

information and does press conferences and talk about risk communication. And then other schools of thought think, well, we don't have to do it because other people are doing it for us and so why do we need to put the resources into those sorts of things.

One area that we're working very heavily on right now is actually modernizing and making the interactive experience that people have with our website more attractive, and one way we pull people in is by engaging in social media through Facebook or Twitter and saying, "Hey, we're out there, we're listening, we're talking with you." But one of the major forces that you all are aware of that we come against is institutional inertia. And getting change, instituting change is a very difficult thing, especially in the government, but we're doing it and we're getting closer. Whether or not we will ever be able to compete with the CNN's or the Medscapes, that's a hard question to answer but I think that you're raising that excellent point. We are the holders of the information. Why don't people come to us and then we don't have to worry about distortion?

We can do lots of different things to try and get them there but ultimately they're going to make a decision on what the newest, greatest technology is, and if we don't have flash video or little buttons and bells and whistles

then they're going to go to the site that does. So we have to be able to identify those sites and say hey, we know people are going to you, here's our risk communication - unaltered, unadulterated, pure risk benefit about this drug, use this information as your source.

DR. PAUL: Does that mean that you in effect then are not only monitoring the number but to some extent the distortion? Are you actually going to these sources and saying that's bologna what you've put out there, or it's not what we intended?

DR. BUSSE: We do have - what we do for our drug safety communications is, we monitor 24, 48 hours after the release of drug safety communication what's happening in the digital world. It's not a perfect sampling but we look at new stories, we work with our press officers, we look at the Tweets, whether or not people are accurately putting it in. If a story is wrong, whole cloth wrong, then we actually reach out and say, "This is wrong. Here's the right information" and try and correct it. You are all right that once the genie is out of the bottle, the genie is out of the bottle and it's not easy to correct a story. But we do actively go out and try and make sure that people are getting the right information, especially if it's a safety announcement and they're getting it wrong. Our public health function is to make sure that people

understand the risks and benefits and make appropriate prescribing choices about a compound or a drug.

DR. FISCHHOFF: Okay, Gavin, Val, Dan and Mike.

DR. HUNTLEY-FENNER: I wanted to go back to something that Baruch said about sort of the old model. It seems to me that really one could make a distinction between communication and the regulatory context where you have, let's say, an approval of a new drug. You're looking at having a single voice. It's a highly structured communication. The announcement is a highly structured communication. These are scheduled and relatively rare in terms of how frequently they occur, whereas on the other side we are looking at ways of disseminating health risk information that may involve multiple voices rather than a single voice, using a variety of media, some formal and some informal, timing of course highly variable, highly frequent.

And interestingly, when there is an announcement relating to an approval of a new device or drug, there's a vast interest in it, folks who have a huge financial stake in the outcome of the process. And it would seem to me that that information probably gets disseminated fairly well, but it might represent a floor in terms of what's achievable. I'm curious to know whether you think that that's correct, whether you think that this is a floor or a

ceiling, and what you can do to have a similar type of influence if it's not the floor, a similar type of influence on the health risk dissemination site.

DR. BUSSE: I think that's a very interesting issue and I think what our first steps are in this program is finding out where those floor and ceiling effects are by looking at as many communications as we possibly can. We clearly see that while the majority fall within this cluster in terms of its dissemination and reach may represent the floor, there are some that float up in the stratosphere based on what's involved in it. And I'm not sure what the limits - I don't know what the limits are that we can reach in terms of reach with our communication, but I think one of the points of what we're going to try and do is to test those limits and to see whether or not we can actually manipulate how we present the information or what the factors are that are going into the communication or the roll-out strategy with the communication to see whether or not we can alter that. Will we be able to? I'm not sure. That will be the fun part.

DR. HUNTLEY-FENNER: So is the influence then a function of the outside interest? Is the influence a function of the level of more variety of outside interest, or is there something endogenous to FDA that you can do to enhance your status as an influencer?

DR. BUSSE: I think that there are influencers that exist out there that have a variety of interests, just given the nature of who we are and what we do. So we are not only a public health agency, we are a regulatory agency, and so clearly there are people who have financial interests in the decisions that come out of the agency whether that be approvals or market withdrawals or safety announcements which can affect lots of things. And then there are influencers who are public health oriented who really are champions of getting this information that we have out to the right people.

Do we deal with those differently when we're dealing with a safety announcement? That's a very good question. Perhaps, but what I would like to see, I think, and what - I shouldn't say what I would like to see, I think where we want to be in terms of our risk communications is, we also want to be in that same ballpark. We want to be an influencer. We want people to see us as the resource and come and get our information directly from us, while also leveraging those other influencers who are out there in the game. Because while there's a reality that not a lot of people do come to us as the primary holders of the document that doesn't mean that we shouldn't strive for and move towards a setting where we are comparatively to CDC and having risk communications and

people seeing us as a resource. I think that would go a long way in terms of reinforcing what our actual mission is for this agency as opposed to being seen as merely a regulatory body.

DR. REYNA: I am really pleased to hear that FDA is out there in the marketplace of ideas getting out information. And some of the measures you indicated and the fact that there's empirical measures, that's terrific - dissemination, duration, all of those things. But as many people have sort of said, but I kind of wanted to put more of a fine point on it is, there's the impact or effectiveness of the message. There's the message that's sent, of course, and then there's the message that's received. And the message that's received is the one that influences behavior and so on. So do you have any plans to measure comprehension or meaning?

This relates to the idea of distortion. Obviously distortion is when you haven't captured the intended meaning but there's all kinds of levels of meaning. As the Gist person, actually, I'm interested in this. But I think again that's the ultimate goal of this, and if we don't have a measure of meaning, like what meaning is actually apprehended or comprehended from this message, how do we know we've hit our target?

DR. BUSSE: You are making an excellent point.

What I've focused us in on right now is purely the reach or the diffusion, the dissemination. This is in no way independent of, or in no way at the dismissal of the social science side of it, as whether or not people are comprehending it and what they're doing. And I think that's an extremely important research program, one that we're actively working with and getting clearances for so that we can ask those questions and do that sort of research without waiting years and years in order to complete that study.

But I think one of the important things to look at in terms of the utility of this research for those sorts of questions is, by understanding where our information is going all of a sudden we're now going to know what samples we need to go and test. So we'll know the demographics, or know who's glomming onto what particular resource. And we can partner. So let's imagine that Medscape is picking up our announcements on X, Y or Z, and Medscape has a certain audience that may be different from WebMD. Well now we can actually say, okay Medscape, will you partner with us, and we want to run this survey and ask about comprehensibility of our drug safety communications, as opposed to casting a wide net over millions and millions of people where maybe 10 percent may have seen our safety announcement.

So it's a much more focused approach towards

research that is not independent of the marketing aspect, and it really, it probably will save us a ton of time and energy and resources by understanding where our messages go before we ask what happens with our messages after we release them, like in terms of behavior change. So that's how I'm resolving it in my brain. Whether or not we'll actually get there in my lifetime - I hope so, but it is the government, so --

DR. FISCHHOF: Nan, Mike, Sally and Craig.

DR. COL: Two unrelated comments. One is, just looking at this viral diffusion, it seems to me that if you had a couple of really smart grad students or research staff, if you had a - you just had a couple of these things and just looked at when your spike started to go up, what was the message, how was the message changed when all of a sudden the dissemination increased? There's a few places where there was a pivotal reversal, and it seems to me if you did that in a couple of areas you could learn some extraordinary information about what it is, are there bells and whistles that are on these messages, are there some buzz words, is it a question of fonts? What changed about the message? And if you did that systematically just across a couple of areas and looked at changes in inflection points, you could learn a lot. And I have another question coming after that.

DR. BUSSE: That's a great point, and we have actually looked at a little bit of that, and we're calling it our "aftershocks," if I'm interpreting the point of your data that you're looking at. One was a really interesting one where it wasn't actually the message itself, but it was a thought leader in the area who started talking about the message sometime afterwards who had a following, an influencer.

DR. COL: But how did he talk about the message, is what I'm wondering. Was it the language? What pieces of that message were pulled out? There's probably celebrity or something, but what was it about the way they spoke about it that made that person a thought leader? Because we're sort of assuming there are these thought leaders. They are thought leaders because they can repackage things. Most thought leaders are not thought innovators. They somehow can get a message and they know how to reframe it. If you could learn how to do that reframing by looking at how these thought leaders are doing it, yet assuming you're not - again, making sure you're not getting the distortion, you're keeping fidelity. But learn from the masters.

DR. BUSSE: Yes, you're exactly right. We did the cloud analysis and were able to pull out the words around our message that caused a blip in that diffusion and

that dissemination. Now if memory serves me correctly, some of those words were not very flattering, so that's one way that messages - well, you know, it's the truth. It's that people have opinions and some of those opinions are not favorable opinions and those can get a lot of play on issues.

Other times, we did another analysis and it was announcements that as I alluded to before, on a different drug, same class or same effect of the drug, but it caused a kind of a reverberation of our previous announcement because it was people talking about what is the theme. They're trying to figure out the agency, what is the theme about the program surrounding these class of drugs, and that causes some chatter again.

And I think kind of the third aspect of this is that perhaps we do need to start looking or evaluating whether or not we need a voice, somebody who's very media savvy, who talks specifically about risk communications, who is our person, go-to person that sits on the television. And I know there are some people who are very much in favor of having kind of a risk communications spokesperson. That may not be a bad thing. I'm not sure we'll eventually get there, but it's certainly worth a discussion, I agree.

DR. COL: I think on that second point, I think

that would be a great addition. But the other thing I just was wondering, when you were talking about competing against Medscape and WebMD and all these other sources, these people advertise, and their advertisements aren't necessarily as truthful as they might be, but they're conveying the image of being unbiased sources of information. When people think about the FDA, I don't think they appreciate the kind of rich work that you guys have been doing. Are you able to put out some kinds of an ad so that people can understand what your role is, that you're not in the same function, that you do this kind of excellent work?

DR. BUSSE: There is a lot of energy right now going into looking how the FDA is branded right now in the public space, and I think that's an important thing because, as an agency that is for the people, by the people, we have a public image that is very important to maintain to make sure that people realize that we are a resource for this information. We're looking at placement of widgets and badges that are out there so that people can click, and we've partnered with organizations so that they have our widgets and badges so people can do one-stop shopping and get their risk communication, or at least link to FDA's risk communication. I know we're looking at Google and ad words, and making sure that we get good

placement of our links in our safety communications and searches, search when there are web optimization searches or something - I don't know the correct term.

And so there's lots of energy going in that, because I think that people are realizing that in order to be competitive in terms of a resource for health information we need to apply some of the same practices that other businesses and organizations are going in order to get people to come to their website and use them, in that we live in a different age, a new digital age, and we need to evaluate that and actually move forward with programs like that.

DR. FISCHHOFF: Perhaps another aspect of that, sort of in the history of the Committee, we a number of times have recommended to FDA that people just didn't know what business it was in. And there were times in which FDA, I think we felt in one way or another that FDA was being expected to do the impossible. So for example, until recently FDA had very limited ability to require food recalls, until the most recent, and people expected FDA to do it, if there wasn't an FDA mandate. So there was a basic misunderstanding in which FDA was left trying to do the impossible and hence judged unfairly for that.

And so there is now - you can find at the FDA website - an FDA basics that explains some of those

functions. We might look at how good the execution is, whether people know to get it, whether it actually answers their question. But there is this kind of background that somehow needs to get across and may need to be incorporated in some of the messages so people know what FDA does, that FDA does not regulate the practice of medicine but makes, say, pharmaceuticals available for people and their health care providers to make decisions about. That's probably not what a lot of people think "FDA-approved" means. So let's - Mike, Sally and then Craig, and then Christine.

DR. WOLF: I empathize with the challenge. I'm looking at your tag line: Protecting and Promoting Public Health. Yes, it's more than you have to do the push. You've got to do a lot of stuff. One of the things, I really was, again, blown away by all the data that you have access to and how easily available it can be and what you've done with it already. I kind of make - my interests are really focused on I'd say the bottom up piece where we're dealing with people who are at most risk for not either getting the message, or individuals who are going to be confused or having difficulty comprehending and taking action on some of this information, who are not using the social media taps, the sources that you're using, again, lower literacy, older age. And I recognize whether you're looking at electronic health record technologies, and still

low uptake but it's exponentially increasing social media sites, it's gradually taking hold among some of the population targets that you wouldn't have normally seen it.

But I'm wondering - and to get specific, because I think it doesn't mean that you shouldn't continue and completely utilize this - but are there additional strategies that you might try to target? I'm assuming you're going to continue to use the same sort of channels, but I was wondering with the new REMs, in the case of the REM, the Risk Evaluation Mitigation Strategies - and I'm somewhat familiar; I don't think I am fully understanding all the details that the FDA is providing the industry. But when you're saying, okay, you have to have a strategy in place to convey risks, not just to providers any more but also to the consumers, are there new opportunities as far as getting data, getting information about?

So for instance, if you have to reach prescribers for a medication that has a new black box warning or a new risk around it, and they have to show, or in their plan have to demonstrate explicitly how they're going to permeate the rest of their practice with this information that they're going to trickle down, and also have a plan to get to their patient base, if it's a drug that has to be pulled off or whatever that message, is there information you can tackle - I don't know if this is too indirect but -

information you can tackle with what you're going to be learning as you're having these REMs put in place for these drugs that you might be able to better understand how beyond social media you'll be able to kind of get? Or maybe even provide structure to a federally qualified health center network that has a very low SES population, low literate population, who you want to figure out, maybe instruct them how you best should communicate this information to your patient population?

DR. BUSSE: Yes, REMS is a different animal and it's not unrelated, because oftentimes our risk communications say there is a REMS in place and that these are the element of the REMS and that healthcare professionals need to be aware that there are new restrictions. The REMS, though, is instituted mostly by the manufacturer as opposed to the agency, so we work in conjunction with them to make sure that they have a satisfactory program in place, an education program, and then there are timetables for many of these to evaluate whether or not they're being effective. And I think that's important data. Because REMS is relatively new and these timetables are 18 months out or what not, we haven't gotten that data yet. And to see whether or not there are - how these communication elements of those are working.

But what it does do is show us that it's

important to explore multiple ways of getting to those institutions and organizations that tap into different populations that may not have social media or computer or internet or what have you, and we work very closely, especially on drug safety communications that we believe has a special target audience, with our Office of Special Health Issues. And we work with them to what we call stakeholder calls.

So we identify those groups, those organizations and institutes that need to know about this information, we get on the phone with them and we say here is what we're trying to communicate, what do you think about it, how can we help you get this information to where it needs to be, to your patient groups, anything else that we can do, any feedback that you have with us. And so those discussions go on when we're developing the communication. We bring the people in as needed and then we exploit those channels.

I think I share the concern with everybody here that what we never want to do with these risk communications is take kind of an elitist view of who's going to get it, only those people who can Tweet or Facebook are going to get these, and that this is a public communication. What our analysis basically is, is just getting a snapshot of some easy, low hanging fruit data that's really rich and interesting and it can teach us some

lessons, but that's not at the absence of other programs that we need to put into place to make sure that we're filtering this information down through alternative channels, too.

DR. FISCHHOFF: Thank you. Sally Greenberg is with us. Sally came in just a bit after we all introduced ourselves, so let me ask her to introduce herself.

