

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
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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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OPEN PUBLIC HEARING SPEAKERS:

SAMANTHA WATTERS, M.P.H.
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.)

1
2
3 DR. BLALOCK: I'd like to call this meeting of the Risk
4 Communication Advisory Committee to order.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 Committee meetings.

2 Thank you.

3 (Pause.)

4 UNIDENTIFIED SPEAKER: You broke it.

5 MR. BERTONI: I broke it.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 The Food and Drug Administration is convening today's
15 meeting of the Risk Communication Advisory Committee under the
16 authority of the Federal Advisory Committee Act of 1972. With
17 the exception of the Industry Representative, all members and
18 consultants of the Committee are special Government employees
19 subject to federal conflict of interest laws and regulations.

20 The following information on the status of this
21 Committee's compliance with Federal ethics and conflict of
22 interest laws covered by, but not limited to, those found at 18
23 U.S.C. Section 208 are being provided to participants in
24 today's meeting and to the public.

25 FDA has determined that members and consultants of this

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

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

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

1 Strategic Plan for Risk Communication and Health Literacy.

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

6 We would like to remind members and consultants that if
7 the discussions involve any other products or firms not already
8 on the agenda for which an FDA participant has a personal or
9 imputed financial interest, the participants need to exclude
10 themselves from such involvement and their exclusion will be
11 noted for the record.

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

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

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

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

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

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

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

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

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

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

24 DR. BLALOCK: Thank you.

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

1 Malcolm Bertoni, Associate Commissioner for Planning.

2 Mr. Bertoni.

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

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

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

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

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

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

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

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

7 Thank you.

8 DR. BLALOCK: Thank you, Mr. Bertoni.

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

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

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

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

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

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

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

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

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

1 few of FDA's external communication vehicles:

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

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

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

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

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

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

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

25 Please note: After presentations, there will be a brief

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 - And then *Federal Register* notices.

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

25 So our goals for engagement on these various channels, we

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 could be around 150,000.

2 A couple of weeks ago we had information that went out
3 regarding something called teething tablets, which are used for
4 babies when they're teething, and there are gels and tablets
5 that are used, and there was a new notice stating do not use
6 these, and if you have them, to throw them away. They had been
7 in our search terms for a very long time within FDA, and this
8 is the first update in a number of years. As of last week when
9 I updated these, the reach on this alone was somewhere around
10 8.5 million, and post clicks alone was over one million. And I
11 show the information there as to what Facebook reach and post
12 clicks means. This has been definitely our highest performer
13 on Facebook. I'm not talking about other things that come up
14 via FDA. This has been the highest Facebook performer because
15 there was a lot of interest in it because it applied to babies,
16 and people have an interest in it. So again, a lot of variety,
17 something that was definitely not what we were expecting when
18 we put the information out on this, and very, very different
19 versus the other reach that we typically have on our different
20 posts that we'll put out there.

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

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

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

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

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

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

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

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

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

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

7 MS. NATANBLUT: Close enough.

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

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

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

1 consumers to have the information and understand it.

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

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

1 recommended that we really needed to have a consistent format
2 that we would be using for providing the key information, and
3 we've been using that literally hundreds of times in the last
4 5 years, so that, too, was very helpful to us.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 into one of our considerations.

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

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

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

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

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

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

1 consequences.

2 So what you're looking at here is a webpage with a Drug
3 Safety Communication posted on it. This is a relatively new
4 web posting format for us. In the past, there's been a solid
5 block of text that has been separated into sections, but about
6 4 years ago, shortly after I started, we started using a tabbed
7 format on the website. That worked very well; we were able to
8 tailor some of the information so it wasn't so text heavy for
9 people. They could also find the sections that were most
10 relevant to them and look at those. So that was a tabbed
11 format. We did, again, go to this format; this is a mobile
12 friendly format. We have done some research and testing with
13 consumers on this format as well as this format on the website.
14 People are very comfortable with this; they understand that
15 they need to click down the arrows to be able to get to the
16 full content. They don't have any problem, on the mobile
17 sites, with scrolling through once they get to the pages with
18 the information.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23 Thank you very much.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 So materials that could support patient education for this

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 So Ms. Butler.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 really helps us do our best work.

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

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

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

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

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

25 We do, however, use our channels to communicate closely

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

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

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

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

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

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

1 information.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 Our health promotion program: Our research shows that a

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

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

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

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

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

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

1 materials can be found, including the videos.

2 The dissemination and promotion of this campaign was
3 launched during National Consumer Protection Week, from March
4 6th through 12th, the ethnic and traditional media outreach.
5 We did also media interviews with subject matter experts and
6 spokespersons. We conducted a Google AdWords campaign in
7 different languages. We also conducted a social media outreach
8 through YouTube, Flickr, Facebook, Twitter, and Pinterest. We
9 reached out to our stakeholders via our newsletter and e-mails,
10 and we also sent blast consumer e-mails internally and
11 externally to all our stakeholders and partners alike.

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

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

4 MS. NUNEZ: Our Google AdWords terminology.
5 (Spanish video.)

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

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

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

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

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

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

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

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

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

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

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

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

22 And this concludes the Office of Minority Health
23 presentation.

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

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

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

10 Dr. Pleasant.

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

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

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

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

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

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

6 DR. BLALOCK: Dr. Lipkus.

7 DR. LIPKUS: Thank you.

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

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

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

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

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

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

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

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

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

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

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

10 Thanks.

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

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

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

12 Thank you.

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

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

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

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

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

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

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

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

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

14 Thank you.

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

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

1 anything?

2 (No response.)

