I'm a nurse. They trust nurses, doctors, and other organizations that are involved in the communities in order for them to get information, like in health fairs, so this way they could take advantage of the information that is out there.

DR. BLALOCK: Dr. Harwood.

DR. HARWOOD: I found both of the presentations interesting. I think, though, the first presentation sort of speaks to the need of the variables that are required for an audience segmentation in terms of those technographics, knowing whether the person has a post or a prepaid plan, what type of mobile device do they have, is it a single ownership device, is it a shared device, all of these are going to affect their ability to interact with any of the messages.

And I liked the second presentation as well. From the presentation it seemed as though the text messages were in English, but I think it would be useful from the first presentation to have studies that were conducted for lower income populations that focused on a non-English language.

DR. BLALOCK: Dr. Kreps.

DR. KREPS: I was struck by Vish's presentation about the fact that the digital divide still exists for a variety of low income, low resource, marginalized populations despite a lot of the survey data that suggests that they may be online. And it appears that there are a number of factors that lead to their lack of utilization of these digital channels. It means to me that we need to start thinking creatively about how do we reach out to those populations, because it appears to me that the same group of people who are not getting access online are the same group of people who have the worst health outcomes and often are in the greatest need for health information. So these people are cut out of some of the most powerful channels for communication and certainly the more -- most emerging channels because we're investing a lot in digital health information dissemination.

What can we do to try to make sure that we are really able to reach these people in a meaningful way so to provide them with information that they can use? I mean, I don't really have the answer to that question, but I suspect that it's going to be a fairly complex answer. Maybe we can engage Vish to think with us about what kinds of interventions and innovations need to be made to break down this inequality.

DR. BLALOCK: Other comments?

DR. KREPS: It's a long walk.

DR. VISWANATH: Thank you, Gary. So there is -- as you know, you have done a lot of thinking on this, Gary, as much as anyone else.

There's no one single formula for this. We have to take -- it goes back to some of the observations made earlier too by a number of you.

So we need policy level interventions, number one, right, and I'm a big advocate of subsidizing internet and telephone service, I think is an essential service. Just like anything else, right, we have built railroads and subsidized them. We are building roads, we have subsidized them. We should actually subsidize information highway access, I think, as a national policy.

South Korea has made that policy. Ninety-nine percent of the people in South Korea are online because it's a national level policy. The national level policies are very important particularly when it comes to cell phones, where we are finding great penetration but people going in and out. It's a telecommunications issue. It's a policy issue rather.

Second issue I think is someone I think mentioned this. Community organizations -- community-based organizations are extremely critical. So we work with people, as I said, who are poor but who are extremely smart, right. I mean, in this country, if you are poor, you have to be very smart to navigate the system and survive the system. And they rely a lot more on community-based organizations, organizations with whom they work day in and day out.

So we think in terms of body parts like NIH does, right, kidney, heart disease, cancer, etc. But our community groups, the people we work with, work with community organizations for all their needs. They don't go to one organization for breast cancer screening and a second organization for diabetes. They go to the same organization for all their

needs. So I think the question is in identifying these organizations and working with those organizations.

In fact, the Project CLEAR study, the FDA study I showed, we actually have done a survey of local organizations, because this is a national policy of putting these graphic health warnings on cigarette packs, but what happens at the local level when this policy is implemented? So we scared the heck out of people by putting these cigarette pack warnings. What do I do if I am exposed to it? Where do I go, because I don't have easy access to cessation resources, right? So I go to the local organization. So we actually just finished a survey of capabilities of local organizations to meet the needs and things. So that's a very important organization, I think.

And at the individual level, again, as I said, these are very smart people who navigate very well. The challenge is how do you make certain topics a priority for them, right? If I am dealing with five, six, seven issues at any given time, because of sheer cognitive load, you know, I can't handle everything. I need -- we are all under stress. It's not that our jobs are under stress; it's just stressful jobs. But the kind of stress, I think, and of those -- and Kathryn Eden's work has clearly shown this, and I think the kind of stress they are under is a very different type of stress. And I think Miller, Naughton (ph.), and others talked about this cognitive load issue, you know.

I think so we really need to think through, how do we address the issues of cognitive load? And, again, that requires a very different type of construction of the messages and communicating with them on

a variety of platforms, as you have said this before too.

DR. BLALOCK: Thank you.

DR. KREPS: Can I follow up with that?

DR. BLALOCK: Oh, sure. Dr. Kreps.

DR. KREPS: You know, I really like the idea of increasing access through different systemic and organizational factors, but I think that there's another issue of not just access but relevance of the information, meaningfulness information, inclusion in issues that are relevant and meaningful to the population. I have a feeling that one of the big issues with digital inclusion is that a lot of the stuff on the Internet is not particularly relevant to many members of marginalized populations.