MS. GREENBERG: Hi. Well, you just did a nice job, Baruch, but I'll introduce myself anyway. Sally Greenberg, I'm a consumer advocate. I'm with the National Consumers League but I know we're all representing ourselves here. Lee will get on me if I do this wrong, so I'm trying to behave.

Anyway, the presentation was great and really interesting - over my head, I haven't begun to absorb everything in it - but I think Tweeting, as I looked at the FDA Tweets, it really lends itself beautifully to getting information out quickly. It's a headline format and I think it works really well.

A couple of things. On page 15, one of those slides, I'm trying to figure out exactly the issue of your followers. You've got different followers for different drugs. My understanding of how - for example, my organization's site, we know how many followers we have, and they're reading all of our Tweets. How does this work

where you have different followers for different drugs, if you could explain that.

Secondly, I'd like to ask you to look at the whole idea of re-Tweeting because it would seem to me if we're defining re-Tweeting as sending your exact Tweet to a whole other group of people, I would think that is where you'd really want to see your numbers grow. And the re-Tweets seem to be pretty low. In fact, one of the Tweets re-Tweeting is zero across the board, and acetaminophen and rHGH, and so I'm kind of interested in what was going on, that series of no-read Tweets at all, and then some sort of low level re-Tweets, in the FDA Twitter influence.

And I know we're talking about drugs here, but the third point I wanted to ask you about is, how about are we using this model for other issues that the FDA focuses on outside of drug safety, whether it's medical devices or whether it's cosmetics, and the food safety, it may be outside of your purview, but I'd love to know since this is a risk communication advisory committee and we deal with all the issues that FDA deals with. Is this something that's happening in other areas as well?

DR. BUSSE: Great questions. The number of followers - and I've got Todd here actually, who can actually speak, give you the actual operational definition so I don't do it injustice.

MR. HODGMAN: I will use the microphone this time.

DR. BUSSE: And introduce yourself for the record, I think.

MR. HUDGMAN: It's Todd Hodgman, Global Prairie, in the Deloitte team. So the number of Twitter followers is not specific to the drug, it's just specific to that Twitter handle for that day. So one of the things that's always been a bit controversial is how influential does a Twitter follower number really suggest. Because you could very well be a follower - for instance, over two million followers of At Breaking News - but are they actually viewing that Tweet? Is that Tweet respective to that drug actually important to that follower?

So it's not specific, if that makes sense, it's not specific for that particular drug. And there's really no way to know exactly which ones are resonating with who, because there's no way of knowing which ones are opened up. It's not like e-mail stats where you could actually see how many people opened an e-mail, so there are limitations. Does that answer the question?

I could help with the second one too, if you'd like. As far as the re-Tweets, we were really amazed by that figure as well and I had to go back and look at the data several times. It is the week of, which is - one

caveat. This is the week following the release of this DSC. And I know things, for instance, with acetaminophen, that was, I believe, it was a change in the prescription strength dose of acetaminophen.

So my hunch - and it's just a hunch - is that it was geared towards the professional audience as opposed to patients. The re-Tweeting rate thus for that first week potentially could be low based on engagement of professionals with Twitter versus your general consumers. Whether or not that's a theory that is accurate and explains the other four DSC's, I don't know but it was a surprising stat.

MS. GREENBERG: I would say your equipment malfunctioned that week, to have no re-Tweets on any of those. But so what you're saying is that for these particular drugs people pick up the Tweet for different - you're measuring who's actually reading the Tweet or opening the Tweet for these different drugs? Is that what we're measuring here with the follower's number?

MR. HODGMAN: It is simply the number of followers that each of these handles has. So At Breaking News, that particular Twitter account for MSNBC, at the point that this was measured, has over two million followers. So if you want to suggest that that's a level of influence, but it's not necessarily specific to their

interest in this particular DSC. For example, they may be following MSNBC for information on finances, or housing markets, all different reasons why they're following MSNBC, not specific to this particular drug.

DR. BUSSE: I think you can look at it as a measure of popularity as opposed to whether or not they're glomming on to our drug safety communications. So this person, so Breaking News had the story on the acetaminophen story, and This Breaking News MSNBC was the most popular out of all of them, correct?

MR. HODGMAN: Correct.

MS. GREENBERG: And then 16,000 people actually opened up that Tweet, is what you're saying?

DR. BUSSE: No.

MS. GREENBERG: No? So where does your 16,000 number --?

DR. BUSSE: That is how many followers we have.

MS. GREENBERG: For that particular - okay.

DR. BUSSE: So our followers change over time as well, and so when we did the acetaminophen we had 16,000 followers. When we did the propoxyphene we had 13,000 followers.

MS. GREENBERG: But you do not have an overall number of FDA Twitter followers?

DR. HODGMAN: It is a snapshot, as Greg was

saying. So every minute that can change. People drop off, people follow, they unfollow. So it's a snapshot in time.

MS. GREENBERG: So is it around 15,000, 16,000, you would say?

DR. HODGMAN: I would say that sounds, that's pretty consistent with where it - it's sort of the floor and the ceiling as we were referring to. That sounds about consistent, between 15,000 and 16,000, fairly consistently across all points that we've measured.

MS. GREENBERG: And is one of your metrics about how successful you are, how many - you know that's what the rest of us like to say. We like to say that we have a lot of followers, right, for our Twitter accounts? So my question is, do you have goals for increasing that number. Is that a good number? Is the re-Tweet number also something that you're focusing on as a metric about how effective your messages are?

DR. BUSSE: I think you have to be careful in that popularity doesn't necessarily translate into influence, and we've seen a lot of data there. And so really if you look at some of the other research it's kind of the re-Tweets and the mentions that may be more indicative of our ability. So getting somebody to commit some sort of action in response to our Tweet - either mention us by name or re-Tweet our actual information to

the next person.

The reason I put this up here is to give you a snapshot of how influential we're actually being. And I agree with you, these numbers are a little bit shocking in that not many people are re-Tweeting us, not many people are mentioning us. Is it because we're not good marketers of our Twitter information? Our headlining isn't effective in that it doesn't have enough pizzow or pizzazz to get people interested? Perhaps, you know. You look at some of the people who get re-Tweeted. They're funny, they're creative, they're insightful. We're FDA, right?

MS. GREENBERG: I think you need that television personality that you were talking about, Dr. Doom or whoever is going to tell you about risk communication for the FDA. But one thing I wanted to throw in is we always like to use Ann Brown, who was head of the Consumer Products Safety Commission during the Clinton Administration. And she would go on the Today Show and talk about dangerous cribs or car seats or whatever. And people identified her with somebody who could give them good, really helpful information about risk, and I think there's some value to that. So thank you for your answers. Appreciate it.

DR. FISCHHOFF: Thank you. So we have Craig, Christine, Sokoya, Jacob and Gary.

DR. ANDREWS: I've been hanging around with attorneys too long to ask this question here. You know, you look at DTC advertising and you do have some enforcement options if there's some gross misleadingness, if it's way out of balance on being misbranded, mislabeled, on risk and benefits. What sort of actions could you take, for example, on blogs that might be grossly misleading? Are warning letters sent out? Is it just a simple press release, a phone call? I mean not a phone, but how do you reach out? The reason why I'm mentioning this is that I believe the FTC has formulated things on their endorsement guides for bloggers. So anyway, it's just that small incidence level where there may be major problems.

DR. BUSSE: I will briefly answer that NOW and probably let Nancy take a shot at this as well because this more her area, but our risk communications cannot be used for any sort of promotional item. We work very hard to make sure that they don't have claims in them and that it's a fair and balanced discussion of what we know about the science. Are they enforceable? Can we go out and say, hey, you know, you got our message wrong? We don't have that type of enforcement. People can misinterpret at will, and that's just something that's kind of the nature of the beast. But in terms of blogs and --

DR. OSTROVE: From a regulatory perspective,

unless there is someone here from DDMAC in the audience, we regulate manufacturers, packers and distributors of the products, and in terms of prescription drug advertising regulations, I mean, that's basically the group. So if someone is acting by or on behalf of a manufacturer, packer or distributor, and taking the information and misbranding the product as a result of that, we can take action against that individual.

But if it's simply Joe Sixpack out there who's just saying this is my opinion, and they're potentially misrepresenting the safety information but they're not acting by or on behalf of the manufacturer, we really don't have the regulatory authority to take - I mean obviously we could call them and say, "Do you know what you're doing?" But again, there's a lot of people out there and that would be a resource issue.

DR. FISCHHOFF: Thank you. Christine?

DR. BRUHN: First of all I want to point out that your media use is effective in that you started it all. Your model at the beginning, the A talks to B and C and D and they all talk to E and F and so forth, you're A. So don't underestimate yourself. Things are working. Secondly, if you sign up to get a Tweet from FDA, is that a general sign-up? I mean, FDA will send me all the Tweets they make about everything?

DR. BUSSE: We have various accounts, and so we have a Twitter account for drug and drug information, we have a Twitter account for food, a CVM, or I'm sorry, for veterinary, and then we have a Twitter account for recalls across the board, FDA across the board. So you can pick and choose. I like the drug one. I think you should sign up for that.

DR. BRUHN: But if you sign up for recall you'd get both drugs and food?

DR. BUSSE: I don't think so. I think that --

DR. BRUHN: Nancy is saying yes.

DR. BUSSE: --it's different people Tweeting about that information. I actually looked at it this morning in that the recall one is basically a list of recalls, and then the drug Twitter account is all the various announcements we're making surrounding drugs, and the CVM one is clearly just veterinary medicine.

DR. BRUHN: But a recall would include medical devices as well.

DR. BUSSE: Right.

DR. BRUHN: My point here is specificity, and you know, if you were on line, you get a lot of information and some of it, you just get tired of getting so much. You want things that are specific to you. One of my graduate students, for example, wanted me to be sure to share that

she wants to follow FDA. And she signed up for - I don't know in which account, but she has signed up for information on recalls and she wants to hear about food recalls and she's getting information on drugs and devices and her mailboxes are getting very full and so she's tempted to not sign up any more.

So I think there's a value to guard against information overload. So if there is a way you can organize your information dissemination so that it targets more specifically what people would be interested in, that could be very helpful.

I'm not as familiar with drugs, but even if there's classes of drugs or medical conditions or something, so that if you really care and you're hot on this, as a general consumer person you'd want to hear about everything that's not relevant to you. You want to hear only about what is pertinent for your interests, so that might be a way of actually increasing your followers because you've now personalized it for their interest.

And then another comment. If you're looking at why aren't people re-Tweeting what FDA says, or referring to FDA's blog or so forth, I'd like to acknowledge what one of our other committee members had suggested. I bet we have graduate students who would love to help you and who don't - or even undergraduate students who would be the go-

fers and the analysts and ask us, because they're looking for little projects to do. And I could envision something where you just analyzed the contents.

Two phases then of this project, compare what FDA says versus what some of these others that are following a specific item say, and what's the difference between those and might one be able to identify an appeal.

You mentioned humor and negative comments and indeed, this can be quantified and it could be looked at, but another approach would be to go out and ask the people why did you sign up for this Tweet or blog, why did you not sign up for another Tweet or blog. There's nothing like going to the source and seeing what they could tell you. And again, I think some of your colleagues within the academic communities and perhaps other places as well would be delighted to hear these ideas and would welcome the opportunity to assist, to give our students and our graduate students an opportunity to do an exciting little project.

DR. FISCHHOFF: Sokoya, then Jacob and Gary.

MS. FINCH: I'll pass.

DR. FISCHHOFF: Then Jacob.

DR. DELAROSA: I want to echo sort of what Christina just said. And as a practicing - you know, I think I'm kind of hip - younger surgeon, and that's

debatable, but I'm going to give you a case. Two weeks ago we were giving a presentation on the MitraClip evalve. It's a new way of doing open heart surgery through a closed chest, going up through the groins and doing it.

And so we're moving forward with, like, this is how we're going to get it planned, et cetera. And I'm telling a patient that this is, you know, as soon as it gets FDA approval, and she says to me, "But the FDA put a stop to that last week." I felt like, wow, I'm so misinformed, and I felt like ugh, and I'm sitting here backtracking going, "Oh yeah, but it's going to come back." And you felt like you were really just out there.

And MedWatch was something that we learned about, truly, 2007 we learned about it here. And I still think that you all are lacking in reaching out to, just like Christine said, to the people you really need the information, being able to - again, this was brought up years ago and people who graduate medical school, people who are finishing, getting it from the AMA, getting their e-mail addresses and being able to send those FDA alerts with this to those particular doctors, surgeons, whoever it is, of what the information is going on because I am in the front line, and you don't get that information. And then I just went and Googled it then all of a sudden there it is everywhere, and it's like, "Oh my God." So we miss out.

The second point was to bring up a comment that we made years ago also in regards to getting a face for FDA. It's been brought up year after year, every meeting we bring it up again and you brought it up again today and we discussed it again. But I sort of think that we are moving forward to that face, and that one officer that comes in every year and talks to us, and he's sort of in the enforcement - I'm not sure what his name is. What's his name?

PARTICIPANT: David.

DR. DELAROSA: David has sort of been out there now, and now we've seen him several times on the news and he's kind of becoming the face of what we're talking about. Even if you all didn't want to do it, but now he's sort of becoming that face because he's always the enforcement guy. He doesn't have his gun on his side any more but he's dressed up now. So it's happening and you could still move forward with it but it is truly happening.

DR. FISCHHOFF: Gary, and then Kala and then....

MR. SCHWITZER: I don't think we have talked about this but what do you know about FDA Twitter account traffic driving to the FDA website? How much does the FDA Twitter usage drive traffic to the FDA website? It goes back to the earlier question about why isn't the FDA website the predominant source. I noticed that in the

screen shot in your talk of the drug info Twitter page it looked like every Tweet embedded a link back to the FDA website. So what's happened to traffic over time is my first question.

DR. BUSSE: It certainly helped, having a Twitter account out there, a resource available for people to kind of - a familiar resource out there for people to link back to our pages. But I think our popularity comparatively speaking in the Twitter world for organizations and institutes is not even close to what some of the other organizations have.

And so while we may have - I think the last count was somewhere around 23,000 followers - are people paying attention to that feed or is it just noise that just kind of, oh, another thing from FDA, another thing from FDA? But I have seen some of the metrics, we do see some traffic driving back or at least some spikes for those communications that have Twitter releases associated with them.

Could it be better? Yes. Do we need to market our Twitter account better to drive traffic back? Yes. We also have a person in our Office of Communications now who is taking a long, hard look at how we pull people into our website and what are some of the elements, how can we improve our website to make it more attractive for people

to come and find their information there or spend a little time. We're looking at the inclusion of more video, looking at the inclusion of different web elements that are best practices in design and so all those things, trying to increase our presence as a web force, for lack of a better term. Those are all ongoing.

MR. SCHWITZER: I appreciate your openness. You're guarded about how much traffic is being driven to the website from Twitter. And anecdotally, I've heard this from X number of very active, combined Twitter publishers who try to drive traffic to their website and don't get it. I will say I am one of those people. And I am shocked at the number of even re-Tweets you'll get, but at least with the metrics that I'm using, which are a couple of off the shelf tools, to measure who's coming to my site then, with the links embedded in my Tweet, and from where. I'm shocked at how much Twitter traffic there is and yet how relatively low traffic to the website there is.

So then why are we doing it? We're certainly not doing it because we think we can say everything in 140 characters minus the characters it takes to embed the URL. So why are we doing it? And I think we really have to analyze that question. That's just a statement. Maybe you want to react to that.

