UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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RISK COMMUNICATION ADVISORY COMMITTEE

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November 7, 2016
8:30 a.m.

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

PANEL MEMBERS:

SUSAN J. BLALOCK, Ph.D., M.P.H.	Chair
DAVID M. BERUBE, 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
JAMES DILLARD, Ph.D.	Member
GARY KREPS, Ph.D.	Member
CHARLES LEE, M.D.	Member
ANDREW PLEASANT, Ph.D.	Member
RAJIV N. RIMAL, M.A., Ph.D.	Member
JEANNIE SNEED, Ph.D.	Member
MIRIAN ZAVALA, D.N.S., RN	Member
ROXANE COHEN SILVER, Ph.D.	Member
H. SHONNA YIN, M.D., M.S.	Member
NATHAN F. DIECKMANN, Ph.D.	Temporary Member
ISAAC M. LIPKUS, Ph.D.	Temporary Member
DANIEL G. MORROW, Ph.D.	Temporary Member
WILLIAM K. HALLMAN, Ph.D.	Temporary Member
MICHAEL I. McBURNEY, Ph.D., FACN	Industry Representative
KIM O. WITCZAK	Consumer Representative
NATASHA FACEY, M.S.W., M.P.H.	Designated Federal Officer

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National Center for Health Research

JAMES (JAY) DUHIG, Ph.D.
AbbVie, Inc.

LAURIE MYERS
Global Health Literacy Director
Merck & Co., Inc.

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M E E T I N G

(8:35 a.m.)

DR. BLALOCK: I'd like to call this meeting of the Risk Communication Advisory Committee to order.

I'm Dr. Susan Blalock, the Chair of the Committee. I am a behavioral scientist and am a professor at the Eshelman School of Pharmacy at the University of North Carolina Chapel Hill.

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

For today's agenda, the Committee will hear presentations on some of FDA's external communications. The Committee will also discuss and make recommendations on FDA's draft Strategic Plan for Risk Communication and Health Literacy.

Before we begin, I would like to ask our distinguished Committee members and FDA staff seated at this table to introduce themselves, and please state your name, area of expertise, position, and affiliation. So I'll start with Dr. Lee.

DR. LEE: Hi, my name is Charles Lee. I'm an internal medicine physician and president and founder of Polyglot System. My area of expertise is around using technology to provide medication instructions to address language barriers and health literacy.

DR. KRISHNAMURTHY: Good morning. My name is Partha Krishnamurthy. I'm a Professor of Marketing at the University of Houston. I also have additional appointments at the Baylor College of Medicine and the University of Texas Medical Branch. My expertise is framing of information, decision making, and marketing.

DR. SNEED: Good morning. My name is Jeannie Sneed. I'm a retired professor from Kansas State University. My area of expertise is food safety.

DR. PLEASANT: Good morning. I'm Andrew Pleasant. I'm employed at a small nonprofit called Canyon Ranch Institute, and I always say the experts in health literacy are the people that actually live it, so that's not me.

DR. LIU: Good morning. I'm Brooke Liu. I'm an Associate Professor of Communication at the University of Maryland, and my area of expertise is crisis and disaster communication.

DR. LIPKUS: So my name is Isaac Lipkus. I'm a professor at the Duke University School of Nursing. My expertise, if you could call it expertise, is in different formats of conveying risk information to effect primary lifestyle behavior changes.

DR. KREPS: My name is Gary Kreps. I'm a Professor of Communication and Director of the Center for Health and Risk Communication at George Mason University. I study the role of communication and disseminating health information with an emphasis on reducing health disparities.

DR. DILLARD: Good morning. My name is James Dillard. I'm a Professor of Communication Arts and Sciences at Penn State University. My research expertise is in the role of communication and emotion.

MS. WITCZAK: Good morning. My name is Kim Witczak, and I'm the Consumer Representative on this Committee. My background is in advertising, so I guess my expertise would be advertising and marketing, and I also represent -- I'm the Consumer Representative on the Psychopharmacologic Drugs Advisory Committee working with drug safety issues.

DR. McBURNEY: Good morning. I'm Michael McBurney. I'm an Industry Representative. I'm Vice President of Science, Communications, and Advocacy for DSM Nutritional Products, which is a B2B. It's the world's largest manufacturer of vitamins and Omega 3's. I'm also an adjunct professor at Tufts University in nutrition. I am a nutrition scientist. Five and a half years ago I developed the first blog and social media activities at DSM, which is a Dutch-based company.

MR. BERTONI: Good morning. My name is Malcolm Bertoni. I'm Associate Commissioner for Planning here at FDA. My areas of responsibility include the Risk Communication staff, as well as strategic planning and performance management, economic analysis, program evaluation, and process improvement, and my area of interest is management science and decision analysis, and I'm always very, very interested in attending these

Committee meetings.

Thank you.

(Pause.)

UNIDENTIFIED SPEAKER: You broke it.

MR. BERTONI: I broke it.

MS. DUCKHORN: Good morning. My name is Jodi Duckhorn. I'm the Director of the Risk Communication staff here at the Food and Drug Administration.

DR. MORROW: Good morning. I'm Dan Morrow. I'm Professor and Chair of Educational Psychology, University of Illinois. My research relates to aging, cognition, and some aspects of health literacy.

DR. ZAVALA: Good morning. My name is Mirian Zavala. I'm an assistant professor at the College of Mount Saint Vincent, Nursing, and my area of expertise is health disparities.

DR. DIECKMANN: Good morning. My name is Nathan Dieckmann. I'm an associate professor at Oregon Health and Science University. I study judgment decision making, risk communication, and I'm a statistician the other half of the time.

DR. SILVER: My name is Roxane Cohen Silver. I'm Professor of Psychology and Social Behavior, Public Health, and Medicine at the University of California, Irvine, and my area of expertise is in community response to disaster, both manmade and natural disasters.

DR. HARWOOD: Good morning. I'm Paul Harwood. I'm Market Research Lead at Twitter, and my expertise is in usability and user experience.

DR. RIMAL: Good morning. My name is Rajiv Rimal. I'm a Professor of Public Health in the School of Public Health at the George Washington University, up the street. My area of expertise is the intersection of health communication and behavior change.

DR. HALLMAN: Good morning. I'm Bill Hallman. I am Professor and Chair of the Department of Human Ecology at Rutgers, the State University of New Jersey, former director of the Food Policy Institute there and currently a visiting scholar on sabbatical at the University of Pennsylvania's Annenberg Public Policy Center. My area of expertise is risk communication and especially around issues of controversial science, food, and health.

DR. YIN: Hi, everyone. My name is Shonna Yin. I'm a general pediatrician and am Associate Professor of Pediatrics and Population Health at the NYU School of Medicine. My research focus is on design and evaluation of health literacy informed interventions to improve the way parents understand health information, with a particular focus on medication safety.

DR. BERUBE: My name is David Berube. I'm a Professor of Science Communication at North Carolina State University. I

direct a program on public understanding of science and tech, and I'm the Director of Communication and Assessment Office for the Risk Triangle Nanotech Network, and my expertise is in communication of emerging science and technology.

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

DR. BLALOCK: Members of the audience, if you haven't already done so, please, you'll sign in the attendance sheets that are located at the registration table just outside. And then Ms. Natasha Facey, the Designated Federal Officer for the Committee, will make some introductory remarks.

MS. FACEY: Good morning, I will now read the FDA Conflict of Interest Disclosure Statement.

The Food and Drug Administration is convening today's meeting of the Risk Communication Advisory Committee under the authority of the Federal Advisory Committee Act of 1972. With the exception of the Industry Representative, all members and consultants of the Committee are special Government employees 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 who have financial conflicts when it is determined that the Agency's need for a particular individual's services outweighs his or her potential financial conflict of interest.

Related to the discussions of today's meeting, members and consultants of this Committee who are special Government employees have been screened for potential financial conflicts of interest of their own as well as those imputed to them, including those of their spouses or minor children and, for purposes of 18 U.S.C. Section 208, their employers. These interests may include investments; consulting; expert witness testimony; contracts/grants/Cooperative Research and Development Agreements; teaching/speaking/writing; patents and royalties; and primary employment.

For today's agenda, the Committee will discuss and make recommendations on FDA's draft Strategic Plan for Risk Communication and Health Literacy. The purpose of the Strategic Plan for Risk Communication and Health Literacy is to clarify how the Agency can communicate the benefits and risks of FDA-regulated products to target audiences more effectively and so promote better informed decision making. The Committee will also hear presentations on some of FDA's external communications and how these communications relate to the draft

Strategic Plan for Risk Communication and Health Literacy.

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 with 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.

For the duration of the Risk Communication Advisory Committee meeting on November 7th, 2016, Ms. Kim Witczak and Dr. Michael McBurney have been appointed to serve as temporary non-voting members. Dr. Michael McBurney is serving as an Industry Representative, acting on behalf of all related industry, and is employed by DSM Nutritional Products.

For the record, Dr. McBurney serves as the Industry Representative for the Food Advisory Committee in the Center for Food Safety and Applied Nutrition. Ms. Kim Witczak serves as a consultant to the Psychopharmacologic Drugs Advisory Committee in the Center for Drug Evaluation and Research. Ms. Witczak is a special Government employee who has undergone the customary conflict of interest review and has reviewed the material to be considered at this meeting. These appointments

were authorized by Dr. Janice Soreth, Associate Commissioner for Special Medical Programs, on November 1st, 2016.

A copy of this statement will be available for review at the registration table during this meeting and will be included as part of the official transcript.

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

Handouts for today's presentations are available at the registration table outside of the meeting room.

The FDA press contact for today's meeting is Ms. Gloria Sanchez-Contreras. Members of the press, please sign the sign-in sheet located at the registration table.

I would like to remind everyone that members of the public and press are not permitted in the Committee area, which is the area beyond the speaker's podium. I request that reporters please wait to speak to FDA officials until after the Committee meeting has adjourned.

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

Finally, please silence your cell phones and other electronic devices at this time, and I'll turn it back over to Dr. Blalock.

DR. BLALOCK: Thank you.

We'll begin today's meeting with opening remarks by

Malcolm Bertoni, Associate Commissioner for Planning.

Mr. Bertoni.

MR. BERTONI: Good morning, everyone and welcome. I really want to start by thanking everyone here. You know, it's a couple weeks before, about a couple weeks before Thanksgiving, so I have a few different thanks. First of all, thank you to the Committee. We greatly appreciate your service and your leadership. I've been thinking about this. It's been 8, almost 9 years since the Committee began. I was here when the Committee was formed, and you folks have really demonstrated an incredible benefit to this Agency in how you supported how we implement this crosscutting interdisciplinary area.

You know, risk communication, as we'll talk about today, is an important and essential part of our mission. It's reflected in our Strategic Goal No. 3, promote better informed decisions about the use of FDA-regulated products. And this Committee has really been instrumental in motivating and supporting the development of the original crosscutting strategic plan for risk communication, as well as this draft Strategic Plan for Risk Communication and Health Literacy that we'll be talking about today, and you've been very supportive of how we've been advancing evidence-based approaches to risk communication, so we greatly appreciate that.

As we like to say, you know, first we need to get the

regulatory science and regulatory actions right, but then we need to follow through and get the communications right because if we don't follow through with that essential step, then we're not taking full advantage of the opportunity to protect and promote the public health.

I also want to thank the community of experts in risk communication here at FDA, several of whom you will hear from today. You folks have really worked collaboratively with our Risk Communication Staff and with this Committee over the years, and you've worked hard to put into practice the improvements that this Committee has recommended, and I greatly appreciate the work that you've done.

You've also worked diligently to produce this new draft Strategic Plan for Risk Communication and Health Literacy, which incorporates many of the best practices and not just for risk communication, but also for the development of strategic plans. You see the framework that you're going to be discussing today links activities to outcomes, and it also provides measures and methods for tracking progress, and I think it's a great example of how we should be developing strategic plans that are really forward leaning toward actions that improve the organization, improve results. So I think it's a great example of how we use planning to be a bridge to a better future, and I appreciate your efforts on that.

Finally, I'd like to thank everyone for providing a very

fascinating topic to focus our attention. For me, it takes my mind off all the other things that are going on this week, and it's nice to have something that takes my mind away from that, so I'm going to spend as much time as I can this morning with you, and I really appreciate the dialogue here and looking forward to a good conversation.

Thank you.

DR. BLALOCK: Thank you, Mr. Bertoni.

We'll now move on to FDA's presentation. I need to remind the public observers at this meeting that while the meeting is open for public observation, public attendees may not participate except at the specific request of the Committee chair.

So, Ms. Duckhorn, you may approach the podium and begin FDA's presentation.

MS. DUCKHORN: Good morning, and thank you all for coming today. In the most recent meeting of the Risk Communication Advisory Committee in February of this year, you, our members, requested an environmental scan of FDA's external communications. In response to your request, we have spent these past months compiling a summary of the various ways FDA communicates to external audiences.

A few weeks ago, you received a briefing document, which is posted publicly, that includes descriptions of FDA's external communication vehicles. The briefing document

includes descriptions of how the Agency refers to the communication, the intended purpose of the communication, the target audience for the communication, how the Agency ensures comprehension of the communication, how the communication is disseminated, if the communication is required by regulation, if the communication follows a template, and if so, can the template be modified, or what is required to make modifications to the template.

The environmental scan includes 128 types of external communications, including safety communications, fact sheets, brochures, and social media accounts.

The types of external communications from the environmental scan are developed by offices and centers that have their own communication department, and some have multiple communication departments. These are the areas of FDA that communicate most with external audiences to provide information about FDA-regulated products.

Each office and center operates under its own legislation, so there are types of external communications that are specific to a center or office, such as risk evaluation and mitigation strategies, which you will hear more about later. There are also types of communications that are commonly used across multiple centers and offices, such as product labeling or fact sheets.

This morning's presentations will take a closer look at a

few of FDA's external communication vehicles:

- The Office of External Affairs will speak to us about FDA's use of social media, such as Facebook, Twitter, blogs, and YouTube.

- The Office of Food and Veterinary Medicine will speak to us about foodborne illness outbreak communications.

- The Center for Drug Evaluation and Research will speak to us about Drug Safety Communications and communications within risk evaluation and mitigation strategies.

- The Center for Devices and Radiological Health will speak to us about consumer-friendly Class I recall notices.

- The Center for Tobacco Products will speak to us about e-mail outreach, including their newest communication vehicle called CTP Connect.

- And the Office of Minority Health with speak to us about their use of videos addressing minority health topics.

The purpose of this morning's presentation is to take a deeper dive into a few of FDA's types of external communications. These presentations are an opportunity for FDA to be transparent in how and what we communicate, and it allows you, our members, to learn more about the different types of communication vehicles the Agency has available. These communication vehicles will be important to remember when providing advice at future meetings of the Advisory Committee.

Please note: After presentations, there will be a brief

period for clarifying questions only. During the first portion of the meeting, we are not looking for feedback from you on the specific communication types. However, there will be other opportunities for discussion and recommendations on particular communications in future meetings of the Risk Communication Advisory Committee.

As I mentioned earlier, you, our members, requested an environmental scan of FDA's external communications in our last meeting in February. Also during that meeting, you offered to help or to provide your review to an update of the Strategic Plan for Risk Communication. That was a very well-timed offer, as we were already working on updating the Agency's Strategic Plan for Risk Communication. You asked, and you shall receive.

A few weeks ago, when you received the publicly available briefing document for today's meeting, it included the draft Strategic Plan for Risk Communication and Health Literacy. We will end the morning with a presentation about FDA's draft Strategic Plan for Risk Communication and Health Literacy. As many of you know, the Federal Government loves acronyms, and this is no different. The Strategic Plan for Risk Communication and Health Literacy, S-P-R-C-H-L, is fondly referred to as SPARKLE.

Over the past year, SPRCHL was drafted by a broad, cross-agency working group consisting of more than 100 FDA communicators. In August, the draft was reviewed by FDA's

Communication Council, which includes communications directors from across the Agency, and in September, it was reviewed by FDA's Leadership Council, which includes the highest-level executives from across the Agency. Today we bring the draft SPRCHL to you.

This afternoon, we have specific questions for the Committee to address the strategic framework, performance indicators and outcomes, implementation plan and activities, performance monitoring plan and measures, and the narrative. We want to make sure that we hit the sweet spot where everything is included that should be, and we aren't committing to more than we can do. We look forward to hearing the Committee's recommendations about the draft SPRCHL.

This concludes my introduction. We will now get started with the external communication presentations. The first presenter is Paul Bove from the Office of External Affairs. He will be presenting on FDA's use of social media.

MR. BOVE: Good morning. I'm Paul Bove, the Social Media Lead for FDA, and as Jodi said, I work for the Office of External Affairs.

Before we get into a discussion of what FDA does or why we do different things on social media, I think it's always good to have a little bit of a background as to why government uses social media. Basically, our marching orders came many years ago from President Obama, who had, as one of his first

Executive Orders, transparency and open government as something that he wanted to accomplish during his presidency. That was based largely on his success using digital communications in his campaigns, and it has continued since '09, and that was the first time that we basically saw these types of communications being promoted within government.

In 2011 there was another Executive Order basically saying start streamlining how you're providing information and customer service to the citizens, make sure that information is easy, declutter your websites, and go out and put information where people are participating; and for us, that largely means social media sites. So the result was the government going through, doing its research, seeing where the citizens are hanging out, and trying to figure out, well, how do we participate on these different sites? It was very apparent that they were going onto different social sites and platforms and looking for information and wanting to use those tools to communicate with the government and elected officials.

So that's where we come in as OEA web and digital media, and our mission is to provide leadership and coordination for digital communications across FDA's centers and offices. We're responsible for FDA.gov, which is the external website of FDA. We manage the social media channels, which include Facebook, Twitter, YouTube, Flickr, Pinterest and potentially anything else that comes up later, and also develop innovations to meet

the needs of visitors anytime, anywhere, and on different devices. Like right now, it's making sure that people have accessible material on mobile devices, which as we see government-wide are becoming more and more popular.

So the viewpoint from FDA is that we encourage fully the use of social media technologies within the Agency to enhance communication, collaboration, and information exchange to support our mission, which is to promote and protect public health. We encourage the employees within FDA to use social media to share information that may benefit public health, and we're also helping the public to make better informed decisions about FDA-regulated products by giving them clear information that's easy to understand and, again, in platforms and tools that they happen to find most useful and where they participate.

So where is FDA when it comes to social media? On our website, we have a list of all interactive media, and on here you can see we have Facebook, there's a Facebook en Espanol page, Pinterest, and then a number of Twitter accounts numbering 20 at this moment, which are run by the different centers and offices to provide information that is specific to their audiences or that delve into the expertise of that particular office. And we also have a Flickr page, YouTube, and then FDA Voice blog. So all these different sites are out there.

We, as OEA, manage the Agency-wide account called USFDA and then we have all these other ones, as I said, from the different centers, and we share that information collaboratively. We'll retweet information that comes out from a different center, they'll share our information, and they'll feed us information to put on the Facebook page, of which, again, we only have one, aside from the Spanish language one. And again, it's very collaborative, and it's a way for everybody to get as much information sent out to as many different audiences as possible.

So again, by the numbers, we've got 20 Twitter accounts, two Facebook accounts. Our main page alone has over 480,000 likes, and it's tapping into half a million probably this week, I would imagine. One Pinterest account, one YouTube account, a Flickr account, and a blog. And collectively, between all those different Twitter accounts and Facebook accounts, our reach is over two million and continues to grow as the information and strategy that we use to provide information gets stronger, and again, we change what we're doing on a regular basis to make sure that we're reaching people and providing them with solid information.

So what do we share on all these different channels? FDA has a lot of different material that comes out:

- One of our biggest things that we'll put out is a rollout; that's different major announcements that you might

see in the news, something like new food labels, for example.

- We have consumer updates, which could be information that's specific to a consumer who's suffering from diabetes, for example, or maybe something about contact lens care.

- Evergreen material and current events, that's the type of stuff that doesn't change, but it's still helpful to keep sharing. You know, current events kind of goes into health observations like World Heart Day or Health Literacy Month.

- A lot of collaborative material, we share a lot with other HHS and different government agencies and vice versa. They'll send us material, we'll send them material, and then we'll share it on our different channels to make sure that we have as much amplification as possible.

- Press releases, responsive statements, customer service. Something as simple as a person asking a question about where do I find information about how to file a certain report, we'll share an FAQ or perhaps a link or a phone number, e-mail, whatever happens to be that helps the folks to find what they're looking for.

- And then *Federal Register* notices.

In short, it means anything else that helps the public, industry, and healthcare professionals better understand what FDA regulates and how it relates to their health, their business, or their profession.

So our goals for engagement on these various channels, we

look at it as having a hand in consistency and branding, interaction, and sharing.

We do content and community outreach through the use of blogs, different types of innovative campaigns, educational content, employee evangelism, different things like that. You know, we'll post listings for jobs even and make sure that people know that, hey, there's a job fair coming up if you're interested in working for FDA.

Our products: We're aligning regulated products with industry trends and customer needs.

Reputation management: That's creating buzz around the Agency and what we're doing and ensuring quick reaction to crisis or negative posts.

And then customer advocacy, which for us means advocating for the best customer experience while keeping in mind that we have many types of customers. "Customers" I put in quotes there because we have a lot of different types of audiences, so it could be industry, it could be healthcare professionals, it could be patients, whoever it happens to be, we constitute those as our customers.

And these are just some of the characteristics for when we're trying to provide and create material. We want to make sure that it's relevant, personalized, interactive, integrated, authentic, and easy to understand is a big one because a lot of material that comes from FDA and other health agencies could be

very, very difficult. Even some of the names of the things that we put out there, including drugs or diseases, are hard to understand at times, so we're trying to make it as simple as possible for people to get a better handle on what it is that we're talking about and how it might affect them or their families.

So with all this different material that we're putting out there, we have a very, very large amount of variety, and for us, that's the cornerstone of our public health and social connection. We have lots of different material, we have lots of different centers here. As I mentioned, there are 20 different Twitter accounts. We put out all kinds of material.

These are just a couple of screen grabs of recent posts that we've had. There was a Naloxone App Competition that we recently ran, that was something that we shared far and wide on Facebook and then sent out multiple tweets to let people know that this competition is going on, collaborated with different HHS agencies to make sure that they were aware of it. Again, variety, you know, reaching a lot of different audiences to let them know about something like this.

Another big thing that goes out, as another example, is food recalls. These can constantly be occurring, and we're always putting out information on food recalls to make sure that people know about it, not just hearing about it in the news or on the news or seeing it in a newspaper. We want to

make sure that people are getting it in their news feeds so that they can be aware, hey, there was a food recall on this particular product.

This summer there happened to be something, a food recall on flour, so we shared a lot of information about that to let people know this is going on with Gold Medal flours, and this is also the screen grab at the bottom. That one was a consumer update that we shared about why you shouldn't eat raw cookie dough and other raw baking products because it tied into this particular recall: Eat raw flour, you could end up very sick. So we had a tie-in with that to make sure that we're not just telling people here's a recall, but here's what might happen to you.

And these were a couple of the other screen grabs. I think after all was said and done, on Facebook we had five different posts regarding flour recall, and the overall reach on that alone was 568,862, so well over half a million by putting out this type of information just on Facebook. And again, it was also shared on Twitter and through our other different accounts.

So in terms of the material that we send out, typically an average post of something that we're sharing, let's say a consumer update or a press release, the reach could be somewhere around 25,000 to 55,000. A high performer, which for us typically means a food recall or perhaps a drug release,

could be around 150,000.

A couple of weeks ago we had information that went out regarding something called teething tablets, which are used for babies when they're teething, and there are gels and tablets that are used, and there was a new notice stating do not use these, and if you have them, to throw them away. They had been in our search terms for a very long time within FDA, and this is the first update in a number of years. As of last week when I updated these, the reach on this alone was somewhere around 8.5 million, and post clicks alone was over one million. And I show the information there as to what Facebook reach and post clicks means. This has been definitely our highest performer on Facebook. I'm not talking about other things that come up via FDA. This has been the highest Facebook performer because there was a lot of interest in it because it applied to babies, and people have an interest in it. So again, a lot of variety, something that was definitely not what we were expecting when we put the information out on this, and very, very different versus the other reach that we typically have on our different posts that we'll put out there.

One of the other big things that we do is use social media as a customer service tool. When we put information out on Facebook, we have different groups within different centers who will go and look at the comments from the public, and they will share information to those people if they have a specific

question. So I'll go through and look to see is this something that might require a response or is somebody asking a question about something, do they need clarification? So we go through and look at the different questions and see what can we provide this person, again, using it as a customer service tool based on that Executive Order from 2011 that I mentioned. We're streamlining how people are getting information. We're ensuring that they have the opportunity to find what they need via our websites.

So these examples here are just a screen grab of a blog post that had gone out, and there were a couple of questions that came from the public. In this particular instance, some of the pharmacists from CDER, they had gone on, and they looked at the questions, and they were able to provide responses, as they frequently do. In the instance of CDER, they've already had a number of pharmacists who answer questions via phone or e-mail. So it was kind of a natural progression that they would go through and continue answering questions on Facebook and also Twitter.

So the example that I show here with the response, that shows a little bit of how we try to make sure that the answers are going out on Facebook when we're able to. We have empathy for the patient or customer or whatever you want to call that particular person, it could be industry, again. We educate them. We provide something that shows here's a link, here's

where the information is, here's maybe a correction of error, here's what you might need to know further about this, and then a feedback loop.

That's one of the biggest parts that we're trying to make sure that we include all the time is a way for somebody to get extra information or further information. We don't want to just say here's your answer, now it's just up to you find out more. If somebody has further questions, we want to make sure that they're able to go and give a phone call, maybe e-mail, or again, just simply looking at an FAQ or other page.

And we do the same thing with Twitter. I mentioned that if somebody has a question about a particular industry product, we might go through and share the details with them and say this is where you find out information, this is where you come to learn a little bit more.

So that's us trying to provide a touch of customer service from a regulating agency. It's not something that we would normally do in the past, but it is something that's happening more and more. These things were typically via phone, maybe via e-mail, but again, we're trying to make sure that people have the opportunity to find out what they need where they need to find it. And as I mentioned, we're looking to see what other tools might be used in the future, but for the time being, these are the places that we participate, and we try to keep an eye on what the public's asking for so that we can give

them these types of communications back to them, again using simple easy-to-understand language that hopefully helps them in the future.

And that's it. Thank you very much. And that concludes OEA's presentation, and up next is Sharon Natanblut from the Center for Foods and Veterinary Medicine.

MS. NATANBLUT: Close enough.

MR. BOVE: Sorry, I knew I was going to mix that up.

MS. NATANBLUT: Thank you. Good morning, everyone. It's a pleasure to be here today. I have to note that 2 years ago I was here before you talking with you about our seafood advice. You may be wondering where it is. I am, too. We are very hopeful we will be getting it out in the near future, and I really do want to say that the advice that the Committee gave us then was very helpful, and I hope that you will see that reflected when, in fact, it does appear.

So I'm with the Foods and Veterinary Medicine program, which oversees two of the centers in FDA, the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicines, so we have the human and the animal side. Today I'm going to be focusing on the human side on the topic of food outbreak and recall communications, which as Paul noted is an area of extreme interest to the public and one that we've spent the last few years really trying to figure out how we can improve what we're doing and make it as easy and compelling for

consumers to have the information and understand it.

So today's presentation, I just want to focus on three aspects of what we've been doing. First is, we do something called FDA CORE web postings. The CORE is the Coordinated Outbreak Response and Evaluation network, and that's the system through which and the program through which we do all of our outbreak communications. And we have been doing a number of web postings, and I'll talk to you a little bit about those in a minute, when we have outbreak-related issues. The next I want to mention is firm recall postings. We require for the most serious recalls that the companies issue their own press release, and we have some oversight of that that I want to share with you as well. And then I want to talk very briefly about the way we supplement the recall and outbreak communications on certain issues as needed.

So first, for the web postings, so this is our primary vehicle for communicating about outbreaks and recalls. It's faster than our standard press release. This will surprise you, I'm sure, but FDA has quite an extensive clearance process for anything that comes out, and press releases are ones that can take some additional time. And so one thing we wanted is to have a web posting that if we need to get something posted that day, we have the ability to do it, and so it's really an accelerated process. And the second thing I want to note is that the format is something that, back in 2009, this Committee

recommended that we really needed to have a consistent format that we would be using for providing the key information, and we've been using that literally hundreds of times in the last 5 years, so that, too, was very helpful to us.

We coordinate our postings with the CDC's postings. We work very closely with them on outbreaks, and so they go out with information that focuses on the epidemiology, and we have information that focuses on the work that we're doing with respect to the investigation, the trace-back, the work with the firms that are involved. So we find it's very important to go out at the same time and make sure we know what one another is saying and help to promote one another's postings. And we post these on our home page, we use GovDelivery, we tweet them, we respond to a lot of media inquiries.

So this is just the headlines of the headings for what the template looks like. And so we start off with the fast facts, and that just means at a glance you can tell what the key information is. We talk about what the problem is and what is being done about it, and I'm going to say a little bit more about that in a second. We talk about what the symptoms are. We specify the products that are, in fact, being recalled. We give consumer advice, and then we say that more info can be found on the CDC site. So that's the template that we've been using.

There are a few things we're doing now to try and enhance

what we've done before. One thing is a lot of -- the traditional advice was that, or the thinking was, just get the recall information out so people have what the consumer should do and what products are affected, and really, that's all you need. And what we find is that's not all you need. Consumers really want to know, well, what are we doing about it, you know, what are we learning, how strong is the evidence, and how can we build their confidence in what's going on so that they then will take more seriously the information we're providing. So one of the things that we do is we're giving more information about the scientific basis for the action. And very recently, whole genome sequencing has just so strengthened our ability to detect the outbreaks and recalls that need to be undertaken, it gives us the scientific footing for it, and we see we're going to have more and more of these announcements, not because there are necessarily more and more outbreaks, but because there are more and more ones that we're able to figure out what the problem is and then take action. So we're really spending more time providing the scientific basis.