3 DR. BLALOCK: Then Dr. Berube.

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

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

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

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

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

6 DR. BERUBE: Yeah.

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

9 DR. BERUBE: Right.

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

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

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

17 Thank you.

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

20 (No response.)

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

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

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

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

18 MR. VENTURA: Jeff Ventura again from CTP.

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

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

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

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

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

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

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

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

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

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

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

1 wherever you may see it.

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

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

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

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

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

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

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

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

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

23 DR. BLALOCK: Thank you.

24 And just one final question before the break.

25 Ms. Witczak.

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

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

18 So those are my questions. Thanks.

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

20 MS. BUTLER: I'm sorry.

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

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

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

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

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

23 DR. RAUSCH: Paula Rausch from CDER.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 So Dr. Zwanziger.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 code is yellow.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 DR. BLALOCK: Thank you, Dr. Zwanziger.

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

1 clarifying questions from the Committee.

2 (Off microphone comment.)

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

7 So Dr. Lipkus.

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

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

1 the term "health literacy."

2 DR. BLALOCK: Dr. Yin.

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

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

16 DR. BLALOCK: Dr. Liu.

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

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

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

14 DR. BLALOCK: Dr. Lee.

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

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

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

22 DR. BLALOCK: Dr. McBurney.

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

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

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

16 Thank you.

17 DR. BLALOCK: Dr. Kreps.

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

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

8 DR. BLALOCK: Dr. Hallman.

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

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

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

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

18 DR. BLALOCK: Dr. Berube.

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

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

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

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

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

17 DR. ZWANZIGER: Um-hum.

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

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

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

4 DR. BERUBE: Can you explain direct influence over?

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

18 DR. BERUBE: Point taken.

19 DR. BLALOCK: Dr. Bertoni.

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

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

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

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

25 DR. BLALOCK: Thank you. Dr. Dillard.

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

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

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

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

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

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

13 MR. BERTONI: Malcolm Bertoni.

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

1 Thank you for that.

2 DR. BLALOCK: Thank you.

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

8 So Dr. Pleasant.

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

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

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

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

13 And I'll stop.

14 DR. BLALOCK: Yeah, I --

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

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

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

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

21 Thank you very much.

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

23

24

25

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

(1:31 p.m.)

1
2
3 DR. BLALOCK: Okay, I've got that it is 1:31 now, so I'd
4 like to call us back to order and resume the Committee meeting.

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

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

11 MS. FACEY: Both the Food and Drug Administration and the
12 public believe in a transparent process for information
13 gathering and decision making. To ensure such transparency at
14 the Open Public Hearing session of the Advisory Committee
15 meeting, FDA believes that it is important to understand the
16 context of an individual's presentation. For this reason, FDA
17 encourages you, the Open Public Hearing speaker, at the
18 beginning of your written or oral statement, to advise the
19 Committee of any financial relationship that you may have with
20 any company or group that may be affected by the topic of this
21 meeting. For example, this financial information may include a
22 company's or a group's payment of your travel, lodging, or
23 other expenses in connection with your attendance at the
24 meeting. Likewise, FDA encourages you, at the beginning of
25 your statement, to advise the Committee if you do not have any

1 such financial relationships. If you choose not to address
2 this issue of financial relationships at the beginning of your
3 statement, it will not preclude you from speaking.

4 DR. BLALOCK: And for the record, there were no written
5 comments received. For today's Open Public Hearing, we've
6 received three requests to speak. Each scheduled speaker will
7 be given 8 minutes to address the Committee. We ask that you
8 speak clearly to allow for an accurate transcription of the
9 proceedings of the meeting. The Committee appreciates that
10 each speaker remains cognizant of their time.

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

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

25 My background is an unusual one. I have degrees in

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

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

25 Second, you mentioned consistency in branding, formatting,

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

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

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

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

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

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

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

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

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

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

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

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

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

13 DR. BLALOCK: Thank you very much.

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

16 DR. DUHIG: No.

17 DR. BLALOCK: So you can correct me.

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

1 applied in service to patients.

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

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

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

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

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

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

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

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

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

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

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

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

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

21 Thank you.

22 DR. BLALOCK: Thank you.

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

25 MS. MYERS: Thank you.

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

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

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

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

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

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

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

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

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

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

1 partner, Sommer Consulting, who does this for us.

2 And then we had to actually ask health literacy questions.
3 When you do phone screening to get people into market research,
4 we now ask the one question: How competent are you in filling
5 out medical forms by yourself? That's not perfect. We've seen
6 over the years, you know, some people switch. We ultimately
7 categorize people using the Newest Vital Sign, which for those
8 of you who are not familiar with it, is about reading an ice
9 cream label. Now, until the consumer food labeling changes in
10 2 years, this is what we do. We'll figure it out. We'll have
11 to look towards that, too.

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

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

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

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

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

25 We've been able to achieve high comprehension of patient

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

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

16 Anyway, thank you.

17 DR. BLALOCK: Thank you very much.

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

23 (No response.)

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

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

3 (No response.)

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

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

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

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

20 DR. ZWANZIGER: Thank you, Dr. Blalock.

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

24 a. Does the Overarching --

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

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

5 So Dr. Rimal.

6 DR. RIMAL: Thank you.

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

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

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

5 DR. ZWANZIGER: Thank you.

6 The top boxes do -- and if you want to look at your
7 questions, those are those -- the top boxes are in Question No.
8 1, as Dr. Rimal just mentioned. Those do look at knowledge,
9 and we recognize that knowledge doesn't automatically result in
10 behavior change for me or for anyone else. There has to be
11 something more to it. The FDA sometimes is looking for
12 behavior change and sometimes really isn't in a position to do
13 that because it may be that the outcome we really are in a
14 position to want is an informed healthcare provider and patient
15 or an informed consumer, and what kind of behavior there is to
16 do will be appropriate in one way for one individual and
17 another way for another individual.

