DR. NEUHAUSER: Well, luckily, I was going to say something along the lines of what you just mentioned and others here. And that is about the problem of trying -- well, two problems. One is, how do you actually reach people with things that are uncertain and complex, and so forth? Especially, if most people are avoiders of doing anything that they don't have to do. So, given that as kind of a factual statement, how do you do it?

And I think what we know from risk communication and public health and all kinds of other fields is that you need to be able to touch people very closely geographically by trusted people that they know. So, for example, we have failed miserably in emergency preparedness. People in the New Orleans area are less prepared now than they were before Katrina, which flies in the face of intuition, of course. But people are avoiders.

So what we have learned in emergency preparedness, for example, is that

community based approaches that reach out to people, especially vulnerable groups for whom emergency preparedness is not high on their list any more than food safety and a lot of the other issues that concern the FDA, that kind of outreach, local outreach is very helpful.

And during the whole issue of contaminated spinach and tomatoes, peppers, etcetera, I had a fantasy in which the world was different. And how the world was different was that every public health officer in every county and city received very good advice about very practical things that people could do. Because I personally was besieged by people calling the university saying, how do you, what should I do? I don't know what to do. There is no advice. You know, I get something from television but it is one way this day, one way the next, and it is all sort of tabloid-ish. So what should I do?

And it is a very simple thing.

Every public information officer, every public health department head, that is their job. All they need is trusted accurate information from the FDA and timely, you know, changing by the day. It is very easy to get out through networks like NACCHO, National Organization of City and County Health Officers, and ASTHO, and so forth. They would be glad to join as partners and say, okay, how do we do it. You give us the information, send it out and we will do it on a daily basis.

My other fantasy was that every front page of every newspaper had a safety corner. And this was maybe like product safety or safety news in general, whether it was defective toys, contaminated food, drug issues. That was right on the front page with the website and with a phone number, if possible, either for the local public health department or FDA website, USDA website, whatever it might be. And then everybody would know where to go when they had a

question. It also could be a place that says, where is what you need to know today and here is what you need to know to do.

So, I think there are some fairly simple, practical things that can get to people at a very granular level that we just haven't gone far enough to set up partnerships and just to think differently about it. Because it is not that the public health officers are going to come here and say, hey, I am here. Is there anything I can do to help? I don't see them here at this table. So maybe that is the kind of person that could join up.

And the other response to you, Musa, was that I think we need to have perhaps another kind of person here who looks at systems. I think, Baruch, you called it a systems analyst, but the kind of people that look at multi-level systems and how those are built and maintained and so forth.

CHAIR FISCHHOFF: Let's see.

Ellen, Mike.

DR. PETERS: I was actually going to return back to the question that John brought up, this idea of looking at some less difficult issues first, or at least when you have time. If you have time. I heard the laugh.

One of the things that starting off with these less difficult issues can help with is to help build this perspective of what other people actually know and what they don't know. And start to learn what the extent of the gap is between your knowledge and this infamous other person or the most people model.

And then once you start to -- not that you haven't already started. You have started. Once you continue to build that model of what other people know, you can start to look at variations in complexity which probably are not going to completely change what you have ended up finding out about these

less difficult issues. You are going to add in complexity around ambiguity or time pressure. And it will alter, probably what works and what doesn't work. But it will alter it. It probably won't completely change it.

So do the issues need to be exciting and new? I am not so sure that the issues need to be exciting and new to look at them because people value their health.

A couple of examples that I have seen recently. There was a Dear Dr. Donahue letter in our local paper that came out recently. And it was an 86-year-old man who had written in and he said that he had been having some trouble sleeping. So he had taken Tylenol7PM for a little while. And then he, I don't know, I think he fell and hurt himself so he was taking aspirin for a little while. And then he switched from Tylenol7PM to some other NSAID. And oh, by the way, now he has lots of health problems because of these

medications. And he is trying to regain his health. And the last sentence of his letter to the doctor is, "Why doesn't anybody ever let us know that there are risks that come with these medications?"

Now, you could argue that these are people who are information avoiders and perhaps are even unreachable. You could argue that. But let's even look at the nutrition facts that Dr. Smith brought up. There was some testing that was done recently. Just simply looking at people's comprehension of those nutrition facts, fewer than half of the people in the sample were able to calculate the number of carbohydrates in a 20 ounce bottle of soda, given that there are two and a half servings in it. So, it is not working perfectly.