The second thing that we're doing is we're trying to be more transparent about what FDA's role is leading to the recall. And so in the past, we would have information, and the company would say that they voluntarily recalled, it was just magic happened, company chose to recall. And well, behind the scenes, there was a lot of work going on, there was the trace-

back, there was the exchanging the information with the company, and there was the communicating to the company in pretty clear terms we have strong reservations about this, here's where evidence is, here's what we think needs to be done. And yet, you wouldn't know that at all from prior announcements.

So now we're putting in, on May 2nd, following a conversation between FDA, CDC, and the firm, the company chose to expand its recall. We're just trying to give a little bit more of the back story, and we think that that's important for consumers to see that there really is a lot of work going on behind this, an effort by FDA, working with the firm, working with the states, working with the CDC to protect consumers; we want them to know that. This is also of great interest to reporters. And so we could spend all our time putting out minimal information in web posting and then responding to numerous media inquiries. We'd like to get that information right up front.

The other thing that we're spending time doing for the first time is actually explaining why sometimes there's information that we're unable to provide. There's commercial confidential information. If it's deemed to be CCI, we're legally not allowed to reveal that information, and it's information that reporters and consumers are really interested in, so it's very frustrating. I can tell you, not as a lawyer,

as a communications person, it's incredibly frustrating that we can't get this information out, but that's the law, and so we're at least trying to let people know that's the situation so they understand both what information are we providing, and are there circumstances in which we're legally not able to provide that information. So that's what we've been doing on the web posting side of things.

Now I want to talk a little bit about the firm postings. So there are three levels of recalls that take place, and they're Class I, Class II, Class III, and that's by level of severity with I being the most severe. And for Class I recalls, the company needs to issue a press release. We get to see it, we get to -- we have a template for them to follow. We can review it, there is some exchange; sometimes they take our advice, sometimes not so much, but you know, we work closely with them on that. But that's been for the Class I recalls.

Class II, granted, are not as serious; however, there are -- some of those Class II's may involve, you know, certain populations or certain levels of seriousness that we feel are important for them to go out with their own announcement. And there are also ones that we are going out with announcements. So we're not going out only with Class I recalls at this point, we're also doing it with certain Class II's, and we want to work with the firms, and in the last 6 months, if you go back and look, you'll see that there have been a handful of Class II

recalls where we've gone out with announcements and where the firms have as well.

And so in the situations that have occurred most recently, they've involved some reports of illness or injury, foods consumed by vulnerable populations, by infants, toddlers. They've also been those situations involving manufacturing deviations with significant health impacts, and then also, it's been those situations where we have found positive pathogen findings and environmental testing. And again, these are certain situations where, on an ad hoc basis, we've been indicating we really think that it would be good if you went out with a press release; we're going to go out with a web update. So that's another area that we're looking into.

Now, the third I want to mention is the additional efforts. So when we do these web postings, we're interested in getting them out quickly, getting the key information that's necessary, and then responding to media inquiries. But there are these situations in which it's a very unusual situation, it's a widespread situation, it involves a vulnerable population, it's just something that we want to do more than just get the web posting.

And so, as Paul mentioned to you, the General Mills recall of 10 million pounds of flour due to E. *coli* contamination was one of those situations that happened earlier this year, and what really concerned us is that there are children who are

playing with and eating raw dough, that actually you can go to certain restaurants and they'll give the kids some raw dough to play with to kill time and hopefully get them to behave well while you're waiting for your food to arrive. This is an area that people really didn't have any awareness. People think of raw dough risks related to eggs, but they don't think that is the flour itself.

And so we wanted to do more activities, and I'm not going to rehash it because Paul did a great job of mentioning the variety of things that we did to reach out to parents and caregivers of young children, and so we used a variety of our tools that are listed here, the web posting, consumer update blog, social media, and interviews. It was an extraordinary amount of interest that was generated. And when we go out with the blog, the blog is really more targeted to our stakeholders to help them understand the back story, what we're trying to do, what we hope they will do. And then the consumer update, the primary target is the consumers. We also reached out to the National Restaurant Association, and we told them about the situation, and we asked them to help us reach out to their members to make sure that they were aware of what was going on. So there's raw dough media coverage.

And with that, I just want to end by saying we care deeply about this area; we want to improve as much as we can. We see this as an ongoing process. We try to talk to our

stakeholders; we try to talk to experts to find out what more we can do.

And so thank you very much for this opportunity. I appreciate it.

Oh, that wraps up my remarks, and now I'd like to introduce you to Dr. Paula Rausch, who is with the Center for Drug Evaluation and Research.

DR. RAUSCH: Good morning, everybody, and thank you for having me. I am Paula Rausch. I am the Associate Director of Research and Risk Communication in CDER's Office of Communications. I'm going to talk with you today about the Drug Safety Communications, and here's just sort of an overview of the things that I will be talking about.

The Drug Safety Communications, or the DSCs, are CDER's primary way of getting out postmarket safety information. This is new or emerging safety information that we think healthcare professionals, the public, and patients need to know about in order to make informed decisions. As Sharon mentioned, CDER has a very extensive review process, and so these are not meant to be crisis or urgent communications; they take a lot of time to put together, and they're developed in close collaboration between CDER scientific staff and the Office of Communications, our safety and risk communication team.

Why does CDER issue Drug Safety Communications? Again, because we want to provide the public, healthcare

professionals, and patients with the kind of information they need to make relevant healthcare decisions. We try as best we can to provide actionable recommendations for them. We want to foster trust in the FDA. A lot of people are very aware of the FDA, but our research shows that there is a lot of lack of trust in the FDA, especially among certain populations. We also want to be more transparent, and so we try to put out as much as we can about drug risks that emerge after a drug is approved and on the market. And in addition, we also want to raise the education of people to let them know that FDA doesn't just stop looking at drugs after they've been approved, that we continue to look at them through the lifecycle of the drug.

So some of the things that -- some of the types of issues that we communicate through a Drug Safety Communication, a lot of times it's issues that affect a large number of people due to widespread use of a drug, whether there are really serious or life-threatening issues that arise, adverse events that arise, after we've reviewed some information and some investigation, done some investigation, if there are clinically relevant changes to information about a known adverse event, and we also talk about medication errors that might result in serious or life-threatening issues. Most of those relate to confusion over the names of drugs that are similar or otherwise dosing confusions about different doses of drugs.

So we get asked a lot about what the criteria are for

issuing a Drug Safety Communication. We get that asked externally, and we also get that asked by our own internal scientific reviewers. Because all of the adverse events and the safety issues that we deal with are so different, we don't have set criteria, but we do have quite a number of considerations that we look at when we're trying to determine whether or not to do a Drug Safety Communication.

The first one is whether or not there's going to be regulatory action associated with the issue and what the timing of that action is. We also look at what the timing of the regulatory action is or the safety issue and whether it's important to communicate at the current time about that issue. We also are very concerned about whether there are potential unintended consequences or downsides to communicating about an issue at a certain time, especially related to the issue of scaring the public or having them be anxious to the point of stopping using a drug, a necessary drug. And we also, of course, look at whether or not the Drug Safety Communication is the appropriate tool.

As Jodi mentioned, we have over 120 different external communications within FDA. CDER has more than 40 on its own. So we have a lot of different ways to communicate this information, but again, the Drug Safety Communication is the primary way that we look to do drug safety information particularly, and we look at other things if it does not fall

into one of our considerations.

Some of the other things that we look at is the strength of the evidence of the investigations that were done or the studies that we reviewed, whether or not we can give actionable advice to patients and healthcare professionals. That's a very key element of our Drug Safety Communications. We've tried to build that up. We found, through our research, that that is a very important element; we knew that going in, but we've tried to build that as well. And we also look at whether or not we've communicated about the issue before and if there are things that we need to educate the public about, and of course, we also look at our target audiences.

We discuss and consider when to communicate about a Drug Safety Communication or about a drug safety issue through a Drug Safety Communication; again, some of the things that I've talked about already, whether or not we have actionable issues that can be provided to healthcare professionals and patients, whether it might change the risk-benefit analysis of a drug, whether or not there is regulatory action associated with the issue and what the timing of that regulatory action is, and then again, the need to balance the concerns of unnecessarily alarming the public with the public's right to know.

As I mentioned, we have done some research, and I'll talk a little bit more about that, but we have found overwhelmingly that while in the past the likelihood was that we would wait

until we had all the evidence in before we would communicate about an issue, we're finding that both healthcare professionals and especially patients really want to know this information as soon as possible. So we balance all that as we're considering whether or not to do a Drug Safety Communication.

We try to use all evidence-based practices when we do the Drug Safety Communications. Consumers really want to have more information than we used to put in the Drug Safety Communication, and we've learned that through some of our research. Again, we have found that unintended consequences such as stopping a drug are related to some communications, and we're doing more investigations on that.

For example, one of the things that we found out is that including the words "death" or "life-threatening" in the title or the first paragraph of a Drug Safety Communication really tend to scare people. Although our goal is to make people aware that this is a really serious issue, it had the unintended consequence, in a lot of cases, of scaring people to the point where they didn't read the rest of the Drug Safety Communication and just decided, based on that information, that they would stop taking the drug. So we are doing a lot more investigation with respect to that. And now we include that information, but we include it down further, and that is part of our attempts to mitigate and minimize these unintended

consequences.

So what you're looking at here is a webpage with a Drug Safety Communication posted on it. This is a relatively new web posting format for us. In the past, there's been a solid block of text that has been separated into sections, but about 4 years ago, shortly after I started, we started using a tabbed format on the website. That worked very well; we were able to tailor some of the information so it wasn't so text heavy for people. They could also find the sections that were most relevant to them and look at those. So that was a tabbed format. We did, again, go to this format; this is a mobile friendly format. We have done some research and testing with consumers on this format as well as this format on the website. People are very comfortable with this; they understand that they need to click down the arrows to be able to get to the full content. They don't have any problem, on the mobile sites, with scrolling through once they get to the pages with the information.

You'll see several red circles here that I want to point out information about. In the title, you'll see that the titles are kind of long. Part of that has to do with our web content management system; we have very little flexibility with respect to that, and we can't have, for example, a headline and a subhead like we would like to have. But what we have found through our research is that what people really want to see in

the headlines is what the adverse event is, in this case serious skin reaction, what the drug is, and we include both the generic name of the drug and the brand name of the drug, but we also include a description of what that drug is, in this case mental health drug, so that people who might not know the names of their drug off the tops of their heads will be able to understand whether or not they need to be interested in this information based on the description of what the drug does.

The large circle shows the different sections, and I'll go through those separately, but again, they are all tailored information. And then the two bottom circles, one shows that all of the Drug Safety Communications are translated into Spanish and posted on the website within a few extra days, and then a PDF version, so there is a long-form version with all of the information so that it can be used as a fact sheet or as educational material.

So this is one of the safety announcements, and all of this information, again, is evidence based. What you'll see here is our attempt to use a risk-based approach developed by Dr. Vincent Covello, who is a world-renowned expert in risk communication. We had Dr. Covello come in and do a number of risk communication trainings for us in CDER, and he spent an entire day with us talking through the Drug Safety Communication. So we looked at some of that, and what we have decided is that for the most part, the approach of know/do/do

works the best for the Drug Safety Communication. That is giving the most important thing for readers or listeners to know first, followed by what FDA is doing about this issue, and then by what they can do about this issue.

Those things fall into -- we've sort of separated those in the Drug Safety Communications to prevent this sort of block of text. So the first two are usually in the first paragraph, what the most important thing to know is and what we are doing about it, and then we separate it into the patients and the healthcare professional sections, what they can do about that. We've also gone to using "we" instead of "FDA" after the first reference because we think that better allows people to understand that FDA is filled with people and scientists rather than an impersonal organization.

We've tried to beef up, and we're still working on that, and doing investigation and research into benefit information, including benefit information, more and better benefit information, because we think that will help balance out the risks. We've heard, across the board, that that is one of the things that we need to do with the Drug Safety Communication is better balance the risks. By their very nature, this is a risk-based tool, and we're getting out safety information, but we want to do a better job of balancing that with some benefits.

And then the other thing that we've heard is we used to

put most of the quantitative information in the data summary, which I'll talk about in a minute, but we've heard from consumers that they really want that information, so we've tried to summarize that and simplify that and put that into the safety announcement. And the safety announcement is written as well as we can with using as clear and plain language as we can, going through all of the complications of all of the scientists and all of the clearance levels; we do the best we can, and we try to improve that every time.

This is the facts about the drug section of the Drug Safety Communication. The only thing that I want to point out here is that as a result of our research, we started adding other important side effects and drug interactions, and that was at the request of consumers.

Additional information for patients, again, this is a section that tailors the information to patients; it's written in plain language, and we try to give additional information in addition to repeating the information that is in the safety announcement. We do that for two main reasons: number one, because when people see tailored information, they may go to that directly without reading the safety announcement section, and because repetition aids learning and memory.

We also have a similar section for additional information for healthcare professionals. This is a higher-level summary for healthcare professionals and provides additional

information that they may need on the clinical side, and then the data summary section points out the scientific evidence; it's higher-level language, but again, we try to make this accessible for reporters and other folks who would be interested in this more in-depth information.

This is just a look at some of the ways that we disseminate the Drug Safety Communications. We know, from our research and just inherently, that people are not going to the Drug Safety Communication or to the FDA website for this information, so we really want to get it out as broadly as possible, and we're doing whatever we can to expand that as we go along.

And then I mentioned throughout this presentation that we're doing some research. Here are some of the projects, and we're continuing to do that with the idea of continuing to improve the Drug Safety Communications. CDER is committed to providing the public with up-to-date drug safety information, and our goal is to ensure that the right people get the right information at the right time.

This concludes my presentation, and the next presenter will be Kate Oswell. She is with CDER, and she'll talk about the risk evaluation and mitigation strategies.

Thank you very much.

MS. OSWELL: Good morning. As Paula mentioned, I'm Kate Oswell. I work as a health communications analyst in the

Division of Risk Management, and I'm going to be discussing the communication tools, if I can get over this frog in my throat, the communication tools used in risk evaluation and mitigation strategies.

So to start, I will be giving some background information about these risk evaluation and mitigation strategies, and this will include how these programs are developed, the audiences that are targeted, and the various components. I will touch on different elements of the programs and communication tools that support these elements. And I will walk through an example to show how a REMS program could be created using possible components and communication tools involved. Finally, I will discuss some of the limitations with these programs and improvements that we have made with them.

So what are these REMS, what are these risk evaluation and mitigation strategies? Well, they are risk management programs that the FDA can require for a drug product or a drug class that the FDA determines that it is necessary to ensure the benefits of the drug outweigh the risks of the drug. These risk management programs go beyond professional labeling, and FDA can determine if a program is necessary either pre- or post-approval of the drug. Now, these risk management programs are designed to achieve specific goals to mitigate serious risks, but one thing to keep in mind is that these programs do not address the overall medication safety or medication

benefits. They are focused only on the serious risk or risks being mitigated by the program.

So before getting into more background detail about these risk management programs and hopefully to help provide more context, I put together an example of what a program could look like. So this would be a program to mitigate the risk of severe drug-induced liver toxicity. So we'd have our target audience: prescribers, patients, and pharmacies.

And for program requirements for prescribers, to be able to prescribe the drug, they would have to have mandatory training and enrollment into the program, perform baseline liver function testing prior to prescribing, conduct liver function monitoring throughout treatment, and have patient counseling as well on the risk and the program benefits.

So patients would acknowledge the risks of the drug and the program requirements, which would be the testing and the monitoring, and they would also receive the counseling.

Pharmacies, they would have to verify -- oh, excuse me. They'd have to have training and enrollment into the program and then verify prescriber enrollment, patient acknowledgement, and that the testing has taken place.

So how are these REMS programs developed? Well, FDA specifies the required elements of the REMS. And although this bullet here seems simple, there are many different factors involved in determining the risk strategies. In fact, there's

an entire draft guidance that's been recently issued on this topic, so I won't be getting into that today. Next, the drug sponsors develop the REMS program based on the required elements, and FDA reviews and approves the program. Each REMS program will have specific safety measures targeted to mitigate the serious risk or risks associated with the drug or class of drugs.

So who is our audience? Well, first, we have healthcare providers. These could be prescribers, pharmacists, other healthcare providers such as nurses, physician's assistants in the office, hospital, infusion center, patients or caregivers. We've even had wholesalers and dispensers. And again, this all depends on the program.

So all REMS programs include communication and/or educational materials to communicate risk information to various stakeholders. We educate about the risk or risks within the REMS, and we inform about the program requirements. Now, depending on the risk of the medication, the program may be more or less complex. Some programs may only have communications sent to a target audience such as healthcare providers, whereas another program may have restrictions put in place before the drug may be dispensed to the patient.

So this slide shows the REMS components from the regulations. So the regulations state that the REMS can include a medication guide or patient package insert, a

communication plan for healthcare providers, elements to assure safe use, which I will get into, an implementation system, explain how the components will work together and will put into place, and then all REMS must have this timetable for submission of assessment so that FDA can evaluate the effectiveness of the programs. I bolded the "communication plan" and "elements to assure safe use" because those are what the communication tools support.

So let's get into what are called these ETASUs, or elements to assure safe use. Again, these are from the regulations. So it tells us what components we can put together when we are developing a REMS program, so you can have one or more of any of these. Prescribers have specific training or experience or special certifications. A pharmacist or other dispensers may be specially certified. The drug may be dispensed only in certain healthcare settings, such as an infusion center or hospital. The drug may be dispensed with evidence of safe-use conditions, such as laboratory test result. Each patient using the drug may be subject to monitoring, or patients may be enrolled in a registry.

So communication tools. Here are some of the communication tools we've used to support the components of our risk management programs: Letters, they're e-mailed or sent by U.S. mail. Fact sheets, basically one or two-page documents that focus on the REMS program and the risk within. We've had

REMS-dedicated websites. We've used informational slide decks or webinars for training. We've had journal information pieces, which would be a one-page piece in a professional journal, focusing on, again, just the REMS and the REMS risks. Training programs, these could be online, in person. Paper-based enrollment forms for anyone that it's necessary for, patients, prescribers, pharmacies, dispensers. We've used prescription authorization forms. These must be sent from the prescriber to a pharmacy before a drug can be dispensed. We've used field representatives and medical liaisons to hand out program information. There have been call centers to provide more information, if necessary, for certain programs. We've had patient counseling tools. This could be a patient guide, this could be a patient brochure, a patient-prescriber agreement -- excuse me, acknowledgement form, a patient continuation form, which a patient would sign to verify that they understand the risk before continuing their treatment. We've used wallet cards for patients, and we've even more recently used apps.

So again, let's go back to our example of a risk management program, look at the components, and then we'll put in some tools that would support these requirements. So again, we have our three audiences and we, just a reminder, real brief, we have training and enrollment for prescribers that require testing; patient counseling for patient, they would

have to acknowledge the risks, the program requirements, agree to the testing and monitoring, and this would be through counseling; and then pharmacies, again, would be trained and enrolled into the program. They'd have to verify all these other pieces, the prescriber enrollment, the patient acknowledgement, and that testing has taken place.

So what types of materials or tools could be used to support healthcare provider education and program requirements? Well, if it's a new drug, we could send letters to the target prescriber, and we could include a fact sheet highlighting the serious risks, a brief overview of the program requirements, including what actions the prescriber must take in order to prescribe the drug. If there is training that's required, this could be online or paper based; it could be, say, a slide deck that's used with a knowledge assessment at the end that the prescribers must complete. And again, this information would have the risks of the program -- excuse me, the risks that the REMS is in place to mitigate, the program requirements, including testing, monitoring, and the counseling, required patient counseling. And then there would be a prescriber enrollment form, and there would be some attestations on that form; the prescriber would attest that they know the risks, they understand the requirements, and they will do these -- they will do the requirements per the program.

So materials that could support patient education for this

program: Well, there could be what we call a patient-prescriber acknowledgement form. And again, this form lays out the risks in plain language for the patient, the program requirements; they would agree to do the lab testing and be monitored throughout treatment in order to receive the drug. This would be signed by the patient and prescriber, and it would be sent to the REMS program and be put on record or on file. There could be a patient brochure, which again would have the same information in there. The healthcare provider could use this brochure to counsel the patient, and then the patient could take this brochure home to keep for future reference, if necessary.

And then the communication tools or materials for pharmacies: Again, they would have some training, could use a similar slide deck to contour the information as needed for the pharmacies, including the risk and their program requirements, so to verify the prescriber and the patient acknowledgement forms have been received and that the testing has taken place. Again, they would have enrollments with attestations as well, to go over the risks and requirements and what actions they need to take to be part of the program.

So here are a few limitations that I put together, talking about the REMS programs. A big one here is that the pharmaceutical industry is responsible for dissemination of the REMS program information. So unlike some of the earlier

communications we've heard from FDA, these communications do not come directly from the FDA, and we've heard feedback that it's difficult to distinguish REMS program materials from other materials sent from industry, such as promotional material. And you can imagine that has increased the difficulty in getting the message out, and the message we are focusing on is on the risk message for these drugs that have these REMS programs.

Another limitation would be the defined deadlines in the review of new products and in the review of any modifications to an existing program. There are typically a number of rounds of back-and-forth between FDA and the drug companies as we work to develop these materials. We both have input, and we both have our internal clearances. Sometimes drug companies use a third party for development of some of their material. So if you have a very short timeline, it's tough to get some things done like -- especially the ability to pretest the materials. That's been a big challenge that we have faced and the drug companies as well.

So another consideration I would add to this list would be balancing the burden of the program with the tools and the strategies that we have in place that have been shown to be a bit more effective. So, for example, a hard stop at the pharmacy where a drug cannot be dispensed without, say, a testing result on file, that might be a very effective way to

mitigate a risk. However, that level of burden might not be appropriate for each REMS program, and we wouldn't want to, say, withhold a drug from a patient unnecessarily because the risk doesn't rise to that level, because that actually could be a risk in itself as well.

So we have made some improvements over the course of time here. REMS letters have replaced the Dear Healthcare Provider letters. We gave it a new name, and we've changed sort of the formatting. We make it a little bit more concise now, risk-focused messages. We took out a lot of the extra language that wasn't necessary to have in a REMS letter as opposed to a Dear Healthcare Provider letter. They're available in two formats now, print and we do send them electronically. And then we also have fact sheets that we've been using more; they either go out with the REMS letters or distributed when healthcare providers are being detailed by the sales or medical liaisons, and that seems to work fairly well to get the message out. They are also available at professional meetings. And again, these fact sheets, just a very concise message of -- the key message of the risks and the program requirements. It's not in-depth like the training would be, if that's required of the program.

So let's see. So we continue to encourage pretesting and post-evaluation of materials. If it can't be done prior to a REMS program being approved, we do encourage them to do it

while the program's in place to make improvements, so that when the assessments come in, we can see what kind of changes can be made to the materials and to the program. And we have expanded the types of communication tools. There are apps now in a few programs for patients and healthcare providers for the required maybe surveys that they must take. In some situations we've replaced medication guides with the patient guide, so it's able to more narrowly focus on the REMS risks and the key messages about the REMS program, again, instead of all the other language.

So this concludes the Center for Drug Evaluation Research presentation on REMS communication tools. Thank you.

DR. BLALOCK: Thank you very much. And I'd like to thank the first four presenters. It's time for a break, so we'll take about a 15-minute break, and we'll take questions, related clarifying questions, for all the presenters after all of the FDA presentation.

So Committee members, please do not discuss the meeting topic during the break among yourselves or with any members of the audience, and we'll resume at 10:15.

(Off the record at 9:58 a.m.)

(On the record at 10:17 a.m.)

DR. BLALOCK: So if I can get folks to take their seats again. And I'd like to call the meeting back to order. We'll now continue with FDA's presentation on external

communications. And just as a reminder, although this portion is open to public observers, public attendees may not participate except at the specific request of the Committee Chair.

So Ms. Butler.

MS. BUTLER: Good morning, and thank you for having me. I'm going to talk today about the Center for Devices and Radiological Health consumer-friendly Class I recall notices, both as an opportunity to demonstrate an instance where CDRH recognized a risk communication need and met it, as well as recognizing the need to continually evaluate and revise that over time and how our FDA Risk Communication Staff was able to help us with some of that research. And there are actually a few members on the Panel here today that were involved in that as well, so thank you.

The Center for Devices and Radiological Health has been doing consumer-friendly Class I recall notices for 12 or so years. A Class I recall is our highest level of risk for a recall where there is a reasonable chance of causing serious health problems or death. As you all, I'm sure, are aware, the FDA does not conduct recalls; we oversee them. The manufacturers are responsible for initiating their recalls and for coming up with a recall execution plan which includes communication. However, the companies are required to inform, but they don't do that in a standardized way. It may be via a

press release; it may be via an e-mail to consignees. It kind of runs the gamut and except where we -- in cases where we really disagree with their message or we notice inaccuracies in our review of their recall communications, we can't really require them to do specific things with their communications. But that is in within our control for our own communications.

And so we made the decision to do a write-up for every Class I recall, in part because following along with how the Center conducts its other postmarket activities, we do that on a risk basis, so it was very important to us to make sure that consumers and people without a clinical background had access to accurate and understandable information about the things that put them at greatest risk.

So in deciding what the template for the recall notice would look like, it was a very long negotiated process, actually predated my tenure. I've been here about 12 years, and as one of my first tasks when I joined the staff was to do these write-ups, and I was told that I had control over the content but not over the categories because those were heavily negotiated and everybody was liking them just fine. And so this is what it looked like, including a very vague category called FDA comments, which was essentially recommendations for what people should do to keep themselves safe and what to do about using or not using the product. However, we couldn't call them recommendations because, as I said before, the FDA

doesn't conduct the recall; the company conducts the recall. It's the company's recommendations; however, we may have added to it.

So we arrived at FDA comments, and you know, we got questions about that a lot: Well, what does that mean? So it was one example of the template being fine but very FDA-focused and FDA-centric in its prioritization. One of the things we hoped that we were doing well was taking into account plain language, health literacy, variances, and the need for unbiased information. I will say, though, that after a number of years of doing this and our staff priorities and work shifting a bit, these were becoming more and more burdensome for our staff to produce, in part because they were chasing after information that wasn't necessarily readily available or necessarily very helpful or important, but it was in the template.

So we proposed revising the template. This is the previous template, and the FDA comment section is below the screenshot, but you know, it went through what level of recall it was, the date that the recall was initiated, which was another point of confusion for people; what did the initiation date represent. We identified the user, the recalling firm. Also, below the screenshot is the FDA district where it initiated, a lot of different kinds of information that, you know, your average consumer or a patient isn't necessarily going to need.

So we proposed revising the template, and we did that in a couple of different phases. You know, best practice and risk communication is to test your messages, to test what you're doing with a representative audience; that's the gold standard, not one that's always necessarily available to us if we want to be both accurate and targeted and also timely. Paperwork Reduction Act constrains us. Funding availability is a constraint.

So part of the story is the creativity and the innovation that the Risk Communication Staff here at FDA has helped to provide the centers with in terms of a testing mechanism, so one of which was the special government employee homework assignment. Drs. Krishnamurthy, Pleasant, and Rimal participated in that with us. I don't know if you even remember, but it was a couple of years, the summer of 2014. So we started with giving them a comparison of -- well, we let them see what our current template looked like and some of the issues that we were having with it and the ways that we wanted to fix it and seeking their opinion. So we sought their feedback, and then we took that feedback, and we revised it based on what they had observed but also based on some things that we wanted to achieve.

Then the second part of that research involved pulling together a cadre of internal testing volunteers, not people who work in CDRH because we didn't want them to have a direct

familiarity with the device recall, but people from other centers who may have been affected by the recall, may have been -- may have remembered seeing it in the news media, may have a family member that was affected by that device, and to give them a chance to look at both the previous template as well as the proposed revision and to get their feedback on it.

So the results of that research were that the testing cadre did find the new template easier to read, they liked the design better, the headings were in conversational style as opposed to the sort of vagueness that we were struggling with in the previous template. The new template makes it clear who is affected and what they should do, still maintain our commitment to plain language, which can be difficult sometimes with recalls for the products that we regulate. Sometimes there is no way to plain-language some of the technical information that's in there, but we at least then try to explain it or refer people to resources where they can get more information.

And the simpler format also helps our multipliers; it helps healthcare providers and the media describe these recalls in ways that patients and consumers will understand them, and it reduces the burden on our staff when people don't understand our communications and then they call into our consumer or industry helpline to ask for a translation of what was supposed to be, you know, a mitigating measure. So that was the result

of the research. As I said, the majority of people preferred the redesigned template; it includes a picture of the device and the packaging so you can more clearly identify the product that we're talking about. Recommendations for further improvements to the template included capitalizing the word "recalls" and highlighting explanation for "Class I Recall," both of which we built in now in a couple subsequent iterations.

Another thing that we're looking at for the future is -- and it's a question for a lot of our different types of communication products -- is when do we close it out? When are we done talking about this? How long do we leave it on the website? How long do we leave it publicly available? What does it mean for a recall to be finished? With medical device recalls in particular, many of the corrections don't involve taking the product off the shelf or out of a patient. We're talking about a lot of implantable devices, and so that's part of our challenge, too, is helping people understand what the word "recall" means. It's a regulatory term, so it's not likely to change, but it can be misunderstood. So this is part of the conversation that we're having right now in terms of how long do we leave that available and how do we communicate it to people when we no longer need to look at this.

Here's an example of the first half of the screen of the new template. You can see it's a lot cleaner, it's a lot more

straightforward, it has the picture, and you can look at other examples on the URL that we provided.