If you go to kind of the Maslow's hierarchy issue, they've got more pressing issues in mind than dating and mating and, you know, puppy pictures. It's not hitting them where they live.

DR. VISWANATH: Let me give you an example of what cognitive load and the number of issues people are wrestling with if you are from that group. So in this randomized controlled trial, one of the things we have done is social networking sites are exactly that, social networking. These are not top-down pushing information but engender conversation. That's what social media are about, right?

So we started doing that. We had a discussion forum on our website for this intervention group, and the discussion forum was not going anywhere, right. As we all know, we can always build these discussion forums; no one comes, right. However a substantial group of

people in our intervention group were from Haiti. When the Haiti earthquake happened, one person posted saying, I have been calling the State Department, I cannot get hold of anybody that -- those were the instructions, call the State Department if you have a family -- you know, if you want to know.

They have been calling the State Department. They could not get ahold of anyone; I am running out of minutes on my cell phone, what do I do? A number of people started answering that question, and we actually went out of our way and put some additional information for them. So, again, if it is relevant, right, they will absolutely use it in a very meaningful way. So they have been observing our discussion forum, which was not relevant to them until the moment it became relevant and just started exploiting it.

So we need to really think through, really get into the mindset there and work with them in identifying the issues that are relevant to them.

DR. KREPS: Thank you. I think the implications for the FDA from this are that we need to start thinking about different ways of presenting risk information to different audiences. And it may behoove the FDA to start thinking about the most at-risk populations, kind of the low hanging fruit, who are the groups that really need the information the most, and if they're part of these marginalized groups, they may need very different kinds of information, different messages, different reference, different sources, different channels to make it work for them.

So it goes back to the earlier statement about segmentation that came up in one of the earlier presentations. I forget which one, but I think that we need to maybe start segmenting risk communication based on priority and then making some good determinations about how to provide the information to those individuals who both need that information and also may have the least availability to getting the information they need.

DR. BLALOCK: And I'll just echo one thing in relation to that that Dr. Viswanath mentioned, is working with local organizations and the folks who are closest to the groups. Because I think as you get away from people, it's easy to make stereotypes about what people need, but when you work with people who really have firsthand experience with those people and who really know the stresses that they encounter, it can make all the difference in the world.

Dr. Krishnamurthy.

DR. KRISHNAMURTHY: Following up on Dr. Aldoory's presentation, I had both a question and -- a question for the presenter as well as the FDA too. I do see that the FDA has an app for drug shortages, but does the FDA have a mobile platform where people can opt in and get messages on a routine basis? Is it something that the FDA does do, and is there any statistics on how much uptake of that information there is?

And, of course, Dr. Aldoory, I wanted to ask you whether that -- is it the content of the text messaging that makes a difference or the mere fact that people are being cued into self-regulation that makes a

difference? Because if you want to manage content, the level of managerial effort that needs is much, much higher than just merely cueing people to behavior. So I just thought if you cared to comment on that?

DR. ALDOORY: Thank you. So, first of all, yeah, people are opting in, right, so these are not -- and again, this goes back to my thought it's not just the channel, it's the content of the messages, the number of messages, and yes, actually how many -- what you're saying in the messages. And so a lot of the work that we have done has looked at cues versus support messages versus fact messages versus request to act messages. So those are the four types of messages that we looked at over time.

And what we found is a variety over time to not get repetitious was the best. And so by sending, for example, one message would be from Miss Peg, and Miss Peg would say, you know -- for rural audiences again, this is all tailored, right? And so fluoridated water is a really big challenge. And so maybe in D.C. we say don't buy bottled water because of the recyclable issues; for a lot of rural populations, we encourage bottled water because their well water is not fluoridated.

So, anyway, so we might say, oh, Miss Peg says, guess what I heard? You know, I heard that we really should make sure our children have fluoride in their water. I'm going to go buy -- and then so it would be a fact and then it would -- the next message in the week would say, you know, Rite Aid down the street, why don't you go to Rite Aid, we know it's only a few miles from whatever. You can go with friends to

save gas, and somebody can watch your kids and go get food. And then the next Friday we would send a text that says, did you get the message? You know, did you do anything about the message? And then we would call them and ask more questions.

And they really liked that. They liked the balancing act. So it wasn't all facts. It wasn't all this, but the content was very important.

Was there a second section to that question or was that -- okay.

DR. BLALOCK: Other comments by Committee members?

Dr. Yin.