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

1 they could look for to try and achieve behavior change.

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

5 DR. RIMAL: Not right now, right?

6 DR. ZWANZIGER: Oh, right. Sorry.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 Dr. Dillard.

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

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

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

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

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

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

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

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

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

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

1 parameters that define whether a decision is a good decision.

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

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

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

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

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

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

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

25 DR. BLALOCK: Dr. Yin.

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

14 DR. BLALOCK: Dr. Berube.

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

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

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

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

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

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

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

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

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

5 DR. BLALOCK: Okay. Dr. Lee.

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

20 DR. BLALOCK: Dr. McBurney.

21 DR. McBURNEY: Thank you very much.

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

1 was their reason for subscribing.

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

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

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

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

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

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

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

24 DR. BLALOCK: Dr. Dieckmann.

25 DR. DIECKMANN: Thank you.

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

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

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

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

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

11 DR. BLALOCK: Dr. Pleasant.

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

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

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

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

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

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

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

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

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

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

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

24 DR. BLALOCK: Dr. Krishnamurthy.

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

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

5 And the second question is do the proposed performance
6 indicators provide meaningful measurement of progress towards
7 the Overarching Outcome? And for that I looked at page number
8 21 on the document that was given to us, which specifically
9 lists out exactly how it will be measured. For example, it
10 says the measure indicator for increased accessibility for
11 actionable and accurate information is the percentage of total
12 FDA communications that are developed or revised using health
13 literacy or plain language principles. And then they go on to
14 tell, in the next column, it is going to be -- the unit of
15 measure is going to be the number of FDA communications or
16 campaigns that use health literacy or plain language
17 principles.

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

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

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

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

24 DR. BLALOCK: Great. Dr. Hallman.

25 (Off microphone comment.)

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

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

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

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

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

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

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

13 DR. BLALOCK: Dr. Hallman.

14 DR. HALLMAN: Thanks.

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

1 health. So that's sort of one point.

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

21 DR. BLALOCK: Dr. Sneed.

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

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

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

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

21 DR. BLALOCK: Dr. Rimal.

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

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

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

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

1 that knowledge into behavior.

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

5 Dr. Dieckmann.

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

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

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

6 DR. BLALOCK: And Dr. Lipkus.

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

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

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

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

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

1 wanted to say something in response.

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

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

25 And then we use this overarching framework to help, first

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

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

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

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

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

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

7 (Laughter.)

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

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

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

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

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

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

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

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

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

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

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

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

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

17 DR. KRISHNAMURTHY: Okay.

18 DR. BLALOCK: Okay.

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

21 DR. BLALOCK: It will come up a lot more in the next hour.
22 Dr. McBurney.

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

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

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

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

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

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

21 DR. BLALOCK: Dr. Pleasant.

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

25 DR. BLALOCK: Absolutely.

1 DR. PLEASANT: Okay, thanks.

2 DR. BLALOCK: Absolutely.

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

16 DR. BLALOCK: And then Dr. Yin.

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

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

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

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

6 DR. HALLMAN: Yes.

7 DR. BLALOCK: Go ahead, then.

8 DR. HALLMAN: Okay.

9 (Laughter.)

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

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

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

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

20 DR. BLALOCK: Dr. Lipkus.

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

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

8 DR. BLALOCK: Thank you.

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

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

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

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

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

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

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

3 And Question (b), 2b, is

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

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

14 Dr. Berube.

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

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

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

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

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

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

19 DR. BLALOCK: Dr. Krishnamurthy.

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

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

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

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

1 and actionable?

2 DR. BLALOCK: Dr. Pleasant.

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

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

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

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

1 increasing population health literacy? Is that what I heard?

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

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

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

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

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

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

4 DR. BLALOCK: Dr. Sneed.

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

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

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

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

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

16 DR. BLALOCK: Dr. Zavala.

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

23 DR. BLALOCK: Dr. Hallman.

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

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

7 DR. BLALOCK: And Dr. Rimal.

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

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

24 DR. RIMAL: I think that would be fine.

25 DR. ZWANZIGER: Okay.

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

4 DR. ZWANZIGER: Yeah.

5 DR. BLALOCK: Dr. Cohen Silver.

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

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

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

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

4 DR. BLALOCK: Okay. Dr. McBurney.

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

7 DR. BLALOCK: And Dr. Krishnamurthy.

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

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

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

3 (No response.)

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

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

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

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

14 (Off microphone comment.)

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

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

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

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

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

4 DR. ZWANZIGER: Thank you, Dr. Blalock.

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

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

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

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

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

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

1 and performance indicators first.

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

5 Dr. Dieckmann.

6 DR. DIECKMANN: Thank you.

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

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

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

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

22 DR. BLALOCK: Dr. Lee.

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

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

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

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

6 DR. ZWANZIGER: Uh-huh.

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

9 DR. BLALOCK: Dr. Sneed.

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

17 DR. BLALOCK: Dr. Krishnamurthy.

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

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

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

19 Dr. Krishnamurthy.

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

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

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

4 Dr. Hallman.

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

7 (Laughter.)

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

22 DR. BLALOCK: Dr. Yin.

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

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

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

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

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

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

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

8 DR. BLALOCK: I definitely agree with that.

9 Dr. McBurney.

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

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

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

8 DR. BLALOCK: And Ms. Witczak.

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

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

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

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

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

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

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

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

8 DR. BLALOCK: Dr. Lipkus.

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

24 DR. BLALOCK: Dr. Hallman.

25 (Off microphone comment.)