The new template is now standard. We've been using it for about a year. It's been very well received internally and externally; our staff likes it a lot more because it's a lot easier to produce. We don't need to involve nearly as many as people across the center to cross-check our information. It highlights what's important. It reports the states affected by a recall rather than the FDA district, again, you know, giving people the information that's relevant and meaningful to them rather than the things that, you know, we explicitly find important. It presents information in chunks with more white space; again, there's a link to more examples.

And I really do just want to emphasize, again, the value of the innovative approach to the research on this. If we wanted to -- had we wanted to do focus groups or surveys about this and test it with a wider audience, it would've taken us a lot longer to get a result, and I'm not sure that that would have gained us much more than what we obtained through the assistance of the panel members and the volunteer testing cadre drawn from the other centers, which we found helpful not only in this case but we have tested many messages for safety communications and websites and other types of things where it was important to be accurate, targeted, and timely. So it's a wonderful service, and I hope it never goes away because it

really helps us do our best work.

So this concludes CDRH's presentation. The next presentation will be from the Center for Tobacco Products. Thank you.

MR. VENTURA: Good morning, everyone. My name is Jeff Ventura, and I'm the Division Chief for Regulatory Communications at the Center for Tobacco Products. We are not "for" tobacco products, as the name often confuses people. I went down to a conference in Orlando, and everyone kept coming up to me, asking me if I could provide them with packs of cigarettes as I staffed the booth.

So I want to just talk to you about something today that is not as sexy as a lot of the tools that we're using to communicate; it's not social media. It's actually, you know, something that we've had at our disposal for quite a while, and that is e-mail. We are really spring-boarding off of an increasing understanding that the importance of e-mail, and its impact, if used and enhanced, really is formidable. And so, for example, this stat here sort of outlines what e-mail -- in the private sector, they're calling it e-mail marketing. For the sake of this presentation and for government, given that I'm not marketing any widgets, per se, I'm looking, as the Division Chief of Reg Comms, to really kind of take a look at what enhancing e-mail can do for us in terms of communicating with our various constituencies.

Without any promotion whatsoever, our e-mail program currently has 33,000 stakeholders subscribed to it, so this is formidable. We've really attained this without, you know, any push whatsoever, and it started to beg the question for us, if this is how many people are organically interested in what we do at the Center for Tobacco Products, should we capitalize on this by not only enhancing that channel through which they're subscribing currently, but also could we think of other e-mail marketing tools that may capitalize on this interest in receiving information via e-mail?

So in looking at communication, it's important, first of all, to really talk about the fact that what CTP, or the Center for Tobacco Products, regulates, all of our products are, you know, harmful if they're used as intended. So we have a unique role given that all of the things that we regulate carry a level of known risk, specifically e-cigarettes, cigars, hookah tobacco, pipe tobacco, dissolvables, nicotine gels, cigarettes, roll-your-own tobacco, and smokeless tobacco. This alters slightly how we use day-to-day communication channels especially because one of our charters to warn you of the risks of smoking is handled through national advertising campaigns mostly, which is a different division than the one I'm in, versus agency-run day-to-day comms vehicles, which is really what I'm overseeing.

We do, however, use our channels to communicate closely

with industry to mitigate the risk that they are not in compliance with federal tobacco control laws, and with public health advocates to ensure that they are informing their constituencies on our ever-changing and emerging regulatory landscape.

Just in brief, I thought it was beneficial just to kind of take a look at CTP's mission, which is largely spelled out in the Tobacco Control Act, so this is very legislatively driven, but our legislative mandate, you know, really puts us in a position to protect youth, provide information to help educate consumers, provide more information on public education campaigns, ensure compliance with the law, reviewing new products and product changes, and leading cutting-edge research. So there's a wide sort of swath of topics that we are tasked with communicating about. In terms of e-mail enhancement, we are specifically focusing on 2, 3, 4, and 6, so protecting youth is really more of our campaigns division, although we do a little bit of that, and reviewing new products and product changes obviously is sort of a function of our review division, but these other elements certainly fall into the purview of what we're communicating about and make their way into some of our e-mail communications.

Just a bit of background in terms of our e-mail outreach. We've been doing it now for roughly 5 years. We have relied on the GovDelivery platform, although in the past we weren't

taking advantage of the full functionality that GovDelivery offers, so we've really looked more closely at that. And we did a comprehensive analysis that took into account how we could expand GovDelivery, how we could use it to improve basically our fundamental vehicle that we use, *This Week in CTP*, and we really wanted to figure out whether or not there was room to develop other tools as well.

That analysis motivated us to make some significant changes to our program. The maturation of our comms program as it relates to e-mail really ties into the growth of our center. As the Center for Tobacco Products becomes more regulatorily relevant and our regulations impact the lives of more and more Americans, people expect more than just a simple e-mail newsletter; they expect a more sophisticated communications product that's easy to find, subscribe to, and read. So as the slideshow suggests, we made some specific changes with the user in mind.

Here is the profile questionnaire that we added that's basically trying to identify who our subscribers are. We, at one time, knew nothing about these 33,000 subscribers really, and so now when they come in through the portal to subscribe, they're asked to sort of categorize themselves. And the reason that we're asking this is we're obviously looking to tailor some of the communications that we do with them, and we feel like there's a real opportunity to provide them with specific

information.

I would be remiss if I didn't mention that one of the reasons that we're doing this is that in terms of our -- what we are regulating, with the deeming regulation, which actually took place this May, our remit as to what we're regulating, the products we're regulating has expanded, and it's now including a slice of industry that is not sort of big tobacco. So we have a lot of mom-and-pop vape shops and smaller to mid-size businesses that previously had not been regulated. So we really need to understand, you know, how many of these people are actually coming and looking for information and what is the impetus that's put upon us to convey -- you know, to speak directly to them as well.

So with that, we discovered that it was worth making a concerted effort to give our e-mail a facelift, so we are aiming for more diverse e-mail lists and content, better administrative organization, improved process, and enhanced tactical delivery.

We decided that it was important to tailor our content, and the tailoring kind of segments down the line of where we are in terms of our communication strategy. So our communications kind of break down into three pillars: science, because we're supporting a lot of the science around tobacco research; reliance, we feel that the American consumer relies on us for solid information about these products and what their

inherent risks are; and compliance, because we have a large swath of industry, both in terms of big tobacco but also a lot of the mid-size to smaller players that I mentioned who are, in good faith, really looking to comply with some very complicated regulations and where the onus is on us to make sure that they understand what they are.

So as I mentioned, *This Week in CTP* is our sort of stalwart communications vehicle. It's been around the longest, it has the most subscribers, and it's really sort of our straight news vehicle, so think of it as sort of a daily newspaper, although it's not daily and it's actually not even weekly. We call it *This Week in CTP*, but it refers to the moment in time that it comes out. But the growth of this has continued, again, without any promotion, to steadily increase over the last 5 years, and so we really think that it underscores a real appetite and need for the kind of information that we're brokering.

This is newly introduced, so this came out of our analysis of sort of the terrain of vehicles that we're currently using. We realize that we needed some way to go into greater depth, so we came up with CTP*Connect*, which is -- think of it as sort of our news magazine. It allows us to go deeper than the *This Week in CTP* vehicle.

These are our new templates. I mean, I think it's worth noting that prior to this, we were just literally sending out a

text-based e-mail, and now, through using GovDelivery and various in-house talent that we have, we've developed templates that actually have sort of a look and feel and are certainly more alluring and provocative in terms of it makes you want to read these vehicles.

We also use these vehicles to drive traffic back to a lot of the web work that we're doing, and I'm not going to go into that today, but we've been using the same sort of analyses to rework all of our web content so that it's more specific to the audience that's seeking out the information, and this just brings those eyeballs back to our site.

We're already seeing success. We've got increasing success to talk about with our open rates and with our click-through rates, but we -- you know, the metrics are interesting, but we see this and hear this anecdotally that, you know, these vehicles are successful because we actually have a call center that receives inquiries from consumers and from stakeholders, industry stakeholders and public health stakeholders, and time and time again, they're echoing that they're getting this information from our e-mail vehicles, so we know that we're having success there.

Closing takeaways: Aside from the two points listed on the slide, I'd just like to decode some jargon, that we talk a lot about increasing engagement. For us, it doesn't mean just getting our subscriber base up. It's more than that; it's

driving a perception among our stakeholders that we are not regulating in a vacuum. So every e-mail we send out, we feel, fortifies the notion that we're being transparent and engaged as an agency that cares about the public health and is fulfilling our mission on behalf of the American people.

And with that, I'd like to introduce Cariny Nunez, the Office of Minority Health. Thank you.

MS. NUNEZ: Good morning, everyone. My name is Cariny Nunez. I am a Public Health Advisor with the Office of Minority Health.

The vision of our office is very simple; it is to create a world where health equity is a reality for all. Our office aims for all minorities to have access to FDA information regardless of their level of education, literacy, and language proficiency. We are here to make sure that all minorities have information they need in a way that they can understand it. We also want to make informed health decisions. We work across the Agency and with external stakeholders to identify disparities and strategies to address them.

Office of Minority Health mission is to promote the health of diverse populations through research and communication of regulatory science that address health disparities. The key here is focusing our efforts within the regulatory framework, which makes us unique from other HHS agencies.

Our health promotion program: Our research shows that a

vast majority of minorities are on the Internet today, in particular, social media. Social media outreach is amplified through the use of media such as videos and images. We are now seeing that more and more people are relying on social media to receive their information, and that includes the news.

The Food and Drug Administration Safety and Innovation Act, Section 1138 of July 2012, ensures adequate information on medical products for all, with special emphasis on under-represented subpopulations. OMH key strategy is simple. It's meeting consumers at their point of need. This year we created two multimedia campaigns to address critical issues affecting minorities: one was addressing health fraud, and a second one addressing clinical trial diversity participation. One of our key areas is to address health disparities through health promotion. We use several strategies, including developing health education materials, electronic platforms to promote health equity, social media, newsletters, and websites, for example.

What are motivators for these campaigns? Through research, we know that negative messages are looked at unfavorably by consumers, unlike positive messages that have demonstrated to resonate with them. We hear all the time what's wrong and all of the many health issues plaguing minorities, but we want to add a positive perspective and create actionable materials that consumers can use to make

better health decisions. We want to add positive enforcement as to why minority health issues matter. We want to educate consumers about key issues and help stimulate a dialogue among peers and patient-providers.

Our first campaign is our health fraud multilingual campaign, and let me state that this is the first multilingual campaign for our office but also for FDA. This campaign was developed in five languages outside of English. The purpose of the campaign was to develop a multimedia campaign to educate minority consumers about -- to make them aware that some imported dietary supplements and nonprescription drug products can be harmful, because many minorities turn to herbal and natural remedies to treat their chronic disease illnesses.

We developed a series of campaign materials, consumer articles, one 60-second minute -- 60 seconds, sorry, educational video, Flickr videos, infographics, a social media toolkit, FDA Voice blog. We also place infographics on our Pinterest page and internal key messages with Q&As. This novel campaign of FDA has never -- as I mentioned before, has never been produced in multiple languages. For this campaign, we partnered with our Office of External Affairs, Office of Media Affairs, and the Office of Regulatory Affairs, Office of Health Fraud. Materials were translated into Spanish, Chinese simplified and traditional, Korean, Vietnamese, and Tagalog. And for this campaign, we also designed a unique URL where all

materials can be found, including the videos.

The dissemination and promotion of this campaign was launched during National Consumer Protection Week, from March 6th through 12th, the ethnic and traditional media outreach. We did also media interviews with subject matter experts and spokespersons. We conducted a Google AdWords campaign in different languages. We also conducted a social media outreach through YouTube, Flickr, Facebook, Twitter, and Pinterest. We reached out to our stakeholders via our newsletter and e-mails, and we also sent blast consumer e-mails internally and externally to all our stakeholders and partners alike.

VIDEO: Do you use imported dietary supplements or nonprescription drugs? Do you use them because they're labeled in a language you know? Not all imported products sold as dietary supplements or as nonprescription drugs are safe. Some may not work, and others have been found to contain hidden chemicals that could hurt or even kill you. They may claim to be all natural, alternative treatments, or herbal remedies. They promise things like weight loss, bodybuilding, sexual enhancement, and pain relief. Some even claim to treatment cancer, HIV, or diabetes. But beware: Claims like these don't necessarily mean the products work or are safe, and often they aren't. They are sold at ethnic stores, flea markets, gas stations, online, and in many other places throughout our communities. The best way to protect yourself and your family

is to talk to your healthcare provider about safe and effective medical options. To learn more, visit www.fda.gov/supplementsafety.

MS. NUNEZ: Our Google AdWords terminology.

(Spanish video.)

MS. NUNEZ: In-display ads expand the reach of the message through Google, appear in YouTube search results, watch pages, and homepage; also appear in YouTube mobile apps search results, watch pages, and homepage. The Google Display Network, such as the website and Google ads. The impressions are the number of times the ad displays in YouTube. There is no cost for impressions. The view rate is the number of times the ad is clicked divided by the number of times it was seen. Our cost per view is the average cost when an ad was clicked and video was watched. We only pay when the ad is clicked.

So this is a sample of our metrics for the campaign. We had approximately 3.6 impressions on this campaign, and it's important to state that the Spanish video was not only seen here in the United States, but also it went across our U.S. borders. It was seen in Mexico, Colombia, Puerto Rico, Argentina, and Spain. The average duration of the video was 43 seconds. Our impressions -- and which for us was sort of a lesson learned because if we understood that our message must be presented at the beginning of the video, otherwise you're risking to miss your message with your consumers.

Our second campaign was minorities and clinical trials. The campaign purpose was to develop a multimedia campaign to raise awareness around the importance of minority representation in clinical trials to ensure medical products are safe and effective for everyone. The campaign materials were -- we developed six videos, one video featuring our acting chief scientist, Dr. Lu Borio, and five videos that use a patient representative. We also developed a series of print materials: brochure, fact sheet, blog, newsletter, and e-alerts. Our social media campaign was through Twitter, Facebook, Pinterest, and a Thunderclap. We also designed a dedicated webpage on our Office of Minority Health website for minorities and clinical trials and developed a stakeholder communications toolkit.

The dissemination and promotion of this campaign was during Sickle Cell Disease Awareness Week. That was June 13th through June 27. We did also a soft launch a week prior to Sickle Cell Awareness Week. We also promoted the information through Google AdWords again, and we e-mailed our stakeholders the communications toolkit, and we conducted a social media outreach.

VIDEO: I'm Shirley Miller, and I have sickle cell disease. I have participated in clinical trials as a way to get access to promising cutting-edge therapies and treatments before they come to market. This is an important opportunity

to ensure that the benefits and risks are studied in diverse patients like me. With my help, researchers are able to make new medical products available much quicker so that they can help people in our communities. To find out if there's a clinical trial that is right for you, visit ClinicalTrials.gov.

MS. NUNEZ: And this video, as well as the health fraud video, are both available on our YouTube page. For this video, our metrics of ad performance, we saw that we had 7.3 million impressions. Majority of viewers were female with almost 3.4 million of them. And our age group, majority of age group was between 18 to 24 with 9,000 viewers. So that also gave us food for thought when planning our future videos, which are our audiences and who is actually watching our videos.

Our discussion is coordinated across the Agency to develop and promote campaigns. We work with the Office of External Affairs, Office of Media Affairs, and the Office of Hematology and Oncology to review content, coordinate the FDA and HHS clearance process, provide input into content, filter messages through FDA social media accounts, work with external media to conduct interviews and guidance on effective outreach strategies.

Our return investment was high, over 10 million impressions and almost 9,000 views within 1 week; stimulated dialogue around important health issues, increased utilization of our materials. And as a next step, further research can

assess the effectiveness of our materials and outreach strategies through cognitive testing and focus group testing. We are also in the last stages of launching a new video educating Latinos about the importance of participating in clinical trials, and this video is entirely in Spanish; it's the second video that will also be placed in our YouTube page. And a second video targeting physicians and engaging their patients in participating in clinical trials. Our research shows that physicians are not fully engaging their patients; they're not talking to their patients about participating in clinical trials, and it's something that we want to address with them through this campaign.

With that said, please stay connected with us. We have dedicated e-mail, OMH@fda. We also have our social media accounts, our Twitter account, YouTube, Flickr, and Pinterest. And our dedicated webpage at fda.gov/minorityhealth.

And as I always said, there's no "I" in team. We work with a dedicated team in our office. We're a small office, we're very dedicated to our work, and I just wanted to thank our director, Dr. Jonca Bull, for her leadership and support, and also to all our staff. Thank you.

And this concludes the Office of Minority Health presentation.

DR. BLALOCK: Thank you very much. I'd like to thank the FDA for their presentation on their external communications,

and I think that these presentations, you know, definitely gave us a good sense of the wide variety of topics, as well as the communication tools that are used.

So, you know, we have a few minutes if Committee members have clarifying questions. And I do want to remind Committee members that you will have ample opportunity at future meetings to discuss a lot of -- you know, the material that we discussed today, this morning, so if you can limit your questions to brief clarifying questions. So any clarifying questions?

Dr. Pleasant.

DR. PLEASANT: Sorry, couldn't resist. First, before I say anything today, I want to say this over and over again, I love that you're doing this and heading in this direction, and I'm going to remind myself to keep saying that.

Clarifying question: By my count, of the seven presenters, three of them did not talk about testing the comprehension of the material; two did. One said it was something in the future; another one said it was going to be a great challenge. By my count, only one of the presenters mentioned the phrase "health literacy," and frankly, we saw a lot of font sizes and graphics that don't reflect the goals of this effort in some of the presentations. So just what I'd like -- my clarifying question based on that is what remains the greatest challenge to adoption of this sort of approach within FDA, and then how can we help?

DR. BLALOCK: Is there someone who might be able to address that?

DR. RAUSCH: Do I have to turn this on? Can somebody help me? I'm on. Okay, sorry. I can speak for the Center for Drug Evaluation and Research. I talked a lot about the research that we're doing in the Office of Communications. I didn't mention specifically what we're doing. In addition to some of the things that I did mention, we are looking at some comprehension issues. This group and other groups have said to us in the past that we should look at things like trying to identify a way to identify, on our Drug Safety Communications, a risk grading scale, so we're looking at that; we've done that qualitatively. But I would say that the biggest challenge for us right now is the inflexibility of our web content management system and our ability to get some of our information out more broadly than that. As I said, on the Drug Safety Communications, we're trying to disseminate those as broadly as possible, but what we're hearing is that what people want is information that's specifically targeted to them, so they want information.

Doctors are very busy, healthcare providers are very busy; they want to know about the drugs and the safety issues with the drugs that they prescribe and that their patients are taking, and we just don't have a way to do that. Our listservs are broad-based. Because it's the government, we often cannot

even tell who is subscribing to our listservs. So I hope, as we move forward and are able to do some more research into the dissemination aspects of the Drug Safety Communications and our other communications, that we'll start to understand that better and be able to better tailor it.

DR. BLALOCK: Dr. Lipkus.

DR. LIPKUS: Thank you.

First of all, I just want to say I'm really impressed with the amount of work that's been done in all these various programs. It's really just awesome that you're doing this, and the questions that I have, I think, cuts across the various programs, and it kind of follows up on what was just said. A lot of the information plays up on people understanding the facts versus do people understand the meaning of all this, you know, what has been termed just understanding.

And the question I have is, across the different programs, do you have a standard way of pilot testing your participants to ask questions about meaning and understanding in comparable ways so you could actually compare across the various goals that each of the different programs have been trying to do? So that's number one.

And the second question I have is, in some presentations, you disseminate information to pharmaceutical companies, sometimes to providers, and I know one of the goals is for you, as an agency, to communicate more effectively the information

and some of the risks and benefits, etc., but the question is have you done anything that tries to inform the agencies and the people that you're in contact with how they can effectively communicate to their target audience? Because one of the things we know in the literature is that providers, you know, pharmaceutical companies, etc., aren't necessarily very good at conveying risk information and interacting with the public in a way that they get the gist and the meaning of the information.

So those are my two questions. Is there a standard way of pilot testing materials that get at meaning, understanding in a way that could be compared across agencies? And the second one, is there any work towards how do you actually help the public who -- you know, the organizations that deal with the public communicate more effectively?

DR. BLALOCK: And I think, probably for the transcriber, if you can say your name when you start to respond.

MS. NATANBLUT: Sure. I'm Sharon Natanblut, and I'd like to focus on the second question, which has to do with -- part of my responsibility is, in addition to communications, stakeholder engagement, and we have an extremely active stakeholder engagement program that has us really working very closely with the wide range of stakeholders that we deal with on the food side to try to first learn from them about how they -- they know their members. We have consumer groups that we work very closely with, as well as industry, as well as

health professionals, etc. And so what we do is we meet regularly, we meet often, we have large group meetings, we have individual meetings, we get on the phone to them whenever there's an opportunity to find out here's the kind of thing we're going out with, what do you think of it. You know, how can we improve it, how can you disseminate it, how can you get it out a lot further, what should we be doing differently, and that's really been a very important component for us. And we work with our colleagues elsewhere in the program who have other contacts with groups in the Office of Minority Health, for example, in the Office of Health Communications, if they have better contacts than we do or they're having upcoming meetings. So we are always looking to extend our reach. We are always looking to not just assume that our -- what we put up on our website is, in and of itself, going to be sufficient.

We've made a lot of changes to our materials as a result of what we have learned from them. We've made changes in the way we disseminate the information, and I think that it's been one of the most important things that we've been able to do. All of these groups know that when we go out with these announcements, that we want them to contact us. They often call us with ideas of things that they want that they think we should be doing, they sometimes will want us to do things jointly, and we'll evaluate any and all of those options. So I think that's one way we've really been able to improve our

materials, expand our reach, and get a lot of feedback.

Also, I'm fairly shameless at explaining to organizations the challenges that we face in doing focus group research and other kinds of research, and I'm always like, and if I'm not asking you to do this, but if this suits you and you have information you can share with us, we would more than welcome that. And it's been wonderful to see the efforts that these outside groups have gone to, to try and provide us with information.

Thanks.

MR. VENTURA: Jeff Ventura again from the Center for Tobacco Products. I just wanted to add as a footnote, I echo what Sharon said there with regard to relying on stakeholder relations fairly heavily to help explain some of our key messages to our various constituencies. We also are really looking into how we do that digitally, so we have something called the exchange lab that we're using quite a bit now, and our intention is to grow it in its importance. But that is a sort of digital clearinghouse where every communication that we develop, be it a poster or a flyer or what have you, we're putting that into the clearinghouse so that, for example, our local and state stakeholders in the public health arena can then amplify any of those messages.

And with regard to your questions around understanding, I think, you know, although there's no sort of, at least on the

regulatory communication side, formal assessment of that, again we are, through our stakeholder relations folks, in a constant sort of liaison with them to get the feedback from the field from what people are -- you know, what people are saying about whether or not the communications make sense. I personally, as I mentioned earlier, went down to Orlando to staff one of our booths at a show just to get the feedback from the stakeholders that were attending this particular event, and so I think keeping those feedback loops open and encouraging them, although not formal survey work, definitely helps to inform the process.

Thank you.

DR. RAUSCH: And let me just add that a lot of the research that we're doing, although it's focused on the Drug Safety Communication, our goal is to eventually share that, once we have finalized results, across all of FDA so that the communicators can use that information and tailor it to their own needs. So that is our goal; we're obviously focused on the drug side of things because the Center is focused on that, and we are very siloed, as much of the government is, but I think the Risk Communication Staff has done a really good job of trying to bring everybody together. There's been a lot more conversations. We've got a social science forum, we have the group that worked on the strategic plan, and I think we're talking a lot more, and I think all of that really brings us

together and makes us able to share better the information. As far as pretesting, just from my perspective, we're not really able to do that very well because there is the proprietary information with the drug safety issues and the issues with the potential release of that information, so we can't really do any kind of testing in advance. We have worked with the Risk Communication Staff on some things when we have had the ability to do that and not had to turn things around very quickly, but I think that's relatively limited in a regulatory environment.

MS. NUNEZ: Cariny Nunez, Office of Minority Health, and I just wanted to answer to both panelists. Our office have conducted a series of outreach engagements through this year, and as a result of these meetings, we have developed some of the materials that we currently have available. We do take notice, we do have countless conversations with our stakeholders, our community-based organizations, also with our partners from other agencies.

One example is this year we also hosted the first multilingual workshop for our internal audience, and when we started on the planning process of this, what we saw is that there was large interest outside FDA, and we ended opening the meeting to not only our HHS counterpart, but also other federal agencies. We invited them to talk about improving communications for LEP communities, and our limited English proficient communities, and how can we do this better, how can

we address their needs better. We ended up having over 100 participants at this meeting, and it was a 3-hour workshop that was quite successful, and we have decided to do it now, to turn it into an annual event, so we are going to be hosting another, a second meeting in the spring of 2017.

Another thing that our office is doing around -- on better improving communications with our stakeholders and our -- for our consumers, I should say, is to -- last year, we developed and launched the first FDA Language Access Volunteer program, and this program is an internal program to FDA. Right now we have close to 100 volunteers. They're native speakers; they speak around 19 languages. And one thing that we do is we have a translation contract with an outside company, and we send our materials for translation. Once we receive those materials, then we send it out to one of our volunteers for another layer of review to make sure and ensure that those materials are adequately translated, they are also culturally responsible and sensitive. So we wanted to -- we take our communications very seriously for our consumers, and we want to make sure that when they receive this information or the information is made public, it is adequate regardless of the language that has been provided.

Other areas that we're focusing on in engaging with our stakeholders is that we also conducted a symposium this past September with industry and -- around clinical trials, and we

see, as many of you know, FDA carries the bulk of clinical trial studies in the United States. It's not actually NIH. So we convened a meeting in Miami -- it was a 2-day workshop -- talking about clinical trials, talking about regulations, compliance issues, but also talking about recruiting and education and better communicating with the recruiters around this area.

And lastly, around language access, we are -- we're having a meeting on November 21st with our Asian-American community organizations as well as Latino organizations to talk about improving communications for these two communities and how can we do better. And this is part of our language access plan deliverables.

Thank you.

MS. BUTLER: Hi. Very quickly, just to answer your second question from the Center for Devices and Radiological Health perspective, the primary way that we demonstrate to medical device manufacturers how to more effectively communicate with their target audience is through a guidance document. We have a guidance document on medical device patient labeling that emphasizes how to clearly communicate the content that's in patient labeling to a lay and lay caregiver audience, and that's currently under revision; it should go out in draft next year.

DR. BLALOCK: Did anyone else from FDA want to add

anything?

(No response.)

DR. BLALOCK: Then Dr. Berube.

DR. BERUBE: Hi. I do a lot of social media protocol work, and so this is directed mostly at Mr. Bove, but also I think generally the argument that you want to tailor your communications to what the person who fills in the RSS feed gets, have you anticipated maybe designing a personal accumulator so when people enter into the system, they can specify their high-hit potentials, like what they think is the type of material they desperately need? That way you can have -- it's like a news accumulator in the general sense, but a personal accumulator where they can actually establish their own preference levels.

MR. BOVE: Not currently, but there is a giant migration going on with the website that will be hopefully completed next year, so there is talk of different strategic tools that we built into that. I don't know all the technical aspects because I'm not a technical person, I'm a communicator, but there is talk of trying to make the different parts of the website more responsive and more tailored perhaps. So I don't know whether that's indeed going to be included or not, but there is talk of trying to add different parts into the new system; that will be next year.

DR. BERUBE: It's worth looking into. I think the

literature is saying that the personal accumulator reduces the level of frustration, retains people in your RSS feed, and tailors your offering directly to what they specifically need.

MR. BOVE: Um-hum. And that would make sense. I mean, certainly what we've seen already with things like GovDelivery.

DR. BERUBE: Yeah.

MR. BOVE: I mean, it's so very, very specific. You could pick pretty much anything that you want to tailor --

DR. BERUBE: Right.

MR. BOVE: -- for your own needs or your family's needs or whatever.

DR. BERUBE: They need something bigger than an office to click on; you need something really specific.

MR. BOVE: Um-hum, yeah. So I will talk to the folks who are working on the web aspect of it; hopefully it is something that's available.

Thank you.

DR. BLALOCK: And did anyone else from FDA want to address that?

(No response.)

DR. BLALOCK: Dr. Morrow. Oh, I missed -- Dr. Morrow.

DR. MORROW: I want to thank everybody for those wonderful presentations. One thought that kept coming or a question, I guess, that kept coming up across multiple presentations is -- I was struck by, for a given campaign, whether it's about

medical devices or medication or tobacco, the number of different channels or media outlets, opportunities to communicate you use, which I think is great, but there's probably a management issue there where each of these approaches has different affordances and constraints.

And so the difference between a Twitter announcement versus a brief post on an FDA website versus a fact sheet, I guess, presupposes some kind of an analysis of the information you want to convey in terms of how much of it is the gist that has to be conveyed quickly and people have to get that versus, I think, what some of you called the back story, where you got levels of specificity. So when you create a plan for a campaign, is there explicit thought to what information goes out through different channels, and how do you kind of link across those channels to make sure people are getting -- know that it's the same message with different facets of the message?

MR. VENTURA: Jeff Ventura again from CTP.

It's a great question. I think that one of the things that we wrestle with is -- I mean, obviously the reason why there are so many channels in the various centers is because not all the news rises to the level of going out through the Office of External Affairs as a major, you know, press release from the Agency. Yet there's still quite a bit of news with a lot of sort of gradient of detail that our stakeholders, maybe

not all of the American public but certainly our stakeholders, in all of their various forms need to have. I mean, it's a struggle to -- I mean, I think a part of why you're seeing all these channels is because there is that inherent struggle where we've got to get the news out to them, and we can't funnel it all through the Office of External Affairs.