DR. YIN: I also had a comment related to Dr. Aldoory's presentation. You had discussed how important it is to engage the community to really maximize the buy-in in the text messaging programs. At the same time you mentioned this idea of text message libraries that might be beneficial. And I like that because it sounds like there's a real science in developing these messages and doing these production analyses, as you were talking about for one of your studies. How would you envision these text message libraries being scaled up?

DR. ALDOORY: I was just pointing to Jessica. So this is something that actually, like I said, others might also be able to address. But the Healthy Families text library did in fact begin with groups of families. So the moms got together. They talked about, well, what are the challenges to physical activity with young children. And we, of course, found out the typical challenges was time, ideas, boredom, and what can they do where they're doing the dishes and the kid is on a video, right? And so we talked all about that, and then they helped

develop the messages. But there is a fine line between taking those message that were tailored and then adding the evidence base and then putting it in the library.

One thing we did was that the library, it was not only searchable but it had subtopics. Okay. So the library, we attempted a minor tailoring. So for children 0 to 1, rural versus urban. Access to parks was a big thing. Access to physical equipment, physical activity equipment was a separate section. So we tried to allow the library to reflect some of the tailoring we heard, needs from the families.

And then we shared the library with the Office of Women's Health at that time. But I know that there's others that are out there that are large libraries. And you can -- they're free, and you can just download the text messages that you need when you need them into your own bank system and then use them as you need them.

So there is a balancing act between tailoring and standardizing, but I think without the evaluation research, we can't really know how well it works, and that's why I'm encouraging more evaluation in the libraries as a model to see how well it works.

DR. BLALOCK: Other comments?

Dr. Rimal.

DR. RIMAL: I don't quite know how to address this. I guess, you know, I'm going back to my grad school days when -- in the communication department. The message that -- one of the messages that was drilled home to me was that not all problems are communication problems, and that in trying to fix a not communication

problem with more communication is maybe not the way to do it.

And I was thinking about that as I was listening to Dr. Viswanath's presentation and how, when the structural disparities are so large and span so many domains of day-to-day living from housing to poverty to crime to you name it, when the challenges are across the spectrum, one part of me was asking, if we are advocating a policy of more access to communication, are we just tinkering at the edges when the real problems are so much larger?

And I think a sensitivity, sort of, I came with after listening to the randomized trial study was that when you try to level the playing field with more communication, better communication access and so forth, that there are wonderful things that do happen. So there are things that can be brought about -- things that can be changed and others that still remain stubbornly unchangeable. So I wonder if we shouldn't be thinking about things that are within the purview of more, better, fancier, more effective communications, than ones that are not.

DR. BLALOCK: Dr. Sneed.

DR. SNEED: Just a follow-up. I was sitting here kind of thinking a bit the same way but thinking I'm glad I'm not Jodi Duckhorn, who has to take this and do something with it.

Because there so many segments of the population. There are so many health issues, etc. So I'm wondering if, just being a very practical person -- we know that a lot of the communication goes one-on-one with the nurse, the physician, the dietician, healthcare providers, maybe extension educators that are out in the communities,

and they understand their communities, and they understand what the problems are in the communities. So maybe the contribution that we could make would be to do something -- I'm a dietician, okay, for full disclosure, I guess. But I think a lot of times there's so much that we focus on in terms of the technical that we may not be as good at developing messages, at identifying how to communicate, that sort of thing.

I'm guessing that probably other healthcare practitioners have kind of the same approach. So perhaps developing some tool, maybe an online training course. So much of the information that we shared in the last 2 days is so pertinent and is so good, but can that be somehow put together in some kind of a web-based course that could help the various practitioners in the various areas do a better job of communicating. And that might be a way to get more spread, rather than FDA trying to take a lot of different topics and coming up with the messaging and how to approach and what segment and that sort of thing.

DR. BLALOCK: Dr. Krishnamurthy.

DR. KRISHNAMURTHY: I'm glad Dr. Rimal kind of brought up this point, and I was sort of like, you know, thinking a little bit along those lines but was more inspired when you said what you said, that is this a communication problem? And I think it is a communication problem in the sense of not all communication is equal for all segments or all groups or all final users of the communication. So the point might be that if there is a group of people whose health is being adversely

affected because they just don't have access to this information, it could be the result of social issues, it could be the result of a whole host of other things, but at the end of the day, any agency that is tasked with communication, being blind to that is a bad idea.