DR. BUSSE: The only reaction I would have is,

Twitter is an interesting creature, an interesting ecosystem. I was doing some research on it. What I was feverishly trying to do prior to coming to this Committee was to find out what the total number of Twitter users were over time. And so I thought to myself there's got to be a database there. Somebody's got to have this data set.

And I finally came upon this news release, I think it was 2010, from the Twitter folks that basically said we're going to stop counting because it's just too much to count, how many people are using, how many Tweets there are. So clearly it's a very popular channel and it's got a lot of traction and a lot of press. I don't think it's a matter of using it or not using it. It's a matter of knowing how to use it effectively that I think eludes a lot of people, including us. I'll be the first one to admit it. I tried Twitter for 30 days. I think I had four followers and nobody found me interesting at all. I think I'm interesting, but --

MR. SCHWITZER: Pulling on the heartstrings, see? The next comment actually is a follow-up to something Christine talked about, your grad student signed up for a Twitter account and felt she was getting messages that she hadn't really asked for. We haven't talked that much about signing up for FDA e-mails, which I started within the past year and found frankly, overwhelming because of the depth

of offerings. And I think I'm fairly savvy, maybe not around this table, but I thought I was selective and yet I've been overwhelmed by what I'm getting, to the point where I'm - and people lose patience with e-mail or with any e delivery - to the point where I've just been tempted to turn everything off. So I think the framing and the offerings of e-mail and perhaps multiple Twitter accounts is something to take into account.

But I'm wondering, what do you know about numbers of penetration or dissemination, or whatever the right word would be, between people signing up for various FDA e-mail accounts, and Twitter accounts?

DR. BUSSE: I can't answer the question accurately and give you one number versus another number, but I do know that our MedWatch lists are enormous and the audience, it's over 100,000 people. Is that correct?

AUDIENCE MEMBER: 180,000.

DR. BUSSE: 180,000 people who have signed up for MedWatch alerts. So it's a significant portion in terms of lists, and our Twitter is now 23,000 and growing, and then ebbing and flowing around those numbers. And I also know that MedWatch has and OSHI, our Office of Health and Special Issues, has recently done a review to make sure that they are not overwhelming people with the amount of information, looking at how many e-mails are going out,

consolidating things, what is working, what is not working. We haven't done that with Twitter. Twitter is so new to us.

This program that we have right now is really kind of the first evaluative data that we have on it, which is why it's so important to get at, and I think what you're suggesting is extremely important. What is the way to the value of one channel versus the other, how do we maximize the various channels that we're using, do we even need to have a Twitter account, is it cost-effective for us? Our Twitter influence data suggests that perhaps not at this point in time, and that our e-mails and MedWatch is really kind of our tip of the sphere in communicating about drug safety and drug risk.

MR. SCHWITZER: I only recently became aware of and signed up for any of these e-mail offerings, but has there been a recent explosion in the number that are offered? I don't know how I became aware of it, sometime within the past year, but --

DR. BUSSE: I think one of the issues there is - I can only speak for CDER, and we have CFSAN, CDRH, CBER, CVM, and each center has a communication program and has their own channels in which they get things out, and some of those are overlapping, some of those are not overlapping. And so I'm almost positive that we all run at

a very rapid pace with lots of announcements that we have to announce in some way, shape or form.

So if you choose, "Oh, I'm interested in biologics, drugs and food," then you're going to get three communication shops worth of information on top of the Commissioner's Office, which has its communication shop as well. So the potential for information overload is certainly there. There is no shortage of information at FDA. We can take care of your needs, that's for sure. But we do need to look at that and evaluate it.

DR. FISCHHOFF: Kala and Mary. Let me invite everybody to take a look again at the questions, just to see whether we've gotten - let's take a look at those questions while we're doing it.

The questions are all framed in terms of what evidence do we have and do we most need regarding various aspects of this. So let's hear Mary, Kala and then Nan, and then let's just check that we've done all that we can to answer these questions for Greg and his colleagues.

DR. PAUL: This is regarding the FDA's communications. I routinely get communications. I sign up for them, and they're e-mails, and they're very effective. They come out rapidly, and DIA News is another source which comes out very rapidly, using the same communications from the FDA. But I was curious about Jacob in particular,

because I find those communications are there. They're rapid, I scan them pretty much daily, and yet Jacob, if you were getting communications on e-mail, I don't know what you're schedule is like, you have to be able to sit still on e-mail generally to look at it.

And it may be that the question would be if possible do you prefer Twitter, do people who need to get these communications prefer one medium over another. And I certainly prefer the FDA's website in e-mail because it gives me the option to do a lot of things with it and I have that stability. But I tend to stay put. My hip nature is generally flexed and stable. So I'm just curious as to looking again at the potential for the next generation. E-mail may not cut it even though it looks to you like it's doing the most. It may just be that it's not going to be where it's at, say, in the near future.

DR. FISCHHOFF: Mary?

DR. BROWN: Again, thank you. I mentioned this to you privately, but I thought that was a wonderful presentation, Greg, and I think you're right out in front among the federal agencies, working with this sort of communication, new media. So I was looking at the discussion topics, and we earlier, someone mentioned the issue, or several people mentioned inaccuracy, or the problem of accuracy, and I can't give you the specific

research, but in general what we know is that the more you repeat something accurately across a number of different channels, the more likely it is that people will get the right message.

So what I was wondering - and you did mention stakeholder calls, and you also mentioned having partners that are involved in doing research with you, and again you could expand that to the graduate students, to the academic world. I'm sure there's quite a market for that.

I know that your Office of Communications must partner with external folks, either journalists or whatever, to disseminate as opposed to just to do research. And I'm just wondering how many, or do you know how many points of contact there are, and how big an effort is there with an ongoing relationship management with media or with influencers so that if there is a problem that you can utilize that network to correct messages or keep them accurate?

DR. BUSSE: It would be hard for me to give you a number but it's a very complex interaction and relationship we have with media, and influencers, and especially with the advent of all these new communication technologies some of those connectors and influencers, we don't even know who they are. It could be somebody sitting in their basement, an influential blogger who has a great following, not in a

traditional media role. Our media contacts, the traditional media contacts, the MSNBC's and the NBC's, are very solidified and we have a great, at the Commission level, a press office that goes in and works with the media contacts to make sure that if stories are wrong they can get corrected. But this idea, this analogy of the Wild, Wild West and new media, digital media, I think that's probably the best way to describe it, because once the genie is out of the bottle --

And you almost can't help it, so even if we only talked to NBC news they're going to Tweet it and put it out into the social media, somebody else is going to blog about it, and so it's almost impossible to try and correct every story that's out there. But what we can do and I think what this research is going to allow us to do over time is really kind of focus in on those people who seem to be interested in FDA stories and are pushing that information. If there's something wrong then we can contact those folks and say, look, we notice the story is wrong, here's the right or the corrected information. So it's an evaluative, it's an ongoing evaluative mechanism for our ability to keep the message accurate as much as it is an academic pursuit, as much as it is a question of whether or not we can get farther or broader reach of our message.

The way that this research program is set up is

that - and this actually goes back to a question that came from down here as well - is that it applies to risk communication. That's what we're looking at right now. But it's also applicable to any communication that the agency has. Functionally the model is built to identify factors that are common themes to agency communications and throw them into this hopper and understand what's going to have to happen to them beforehand as well as identify who out there in the digital world is interested in our stories.

And so as we build up our discipline and as we get more savvy and smart about how we view communications in today's day and age, we're going to start applying those same traditional practices of contacting the journalists, correcting the story, to the new digital media, contacting the blogger, contacting the Tweeter and saying, "Hey, this is wrong, we need to correct it, let's re-Tweet it, and we'll partner up with you, we'll make sure you get the right information out there."

DR. BROWN: Thanks, and I recognize that your focus is primarily with digital media. So I may be asking a broader question than you can answer, or commenting on a broader topic. But I'm thinking of not just the media folks but people like the National Consumers League, the Association of Community Health Centers, and even

internally MedWatch. There are - is MedWatch internal or external?

DR. BUSSE: It's internal.

DR. BROWN: Okay, it's internal. But you have potential partners that are really considered leaders in the field, opinion leaders, that could be of assistance if there is a problem. Again, there's this tension of too much information, etc. So I just wanted to suggest that.

Also, I wanted to echo the words of others about the value of putting out PSA's that brand FDA beyond it's thought of as a "regulatory agency" by the public and it does so much more than just regulate. So there's that value. Also the notion occurred to me of we talk a lot about personalized medicine these days. Well now we're talking about personalized information, and I really think this issue about focusing the information, finding ways to limit the number of communications that go out to people to only the relevant ones, would be key for you.

And then the last comment I had - and I'm just going to throw it out there - relative to methods to understand what's going on, I want to go back to the notion of the word clouds, because those will show you meaning in ways that you can't really derive meaning out of traces on networks. But looking at themes and valence of words, and perhaps it would be - and I'm not a linguistics expert but

it might be useful to find a linguistics expert who really knows about words and how people assign meaning and that sort of thing.

DR. BUSSE: That is an excellent idea. Thank you.

DR. COL: I wanted to focus on this question three: What evidence do we have, and most need, regarding the impacts of different media, including new technologies? Two things came to mind and I think they're related. One is that essentially you looked at a convenient sample of things that you could - which is what we always do as a start. But what you really want to get at is what's the real universe, what's the real denominator of these kind of communications, and that's going to be a real moving target.

And so it seems to me what would be really helpful would be to have a representative sample where you're asking people what are you using, how much of your information. Maybe this is a small, small, small percent of what's actually happening with forwarding e-mail messages or people logging onto websites after they hear a broadcast on NPR or on the news or something. And there may be a lot of other stuff going on. This may be the tip of the iceberg and it may not be representative of what's happening in the media.

And I think that that would be really important

given that most of the conditions and diseases that we have are not equal, they're not, most of the diseases are not affirmative action diseases. They tend to strike people in predictable genders and age distribution. So if you're trying to get out a message about something for prostate cancer survivors, you're going to be targeting men that tend to be in their sixties or older, and for breast cancer survivors similarly it's females and so many conditions you can actually pretty well characterize the gender and age distribution, and knowing what media those people use. If you can get your Twitter stuff down perfectly, but if that group you're targeting --

So it seems like we need to really, one, we know a lot about by just looking at the epidemiology of diseases, but then if we could match that to the social media, and then really make sure we're getting that message to the right people, knowing what they use.

DR. BUSSE: I agree 110 percent. In fact, what this metrics is going to tell us is, if we see that we have an important announcement, we believe, fervently believe that it's important that people get it yet we see zero pick-up, obviously that's not where that audience is. We need to look at other channels. And so by making those predictions we can adjust communication strategy accordingly based on what our announcement is and what

factors have gone into that message.

MS. FINCH: My question is around number four, looking at the FDA overall communication strategy as it relates to diverse populations. I'm just curious as the tweak or tweeter goes to the blog and the blogger. If you've had situations where it may have been transformed from English to maybe Spanglish to Spanish, and looking at the effectiveness and the accuracy of that information and the impact on that population and if there have been any needs to be able to go back and retranslate it back to the original intent of the message.

DR. BUSSE: So, that is a great point that you bring up. And in fact we are actively looking at translating our drug safety communications into Spanish as we speak, exploring different ways, groups, in order to make sure that we're doing that because we believe that there is a large percentage of people who probably should get these communications but may not be able to understand them because they're only in English. I think that's a high priority of ours.

Whether or not it gets translated back - one thing that we've been discussing is, as we move forward in our translation program - and mind you, this is just getting off the ground - is that we will have to, because these messages are so carefully crafted, nuanced language,

and the amount of discussions that go into the development of these communications would amaze and astound everybody, but we want to make sure, we want to actually test, focus group test our communications once they're translated.

Is the same message that we have written in English, is that translating into the Spanish version accurately so that people are getting the right information? Or are we losing something in translation given how different languages form sentences together versus intents and inflections and all these sorts of things. And I think that's going to be a really important step for us to do and to actually evaluate, so thank you.

MS. FINCH: Just one comment. I just want to say that's awesome. We've been talking about the translation of English to Spanish because the population has really increased to almost the majority. So great, and thank you.

DR. ANDREWS: This is just a follow up to what Nananda said. I think this is very important on strategy, Greg, on what the FDA is thinking about this. She's talking about the general population, Mike was talking about level of literacy, all of that very, very important. But I looked at the number of followers and it's about one percent of the population, younger cohort. Do you care? In other words - and I'll put this bluntly - is the strategy a two-step flow of communication where you're

aiming at certain influential folks out there, opinion leaders who then disseminate it to the others? What's the strategy here? Or do you care about the general population in all of this? Or do you realize that that's not going to happen?

DR. BUSSE: Well, yes. We have communications that are meant for everybody in the United States. So we have basically an over-the-counter drug that's commonly used, new safety information, we need to get that to 270 million people within 24 hours, and that's what we focus on. Major roll-out, major press, we talk about it.

But the second half, or the second answer to your question is, no. So we have other communications that it really doesn't matter whether or not a healthy, 20 year old in California who's on a surfboard hears about whether or not this drug has some risk. And so the strategy in that case would be, okay, this is not a major roll-out. We don't need to put in press releases and podcasts and all that sort of stuff. What we need to do is release this information. Where it goes, we can't control that. But then also put on secondary ancillary communication activities to say stakeholder call, who are the organizations that talks to the elderly person in Minnesota who maybe has this condition. So yes and know.

DR. ANDREWS: Even indirect tracking of this,

where the 20 year old on the surfboard tells an elderly parent or something, as far as indirect tracking of some of this.

DR. BUSSE: Right, and in fact I think we almost count on some indirect pathways of communication. I can't tell you how many times I've heard my mother coming up to me and saying, "Did you hear about this FDA announcement?" I go, "No, I have no idea." And then I go back and try - exactly.

DR. DELAROSA: Welcome to my world.

DR. FISCHHOFF: We will pick up these issues afterwards, so I do encourage others to look at these questions. We'll hear from Nancy in a bit. And it strikes me that - and one way I've been thinking about this is that the presentations, I've had the opportunity to hear parts of it before, is it's kind of getting the natural history of this ecology - it's sort of information ecology, some of which is familiar. We are all this kind of broken telephones, fragmentary communications, there was somebody on a surfboard 20 years ago and now the electronic communications have made it more visible so we're able to instrument things that were going on already.

But it's also dynamic, in which it's changing the ways that people communicate in ways that the measures themselves may be unstable over a period of time. So

people who once relied on land line phones, to do their surveys are in - so that's changed at a fairly glacial pace. Some of this may change very quickly. So we have this sort of natural ecology. There's a kind of sophistication that people who work with it have, and people who do related things have a sense for how it works.

I'm wondering how you capture that so that people who haven't had the opportunity to hear an exchange like this, or to have a long conversation with people who know this, don't misread what you've got, and look at 16,000 re-Tweets as good or bad when it's one thing or the other, it's good for one thing, not for others. So I think in the jargon I'm looking for some way to capture the construct validity of these different measures, what they capture and what they don't, so that you all have appropriate goals and not inappropriate ones, that people don't take after you for failing to do something that you didn't really want to do. So that strikes me as just an institutional challenge, to pull the science together in some way.

DR. BUSSE: I could not agree more, that the constructs that we are measuring, they're elusive. I don't know exactly what it is that we're looking at sometimes and I have guesses and I'm scouring the literature to look for those people who are evaluating in similar sorts of ways. It appears that there's one group out of Yahoo! led by

Duncan Watts, who seems to be kind of the big - and I sent you a bunch of papers associated - the big kind of guru in this. But I think this is so new. I think this is just such a new way of looking at communication effectiveness, marketing effectiveness, that people are trying to wrap their heads around it and use it to their best ability. There's lots of chatter that's going on.