That said, I think that there is an effort under way to ensure that even when we're communicating across these channels we have, we're trying to strip away the sort of silos. For example, I have my web folks, and then I have my regulatory comms folks, and I have my stakeholder relations folks that all work for me in my division, and if I let them all sort of, you know, function in their own little fiefdoms, organically you would see a lack of uniformity in that messaging that you're talking about. But I think if you foster sort of an environment where, you know, a tweet doesn't just happen in a vacuum, that it has to come from somewhere, and regulatory comms has to know about it, and stakeholder relations should know about it if they're communicating with each other, I guess what I'm saying is it's really a human -- it can be a human resources solution that sort of level-sets that communication. That's it.

MS. NATANBLUT: Hi, Sharon Natanblut, the Foods program.

So I think this is one of the most important things that we try to do, and we spend a lot of time going through, from

the day we consider an issue, one that we communicate about. We put it on our comms tracker. We have our comms specialists work with our stakeholder specialists, and we assess for each and every one of these communications what the right mix is, and we do it based on quite a few items. We think about what the goals of the communication are, what the target audience is, what the timing is, what's the level of effort that's needed, how insane we're going to make our lawyers that we want to communicate something. We think about what the appropriate interaction is, and we think about the timing of it.

So just because you're announcing something one day doesn't mean it's a one-time thing. And so one of the things that we may do when we're thinking about it is we will decide what do we want to have out there in advance of the major announcements or an announcement. How do we lay the groundwork? We may have some -- a Q&A on a popular topic. We know that 3 months from now, that topic is going to be something we'll be focusing on, so we may put that background piece out there in advance.

Then we're going to figure out for the day of, what's the information that we want to have, and how does it fit, and that may be a package; it can be, you know, something that involves a press announcement with a media briefing, as well as a press release, as well as a blog targeted to our stakeholders, as well as some Q&A's for consumers that we post on our website at

the same time. And then 2 weeks later we may go out with a consumer update that, at that point, we can quote from some of the key organizations that have had an opportunity to think about what our announcement is and how they want -- what messaging, because we know that validators, consumers, don't just hear from FDA and go, oh, totally believe everything you say, and we're going to do exactly that. We know that it's important to have others giving similar messages. So I would say that's one of the major things that we spend our time doing on announcements big and small. And then we also work with the stakeholder groups to see what they'll be going out with.

We also have to remember that there are some constraints if we're doing a regulatory announcement. If we're taking action against a specific company, an enforcement action, I mean, there are limits also to -- based on time sensitivities, legal sensitivities, and all other constraints. So it's that entire package, that entire strategic analysis of what we're trying to do that is just critical, I think, to the success of the effort.

MS. BUTLER: I just want to say I love the question because a lot of times what we get to talk about is our output but not, you know, how the sausage is made behind the scene, so to speak, and I think it's important because I don't think a lot of people are aware of what it takes to get the information and the different products that we produce on the website or

wherever you may see it.

In CDRH, it's -- I mean, we've worked very hard at developing an extensive coordinated process that involves very comprehensive planning of our communications. So if it's a public health emergency and we need to get something out quickly, we want to be strategic, and we're probably going to communicate through one vehicle only. Situations are evolving, information is changing, and we don't want to have to cross-reference, you know, six or seven different products just to make sure that the information is consistent. We need to get a targeted message out, and we'll focus on getting the message out in the most appropriate, most broadly applicable vehicle possible and then focus on distribution, whether that's Twitter or other social media, patient advocacy networks, provider associations, that kind of thing. When we have the luxury of more time, then we will build in more products, as appropriate, and more multipliers. We may do some advanced testing through confidential disclosure agreements with the professional societies or patient advocacy groups or what have you.

As far as message discipline and making sure that we're as targeted and strategic as possible, we work off of a master document, and we have our key messages, questions and answers that then become the source document for whatever other vehicles may be appropriate, whether they be press releases or some of the other vehicles that my colleagues mentioned. And

we have a pretty extensive system of checks and balances in terms of clearance in each center, as well as the relationship between the center and the Agency-level communication staff, and we need to make sure that everything checks out not only at the risk communication level, but passes through legal counsel and that the right hand knows what the left hand is doing. So that's why also in situations where it's important to be as timely as possible, even the same day in some cases, less is more, you know, because we need to be respectful of making sure that we have the right level of clearances and getting things through quickly.

MS. NUNEZ: First of all, I wanted to say that I echo my colleagues' comments. Our office is a bit unique; we are policy driven but educational focus. And one of the things that we do is, when designing our messages, that we also try to be as strategically about it. And however, when deciding on a message, we look at one message, and we just make the difference on how we're going to present it in the different platforms. We know, for example, Twitter is only 140 characters, so -- and Facebook you have a little more space to disseminate your message. So however, at the end of the day, we understand that our audience is -- they navigate through different social media platforms, and so we want to ensure that regardless of which platform do you use to receive your information, the message will remain the same.

And so also one other thing that we do, and it's our additional layer, is looking -- okay, looking at the language that we're going to present that message to. For example, for sickle cell, we know the sickle cell is a condition that African Americans as well as Latinos are affected by, so our message is not only being produced in English, but we also translate it into Spanish to ensure that our Latino population receive the message and understand it, and so we're aware of what are we doing.

But it will be a disservice to translate it into Asian languages because we know that they are not being affected according to what the data shows. So we also look at which minority groups are heavily affected by the different conditions, and then we strategize how we're going to present it. As I mentioned before, through countless meetings with our stakeholders, we ask what are the best avenues to disseminate this information, and they can -- and using platforms that people don't use is doing a disservice rather than a service to them and to us as well.

One other thing: I wanted to say that, in terms of focus testing, we also have conversations with our volunteers, and we ask them when you look at this information, what do you see? Does it resonate with you? And we take that into account, and sometimes we have -- make something public and have to go back and take it down and revise it and rewrite it to ensure that

our audience really can understand and benefit from it. And we're going to be expanding our focus testing for next year.

DR. RAUSCH: I just want to echo a lot of what's been said already. I talked about one communication tool that CDER uses, the Drug Safety Communications. At the time that it's decided there might be a need to be a public communication about a safety issue, there's a communication planning meeting called that includes members of the Office of Media Affairs. It includes our broader strategic communications team in the Center for Drug Evaluation and Research's Office of Communications. It includes the scientific side, it includes our stakeholder engagement folks, it includes our Office of Constituent Affairs. So it includes a broad group of people that are all discussing what -- how best to disseminate this information. But it also includes discussion of what other tools might be used to augment the message that goes out in the Drug Safety Communications. The Drug Safety Communications, again, is our primary tool, it is the source document for everything else, but we have many other tools including the MedWatch LISTSERV and other things that people look to and media look to, so we try to coordinate all of that and use as many tools as we can.

DR. BLALOCK: Thank you.

And just one final question before the break.

Ms. Witczak.

MS. WITCZAK: Thanks for your presentations. I do this for a living every day, but on the consumer side of things, so I know the -- I respect and understand the challenges.

Maybe it's a question for how you communicate to the public, and I know there's different audiences, but how do you define plain language, and is there like -- is that universal, a class, all the divisions? Is it like eighth grade? Is there something at -- you know, how do you define that? Because I think, you know, some of the videos that you showed do a really great job of communicating to the average layperson, so I think that's something that I'm always concerned about is that. And then who -- and does everybody go through some kind of training to learn this, and is there, like, a person -- because it seems like, you know, knowing that the FDA has a lot of responsibilities, are there -- you know, I'm guessing there's a small number of people that are responsible for a huge amount of communication.

So those are my questions. Thanks.

DR. BLALOCK: And can you be sure to say your name?

MS. BUTLER: I'm sorry.

DR. BLALOCK: Just be sure to say your name.

MS. BUTLER: This is Kris Butler from the Center for Devices and Radiological Health.

You hit on one of the challenges that we're confronting with updating our patient labeling guidance right now, is that

everybody wants us to say is it a sixth-grade level, eighth-grade level, somewhere in between, and you know, some of the more recent research is moving away from reading level to a more comprehensive assessment of what people are coming to the table with in terms of their comprehension ability. So it's a difficult thing for us to pinpoint. We give some broad parameters in terms of, you know, the readability algorithms, Flesch-Kincaid, SMOG, but also counsel that that doesn't get you -- you know, all the way where you want to go. To really measure comprehension, you have to do some sort of testing.

As far as the standard that we hold ourselves to, you know, the government agencies abide by plainlanguage.gov. The Agency and the Department offer training for staff on plain language writing, and that's a requirement for all of our staff in CDRH that work in communication. And you're right, there are only a few of us responsible for a large volume of information. So it's helpful training, but again, we support an ongoing continual professional development for our communicators that involves not only writing ability but really being able to identify and analyze target audiences, health literacy needs, and point them to the resources that are out there to complete the picture.

DR. RAUSCH: Paula Rausch from CDER.

This is something that we struggle with a lot. On the communication side, we understand the value of plain language,

but our content is very complex, the topics are very complicated, the words are very long, and when we've tried to use any kind of a system, for example, that's on Word, we just have a very difficult time trying to narrow that down to lower grade levels.

So what we've done as an alternative, and we're constantly working on this, again, on every Drug Safety Communication that we do, but what we've done as an alternative is try to use that as an opportunity to educate people. So we give sort of a plain language definition of something and then the more advanced definition. For example, if we're talking about -- I can't even think of anything off the top of my head, I'm sorry. But if we have -- we want people to know the medical language because we think it's a disservice to them if they don't know when they hear this other places.

So we do try to -- struggle with that. We're doing a lot of research again, and it's a lot of work with our review staff because there's a lot of concern on the scientific side that when we try to make things too plain language, that they are not exactly accurate. And on the communication side, what we've tried to explain and try to explain every time we deal with this, and it's constantly, is that if people don't understand the information, it doesn't matter how exactly accurate it is because they're not going to take anything away from it. So it is something that we're working on, and I think

you'll find that across FDA with all the communication teams, and that's a lot of what we talk about in some of our group meetings.

DR. BLALOCK: And one final question from Dr. Rimal.

DR. RIMAL: My question was for the Office of Minority Health. I was curious how the two issues that you focused on, which was fraud and participation in clinical trials, how were those two issues chosen over, I guess, many other possible issues, and what's the mechanism in place for figuring out what issue to focus on?

MS. NUNEZ: Cariny Nunez, Office of Minority Health.

For our first campaign on health fraud campaign, we sat down and looked at our two major communities in our groups, I should say in the United States, which are Hispanics and our Asian-American groups. We look at our census data, see how the percentage of these communities are and how they're being affected. And we are in regular communication with our Office of Health Fraud, and we receive their alerts when products are being recalled, when warning letters are being issued to companies and whatnot. Time and time again we see the need for more education with our minority groups.

And so also before joining the Office of Minority Health, in my previous life, I was a public affairs specialist in the field working out of the Florida district office, and that was something in 4½ years that I saw time and time again, our

minority groups being -- having issues dealing with trusting diet companies or dietary supplements that were not exactly trustworthy or turned out to have -- contained active ingredients. So we looked at all that and decided that it may be beneficial to put out a campaign to address these issues with our minority groups. And so through months of conversations and with our other partners, Office of Health Fraud as well as the Office of External Affairs and Office of Media Affairs, the idea came up about doing a PSA around this issue.

We also look at -- we know that people have a short attention span because they're being bombarded with information on a daily basis, so we also talk about less -- try to make these as evergreen as possible, so we can continuously launch it every so often, particularly during the -- Heritage Month, I should say, so people do not forget this information, because doing it only once is also a disservice to the work that we have done and also to our communities.

Our second campaign is part of an initiative that Dr. Robert Califf, our Commissioner, launched this year. Dr. Califf dedicated 2016 to be the year of clinical trial diversity. Our data shows that minority groups are not being enrolled in clinical trials. When we look at our demographics, we see that a majority of participants into clinical trials are white, and if we see people from other groups participating,

largely those studies were not conducted inside the United States; they were conducted overseas in places like India or China and whatnot, so we -- and this is a yearlong campaign that is being conducted, and that's how the idea of producing this video, increasing and educating our groups, minority groups, the importance of participating in clinical trials here in the United States.

DR. BLALOCK: Thank you very much. We're running a little bit long, so I am going to have to sort of wrap things up and -- but I do want to thank all of the FDA presenters for excellent and informative presentations.

So we'll take just a short break and come back at 11:45. And just to remind Committee members, so please don't discuss the meeting topic during the break amongst yourselves or any members of the audience, and we'll come back at 11:45.

(Off the record at 11:39 a.m.)

(On the record at 11:47 a.m.)

DR. BLALOCK: Try to call us back to order. It is 11:47. And if I can get folks to take their seats. And I'd like to call the meeting back to order. So we'll now hear a presentation on the second topic of the meeting, the Strategic Plan for Risk Communication and Health Literacy. And again, just as a reminder, although this portion is open to the public observers, public attendees may not participate except at the specific request of the Committee Chair.

So Dr. Zwanziger.

DR. ZWANZIGER: Thank you, Dr. Blalock, and thank you, all the Committee and our additional consultants, and thanks to members of the audience for your attention to this.

So I'm Lee Zwanziger of FDA's Risk Communication Staff, which is part of the Office of Planning, and I'm going to describe the draft SPRCHL that Risk Communication Director Jodi Duckhorn mentioned earlier this morning.

In overview, I'm going to summarize some of the history of strategic planning for risk communication at FDA and the aims of our current planning process and some of the characteristics of our strategic plan development following up on Associate Commissioner Bertoni's introductory remarks this morning. The main part of the presentation, though, is going to be a tour of the draft strategic plan so that when we get to the final part, the meat of this advisory part of the day, our questions to you, we can all be sure of speaking a common language.

On a recommendation in the early days of this very Committee, we developed a Strategic Plan for Risk Communication called SPRC. It was based on three general goals: strengthen the science that supports effective risk communication; build FDA capacity to generate, disseminate, and oversee effective risk communication; and optimize FDA policies for communicating risks and benefits. We presented it in draft at a Risk Communication Advisory Committee meeting very much like today,

and then in the fall of 2009, after we finalized the document, we put it on FDA's website, and we then monitored it and finally reported on our accomplishments. But we knew that we were going to need a revised and updated plan.

And so we've developed the current SPRCHL to support FDA's Strategic Priority Goal No. 3, and you can find the strategic priority goals on our website, and I also included the table of contents just for your convenience. So we designed it with a view to not only supporting that goal, but from the point of view of what a working group of employees involved in risk communication and health literacy in plain language can do to support the accomplishment of that strategic goal. That's our major aim. We also aim to involve communicating professionals across FDA. And I just want to take an aside to say it's been a huge honor to work with so many totally engaged employees across the FDA to be working on this endeavor. And finally, we aim to use existing resources to implement this existing priority goal and then to track and routine-ize our best practices.

So the target audience for this plan is us; it's FDA itself. But it's certainly no secret, and so we want to be open about what we're trying to do in promoting better informed decision making.

This is a diagram that shows the method we used in SPRCHL development. It's called strategic program planning, which the

Office of Planning has expertise in. The focus of strategic program planning is outcomes, and outcome here is the intended effect or result that is the end state we're trying to achieve by doing whatever we're doing.

So we, first of all, started to get the lay of the land by brainstorming our current relevant activities, and then we asked ourselves what is the Overarching Outcome we could influence currently that leads to accomplishing Strategic Priority Goal No. 3? And then what contributing outcomes would lead to that Overarching Outcome? The answers to those questions lead to our strategic framework. We then asked ourselves what activities lead to the contributing outcomes? And the answers to those questions lead to our implementation plan. And then we turn to what would indicate performance? What can we look at to tell whether we're making any progress toward these outcomes? And the answer to that question led first to our list of performance indicators and eventually to a detailed plan for how to track performance indicators, which is our evolving performance monitoring plan.

So the SPRCHL structure is the deliverables I just mentioned, which were sent to you in your briefing document and are posted on our web as part of the meeting materials here, and they're listed on the slide. Jodi also summarized them. First, we got the strategic framework linking outcomes and activities, and the strategic framework linking outcomes is

really expected to have some staying power because what it's really doing is laying out our risk communication and health literacy mission in some detail.

Again, I mentioned an outcome is the intended effects or results we're trying to achieve, and activity or interaction is the processes that we're going to do to contribute to reaching that outcome. For example, I really like to cook. So if the outcome is a meal, serving a meal, then one of the activities leading to that outcome would be cooking, another would be planning, another would be shopping, etc. But for the activity, general activity, of cooking, maybe an example of a specific action step could be following a particular recipe.

So we went through that and listed the results in our implementation plan, showing the activities that we could undertake to accomplishing the outcomes, and then we worked on our performance indicators, and that's a variable that we can observe to track progress. And finally, we aimed to tie it all together with a narrative. Unlike the strategic framework, the performance indicators, the performance monitoring plan and the implementation plan are things we fully expect to be continually updating as we go along, as some activities get finished and their associated indicators are no longer necessary, or as priorities and our environment changes and we decide we need to change some of the specific activities that we're going to do to reach our outcomes.

So let's look at the strategic framework. Now, the point of this slide is not to read the fine print, the point is to show the overall shape or structure of the strategic framework. Namely, it's a hierarchy. And at the very top of the hierarchy is FDA's Strategic Priority Goal No. 3. The rest of those boxes are all contributing outcomes. And you're going to see them in more detail and a greater magnification shortly.

Please note: We note that in the framework, all the boxes are outcomes. I'll be talking about the top three boxes shortly. The next level of the strategic framework where it starts to branch, you see four boxes in a row, those are our Major Contributing Outcomes, and the boxes below that are other contributing outcomes. Finally, at the very bottom you see circles, and those circles represent the activities that will help bring about the lowest level outcomes. So this is what we expect to pretty much stay in place.

This slide shows the beginning of our implementation plan, which starts on page 12 of your briefing document for this part of the meeting. The implementation plan is where we focus on what we're going to actually do to bring about these desired outcomes. Note that in the left-hand column of the implementation plan, we list the outcomes, the lowest-level ones in our strategic framework.

Here I've just shown outcome Roman numeral I.A, increased accountability across FDA for plain language requirements and

FDA best practices. And then in the strategic framework, for each such lowest-level outcome, you see one or more numbered circles nearby. So the second column here corresponds to those numbered circles, and those are the activities we are recommending to help us get to that outcome, which are written out, not on the strategic framework, but on this table. But still, these activities are pretty general, and so we added an additional column of examples of specific steps. This column lists some specific steps that different parts of the Agency could take to be doing the recommended activity and thereby bringing about the outcome. For example, on this slide, one of the recommended activities is promote plain language awards, but that could be done in a number of ways, and we gave some specific steps that could be undertaken there.

In addition, I'll just tell you that we really tried to include specific steps that we're already being asked to do, both to show them as part of our strategy at the Agency and also to help make them more of our standard operating procedure, like collecting information for plain language and health literacy by annual action plan reports that we turn in to HHS, the Health and Human Services Department.

Finally, we do not for a moment think that our list of examples of specific steps is complete; it's not. These are just intended as examples. Different centers and offices are very likely to come up with different ones, and as noted

before, the implementation plan is a part of the SPRCHL that we do expect to be changing over time.

Let me now direct your attention to the first part of the table of performance indicators, which starts on page 9 of your briefing documents. Again, you'll see the outcomes column on the left listing the states we aim to get to, which are also the boxes in the strategic framework. Okay, at this point we then sat down and brainstormed as many different ways to track progress as we could come up with. We then discarded quite a few of them as being just too impractical for us to do. For the performance indicators that remained, we listed those in the performance indicator column on the right side of this table, and then we further scored these for feasibility; that's in the middle column, which is color-coded and probably shows up better in your briefing document than here.

The performance indicators that seemed like kind of a stretch, we wanted to record them because they're important ways to track progress, but we figured we probably couldn't -- we might have to postpone doing them. These we color-coded as white, and the label is postpone.

Then there are performance indicators that seem feasible but would take some investment, like FDA staff time to develop an internal survey of FDA staff members who are involved in communications. These we scored as feasible but with a caveat that they might not be immediately feasible, and so that color

code is yellow.

And the performance indicators that are most immediately feasible we coded green. You'll see that some of those most feasible green indicators also have an asterisk. Those are just labels for us to remind us that those are performance indicators we're also tracking to report about the HHS Health Literacy Biennial Action Plan.

So one of the points of having a whole lot of indicators is that we really want to do as much tracking as we can manage, but we know we can't do everything, and so we're going to focus on the most feasible measures and probably start with a subset of those and then expand our tracking efforts as much as we can. The details of how we're going to collect information on performance indicators where, when, from whom, that's -- we're recording that in our performance monitoring plan which we're continuing to add to but is an appendix to your briefing document.

So with that orientation, let's now shift back to the strategic framework and turn to what we're asking you to consider. Basically, we're going to ask you to step through the plan, and very deliberately, and consider whether it's adequate. Do the lower-level items support the higher-level items? Do the actions and performance indicators we've identified seem appropriate, and can you suggest others that we might consider, if possible?

So first we're going to look at the highest level of the strategic framework, which is circled in red here and a little more readable here. The very highest level, of course, is FDA's Strategic Priority Goal 3. In order to get there, we recognized that in order to perform better -- promote better informed decisions, we need improved knowledge of the risks and benefits and other important information related to FDA-regulated products by all of our target audiences.

And in order to get to improved knowledge, we asked ourselves what can we, at the working group level, do to bring this about. We thought that what we can do is increase the accessibility of actionable and accurate FDA communication and benefit-risk information. And this we saw as the highest-level outcome that we, in the Risk Communication and Health Literacy Working Group, can directly influence, so this is what we're calling our Overarching Outcome.

What we're looking at in the strategic framework is pathways to our outcomes for risk communication and health literacy. That doesn't mean that nothing and no one else in the Agency may not also be contributing to promoting better informed decisions about FDA-regulated products, but we're looking at where we come into this.

So when you consider these outcomes, could you please help us with these questions? Looking at thinking specifically of risk communication and health literacy at FDA, does the

highest -- does the Overarching Outcome support our Strategic Goal No. 3? Do the proposed performance indicators provide meaningful measurement of progress, and can you suggest others that we should consider?

And before we go on, let me just go back to this slide, and as a reminder, here's the first part of the performance indicators, page 9 of your briefing document; okay, we didn't come up with indicators for Strategic Priority Goal 3 itself, but we did try and develop some for the next outcome, improved knowledge among our publics. Those indicators we recognize could be resource intensive, like doing a large survey, or they could take time to be feasible, like a literature search, which takes some time for literature to appear. So we coded those white, but we also reference some indicators that address the Overarching Outcome, which are the next listed there. The last row with the yellow indicators is for the next part of the strategic framework. But when we're asking you to consider the indicators, we suggest that this is what I would suggest turning to.

So going on to the next part of the strategic framework, we're going to ask you to examine the first branching of this hierarchy. This first branching into four contributing -- four outcomes, these are our Major Contributing Outcomes again and in more detail. Well, actually in less detail but more legibly. They are clear communications -- that is Roman number

I of Major Contributing Outcomes is increase use of clear communication, best practices, and plain language in developing messages; Major Contributing Outcome Roman numeral II is increase use of more targeted messages and communications; Roman numeral III, improved efficacy of -- efficiency, sorry, improved efficiency of internal operations for writing and developing communications; and Roman numeral IV, improved dissemination of FDA's communication and information.

So as you look at that Major Contributing Outcomes level, could you please consider collectively do these things support our Overarching Outcome, and do you see gaps in the support? And do the proposed performance indicators on the table of performance indicators provide meaningful measurement of progress, and can you suggest any others that we could consider?

Okay, for the rest of this presentation, we're going to be talking about the four branches of the more specific contributing outcomes in the strategic framework. And for Question 3, I will ask you to consider each contributing -- each Major Contributing Outcome in turn, I through IV, and for each of these consider the questions, whether the still lower-level contributing outcome support the Major Contributing Outcome and whether there's gaps, whether the listed activities and specific actions for each contributing -- sorry, each contributing outcome implement that outcome; can you suggest

others that maybe we should consider, if possible? And do the proposed performance indicators provide meaningful measurement of progress toward those outcomes? And again, can you suggest others for us to consider?

So taking the branches in turn, let's look first at the left-hand side of the strategic framework, circled here in red. This is Major Contributing Outcome Roman numeral I, increased use of clear communication best practices and plain language in developing messages. And there are three additional contributing outcomes that we identified: I.A, I.B, and I.C, and eight recommended actions to consider as you answer the first round of Question No. 3.

So next, I'd like you to turn to the second branch of the strategic framework: this is Major Contributing Outcome Roman numeral II, and here at greater magnification and still probably easier to look at in your briefing documents, we see Roman numeral II Major Contributing Outcome is increased use of more targeted messages and communications and along with three first-level contributing outcomes and seven still lower-level contributing outcomes and actions identified for each of the lowest-level contributing outcomes. This is the branch where you see the most references to research and to communicating about research.

The third Major Contributing Outcome is next, and at greater magnification here you see Roman numeral III, improved

efficiency of internal operations for writing and developing communications, and along with two additional contributing outcomes and three recommended activities.

And then we'll turn to the fourth Major Contributing Outcome, which is Roman numeral IV, improved dissemination of FDA's communications and information, and this has 4 additional contributing outcomes that we identified and 11 recommended activities to consider.

So again, for each of these four branches associated with each Major Contributing Outcome, to please ask yourselves and advise us about whether the outcomes adequately are supported, do the listed activities and sample actions seem appropriate to implement, can you suggest others? And again, for proposed performance indicators, do they provide meaningful measurement toward progress, and can you suggest others for us to consider?

So moving forward, today we're seeking Risk Communication Advisory Committee advice on this still draft of SPRCHL. After we receive your input, we will expect to modify that draft and then return again to FDA leadership for their clearance. And finally, when we have finalized the document, we'll publish it on the FDA website and then execute and monitor.

So thank you in advance for your advice, and thank you right now for your attention.

DR. BLALOCK: Thank you, Dr. Zwanziger.

So I'd like to open it up for clarifying Committee --

clarifying questions from the Committee.

(Off microphone comment.)

DR. BLALOCK: Yeah, after lunch we will -- you'll tackle all of the questions that have been, you know, posed to the Committee, so this is some time set aside just for some clarifying questions.

So Dr. Lipkus.

DR. LIPKUS: So one of the things that I noticed a lot when you talk about health literacy is you seem to relate plain language with health literacy. So how are you defining health literacy, because health literacy can include numeracy, it could include graphical literacy, which is now becoming more prominent; so how are you viewing that as a whole?

DR. ZWANZIGER: I'd say we're -- am I on? I'd say that we are looking at all of the above, depending on the context, because we're aiming at a situation where viewing health literacy as -- where the audience of the communication, where -- whoever is the target audience can find and can use the health information they need in their situation, and sometimes that's going to take numeracy, and sometimes it's going to take textual literacy, and sometimes it's going to take graphics, depending on what our target audience needs and the kind of message we're trying to communicate. So clear communication would probably be a pretty reasonable synonym, but we're certainly talking in a health context at FDA, so we stuck with

the term "health literacy."

DR. BLALOCK: Dr. Yin.

DR. YIN: I have a quick question about the scope of the plan. Are issues of limited English proficient patients part of this in terms of language access or in terms of plain language translations, or how should we think about those issues?

DR. ZWANZIGER: That's -- first, yes. And if we turn to the implementation plan, and it will be a couple of pages into the implementation plan, one of things we're looking at under dissemination is to continue to support FDA's language action plan, which is run out of the Office of Minority Health, addressing issues of limited English proficiency. So we're seeing that as a part of dissemination and addressing it as important actions and then specific action steps.

DR. BLALOCK: Dr. Liu.

DR. LIU: Thanks for your presentation on a very complex plan. When I read it over the weekend, I was curious about timing, and when we start measuring success, we also know the time frame when these things are going to happen, so maybe talking about the yellow items, the ones you think are reasonable and whether you've given some thought into how much time you helped to implement all of this.

DR. ZWANZIGER: I would say that -- first of all, let me emphasize that the strategic framework is probably not going

to -- we see that as really having staying power, that promoting better informed decisions about FDA-regulated products is not something we can finish and stop and move on; we're always going to be doing that. And so this plan is something that we said, okay, given -- now that we've -- first of all, we had to develop the strategic framework, but now that we've got that, what are some actions that we think we can take in the next 1 to 3 years and take a look at measuring, through those actions, progress toward our outcomes. However, let me again caveat that with the implementation plan and the performance indicators are things we expect that we may have to change as either we finish things or as the environment changes and calls on us to do different things.

DR. BLALOCK: Dr. Lee.

DR. LEE: Yeah, as I was reading this over the weekend, I was actually pretty impressed with the overall scope and your attention to literacy and communication. One thing that kind of stood out for me, though, was that the assumption that increased accessibility leads to better informed decision making, and I think there's a jump there, and you know, when I -- I look at medication instructions every day, and when patients look at which medicine to take or whether to take it, they look at the side effect message. The longer it is, the probably worse it is. But it doesn't look at the relative frequency of and the severity.

So I was trying to think of a way to express this, and your concept of a recipe made the most sense to me; that is, if you go to the supermarket you, say, get lettuce, tomato, whatever, versus getting one of the salad packs. So if you can present the information in a form that's more consumable to make decisions, I think, would be more effective in terms of jumping from the overarching goal to the Strategic Goal No. 3. So the issue is have you looked at how people actually make informed decisions based on the content, and could you format the content in a way that's easier for them to more quickly make decisions?

DR. ZWANZIGER: Great comment, great questions; thank you. I would say that where we're looking at that probably the most is actually further down in the strategic framework in Major Contributing Outcome No. II, where we're trying to make room for us to do research on our target audiences to figure out what information do they need, and how can we give it to them in a way that is most usable for them to make those informed decisions. So that's where I was seeing it come in. If you see gaps other places, though, including this, that's the advice we really would love to hear.