So knowing that we are not reaching some groups would come up with solutions like what you mentioned, Dr. Sneed, like the communication should be the community organizations and reach them through other channels that are not otherwise accessible. Especially like Dr. Viswanath was mentioning, that they looked to the community organizations as a one-stop shop for every solution. If that is the case, then the target market for the FDA communication where they can automatically reach the consumer is to go through the community organizations, which sort of opens the eyes and the possibilities to what we should communicate and how we should communicate, again, which comes back to the question.

DR. BLALOCK: Dr. Cohen Silver.

DR. COHEN SILVER: And I'm remembering -- in follow-up to that, I'm remembering that perhaps it was our first presentation about the food servers yesterday and -- so we have to think even more broadly, you know, the waiters or the people that work in the fast food restaurants, to think about communicating -- to think downline where you might want to communicate. So I'm just even thinking -- and we were talking about Chipotle. So Chipotle did a very public 3-hour food safety presentation for all of their employees. Now, that was clearly targeted -- they didn't hide that. They certainly wanted to make that

clear. But you could see that kind of activity being done more broadly in food, in pharmacists, you know, something like figuring out how to specifically speak to the consumer, because those consumers are not going to the website.

DR. BLALOCK: Other comments?

Dr. Yin.

DR. YIN: I also wanted to echo what others are saying about how it's so important for the FDA to really think about how they can support the people in the front lines, whether it's by doing some sort of training program in communication or -- I mean, I think even the materials that you're developing for -- that you're giving out to patients, if those are -- like the REMS or things, that they are structured in a low literacy way that in itself supports the conversation to be more action oriented, if those materials already designed in that way.

So I think that making some of those policies around the plain language documents, those kinds of standards using the CDC's Clear Communication Index or the AHRQ's PEMAT or those things that will in and of itself -- that'll help the patients, but it'll also help the people who are communicating to the patients.

DR. BLALOCK: Other -- Dr. Rimal.

DR. RIMAL: Sorry. Just one last thought. I think I want to articulate the fact that I feel very much like a non-expert even though I'm on an expert panel, especially when it comes to this topic. And I also sense, just listening to the language that we're using, there's a lot of third-person terms, pronouns being used, and that makes me very

uncomfortable. So I wonder if as -- you know, if community organizations are so important, perhaps the next expert panel should comprise of people who know that from the ground up and who are working there to constitute a panel like this at the FDA.

DR. BLALOCK: Other comments?

This is again sort of a challenging one to try to summarize because I think that when you're talking about underserved populations, it just has so many issues and so many issues that I think are far beyond the ability of the FDA to really address. And I think some of Dr. Rimal's comments sort of relate to that. You can only solve so many -- you know, you can only go so far with education.

But I think that one of the -- my background again is -- my Ph.D. is health behavior and health education. And one of the things I think is -- you know, sometimes you think that, well, if -- and I think I've said this before yesterday -- if you provide people with information, then of course they're going to -- if you tell someone that they're overweight, of course they're going to lose weight; if you tell someone that cigarette is going to kill you, of course they're going to quit smoking. So information only goes so far with anyone.

And as people were talking and as I was trying to think and sort of synthesize, one phrase that I wrote down here is "equal access to information." We often talk about sort of equal access to different kinds of healthcare services, and that's probably beyond the scope of what we're talking about here. But it's probably not beyond the FDA's scope to think about equal access to information. And if there are risks,

what can the FDA do to ensure that all the people who need the information have the ability to access it?

And, you know, I think that through all of the presentations, we've talked a lot about social media and we talked about -- Dr. Viswanath talked about people's access to cell phones and internet capability and Dr. Aldoory text messaging, and I think that one take-home message that I would kind of take from this is that we have a lot of different channels, and those channels aren't going to solve our problems. Probably 30 years ago we thought that if we handed someone a brochure, it would solve our problem. And probably sending someone a Tweet is not going to solve the problem either. But those are different tools that we can use. And we have new tools, many new tools and emerging tools, you know, text messaging and all of that. But we can't just put those things out and assume that they're going to have some type of effect. We really need to figure out who they're reaching and how they're able to use the information and what's the limits of what we can expect from the information in relation to behavior change, because again, I think it's naïve to think that just information by itself is going to result in behavior change. But I do like that notion of sort of equal access to information and how we might go about achieving that.

So, again, let me just see if there are any responses to that or additional comments that might be stimulated.

And, if not, Ms. Duckhorn, did you have anything to add? Do you feel like you've gotten what you need or --

MS. DUCKHORN: I think this is good. Thank you.

DR. BLALOCK: So we'll now proceed to the public hearing portion of the meeting. Public attendees are given an opportunity to address the panel to present data, information, or views relevant to the meeting 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 your individual 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 to the podium, and you'll have 5 minutes.

And we ask that each presenter speak clearly to allow the transcriptionist -- to allow an accurate transcription of the proceedings.