Basically there was an article that John Kregan(?) had sent me saying that - and not to dismiss the work that we all have done in the past - but that survey research may be going by the wayside and that people may actually now, instead of actually doing formal surveys and sitting down and getting in subjects or undergrads to get extra credit for sitting in their surveys, that people are now shifting to using social media as the mode of capturing opinions and attitudes and behaviors of the folk, of the population - which certainly in my academic career would put me out of business, but which is why I'm redefining.

As we try to figure this out, I think we're all in the same boat. It's what is it that we're actually looking at, which is why we're taking a very programmatic approach to evaluating this data and before saying, "Hey, we've got the answer," to actually know what the question is that we've answered in the first place. If that makes sense.

DR. FISCHHOFF: One thought, as Lee warned us at the very beginning we're talking in generalities here and we could probably say a lot more about - if you say, that one where there was a blip at the end and you can say, was that a communication success or was that a communication failure or is there something wrong with the measures. And you could spin out any of those stories.

So we don't want to talk about that example. But if you've thought - something that you might think about bringing back to the Committee would be a worked-out strategy for the communication and the metrics that you would look at, and how good they are, for a couple of things. Maybe they have to be specific products, in which case Lee would have to clear everybody, or maybe just a hypothetical something small, targeted, hard to reach audience, and another one an over the counter drug that has ambiguous - but information that people need to get out, and kind of work out the plan for how you would do that. Because sometimes using this as kind of a research seminar sometimes has been useful.

We will take a break now. We'll convene back here at 1:00 exactly for the open public hearing. If there's anybody who'd like to sign up and hasn't, please do, and Lee will take you and we'll see you again, and then we'll go on to Nancy's presentation which will be in the

same general space.

(Whereupon, a luncheon recess was taken at 12:04
p.m.)

A F T E R N O O N S E S S I O N (1:05 p.m.)

Agenda Item: Open Public Hearing

DR. FISCHHOFF: Let me welcome everybody back. We now have in some ways one of the nicest parts of these meetings, which is the open public hearing. We had a little bit of communication - is Diana Zuckerman here? And Elizabeth George is here and would like to speak. And Linda Christy - Linda, are you here? Did you want to speak? Okay. So I guess we have just one speaker, who will be Elizabeth George. But if there's somebody else here, sneak around back and let us know. So let me read the boilerplate to you. You're welcome to come to the mike. It will just take a second.

Welcome to the open public hearing. Please state your name and your affiliation if relevant to the meeting. If you have any financial interest relevant to this meeting such as a company's or a group's payment of your travel or other expenses, FDA encourages you to state the interest as you begin. If you do not have any such interest you may wish to state that for the record, and if you prefer not to address financial interests you can still give your comments. So welcome.

MS. GEORGE: Good afternoon. My name is Elizabeth George. I'm the Vice President of Global Government Affairs, Regulations and Standards for Philips Healthcare.

So my boss paid for me to come here, so I don't get any payment from anybody else. My affiliation actually with this panel is, I am one of the industry reps that you guys have not had the opportunity to interact with yet. My focus on products actually for that is on radiation emitting products. So obviously there are some risks associated with those.

First I want to thank you all for this meeting. I think the information, all the questions, answers, comments have been wonderful and very informative. One of the things I did want to bring up was, many times this morning the discussion of distortion has been discussed, distortion of information. I know that Dr. Busse - I'm never sure how to pronounce it - mentioned that CDER has oversight of the accuracy of the information that's communicated. But as a medical device manufacturer we develop labeling, advertising and promotion materials, and a lot of communications when it does come to product recalls. Most of your discussion in the last few meetings that I've been to have been focused more on what the FDA generates associated with that. But we as manufacturers generate quite a lot of information that goes to whoever the impacted persons are, whether it be a physician or a patient.

So we are expected by the regulatory authorities,

the FDA and everywhere else in the world as well, that if there's any off-label use that's being done with our products, or if there's any misinformation associated with the claims of safety and efficacy, that we need to take action, and it needs to be well-documented, because as the FDA always tells us, if it ain't written down it didn't happen. So if it's not written down that we took action, then as far as they're concerned it didn't happen.

So my general question to all of you is, with this new social media blow-up that's occurring, what is the expectation of everybody's responsibility associated with the information that could be communicated on these media forms. I know that my company, we actually have people that are trying to monitor as many of those places as possible. We in fact actually sometimes have people that will go on, if we start to see chatter about our products, emphasizing control and try to put something out there to say misinformation, wrong information, go to our websites or go to the FDA's site. But I'm just curious as to what your thoughts are on who should be responsible and then how that should be handled.

And first and finally I want to wish you well in your adventures, and I look forward to the future meetings, and hopefully industry will be able to get a little more engaged in this process. Thank you.

DR. FISCHHOFF: Thank you very much. We look forward to having you at the table before too long. Let me just check, was there anybody else who had wanted to speak at the open public hearing? Anybody in the cheap seats behind the pillar? Thinking of old Tiger Stadium. Anyway, there are some knowing heads here, so hallowed ground.

So let's move on now to Nancy's presentation, and we'll be continuing in the same vein, addressing the same problems from a somewhat different perspective, taking advantage of some additional work, some other projects that FDA has had.

Agenda Item: Using Social Media Feedback to Improve FDA Risk Communication

DR. OSTROVE: I am actually going to be talking about the more applied end of some of the social media research that FDA is doing - not to say that Greg's isn't applied, but this is even more applied. And I think you'll find that it's complementary to what he talked about earlier. So just kind of to set the stage, you will recall that I talked about our strategic plan for risk communication. It has to be mentioned more than once. And one of the major goals, the three interlocking goals of that strategic plan is to strengthen the science that supports effective risk communication at FDA.

Under that goal is a specific strategy, which is

to evaluate the effectiveness of FDA's risk communication and related activities, and monitor those of other stakeholders. And we had two actions that we'd identified in the plan to help us achieve that strategy: monitor media and web coverage of risk communication messages and survey consumer understanding and reported behaviors in response to risk communication during a food outbreak recall; and assess the utility effectiveness of social media tools for reaching target audiences, including how the social media is covering FDA's messaging during a recall. So as you can see, we were thinking about social media even back in 2009. Not that long ago.

A second overarching goal of the strategic plan is to expand FDA's capacity to generate, disseminate and oversee effective risk communication. And a particular identified strategy under this goal was to plan for crisis communications. From our perspective a critical action to do this was to institute a way to measure consumer reaction to food recalls and outbreaks in as real time a manner as possible. This was to allow us to be able to adjust our public communications as we needed to, in order to address gaps in audiences' understanding and any misinformation being further disseminated that might exist.

And in terms of addressing those actions, there are three things that I think kind of stand out. One is

the interagency agreement that we have with CDC to enable us to use Harvard Opinion research program to go out and actually poll the general population as to how they reacted to a particular crisis. We used that for the shell egg recall, and we're actually in the process of getting some baseline data of consumers understanding of over-the-counter pain relievers, to help us in planning for any kind of future emergency communications that might occur around those.

And there are some other things where we're kind of trying to look where we can get some information in advance to help us plan, because as it turns out there haven't been as many - which is kind of a nice thing - there haven't been as many crises and emergencies with regard to recalled products recently. So we're happy about that for the public health but we have this thing in place to be measuring public response and it's just not happening. So you've got to find a way to use the funding if it's been committed.

The second piece that we had to address these actions was another interagency agreement with CDC, and we worked with CDC and researchers at the University of Georgia to sponsor an on-line survey of social media users about how they get food recall and specifically how they got egg recall information because they ended up going into

the field right after the egg recall. So that was a serendipitous set of circumstances.

Oh, and by the way, those of you who were here in November may recall how we had Dr. Robert Blendon in to discuss how we used the HORP polling capability to examine responses to the shell egg recall. I meant to point that out just to remind you about that.

The third thing, and that's what I'm going to be focusing on today, is this contract that we have in place with Nielsen-McKinsey Incite to follow social media coverage of food outbreak recalls over a period of weeks. So that's what we put the contract in place to do, to follow social media coverage of food outbreak recalls.

The contract itself was designed to follow one food-borne outbreak retrospectively, and then one outbreak prospectively, the first one for 22 weeks and actually the prospective one was supposed to be for 20 weeks. The food-borne outbreak, we basically had Incite, the Incite team, follow from the beginning of December through the end of April, the beginning of December '08 through the end of April '09.

And why did we do this? Well, FDA, CDC and other federal agencies have been using social media more and more to complement traditional channels of dissemination. We've been talking about that. So our best practice

recommendation for conducting effective communications is to assess the impact of various communication channels, especially novel channels. So what value is there in doing this, and how can we best take advantage of them?

So these were our purposes. We had these multiple purposes. One was to get feedback on social media users' reactions to these two outbreaks. But what we found - so we had the initial report that detailed online conversations about the peanut product/peanut butter, the salmonella typhimurium outbreak. And we had them follow that for 22 weeks. And so we had a great deal of data broken down, and I'm going to show you more about the kind of data that we got. But let's leave it here for now.

And then in early fall of 2010 we also had Incite follow four weeks of coverage associated with the shell egg recall. What we found though, is that that particular recall, the second one, that the impact was going to be relatively limited because, well, probably the nature of the products. The peanut products were in a lot of things. It ended up being in thousands of products. So every week we'd discover more and more things that the peanut paste had gone into. But with the shell eggs, they're just shell eggs. They were sold as shell eggs and at some point they either get used or they get thrown away. So after four weeks there was not a whole lot happening.

What the experience, though, showed us is that we needed to be more flexible in how we used this particular mechanism. Our primary kind of strategic takeaway was that short-term use would probably be more useful, so we did learn something very quickly. The second purpose of the contract was to examine in more detail relative to particular incidents, how useful the information available to us might be. So that leads us to the next slide here, which details the kind of information that we asked to get from the analysis.

So what we wanted to find out, basically, is what were the most frequently-discussed themes and online conversations relating to these outbreaks, what information sources people were most commonly using, and the degree to which the users appear to understand and what their reactions are to information that FDA and CDC supplied about an outbreak. We also wanted to determine how people felt about the government's handling of the situation and about the organizations themselves that were involved in communicating about the event. So that's where you know sentiment - and I think one of the committee members mentioned the issue of sentiment - and also the themes of the conversations. And that was something that we wanted to be able to get using this particular mechanism. So that was built into the contract.

Now in terms of the methodology, Incites system - and I can't say specifically whether it's, I should know this, I think it's probably not Radian6, it's their own, it's Nielsen's Incites own proprietary system - searches millions of online sites. How the cites look is retained for about 20 months, and they can actually take a picture, basically, of what all this stuff looks like every four hours. And then they keep it for 20 months.

So next week, or next month, basically, whatever month was 21 months past from now, will get dropped, and then they'll have the most recent 20 months. And they can go back at any time and see what these cites looked like, these millions of cites looked like at that particular point in time. So that's what allows us to retrospectively assess responses to past events.

Now message sampling is how we get to other than volume sources and terms. The computer basically, their computer spits out the information about what they call "buzz volume", the sources of the buzz, and the terms that are used. And I've got, in fact, a couple of word clouds in the examples that I've got here today. But in order to get its sentiment and kind of the themes of the individual conversations, it was really important to actually sample, to take a sample of these conversations, of these messages. So built into the contract is a sample of 100 messages

randomly selected from those that were identified during the search. They are analyzed qualitatively by a couple of analysts, and we've basically been using the same analysts over the course of the contract so they have learned to understand FDA issues.

Now it's important - and this caveat I think is extremely important and I can't emphasize it enough - there is a margin of error. We're talking about a random sample of 100. Now that gives you a margin of error of about plus or minus 10 percent of the 95 percent confidence interval. If we had more money, we could have them take about 400 messages, we'd be able to have a precision of plus or minus five percent. But it's a matter of balancing the funding against what you get.

So I think the major thing that we want to take out of this is that while it isn't large enough to give us very confident estimates - well we can get confident estimates within that plus or minus 10 percent of population parameters, and of course that's the population of people using social media, not the general population. Still, it's definitely enough to give us a general sense of the themes of the conversations, the way people feel about the topic and any agencies involved in the particular proportions of conversations that include particular themes or express particular sentiments. There's going to be some

amount of slack, but we're confident that it gives us a pretty good sense. So for instance if we want to look at personalities or issues associated with particular conversations, like the Surgeon General or even other federal officials, we could do that.

This - and again I would just stress that this is a methodology that gets at the public-facing areas of social media. So in terms of Facebook it's not going to get to the stuff that people are keeping private. It's only the stuff that they're making available to the general public. It's walls and pages kinds of thing. And these are the issues that we followed since we put the contract in place at the end of September 2009. We followed the peanut product recall for 22 weeks, we followed the shell egg recall for four weeks. We followed a ban on - well basically it was a warning and a ban - on caffeinated alcoholic beverages for two weeks, basically FDA saying that the combination in those beverages is not a good thing for the public, and they would not be allowed any longer.

We followed conversations around genetically engineered salmon for a week to get some background information, we followed what happened after we made the announcement about graphic cigarette labels, the warning associated with infant sleep positioners, the combination acetaminophen products that we heard about earlier, we

followed that warning, and a number of others. And right now we're in the process of following the most recent large rollout, which is about products that are being marketed that are making fraudulent claims about their ability to diagnose, prevent, treat or cure sexually transmitted diseases.

So we've looked at foods, tobacco, devices and drugs. Not the whole gamut of FDA regulated products, but a lot of them. Now recall that the contract, the original contract had this initial focus on following two recalls related to food-borne illness outbreaks over a period of weeks. In fact, back in August of 2009 Alan Levy discussed with the members at that time how to use social media content surveillance as a research tool, and that discussion was related to this capacity we were in the process of building.

Now obviously this following a particular event over a period of time, this longitudinal analysis is that it allows us to get a fairly detailed look at reactions to the events in question. And that's - actually we've kind of talked about that already so I don't think we need to go into any detail. But what I want to do now is, I'm going to start showing you a number of slides taken from the various reports we got about different topics. And again, another important caveat is that note at the bottom. All

of these examples are included only for illustrative purposes. They're only meant to illustrate the kind of information that we've obtained through this mechanism. Even if I highlight specific results, by doing so I only want to demonstrate possible analyses. I don't want to talk about specific products or product classes or have anyone come to any kind of inferences about those products or product classes. This is general stuff.

So first and most obviously let's talk about longitudinal analyses first. We can track the volume of conversations over a period of time that we can specify as needed. So for following events that we think will have a short lifespan, days might be appropriate. For the rare events, where we expect to have a lengthy lifespan, weeks might make more sense, as was the case for the peanut product outbreak because that was going on for months.

So we can see here how the conversation changed over time. Before the outbreak there was relatively little conversation about peanuts. You see an increase as a voluntary recall was announced. It spikes up there where the firm's receipt - where FDA says that there's 125 recalled products. We launched the website with searchable database and the recall expanded to pet foods. And then there's another - it kind of starts going down, as we would expect from what Greg told us this morning. It starts

going down but then it stops going down, it levels off a little bit, and that's at the point where the recall expanded to all peanuts, dry and oil roasted, granulated peanuts, peanut meal, peanut butter. Then it started going down again, and you can see by about the end of April it's pretty low because we're starting here, December, before it started, and then the end of April.