DR. BLALOCK: Dr. McBurney.

DR. McBURNEY: Thank you very much. I think this is really interesting and huge, and I commend you for the effort that you've done. It seems to me there is sort of many layers

to this onion, and that's sort of just how do you strategically prioritize? Because one is sort of assessing FDA's efforts to change and to change in their accessibility, their plain language, their interagency communications. The second then is to measure your engagement with your target audiences, and that's internally, that's patients, that's consumers; there's lot of different target audiences. And then the third is sort of their understanding and seeing whether health literacy is changing within that community, which I think is way bigger than the FDA's task.

So you have all of these outcomes, but you sort of have priorities and measurements of how you want to measure your own internal progress against -- or your own progress against these, and then your measures of engagement with those and getting that feedback loop operational.

Thank you.

DR. BLALOCK: Dr. Kreps.

DR. KREPS: I really applaud the scope of the strategic plan. I was wondering if there was -- as part of this, there were plans to do ongoing tracking and analysis of all FDA communication efforts, as well as the efforts of their partners who often will not communicate for FDA. I think having those data would be critical for assessing whether or not you're achieving your goals and tracking over time. And if it's not there, then I would recommend it.

DR. ZWANZIGER: Thank you. What's there now, I mean, we certainly are trying to expand our ability to track FDA communications with respect to use of health literacy principles and plain language principles. And we're also aiming to expand our engagement with partner groups. So yes, we're trying to include that, and if you have suggestions about how we can do it more and more easily, that would be great.

DR. BLALOCK: Dr. Hallman.

DR. HALLMAN: So thanks very much. You're not going to like this question. So starting with the Priority Goal 3, I think it's important -- well, let me -- so let me pose the question. So the Strategic Priority Goal 3 is promote better informed decisions; it's not promote better decisions. And it struck me this morning that, you know, in a number of the communications, there's specific advice that's given, and the measure of success would be whether people actually took that advice, you know, got the recall information and didn't eat the product or, you know, returned the medicine or whatever. In other cases, really the job is to simply provide information and let people decide on their own what the right decision is. And I don't see a lot of differences, necessarily, in terms of measurement of success. So I'm giving you the opportunity to sort of clarify that really difficult issue.

DR. ZWANZIGER: Okay, I'll have to disagree with you. I love the question. So Strategic Priority Goal No. 3 addresses

the entire Agency's efforts, and some of those efforts, as you say, start with a presumption that there's a better answer for health, and others recognize that what is an appropriate -- with a more appropriate answer for one patient or consumer, it might be different than another patient or consumer depending on their individual circumstances, and we defer, of course, to healthcare professional judgment in, you know, such cases any time there's a learned intermediary involved.

Strategic Priority Goal No. 3 sort of aims to include all those possibilities. And then within the strategic framework and our recommended actions, we're trying to allow for those different possibilities in different centers with their different missions, sometimes under different parts of the law, certainly different kinds of products and different health situations among their target audiences to address that. So it's a hugely important question, and the answer is going to be in the details depending on what the different situations are.

DR. BLALOCK: Dr. Berube.

DR. BERUBE: A few things. First, having done multi-objective optimization maps, congratulations; this is a lot of work. Secondly, everything here has value even in -- if the entire thing implodes one day, I think you've learned an incredible amount about how this entire operation works.

My concern is with II.B, which I think is a fulcrum point in the mapping, which is the increased skills and abilities of

FDA staff to develop accurate and actionable communications. I mean, this is a fulcrum point, and when you look at the breakdown, you have two rather conservative recommendations about how you would want to do that. Now, I sort of read tension where tension may not be, but it seems as if you're incredibly conservative here and that you may have had aspirations to take this a step further because it also has a weird relationship in your map, to be honest, right? I mean, it's given a unique setting in the map. I just wonder if you could chat a bit about where you wanted to go with this or -- I'd like to know where you wanted to go with this because it seems like it stopped.

DR. ZWANZIGER: Okay, let me -- I just realized I'm looking at the wrong slide, so II -- I'm going to turn to the --

DR. BERUBE: To be or not to be? II.B is number 19.

DR. ZWANZIGER: Um-hum.

DR. BERUBE: Increased skills and abilities of FDA staff to develop accurate and actionable communications.

DR. ZWANZIGER: Yes, okay. So you're right, it does have a slightly odd position in the strategic framework, and we did have discussions internally about, you know, how can we really claim to pull off our aspirations of Major Contributing Outcome No. II if we don't also look at increasing our own skill, so we try to acknowledge that by doing so. And, of course, we're

also aiming to find ways to achieve these outcomes that we, ourselves, have direct influence over, and so that affected what recommended actions that we selected to put in the plan.

DR. BERUBE: Can you explain direct influence over?

DR. ZWANZIGER: Well, for example, we can't -- okay, just to take a very hypothetical situation, we could probably achieve some efficacy if we mandate in everybody's performance, employee performance plans, that they achieve certain outcomes with plain language and health literacy. But that is not something that a working group can do; that's something that a supervisor decides for and with an employee, so we -- it came up in discussions, and it went down in discussions because that's not something we have direct influence over. We can suggest things, we can suggest that members, that employees think about it on their own for how to include it in their work, but we can't tell FDA supervisors what they're going to do in FDA priorities.

DR. BERUBE: Point taken.

DR. BLALOCK: Dr. Bertoni.

MR. BERTONI: This is Malcolm Bertoni, Commissioner for Planning at FDA, and I wanted to chime in and add to what Lee has said. I think when we say that the framework is more durable, it won't change as much over time, let's not overemphasize that aspect because this is a first iteration, and planning is an iterative exercise, and I think you've put

your finger on a very, very important issue. The working group, in developing this, did not want to overstep their bounds, and they're really -- I will say it -- maybe they didn't directly.

There is something about FDA culture where the different programs are very strong, and they regulate their different products with the authorities and the resources that they have, and when you go about doing a central plan like this, you have to pull together a lot of different interests, and it's very, very difficult to put something out there that is going to have resource implications, and this is, as you pointed out, a real fulcrum point where there probably can be more done. But in this first iteration, I gather that the work group didn't want to take that on in a stronger way; that does not mean, in future versions, we won't build that out further and dive a little bit deeper. But I think it's good, in these conversations, to sort of surface these kinds of challenges where it's just very difficult to have a uniform approach to this kind of problem.

Now, in our defense, the last thing I'll say is that each one of the programs can take this and then build it out and set the priorities for their own center or office as appropriate, even though we may not have specified more detail at the Agency-level plan.

DR. BLALOCK: Thank you. Dr. Dillard.

DR. DILLARD: Let me join in the chorus of voices congratulating you on the ambitiousness and thoroughness of your plan. One of the things that is -- that I find particularly attractive about it is the hierarchal nature of it. It clearly reflects the fact that reality is experienced in little pieces, and those little pieces build up into bigger things.

But your diagram also suggests to me that there may be something that's been overlooked, which is that the performance measures are at that microscopic level, and that's certainly valuable information, but there aren't performance level indicators at higher levels. And it strikes me that, as you move up to your top three boxes there, you may be concerned with issues such as whether or not the American public perceives the FDA as a credible and trustworthy source, whether or not the American public believes that they are making good decisions based on information they receive from the FDA, which suggests to me a different kind of performance measure, something like a national survey.

And so the general point is maybe we need to consider performance indicators at multiple levels, and the minor point is maybe a national survey that you conduct every year to see how you're doing.

DR. ZWANZIGER: Yeah. Actually, maybe I should -- if thinking about -- oops, there I go -- performance indicators,

like one of the things we were imagining for the middle one of the top three boxes, improve knowledge of benefits and risk, would be a study, probably multiple surveys of knowledge of important information of FDA-regulated products, and we see that as really important but really resource intensive. And maybe I'm hearing your question and suggesting we might want to add other surveys to our study wish list here of perceptions of FDA information and maybe other things, and you know, any suggestions you have all afternoon, we'd love to hear them.

DR. BLALOCK: And we're approaching our lunch break, so I think I'm going to take one more clarifying question from -- oh, did you have something to add?

MR. BERTONI: Malcolm Bertoni.

I just had one quick comment. There has been an attempt and acknowledgement that we do need these higher-level outcome measures at -- and I think on page 11, it's not very clear, but there are some places where we've gone up a level, but I think we need to do more work at that. That is something we encounter on other kinds of plans where the expense and the long-time horizon for measuring those really important national-level outcomes is something that we take seriously. We partner with other agencies, we look to things like Healthy People 2020 is another place to do that, and it's something that we'll take a closer look at based on the recommendations of the Committee.

Thank you for that.

DR. BLALOCK: Thank you.

And one more clarifying question from Dr. Pleasant. And then I've actually got a couple other folks on my list, Dr. Rimal and Dr. Lipkus. And so we'll come back to those before we start the more in-depth discussions after the public comment session and after lunch.

So Dr. Pleasant.

DR. PLEASANT: Thanks. Last question before lunch. No one will remember it. Sorry, but it's -- I'm going to do it quick, but it's still a three-part. It's just -- again, I love that you're doing this, but I have more questions and comments. I could take the next 4 hours, I kid you not, so I'm going to limit myself, but I don't think this is a sufficient amount of discussion among the members of the Committee for something so significant, at least potentially so. Just to say that.

So I do agree that there is probably a need for a further level of detail here that isn't really addressed in either the framework or the report. I think you can do that without limiting yourself and removing that adaptability to future changes, and it would be oh so helpful to have. I just wonder how much you discuss that, (A). To reinforcing this, what you're really asking for is change of internal FDA culture, and the methods to achieve that are not addressed at all. I understand the hesitation, but that plus other things like the

gap between what people know and what they do leaves an incomplete vision, which means it's going to really be difficult to change culture when people can't see that whole, at least 80% or 90% of a plan laid out in front of them.

And then finally measuring effects versus measuring inputs is really lacking on the most part, too. And I think that's where you're going to get sustainability, by showing that you've actually changed the world. And just a subtext to all of that is the difference between tailoring and targeting. Your report language uses target at least 10 times more than tailor, and that should probably be quite a different balance from a health literacy perspective.

And I'll stop.

DR. BLALOCK: Yeah, I --

DR. ZWANZIGER: I'm not totally sure. Is that, I mean, should I -- I mean, I guess I would see -- I certainly acknowledge that culture change is huge, difficult, and ongoing, but this is culture change. I mean, having the whole Agency do this together is part of that, and having the whole Agency see themselves as part of this plan, there isn't -- well, I don't know if I should be universalistic and say there's nobody, but most parts of the Agency wouldn't see themselves everywhere in this plan, but if everybody sees themselves as somewhere in this plan, as part of this plan, then that's seeing the risk communication and health literacy

effort as an Agency effort that we're all contributing to, which, in theory, of course, anybody would have said that, but now we've really thought through it, and so I think this is part of that culture change. There's no doubt there's, you know, much more that -- there's much more to be done, I'm sure, and your advice will be welcome.

DR. BLALOCK: And so we're going to go ahead and, you know, break for lunch, but I did want to, you know, clarify that, you know, there will be lots more time this afternoon to discuss each of these boxes in a lot of detail, and this short amount of time was really just intended to allow, you know, Committee members to ask something that was truly unclear from the presentation so that when we begin, you know, the real in-depth discussion later this afternoon, that everyone would be on the same page.

So let's go ahead and break for lunch, and Committee members, please don't discuss the meeting topic during lunch amongst yourselves or with any member of the audience, and we'll convene in this room exactly at 1:30, and so I'll just ask all the Committee members to return on time.

Thank you very much.

(Whereupon, at 12:33 p.m., a lunch recess was taken.)

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

(1:31 p.m.)

DR. BLALOCK: Okay, I've got that it is 1:31 now, so I'd like to call us back to order and resume the Committee meeting.

So we'll now proceed with the Open Public Hearing portion of the meeting. Public attendees are given an opportunity to address the Committee, to present data, information, or views relevant to the meeting agenda.

And Ms. Facey will now read the Open Public Hearing disclosure process statement.

MS. FACEY: Both the Food and Drug Administration and the public believe in a transparent process for information gathering and decision making. To ensure such transparency at the Open Public Hearing session of the Advisory Committee meeting, FDA believes that it is important to understand the context of an individual's presentation. For this reason, FDA encourages you, the Open Public Hearing speaker, at the beginning of your written or oral statement, to advise the Committee of any financial relationship that you may have with any company or group that may be affected by the topic of this meeting. For example, this financial information may include a company's or a 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: And for the record, there were no written comments received. For today's Open Public Hearing, we've received three requests to speak. Each scheduled speaker will be given 8 minutes to address the Committee. We ask that you speak clearly to allow for an accurate transcription of the proceedings of the meeting. The Committee appreciates that each speaker remains cognizant of their time.

So the first speaker is Samantha Watters with the National Center for Health Research.

MS. WATTERS: Hi. So thank you so much for giving me the opportunity to speak today. As you mentioned, my name is Samantha Watters. I'm the new Director of Communications and Outreach for the National Center for Health Research. Our center conducts and scrutinizes medical research to determine what's known and not known about specific treatment and prevention strategies. We don't accept funding from any companies that make medical products, so we can be unbiased while focusing on a patient-centered and public health perspective. We then translate that complicated information into plain language so that patients, consumers, media, and policymakers will understand it.

My background is an unusual one. I have degrees in

biochemistry, English, and public health, with a focus in health communication. I've also written health communication materials for the NIH. I'm well aware, as I know you all are, too, that great scientists don't necessarily know how to communicate that science to the public. So that's something that our center constantly struggles with and I know the FDA does as well. So after reviewing the draft plan and numerous current FDA documents and communications, our center has several comments that we would like to make.

First, we feel that FDA staff needs -- FDA needs more staff who are extensively trained in plain language communication and truly understand its value and importance, which is part of that culture change that was mentioned earlier. This means going beyond the standard computer course training that a lot of government agencies do, that everyone has to take and no one really reads. FDA materials do not seem to reflect best practices in health communication currently, though obviously the plan is in place to try to address some of those issues. So it's good that you recognize that there is room for improvement. Our center does feel that FDA's Office of Women's Health seems to do a better job of communicating to patients specifically, so other staff at FDA could possibly learn from them, as well as colleagues at the NIH, who we feel does do a pretty good job.

Second, you mentioned consistency in branding, formatting,

and communications coming from the FDA, with an understanding of all your potential communication channels. This is good. But while consistency is important, we recognize that tailoring your message to your target audience means varying format as well as varying method of dissemination. Many of your current educational materials are not easy to find online and are not readily accessible, and those that are easy to find are not always that easy to read. A lot of people don't like to read at all or don't read well, which is the health literacy issue that you see, but just in general, literacy as well. That's why it's important to communicate risk information at the eighth grade level, as we mentioned earlier, obviously recognizing the challenges that we discussed earlier as well, that the FDA has.

Third, FDA communications to patients: We feel they need more graphics and fewer words. Just adding a graphic, as well, doesn't necessarily help if it's still full of words, too busy or confusing, or not colorful and engaging. This is always going to change, obviously, based on the age of your audience as well. So size and color of font, both on paper and on a screen, is going to be crucial, especially for an aging population. There's also a tendency to include a lot of information because we know there's a lot to know on all of these topics. However, the more focused your piece can be, the better. The more complicated it is, the less likely someone

will either read it at all, let alone retain what they've actually read.

Fourth, one of the major problems that we've seen for FDA communication is how it's increasingly become promotional rather than providing objective information about the products that the FDA regulates. Academic researchers have been studying FDA press releases and other materials and concluded that FDA press releases are often used for promotional purposes and that doctors and patients misunderstand that content. The underlying message for FDA press releases seems to be that the FDA has done something wonderful by approving a new product and that the company has done something wonderful by getting this product on the market.

Information about risks and restrictions seem like they're downplayed. For example, the FDA approves drugs through the breakthrough pathway, and the use of the term "breakthrough" in press releases makes the media and the public think that it's the best drug available. However, FDA doesn't convey that there are a lot of unknowns about breakthrough drugs, which are often based on smaller, short-term studies of surrogate endpoints and outcomes rather than clinically relevant benefits.

Sadly, when drugs and devices are found to have life-threatening side effects, FDA isn't always likely to send out a press release to warn doctors and patients in a way that

gets their attention. For example, if a product has a brand name, it should be prominently used in the warnings so that patients will know and understand what you're talking about.

So the slides that I have are an example of this. So an example of this would be Infuse bone cement, which is approved in adults 18 and older but contraindicated for children who are still growing. However, it did get used; it was used in spinal surgery with children because the risks were not well understood, and several experienced cranial swelling so severe that their faces became terribly engorged, requiring additional surgeries. So the photos speak louder than my words can. So these are examples.

And then the next slides are current FDA warnings that -- this is the language that the FDA provided years later to warn doctors and patients, and it's still not quite as strong as we would suggest, given the warnings: Carefully consider benefits and risks before using products in patients; closely monitor under the age of 18 for adverse device -- we don't feel it was a strong enough warning.

Similarly, FDA needs to do a better job of preventing misleading information and inadequate explanations of risk in direct-to-consumer advertisements as much as possible, obviously.

Requiring companies to list risks doesn't necessarily tell patients what they need to know, since most patients will not

have the health literacy to understand those risks. For example, commercials that start with a list of warnings -- don't take this drug if you're allergic to it -- it's a surefire way to get viewers to turn out -- to tune out because it's so obvious. This is also true when listing effects of a drug in a press release on labels that are required for all prescription drugs. The way that those risks are rattled off, it doesn't really convey the severity, and it doesn't really seem like you want patients to read that information and really understand it.

So that's really what I have to say, and thank you so much for the opportunity to share it with you.

DR. BLALOCK: Thank you very much.

Our second speaker is James Duhig, Dr. Duhig, with AbbVie, Inc. I may not have pronounced that correctly.

DR. DUHIG: No.

DR. BLALOCK: So you can correct me.

DR. DUHIG: No, it was right on. Thank you. I'm Jay Duhig with AbbVie Patient Safety Pharmacovigilance Group in Safety Decision Analytics. So thank you very much to the Agency for conducting this meeting and for the service of all the Committee members, and for making this open and public strategic initiative so that we all have the opportunity to learn from the discussion and the advancement of risk communication science and to how and where it can best be

applied in service to patients.

I work with graduate students at Northwestern and the University of Illinois College of Pharmacy, and what we've been talking a lot about lately is everything that they'll see on the web, in ads or anywhere else, both from industry, from provider organizations, along with the concepts of patient centricity and patient engagement. And as a risk communication person, that being my background, we try to get them to engage with -- to go from patient engagement, patient centricity sounding good to actually having meaning requires a meaningful discussion and a strategic approach to risk communication and health literacy. So I hope that they're viewing some of these training links today. I invited them to also participate. I told them if they had any great ideas, I'd be very happy to bring them to the Committee and represent them as my own. They understood me or knew me well enough that none came in, but they did have one abiding question that I'd like to get to at the end.

So a brief case example that I'd like to cover, because I think it's instructive and helpful for the Committee's discussion, along with the Agency, regarding one thing that's working well within risk communication and health literacy at an organizational level. And again, that's kind of how I'm hearing it throughout and consistent with the FDA's mission and service to the public: one thing that's working well, one thing

that can potentially be improved, and one thing again where we need help on, and these are specific to human factors and the regulation within drug product cycle and combination product and medical device product review cycles and the Agency's role there.

Over the past 5 years, both CDRH and CDER have had a remarkable impact across the industry with respect to patient centricity with encouraging sponsors of applications to think through the risks to patients, the product that the patients will have on their kitchen table and all the associated labeling in front of them and how it will be used in the appropriate use environment, so getting at this real-world concept and doing so in a complementary method that is typically outside of a clinical trial and yet can be done on a very quick basis or on a less burdensome basis than we might associate with a larger trial that would trend towards an outcomes-related study. And that's really where I think the principles of user-centered design and human factors have had a terrific overall effect on product development with respect to some of the issues that the Committee was talking about earlier: evaluating comprehension, having patient understanding, and measuring the impact of messaging upon individuals' actions.

So what's going well -- and again, I think that this is exemplative of where the Agency can have a tremendous effect,

is by making recommendations upon best practices with a focus towards not just those practices as activities, but embracing the science. And I think we've seen that happen very well from both CDRH's human factors premarket evaluation team, the device side, then also within CDER Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis on the drug side, and then meeting together for advice and recommendations on combination products.

The response over the past couple of years on the industry side is that labeling, packaging design, so many product design considerations that previously, if they weren't, didn't have the regulatory requirement being taken into consideration for human factors, are now brought in. So what that does is help and encourage all sponsors and manufacturers to think through who people are that would intend to use the product, what they're actually going to be doing, and then how they're going to be doing that, where they can get hurt, and then eliminate those risks by design.

Now, I'm not saying those issues weren't happening before, but the difference now is the evidence base that's generated, and that's hugely helpful in conversations when we're looking at the overall benefit-risk. It also gets us at that point of when we're evaluating comprehension or overall use of the product, taking patient perspective, and continually, through the process of design iteration, move ourselves towards a point

of optimization. So that's working really well at an organizational level, and I think that that's something that can be -- that's working well there on the outside; that can be reapplied in some instances to the Agency itself on the inside.

One of the watch-outs that happens within that process is the swim lane effects, and this is as true at AbbVie or any other large organization, and presupposing that it could also be true at FDA, so because of are all groups aware of what other groups are doing when they have a common purpose or if they have a common goal. So if we're talking about patient labeling or looking at embracing plain language and what that means, if that's being applied by different organizations or different parts of the FDA that have a similar mission but are applying those principles in a different fashion, what you can wind up with is competing reviews or competing expert information.

And again, I'm saying reviews because that's within our cycle of specific products, but it's just as applicable to any external communication. And I think it does get at that idea of when we're looking at making this type of cultural change that's been talked about this morning, one of the most important pieces that we've seen with this and had success with is not embracing a series of activities, but embracing this as the science and the platform of why we are doing this. And that can be, again, hugely helpful.

The last point that I'd like to leave for this afternoon's discussion is where we need help, and this is one of the first things that came up in conversations with Northwestern healthcare communication students is they're looking at all the different information that's coming out and that would be in front of someone, so everything that they would receive from the company, from the FDA, from all the different provider organizations, and it's a lot of stuff, and how are they going to make sense of all of this stuff?

So I think an important point of this goes back to the Agency's work on communicating risks and benefits and towards points that were brought up on usability. There has to be a limit. You can't flood people with an overabundance of information. That's generally just simply not functional. And in that case, if everything is in, nothing is out, and it's fine, but it's not usable. Where we very much appreciate increased Agency guidance is that benefit-risk conversation of how we can increasingly highlight the product benefits and overall health benefits in context with risk in a more usable fashion.

Thank you.

DR. BLALOCK: Thank you.

And our third speaker is Laurie Myers with Merck and Company.

MS. MYERS: Thank you.

So my name is Laurie Myers, and I'm the Global Health Literacy Director at Merck. I've had the privilege of focusing full time on health literacy for the last 6 years. So along with the disclosure, I am an employee of Merck, and they did pay for my travel here and those kinds of things.

I want to talk about a case study and how we really thought about making sure that risks are clear, particularly to patients with low health literacy. And so patient labeling we've talked about a few times, but the reason that's so important is it's the foundation for all other communications about our medicine that happen to patients later, right? So whether you're talking about direct-to-consumer advertising, whether you're talking about your website, or whether you're talking about your print advertisements or radio, they're all driven by your patient labels. So that's why a lot of my focus has been on this, because to really address this and make sure it's clear will help, hopefully, to solve some of the other problems upstream.

So a number of years ago we realized that we wanted to create patient labels that reflected health literacy principles. We also knew that we didn't have the internal knowledge to do that by ourselves, and so two things happened. First of all, I formed an internal working group, and it was across many different parts of the company. The most important is legal, right? So we had a lawyer at the table who believed

that it was possible to honor both the spirit and the letter of all rules and regulations and be clear with patients. And I always joke that without her, I wouldn't be here today, right? That's so important to make sure that they're on board, and then with others, with regulatory policy and marketing, market research.

And then Dr. Mike Wolf at Northwestern and Dr. Ruth Parker at Emory and their teams had already been doing a lot of work about communicating about medicines in a clear way. So we engaged them, and when we engaged them, I think we all knew the format of our patient label would look different. So to highlight an earlier point, this isn't just language; this is things like white space and the use of bullets and formatting. Another piece of it is what's extraneous information, right? What is all the stuff we always put in there that doesn't actually help patients, because that's also really important to think about; that distracts. But at the same time we want to make sure we have all of the information in there necessary to make an informed decision.

The other aspect, which I didn't know and I quickly learned, is that we would overall -- how we test our patient labeling. So we have always done comprehension of our patient labeling, and we didn't -- we had always worked to assure a broad range of education levels. But what we failed to appreciate, and which we now understand, is that that isn't the

same as low health literacy respondents, right? So people who aren't competent in their ability to read are not raising their hands proactively to participate in internet research for an hour that requires them to read.

So we had to think very differently about this. Those few that we did have in there had lower scores generally than us, and we didn't even have enough of them necessarily. And again, this wasn't because our heart wasn't in the right place with comprehension testing. This wasn't something we even didn't know we didn't know, right? And that's the other part of this.

So here's -- and yeah, I still have 5 minutes. So I just thought it would be very helpful to talk about some of the practical things that we did to try to make sure we had people with low health literacy in research, because I think these are learnings, and none of this is proprietary to Merck. We're happy to share this with anybody, and it could probably help the FDA, too, as we learn -- as we make sure we have respondents with low health literacy in some of these studies.

So we required a desktop computer to participate in research. Well, guess what? Many people with low health literacy have their phones -- you know, have their mobile and that's their -- sorry, have their computer on their phone, and so we were inadvertently excluding them from participation. We went to different places to find people, so we went to literacy centers, we went to senior centers. We have a wonderful

partner, Sommer Consulting, who does this for us.

And then we had to actually ask health literacy questions. When you do phone screening to get people into market research, we now ask the one question: How competent are you in filling out medical forms by yourself? That's not perfect. We've seen over the years, you know, some people switch. We ultimately categorize people using the Newest Vital Sign, which for those of you who are not familiar with it, is about reading an ice cream label. Now, until the consumer food labeling changes in 2 years, this is what we do. We'll figure it out. We'll have to look towards that, too.

But we also partnered with Schlesinger, who recruits patients for us, and they're now actually adding the health literacy assessment questions as they pull in new respondents. So we actually now have -- 7% of their national database has people with low health literacy. That's actually a really big deal. It may not sound like many, but it gives us access to people.

And then we also have to train moderators to be sensitive to the needs of people with low health literacy. We learned this again the hard way. We brought people with low health literacy into -- I think it was message developing testing, where we put 30 pieces of paper in front of them, and that didn't really work very well. So you really have to think about how do you engage with people to get the same information

but maybe in a way that's more sensitive to their needs.

A combination of open and closed books: So the other thing is we always used to do only closed book. That's memory test, right? That's not really a test of understanding. And so now we -- and all of us, if we have a question about medicine, we can go to the Internet to find information. I imagine that's what most of us do. And so we ask people to find information, but then we also close the book and say a question such as what is this medicine for? What are the serious side effects? What are the common side effects? And how do you take it? We make sure people can use that -- can recite that afterwards. And then we try to aim for about 25% of people with low health literacy.

The process is we develop our own health literate patient label, what we think it is. We have Dr. Wolf and Dr. Parker and their teams send it back to us. We try to honor the knowledge that they have. Then they do focus groups with respondents with low health literacy, and we actually see if there are any red flags, or we also can probe for things that we're not sure how to say. And then it comes back to us, and then we do our comprehension testing. So we're really making sure that we have the input of respondents across a range of top literacy levels throughout the development process. It works.

We've been able to achieve high comprehension of patient

labeling, even among people with limited health literacy. And there was a woman -- it really came home for me when a woman who was Hispanic, English was her second language, and she read one of our draft patient labels, and she started crying, and she said I never understand these things, and if something went wrong, not only would I know it, but I'd know what to do. And that's why we're all sitting here, right, is so that people are empowered to understand risk, and also benefit is another part that they'd like a little more about in the patient label. That's a different conversation for a different time. But anyway, they say they're more likely to keep it, to understand it, and to ask questions of their provider.

And then, yeah, this is an example of a recent label that we did have approved by the FDA, going through this process. I forgot I had that in here.

Anyway, thank you.

DR. BLALOCK: Thank you very much.

Does anyone else in the audience wish to address the Committee at this time? If so, please come forward to the podium and state your name, affiliation, and indicate your financial interest, and you'll be given 3 minutes to address the Committee, if there is anyone.

(No response.)

DR. BLALOCK: It looks like there is not anyone. So moving on, would any of the Committee members, do you have --

would you like to ask any questions of the three public speakers, any clarifying questions based on their remarks?

(No response.)

DR. BLALOCK: Okay, it looks like there are none. So I now pronounce the Open Public Hearing to be officially closed, and we will not take any additional speakers for the remainder of the meeting, and we'll now proceed to today's agenda.

So at this time, let's focus our discussion on the FDA questions, and copies of the questions are in the folders that you received this morning. And I do want to remind public observers that this is a deliberation period among Committee members only. Our task at hand is to answer the FDA questions based on the draft strategic plan, the presentations and comments we heard today, and the expertise around the table.

So with that said, I'd like to ask that each Committee member identify him or herself each time you speak, just to facilitate the transcription.

So Dr. Zwanziger, there you are. Can you go ahead and read the first question?

DR. ZWANZIGER: Thank you, Dr. Blalock.

So read these into the record. The first question for the Committee is No. 1: Looking specifically at Risk Communication and Health Literacy at FDA:

a. Does the Overarching --

DR. BLALOCK: Dr. Zwanziger, I'm sorry, I just was

reminded that I forgot to allow some time for a couple folks that I cut off for -- who had clarifying questions before we took the lunch break. I'm sorry. So now I'll cut you off as well and compound my error.