1 DR. BLALOCK: Dr. Harwood.

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

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

23 DR. BLALOCK: Dr. Liu.

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

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

8 DR. BLALOCK: Other comments on No. II?

9 Dr. Cohen Silver.

10 DR. SILVER: Just in thinking about understanding the
11 audience, I think just reflecting on the lifespan perspective,
12 so not just only kids but, you know, older people are less
13 likely to use Instagram than younger people, so recognizing the
14 range of preferences and skills of the different target
15 audiences across the lifespan and then also across cultural and
16 language groups.

17 DR. BLALOCK: And other comments on No. II?

18 (Off microphone comment.)

19 DR. BLALOCK: Oh, Dr. Hallman.

20 DR. HALLMAN: So I wonder if it's appropriate, under II,
21 to include something about this Committee itself, and use of
22 this Committee or perhaps attendance by people at FDA at some
23 of these Committee meetings that are relevant. Maybe I missed
24 that.

25 DR. PLEASANT: Sorry. Isn't it in the activity listed as

1 one of these? It's just not an indicator, but --

2 DR. HALLMAN: It was not an indicator, so it's an
3 activity.

4 DR. PLEASANT: Yeah, sorry.

5 DR. BLALOCK: Okay. I sort of want to reiterate the
6 comment that I made before, that it seems to me like there's a
7 fair amount missing, you know, when you think about the science
8 of risk communication and where emotion fits in. You know, we
9 heard about that at the last meeting. You know, like I said
10 before, how you present quantitative information -- and I see
11 II.B -- II.C, I'm sorry, II.C, include application of research
12 evidence and feedback knowledge into operations. Perhaps it
13 goes there, but I just don't see a lot -- you know, in contrast
14 to everything related to plain language, I don't see very much
15 related to other aspects of risk communication anywhere else,
16 really. And it's really different -- I'm looking to see -- you
17 know, it's really different than targeted messages you might
18 sort of fit underneath that box but would be kind of squeezing
19 it in. So, you know, where is all the science of risk
20 communication? And I honestly don't see that beyond the plain
21 language, and I don't know. I think that's a kind of big
22 comment. Does anyone else share that concern, or am I just
23 kind of off the mark?

24 Dr. Lipkus.

25 DR. LIPKUS: One of the things in the morning when I posed

1 a question about how are you defining health literacy, you
2 mentioned, well, it includes the language, it includes
3 numeracy, graph literacy, and so forth. I think it may be
4 useful to maybe say this is how we're defining this, and it
5 includes these components, so it's more encompassing, that
6 people could refer to in a document, that they know that that
7 one's included.

8 And I think also taking into account what Dr. Dieckmann
9 said, you know, you could also think about risk communication
10 in terms of if its purpose is for knowledge, to improve
11 knowledge, whether the purpose is for persuasion, whether the
12 purpose is for conflict management, because sometimes you're
13 going to have contradictory information and conflict because of
14 risk, and the fourth one is crisis management. So those are
15 the four major sections of risk communication. So if you could
16 say risk communication encompasses these domains, which the
17 Agency would look over, and I think people will know that's
18 part of this over-encompassing document.

19 DR. BLALOCK: Dr. Zavala first.

20 DR. ZAVALA: Hi. McCormick 2006, out of Cornell, she
21 reviewed like 10 years' worth of risk communication research,
22 and she started to speak to values, and that's something you
23 mentioned, a comment.

24 DR. BLALOCK: And Dr. Berube.

25 DR. BERUBE: Yeah, I'm less concerned because I think,

1 under II.A.b, I think you address risk communication, and I
2 think, on page 14, you address the SGE. I think you also
3 address contracts and grants and cooperative agreements for
4 research. I think it's pretty well done. I just want to
5 remind everybody, if we have moved increased skills and
6 abilities of FDA staff up a level, we're going to have to look
7 at some lower-level outcomes in order to figure out -- because
8 right now it's just a grand "let's make them all better," which
9 is great, but we'll need to have some way to parse that out.

10 And No. 19 on page 15, oddly enough, under 19 you have
11 examples of specific steps and recommended activities. That
12 could be re-culled, I think, to produce lower-level outcomes.
13 I don't think it would be too hard, but I sure the hell
14 wouldn't want to see that all by itself without being
15 delineated and, you know, given its time in the light.

16 DR. BLALOCK: Okay. And I think probably I'll need to
17 move on to the third box here. I do want to echo a little bit
18 of something that Dr. Lipkus said, you know, in terms of the
19 persuasion versus just information, that that is, I think, a
20 huge issue, and I think that the FDA does do both, that
21 sometimes there really is something that you're trying to get
22 people to do, whether it's to throw away the flour that might
23 be contaminated and in other cases where it's just
24 informational, like a lot of the risks of drugs, and that it's
25 really important to distinguish between those, and I'm not

1 quite sure that that kind of issue I saw here anyplace.

2 So let's move on to No. III.

3 DR. ZWANZIGER: So for Major Contributing Outcome No. III,
4 the questions again:

5 a. Do the lower-level contributing outcomes support
6 it? Are there gaps?

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

11 c. Do the proposed performance indicators provide
12 meaningful measurement of progress toward the outcomes?
13 Can you suggest others for us to consider?

14 DR. BLALOCK: Dr. Krishnamurthy.

15 DR. KRISHNAMURTHY: I had a question in this regard. This
16 one seems to relate to internal processes for improving
17 outputs. Do you have some kind of a meeting or a written FDA
18 communication, personnel kind of sharing ideas? Do you have a
19 structured mechanism for things that work really well and
20 things that -- where you can share ideas within the FDA itself,
21 like almost a seminar or whatever you want to call them, best
22 practices and things that do work? That will actually allow
23 you to expedite some of the learning from within the
24 organization, given that there are multiple units that are also
25 simultaneously trying to come up with communication outputs.