DR. LERNER: Hi. I'm Jen Lerner from Harvard University. I hope I'm allowed to count as the public even though I'm a guest speaker. I have already disclosed any financial relationships.

And I wanted to ask Dr. Aldoory if she's thought about one way that this might be able to scale up is to use -- to draw on the really remarkable advances in affective computing, where now people like Roz Picard at MIT and Jonathan Gratch at USC have digital avatars that can be personalized to have the kind of similarity between the individual who's receiving the health information and the avatar. And there are studies showing that, at least with veterans who are returning from combat deployments, that the veterans are more willing to disclose sensitive information, like having PTSD symptoms, to the computer avatar than they are to a human nurse or health professional within the VA system. And so there might be a way, especially for people who have sensitive information, like STD exposure, that kind of thing, to be able to disclose more and then in a confidential way receive the information that they need. So it's just one thing to consider in terms of scaling up and making it actually affordable.

And then the second and final question I wanted to ask is whether there is a conflict between the data that Vish presented and Dr. Aldoory's data, because Dr. Aldoory showed above 90% on cell

phone usage, whereas my understanding, and I may have misinterpreted Vish's data, showed that actually most major national surveys like the Census aren't sampling the population that is least well off and therefore 90% may be an overstatement of the number of people who are actually connected. Thank you.

DR. BLALOCK: Dr. Aldoory, would you like to -- and Dr. Viswanath, one of the questions was, was there conflict, so feel free to come up as well.

DR. ALDOORY: On the first point, thank you very much for all those suggestions. Actually I cut out of the presentation to make it shorter, some of those newfangled ways that texting is being used.

A lot of work now is distinguishing between smartphone use, because you can do text campaigns when people have smartphones where you can share links and other kinds of bells and whistles that they can then interact with. But with low-income populations that, for example, that I work with, there are still a lot of flip phones. And on one hand, that's why text messaging is great, because you can still reach out to people who just have flip phones. But on the other hand, people always want to send links and all of these web and app things, and you can't do that. So we kind of balance between the research that shows absolutely what you're saying and the low tech version that a lot of people are using in the field.

And then the second thing I want to say is I don't necessarily think that there's a conflict so much as -- so my -- he also used the Pew research, and that's where my data comes from is Pew. And I just think

what it shows is -- like I work with -- my populations are actually where -- like in Prince George's County, Capitol Heights, Maryland, where there's zero primary care providers, it's a food desert. It's a lot of problems going on in zip codes 20743 and others. And they all do have a mobile phone because that's all they have. So it's not in addition to their computer or other things, but it's the only thing that they have. And they go in and out. But the text campaigns that we do, they opt back in, but if they don't opt back in, we can't reach them.

So I don't know if it's a conflict so much as together we need to look at these as problems, how the surveys are done, how Pew does their data, and then dig deep into what's going on in individual communities.

DR. VISWANATH: So actually there are a number of creative approaches that one can take. Avatar computing is very promising. You know, the people in Children's Hospital, Washington Children's Hospital are actually trying to do some of these things. There's an empirical question in what will eventually happen and what the outcomes will be, but I think these experiments are exciting. I think these are the kind of openings we should be looking for as we move forward because technology is not going to be static but dynamic. So I think those are exactly the kind of creative experiments that we should be looking for and see if there are some openings for us, especially for the kind of people I'm interested in working with, I think. And that's absolutely correct.

Second, on the data, on the conflict, I think it's -- my contention

is exactly that. My contention is that surveys such as Pew, and I like Pew data -- Health Information National Trends Survey, I had a hand in creating it at the National Cancer Institute when I was there -- overestimate the presence of these technologies because they undersample those who are poor. That's exactly my contention.

My contention is that if you are -- this kind of probability-based sampling, which we all take for granted, is actually not working in recruiting people from underserved groups, and then that is actually overestimating. And we don't ask the right kind of questions about connections going on the grid and off the grid. In fact, when we ask those questions, when we go out of our way to sample these people, we actually get these answers. So that is exactly our contention with the national surveys, except the Census. And American Community Survey obviously, they take great care, but most of the national surveys don't do that. And that is a problem in our view.

DR. BLALOCK: Thank you.

And, you know, we are going to, when we have the general discussion, give a little bit of time for guest speakers to address the panel and make some final statements.

But for the Open Public Hearing, let me ask if there are, you know, any members of the audience who are not guest speakers who have any comments that they would like to make to the Committee.

Okay. I'm going to now then pronounce the Open Public Hearing to be officially closed, and we will not take any additional speakers for the day and we'll proceed to today's agenda.