This longitudinal perspective allows us also to compare over time the sentiment around particular parties involved in an event. So for example, here over the course of the four weeks of the shell egg recall, which are broken down a little bit more here, we can see the volume of conversations that include references to FDA - that's the blue line - USDA is the dark line, and CDC is kind of that greeny line. We can also see how the volume of conversations react to different public announcements or occurrences. So that's where you see the spikes.

The longitudinal perspective also allows us to look at differences in the content of the conversations prior to, during and after a risk communication event. So this is an association map that shows how conversations around peanut butter changed when looked at before the recall, and in the midst of the recall. So before the recall, the peanut butter is kind of the center of the map and you see there are things like PB and honey, bagel with

PB, PB cups, PB sandwich, natural PB, and then around a little bit further around you've got almonds and milk and egg and protein and crackers. A little further out you get PB cookies and granola. When you look in the midst of the recall where peanut butter is in the middle you've got right on top of it salmonella outbreak, right under it, salmonella. And then you still have PB cookies, PB recall, PB cups. But you're seeing things, like out toward your right you see Kellogg, you see contamination, you see nationwide salmonella outbreak, Blakeley, so you can see how the terms that are used in the conversations change. And presumably this is what we would anticipate would be happening.

We can also look at whether there are relatively enduring differences in volume and potentially in the nature of the conversation that may have resulted from an event. And keep in mind that with each of the points that we got over the 22 weeks that this was looked at, when we start looking at - this is not a sentiment one, actually. Let me talk about the sentiment when we get to that. This is the buzz volume. So this is just the number of mentions of food safety.

So not looking at peanut butter per se but looking at food safety as a search term you can see how the blue shaded area is when the recall was, so you can see how

it goes up and it spikes in that area and then it starts coming down and it comes down gradually, but it still, at the end of it there was about a 60 percent increase in the total messages about food safety, even all the way in December of '09. So it suggests that there was a continuing concern about food safety even after the event was over, at least through this time period.

That's some of the information we can get when we're looking at it from a longitudinal perspective. But as you can tell from what I mentioned, we started actually looking at individual events for maybe a week or two weeks, once we realized that we could get more useful information at that point. And here's why we thought that this could be useful. In terms of the short-term analyses, both in terms of volume but especially in terms of the qualitative part of it, we can use it for communications planning purposes. So it can help us to identify areas of concern in a particular topic area, it can help us to identify knowledge gaps, it can help us to identify what people's trusted sources are.

We could even, for instance - you may have a population of interest that is mothers. Well, if you have a panel of mommy bloggers you can focus in on that particular population of interest. So it depends, obviously it's going to depend on the supplier, in this

case Nielsen-McKinsey Incite - I really just need to call it Incite for short - and what they've produced in terms of the basis. Obviously they're doing business with a lot of other groups. In fact the genetically modified salmon analysis that we got was actually one that had been done for a whole bunch because it's of interest to a lot of different areas.

I have some additional examples showing how the data can be useful for its communications planning. Same caveat as before. So looking at genetically engineered or modified salmon, this shows the general sentiment around genetically engineered salmon. Remember, sentiment here is assessed from a qualitative analysis of a sample of 100 messages. And that's in the footnote at the bottom, and these were taken last September from blogs, boards, groups, Twitter and media sources.

Well the precision is limited to plus or minus 10 percent. We can probably still assume that generally people's feelings about genetically engineered salmon are more negative than positive given the size of the negativity determined in this particular sample. What this analysis does is, it drills down to identify the themes that were discussed by those in the sample who expressed fears or negative sentiment around genetically-engineered salmon. Knowing this can help us ensure that future

communications related to this issue can acknowledge and where possible can address people's concerns.

So you can see, again, not necessarily paying attention to the percentages, because they're plus or minus 10 percent on either side, still it's very clear that people who have a lot of fears or negatives about genetically engineered salmon, it's clearly related to the genetic manipulation being unnatural, because you've got that genetic manipulation/unnatural. The second one there is "Frankenfish," which I'm sure some of you have seen. And then some others as well, including a few people who've talked about steroids, early puberty, labels needed, allergies.

We're not saying we could necessarily address all of these concerns, but knowing about them allows us to think about how we might be able to address at least the ones that we are able to. Here, this is from a sample of 47 messages that expressed positive feeling or support for genetically-engineered salmon. So this is the opposite end of the sentiment and it shows the themes that emerged from those messages. What this illustrates is that we could get some information that it may not be appropriate for us to follow up on because cure for poverty, cheaper food source, those are not really FDA issues. So we're not going to be able to say anything about if we say anything about

genetically-engineered salmon we can't talk about how it might be a cure for poverty or it might be a cheaper food source, but at least we know where the concerns are, and in this case where the support is.

To better understand public perceptions and plan for communications for another continuing issue relevant to FDA, we looked at social media conversations to identify the major issues that were being discussed by women thinking and talking - not just thinking but talking - about breast implants. So you can see here that 22 percent of the sample conversations - and again, this the 100 total, so it's 22 percent plus or minus 10 percentage points - included questions such as which doctor to use when getting implants, what the procedure options are, and how much time it takes to heal after surgery.

So the concerns are about basically practical aspects of having breast implants. Some were concerned about implant risks, some were about breast feeding, but most of them were about these kind of practical, pragmatic kinds of things that chances are the women are going online and asking others what their experiences have been. The interesting thing is, you see the 22 percent that are labeled as questions. And this is important, and I'm going to bring it up again a little bit later, because you've got a lot of people out there specifically looking for

information and asking questions about the topic. And we see that in a lot of these analyses.

So we've seen that this mechanism can give us information to help us plan communications. But a second objective of short-term analysis is to qualitatively assess the impact of any FDA or other communications about a particular issue that we've been talking with the public about, because we can look at what sources were most attended to, what channel seemed to account for the greatest dissemination, we can assess pick-up and understanding of FDA messages and other government or non-government messages as well. So oftentimes FDA will go in and work on something with CDC or with USDA or CPSC - that's happened in all of these cases. We can see what people are attending to.

One important piece of information to know is where most of the conversation is coming from. In this case it was FDA and the Consumer Products Safety Commission. We had issued a warning about the danger of using positioning devices, which is by the way a hard thing to try to figure out how you search for because what is an "infant positioning device"? Nobody out there is going to say, "Do you know anything about infant positioning devices?" So you had to look at things like bolsters and pads and that kind of stuff. And people use these to keep

babies sleeping on their backs. Now that years ago we found out that SIDS - Sudden Infant Death Syndrome - seems to increase when babies are sleeping on their stomachs, the babies are at higher risk. So what does every parent want to do? They want to keep them sleeping on their backs. So obviously when something like that happens the market rushes in to see how it can help, and creates these devices. Except these devices don't actually help in some cases because the infants can roll over and be suffocated.

So we see here that the primary conversations around that warning occurred in boards. Blogs to the green, micro blogs - which as the others have pointed out micro blogs are basically Twitter - and boards, 46 percent. Mostly parenting boards. So we can also get a listing of where most of the warning-related sleep position or discussion was from: we had justmommies.com and pregnancy.org, cafemom.com, community.babycenter.com. So we kind of know where the conversations are taking place.

Just this past January FDA issued an update about the risks of liver damage caused by taking too much acetaminophen. Greg talked about this, and we also restricted the amount of acetaminophen that could be in prescription opioids.

So to respond to this - this is a continuing problem - FDA - I've already said that, sorry. So this

slide shows that most of the buzz around this matter was in health-related boards. Medhelp.org, allnurses.com, arthritis.org, dailystrength.org, topix.net. We had one group here, an old Yahoo! group, but these were the top cites. And by the way you can also see not a lot of messages, but they're there.

We can get such source information also compared pre- and post-announcement. So here it's clear that the January announcement we made - now we made, but actually USDA - of the new sodium guidelines in the Dietary Guidelines for Americans, was disseminated primarily through Twitter and other micro-blogs. Here's the announcement. This is the pre-announcement. This is the Twitter, the 60 percent, that's Twitter. Prior to that, most of the conversations had come from traditional media and blogs, the green. So this is how it changed with the announcement. Of course the question is always, is the news driving the buzz or is the buzz driving the news. That's a hard one to answer.

In this case we had an updated announcement about tainted products that were being marketed and sold as dietary supplements, which is another interesting thing. We say tainted products being sold as dietary supplements. How does the public understand that? Generally that gets translated as tainted dietary supplements, which of course

from a legal perspective is not right because they are not really dietary supplements. They are tainted products being sold as dietary supplements. It's another illustration of how difficult the communication can be when you're working in a regulatory agency.

But here, while the sources of buzz were very similar overall, the second iteration which was in March got much less attention on Twitter - Twitter being the micro-blogs - than it had with the initial announcement in December. So it was 50 percent in December, it was 34 percent for the second one.

So here's one of your word clouds. They take this from Wordle. We haven't always done it. We are thinking more and more about trying to get a before and after picture of on-line conversations about communications that are relevant to FDA. So here we looked at the buzz around sodium or salt in foods in relation to that rollout of the new dietary guidelines related to sodium. So between this slide and the next one we can see how the words used in the on-line conversations change before and after the roll-out, and also how references to organizations change.

So for instance, here before the rollout there's no references to government organizations and there's only a loose association of the American Heart Association in

these particular salt-related conversations. You see "salt," you see "healthy," you see "sodium," you see "diet," "pressure," for high blood - "blood," "blood pressure." But in the second one, in this follow-up word cloud, you see that both USDA and the government are mentioned by consumers in association with the guidelines. So we've got "guidelines" here and "government" over here, we've got some companies over here. There's "UDSDA," and there's "agriculture."

So using the messages that are selected for the in-depth analysis, we can also look in more detail about how the discussion topics change over time, either pre-post or even over a more shortened communication lifespan. This graph for example, this shows the information from the days that are just before and just after, versus one to two weeks after an announcement this past November about letters that we'd sent to the caffeinated alcoholic beverage manufacturers.

We can see here how the social media buzz changed over time based on the two samples of 100 messages, each from the different time periods. Article sharing increased over this time frame, so here's the article sharing. It went up from 35 percent to 57 percent within this selection of messages. It also appears that the percentage of people expressing both opposition to - here's the disagree - and

support for the action decreased, suggesting that the conversation became less polarized over this time frame. Or maybe it only suggests the people who had a clear opinion had already expressed it earlier on. It's hard to say, but you do see the differences.

We can also see how sentiment toward different entities changes. This is sentiment toward the FDA, which is by and large neutral, that 91 percent and the 82 percent. That's the neutral point. But it changes a little bit from before two to after the recent announcement that FDA will require educational programs to be instituted for professionals and patients who are using marketed prescription opioids. So that's the REMS that people were discussing earlier.

And what seems to be happening - here we have the positive is the blue. You've got a little bit of an increase. Negative is the orange. You've got a little bit more of an increase. Again, the increase is probably within the confidence limits so it's hard to know whether for sure that's anything - I certainly would not say that it's statistically significant by any means but this would appear that there was just a little bit more polarization happening. Again, taking it with a grain of salt.

So even when we're not taking a before and after look, it's often valuable to get a sense of the degree to

which people are sharing articles. So as was the case for the caffeinated alcoholic beverages, which we call CABs for short at FDA. We can see here that there's a significant minority of individuals, of the messages that were pulled for analysis during the egg recall that included article sharing. So that's this top.

When you're in here, this is from after the announcement of the government's overall prescription drug abuse initiative and our piece of it was the REMS programs, basically. You can see it's up at 57 percent, a lot of article sharing. So what this suggests is that by providing understandable, comprehensible articles for people to share with each other, or materials, that could be a very effective means of disseminating useful information. Because clearly, people are sharing.

Now this graph is kind of like a benchmark graph. It shows a comparative analysis that we expect to keep adding to over time. It shows the relative strength of a selection of the topics that we've had analyzed with respect to volume of social media-based conversations in the weeks following an announcement. So clearly we had the most buzz associated with the caffeinated alcoholic beverages ban, next most ban associated with the egg recall, then graphic cigarette labels and going down from there. Thank you. Happy to take any questions.

(Applause)

I wish we could have the Neilsen, the inside people here, but our major contact works out of Florida and some other people are in New York. It's amazing, it's the whole virtual office situation, people working out of their homes. It's kind of fantastic. It's really neat. But as a result we would have had to fly them in and it wasn't in the contract and we didn't have the money to put it in the contract. But I did ask some questions of our leader, our team leader Sue McDonald, and I might be able to answer some and if not I could get the information for you.

Thanks.

Agenda Item: Committee Questions and Discussion

DR. FISCHHOFF: Thank you. That was really fascinating. Go ahead. You looked expectant.

DR. ANDREWS: Nancy, thanks. That is exactly what I was talking about with a sentiment analysis. What do you think as far as expanding that to what Greg had been talking about earlier? What's the prognosis of - I mean, you had a sample of 100 messages up there - the difficulty of expanding that whole methodology to the major thing that Greg was talking about? In other words you just add a sample of 100 messages there, whereas you have thousands of messages overall.

DR. OSTROVE: It is a cost issue. A large part

of it is a cost issue. So for instance, the cost that we have - what it costs us for a weak analysis, most of that cost is really in that qualitative assessment. So I'd like to think that maybe we could think about somehow if it would be possible to get random selection of messages and have it done kind of internally, but again, you're talking about a huge resource contribution and so I honestly can't say at this particular point.

I think what we need to do before we even go that far is to figure out how useful this is, at this point, for the people across the agency, because if the agency as a whole doesn't feel that the information is going to be helping them, that it's going to be useful to them, then there's no point in continuing it. So that's one of our major goals here, is to get feedback from the internal clients that we're getting this information for, to determine that it's useful, whether it's useful or not.

DR. FISCHHOFF: Val, and then Christine.

DR. REYNA: Let me echo that this is exactly what I was trying to put my finger on before, too, about the content of the messages, in addition to the quantitative aspects of who they're reaching, how many are reaching out and so on. But I should say I think it's a great beginning to do this kind of qualitative, in-depth analysis, but there are certain things you can't infer from qualitative

methods. The kinds of things we want to infer, like comprehension and attention and so on, you normally can't from those methods. You can describe, and especially if you've got interrater reliability that's high, and it isn't always clear that that has been done, and that's important.

But in terms of scaling it up to larger databases, there are techniques that are available that are reliable, that can give you a sense of the themes and the semantic content, things like latent semantic analysis, for example, is a reliable technique that not only counts the association of individual surface words with one another but sort of these indirect associations as well. So if two words are associated with a third word, it kind of is almost an inference engine for connecting things semantically.

They use huge databases of word types and so on to analyze, and they've automated this so it can be much more cost-effective. So it's both easier to do and also more reliable. The results are more reliable than some of the qualitative methods, although again, that's a fine place to begin.

DR. FISCHHOFF: Christine, and then Gavin.

DR. BRUHN: Wow, I was really excited. I'm sorry that my print-out is too small to read but I do have a magnifying glass at home so I will be looking at it.

Looking back at your original goals here you wanted to assess understanding of and reaction to the information. And what you presented was fascinating and I appreciate this is a first cut but I'm hoping you're going to be able to get into greater depth on understanding because just showing - for example, the egg recall, so what things did they talk about. Did they understand - it would be intriguing to know did they seem to know what was going on here and are they going to be acting on it. And so mining those blogs and tweets for that information would be very interesting. And then did they misunderstand? Where did they misunderstand? Because then that's what you would be using to modify your announcements and represent something.