1 DR. ZWANZIGER: Well, that is one of the important
2 activities of the Risk Communication and Health Literacy
3 Working Group that meets monthly, internally, to share
4 information and undertake communication campaigns sometimes,
5 like for Health Literacy Month. But yeah, we also have an
6 internal Social Science Forum that meets quarterly, and a
7 Social and Behavioral Sciences Subcommittee that meets
8 quarterly. And I'm sorry, I apologize to the FDA. What I
9 really should have said is that we have an FDA Communication
10 Council made up of all the communications directors at FDA, and
11 the Risk Communication and Health Literacy Working Group -- you
12 know it from me. But in fact, we report to the Communication
13 Council. We're a subgroup of that.

14 DR. KRISHNAMURTHY: A follow-up question that I had was,
15 is it possible to have some structure or mechanism by which you
16 could pose questions? Do you have an internal bulletin board
17 kind of a thing where you could serve up problems that people
18 could -- based on their expertise internally?

19 DR. ZWANZIGER: Yeah, we use both SharePoint, which is the
20 Risk Communication and Health Literacy Working Group, and we
21 also use just kind of a sort of internal listserv with the
22 social science formally. You just say hey, folks, here's a
23 question.

24 DR. KRISHNAMURTHY: So could that be an indicator, as
25 well, as to how much you bring your challenges to a cross-

1 functional team that can look at it as a potential indicator of
2 improving the quality of communications?

3 DR. ZWANZIGER: Certainly, we'd be happy to consider that.

4 DR. BLALOCK: Dr. Berube.

5 DR. BERUBE: I think, under III.B, I would probably want
6 to plan something like improved consistency and the branding
7 and framing, and separately, formatting and presentation. They
8 are two different things. Branding and framing is, you know,
9 the cues you give somebody to figure out what the message is
10 about. Formatting and presentation is almost a management
11 process. You're trying to maintain consistency across the
12 entire institution for credibility purposes. They're just
13 different goals, sort of.

14 DR. BLALOCK: And we've got just a few minutes left to
15 move on to No. IV. Whoops, Dr. Pleasant first, and then we'll
16 move on to No. IV.

17 DR. PLEASANT: This is quick. Just efficiency isn't
18 always the outcome that you want. Efficiency isn't guaranteed
19 to lead to increased accessibility to actionable and accurate
20 FDA communications and benefit-risk information. Medical
21 doctors are incredibly efficient in their communication with
22 the patients. That's why we give 5 to 8 minutes. So you just
23 need to balance that efficiency with a desired outcome like
24 effectiveness.

25 DR. BLALOCK: Now I think we're ready to move on to IV.

1 DR. ZWANZIGER: Yeah, thank you for that.

2 So for Major Contributing Outcome IV, improved
3 dissemination of FDA's communications and information:

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

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

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

13 DR. BLALOCK: Dr. Lee.

14 DR. LEE: So I see dissemination as being one of two
15 groups. One is passive information and the other being active
16 information. And in the active information-gathering process,
17 I think you can do some performance measures as to given a
18 consumer task, can they find and reach the appropriate
19 conclusion, and how long does that take? So I think that gives
20 you an overall sense of, can they -- is it organized properly?
21 Once it's organized and you find it, can you understand and
22 then give the right answer? So I think that's kind of a nice
23 overall progress measure that you can see if you're actually
24 making improvements in those things.

25 DR. BLALOCK: Dr. Cohen Silver.

1 DR. SILVER: One of the things that I think is really
2 important to consider is the coordination with traditional
3 media sources. We heard this morning about press releases, but
4 there are ways in which one can have preexisting relationships
5 with certain media sources to ensure that there is an immediate
6 distribution of trusted material. And so I was surprised that
7 there was, at least unless I missed it, no mention of working
8 with the media in any of this discussion, and I think, for
9 dissemination, that's a really critical point.

10 DR. BLALOCK: Dr. Lipkus.

11 DR. LIPKUS: For IV.A, at the very top, No. 27 -- for the
12 bullet point on the right, I'm not sure why you're limiting
13 necessarily to informed consent documents, recruitment tools,
14 questionnaires, and surveys. But it seems you've created a
15 whole big messaging library, right? So I would think it's also
16 dissemination of the messaging library, which is identified
17 somewhere later in the document, but also not in terms of
18 messaging, but also what you've learned about the channels of
19 communications, being able to communicate with outside agencies
20 about how those are being used effectively and what some of the
21 challenges were.

22 DR. BLALOCK: And Dr. Harwood.

23 DR. HARWOOD: For me, I think some of it is the actual
24 placement of the message. So we've mentioned some of the
25 social media, but it seems as though the FDA puts out a tweet

1 and people are expected to just come to the FDA, but maybe a
2 more active finding where the conversation is and better
3 literacy on how to apply social media. So if there are recalls
4 of drugs, then period, mentioning the "at" handle of, say, the
5 drug company and putting it on their actual Twitter feed would
6 take it to the conversations of people who are following the
7 drug as well. The same message, just a different placement.

8 So I think something on the actual placement of these
9 messages. And hashtags are used obviously on multiple social
10 media. There don't seem to be, in the examples we saw this
11 morning, many hashtags on Facebook or other ones that were
12 being applied either to place the FDA communication within a
13 dialogue that may have already been going on.