So with that said, I just promised that -- do any of the guest speakers have any final suggestions that they would like to address to the Committee? I see Dr. Lipkus, and I'll give each person who'd like to say maybe a couple of minutes for any closing comments for us to consider.

DR. LIPKUS: Yes. Thank you very much. Isaac Lipkus, Duke University School of Nursing. No conflicts I think.

So I have, I think, three random thoughts. One of them is we hear a lot about how we want to influence health behavior outcomes and so forth. The one thing that we don't have a lot of the discussions about is what do we consider a success story and how much of an effect we want to achieve. So that's kind of an ambiguous area, but I think that deserves more discussion about what are realistic kinds of achievements that you could do given the current standings of types of interventions we have.

Second thing is I sometimes get confused whether the role of the FDA is information delivery versus and/or the role of persuasion. Depending on who you talk, information, if you just think about just increasing people's knowledge in facts, is actually persuasion. So I don't know what the crossroads of that is, but one thing to consider is that ultimately people have to convince themselves to change, and we seem to have this focus on we're going to give you information, or what have you, and that's going to create persuasion. I think it would be useful to think of ways to get people to think of how they can persuade themselves and study those mechanisms.

To just give you an example. In a study we've just completed on text messaging, we have people generate their own text messages, and they get their own text messages using their own words and emotions and what have you. And they love that. And that's not something that we generate but they generate to themselves, and they find that that's quite persuasive because it has some personal relevance and meaning to them outside of any context that we could ever deliver in creating our own messages for them. So that's that.

And the third one is I've noticed throughout the hearing we sometimes say, well, the FDA, you have this group of people who you could go ahead and recruit as participants or you do your own research. One of the things I have found in terms of research is that when you ask a research organization to do research, it usually takes quite a bit of time for them to get you the results. Just what I've noticed. What I have found is that industry is really, really great at looking at cutting edge ideas and implementing them. So one of the things I would recommend is that -- and if this is doable, is to what extent can corporations, industry actually be more of a partnership with the FDA to facilitate some of the goals that are trying to be achieved instead of saying let's just have the FDA look at it. I think those kinds of partnerships with other organizations would be extremely valuable if done correctly.

Thank you.

DR. BLALOCK: Other guest speakers?

Okay. Then I'll open it up to the members of the Committee to

discuss any thoughts that you may have about any of the information that you've heard over yesterday and today that should be considered to provide final recommendations to the FDA.

Let's go around the table, and Dr. Krishnamurthy, do you have any thoughts to provide?

DR. KRISHNAMURTHY: The reason why I did not jump on the opportunity was in part because we've had very nicely organized sessions. I want to first commend the people who put this together because the speakers were topnotch, and the way the sessions were put together was nicely bracketed so that the organization could be focused on certain points. And I think, at least as I can speak for myself, that I could focus on what was the topic at hand and offer whatever thoughts I could at that point in time, so I don't have a grand point to make overall.

DR. BLALOCK: And, you know, one specific thing to think about is what the FDA might do with the information in terms of their communication strategies.

Dr. Sneed.

DR. SNEED: Thank you, and thanks to all the speakers. It's been a very interesting couple of days and lots of good points of discussion. Like I said earlier, there's so much, I don't know how you quite whittle it down to something that's doable.

But I do think that it was good emphasis on looking at underserved populations, looking at ways that we can actually affect behavior change, not just get information out but actually focus on

behavior change. And then I think it's working with related groups, be it community organizations, healthcare groups, extension groups, that are actually out in the community and can reach out and help get the message out there.

DR. LIU: I think I have the same struggle, that we've covered just a ton of really interesting and great presentations, but it's like the whole suite of risk communication.

I do have one comment on the structure of the meeting. In the past we've had an FDA client kind of present at the beginning what are the goals of the meeting, what are you most hoping to get out of this? And I understand why that wasn't done today, but I think that would have helped structure the conversation a little bit more. Hopefully, you've got what you needed out of it, but I think that is helpful for the Committee to structure what we're saying.

In terms of takeaways, I think the -- a typical risk communicator is a front-line person, and that's kind of come through more in this meeting than past meetings I've seen, so less health practitioners, more people who aren't necessarily trained in health or communications but are still doing it. Obviously the multiple channels, multiple audiences, multiple ways to get information out and not be conflicting, I think, is also really valuable takeaways from today.

DR. BLALOCK: Dr. Zavala.

DR. ZAVALA: In the dissemination of risk communication information utilizing all the evidence-based practice that was stated yesterday and today, what I'm hearing is using engagement in

multidirectional format with trusted information keepers, guardians like us and other trusted organizations; and using different channels, which I feel very strong about, for a different segment of the population, particularly those with the lower SEPs because they tend to have more of the health issues. So keeping that in mind would be important.