So Dr. Rimal.

DR. RIMAL: Thank you.

I think this relates to the glimpse of the discussion question I just saw up on the screen. Listening to the presentation right before lunch, one thing that sort of jumped out at me was that -- you know, I have to say I am looking at everything from a behavior change kind of lens because that's -- I guess that's the tool I have, and you know, when you have a hammer and you see the wood, that's nails, right?

So my question was it seemed to me that the top three boxes that you've got are very much driven by "if you have knowledge, they will change" kind of model, that the aim is to increase knowledge so that they can make good important decisions. And I just wanted to kind of problemitize that for a second and say surely we know that from, you know, years of research, behavioral research, that that works some of the times. Often you need something else to propel people to change behaviors, and I was wondering if you've given thought to, or if you have thoughts on, what some of those factors might be and why they did not end up in your model. So, for example, things like how do we facilitate that behavior change?

How do we improve the efficacy? You know, what's the role of emotions, these kinds of factors that could propel or convert knowledge to behavior, and is that something that you might consider thinking about?

DR. ZWANZIGER: Thank you.

The top boxes do -- and if you want to look at your questions, those are those -- the top boxes are in Question No. 1, as Dr. Rimal just mentioned. Those do look at knowledge, and we recognize that knowledge doesn't automatically result in behavior change for me or for anyone else. There has to be something more to it. The FDA sometimes is looking for behavior change and sometimes really isn't in a position to do that because it may be that the outcome we really are in a position to want is an informed healthcare provider and patient or an informed consumer, and what kind of behavior there is to do will be appropriate in one way for one individual and another way for another individual.

That said, there certainly are times when we want people to get rid of the flour, not eat the raw dough, take a behavioral action. And so in the strategic framework and the activities and as we currently have conceived it, I would find those in the more specific parts of the plan, because it would have to be at the level of a particular communication that has a behavioral outcome, and then that communication or that program could define or specify the action and the measure that

they could look for to try and achieve behavior change.

All of that said, if you have some additional suggestions on how we can be more effective in either taking action or measuring, I'd welcome it. We'd all welcome it.

DR. RIMAL: Not right now, right?

DR. ZWANZIGER: Oh, right. Sorry.

DR. BLALOCK: Yeah, I think that there will be more time for more in depth and suggestions later on. And so just had one more clarifying question left over from this morning.

DR. LIPKUS: So the idea is to make better informed decision making, and as I go through the materials you have here, a lot of it is focused on better communication, plain language, etc., but I didn't really see a lot in terms of understanding decision making in and of itself. And we know that information influences people's decisions. We know that sometimes people process information heuristically versus more -- you know, centrally more engaged with the information.

So one is just a general comment of where is decision making in here. The other one is, if you look at definitions of informed decision making, it usually has some component to it that says making a decision that's congruent with the person's values. And again, in here I didn't see anything in particular about values, other than you're going to be approaching different stakeholders and getting their opinions.

But as I look at this document, one of the things that

would help me, at least, would be how well do these different metrics and strategies map onto different versions of the definition of what you're trying to get at, which is better informed decision making. So what do you have there that makes people do, for example, value clarification exercises? You know, people sometimes don't really, on the spot, know what they value and what they think is important. How well will the FDA understand how presenting this kind of information may lead to a different focus on the information and differential effects on decision making? You know, things like that.

And then ultimately is this definition of "better." What is better? And that's never really clarified. So one way of doing better is to say, well, you've got a statistically significant effect even though the effect size is trivially better, but it's still statistically significant. So I think, at least from a philosophical perspective, I was trying to get some discussions of what does the FDA mean as "better"? Because if you do something with value clarifications, the FDA may say this is really the decision that we want people to make. The person doesn't make that decision, but it is a decision that is congruent with that person's values. So would the FDA then consider that to be a wrong decision that's not better? So I know I'm starting to think like a researcher, but it would really help to understand what do you mean by "better"? What are the threshold values? How are you going to

get things that really fit within your definition of what you mean by better informed decision making and all of those components?

Like, for example, one of the things that you do is you talk about talking to stakeholders and having them disseminate the information and know how to do this. This now gets into the area of shared decision making, which adds another level of complexity. And by the way, there is no consistent definition of shared decision making, and it has multiple components to it. So I think there are consequences that have hierarchical levels in terms of what does it mean if you achieve this, and what's the implication for some downstream effects as this gets more into the population.

So these are just some of the topic-of-mind things that came up to me, and I'm wondering if you have any kind of comments that you want to speak to about those issues, if any.

DR. ZWANZIGER: Well, first of all, thank you for bringing it up, all of them. And I, too, was thinking, as you were presenting some of these thoughts, boy, that sounds like a research project, and that sounds like a different research project, and that sounds like something we should think about in terms of research prioritization. I don't know that I can clarify that right now, except to say that I appreciate bringing it up; that's something we need to address.

DR. BLALOCK: And I think some of these issues will come

up in other contexts as we go through the questions. So let's go ahead and move to the specific questions.

DR. ZWANZIGER: Okay. Then for the record, Question No. 1 is: Looking specifically at Risk Communication and Health Literacy at FDA:

a. Does the Overarching Outcome (the bottom box here on this slide) support Strategic Priority Goal No. 3 (the top box)?

b. Do the proposed performance indicators provide meaningful measurement of progress toward that Overarching Outcome?

c. Can you suggest any other indicators for us to consider?

DR. BLALOCK: So do we have your responses from the Committee?

Dr. Dillard.

DR. DILLARD: This is really echoing Professor Rajiv's comments of a moment ago. But as I look at your -- the movement through your model, from overarching diagram, which includes accessibility of knowledge to inform decisions, each of those strike me as necessary conditions for the -- each of the preceding ones are necessary for the subsequent ones. What's missing, of course, is the moderator variables, the things that would enable -- would become sufficient to move from one box to the next. And I don't know if we're in a

position to elaborate on all of those variables, but it's surely the case that it would be wise to consider them, some horizontal arrows that make those vertical arrows happen.

DR. ZWANZIGER: We did actually talk about necessary and sufficient conditions and how they would fit in here or not. But I think, at this point, probably you guys are addressing your questions at each other and not me. But if you want me to respond to something, tell me. Or how do you want to --

DR. BLALOCK: For right now, go ahead and respond. But yeah, I think you're right that we're addressing one another.

DR. ZWANZIGER: Okay. Well, then, just as a point of clarification, I completely agree. I would say that the lower-level boxes are not, logically speaking, necessary for the higher-level boxes, but they are part of a cluster of what would be necessary. I could conceive of ways you might get around to get the higher-level boxes with different lower-level boxes. I certainly agree that the lower-level boxes are not sufficient for the higher-level boxes because there are many other environmental conditions that have to come into play, some of which we can discuss, some of which we didn't really discuss because we already know they're way out of FDA purview or in FDA purview but way out of risk communication and health literacy communicator's purview, but very important to recognize. And maybe if you -- you know, if we specify some, maybe it will turn out we were wrong. Maybe some of them are

things that we could effect. So please, you know, feel free to comment further.

DR. BLALOCK: And I think I'll just kind of go ahead and echo that, because as you were articulating what you were saying, I was kind of thinking exactly the same thing because I always describe myself as a behavioral scientist, and so my focus is always on behavior, not necessarily decision making. You know, decision making is a precursor to behavior, and then lots of things can interfere with this, actually enacting all of the decisions that we make.

But I think that what I've heard today, both just now and previously this morning when we were talking of getting clarifying questions for different things, was that there is a limit to what a government agency, you know, can do from such a distance. You know, the FDA is not a healthcare provider, they don't have relationships with people, and I think that that's -- at least that's what I'm hearing as the explanation of why the focus here is on increased information, accurate information, and improving knowledge. So that's what I'm hearing from the presentations.

And I think I'll put Dr. -- Dr. Krishnamurthy is next.

DR. KRISHNAMURTHY: My thought about the overall Strategic Priority Goal No. 3, promoting better informed decisions, I echo the point that what makes a decision a better decision and -- but I do think that there are boundaries or there are

parameters that define whether a decision is a good decision. (A) Was it considered -- were people cognizant of the fact that they were making a choice? Were they cognizant of the options that they had in front of them? And after having made the choice, did they regret making the choice? And was it due to incompleteness of the information? Now, we cannot ask the FDA to be kind of now focusing on end-user research to come and answer these questions. That should be part of academic research as well, I believe, and therefore I do think that there is a way to operationalize what constitutes a good decision, a decision in which options are known, outcomes are understood, and a choice is embraced with as minimal regret after the outcome is known.

And there is lots of research out there that one could leverage to figure out what constitutes a good quality decision. And so that's a point that I wanted to make. I think it's a very valid point, what you were telling, and throughout the strategic framework, it calls for what is the operationalization of the box that we are talking about? If it is an informed decision, what do we mean by an informed decision?

And there's another point that I want to bring to the Committee here, is that Box No. -- the top-most box is actually multi-focal. It talks about informed decisions by consumers, patients, providers, and professionals. So now this becomes a

complicated process, even more complicated. I do believe that there has to be one focal point here, and that should be the patient. Did the patient make a choice that was informed, informed by providers and so on and so forth?

DR. BLALOCK: And I'm going to go out of order just a little bit because I think, Ms. Witczak, you raised your hand in a way that it looked like you were responding to something.

MS. WITCZAK: Thanks. I think it had to do with the outside forces, even under that overarching. Like what things that maybe the FDA can do and what's in your -- but like direct-to-consumer advertising, you know, the messages that the consumer is hearing from the outside, I think that is something, and I don't know if that has been -- or where that comes into, but that is something that, you know, as consumers as well as doctors and we as people, you know, we're inundated by messages. So I think that's one thing.

I would also think the idea of when it gets up to informed decision making and making it better, you know, one of those things is the premise that it is doing a treatment of some sort. Or what about the idea of like doing nothing at all? And so like that, to me, is part of that better informed decision. It may not be just the risks and benefits, but what about that idea that that is part of the conversation? You know, if you do nothing, what could happen as well?

DR. BLALOCK: Dr. Yin.

DR. YIN: You know, I just have a comment about the outcome of improved knowledge, and I was looking at the performance indicators for that, and I was a little disappointed to see that it was white, meaning postpone, and not one of the yellow or the green areas. And I wondered if there was some consideration for perhaps trying, as a first step -- because I can understand how it might be overwhelming to do that for all types of communications, but as a first step, to create some sort of model approach or some sort of protocol for user testing, just as a first step to -- as a test case, for example, that could be used in one particular case that's a high priority, you know, one that could then later be disseminated. That might be a more feasible sort of goal.

DR. BLALOCK: Dr. Berube.

DR. BERUBE: I have a few comments here. I agree a bit with what Dr. Lipkus mentioned when you were talking about the universality of this. I have a problem, first of all, with the four categories of audience you're playing with. I mean, I just wrote a chapter a year ago about how when consumers become patients, they become totally different animals. It's a whole different psychological dynamic that takes place. And these are so different. But when I look at the meta-piece, like when I read of all of this stuff, I understood immediately that this was a way to make your staff better. It just seems that we look at the Strategic Priority No. 3, the focus is a step away

from the staff, which it's like there almost is like a missing box in here, right? And it's not that making the staff better is such a bad idea. That's a great idea probably. The relationship between these three boxes may be incidental rather than causal. You know that you're going to have a real hard time demonstrating this.

There's wonderful argumentation theory and texts that are out there which explains what a good argument is, and they have characteristics. And you could use Stephen Toulmin, you could use Burke. There are a lot of folks out there that came up with a lot of quality, or good reasons from Scott. There are a lot of folks in the field of communication that you could draw from which would give you categories that you could actually quantify. You would look at the argument that's being made, and you would say does the argument have these components? You know, if these components are there, how significant are these components?

The other thing I just -- this keeps coming back to me. I had a bizarre experience about 6 years ago working for a corporation, and you know, you're trying to apply this as an over -- a piece that goes over the entire operations of a strategic framework in risk communication. The reality is you've got a lot of units that are certainly better than other units at what they're doing, and there's no way any of this is weighted. And I have an odd feeling that if I was running a

minority health division, there are some of these things which are more important to me than other things here, and I think that's what boggles me the most, that we have a multi-objective model here, but none of the components in the model have been weighted.

Anybody in the room who has ever done an algorithm understands how critical it is to make sure that when you're offering this through a broad range of people, you're not discounting the work some folks have done and bringing them back down to a level they approached 5 or 10 years ago. It doesn't make people happy at all when you do that. Or vice versa. You don't want to give people who have never done this before access to upper levels where they don't know how to get there. And so the weighting thing just really knocks me for a loop, I guess, because I think that's -- I think these -- and when I look at the pink block -- I don't know what color it is.

DR. BLALOCK: Okay. And let me just interrupt for a second, because the way that I think that the questions have been structured for today, you know, we're really only supposed to sort of be trying to focus on one specific part at a time. So right now we're literally just in those top three boxes, and I think that some of these issues will come up as we sort of walk through this at the --

DR. BERUBE: I just don't see it, I don't see the practicality in this that you're obviously seeing. I don't see

this as -- I don't see its practicality. I think it's a whole functional algorithm, and you know, just look at the first variable and then say, well, that's done. Now we can look at the second variable. I think that's why I get on this.

DR. BLALOCK: Okay. Dr. Lee.

DR. LEE: So I agree that, you know, informed decision making is multifactorial, but I don't think any of us expect the FDA to be responsible for people's decisions. And I think instead of promoting, contributing information for better decision making might be a better way to look at it. And to that degree, I think the most common decision that healthcare providers and patients make is comparing two drugs, and can you give information in a way that makes the risk-benefit of each drug, relative to each, easier to understand? And I think that would make that decision-making process easier, but obviously there are a lot of other factors going into this. So I think if you can just do that particular thing that's very frequent, I think that would go a long way to going from the bottom box to the top box.

DR. BLALOCK: Dr. McBurney.

DR. McBURNEY: Thank you very much.

I'm going to make a comment first, and it's sort of building on a comment that we got from Jeff Ventura, when it was looking at the Center for Tobacco Products, and it was for their newsletter, where individuals had to self-identify what

was their reason for subscribing.

And I think that, frankly, we don't always fit into one box. Sometimes we don't want to admit which box we're subscribing to and for what is the reason. And so it feels to me that rather than it being my place of employment, it really is whether I'm asking out of a personal or a professional interest, and then within that interest, whether it might be science based or it might be regulatory or it might be recall and safety. And so there are categories that I wish to have information or to obtain information on the FDA so I can be more informed and hopefully make a decision.

And so I really like the framework that you have here. I'm not always convinced that behavior change comes from knowledge. But I think what you have -- and in that (c) question, what are the indicators for us to consider, you have a lot of different centers, and so their agenda is very, very different and for that reason I have a hard time thinking about this framework because the entity in my head isn't really a drug that's being approved, it's a recall situation that may be on the drug or it's a tainted product or it's the National Center for Toxicologic Research that I'd like to know what's the latest science on that out of personal interest or maybe out of professional interest because I'd like to get a research grant and become involved with a community.

So if I was to give you a suggestion, the suggestion would

be -- I like the framework -- move down to your centers, and charge them with the outcome indicators of what is their audience and what does success look like and how are they going to move that needle. And I don't think I can do that at a top line because if I'm thinking about toxicologic research, I'm not going to have an answer for that, that is looking to what do I do with that product, or the example we heard earlier, that a product that's been used contrary to what indications are.

So I don't know. I think the FDA -- the challenges you have to look at for all of it, to me, the indicator or the suggestion is, is to go to your centers and put them in place saying you tell us who your audience is you have to reach and how you're going to do that, and make sure that they don't raise the bar too low for the low hanging fruit.

DR. BLALOCK: Dr. Harrell. Harwood, Dr. Harwood.

DR. HARWOOD: So I think that it provides a meaningful measurement for the FDA, but we don't have a baseline, and from the discussion this morning, it's apparent that some units are starting at Point A and some are starting at Point B and C. So not all units are at the same level of plain language and health literacy. So a meaningful measurement of success or increase without the baseline is lacking somewhat.

DR. BLALOCK: Dr. Dieckmann.

DR. DIECKMANN: Thank you.

So I'm trying to focus only on those top three boxes. I feel like it's easy for us to get too broad and start talking about everything at the same time. But I think one of the complications, at least for me, in those three boxes there, that it's very clear from just thinking about the different communications that are being made here from the Agency presentations that there are different classes of communications that have quite different goals and would require much different information to actually making an informed decision in those cases.

So when I look at, like, the second box here that's talking about risk and benefit information, that seems to be useful for a particular class of communication in which someone may need to weigh against risk and benefit and so on. But there would probably be a whole or there is a whole range of other communications, like an extremely dangerous recall situation where the goal is not to communicate risk and benefit information; it's to tell people stop using this or whatever. And you kind of alluded to that a second ago.

So I think part of these here, what kind of confused me is I kept slipping back, as I was reading through these, to different types of communication goals and different types of tasks that a patient is actually being tasked with, with that information. So if there would be some way to kind of integrate into this those different classes of communication

goals and exactly what sorts of information, this would be a useful exercise just in general, to create kind of a general process for this that could potentially go across the agencies to really doing a task analysis of what do these people really need to know in each of these contexts and what are the goals of the communication.

So just on those three boxes there, I feel like that was the thing that was kind of stopping me. It seemed like a uni-directional, one-size-fits-all, when there's very different communications that are going on.

DR. BLALOCK: Dr. Pleasant.

DR. PLEASANT: I'm fine to go, but I think you wanted to also be on the list. And I don't know that you've seen Dr. Sneed or Dr. Hallman, to just have a different -- I can see down this row, and you guys can't as easily.

So how I came to this was I actually started reading the Strategic Plan for Risk Communication and Health Literacy. I bring that up on purpose because then I got to the questions, and I was still surprised that the questions are only about the strategic framework. But there are things in the strategic plan that aren't in the strategic framework, and there are also things in the communication review that aren't in either.

And so on a micro-level, the hardest thing to do sometimes is practice what we preach. So in health literacy, one of the things is put your most important message up front. But when I

got to the strategic plan, the very first thing I said -- I read, still refer to Appendix 2 because that's where the strategic framework is, which means maybe that's the most important thing, and then all the questions say, well, maybe that's the most important thing also. But when I look at the evidence and at a very micro-level, just the way some of the strategic plan is written, it's not following the strategic framework. And the external communication evidence, like just about the one question, how do you ensure comprehension, the variability in the responses to that question across all the units and elements is again not really aligned with the strategic framework.

So the question I have is how do you get there? I feel like there's another document that needs to be done, which is the operational document. But how are all these things going to actually happen, because we all seem to be struggling with putting all the pieces together. And even if you think about it, on just the little level of -- you know, the strategic plan doesn't define health literacy or clear communication or plain language, and I understand why not. But then again, it also doesn't use plain language or some of the basic principles of health literacy.

So even within the Committee working group, there seems to be a challenge to get from the vision to the practicality and at the organizational level. With all of this variation,

that's even going to be more significant of a challenge. And it just strikes me that there's a piece missing in all of this that's going to be a real problem when you try to put it in place across all the diversity within FDA. And all I can come up with is there are some operational guidelines that are just missing, and we're trying to fill them in. I don't know, maybe I'm just out of my mind, but does that sound familiar at all? You've worked with this in your process, I'm sure.

DR. BLALOCK: Did someone from the FDA want to respond or --

DR. ZWANZIGER: I'll at least start a response, to say this first question just refers to the strategic framework, and the strategic framework is kind of like the central document. But then other questions later also refer to the activities and actions. I think that the operational level is probably the specific steps that different -- and you guys are all right, very different across the Agency. A work unit would be taking in their efforts to be doing a general kind of activity in support of implementing one of the lower-level outcomes, and that indeed -- I don't know if it's -- well, I'll just say that document doesn't exist. There would probably be many different documents or many different, you know, decisions at specific parts of the Agency. I don't want to say lower level. I mean more specific areas in the Agency's work. Did that answer any of this?

DR. PLEASANT: Can I quickly -- yeah, to an extent. And I agree, there probably would be one for every different one, but I'm just trying to suggest but also learn more about how you discussed it previously, right? Yeah, there probably should be one for each unit or one for -- because they're clearly starting in different places. Some people didn't know evaluation of understanding, just to limit it to knowledge. Some people have a pretty robust one. Some people just say they do internal, but they don't define what that is. But in terms of rollout organizationally, I don't think you're going to write every one of them, but people need something to follow.

I could just imagine I'm a mid-level manager, and this hits me, and what am I supposed to do, right? How am I supposed to get some of these done in a just basic fundamental way? So even if you do a template, right, here's an example in a unit of how they could operationalize some of this. I think that would help internally a great deal, and it would also help me figure out how this is actually going to work. Because even the gap between knowledge and action, there are plenty of theories that you could have stuck in there, three in health literacy particularly that explain how people move from knowledge to action, but they're not there.

DR. BLALOCK: Dr. Krishnamurthy.

DR. KRISHNAMURTHY: So I'm looking at the three boxes

here, and the question in front of us is, going from the bottom up, would increased accessibility to actionable and accurate information result in better informed decisions? And the answer to that is yes, it will.

And the second question is do the proposed performance indicators provide meaningful measurement of progress towards the Overarching Outcome? And for that I looked at page number 21 on the document that was given to us, which specifically lists out exactly how it will be measured. For example, it says the measure indicator for increased accessibility for actionable and accurate information is the percentage of total FDA communications that are developed or revised using health literacy or plain language principles. And then they go on to tell, in the next column, it is going to be -- the unit of measure is going to be the number of FDA communications or campaigns that use health literacy or plain language principles.

To me, I really think it is as clear as it can be in terms of what are the indicators and what are the proposed effects. And maybe I'm just missing something. So to me, the answer for Question 1a is yes, 1b is yes. And the third one is 1c: Can you suggest other indicators for us to use? Yes, indeed. Like, for example, some of the things that have come up, like can we operationalize the outcome variable. But I don't think it is necessarily that easy, given the limitations that FDA

operates under, where it cannot do message testing and so on and so forth. I see that you can clarify what constitutes informed decisions a little better, and perhaps like some of the Committee members can share with you what constitutes a higher-quality decision versus a lower-quality decision. I have some recommendations I'll suggest offline to you.

So I do see a clear link between the three boxes that you have and what you're suggesting in between. The second box says does it lead to improved knowledge of risks, benefits? That is to be presumed. I mean, if you provide actionable information, it is going to likely increase better knowledge.

But I do want to add one thing, timeliness. It is not that whether there is higher knowledge and increased accessibility, but is it accessibility at a time when people are making the decisions? This is why a few meetings ago we talked about the importance of point of decision rather than kind of asynchronous information being sent out. And if there is something that can be done about that -- and I don't know whether it's the FDA's job or not, but making that information available at a time when the patient can consider it and at a time when the physician can consider it would go a long way, more than any of the other things. But in general, I do think it answers those questions.

DR. BLALOCK: Great. Dr. Hallman.

(Off microphone comment.)

DR. BLALOCK: Oh, I'm sorry. Dr. Morrow.

DR. MORROW: My puzzled look. Thank you, Bill.

A follow-up: I think increasing accessibility will only improve knowledge and maybe decision making if it's -- so the key thing is actionable, and I'm not sure I've seen how -- what the guarantee is for actionable. And I know I'm glossing over lots of things in this, but the way in which information -- comprehension will be tested is going to be really crucial for being able to say yes, it's actionable.

DR. BLALOCK: Can I ask a question? Actionable. Where is that coming in, that there are no indicators for whether it's actionable or --

DR. MORROW: I think there's discussion about how comprehension will be measured. So just to say a few words there. And I think this is probably really well known. If you're asking people do they understand, you know, if it's rating scales that are very easy to operationalize, but it probably won't tell you very much. So you can go to objective measures, if those are memory based, for content of messages. Will that guarantee actionable? No. So you're going to have to start getting into the link between comprehension and task analysis, where you're doing maybe scenario-based, sort of deeper measures of comprehension, and then that will start to get to it. And I know that's harder to do, but that's kind of my thinking behind that.

DR. BLALOCK: And Dr. Krishnamurthy, did you have something to jump in with?

DR. KRISHNAMURTHY: Yes, I think that's an excellent point, Dr. Morrow. I do think that, one, you could potentially consider an amendment to that in the sense that increased accessibility to the actionable information, they're applicable because not all recommendations are actionable. Like you mentioned that the flour situation where you avoid using. So there is an actionable component that can be defined. And there are other places where the goal is to inform, and therefore the goal will be more comprehension rather than actionability of the information, I think.

DR. BLALOCK: Dr. Hallman.

DR. HALLMAN: Thanks.

So let me bring this back around to Dr. McBurney's point about why it is that people are seeking the information in the first place, so what are their roles, and to tie this together with this other part of the conversation. So one of the things that I would suggest is that if we revisited the environmental scan, which I think is fabulous, and added a column to the intended purpose or perhaps redid that, the word "persuade" doesn't actually occur at all in that document. It's always provide information and provide information. And clearly there are some cases where there are outcomes which are -- which we prefer, either to protect individuals or protect the public

health. So that's sort of one point.

Back to the actual questions: Strategic Priority Goal No. 3 asks the question or raises the question, informed decisions by whom? And the list is consumers, patients, providers, and professionals. I would add to that category, as Dr. McBurney would suggest, perhaps, that not all of the information is -- let me put this a different way. Not all of the information that is provided is actionable by the final user of the product himself or herself. So I may be helping -- I'm not a professional, but I'm helping my mother-in-law try to figure out what the best course of care is going to be, or whether she should use this drug or not. Or I'm assisting my child or assisting my sister-in-law. So I'm not the ultimate consumer of the product itself. I'm certainly not a professional, but I'm an interested person who's trying to help somebody else make a decision, and I don't see that role anywhere here, and I think it's a role that gets played a lot. And the provision of misinformation by those who think they're being helpful, I think, is one of the major stumbling blocks to actually helping people make better informed decisions.

DR. BLALOCK: Dr. Sneed.

DR. SNEED: I apologize, these are kind of random thoughts that you're getting just because of sequencing. But I agree with Dr. McBurney in that there are so much difference in FDA-regulated products, and I think one important concept in making

an informed decision is, you know, how much influence do I have or how much control do I have over that decision. So, for example, I have to have a hip replacement. So I don't really get to choose which hip I get; my doctor makes that decision for me. So that's not really an informed decision that I get to make. But if I get to -- if FDA has a campaign, which I understand they are, to eat more fish, eat more seafood, well then, I certainly have control over that. So that whole concept in terms of decision making, I think, becomes really important.

So I think having unique -- so this is an overall framework, but each group is going to have to have different anticipated outcomes. I also, from -- and I'm just going to get it in here now, but I also don't like the word "better" because it is hard.

And then in No. II, more targeted messages: Numbers probably don't matter; it's the quality of those messages that are important. So in that one, I'm not sure if you mean more in number or just more targeted. So that language, I think, would be better clarified.

DR. BLALOCK: Dr. Rimal.

DR. RIMAL: I think I now know the source of my discomfort, and that is that I think most of the chart elements are written in what we would call, in marketing, the supply side. They are the producers. This is how we put out

information; this is what we will ask people to do and so on. And the top thing at the very top is sort of the demand side, right? It's what we want the consumer to do. So I think there is this element of let's put all of this out there, and we'll build it and they will come, and we know that sometimes they do not come.

But I think there are ways of -- given the constraints that FDA has to work under, there are certain things that could be done to translate that supply side approach into a demand-side behavior or decision-making kind of change, one of which is providing some role modeling of how that decision could be made, right? Let's say go back to that fish-eating example, what are some of the factors that people are wrestling with when we are asking them to eat more fish? That may not be consistent with their values, as Dr. Lipkus mentioned. That may be not consistent with how much it costs them, etc., etc.

So if we could, on the website or somewhere, just role-model some counterarguments. So if you're thinking it's too expensive, you have things to consider. If this is important to you, there's somebody in your home who is pregnant, you have things to consider, right? So it's creating those scenarios that help people make that decision, facilitate that decision making through those kinds of walking people through the various scenarios that they may be encountering, given their value structure, I think, would be one way to go to translate

that knowledge into behavior.

DR. BLALOCK: Okay, I've got two more folks with comments on the list, and then we'll try to wrap this question up and move on to the next one.

Dr. Dieckmann.

DR. DIECKMANN: I want to say I completely agree with your comment, actually. One of the things that I was thinking of, instead of just talking about improving knowledge here and that it's going to create more informed decision making, there would be kind of simple decision-aiding scenarios kind of from a structured decision-making approach that you could talk about the very simple things. Like it's important to think about your values and trade that off with the risks and benefits and so on. So there are certain things that you could do there.

The point that I wanted to make had to do with the performance indicators, and I think that the answer to the one question is yes, there is meaningful performance indicators here. But I was dismayed a little bit to see that the one that I would think of as kind of the most important was whited out as something that's not going to be done, which would be the research and the surveys to see whether you're actually making a change on these large -- on the high-level goals here. I think there would be an easy tendency, throughout this whole plan, to measure a bunch of easy things to measure, and then you end up just running around and measuring a whole bunch of

things that are easy to measure, and it seems like you're doing a lot when really, in the end, I'd be happy to not do all of those things at the bottom and design a really high-quality study to see whether you're actually making a difference in terms of actionable intelligence or actionable decision making.

DR. BLALOCK: And Dr. Lipkus.