And I was hoping that this information, when it is further developed and used by the agency, I urge you to consider ways to publish this information because those of us in food safety education - and I'm sure people in other areas of education as well - would be equally intrigued as to what's working and what isn't, and where do people seem to be misunderstanding information, and is there a way that we can assist them. I'm thinking specifically - let's say the sodium discussion. Again, were all those blogs about "oh, we're having to reduce sodium and this is why." Were they repeating the information and commenting on its importance, or were they lamenting "and how in the world am

I going to do it and is it really useful"? Because that also guides future communication. So mining the content would be very, very useful, and then sharing this all with a professional community would be very helpful.

DR. OSTROVE: One of the things I did not do and probably should have done is to show you that as part of the reports the qualitative analysis pulls out the themes that are most often coming out in those hundred conversations, and they'll pull out, just as you would pull out a verbatim from a focus group report, another qualitative methodology, they will pull out verbatims to illustrate - like they'll pull out three verbatims to illustrate a particular thing. So it does get more into the content. I just showed what could more easily be quantitatively shown here. But we do actually get more than that. But again, it's qualitative. I would put it on the same level as the kind of feedback that you get from focus groups or from structured, in-depth interviews. We can necessarily quantitate it, but we can at least hopefully identify all the major issues and all the major themes.

And to Dr. Reyna's point, absolutely. Comprehension and understanding - I'm probably throwing these around a little bit too sloppily - I completely understand that. I don't think this is the right place.

I'm not sure that these data are going to give us that very well, and there may be opportunities in the future with some of these more quantitative methodologies, but that was one of the reasons that in addition to following the shell egg recall with this, we also got the Harvard Opinion Research Program, the HORM program, to do a poll of the population, and we got information that I think is better suited to answering the questions about how many people really understood this, maybe, certainly how many people took action in response to it. Understanding is - to try to get understanding, comprehension for a total environment, I mean a whole population is just an incredibly daunting task nowadays. I don't think surveys are dead.

We're working right now with a contractor that's using an address-based sampling method, and a lot of survey researchers nowadays are going to multi-method methodologies as well. But on the other hand it's definitely ailing. You can probably more easily look at comprehension in an experimental design where you're taking some samples and then comparing different presentations and seeing how the comprehension goes. So I think we need to look at the various different methodologies and figure out where best they fit in, and I agree with you in terms of trying to make it all public. It's just a matter of

finding the --

DR. HUNTLEY-FENNER: I was very interested in the breast implant chart, which showed that there are a large proportion of questions, because that signaled to me that you had a proportion of folks who were information-seeking, and we know that that's an important variable in warnings comprehension and behavioral change. So I was wondering whether you see any possibility of tracking when people are receptive to receiving risk information and sort of pushing it out where and when it's most likely to have an impact.

DR. OSTROVE: We are open to suggestions about how we could do that. I liked seeing how many individuals are going to these sites for information, because it suggests that they are open, and it's like they're primed to get the information. But I don't really know what the capabilities are of doing any kind of longitudinal look and figuring out what people's receptiveness is to information from particular sources.

DR. HUNTLEY-FENNER: It is a good question. In a way Google has built a business on this, so if there are search terms that suggest an interest and a topic that information gets put out there. I'm not suggesting you use Google in the same way but maybe there will be a possibility to get information to people when they're most likely to be receptive.

DR. OSTROVE: Absolutely and I think Greg may have mentioned that we have been experimenting with, for certain types of roll-outs, buying Google ad words. Basically if people put in a particular search one of the things that comes up on the right-hand side would be the link to FDA's website. Our understanding is that people don't necessarily go to FDA. They don't think of, oh, I should go to FDA for that information. They go to Google and they put their search term in and then if FDA shows up that's great. But organizations pay to have their cites come up higher up, and that becomes another resource issue and you have to figure out, okay, where is it important that we do this. And you also have to look at the type of topic and how people are going to search for it and make sure that you're not ending up showing up in places that you probably don't want to show up.

DR. HUNTLEY-FENNER: Right. If you continue to sort of develop this capability, one argument for developing the capability for being present in social networks, you'll automatically rise to the top in a normal situation. So you wouldn't have to pay extra to do it.

DR. COL: I had a question about slide 12. Forgive my ignorance, but you talked about an association map. This was the negativity clusters around peanut butter and there were two maps that were shown before and after.

And I don't know if the distribution of things on this map meant anything. There were certain areas where nothing, I don't know if it's possible to show slide 12. Is the AV guy here? No? Because I was just thinking, in my field when we do cost effectiveness analysis, when we look at these things, there are quadrants where you basically have a quadrant where you have effectiveness on one axis and cost on the other, and anything that falls as a quadrant where interventions save money and save lives and that's kind of a no-brainer because you want to be there, most things fall in the area where they save lives but they cost money and you're trying to figure out which is more cost-effective. But there are actually some that fall in the cost lives and cost money. You don't want to be there. Is there a reason why the one on the right, there's nothing in that top area? Is that significant?

DR. OSTROVE: I am sure it is but I don't know enough about the association maps. I have to admit to ignorance in this particular area, because I know that the word clouds, I've been told that the word clouds don't really give you a sense of how far - I think most of this is about how close is it, and the closeness to the central point tells you how closely associated each of those different terms is with that central term. So as you get further and further out, that means that it's less closely

associated. So the ones that are kind of clustered toward the middle, are the ones that you're going to see most often. So you're going to see more volume associated with those.

But in terms of whether it's in the north, south, east or west, I can't tell you. I could find that out, but I don't know.

DR. COL: It would be really helpful because we keep getting what's the gist of the message. Is it appropriate? Are the benefits outweighing the harms or vice versa, or are we in a neutral territory? And it would seem to me, we have these methodologies in other areas where you simply have two, you identify the two major axes, which would be effectiveness, or it could be net benefit risk, and known damage would be on the other one, where you could actually identify quadrants and you could see, you could track quantitatively whether the bulk of things are sitting, are shifting where in a quadrant and how far are they going towards a good zone versus the bad zone. It seems to me that that might be a useful way of measuring shift in the content of the message.

DR. OSTROVE: Absolutely. And I could actually try during the break to find out whether there's more information about that.

DR. FISCHHOFF: These are kind of projective

tests. Val, and then Kala.

DR. REYNA: There is at least one among us who has done some work in this area - Dr. Fischhoff. Years ago on multidimensional scaling of various kinds of risk according to three major dimensions - this is classic work on, let's see, controllability, dread and what's the third one again? Uncertainty. If our students can do this on the exams we don't pass them, if they can't name those three. So that's a bottom-up process where you just look at associations and you extract how many significant dimensions describe how they're related to each other. And those are three that generalized across a lot of different kinds of risks and technologies and so on.

DR. PAUL: This is a question for both Nancy and Greg. In terms of with 100 messages, is there anything that you're doing either with this work or in future work where you're looking at how many people that represents? Do the 100 messages represent 100 people? Or is it maybe one person who's crazy, on 10 blogs, or 10 different - or not crazy, I'm sorry. But just that there's somebody out there very active, and what you've got is maybe the same message, the same buzzwords, the same word cloud, but you've got it coming in through portals.

DR. BUSSE: There is some work - we haven't started looking at this yet but there is some work out

there where people are getting classified on their Twitter behavior, as to whether or not they are pushers of information or interactors, or just receivers, lurkers, people who just listen to information. And yes, a lurker. So if memory serves me correctly these breakdowns really coincide with what their function in the information age is.

So for example, a new site is just going to be a pusher of information. They're going to have lots and lots of posts perhaps on the same topic. And then you'll have social commenters or bloggers who actually invite dialog and want to be part, and so they're going to have less volume but more meaningful volume, and then the lurkers will have no content pushing out. They may push out one tweet or one post. And so really there are multiple kind of populations of people out there and it would be interesting to see who is really talking about our stuff. My guess is that it will break down based on which channel you are actually evaluating, whether that be the micro-media or the blogs or the mainstream news stories. And it may be worth our while to spend some time breaking our data down that way.

DR. PAUL: If you have got fewer people doing multiple things, then maybe - I'm likening this somewhat to reporting drug safety issues, where if you don't count just

the number of adverse events, you also count the number of people who have had adverse events or a particular adverse event so that you don't do multiple counts of the same thing. But maybe - I'm just thinking when you're looking at the buzz on the web, or out in the air, if there are fewer people but doing the same thing over and over again, that still constitutes the buzz. Maybe you can comment whether, is there any need to tease out the number of people commenting versus the number of comments.

DR. BUSSE: I can give you one example where that's important. We issued a communication basically saying that this drug would not be approved, and it stirred up a campaign of a very small, select few individuals who were very loud and loud for a very long time. Understanding that was where that information came actually shaped our communication policy so that we weren't saying, oh, this is the whole public that's talking about this, this is just this very vocal minority group and we need to deal with that accordingly. And so it does have a place and it is an important thing to look at.

DR. FISCHHOFF: For both of you, let me pick up on a comment that Christine made and a number of other people have made. These are really precious, fascinating data that require multiple disciplines to look at. People need to know the technology, the statistics, the

alternative analytical schemes and so how does that happen? We had a meeting. I think it was in this room. It might have been the meeting where we provided advice on the strategic plan, where we talked about the organization of research here. And one of the topics that came up and has come up occasionally other times is, is there some way for FDA to create ties with the academic community that will enable researchers to cycle through here, to learn your data and your problems enough to be able to do applied basic research that's pertinent to what you do.

The real world is much more complicated than one would imagine when one does basic research, and one wouldn't do basic research, one couldn't do basic research on applied problems if one knew how complicated the world really was. You need that kind of illusion of helping to change the world when you're doing your little lab stuff. But there are people who do that, who have students, who could cycle through, who you could get some of the academic community both to be working on the basic issues that you're interested in but also to close the deal on some of these problems. So you're stretched too thin to write these up, the cost structure of your contractors is such that they can't do basic research and argue with the editors and get it through.

There are graduate students for whom one of these

projects - so say taking 100 interviews, doing several kinds of machine, linguistic analyses of them, looking at alternative sampling schemes, doing comparable tests of comprehensibility with people where you can actually test what they know in conjunction with people who know what you really need to know - it's a kind of big science that you all need that most of us that come up from psychology are accustomed to doing a kind of boutique science.

But I think that that may be really a missing piece, that you can't really take full advantage of what you're doing for the world in general that's interested in these phenomenon, which you have I think some unique data and certainly you have unique data and unique insights. And the kind of hard look that this little research seminar has given you I think would be helpful to your work, would help you to figure out which of these things are most worth doing and to make the case to manage it for the suitable budget. So I think this idea of finding some way of rotating academics through those who have graduate students who might spend a summer here, or a term, I think that's a missing ingredient in this recipe.

DR. OSTROVE: If I can respond - absolutely, I think that would be great. We have had both positive and less than positive experiences trying to bring in academics. For a number of years a marketing professor at

American University has been working as a special government employee with DDMAC, with the division, in CDER. Also the people, the Consumer Studies team in CFSAN has a relationship with the Center for Risk Communication Research at the University of Maryland as part of their JIFSAN, which is the Joint Institute for Food Safety and Applied Nutrition. And they have often worked with outside academicians as have I, as have the other people in DDMAC, and I'm pretty sure they're currently working with one of Craig's colleagues right now.

I remember one time last year, I guess, I was trying to bring someone in on an IPA and if you come in and you become part of the agency, it has implications for you in terms of the kind of funding you can get. So if you're dependent on grant funding for most of your work and you come into the FDA, then all of a sudden you can't represent yourself or someone else in front of the agency for a period of time after you've been working for the agency. So there are these restrictions on behavior.

And - here's the other issue - we love to have people come in as interns. We have actually programs with a lot of summer interns. So if we can find someone we can work with and we're very interested in the people on this committee particularly. If you have graduate students who are interested in coming in and working at FDA we have to

figure out one, whether we can afford them, if they're willing to do it for gratis then we have to make sure that we have a place to put them in terms of office space. Because as Greg will attest, his group came out to White Oak before my group did, and then they took his group and put them in another building because we ran out of space again. So you want to take intact groups. So there are a lot of interesting logistical issues that I think the people internally would be very happy to try to overcome if we can get interest among the academicians.

I would also note that the position that I'm currently in, at some point will be advertised. And if you know people who would be interested in that, just a word.

DR. BUSSE: I just want to add too that I too fully support that, working with graduate students. In fact I get calls often about people interested in what kind of ideas do you have for my thesis or my dissertation that I could do. One of the great things about this data set is that it's public, it's out there, and people can replicate and do the same thing that we have done, or that we are looking at, and use us as a sounding board for any sort of insight that we have. And I fully encourage that because as Nancy will be the first one to admit, we can't do it all ourselves. It's a huge program, it's a huge idea, and our expertise is narrow and limited and there are lots of

people out there who have expertise in linguistics or some other behavioral science that can contribute to this ongoing effort, and the more data the merrier is what I say.

DR. FISCHHOFF: One mechanism might be to have a bit of a road show. These are really fascinating data, but to go to professional meetings, discuss this, and put out the welcome mat for people. There may be people in a position that they can do it within your resource constraints. It would be nice to have a proper program but until then, just going on the road, I think you could get an interesting audience. Lots of people are interested in peanut butter, although I realize we're not talking about a particular product here.

MS. GREENBERG: So, Nancy, I am having trouble sorting out how you draw major conclusions from this survey. And I'll tell you why. There's different kinds, very different kinds of risks that were surveyed here. There's risks that could kill you, like eating eggs or eating peanut butter. And consumer reaction to that is going to be different, and much more desperate to find information. So I think the methods of getting information are going to be different than, let's say, the genetically modified salmon, which is an ongoing risk, it's something that you may be able to avoid, you may not be able to

avoid, but it's not going to kill you tomorrow.

And then there's the risk of breast implant, which is a completely voluntary decision on the part of the consumer. So I guess what I'm trying to glean out of these data is we're sort of conflating all of those issues in how we perceive consumer response, and I actually think they're very different. It's a very different set of decisions that consumers are making, or inability to make a decision, because you may be eating a food, like tainted eggs, you have no idea that you're eating tainted eggs whereas you certainly make a decision as a consumer to get breast implant surgery. So that's why I started out saying I'm having a hard time sorting this out in how we respond to this information and how we can use it, and how the FDA can use it.

DR. OSTROVE: That is very fair and I really appreciate your pointing out where I have not been clear enough. We are not putting all of this information together. These are separate, small, qualitative analyses for different purposes for each one of these events. So for instance, for the genetically engineered salmon, that was done, we looked at a sample there of 100 messages just to give us, again, a qualitative sense of where people's thoughts are, those who are positive about it what are they positive about, those who are negative about it, what are

they negative about. And that wasn't even the major thing. And we put that together with a review of the literature on consumer understanding of genetically-modified foods and engineered salmon that one of our analysts did, and we sent it to the people who basically, if there are any communications, any ongoing communications about genetically-engineered salmon, will have this as background to help them plan those communications.

So a number of these, including the breast implants one, were done just to give some basic information to add to whatever literature is already out there in the environment, to help them plan how they're going to communicate about something. It also can tell them what sources are. So I just gave little snippets of each one of these. It doesn't go together in a large packet, they're all separate efforts. Some of the other efforts were to give us an idea as to how was the social media space, the people who engage in social media conversations, reacting to a particular roll-out, so a particular type of event. And we expect that the people who are talking about it are going to be different, the areas that they're talking about it in are going to be different for each one of these.