14 DR. BLALOCK: And Dr. McBurney.

15 DR. McBURNEY: To build on Mr. Harwood's conversation, if
16 I look at the indicators, it's sort of number of retweets from
17 outreach partners, number of documents that show -- industry
18 documents that show improvements. I think really what would be
19 very helpful is for you to sort of proactively plan with your
20 stakeholders, with the industry, if these situations prevail,
21 heaven forbid, then what would be the terms of engagement? And
22 that could be done at a center level, in terms of what would be
23 the hashtag approach, what would be the social media. And to
24 actually have that conversation with the industry or industry
25 stakeholders so there's sort of a collective, you know,

1 emergency response plan for whether it's a recall or whether
2 it's an update on a product that already is regulated by the
3 FDA and what you want to do then. And I think there are many
4 industries and coalition partners that would help and be glad
5 to have that framework because then everybody's prepared. It's
6 like having your emergency response plan in place.

7 DR. BLALOCK: And one final comment, I think, by Dr. Lee.

8 DR. LEE: Yeah, following on Mr. Harwood's comment about
9 the social media measures, the other thing is to look at term
10 searches on Google to see if you get a little spike or a
11 sustained discussion around that particular topic after your
12 messaging gets out there.

13 DR. BLALOCK: Okay. And I am supposed to kind of
14 summarize, and I'm not going to. What I am going to say -- I'm
15 supposed to sort of summarize what I've heard from other
16 people, and I think that's a little bit too challenging for me.
17 What I'm going to do is say a couple of things about what I
18 think are a couple of the most important things that I've heard
19 today, and then I'm going to send it around for everyone to
20 spend, you know, about 30 seconds or so each, you know, 30 to
21 45 seconds or so about sort of the take-home message, what's
22 the most important thing that you hope the FDA heard today?

23 And for me, I think that -- number one, I think that
24 you've done an amazing amount of work in a year. So I hope
25 that nothing that you've heard discourages you from that. And

1 I did hear a fair amount of talk about maybe a little bit of
2 the structure and especially the different audiences, and maybe
3 it might even be valuable if somehow it could be restructured
4 so the things that the audience really was -- at least the FDA
5 staff could be separated from, you know, goals and objectives
6 that are related to people external to the FDA.

7 So I'm going to start with Dr. Zavala. And what would you
8 like the FDA to remember about today's meeting?

9 DR. ZAVALA: Firstly, environmental scan was spot on. And
10 I've been trying to connect this morning's presentation to this
11 afternoon's strategic plan, and then going to what
12 Dr. Krishnamurthy said so nicely, that this is more for staff
13 as opposed to audience. But then I'm also hearing and feeling
14 about one of the end users, the consumers. So as you go to the
15 iterations of your strategic plan, I feel strongly about strong
16 partnership with grassroots organizers and events to
17 disseminate information and also another way to gather data to
18 see if they actually are comprehending.

19 Thank you.

20 DR. BLALOCK: Dr. Dieckmann.

21 DR. DIECKMANN: I think the most important thing for me
22 was what I was talking about in terms of coming up with a very
23 clear and explicit process document, at which you would make
24 sure that someone could actually walk through, taking into
25 account the different goals of communication and the different

1 decision contexts, the different targeted audiences. And that
2 document could even be broader than what I was saying before.
3 It could even walk through -- therefore, then you test the
4 message. Then you circle back to the beginning and make
5 changes to the message and so on, and you would have a complete
6 document there which would have all the state of the science of
7 these different paths on the decision tree.

8 And it wouldn't be that every agency would have to go
9 through every one of these steps, because sometimes it's just
10 not plausible to test or sometimes it's just not just plausible
11 to do something else. But at least it would all be explicit
12 there and people would see what an optimal procedure would
13 actually look like. Let's get as close to optimal as we can in
14 terms of testing these things and make sure, in the end, that
15 we're coming back to actually testing the impact on the public
16 or going back to what you had for target audiences and making
17 sure that even if we leave out some of these lower-level
18 performance metrics, that we're getting at least a few studies
19 on the main things that we're trying to change.

20 DR. BLALOCK: Dr. Cohen Silver.

21 DR. SILVER: I think that this is an outstanding document
22 and a fantastic start. I think that one of the challenges for
23 me is recognizing that, as a one-size-fits-all kind of
24 document, it's perhaps not ideal for any one of them. And so I
25 think the possibility of making the distinction between FDA

1 versus the consumer -- and we heard before the difference
2 between consumers and patients, they're very different in terms
3 of worrying about a drug that needs to be recalled versus
4 flour. So consumers are different from patients, and providers
5 are different from other professionals.

6 So I think that there is -- I guess one needs to make a
7 decision. Are we going to try the one-size-fits-all, or are we
8 going to have an overarching theme but then different potential
9 plans for different audiences? And I think the challenge is,
10 you know, the decision that the FDA needs to make. Does it
11 make more sense to keep this large overarching plan or to
12 target a specific audience for each one?

13 DR. BLALOCK: Dr. Harwood.

14 DR. HARWOOD: I think, for me, it's that although they're
15 characterized as lower-level outcomes, they will actually
16 provide the big impact at the sort of upper level. So if
17 you're going to use these two-way communications, you have to
18 be an equal partner. You can't just put your message out there
19 and expect people to read it. You must participate in the
20 conversation. And to that, I think also just again the
21 placement of the message is equally as important as the message
22 itself.

23 DR. BLALOCK: Dr. Hallman.

24 DR. HALLMAN: Where do I begin? So this is obviously
25 really ambitious. You know, I think it's great that you've

1 recognized that what you're engaged in is trying to change the
2 culture of the Agency. I think that the key to this is making
3 it easy for employees to do this and to make them want to do
4 this. All the other things are ways to help them do this and
5 to recognize whether they're actually achieving the particular
6 outcomes.