DR. LIPKUS: I think these are relatively minor comments. You asked the question, do the proposed performance indicators provide meaningful measurements, which is a dichotomous outcome. Maybe it's something to what degree do these things do things. It gives you a little bit in terms of looking at precision. So I think, you know, do the overarching goals support Strategic Priority Goal 3? Again, I think it says to what extent, because I think, in your strategic goal, you're ultimately going to do some sort of a global evaluation of did this work and to what extent. So I think thinking about those final evaluations in the context that's not just yes or no, does it or doesn't it, just provide a little bit more questions that lead to precision, I think, might be helpful just in terms of communication of the document.

And then I was looking at Point No. II, where you have here, consider the four major contribution outcomes which all feed into the Overarching Outcome. And I'm not sure if this is for the next section, but when I look at these, like, for example, increased use of more targeted messages and

communications, then you have improved dissemination of FDA's communications and information, I almost see IV as being a subcategory of No. II. And then when it says increased use of clear communications, best practices, and plain language in developing messages, and then you have No. III, improve efficiency of internal operations, it seems like III is really a subset of No. I. So I'm even seeing some of these as being hierarchical in themselves, instead of being quite distinct.

And I guess the third one is, I'm not sure by looking at this where the reciprocating systems of communication occur and how they occur and how do they fix or help out creating messaging. In other words, you have all of these organizations. You've got some central organization, I think, that's going to kind of oversee this. But I don't have a real clear indication of all of these moving parts and how do they work in some synergy to ultimately achieve kind of the larger picture, and it would be nice to have, at least in my mind, some greater clarity about that. So, for example, you've got some parts where you want researchers to pitch in and get grants that might feed into the FDA. You've got these stakeholders, and you've got members within the FDA. You've got all of these different metrics. But I'm not sure how they're all coming into sync with each other to give you a more holistic approach to what you're trying to ultimately achieve.

DR. BLALOCK: Mr. Bertoni, we thought you might have

wanted to say something in response.

MR. BERTONI: Well, yeah, because -- thank you very much. These are extremely helpful comments, and there's one thread that I'm hearing that has to do with the fact that, to implement something like this, it really needs to be done in the specific context of a particular type of decision or a type of product or communication, and it has to be done at the program level, and those things are all absolutely true, questions about how does all of this stuff fit together and roll into a more integrated model. Absolutely, if you read this as an integrated algorithm, you're going to be puzzled for quite some time because when we call it a framework, we mean it's an organizing device to try to coordinate many of the things that are happening in the program. You might think of it more like, you know, a self-organizing system.

And at the top level of the Agency, what we're trying to do is kind of -- I don't want to say herd the cats, but it's trying to provide a framework where people can achieve that synergy, but there's not a top-down directive. What you'll find is, within a particular program, they'll have an initiative around, you know, whether it's patient medical information or whether around food safety in a particular aspect of it, and they'll hopefully use these principles to do a better job of that.

And then we use this overarching framework to help, first

of all, allow people to share information and organize a conversation where there's learning across the different components of the organization, and then communicating out all the things that we are accomplishing. And along the way, people realize, yeah, we're working on the same things together. We can share this research. We can come together with a larger research program.

So the way to read this is we have this very diverse agency. This framework is intended to help coordinate the many things going on among all of these different programs, and it's not a well-engineered, you know, logical mechanism that's going to achieve everything in a very neat way. It's a coordinating device and a communication device about how we do this better over time. That may not be a very satisfying response, but it is kind of where the Agency is today.

And I also want to say all of these comments that I'm hearing from you about critiquing how this could be better, we're listening and taking notes because there's a truth in each one of those that we can then take to make it better in the next iteration, add some additional details, clarify some things. So this is extremely valuable.

But do realize that it was a great step for us to try to get this into a coherent, logical framework as it is, but it wasn't like we had the Commissioner tell us I want you to design a plan that will achieve these things and then we're

going to go, you know, down. It's really kind of more of a bottom up.

DR. LIPKUS: So I really appreciate you clarifying that. And when I was reading all of this and the amount of details that went into this, I was thinking they should write my grants and they'll get funded, you know?

(Laughter.)

DR. LIPKUS: It's just the way where you have all of these hierarchies and these links together makes it sound as though there's some pooling of resources and there's going to be some synergy amongst these, and that's a very worthwhile clarifying statement.

And then just a final thing. This is really quick. You know, in terms of risk communication outcomes and comprehension, there's some really nice work that Neil Weinstein has done. Like, for example, he had a classic article called "What Does It Mean to Understand the Risk?" That came out in 1999 in monographs of the National Cancer Institute. That talks about, you know, various ways you could actually look at compression of risk, and then some other of his papers.

So I think taking that literature in terms of what are the probabilities, you know, what are the outcomes, what can you do about them, very global kinds of questions about understanding risk, that could be very useful because people might get some

of these messages, and they say, well, what am I supposed to do now. And it may or may not be clear to them what they are supposed to do now. Why does this pertain to me? What's the likelihood that some adverse event will actually happen? So I think getting at those kind of factual and also just level kinds of questions would be useful for comprehension.

DR. BLALOCK: Okay. And I do want to try to keep us moving along a little bit so that we can get through all of these questions. I just want to try to summarize a little bit, and I know it's not going to be very adequate at all, but sort of just a little bit about what I've heard but really focusing on these questions.

So does the Overarching Outcome support Strategic Priority Goal 3? And I'm actually going to read the Overarching Outcome and Strategic Priority 3 because I think that sometimes in the jargon we sort of lose, you know, what it's saying. So the Overarching Outcome is increased accessibility to actionable and accurate FDA communications and benefit-risk information. And so does that support promoting better informed decisions by consumers, patients, providers, and professionals about the use of FDA-regulated products?

I really didn't hear anything to suggest that Strategic Priority Goal No. 3 does not support that Overarching Outcome. I think it clearly supports that Overarching Outcome. You know, there are questions, a lot of questions around the edges

of what is an informed decision. What do we even mean by "better"? You know, how do you measure actionable? But I don't think that there was anyone really disagreeing that that does not provide support for the Overarching Outcome. And when I get done kind of summarizing, I'll let folks, if they specifically disagree with something that I've said, an opportunity.

So do the proposed performance indicators provide meaningful measurement of progress toward the Overarching Outcome? And I'm going to go ahead and read just the indicators for that Overarching Outcome, which is percent of total FDA communications that are developed or revised using health literacy or plain language principles, and number of FDA communications that are developed or revised using health literacy or plain language principles or tools. And those are the indictors, correct? I'm not -- okay, I'm on the right page. And actually, I didn't hear much talk about those indicators. You know, we got off on a lot of other things about the structure of the plan.

And I think actually, Dr. Krishnamurthy, I think that you said you had ideas about other indicators, and I myself think that there are probably better indicators. And so what I would actually like to spend maybe a minute or two doing is the third question: Can you suggest any other indicators for us to consider?

So I'm going to ask if folks have comments. You know, again, if you really disagreed with what I sort of summarized there, you know, comment. But then I'd really like a little bit more feedback on do you have concrete ideas about other performance indicators that might be feasible to measure. And I know Dr. Krishnamurthy is jumping at that.

DR. KRISHNAMURTHY: Yes, I thought that the indicators that you have are relevant and important to the number of documents that are using the plain language and health literacy principles. But I also wanted to add one more thing, which was about the timeliness of that information, as to whether it is available at the point of decision, not out of sequence. So that's something that I want to mention. I also want to make one broader comment about the four boxes that came about.

DR. BLALOCK: Let's hold off on the four boxes because that's the next hour, okay?

DR. KRISHNAMURTHY: Okay.

DR. BLALOCK: Okay.

DR. KRISHNAMURTHY: It came up. That's why I wanted to kind of make a point.

DR. BLALOCK: It will come up a lot more in the next hour.

Dr. McBurney.

DR. McBURNEY: I think those are appropriate indicators for the FDA to measure itself and whether its units are making changes. As a consumer and a taxpayer, I don't think those

fulfill my need. I think that in those cases you need to have, really, evidence that people -- you know, recalls have been done successfully and quickly and that products were removed, that physicians knew if there was a medication that had a use that had a risk, that that has been monitored and that that has been done. So I think you've got two great indicators for whether you're making your own internal progress, but you need others that show the benefit to the public.

DR. BLALOCK: That is excellent, and it's very concrete.

Dr. Liu. I'm sorry, Dr. Liu, you were on my list.

DR. LIU: I thought you said Dr. Morrow.

I was also thinking along the same lines of kind of real-time data analytics, and one of the indicators is qualitative and quantitative methods, and I thought why not big data analysis, especially given the large amount of social media work that a lot of these centers are doing. So, of course, they're not perfect and you only get online behavior and not offline behavior, but it seems like something that could be done to at least get at the understanding and knowledge as expressed online.

DR. BLALOCK: Dr. Pleasant.

DR. PLEASANT: Okay, the only modification I would -- I think what I heard is that we all -- sorry, that we all agree that it supports it, but not sufficiently.

DR. BLALOCK: Absolutely.

DR. PLEASANT: Okay, thanks.

DR. BLALOCK: Absolutely.

DR. PLEASANT: I think we should call that out. And then just in terms of indicators, I can say this once because I mean it all the way down: More objective indicators are needed throughout. A lot of this is self-report or internal, without any indicator of an actual effect or effectiveness. Just a quick example, percent of total FDA communications that are developed or revised using health literacy or plain language principles. (A) Which principles? (B) To what effect? And (C) For who? And those are not -- actually Dr. Dieckmann -- I said that right? I love your idea of trading off the easy ones for a big hard one. Somewhere there's a balance in there. But clearly what's going to win hearts and minds is more objective indicators across the board.

DR. BLALOCK: And then Dr. Yin.

DR. YIN: I'm wanting to agree with what Andrew just said about the need for more specific metrics, specifically around determining if those health literacy principles are used. Is there some sort of checklist? Is there some sort of cut point for acceptability of these communications?

And then in terms of the percent of total FDA communications, maybe we don't -- we want to look at total, but maybe we also want to look at high-priority communications based on the number of people affected or the importance of the

decision around certain topics, the likelihood of harm. If a person doesn't -- you know, is not informed about a particular topic, that might be another indicator beyond just the total.

DR. BLALOCK: And Dr. Hallman, did you have a specific indicator to suggest?

DR. HALLMAN: Yes.

DR. BLALOCK: Go ahead, then.

DR. HALLMAN: Okay.

(Laughter.)

DR. HALLMAN: So I agree. And so there are different ways to go about putting together these kinds of structures. To my mind, many of the performance indicators are actually outputs; they're not actually outcomes. I mean, one could think of them in certain terms that way. What seems to be what many people are suggesting is that what we're lacking is impact indicators. And I forget who said it. You know, we want you to write our grants with this level of detail. One of the things that granting agencies, including the FDA, expect PIs to do is to say what impact we've actually made. And so we need to have the ability to measure those kinds of things, and I know there are a lot of barriers to measuring those, we heard this morning. But in general, what we need are measures of impacts, not measures of outputs.

DR. BLALOCK: And that's an excellent point as well. So -- okay.

DR. KRISHNAMURTHY: Well, I want to talk about the indicators in the context of the fact that this document is not meant to be a consumer-focused document. It is very clear, in the Executive Summary, this is about the internal processes of the FDA, and this is from the FDA staff members for the FDA staff members. And by design, I think it will be wrong to frame this as a consumer-focused or a patient-focused document. It is not a patient-focused document. If we don't lose kind of the sight of that fact later, then it will focus on the process-level indicators rather than on does it make a decision better or is the consumer more informed, because that's not what the document is intended to be.

So I think like when we are making the comments or observations about whether the indicators are specific or not, it is meant to be an internal process document; therefore, the indicators have to be internal process indicators. In that regard, it makes perfect sense to have a number of documents that are revised using the plain language principles and so on and so forth.

DR. BLALOCK: Dr. Lipkus.

DR. LIPKUS: So consistent with that approach, one of the things, if you're going to be using this as an internal process of how things are working, is to maybe have a category about specific challenges that were met or unmet and specifying why things couldn't have been done the way you planned them to and

so forth. So it's not just how many people improved in being able to write plain languages, but what were all the obstacles that you were facing in trying to achieve these goals and to document them, and depending on how important they are, really having kind of brainstorming groups, internally or with experts, to be able to think of what can be done with the resources available to work on them.

DR. BLALOCK: Thank you.

So I want to move on, but Ms. Duckhorn and Mr. Bertoni, do you think that the information that you got, does that sort of answer these questions?

MS. DUCKHORN: Yes, we do. Thank you.

DR. BLALOCK: Okay. And Dr. Zwanziger, did you want to introduce the next two questions, or am I to do that? Okay.

DR. ZWANZIGER: I think that our procedure in this meeting will be that I'll do it.

So the next question is, as several of you have already brought up, about the Major Contributing Outcomes, which are just shown here for your visual information. And specifically the question is No. 2: Consider the four Major Contributing Outcomes, which all feed into the Overarching Outcome:

a. Collectively, do they support the Overarching Outcome, which again is "increased accessibility to actionable and accurate FDA communication and benefit/risk information?" Here, are there gaps in

support? Is there something that we should add to those four?

And Question (b), 2b, is

b. Do the proposed performance indicators provide meaningful measurement of progress toward the contributing outcomes? Can you suggest any others that we should consider?

DR. BLALOCK: And just to try to keep, you know, folks on the same page sort of as much as possible, let's focus on 2a first, just on whether those contributing outcomes support the Overarching Outcome and if there are gaps. I imagine it would be especially helpful if we saw gaps that we were able to point out.

Dr. Berube.

DR. BERUBE: Three things quickly. You can answer the first one quickly. Your Clear Communication Index, that's the CDC document? Is that true?

DR. ZWANZIGER: The CDC is the developer of the Clear Communication Index. The FDA would like to follow their lead and adapt it where necessary to make it appropriate for FDA use.

DR. BERUBE: I'm not going to do 2a. I'll go to 2. I think 2b needs to be moved into Major Contributing Outcomes. Now, 2b is the increased skills and abilities of the FDA staff to develop accurate and actionable communications. It belongs

at that level. This is the salmon level. I don't even know what to call it. At the level of Major Contributing Outcomes, you need to move a box that's in green up to salmon. Now, that's all some of the structural problems you were having there. Then what we can do is we could specify, below there, the type of activities they can do which won't encroach on the decision making of their supervisors. And I think that solves some of this. The other observation --

DR. BLALOCK: Can I just ask for clarification? I have a clarifying question. So what you're suggesting is 2b, increase skills and ability of FDA staff to develop, etc., belongs up among the Major Contributing Outcomes?

DR. BERUBE: Yeah, because it's not just responsible for targeting; it's responsible for so much more. And the other thing I want to mention, when you do double-check this when you do mapping, of which I do a lot of, you want to also do it this way. Do you know what I mean? You want to do it by branch. That's a double-check at the end. Just we could talk.

DR. BLALOCK: Dr. Krishnamurthy.

DR. KRISHNAMURTHY: I want to pick up on the last point that you made. I think that's an excellent point, in part because I think I appreciate your efforts to put it all together in one page, but this looks like a hierarchy, even when that's what I think you intend. In fact, this is supposed to be a flow from left to right or bottom to top, if that's the

way to look at it. I think most of us would have a much better sense of an X and a Y rather than a hierarchical kind of approach. I think that's the point that I want to pick up on because that's a terrific point that you made.

And looking at the four outcomes -- I'm going back to Dr. Blalock's addition on looking at 2a. I think these are really helpful in the following sense. I look at the Major Contributing Outcome No. I as how to craft the right message. I look at the Major Contributing Outcome No. II as what is the market for the message, meaning like what is the -- who are we talking to? And outcome No. III as how do we do the process, internal process guidance? And the fourth one is how are we going to disseminate that information as more of a medium?

And this, to some extent, covers what at least I talk about in my classes about the six M's of any communication. One is what's the message? What's the medium? What's the kind of market? And also you have metrics in there built in, like do the proposed process performance indicators provide meaningful measurement? And I also agree with the earlier comment, that that needs probably to be elevated to a Major Contributing Outcome or an Overarching Outcome itself. But I think these four points, the four Major Contributing Outcomes are critical, and they are addressing the primary question that you are asking as to whether, if you satisfy these, would you be moving the needle in terms of making information accessible

and actionable?

DR. BLALOCK: Dr. Pleasant.

DR. PLEASANT: Dr. Sneed. Did you see her again? That's looking around the corner. Yeah.

So if all of this happens, at some point in time, the public's health literacy is going to improve. So I'm wondering if you talked about that and whether you would want to include an indicator like that, at this level or higher, so that you say -- and I know this is going to be a stretch for a very conservative reading of the FDA mandate, but it's if this succeeds, that's still going to happen, and it's certainly going to be a contributing factor to reaching Strategic Priority No. 3. And you know the old saying is if you don't put it in the framework, nobody is going to measure it, and you'll never know.

But what would you think about including improving the public's -- not only the public, but also the FDA staff and your other partners, right, industry-wide, improving health literacy, because essentially II.B could easily be rewritten as improving the health literacy of FDA staff if you take the two-sided approach to health literacy, where it's both demand and supply. You can improve it on either side. So it's a question, what would you think about that as an indicator?

DR. BLALOCK: So again, I think I'm not totally clear. So you're suggesting adding, as a Major Contributing Outcome,

increasing population health literacy? Is that what I heard?

DR. PLEASANT: And FDA staff members' health literacy and industry partner staffs' health literacy. All of these people have health literacy, and it can all be increased. Just because someone works at the FDA isn't a guarantee that they have a high level of health literacy coming in the door. But it does fit perfectly in your logic model, but it's not exactly the kind of indicator variable that you've gone with so far.

DR. BLALOCK: And I'll just give my reaction to that. Do you have a reaction to that comment? Okay, I'll call on Dr. Morrow next. But I'll just offer sort of my reaction. I think that there's a big difference between trying to increase the skills and health literacy or whatever of FDA staff and doing it at a more population level, especially when you think about patients. Although that's a noble goal, I think that my own opinion is that it's beyond the scope of the FDA sort of mandate.

But Dr. Morrow, you had your hand up in response?

DR. MORROW: I think I'm just going to echo what you said. I mean, Andrew, it comes down to what do you mean by health literacy. Is it knowledge? Is it knowledge outcomes? Is it achieving health goals?

DR. PLEASANT: No, I mean measurement issues aside -- and I understand that you can interpret the mandate as saying this is outside of it. But logically, if all of these other

elements happen, it's almost guaranteed that you are going to have improved health literacy among all the populations that you're trying to reach right now.

DR. BLALOCK: Dr. Sneed.

DR. SNEED: This is just a question. On II.A, it talks about conducting stakeholder meetings, and those groups are fairly generic. There are groups, like extension educators, that are on the ground with consumers every day. And so do you get specific enough? Would they be included here? It seems like that's a group that not only would you be able to get information from, but you could also use those people as disseminators of information that you all have developed, because I'm guessing you all have the capacity to develop a lot of good information. I think the dissemination is probably going to be more of a challenge. And so, particularly for some of the food and nutrition issues and some of those kinds of issues, you have extension educators on the ground, county health department personnel, groups like that.

DR. ZWANZIGER: Those are all certainly potential FDA stakeholders, and various offices have a lot of stakeholder meetings, and who the stakeholders are varies with the office. I don't want to say anything specifically about what's going on at this end because I'm not from there, but I think that it's certainly plausible to include extension workers as a type of stakeholder.

DR. BLALOCK: Okay, the next person on my list is Dr. Dieckmann. And let me expand the discussion to talk about the indicators, but again just focusing on those boxes: I, II, III, and IV, and the indicators for those boxes.

DR. DIECKMANN: I just had a very simple clarifying question here. So didn't we agree that, for the Overarching Outcome here, when we're talking about accessibility, we're not talking about accessibility of these things to the public? We're talking about accessibility of this to the FDA internally?

DR. ZWANZIGER: We're trying to outline an overall framework of all kinds of different things that all different kinds of parts of FDA could do that would collectively improve the accessibility of FDA information for FDA's target audiences.

DR. BLALOCK: Dr. Zavala.

DR. ZAVALA: Expanding on what Dr. Sneed was saying earlier, to also include or consider including nurses organizations and medical organizations that attend grassroots efforts, because the communities do attend those events, and that would lend itself to obtaining more information as to understanding the information that was disseminated.

DR. BLALOCK: Dr. Hallman.

DR. HALLMAN: Just a minor point. So with Major Contributing Outcome II, we have increased use of more targeted

messages and communications. I would add to that -- and perhaps this also goes with the increased skills and abilities to develop accurate and actionable communications, which I think we're suggesting moving up into the salmon zone. The ability to actually critique or to evaluate communications actually belongs as part of that as well.

DR. BLALOCK: And Dr. Rimal.

DR. RIMAL: This is, I guess, a clarifying question. I wondered if there was room somewhere in the chart for collecting feedback. I mean, it seems like from this morning's presentations that there is a lot of stuff that comes in through the website anyway, you know, in terms of who's there and what they're accessing and so on, and I'm suspecting there's probably a comment section. I'm just wondering if there's a way to collect some sort of feedback as to whether this information, how this information is coming across.

DR. ZWANZIGER: So I have my own clarifying question here. Are you suggesting that collecting feedback should be part of the strategic framework or -- I mean, okay, if we're seeing the strategic framework as outcomes, then I think my assumption would've been that collecting feedback would be part of the performance indicators aspect of the plan, but maybe I'm not understanding what you're saying.

DR. RIMAL: I think that would be fine.

DR. ZWANZIGER: Okay.

DR. RIMAL: I just do not see it anywhere in the chart, and so I was wondering if that was implicit or somewhere explicit.

DR. ZWANZIGER: Yeah.

DR. BLALOCK: Dr. Cohen Silver.

DR. SILVER: I personally have been focusing on No. IV, and I just want to suggest adding a few words to this, which addresses one of your points and something that was discussed earlier about trust. So right now it says improve dissemination of FDA's communication and information, and I'd like to add or suggest a focus on improved dissemination and use of, and that would address the issues of measurement, but of trusted communication and information. I've noticed that earlier on this morning there was some discussion about the fact that the information that comes from the FDA, we assume, is going to be trusted. At this point, we want to make sure that that remains in the equation, and I didn't see it anyplace else.

I have more to say about No. IV later, but I'm assuming that we -- I shouldn't go on to talk more about dissemination because I have another issue about that as well. Do we have the opportunity to flesh out No. IV later as well?

DR. BLALOCK: We'll be talking about, you know, the things that are under IV.A through D. There will be another section later on.

DR. SILVER: Okay, okay. Then I'll just leave it with dissemination and use of, and then adding somehow the word of "trust" in communication and information.

DR. BLALOCK: Okay. Dr. McBurney.

DR. McBURNEY: I can leave my question until we get to the next level. Thank you.

DR. BLALOCK: And Dr. Krishnamurthy.

DR. KRISHNAMURTHY: I want to draw attention to Item No. II, the increased use of more targeted messages and communication. And I want to follow up on a point that was made earlier, that the decision is made as a result of multiple influencers in any given context, and that could be physicians, patients, and other caregivers, and so on and so forth.

Therefore, I think there must be another wrinkle added there. You need to look at what is the influence process, and then segment that, and I'm sort of pretty sure your communication will be very different for the same outcome. It will be different for the physicians; it will be different for the patients and for the influencers. I don't know if I'm making sense. So the idea is the targeting comes as secondary to a segmentation process where you divide the group of potential influencers and any buying or kind of, you know, deciding situation. And then each of the messages becomes targeted to that particular entity, which influences the final choice made by the patient.

DR. BLALOCK: Other comments related to Questions 2a or 2b?

(No response.)

DR. BLALOCK: Okay. And it always is a little hard to summarize. I mean, one of the more concrete suggestions that I heard, you know, one is moving what is now an outcome, II.B, up to make it a Major Contributing Outcome and issues related to segmenting the audience and that the indicators might be specific for different audiences.

Ms. Duckhorn and Mr. Bertoni, is there more discussion that you'd like to have on this?

MS. DUCKHORN: We're good. Thank you.

DR. BLALOCK: Okay. So let's move -- whoops.

(Off microphone comment.)

DR. BLALOCK: Yeah. We're just about at the time for a break, and I could use a break. I've got too many papers in front of me. Are we due for a 15-minute break? I think we're due for a 15-minute break. I can't quite find my script, but I know that it's going to say not to talk about the things that we've discussed amongst ourselves or with members of the audience.

So I've got almost 3:30, and it is a 15-minute break, so come back at 3:45. And I'll try to be better organized.

(Off the record at 3:27 p.m.)

(On the record at 3:40 p.m.)

DR. BLALOCK: So it is now 3:40, and I'd like to call the meeting back to order, and we'll continue with the FDA discussion questions, so I'll turn it over to Dr. Zwanziger.

DR. ZWANZIGER: Thank you, Dr. Blalock.

So now we're going to enter into the more specific part of the plan. Taking each Major Contributing Outcome I through IV in turn, please consider:

a. Whether the lower-level contributing outcomes support this outcome. Are there gaps in support?

b. Do the listed activities and sample specific actions for each contributing outcome implement that outcome? Can you suggest other activities we might consider, if possible?

c. Do the proposed performance indicators provide meaningful measurements of progress toward the outcomes? Can you suggest any others for us to consider?

I'd suggest whipping out your briefing documents and having pages 9 through about 16 or so handy because that's where the table of performance indicators is, and it's also an easy way to read the full text of all of the outcomes. And then, of course, starting on page 12 is the activities.

So moving along, here's the first branch, Major Contributing Outcome I. The text will be the same, but we're focusing on Major Contributing Outcome No. I and its activities

and performance indicators first.

DR. BLALOCK: So now we're looking at the lower-level outcomes for just the Major Contributing Outcome No. I. And so comments on the questions in relation to this.

Dr. Dieckmann.

DR. DIECKMANN: Thank you.

So I'm going to focus on I.B there, so the increased availability and access to FDA clear communication best practices and the performance indicators underneath those, which are on page 9; percent increase and best practices published; number of methods or venues used to distribute plain language practices; percent of respondents report that they know where to find the best practices. I was thinking of a way of somehow structuring the information to make it a little bit more easy for the FDA to actually find than just having random bits of information in some kind of repository or something.

And as I was reading through the whole framework, it kind of occurred to me that one nice kind of pie-in-the-sky thing would be to develop some kind of broad decision tree in some way, where a communicator could actually walk through and ask questions of themselves. What's the goal of this communication? Is it to persuade? Is it to inform? That would take them down a certain branch. What's the target audience? That would take them down a certain branch. What is the decision-making task, or what are the people actually going

to have to do with the information? That might take them down a certain branch. And then within that, you could list the best practices or what we know in the science, under each of those different areas. And that could serve kind of as like a living document that you could update and could potentially -- if it gets broad enough, it could be broad enough to go across the different groups within the Agency, although there's been talk that that might not be possible because people have their own silos and so on.

But if you're actually going to share information between folks, just sending a random paper here or there, these people showed that percentage is better or something, it would be better to have a coherent structure there. So I was just thinking of that as a way of kind of structuring the performance indicators. And then the performance indicator would be the number of risk communications that actually use the decision tree. It would make it a lot more simple than measuring all of these other things in there, and it would also give you some kind of structure of integrating the scientific information and helping people to think about the problems that they're dealing with as well.

DR. BLALOCK: Dr. Lee.

DR. LEE: I'm happy that you're looking at readability scores for these documents, looking at readability scores.

DR. ZWANZIGER: You asked if we use readability scores?

Various parts of all of us use Flesch-Kincaid, but only as one. I mean, we recognize that's not a necessary and sufficient indicator of blah, blah, blah. So we use that as one tool.

DR. LEE: I was thinking that, you know, if you do it before and after and you saw --

DR. ZWANZIGER: Uh-huh.

DR. LEE: -- the readability score improving, that that would just be one component of everything else.

DR. BLALOCK: Dr. Sneed.

DR. SNEED: I really like Dr. Dieckmann's idea. When I went through this and read through it, No. III, I put a question mark by it. That seems like really a weak kind of indicator. It just doesn't seem very robust. Employees knowing where to find the best practices. I mean, I don't think I would want that published about my organization as something to monitor and track over time.

DR. BLALOCK: Dr. Krishnamurthy.

DR. KRISHNAMURTHY: I was looking at No. I, and we're looking at the indicators or lower-level outcomes. I wonder if you want to increase the use of clear communication best practices and plain language, would the lower-level outcome II.A.b, should that be moved to No. I, because that one talks about increasing access to and leveraging off external research related to risk communication, and that you could actually -- you can use that in doing the clarity of communication and the

best practices; that's because that's usually where the best practices typically come from, or at least the cutting-edge research on how to communicate comes from.

DR. BLALOCK: In some ways, that relates a little bit to something that confuses me a little bit between I and II. You know, it seems like I is totally focused on clear communication and plain language, and probably more on plain language than clear communication in some ways. And when you go over to II, you know, one thing I wonder about is where does the content come in here? You know, like when you're providing risk information, do you provide quantitative information? And so that kind of issue, I think, right now as I read this, comes under II when you're talking about attitudes and things like that, and that I is really limited really more to plain language, even in clear communication, which in some ways kind of muddies up what you're talking about, to use the term "clear communication" there. Where clear communication is so broad, plain language is just a narrower term, I think.

Dr. Krishnamurthy.

DR. KRISHNAMURTHY: So along the lines, one thing that is potentially missing from the message box is the framing of information. That would also be part of a clear communication where people could misunderstand what is intended.

DR. BLALOCK: So other comments on -- and again, I just get -- I have trouble keeping the terminology straight. You

know, we're talking about Major Contributing Outcome I primarily. Any other comments specific to it and then the lower-level outcomes and indicators below that?

Dr. Hallman.

DR. HALLMAN: You sat me here so you couldn't see me, huh? I'm pretty clear on that.

(Laughter.)