Now as we learn more and more, we might be able to make some generalizations but I think it's going to be a long time before we can do that. We really did these

analyses for specific individual purposes, either for communication planning or for assessment of how the public responded, the public in the media space. And in the case of the egg recall we did two things, because we had the opportunity to do two things for that particular one because it fell under the categorization that was necessary to be able to do the Harvard survey of the population. The others basically wouldn't have been - we wouldn't have been able to do it for various reasons, various characteristics of the particular event. So I completely agree with you, and these are not meant to be put together and tied up with a bow.

MS. GREENBERG: Do you have, since our charge is risk communication and looking at levels of risk across the board, I'm sure we've talked about this before but I can't recall specifically how the FDA deals with certain kinds of risks because they're very different categories of risks that consumers perceive, of the kind that we just described. Some are acute, some are ongoing, some are the risks that you decide to take. Anyway, does the FDA have, and do you put risks into different categories - I'm sure you do - and how we're talking to consumers, and how consumers are talking to each other, for the purposes of these data.

If I walked away from here and you said to me,

well what conclusions can you draw from here, I would have a hard time, I think, knowing what the FDA learned from this, or what I learned from reading over the FDA results on this survey, sort of as an over-arching statement.

DR. OSTROVE: I think that is good actually, because there's not meant to be any overarching statement with respect to this. I think the only statement we would like to come out of it is that we're using, we're trying to use an evidence basis to do both planning and assessment of our communications. We are not at the point with these kind of data yet, at least, and we may not be for a long time, that would allow us to come to certain conclusions that we could then apply to any particular set of circumstances.

When we look at what kinds of communications we're going to have to do around a particular risk event we absolutely take into account the risk communication, risk perception, characteristics associated with that particular event, you know, what's the size of the population being affected, what kind, is it acute, is it chronic, how dreaded is it, are there children or pregnant women involved, all the different perceptual categories that are going to raise or lower the perceived risk associated with something, whether we can make certain recommendations or whether it's just a - you know, we just want you to know

about it because we think it's something, but there's nothing you can do at this point, maybe you can talk to your doctor. All of that, we apply the information, the evidence that is out there in the literature. The purpose for using these is for a particular instance, or in the case of the work that Greg is doing, is to try to forecast for all drug safety communications. I'm sure that some of the things that they'll be looking at are the characteristics of the particular communication and they'll try to see whether there are any commonalities in what's happening in the social space around those.

Once again, I ended up taking a slide here and a slide there from reports that consisted of anywhere from 16 to 30 slides, just to illustrate the kind of analyses that can be done, and that we're having done for these. But we're not at the point where we can make any, come to any conclusions, overall conclusions about it.

DR. FISCHOFF: Let me just follow up, and then Christine and Craig - which is, let me make sort of the same suggestion for this project that I made for Greg's, which is that in a way I think you're getting the natural history of this ecology, and the test would be to take a particular case and work through what are the metrics that you would like to see if you had a successful program, and that would show what are the things you want to monitor and

whether you'd really stand behind these measures. So if you were thinking here, I notice that the tablespoon was closer to peanut butter heaven than teaspoon. It was a ring closer. And I would say, well now I'm doing nutritional guidelines, purely on fat, not on anything else, not on nutrition, wonderful taste, maybe I would want to say I'd like to get a teaspoon closer to peanut butter heaven than tablespoon. But you could, anyway, think through what the measures are, and that would see just how useful this is. So Christine?

DR. BRUHN: Nancy I just wanted to suggest another factor to look at when you're examining those 100 messages, and that is, look at who wrote them. I recognize that it's 100 messages taken as a sample, but it seems to me that there were groups that would have a vested interest in some of these topics, and may as part of their normal communication speak positively or negatively about an issue. So I believe the use that you are using from this data analysis that is due, inform your staff as they prepare future communications. That's a valid and a wonderful thing to do. But to suggest that these messages reflect the public may or may not be correct depending on who's putting up those blogs.

DR. OSTROVE: Very good point. And in fact, even our contractors who put together the reports basically note

that in some cases the comments are clearly politically motivated. So that's a very good point and to the extent that we can, we will do that, absolutely.

DR. ANDREWS: What Sally said kind of provoked some thoughts about old school surveys. A plug for that. For a given topic, obviously the FDA would know rankings of risk. But for a given topic you have multiple risks, and so we're going to know numbers there but we don't necessarily know from a consumer's standpoint where they would rank the importance of those.

And so I remember back, you would measure certain risks, beliefs, and other things, and then also add a question on importance rankings from consumers on that. So that was just a thought. There were always debates in academia about if it's a first thought on the cognitive responses, maybe that's important. So it's just - I think there's some methodological issues just kind of to work out. Anyway, thoughts from the past a little bit on surveys.

DR. REYNA: Just a little quick yes, yes. I think I've watched these trends in D.C. in some of the agencies here commissioning reports, and I have observed that same trend that you mentioned and that you're commenting on, away from surveys and toward smaller qualitative samples. But then retaining the inferential

power of some of the sampling quantitative techniques, so it's sort of a mixing, for anyone who's a purist about qualitative or a purist about quantitative, either one, it's a kind of mixing of those two. And surveys really can be quite flexible. You can really test hypotheses with them, they don't have to be thousands and thousands of people, you can even do experiments using a survey method. But a standardized methodology allows you to at least be able to make some inferences of the sort that you'd be interested in. So again, a plug for surveys.

DR. FISCHHOFF: How can we help you? In addition to this conversation, what have we missed, or the topics that - Greg?

DR. BUSSE: I like the idea of taking your graduate students, actually, so if you've got any you want to send our way.

DR. FISCHHOFF: And the same applies to the audience. I'd like to have us walk through the questions just one more time. I'll even read them aloud, just to see if anything else comes to mind. But let us know whether we have - I don't want to keep the discussion going just for the sake of keeping it going but we've gotten this incredible group together, you've given this - serve these delicious treats. I want to see.

So the first question that we have here: What

evidence do we have, and most need, regarding the roles of repetition and variety on the impacts of communications, including (a) how those impacts vary with the time since the communications have been released; (b) how those impacts vary as a function of the variety of sources and communication channels; (c) how the answers to these questions depends on the kinds of messages, including the issues involved and whether the goal is persuasive or informations?

So I don't know, a few hours ago Mary gave us a summary, give people more stuff, give people the same general thing in multiple different ways it's more likely to stick because it will resonate with somebody, one person one way and not the other, if they hear there's some buzz about that. We could say, after that it's mostly parametric, that is, you've got to go out and estimate how well it works in particular settings. Or maybe we can say something more specific. Christine?

DR. BRUHN: I think we really hadn't discussed this particular question in today's presentations. I mean, I didn't feel I was looking at what form of social media picks it up. But I think other research has shown, quite clearly shown, that the factors consumers use in making decisions is, part of those factors are have I heard the same message from multiple sources that I believe, is it a

flash in the pan or is it something that is well-developed, makes sense to me and everybody's seeing it. So again, I think we did not discuss that today but I think it's clear that having a variety of sources bring something forward increases credibility to the public.

And maybe if it's on your blog as well as the CNN as well as the anchor news, and somebody else who you belong to and you read all their boards is saying it too, that's helpful. So from this point of view, I guess getting information out and using social media in that it replicates the messages, is a very positive thing.

DR. ANDREWS: I mentioned this to Greg earlier, but there is a tremendous research, a vast research on advertising exposure issues, so repetition of facts, where does it peak depending upon if it's a lab study, field studies, what are the factors to extend the wear in, how do you reduce wear out, so I just thought I'd point that out. I don't want to go over a lot of that, but if people are interested I do have some sources on that.

DR. FISCHHOFF: The people on the committee were fortunate enough to get about a dozen review papers that Greg had sent us. So they're aware about it. Is there anything to be done about translating that research, which has been mostly done in somewhat different arenas, into the social media arena? Or can we - maybe somebody has some

thoughts about whether you can just assume the same principles, or there's something fundamentally different because of the different bandwidth you have here. Nan?

DR. COL: I was going to respond to Christine's earlier comment. I don't know if that's off track, but - and this was something I'd talked to Nancy earlier about. I think having a variety of sources concur is a really good thing, but I think there's also the risk that we saw with the women's estrogen replacement therapy several years ago when companies were hiring a variety of pseudo-academic ghost writers to write favorable opinion pieces not fact based, and it was sort of to counteract the women's health initiative which was a very reputable study. But they sort of were countering a well-done study with a whole bunch of noise but opinion pieces. And so they sort of trumped the message.

And so the concern is, if people learn how to - you could potentially manipulate and have 1,000 voices saying the wrong thing and make it appear right because it's hard for a lay person to understand that. But on the other hand what Nancy and I were talking about this morning, in some ways this levels the field in some way because it may be more difficult to manipulate. But I don't know. If you get some of these very noisy bloggers you may be able to manipulate. So that's a danger. I see

it as a danger because we've seen that, and we've seen people, they hear it again and again, and if you don't know the difference between an opinion and data, and evidence, it's challenging. You can get confused.

DR. HUNTLEY-FENNER: I was thinking along the same lines, and my mind ran to a darker place. I think there's something to be said for making distortions less sticky, and doing what you can to create an environment that's hostile to ideas that haven't been vetted. So part of the role you might consider is identifying and helping to support legitimate sort of clearinghouses of health risk information, and doing what you can to sort of bolster a community that has an evidence-based approach to communicating. There are going to be distortions put out there but to the extent that you can make them less sticky, you'll have the same effect.

DR. PAUL: This is just in response to both Nan and Gavin. I think you both actually supported the point that repetition does reinforce the message. It just, in your case you're saying it reinforced a bad message as well as a good message, but the basic idea is whether we can control the message or not, the question was does repetition reinforce the message and then promote some possible behavioral change after adaptation. And the answer was, for good or for bad, yes.

DR. BUSSE: This is all great, and it actually leads me into our next area which is this idea of influence. So do we as an agency to make things, to make the bad message less sticky, need to take a more prominent role in the conversations that are going on in the public space, to say, "Hey, that should be less sticky, this should be more sticky, listen to us, we're a good source, we're involved in the conversation"? Or do we continue to be kind of the silent government institution for the most part that doesn't have a lot of interaction on a person-to-person, on a one-on-one level, on a conversational level?

DR. BRUHN: And it wasn't even a planted question. Jacob made the point earlier, and I see he's had to leave. Jacob, our chair and I are the only members here today who have been here four years. And I'll repeat - isn't that correct? We're the only ones here who have been here four years - I'll repeat what he mentioned. I think every year we have urged that the FDA consider having a spokesperson. And celebrities - your comment addressed that as well. People used celebrity people, public faces to try to present information, because they knew it was powerful. People like to relate to other people, ones they find are credible and honest and care about them. I think the agency would be more powerful in its communication, or the communications would be viewed more positively, if

there was a face instead of a very nice symbol that they were relating to.

A different generation: Twenty years ago perhaps it was C. Everett Koop. Even though he had retired, he was still doing focus groups - who do you believe? People related to C. Everett Coop. I haven't seen that kind of strong identification since he's left. There is someone with CDC whose manner, the content and the delivery of his information just is overpowering generating trust in my mind. That's Maury Potter.(?) Anyone who's been here long enough knows Maury Potter. I can see his face, he's long retired now. The uniform, the white uniform, the suntanned face, the dark hair going gray. My, and Maury tells me something, and, you know, I just believe it. It's gone straight to the heart and to the head both at the same time. I don't know a personality within FDA, and I realize the challenge of having both political appointees as well as scientists working within the agency. But may it go down on record that at least one if not more of your committee members believes a human factor would be powerful.

DR. ANDREWS: I don't know if there is an answer to this, but I'll still pose it. You were talking about the brand FDA, and I was just wondering where people's priors are today and if there's been some work to evaluate

that. So for example, credibility, you segment that into expertise and trustworthiness, and then you get other source dimensions like attractiveness, that work differently, which I think the credibility issue is very important on internalization of the information. So anyway, I'm just putting that out there. I don't know if you've looked at that as far as the brand FDA, and how people are taking that, what their priors are on that.

DR. BUSSE: I know that we have talked about it multiple times and we haven't formally evaluated FDA as a brand, though others have, and I can't remember exactly what the study was, but it was basically comparing trust in FDA versus other governmental agencies, and where you fell along that continuum. I don't want to do a disservice to FDA but I know we weren't at the lowest part of the government, so we did have some trust and people do hear the name FDA and I think they believe in it to a certain extent. But this is clearly an area of needed research to look at, from at least a marketing perspective, that brand goes a long way and it means a lot.

DR. ANDREWS: There's also other dimensions, too, that you might give yourself a little more credit for. When you get into, okay the brand with - medical devices, etc. - when you get more specific maybe people's credibility will increase rather than just this global sort

of attitude, which actually may color some of the thoughts and opinions.

DR. OSTROVE: It is a continuing challenge that we haven't really been able to address very well. One of the issues is the variety of products that we regulate. I suspect that you would find that for certain messages that have more of a political tinge to them or people perceive them as having more of a political tinge, the kind of credibility that is going to be lent to FDA is going to be different than when it's purely a scientific matter. So you end up, again, my point is always that the world is a mass of interactions rather than main effects, but even if we tried to try to get to that, my concern with trying to clear that kind of research is that it's seen as being public relations rather than being - you know, you can make the argument that you really need to know what the credibility of the agency is in order to be able to communicate effectively. But that's still not necessarily going to fly.

I know I've had discussions with people internally as to whether to include that question on a survey, and had to fight with people to get basically, even for a particular incident, to get a piece of information on a survey that asks about well how did the government handle, how did FDA handle this particular thing. Because

there's so much sensitivity about using public funds to measure your popularity.

DR. HUNTLEY-FENNER: As odd as it may seem, sometimes good communication is a two-way street. What I mean by that is that you can build trust, I think, by engaging people, and it's especially important in the kinds of media that we've been talking about. Accessibility and responsiveness seem to be important characteristics for influencers, for example, on Twitter. So I think part of the challenge is being authoritative and also accessible and responsive. Obviously you're going to have to sort of deal with that as you build your credibility in that space.

DR. BROWN: Responding to Nancy, would the question of the source credibility of FDA be a good one for an external researcher to look at, or one of those graduate students?

DR. OSTROVE: An external researcher, definitely. Can I ask a question of Lee, actually? Lee, do you recall whether on our research agenda that we put out kind of for everybody, whether we had any items in there on trust?

DR. ZWANZIGER: I think so.

DR. OSTROVE: If you recall, we issued a research needs document that we tried to make available to researchers, and I think that that was one of the issues that we raised is, this is something we would kind of like

information on.

DR. BROWN: So it might not be a bad idea to repeat that in multiple channels.

DR. OSTROVE: Right. It is on our website, but as we know our website is not necessarily the most accessible. You may put it out once, but you have to keep putting it out and this is something that we definitely know.

DR. FISCHOFF: Gary.

MR. SCHWITZER: I think that - and people who know me might be surprised to hear me say this, this old hack journalist saying something nice about public relations for once in his career - but maybe doing something for even an admittedly public relations reason might be a good thing. And for a moment - and this is me saying this, so I don't want this committee or this agency to get in trouble with another across town.

But it's interesting, Nananda and I were talking about this at lunch, I think that we can learn from the terrible experience of the U.S. Preventive Services Task Force, an arm of the Agency for Health Care Research and Quality, with its release of the revised mammography recommendations in November of 2009. And so I tracked news coverage which affects - and in that case I think really did affect the public discussion in a way that we've not

yet recovered from, concluding with some new studies that came out this week.