7 But where I think we need to work is getting people to the
8 point where they really, really want to do this and that they
9 are sort of self-correcting as opposed to being externally
10 corrected. And I agree with some of my colleagues that this
11 may be easier to do with particular groups or to start with
12 particular groups and go all the way through and show a success
13 and create a group of apostles who can basically go out and
14 spread the word.

15 DR. BLALOCK: Dr. Yin.

16 DR. YIN: I think I'm probably saying what everybody else
17 is saying about how important it is to measure the consumer
18 impacts of the changes you guys are proposing. So measuring
19 the improvements in knowledge, measuring -- trying to figure
20 out how we might measure informed decision making, but decision
21 making, and to prioritize and not try to do it for every single
22 type of communication, but maybe pick out the really high-
23 priority ones to start with and create models for how you might
24 assess knowledge and decision making. And also I like the idea
25 of prioritizing who you're training to create this group of

1 people who -- as he said, a starting point, who are the
2 apostles.

3 DR. BLALOCK: Dr. Berube.

4 DR. BERUBE: Congratulations. A lot of work. I know what
5 goes into these. My blessings on you. It's a tough process.
6 First, your staff is the fulcrum, right? Always keep that in
7 mind and find every possible way to motivate them and provide
8 enticements, do whatever you can. That's how you're going to
9 make a system here that will work.

10 The other thing I think to consider, it's not just getting
11 the staff on line, it's also the assessment end of this, which
12 I think was not taken as seriously as it could have been. You
13 could have spent more time talking about assessment tools that
14 could be used, could be employed. Given the vagaries of
15 budgets, I'm not sure how much flexibility you have.

16 The last thing: Usually, when I do mappings, I repeat
17 this over and over and over again. You know, the maps work,
18 but they don't work equally for everyone. And so I always talk
19 about how to weight variables, that sometimes some parts of the
20 map are better than other parts of the map for different
21 components in the organization you're working with. And it's
22 just to make that judgment call. And you know your folks, you
23 know your centers, and you have a better understanding of what
24 that's like than we do. But I think you know where this would
25 really work well and where it would have the most challenges,

1 and it would be a good idea to, as the last speaker just said,
2 structure it. You know, try to figure out what goes in what
3 order, not try to accomplish all of this in one fell swoop, but
4 just do it scientifically.

5 DR. BLALOCK: Dr. Lee.

6 DR. LEE: Again, like the rest of us, I want to commend
7 you on this wonderful effort. Sometimes I come to, not this
8 particular panel, but I go to panels, and you wonder whether
9 you're listening to what we're saying, and it's obvious that
10 you guys haven't missed anything, incorporating a lot of the
11 feedback into this document. The only concern I have is
12 whether each one of these elements puts you in the weeds and
13 whether you want to make sure that you focus on the outcome;
14 that is, does this help simplify the decision making for the
15 patient, and is the message reaching the right audience? And
16 if each one of these indicator elements do that, I think you'll
17 be fine.

18 DR. BLALOCK: Dr. Krishnamurthy.

19 DR. KRISHNAMURTHY: First of all, I want to echo the
20 comments made by other Committee members, that this is a
21 massive undertaking that you have embarked on. And I had a
22 little bit of a difficulty initially understanding like, you
23 know, how to grasp this so that we could be of some use. But
24 now I think a metaphor sort of makes a whole lot of sense for
25 me. To me, it looks like a car company that wants to put out

1 daily high-quality output for the customers. You want to put
2 out high-quality information products for your customers, and
3 you are coming up with a process for internally what should we
4 be doing in order to make sure that we can put a good quality
5 output.

6 Having said that, I also want to kind of tell you that the
7 four big boxes that you have seem to be spot on. I would add a
8 few other things. Like, for example, one of the things that is
9 missing from Box No. 2 is, if you want to target a customer,
10 you need to know who the customer is and what their information
11 needs are. I don't see that. Maybe I'm missing something.

12 And also Dr. Cohen Silver made an important point about,
13 in the dissemination box, the media contacts element was
14 missing, and I think that will definitely substantially add to
15 your internal process metrics.

16 Overall, I think this chart is better presented
17 horizontally from left to right rather than from top to bottom.
18 That way, people will understand what is the flow, how things
19 are going from one to another. But overall, it's a very good
20 job. I just want to commend the group for having put this
21 together.

22 DR. BLALOCK: Dr. Pleasant.

23 DR. PLEASANT: Thanks.

24 I'm going to start where I -- stop where I started, which
25 was I'm really glad that you're moving in this direction, and

1 my critique, not criticism, is meant to help it work because
2 it's that important.

3 I want to remind you that you have another resource here
4 in town, that you might want to consider consulting with the
5 National Academy of Medicine Roundtable on Health Literacy.
6 That's a very broad and diverse group of individuals who will
7 bring a different perspective. There were actually three of us
8 who are members in the room today at one point in time or
9 another, which is the most I've ever seen, to indicate the
10 level of interest that you might find there. And, in fact, we
11 will be meeting as a group at the end of next week, which I
12 know is quick, but there is a second day that's a private
13 meeting which might be the venue that you want, and if you want
14 me to make introductions, I'm happy to do that.

15 As to the documents themselves, ultimately, to make this
16 work and operationalized, you know, you're going to have to
17 define terms throughout in order to actually pick your
18 indicators; that includes health literacy and then a subset of
19 health literacy, the plain language.

20 I think it's very important to keep in mind what -- I
21 think it was Dr. Harwood that talked about the supply and
22 demand and the equity in the relationship between who you're
23 serving and who's doing the serving. It's become so important
24 in this area that in Europe -- I imagine some of you know this.
25 They're actually right now creating lay summaries for clinical

1 trials that report back the results of the clinical trials to
2 the participants, and they have to be in lay language. So in
3 other contexts in nations, this is -- that feedback mechanism
4 is really being highlighted.