DR. HALLMAN: So I'm wondering whether it's possible to have an outcome here that's a bit of research. But the clear communication principles actually has an evaluation component to it, where you could select randomly a set of communications in 2016, run through that checklist, give an average score, meaning a standard deviation, and then next year choose another random set, and if you could actually show that the score is clearer, that you've actually achieved this overall objective, which is the increased use of clear communication. The indicators that you have now are about trying to do that, as best as I can tell, encouraging people to do that. But I don't actually see an indicator that says that, on the whole, you've achieved that. So it's sort of like participation prizes rather than actual winning.

DR. BLALOCK: Dr. Yin.

DR. YIN: I definitely agree with that point. I think that that would be a good idea to have an outside kind of observer who is going to rate a subset of random new documents

or communications, as opposed to having kind of a self-evaluation sort of process.

DR. HALLMAN: So just to follow up, there is value actually to having that internal evaluation process. One way to actually get everybody on board is to involve them in that process of evaluating their work and others'. So I think an outside group would be terrific, but let's not discount the advantage of engaging people to looking -- engaging people and looking at what the Agency is doing. It gives them practice.

DR. YIN: And then, also, the person involving themselves within FDA. But my original comment was around I.C, improved knowledge across FDA of the value of communicating clearly and how to write effectively in plain language. And I wondered if there was more clarity on this performance indicator of this X percent scoring above a certain number on a post-class test for classes and best practices and plain language, and I was wondering what thoughts there were about the specific curriculum and how the testing would happen. Is it a test of knowledge? Is it a test of skills in terms of people's ability to create these materials?

DR. BLALOCK: Two more comments, and then I think we'll move on to the second objective. So Dr. Sneed -- yeah, Dr. Sneed and Mr. McBurney. And did I see Ms. Witczak, your -- so three. So first, Dr. Sneed.

DR. SNEED: One thing that just all of a sudden kind of

stuck out at me is we have things related to the customers, but we have mixed in it activities related to development of FDA employees, and it almost seems to me like that should be taken out. That could be somewhere in it, but that piece all of its own, and that would be staff development, that kind of thing, that's more process oriented, where the other one is more leaning toward the outcomes. So just an observation.

DR. BLALOCK: I definitely agree with that.

Dr. McBurney.

DR. McBURNEY: I'd like to build on Dr. Hallman's. You certainly need incentives when you're bringing new policies into a group, but your outcome is really the quality of your publications. There are a lot of these metrics in here that have the sense to me of what I consider liability or become incentives or become programs that are just in themselves the goal of showing -- and really the question is, is it like sexual harassment, that you need to have all of FDA employees showing that they have increased awareness and sensitivity, or do you have a group that you really need to be targeting your resources on? And the product of that group is what you want to show can move across time. I believe it's the latter.

And if you put in metrics that are how many memos, encouraging how many of doing this, you are doing the former of trying to reach the entire FDA population and then measuring that as an outcome, and that to me, isn't a sensible use of

resources. And this overlaps entirely with II.B as well. And in fact, I think these two really are one and the same and that you need to identify who is your internal audience, what is their product, put baseline measurements on the product, have some incentives to bring people up to speed, but use the measures on the product, such as Dr. Hallman did, as being the carrot for moving different Agency entities forward.

DR. BLALOCK: And Ms. Witczak.

MS. WITCZAK: It looks like the only external audience or, I guess, performance measurement would be the percent of increase/decrease into call centers. Is that really the only measurement of like does the public -- is the public understanding this clear communication? So I don't know if there are other measurements you could put in there, but that looks like that's the only external to see if the audience or the public is actually understanding it.

DR. BLALOCK: Okay, let's go on to the second contributing outcome.

DR. ZWANZIGER: And here we are. The questions are the same.

a. Do the lower-level contributing outcomes support this Major Contributing Outcome? Are there gaps in support?

b. Do the listed activities and sample specific actions for each contributing outcome implement that

outcome? Can you suggest other activities we might consider, if possible?

c. Do the proposed performance indicators provide meaningful measurement of progress toward the outcomes? And can you suggest any others?

And again, the activities are in the implementation chart, and you found the performance indicators table.

DR. BLALOCK: Dr. Lipkus.

DR. LIPKUS: So I'm not sure if it does or doesn't fit in here, but from this morning's presentations, you've got a variety of different communication channels. And I don't know where in this plan there are discussions about sensitivity and the strength and weaknesses of each of the different communication channels and how to evaluate them in terms of capturing belief systems and attitudes, and which researchers are going to be giving you what information about what are the critical new media that need to be tested and so forth. So this seems to imply we're just going to be writing something and delivering it, but we know that some media platforms don't allow you to write a life story, and some only allow you what, like 140 characters? I'm not an expert like some of you are. But I think somewhere here about evaluating new media and its effects on communication would be useful.

DR. BLALOCK: Dr. Hallman.

(Off microphone comment.)

DR. BLALOCK: Dr. Harwood.

DR. HARWOOD: My points are in regard to II.A.a, the expanded two-way communication pathways, and also the Implementation No. 9. So some of the lists under Implementation 9 may not serve the target audiences that you actually find. So there seem to be several sort of gaps. So the demographic around this table may not use Snapchat, but youngsters who may be considering an artificial cigarette may. So learning how to use Snapchat and Instagram and including those under Implementation 9 may be applicable.

And then I don't think some of this is an expansion of the two-way communication. It's keeping the message on the actual services that you are currently using. So we saw examples today where a tweet or a Facebook post, if you want more information, you have to call a telephone number or you have to send an e-mail. Again, the target audience may not want the customer service delivered by a telephone call or an e-mail. So keeping your message on the actual tweet or on the actual Facebook and using clear communication to respond in the comments or in the conversation on Twitter may -- it won't expand it, but it may better serve the actual target audience that is trying to be reached.

DR. BLALOCK: Dr. Liu.

DR. LIU: So II.A only has one performance indicator, percent of wide-scale campaigns, undergo an effort to

understand knowledge and attitudes and behavior using different methods. And I wondered if some of the -- similar to II.A.d, whether there should be some interagency sharing there. It seems like centers have -- some centers have similar target audiences and that they could be sharing the knowledge they gained from their research and work, rather than everyone just doing their own evaluation.

DR. BLALOCK: Other comments on No. II?

Dr. Cohen Silver.

DR. SILVER: Just in thinking about understanding the audience, I think just reflecting on the lifespan perspective, so not just only kids but, you know, older people are less likely to use Instagram than younger people, so recognizing the range of preferences and skills of the different target audiences across the lifespan and then also across cultural and language groups.

DR. BLALOCK: And other comments on No. II?

(Off microphone comment.)

DR. BLALOCK: Oh, Dr. Hallman.

DR. HALLMAN: So I wonder if it's appropriate, under II, to include something about this Committee itself, and use of this Committee or perhaps attendance by people at FDA at some of these Committee meetings that are relevant. Maybe I missed that.

DR. PLEASANT: Sorry. Isn't it in the activity listed as

one of these? It's just not an indicator, but --

DR. HALLMAN: It was not an indicator, so it's an activity.

DR. PLEASANT: Yeah, sorry.

DR. BLALOCK: Okay. I sort of want to reiterate the comment that I made before, that it seems to me like there's a fair amount missing, you know, when you think about the science of risk communication and where emotion fits in. You know, we heard about that at the last meeting. You know, like I said before, how you present quantitative information -- and I see II.B -- II.C, I'm sorry, II.C, include application of research evidence and feedback knowledge into operations. Perhaps it goes there, but I just don't see a lot -- you know, in contrast to everything related to plain language, I don't see very much related to other aspects of risk communication anywhere else, really. And it's really different -- I'm looking to see -- you know, it's really different than targeted messages you might sort of fit underneath that box but would be kind of squeezing it in. So, you know, where is all the science of risk communication? And I honestly don't see that beyond the plain language, and I don't know. I think that's a kind of big comment. Does anyone else share that concern, or am I just kind of off the mark?

Dr. Lipkus.

DR. LIPKUS: One of the things in the morning when I posed

a question about how are you defining health literacy, you mentioned, well, it includes the language, it includes numeracy, graph literacy, and so forth. I think it may be useful to maybe say this is how we're defining this, and it includes these components, so it's more encompassing, that people could refer to in a document, that they know that that one's included.

And I think also taking into account what Dr. Dieckmann said, you know, you could also think about risk communication in terms of if its purpose is for knowledge, to improve knowledge, whether the purpose is for persuasion, whether the purpose is for conflict management, because sometimes you're going to have contradictory information and conflict because of risk, and the fourth one is crisis management. So those are the four major sections of risk communication. So if you could say risk communication encompasses these domains, which the Agency would look over, and I think people will know that's part of this over-encompassing document.

DR. BLALOCK: Dr. Zavala first.

DR. ZAVALA: Hi. McCormick 2006, out of Cornell, she reviewed like 10 years' worth of risk communication research, and she started to speak to values, and that's something you mentioned, a comment.

DR. BLALOCK: And Dr. Berube.

DR. BERUBE: Yeah, I'm less concerned because I think,

under II.A.b, I think you address risk communication, and I think, on page 14, you address the SGE. I think you also address contracts and grants and cooperative agreements for research. I think it's pretty well done. I just want to remind everybody, if we have moved increased skills and abilities of FDA staff up a level, we're going to have to look at some lower-level outcomes in order to figure out -- because right now it's just a grand "let's make them all better," which is great, but we'll need to have some way to parse that out.

And No. 19 on page 15, oddly enough, under 19 you have examples of specific steps and recommended activities. That could be re-culled, I think, to produce lower-level outcomes. I don't think it would be too hard, but I sure the hell wouldn't want to see that all by itself without being delineated and, you know, given its time in the light.

DR. BLALOCK: Okay. And I think probably I'll need to move on to the third box here. I do want to echo a little bit of something that Dr. Lipkus said, you know, in terms of the persuasion versus just information, that that is, I think, a huge issue, and I think that the FDA does do both, that sometimes there really is something that you're trying to get people to do, whether it's to throw away the flour that might be contaminated and in other cases where it's just informational, like a lot of the risks of drugs, and that it's really important to distinguish between those, and I'm not

quite sure that that kind of issue I saw here anyplace.

So let's move on to No. III.

DR. ZWANZIGER: So for Major Contributing Outcome No. III, the questions again:

a. Do the lower-level contributing outcomes support it? Are there gaps?

b. Do the listed activities and sample specific actions for each contributing outcome implement that outcome? Can you suggest other activities we might consider, if possible?

c. Do the proposed performance indicators provide meaningful measurement of progress toward the outcomes? Can you suggest others for us to consider?

DR. BLALOCK: Dr. Krishnamurthy.

DR. KRISHNAMURTHY: I had a question in this regard. This one seems to relate to internal processes for improving outputs. Do you have some kind of a meeting or a written FDA communication, personnel kind of sharing ideas? Do you have a structured mechanism for things that work really well and things that -- where you can share ideas within the FDA itself, like almost a seminar or whatever you want to call them, best practices and things that do work? That will actually allow you to expedite some of the learning from within the organization, given that there are multiple units that are also simultaneously trying to come up with communication outputs.

DR. ZWANZIGER: Well, that is one of the important activities of the Risk Communication and Health Literacy Working Group that meets monthly, internally, to share information and undertake communication campaigns sometimes, like for Health Literacy Month. But yeah, we also have an internal Social Science Forum that meets quarterly, and a Social and Behavioral Sciences Subcommittee that meets quarterly. And I'm sorry, I apologize to the FDA. What I really should have said is that we have an FDA Communication Council made up of all the communications directors at FDA, and the Risk Communication and Health Literacy Working Group -- you know it from me. But in fact, we report to the Communication Council. We're a subgroup of that.

DR. KRISHNAMURTHY: A follow-up question that I had was, is it possible to have some structure or mechanism by which you could pose questions? Do you have an internal bulletin board kind of a thing where you could serve up problems that people could -- based on their expertise internally?

DR. ZWANZIGER: Yeah, we use both SharePoint, which is the Risk Communication and Health Literacy Working Group, and we also use just kind of a sort of internal listserv with the social science formally. You just say hey, folks, here's a question.

DR. KRISHNAMURTHY: So could that be an indicator, as well, as to how much you bring your challenges to a cross-

functional team that can look at it as a potential indicator of improving the quality of communications?

DR. ZWANZIGER: Certainly, we'd be happy to consider that.

DR. BLALOCK: Dr. Berube.

DR. BERUBE: I think, under III.B, I would probably want to plan something like improved consistency and the branding and framing, and separately, formatting and presentation. They are two different things. Branding and framing is, you know, the cues you give somebody to figure out what the message is about. Formatting and presentation is almost a management process. You're trying to maintain consistency across the entire institution for credibility purposes. They're just different goals, sort of.

DR. BLALOCK: And we've got just a few minutes left to move on to No. IV. Whoops, Dr. Pleasant first, and then we'll move on to No. IV.

DR. PLEASANT: This is quick. Just efficiency isn't always the outcome that you want. Efficiency isn't guaranteed to lead to increased accessibility to actionable and accurate FDA communications and benefit-risk information. Medical doctors are incredibly efficient in their communication with the patients. That's why we give 5 to 8 minutes. So you just need to balance that efficiency with a desired outcome like effectiveness.

DR. BLALOCK: Now I think we're ready to move on to IV.

DR. ZWANZIGER: Yeah, thank you for that.

So for Major Contributing Outcome IV, improved dissemination of FDA's communications and information:

a. Do the lower-level contributing outcomes support this outcome? Are there gaps in support?

b. Do the listed activities and sample specific actions for each contributing outcome implement the outcome? Can you suggest other activities we might consider, if possible?

c. Do the proposed performance indicators provide meaningful measurement of progress toward the outcomes? Can you suggest any others for us to consider?

DR. BLALOCK: Dr. Lee.

DR. LEE: So I see dissemination as being one of two groups. One is passive information and the other being active information. And in the active information-gathering process, I think you can do some performance measures as to given a consumer task, can they find and reach the appropriate conclusion, and how long does that take? So I think that gives you an overall sense of, can they -- is it organized properly? Once it's organized and you find it, can you understand and then give the right answer? So I think that's kind of a nice overall progress measure that you can see if you're actually making improvements in those things.

DR. BLALOCK: Dr. Cohen Silver.

DR. SILVER: One of the things that I think is really important to consider is the coordination with traditional media sources. We heard this morning about press releases, but there are ways in which one can have preexisting relationships with certain media sources to ensure that there is an immediate distribution of trusted material. And so I was surprised that there was, at least unless I missed it, no mention of working with the media in any of this discussion, and I think, for dissemination, that's a really critical point.

DR. BLALOCK: Dr. Lipkus.

DR. LIPKUS: For IV.A, at the very top, No. 27 -- for the bullet point on the right, I'm not sure why you're limiting necessarily to informed consent documents, recruitment tools, questionnaires, and surveys. But it seems you've created a whole big messaging library, right? So I would think it's also dissemination of the messaging library, which is identified somewhere later in the document, but also not in terms of messaging, but also what you've learned about the channels of communications, being able to communicate with outside agencies about how those are being used effectively and what some of the challenges were.

DR. BLALOCK: And Dr. Harwood.

DR. HARWOOD: For me, I think some of it is the actual placement of the message. So we've mentioned some of the social media, but it seems as though the FDA puts out a tweet

and people are expected to just come to the FDA, but maybe a more active finding where the conversation is and better literacy on how to apply social media. So if there are recalls of drugs, then period, mentioning the "at" handle of, say, the drug company and putting it on their actual Twitter feed would take it to the conversations of people who are following the drug as well. The same message, just a different placement.

So I think something on the actual placement of these messages. And hashtags are used obviously on multiple social media. There don't seem to be, in the examples we saw this morning, many hashtags on Facebook or other ones that were being applied either to place the FDA communication within a dialogue that may have already been going on.

DR. BLALOCK: And Dr. McBurney.

DR. McBURNEY: To build on Mr. Harwood's conversation, if I look at the indicators, it's sort of number of retweets from outreach partners, number of documents that show -- industry documents that show improvements. I think really what would be very helpful is for you to sort of proactively plan with your stakeholders, with the industry, if these situations prevail, heaven forbid, then what would be the terms of engagement? And that could be done at a center level, in terms of what would be the hashtag approach, what would be the social media. And to actually have that conversation with the industry or industry stakeholders so there's sort of a collective, you know,

emergency response plan for whether it's a recall or whether it's an update on a product that already is regulated by the FDA and what you want to do then. And I think there are many industries and coalition partners that would help and be glad to have that framework because then everybody's prepared. It's like having your emergency response plan in place.

DR. BLALOCK: And one final comment, I think, by Dr. Lee.

DR. LEE: Yeah, following on Mr. Harwood's comment about the social media measures, the other thing is to look at term searches on Google to see if you get a little spike or a sustained discussion around that particular topic after your messaging gets out there.

DR. BLALOCK: Okay. And I am supposed to kind of summarize, and I'm not going to. What I am going to say -- I'm supposed to sort of summarize what I've heard from other people, and I think that's a little bit too challenging for me. What I'm going to do is say a couple of things about what I think are a couple of the most important things that I've heard today, and then I'm going to send it around for everyone to spend, you know, about 30 seconds or so each, you know, 30 to 45 seconds or so about sort of the take-home message, what's the most important thing that you hope the FDA heard today?

And for me, I think that -- number one, I think that you've done an amazing amount of work in a year. So I hope that nothing that you've heard discourages you from that. And

I did hear a fair amount of talk about maybe a little bit of the structure and especially the different audiences, and maybe it might even be valuable if somehow it could be restructured so the things that the audience really was -- at least the FDA staff could be separated from, you know, goals and objectives that are related to people external to the FDA.

So I'm going to start with Dr. Zavala. And what would you like the FDA to remember about today's meeting?

DR. ZAVALA: Firstly, environmental scan was spot on. And I've been trying to connect this morning's presentation to this afternoon's strategic plan, and then going to what Dr. Krishnamurthy said so nicely, that this is more for staff as opposed to audience. But then I'm also hearing and feeling about one of the end users, the consumers. So as you go to the iterations of your strategic plan, I feel strongly about strong partnership with grassroots organizers and events to disseminate information and also another way to gather data to see if they actually are comprehending.

Thank you.

DR. BLALOCK: Dr. Dieckmann.

DR. DIECKMANN: I think the most important thing for me was what I was talking about in terms of coming up with a very clear and explicit process document, at which you would make sure that someone could actually walk through, taking into account the different goals of communication and the different

decision contexts, the different targeted audiences. And that document could even be broader than what I was saying before. It could even walk through -- therefore, then you test the message. Then you circle back to the beginning and make changes to the message and so on, and you would have a complete document there which would have all the state of the science of these different paths on the decision tree.

And it wouldn't be that every agency would have to go through every one of these steps, because sometimes it's just not plausible to test or sometimes it's just not just plausible to do something else. But at least it would all be explicit there and people would see what an optimal procedure would actually look like. Let's get as close to optimal as we can in terms of testing these things and make sure, in the end, that we're coming back to actually testing the impact on the public or going back to what you had for target audiences and making sure that even if we leave out some of these lower-level performance metrics, that we're getting at least a few studies on the main things that we're trying to change.

DR. BLALOCK: Dr. Cohen Silver.

DR. SILVER: I think that this is an outstanding document and a fantastic start. I think that one of the challenges for me is recognizing that, as a one-size-fits-all kind of document, it's perhaps not ideal for any one of them. And so I think the possibility of making the distinction between FDA

versus the consumer -- and we heard before the difference between consumers and patients, they're very different in terms of worrying about a drug that needs to be recalled versus flour. So consumers are different from patients, and providers are different from other professionals.

So I think that there is -- I guess one needs to make a decision. Are we going to try the one-size-fits-all, or are we going to have an overarching theme but then different potential plans for different audiences? And I think the challenge is, you know, the decision that the FDA needs to make. Does it make more sense to keep this large overarching plan or to target a specific audience for each one?

DR. BLALOCK: Dr. Harwood.

DR. HARWOOD: I think, for me, it's that although they're characterized as lower-level outcomes, they will actually provide the big impact at the sort of upper level. So if you're going to use these two-way communications, you have to be an equal partner. You can't just put your message out there and expect people to read it. You must participate in the conversation. And to that, I think also just again the placement of the message is equally as important as the message itself.

DR. BLALOCK: Dr. Hallman.

DR. HALLMAN: Where do I begin? So this is obviously really ambitious. You know, I think it's great that you've

recognized that what you're engaged in is trying to change the culture of the Agency. I think that the key to this is making it easy for employees to do this and to make them want to do this. All the other things are ways to help them do this and to recognize whether they're actually achieving the particular outcomes.

But where I think we need to work is getting people to the point where they really, really want to do this and that they are sort of self-correcting as opposed to being externally corrected. And I agree with some of my colleagues that this may be easier to do with particular groups or to start with particular groups and go all the way through and show a success and create a group of apostles who can basically go out and spread the word.

DR. BLALOCK: Dr. Yin.

DR. YIN: I think I'm probably saying what everybody else is saying about how important it is to measure the consumer impacts of the changes you guys are proposing. So measuring the improvements in knowledge, measuring -- trying to figure out how we might measure informed decision making, but decision making, and to prioritize and not try to do it for every single type of communication, but maybe pick out the really high-priority ones to start with and create models for how you might assess knowledge and decision making. And also I like the idea of prioritizing who you're training to create this group of

people who -- as he said, a starting point, who are the apostles.

DR. BLALOCK: Dr. Berube.

DR. BERUBE: Congratulations. A lot of work. I know what goes into these. My blessings on you. It's a tough process. First, your staff is the fulcrum, right? Always keep that in mind and find every possible way to motivate them and provide enticements, do whatever you can. That's how you're going to make a system here that will work.

The other thing I think to consider, it's not just getting the staff on line, it's also the assessment end of this, which I think was not taken as seriously as it could have been. You could have spent more time talking about assessment tools that could be used, could be employed. Given the vagaries of budgets, I'm not sure how much flexibility you have.

The last thing: Usually, when I do mappings, I repeat this over and over and over again. You know, the maps work, but they don't work equally for everyone. And so I always talk about how to weight variables, that sometimes some parts of the map are better than other parts of the map for different components in the organization you're working with. And it's just to make that judgment call. And you know your folks, you know your centers, and you have a better understanding of what that's like than we do. But I think you know where this would really work well and where it would have the most challenges,

and it would be a good idea to, as the last speaker just said, structure it. You know, try to figure out what goes in what order, not try to accomplish all of this in one fell swoop, but just do it scientifically.

DR. BLALOCK: Dr. Lee.

DR. LEE: Again, like the rest of us, I want to commend you on this wonderful effort. Sometimes I come to, not this particular panel, but I go to panels, and you wonder whether you're listening to what we're saying, and it's obvious that you guys haven't missed anything, incorporating a lot of the feedback into this document. The only concern I have is whether each one of these elements puts you in the weeds and whether you want to make sure that you focus on the outcome; that is, does this help simplify the decision making for the patient, and is the message reaching the right audience? And if each one of these indicator elements do that, I think you'll be fine.

DR. BLALOCK: Dr. Krishnamurthy.

DR. KRISHNAMURTHY: First of all, I want to echo the comments made by other Committee members, that this is a massive undertaking that you have embarked on. And I had a little bit of a difficulty initially understanding like, you know, how to grasp this so that we could be of some use. But now I think a metaphor sort of makes a whole lot of sense for me. To me, it looks like a car company that wants to put out

daily high-quality output for the customers. You want to put out high-quality information products for your customers, and you are coming up with a process for internally what should we be doing in order to make sure that we can put a good quality output.

Having said that, I also want to kind of tell you that the four big boxes that you have seem to be spot on. I would add a few other things. Like, for example, one of the things that is missing from Box No. 2 is, if you want to target a customer, you need to know who the customer is and what their information needs are. I don't see that. Maybe I'm missing something.

And also Dr. Cohen Silver made an important point about, in the dissemination box, the media contacts element was missing, and I think that will definitely substantially add to your internal process metrics.

Overall, I think this chart is better presented horizontally from left to right rather than from top to bottom. That way, people will understand what is the flow, how things are going from one to another. But overall, it's a very good job. I just want to commend the group for having put this together.

DR. BLALOCK: Dr. Pleasant.

DR. PLEASANT: Thanks.

I'm going to start where I -- stop where I started, which was I'm really glad that you're moving in this direction, and

my critique, not criticism, is meant to help it work because it's that important.

I want to remind you that you have another resource here in town, that you might want to consider consulting with the National Academy of Medicine Roundtable on Health Literacy. That's a very broad and diverse group of individuals who will bring a different perspective. There were actually three of us who are members in the room today at one point in time or another, which is the most I've ever seen, to indicate the level of interest that you might find there. And, in fact, we will be meeting as a group at the end of next week, which I know is quick, but there is a second day that's a private meeting which might be the venue that you want, and if you want me to make introductions, I'm happy to do that.

As to the documents themselves, ultimately, to make this work and operationalized, you know, you're going to have to define terms throughout in order to actually pick your indicators; that includes health literacy and then a subset of health literacy, the plain language.

I think it's very important to keep in mind what -- I think it was Dr. Harwood that talked about the supply and demand and the equity in the relationship between who you're serving and who's doing the serving. It's become so important in this area that in Europe -- I imagine some of you know this. They're actually right now creating lay summaries for clinical

trials that report back the results of the clinical trials to the participants, and they have to be in lay language. So in other contexts in nations, this is -- that feedback mechanism is really being highlighted.

And finally, you work with a bunch of smart people, and this might sound trite to some, but you really need to practice what you preach. Your documents have to live up to the standards of plain language and health literacy, or other staff are going to not believe that the effort is true to its core.

DR. BLALOCK: Dr. Lipkus.

DR. LIPKUS: I think you folks have done an absolutely great job in terms of starting this process. My comments, which echoes a lot of what has already been said, is one, I think you will benefit greatly by getting as many stakeholders involved in this process as possible, knowing that they each bring a very unique perspective which ultimately boils down to where are the commonalities and where are the differences, and how could you use that to your advantages, understanding the various perspectives.

And that also brings us a notion of suggested best practices. Suggested best practices are main effects when we know in life there are interactions and so forth. So don't take best practices to mean that it generalizes, because oftentimes it doesn't necessarily do that.

And I think my last one is to get real good clarity in

terms of your outcome measures for what specific goals, for which target audiences, for which channels of communication, and ultimately determine what you think is considered a success and why.

DR. BLALOCK: Ms. Witczak.

MS. WITCZAK: Thank you. First of all, I'd like to say thanks for inviting me to be a guest on this Committee. And I would like to echo a lot of what was already said. But I'd like to say, you know, at the end of the day, the consumer is your audience. I think you've got to meet consumers and the public, whether they're consumers, patients, where they're at. Don't be afraid to get into the community and not assume that you know what they want. You know, there are a lot of outside resources, other agencies, ad agencies, marketing communications. I don't know if you've ever considered using some of them, even just as ideas to bounce things off.

But I think that's something I wouldn't be afraid to -- and you know, partnering with your consumer and patients, it's a conversation. Really, it's important to target and tailor, because we need to get back the reputation that the FDA's resources are a trusted resource, because there's a lot of information out there that we're being bombarded by from the industry and their experts, their marketers, and we could learn some things from the industry, because at the end of the day, there are real-world consequences to this information.

So thank you.

DR. BLALOCK: And Dr. McBurney.

DR. McBURNEY: Ms. Zwanziger, Ms. Duckhorn, and Mr. Bertoni, thank you for your efforts today. This is a really important project, and it's clear the depth of thought that the FDA has put into SPRCHL. Because of your oversight, the FDA's oversight, really the breadth of it is so wide, and the variety of topics, you have everything from science and regulatory updates, to recalls, to elevation of new information on risk and benefits.

It's really going to be important that you can encourage acceptance of this strategy and really drive ownership at the priorities, audiences, and goals to each of your centers and offices, because that's how it will be effectively communicated. You need to engage with the private and non-government agencies to work together with them in that regard.

And finally, my guidance would be that you have way too many performance indicators that are activity indicators, and there's not enough outcome indicators. So don't let the process overwhelm the goal.

Thank you.

DR. BLALOCK: And Ms. Duckhorn and Mr. Bertoni, do you have any final remarks?

MR. BERTONI: I really want to thank everyone again. The comments, particularly hearing this round of summation was

very, very helpful, and I've got all kinds of notes all over my thing here, and it's been really a pleasure. But I think if I were to hear -- a couple things that I took away that I think are particularly important is when you take on something at the Agency level, you try to be comprehensive, and yet we all know that the reality happens down on the front lines of these programs. So some of these comments about being more specific, being more targeted, and how you implement it, I think there's a lot of work to do, but we hear that.

You're seeing kind of the tip of the iceberg in some sense here, but it's very good feedback because we can do more to be clear about what we're communicating here and all the pieces that need to contribute to it.

The other thing I'll note is that there is some mention of science here, but I will point out we tied this to Strategic Goal 3, but Strategic Objective 3.1 is to strengthen the social and behavioral sciences to help patients, consumers, and professionals make informed decisions about regulated products. So there is a regulatory science component to all of our strategic goals, and it remains essential to this particular one because of the other part.

And then, finally, I'll just say I heard a lot about the culture change, and that is something that we do pay a lot of attention to, and we recognize the importance of this. And it's not just about our own culture change; it's in response to

what's going on out there. Some great comments from you folks about being engaged, you know, being involved in a dialogue, not just throwing information out there. So just a rich set of feedback that we'll have to think hard and consult a lot to figure out how to incorporate it into this, knowing that no one document will be perfect, but I think this is going to help us make this much, much better going forward.

So thank you again. It's just extremely helpful.

DR. BLALOCK: Thank you very much.

So I'd like to thank the Committee, the FDA, and the Open Public Hearing speakers for their contributions to today's meeting.

And so the November 7th, 2016 meeting of the Risk Communication Advisory Committee is adjourned.

(Whereupon, at 4:38 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

November 7, 2016

Silver Spring, Maryland

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

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TOM BOWMAN

Official Reporter