Over and over again public messages, public discussion, and what news coverage allowed to get out were unchallenged claims of this big government task force. Well, that task force was as if it were this committee. There wasn't a bureaucrat in the crowd. They were independent people who barely get their expenses covered, who go through scads of work because they care about evidence-based recommendations.

Many comments made and promoted that this came out of the blue, that this task force was made up of uninformed idiots because there weren't any oncologists or radiation therapists on it. Since when does it require a subspecialty in oncology or radiation therapy in order to evaluate evidence, and on and on and on.

What in my estimation lost the day that day, and in the ensuing 20 months, was that there's no public relations arm for the U.S. Preventive Services Task Force, and even through that agency. And in fact special interests, with some powerful public relations arms, ruled and won the message that day. And this has had, I think, a lasting impact. This is just my soapbox. I think it has affected subsequent release of information on prostate cancer screening, the national lung cancer screening trial.

We're nuts on screening in general and that day in November of 2009 and the failure to have a public relations arm to guide well-meaning scientists in how to communicate a message, I think set us back years. So yes, I think you need a voice, and yes I think it's all right to have public relations for public relations' sake when trust, credibility, brand identity is at stake.

DR. FISCHHOFF: On that, we did the same thing in the late 1990s on exactly the same recommendations, and we didn't learn.

MR. SCHWITZER: The NIH Consensus Conference in the late --

DR. FISCHHOFF: Yes.

MR. SCHWITZER: Absolutely. So people that said this came out of the blue, no it did not.

DR. FISCHHOFF: A way to think about this as not being public relations but as being risk communication is that part of - as any of the communications scientists will tell you, part of the communication is the source credibility. If you haven't characterized the source - I mean, I don't think they did a particularly good job of communicating the message, but if they didn't characterize the source as the kind of group that it was rather than the kind of group that it was going to be characterized as, I mean, they owed it to their audience. Whatever the

politics were, you owe it to your audience to tell you who you are, where do you come from. You're trying to change people's lives, and you really haven't fulfilled your duty to inform. So if you wanted to cast that just as pure risk communications and not PR, I think there was a failure there, and that one needs an institutional response because you can't expect a group of professionals to anticipate the issues, to know - they have the two-way communication with their audience, to know well enough how they're going to be misunderstood much less to know who might be waiting for them to catch them on any slip-up. And I think the FDA is fortunate to have had this institutional thing.

I would like - maybe I'll bring up a topic I brought up earlier - but I would still, since we're on the second topic - and I'll read this aloud: What evidence do we have, and most need, regarding the impacts of having "influential" individuals deliver message, and then about different kinds of "influentials." It has "influentials" in quotation marks. Perhaps we should have had "individuals" in quotation marks, because are there trusted institutions that could relay the message.

So after an earlier presentation of Greg's report I had an opportunity to have a long conversation with somebody fairly central to one of your partner organizations, who said what I really want to be sure is

that I get those clear summaries of FDA's analysis of the risks and benefits, and the risk management plans and whatever, of its products. And he said nobody does that like FDA. I sometimes don't exactly agree with their analysis of the data, but I know they're doing it as well as is humanly possible. And I don't always agree with their recommendations. They sometimes don't fit my institutional settings. And I like, I want FDA to focus on me, do its work and then get me the evidence in a way that I can then translate it to my people. And in the life of the committee we've heard many presentations about FDA's work with its different partners.

So if this is a non zero sum game in which the communication to the broader public is considered to be a legitimate expectation of an organization to which proper resources will be distributed, then I think - then that's one thing. But if you say we can either have, as you described, the communication safety as kind of a core document that has basically everything that any reasonable person would need to know with an audit trail back to the more detailed analyses done by whatever expert body did them, and we're going to make certain that people understand, that those are understood, I would say that strikes me as being more the core business of FDA if you couldn't do both.

And I would think - I thought you made the point really well this morning, that we actually have to do both, and as some people said here, your ability to get credibility for this conscientious work may depend on the general brand. In thinking through the strategy here, I think both of those, it's important to preserve both of them, and as Gavin was saying, talk to the stakeholders about how you can be more effective to them, and maybe they want more push-out to them but maybe they want it easier to reach in, they want the right documents there, they want to have a website that's more friendly. And maybe the limits to FDA's website, which I assume reflect some sort of bureaucratic infighting, everybody's got opinions and so on, sometimes you can cut through those battles of the opinion through evidence.

You think we should do it this way, you think we should do it that way. Let's get some people and see who can find the recommendations of the Risk Communication Advisory Committee on consumer medication information? Race you. I call Lee. They're hidden in plain sight. So if the job is to get people there, then I think let the evidence cut through the bureaucratic fog. That was a statement. I guess with an asterisk.

Let me go on to item number three: What evidence do we have, and most need, regarding the impacts of

different media, including new technologies such as Twitter, multi-media, and social networking? What measures should be used to assess the impacts of communications using these new media, in terms comparable to traditional media? Okay, I think in some ways your guess is as good as ours, and you've heard a lot of our guesses.

So let's go on to number four: How can FDA develop an overall communication strategy, integrating conventional and new media, across its communication missions, including diverse products, audiences, and time frames? What data should it collect to evaluate its success? My summary there is sort of what I was saying before. We've heard this nuanced discussion, much of which you were aware of and I'm sure your contractors can tell you about other things of it. I think it would be really nice to have that characterization made available to people so that people aren't misled by these simplistic - that was really a touching column in *The New York Times* awhile ago about somebody who had fallen, Linda Tuggant(?), who had fallen prey to her own counts. Like how many people were following her on - more than four, but it wasn't as big as she wanted to.

So you can get captivated by these numbers, and you know better. So I think defending and developing the program would be good, and then I think saying which

standards you would like to be - what would you like to achieve on these different measures for a couple of different kind of products - I think would be a nice way of crystallizing the discussion, because you've really made a lot of inductive progress and it would be a nice way to summarize it. Kala?

DR. PAUL: This is a comment back to number three, because the more I read it the more I just wanted to reiterate what seems to be one of the most important parts about using the social media versus traditional media, and then of course it's something related also to the effectiveness of traditional media has been mentioned here before, but I'd like to reiterate, the need to serve currently under-served populations, the elderly, the rural, the low literacy patient, people who need to have these communications, who don't have the tools and who know matter what we do with Twitter will never get it that way. So I think that's part of the FDA's mandate is to see how we aren't serving people as well as how we are.

DR. FISCHHOFF: Okay, number five: How can FDA's communication strategy ensure that its messages reach all the populations that it must serve, including those not using social media? What data should it collect to evaluate its success?

While we're thinking, let me recall one moment in

I guess our February 2009 meeting. We talked about consumer medication information and David Moxley, who deals with an older, homeless, female population in Detroit, who's a former member talked about - I asked him to speak because I thought well here's somebody, here's a group of women who are kind of out of reach of these messages. And we were talking about better consumer medication information, drug fact boxes and so on. He spoke very movingly about the difficulties that the women that his project works with have, with staying on top of their medications. If you can find it, I recommend reading the transcript. It's at our website.

And then so the question was put, he was listening to this and then at some point he said, if somebody would just organize the information in a way that was readily accessible, we could provide, his organizations could provide the kind of missing link that people need. He says there are lots of people interested in working with the homeless and medicine is something where we have the most difficulty doing with them. We don't want to mislead people on medical issues, but he said his group had just finished the guide to faith-based organizations working with the homeless. And he said he could sketch - he said I could imagine somebody coming in. There are physicians who do this wonderful work, working with the homeless, but

their time is very limited. He said, somebody would bring me their medications. If we had these nice summaries and I could kind of prep, one of our people could prep them for the doctor and say, "You've got this drug, do you have these conditions, do you have these side effects, let's write these all down as questions to put to the physician. I'm not competent to tell you, but you could do that."

So in thinking about this, there may be some hybrid strategies here that would not make the social media competitive but actually complementary to systems that we had by getting it out to people who, they're a relatively small population but they're incredibly valuable. They are not the physicians who, Jacob says, sometimes get it and sometimes don't. But they are these auxiliary, valuable auxiliary people. Maybe we could target them as a way of doing this complementarily. Mike?

DR. WOLF: I agree with that. In my one earlier comment when I talked about REMS, I was just trying to figure out again how do you deal with this. We do a lot of work, and I'm wondering, thinking about things that the FDA can actually get engaged in maybe beyond navigation, involving clinics in the actual direct patient education so much as I'm thinking of Office of the National Coordinator with meaningful use and figuring out how alerts or leveraging CMI - or now they're calling it PMI - into the

electronic health record system so you get information at the point of prescribing rather than at dispensing. Again, also tapping into the pharmacy software systems and looking at - I think one of the big issues we learned is that med guides for awhile were not integrated in the pharmacy software systems, so all of a sudden there's human factors issues in why they're not getting them.

The other partnership - I'm not sure if this is possible or, again, I think of and I do all my work, I'm situated in Northwestern's medical school which has a boutique hospital that really is meant to look like a four-star hotel, and so I have to do all my work outsourced into the community with federally qualified health centers. So partnering with HRSA, within their primary care, you know, like into the FQHC programs, I'm really curious to see if people use MedWatch. I know I hear a lot of times it's a voluntary program, they don't do a lot of adverse drug reporting from my understanding. I have a colleague who had done a lot of work about trying to figure out how do you encourage physicians to actually start reporting adverse events. But the way you're talking about it, you've got a lot of members that may be just getting routine blips, I'm wondering how well we can educate physicians in the FQHC network in the safety net, to make sure that they are getting that information, they are

using, how do they disseminate that to their patient populations in a way, and to learn about that.

DR. BUSSE: Just a quick response. I think that's all very important questions to ask, but in the context of partnering one thing that we have done and continue to build up and be very supportive of is something called a Drug Safety Oversight Board. And this board is represented by not only people within the Center for Drugs but also federal partners, so the VA, the Department of Defense, from AHRQ, or any other federal, or CDC, who may have either contact with patients or contact with organizations that have contacts with patients.

And one thing we do is, frequently consult them on measures of drug safety communication, how is our drug safety communication going to impact the patient population that you may be serving within the VA or the DOD - and Baruch has talked at that meeting before as well - as well as, are we being clear, are we taking into consideration how the drug is actually being used in the practice of medicine, or are we missing the boat completely. And so that sort of feedback is invaluable to us. So what we're finding is invaluable to us, so taking what you're saying it may be useful to extend that model out to some of the other outside organizations, non-federal organizations, and get feedback prior to our release of our communication.

DR. WOLF: I have a follow up. Was it in June 2006 that you made the modification to the prescriber insert to have like a patient counseling session to finally say, okay, here's all this information, now here's what you can say to your patient? Is there any data as far as how people might use that information? Or is it, again, just a passive - I thought that was one thing that you were trying to start more directly, guiding clinicians as to what to say about this medicine, what kind of counseling element should you be passing along.

DR. BUSSE: I am not aware of any data, but I wasn't with the agency at that point.

DR. OSTROVE: Actually that section was always in labeling. It was called Information for Patients. And our sense was, it was actually being used in a lot of different ways by a lot of different divisions, so it had an incredible variety of information. And in some cases docs would Xerox it and give it to the patients, but it was never meant to be Xeroxed and given to the patient, it was meant to be patient counseling information, which is why we changed the name basically to Patient Counseling Information. That was because we heard from the focus groups that we'd done that some of them were doing that, and it was very clear that they really didn't get the purpose, but unfortunately I'm not sure that our own people

necessarily got the purpose either. So changing the name was really just to try to clarify the reason for that.

The other thing that we wanted to do was let the physician, the prescribers know that if there was a medication guide or a patient package insert for that particular product that it would be there. It would say, "See the Medication Guide," "See the patient package insert," so that they realize that was the information that the manufacturers and FDA were encouraging that they give to the patient. But that was the extent of the research on that.

DR. BRUHN: I would suggest that it would be great to have a way to have an active, instead of a passive, information system for some of these issues. Instead of posting something on your website, being able to send an e-mail to people with the information or at least the message that there is new information on X,Y, Z at the website today, to reach these underserved audiences. For example, a way to contact WIC, Women with Infants and Children, on the infant positioning device would be appropriate.

In the food area, instead of having people who are, for example, with USDA extension specialists, or food extension specialists, and USDA has a directory, a national directory, instead of having these people be smart enough

to know they can go to FDA and sign up for food recalls, how about getting that list and sending it to them? I mean sending them, there's a food recall guys, click here, click on the website. Because people, especially new people, might not know to do that, and I would think that there would be other groups that one could reach for other issues, and perhaps Sokoya or others would know how to reach those groups who work with the low income and underserved areas, are there organizations that can be used to reach them. So the people themselves might not use the web, but those who work with them do and then would have that information delivered to them instead of making them go and search it out.

DR. OSTROVE: A quick question for Christine. The Office of Women's Health has a huge mailing list and it sends out information that is relevant to women's health. Our Office of External Relations and some of the others in the commission, they do have their own mailing lists and they try to do that. But I don't know the extent to which they have all these organizations included in that list. So to the extent that Sokoya or anyone else knows of particular organizations that we could then pass on to our internal - the groups that kind of liaise with those particular categories or organizations, that would be extremely helpful.

DR. FISCHOFF: Nan.

DR. COL: I was very interested, when you mentioned that when you created the physician counseling sheets that the docs tended to Xerox them. That just bespeaks that there's a huge, unmet need, that doctors need help educating patients about drugs. And I just want to make another plug for the drug facts box. But also, there's a lot of people commercially developing decision aids now, and decision aids are not far afield from a drug facts box, it's just basically recognizing people are making a decision about a treatment and focusing on that decision point, and giving them a little bit of guidance about how their preferences and values tie into that decision.

But I'm just wondering, has the FDA - I mean, you'd be a great source for developing some simple decision aids. I don't mean like big videos or complicated websites, but just some of the basic information, basically taking what the doctors are looking for when they Xerox and that, but something they can hand to the patient that they can understand, patients can understand the risk benefits and what it is they need to understand about it.

DR. FISCHOFF: Lee informs me this is too specific under the conflict of interest clearances for this meeting. So we have a general topic here. It might be a

nice one to bring back to a future meeting. Sally?

MS. GREENBERG: Uh-oh, I may run afoul if there's a conflict of interest. I hope not. Somebody mentioned C. Everett Koop, who was our Surgeon General, and is sort of an iconic figure. But we have a wonderful Surgeon General now, Regina Benjamin, who is a doctor and serves a lower income part of Alabama in her practice and is in Washington a lot. I would think - I hope this is not considered a self-serving plug - we're rolling out medication adherence campaign that the National Consumers League is heading up with her office next week, on May 11th.

I've been to some of her calls to action and she reaches populations, lower income populations, non English speaking or as a first language populations, that I think would be just critically important. And I hope there is - she's, I guess HHS is the agency under which she works. I would hope and I would ask that that be a great avenue for discussing issues related to our charge here, which is risk communication.

DR. FISCHOFF: Do you have further questions or further comments in either direction? Okay, well let me thank you all for your terrific presentations and for your service, and I have to say I was amazed. One of the wonderful things about this committee is its diction. We must have said the word "re-Tweet" 30 times in the half-

hour before lunch without anybody getting it wrong. So just one more wonderful thing about this committee. Let me thank you all, and thank the audience for being here, and we'll see you again in August for the rollout of our book. Bye bye.

(Whereupon, the meeting adjourned at 3:15 p.m.)