Now the question about how to reach information avoiders. Given a lack of comprehension, when you have people even focusing on the information like in some of

these tests that are done, that is a very difficult problem. And I don't have any easy answers to that, other than perhaps we do need some other people, you know, another type of person on the panel that has some expertise in that kind of area. It is not an expertise that I have.

DR. GOLDSTEIN: This a great discussion. We are talking about key questions like, what are the important outcomes. Should it be behavior or could it be some other outcomes? And I think it does depend on the specific areas that you are focusing on and the specific problems that come up. So, in some cases it is awareness that you are trying to increase as an outcome. When people have to ask does this warning apply to me or not, do I have to pay attention to it or not? Some of the more general ones may have to do with foods and things that apply to everybody.

Then there are times when it is

information seeking we actually want to influence. So we want to help during an emergency for people to know who to go to in their public health community, if it is a medical issue. Or if a specific population, who they can talk to to find out am I at risk taking this medication or not. Should I have a device adjusted? And the behavior isn't necessarily a change in something they do, except seek information from other and have that conversation engaged in a decision, which I guess is another type of outcome. Are they engaging in a decision and what is the quality of that decision-making?

So, it is really important to get more precise. I think this is great. We are thinking about the specific kinds of outcomes, each kind of campaign, each kind of communication is trying to address. And then thinking about what are the mediators of that? What are the ways in which interventions of various kinds can change those behaviors.

With respect to the question of motivation, when motivation is an issue, there are specific kinds of strategies that can promote motivation. And there are experts in motivation, motivational interviewing, for instance. There is a whole body of knowledge that is accumulating around a specific paradigm. It is not a model, per se, but it is a way of thinking about motivation.

I have some interest in it but I am certainly not an expert in it. But can I identify people who have expertise in motivational interviewing as an approach to helping to reach those people who don't seem to think it is an issue or a problem for them? So that is something that we can look at. In that subset of people, the outcome might be, oh, it is a problem. Oh, I better pay attention. It might not even be behavior changes in initial outcome but engagement in thinking about this might be a problem for me. I had better seek more information or monitor

the condition.

DR. KHANNA: I agree with Dr. Goldstein. I think this is a fabulous discussion. And thank you, John, for kicking it off.

I don't have an answer, either about how to motivate people to change but I will tell you that it is a question that I have just been intrigued by for many many years. And one of the reasons I went into medical journalism from practicing medicine is because I made health education my mission. But part of just telling people about things is trying to get them to react to that information, which is what we are talking about.

I don't think anybody who smokes knows it is not good for them. I mean, that is just the most basic example. So then how do you motivate people? It is not answered by Prochaska. He just talks about the stages. Maybe we didn't need an endorsement by Oprah

Winfrey. I think that is the closest we are ever going to get to motivating people to change.

I don't think it would be answered, though by another panel member. As valuable as input may be, I just don't see that being the answer. I think instead, as Michael just mentioned, we have to look at known strategies. We have to understand that women are the health caretakers of the family.

I always thought it amusing when my news director would say to me, you know what, February is sweeps month, so we are going to run a whole series on women's health. And I said why? He said, well, women watch TV, they are the health caretakers of the family. And I said, yes, being that they are the health caretakers of the family, they are interested in prostate cancer, too, because it is their husbands, and their sons, and their brothers, and their uncles.

So, understanding that the approach

might be getting to women with health information because they make the final decision in the household may be one strategy. Taking advantage of the craze in this country that is celebrity worship and possibly getting positive information out through celebrities, and I think we talked about this at the last meeting. I mean, I don't think there is, again, there is not one person probably in this country, perhaps the world, who doesn't know who Michael Phelps is. So there is somebody who is a real, real positive role model and somebody who, again, going on the theme of celebrity worship we could get to, you know, hopefully endorse positive things.

Hitting close to home with emotions. Hitting close to home with effecting diseases, medical conditions, information that affects family members. And then stratifying. And I also find this a very fascinating science. We have the worried well. You know, people who are very healthy

but are the gym every day and reading the nutrition labels and drinking 20 liters of water a day. We have the unhealthy sick, the people who are walking around with pre-diabetes or diabetes and don't know it. And then we have those with multiple morbidities, who possibly have the least motivation to change, in many cases.