DR. BLALOCK: Dr. Harwood.

DR. HARWOOD: So I think for me it was we identified lots of the barriers, both sort of cultural, technological, that can affect a variety of different publics. My takeaway is obviously in terms of the necessity to understand the publics in the form of segmentation.

The last speaker, it would maybe be good to even oversample those who are in the disadvantaged SES so that you have enough, after you've done the segmentation, within the lower SES. And also the necessity of platform compatibility.

I think the other comment would be, you know, some meetings it's -- as we go around the table at the end, it's what are we not talking about. And for me, I think one of the things that we haven't really done is the necessity of taking in user experience in design when we try to communicate the product. As we look in terms of more and more sort of digital communications, it's not just text on a piece of paper, but how it is actually framed within the user experience.

DR. COHEN SILVER: I had two points. One is to follow up on Brooke's comment. I'm just curious as to who is the client? I mean, obviously it's not just you, the Risk Communication Staff, I'm assuming. Can I ask you, do you expect to write a report that would be

disseminated amongst individuals who may not -- who clearly aren't sitting in this room? That's one question I have, is to how can we best help you? Are you going to draft a report? Can we read it? Can we help edit it? You know, how can we help you in that next step?

MS. DUCKHORN: This is Jodi Duckhorn. What we intend to do is take the recommendations and the discussion back and put together -- put it together into a matrix of sorts where we can disseminate it to the relevant groups. For example, when we were talking about specific social media strategies, we can give it to the groups that work with our Twitter and Facebook accounts. We can provide some of the feedback to the people who work with medication guides and REMS, for example. It's not going to be one mass report. We'll probably have individual meetings, and hopefully a lot of these people are also in the room and online and have been able to at least hear that you all have raised very relevant issues that we can try and tackle.

DR. COHEN SILVER: Great. The other thing is my strong takeaway is something that I think we have said at just about every meeting, which is that there is a strong need for research and that it behooves the FDA, if they can't do it themselves, to try to facilitate the research in the academic or sort of nonprofit communities. There was a lot of excitement when we heard that were 2 million people in the government that could be -- that research could be done on without having to compensate them, but then our hopes were dashed a little bit after we discussed that. So I think that it's -- what we heard from the excellent presentations was research that has been done sort of in

individual institutions, and I think that a lot of this research could benefit from even more research so that we can actually have the kind of meta-analyses that you talked about. But in many of these, you know, we heard single studies or some really exciting new work, but I think that more research is clearly warranted.

DR. DILLARD: I was struck by the thought that just about everything the FDA does in terms of risk communication is premised on making an argument, and it's often said that arguments have three parts: They have some claim, you should believe this; they have some evidence, here's a reason for this; and implicitly or explicitly, they have something that ties those two things together.

So we've heard a lot about different kinds of evidence over the last couple days. We learned about biomarkers and how they provide specifically tailored information that is also of a sort of concrete form. We heard about the effect of visuals and how they can be arresting in a visual sense, how they can be impactful, how they can convey information, and they can be emotionally arousing.

We heard a lot about evidence from other people. Other people make similar arguments, and we call that convergence, sometimes cocreation. But we know that experts may disagree and that that weighs on people's judgments. We heard from Andrew -- Dr. Pleasant and others that narratives are an important source of evidence for others.

So I think that across those presentations, there's the opportunity to construct a sort of checklist for argument so that at

every stage of message development, whether it's a one-way message or a response to another argument, you could check the boxes. It would be a did we bother to think about this, did we remember to think about this, sort of activity. And that would be a pretty simple and possibly useful takeaway from the meeting.

DR. YIN: I really like what your comment -- this is Dr. Yin -- your comment about checking off checkboxes because, I mean, there is a lot of research that has been done, and we know some of the important considerations that we should be thinking about for the different communications that the FDA has. And so if we could create some sort of checklist, would have to definitely consider effective science and the implications of that, etc., I agree that would be a really great thing.

One of the things that -- takeaway points for me is the concept of the FDA being proactive, taking a proactive stance in times of non-crisis and crisis situations, the importance of social media and the FDA establishing this kind of longstanding trustworthy position while at the same time identifying different groups that can really help get the messages out there to really amplify these messages, and trying to move towards a place where there is convergence of messages and having some sort of a infrastructure, a planned infrastructure before a crisis occurs to follow.