5 And finally, you work with a bunch of smart people, and
6 this might sound trite to some, but you really need to practice
7 what you preach. Your documents have to live up to the
8 standards of plain language and health literacy, or other staff
9 are going to not believe that the effort is true to its core.

10 DR. BLALOCK: Dr. Lipkus.

11 DR. LIPKUS: I think you folks have done an absolutely
12 great job in terms of starting this process. My comments,
13 which echoes a lot of what has already been said, is one, I
14 think you will benefit greatly by getting as many stakeholders
15 involved in this process as possible, knowing that they each
16 bring a very unique perspective which ultimately boils down to
17 where are the commonalities and where are the differences, and
18 how could you use that to your advantages, understanding the
19 various perspectives.

20 And that also brings us a notion of suggested best
21 practices. Suggested best practices are main effects when we
22 know in life there are interactions and so forth. So don't
23 take best practices to mean that it generalizes, because
24 oftentimes it doesn't necessarily do that.

25 And I think my last one is to get real good clarity in

1 terms of your outcome measures for what specific goals, for
2 which target audiences, for which channels of communication,
3 and ultimately determine what you think is considered a success
4 and why.

5 DR. BLALOCK: Ms. Witczak.

6 MS. WITCZAK: Thank you. First of all, I'd like to say
7 thanks for inviting me to be a guest on this Committee. And I
8 would like to echo a lot of what was already said. But I'd
9 like to say, you know, at the end of the day, the consumer is
10 your audience. I think you've got to meet consumers and the
11 public, whether they're consumers, patients, where they're at.
12 Don't be afraid to get into the community and not assume that
13 you know what they want. You know, there are a lot of outside
14 resources, other agencies, ad agencies, marketing
15 communications. I don't know if you've ever considered using
16 some of them, even just as ideas to bounce things off.

17 But I think that's something I wouldn't be afraid to --
18 and you know, partnering with your consumer and patients, it's
19 a conversation. Really, it's important to target and tailor,
20 because we need to get back the reputation that the FDA's
21 resources are a trusted resource, because there's a lot of
22 information out there that we're being bombarded by from the
23 industry and their experts, their marketers, and we could learn
24 some things from the industry, because at the end of the day,
25 there are real-world consequences to this information.

1 So thank you.

2 DR. BLALOCK: And Dr. McBurney.

3 DR. McBURNEY: Ms. Zwanziger, Ms. Duckhorn, and
4 Mr. Bertoni, thank you for your efforts today. This is a
5 really important project, and it's clear the depth of thought
6 that the FDA has put into SPRCHL. Because of your oversight,
7 the FDA's oversight, really the breadth of it is so wide, and
8 the variety of topics, you have everything from science and
9 regulatory updates, to recalls, to elevation of new information
10 on risk and benefits.

11 It's really going to be important that you can encourage
12 acceptance of this strategy and really drive ownership at the
13 priorities, audiences, and goals to each of your centers and
14 offices, because that's how it will be effectively
15 communicated. You need to engage with the private and non-
16 government agencies to work together with them in that regard.

17 And finally, my guidance would be that you have way too
18 many performance indicators that are activity indicators, and
19 there's not enough outcome indicators. So don't let the
20 process overwhelm the goal.

21 Thank you.

22 DR. BLALOCK: And Ms. Duckhorn and Mr. Bertoni, do you
23 have any final remarks?

24 MR. BERTONI: I really want to thank everyone again. The
25 comments, particularly hearing this round of summation was

1 very, very helpful, and I've got all kinds of notes all over my
2 thing here, and it's been really a pleasure. But I think if I
3 were to hear -- a couple things that I took away that I think
4 are particularly important is when you take on something at the
5 Agency level, you try to be comprehensive, and yet we all know
6 that the reality happens down on the front lines of these
7 programs. So some of these comments about being more specific,
8 being more targeted, and how you implement it, I think there's
9 a lot of work to do, but we hear that.

10 You're seeing kind of the tip of the iceberg in some sense
11 here, but it's very good feedback because we can do more to be
12 clear about what we're communicating here and all the pieces
13 that need to contribute to it.

14 The other thing I'll note is that there is some mention of
15 science here, but I will point out we tied this to Strategic
16 Goal 3, but Strategic Objective 3.1 is to strengthen the social
17 and behavioral sciences to help patients, consumers, and
18 professionals make informed decisions about regulated products.
19 So there is a regulatory science component to all of our
20 strategic goals, and it remains essential to this particular
21 one because of the other part.

22 And then, finally, I'll just say I heard a lot about the
23 culture change, and that is something that we do pay a lot of
24 attention to, and we recognize the importance of this. And
25 it's not just about our own culture change; it's in response to

1 what's going on out there. Some great comments from you folks
2 about being engaged, you know, being involved in a dialogue,
3 not just throwing information out there. So just a rich set of
4 feedback that we'll have to think hard and consult a lot to
5 figure out how to incorporate it into this, knowing that no one
6 document will be perfect, but I think this is going to help us
7 make this much, much better going forward.

8 So thank you again. It's just extremely helpful.

9 DR. BLALOCK: Thank you very much.

10 So I'd like to thank the Committee, the FDA, and the Open
11 Public Hearing speakers for their contributions to today's
12 meeting.

13 And so the November 7th, 2016 meeting of the Risk
14 Communication Advisory Committee is adjourned.

15 (Whereupon, at 4:38 p.m., the meeting was adjourned.)

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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.

TOM BOWMAN

Official Reporter