And the other take-home point for me is also about the research. That's something that Dr. Cohen Silver mentioned that, you know, we do know some things, but we don't necessarily know the best ways to get the most amplification of messages and the best bang for our buck

and how do we reach those most at-risk populations. So thinking about those issues is very important.

DR. RIMAL: I'll just add some things to, I guess, to the running list of checklists. In my own laundry list, if you will, because I found these 2 days of discussion to be really informative for me, so a few things that I took away that -- and much of this will not come as anything new to I think most people around the table -- that how information is presented, how information is framed matters; that we also need to take into account the affective states of the audience; that knowledge and action are not the same thing; even when you show people their biomarkers, they don't necessarily go out and change behaviors.

I was also struck by the fact the distinction that was made between the content of communication and the relationships that are embedded in communication messages, that it's not just about messages but it's also about relationships; that sometimes less is more, that when you add to an already inundated volume, we actually do a disservice, and so we need to prioritize the key elements and then sort of put that front and center.

The need to be aware that the information out there is often contradictory, that -- and I think some way for the FDA to decide when to jump in and correct the record versus when to kind of just lurk might be a very important exercise.

And then the last presentations or the set of presentations about the disparities both in sort of structural issues as well as in

communication access, just -- if nothing else, just being aware that the information that the FDA puts out is going to be received very differently by different segments of the audience, and depending on where they are in that sort of ladder is probably a pretty noteworthy thing.

DR. BLALOCK: And I think one thing that I would like to sort of underscore that we've talked about is the need -- and I actually think even for the Committee, it would sort of help us to -- I'm thinking that there's a need for sort of an environmental scan of -- and I think that we talked about this yesterday -- of what are all the different types of risk communication that the FDA is involved with and what are the strategies that are used for different kinds of -- you know, in different contexts, whether it's a food recall, whether it's a medication REMS program, whether or not it's something to do with veterinary medications. And I actually think coming back to the Committee with the results of an environmental scan like that might help us better understand what is the purview that we're looking at, what is sort of the big picture.

And one of the comments that one speaker said was that -- I think it was in relation to sort of usability testing, that probably people's preferences for information about one medication would be similar to another, that there might be generalizability across those. And that was one of the few things that a speaker said that I disagreed with a little bit because sort of the more -- the longer I am in this business, the more I realize that the minute that you move to a slightly different topic, the

issues are different. So whether you're dealing even with medications that are taken by pregnant women or whether they're medications to treat an acute condition or a chronic condition, you know, the more that you find out about something, the more complex it is, so, again, I think just if an environmental scan could be done with all the different kinds of warnings and risk communication strategies that the FDA uses.

And then the other thing that we talked about yesterday was developing a strategic plan. And I actually wonder if the Committee could help in developing a strategic plan in the context of that environmental scan. And I think that one thing that we might be good at is identifying sort of where the gaps are. Once we get into something that's fairly concrete, then you can look at it and say, well, this is great but here are the gaps. Because I think that one thing that -- you know, with all the presentations that we've heard, you know, there's just great science out there, and it's very complex, and I think it's just sort of a matter of making things more concrete and then really digging in.

It looks like you're jumping at the gun, so I'll turn it over to Ms. Duckhorn.

MS. DUCKHORN: I am so glad you offered to help for our strategic plan on behalf of the Committee, because we are currently working on updating our strategic plan, and we would love to have the Committee's help with that, especially in terms of filling in gaps where it's -- it's a current process, but thank you for offering on behalf of the whole Committee. We appreciate it.

DR. BLALOCK: And let me, since I volunteered, let me open it up

to other members of the Committee to volunteer as well or say more specifically about how we might help, because I was just very vague. But I do sense that people are willing to help. And I do think that that would be a good role for the Committee. Okay. I see a couple of thumbs up. Okay, great.

Other discussion? Dr. Yin.

DR. YIN: I just also wanted to chime in and say that I think the idea of the environmental scan would be very helpful for us also so we can understand where it is that we might be able to provide advice.

DR. BLALOCK: So Dr. -- I mean, Ms. Duckhorn, you feel like you've gotten what you need for today, then? And everyone feels like they've gotten an opportunity to have their views heard? Okay.

So I would like to thank the Committee, the FDA-invited speakers, and open public speakers for their contributions to today's meeting. And I also want to thank the FDA staff again especially for -- I can't believe that you were able in the last minute with all the inclement weather to really pull this together and get all the materials updated and everybody arriving safely.

So with that said, the February 17th, 2016 meeting of the Risk Communication Advisory Committee is adjourned.

Thank you.

(Whereupon, at 1:55 p.m., the meeting was adjourned.)

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 17, 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.

_____

TIMOTHY J. ATKINSON, JR.
Official Reporter