So, I think understanding some of these elements, going with the known strategies that we have possibly to get the information out. And remembering that even though we are talking about risk communication that it doesn't end with communication. The ultimate goal of this panel is really to hopefully change behavior.

CHAIR FISCHHOFF: So we have a window of opportunity for selling the 12,000 calorie a day diet?

DR. KHANNA: Well, you know, it has been shown that VLCD, right, very low calorie diet, do increase life expectancy. That is a

proven fact.

CHAIR FISCHHOFF: No, 12,000. Michael Phelps' diet.

DR. KHANNA: Oh, you said 12,000. I thought you said 1,200.

CHAIR FISCHHOFF: Christine.

DR. KHANNA: Oh sure, if you have a wingspan of 64 feet.

DR. BRUHN: Who wants to live an extra six months, if you have to have all of your years without chocolate and ice cream?

(Laughter.)

DR. BRUHN: I actually wanted to comment on something that Linda had mentioned about the spinach outbreak and perhaps more recently about the tomato, or was it peppers, or was it something else outbreak.

Remember when you were growing up and if one parent said no, you went to the other parent because you hoped maybe someone would say yes? Spinach was a while ago and tomatoes was fairly recently. And I think

actually there was a consistent message. And that is, don't eat it. Don't eat your spinach. Throw your fresh spinach away. And unfortunately, people thought that meant don't eat any kind of spinach. And they also stopped eating the frozen and the canned, which would have been protected because of the heat process that has occurred.

But I believe the issue when they kept coming and saying, tell me what to do, I don't know what to do, is in part because they wanted someone to tell them it is okay to eat this food that they liked.

There was some lack of consistency of the messages in the early parts, the first few days before people really understood. But then after that, it was don't eat, don't eat, don't eat. Truly there was some ambiguity in the don't eat red round tomatoes. And then so what kind can I eat? Well, the cherry tomatoes, the grape tomatoes, the oval tomatoes. But you don't always remember that.

And where did your tomatoes come from? The grocery store. And where did they come from from the grocery store? Well, it depends upon what part of the country you live and how ripe all of the tomatoes were because everybody was repacking it. But the message was don't eat it from certain regions.

So there is some consistency there. And I think that people were just hoping for something else because they don't want to change their habits. And that is the thing. I like tomatoes. I like raw spinach. I want to eat it. I want you to tell me it is okay so I can eat it or tell me how I can make it okay.

And I guess I had one more comment. Oh, yes?

MS. DESALVA: I just wanted to comment as a, I don't know if everybody knows but I happen to be a nutritionist also. And I caught myself during this time, during the spinach episode and then more recently during

the tomatoes, wondering, what should I do? Not looking for another answer but just wonder, what should I personally do? Should I microwave these tomatoes? If so, for how long? Should I boil them? You know, what should I do?

And I was thinking, if I don't know, how could anybody be expected to know and where are they getting their information?

DR. BRUHN: Yes.

MS. DESALVA: So, I think that falls into that middle zone of something that is complex, in the sense that we don't know the source of the contamination but perhaps for which the advice about what to do at the moment might be fairly simple. And Christine, maybe you know or somebody here would know from the FDA staff, about what the actual advice was supposed to be in terms of handling, let's say tomatoes, during the recent episode and maybe how that was put out. And then we could perhaps imagine a way that

a simple message might have gotten out to every part of the United States in a consistent way.

I am not exactly sure how that would be done. That is a matter for brainstorming. But I was very curious about it was actually approached.

DR. BRUHN: Well you know, the challenge at the beginning was that nobody knew where the illness came from.

There was the meeting just last week of the International Association for Food Protection. And we had several different sessions where this particular incident was discussed in length. And it was challenging to know what was the cause because it relies upon human interviews. And interviews of exactly what you ate about two to three weeks ago and where the food products might have come from. And even if your tomatoes had stickers on them, you surely don't remember what that sticker said today. So, it was a

challenging thing.

But the overall thing was, you don't eat tomatoes right now, unless they came from a specific location. AT least you don't eat any from Mexico and, originally, Florida but that was later brought up. So, it was complex but there was some messages to it.

I wanted to mention just one other thing. You mentioned your dreams. And I have got lots of dreams but one of the simple dreams that just was in the news last night was let's call it what it is is my dream. Do you recall when I think it was the first President Bush was in China, and he was at some diplomatic event and he lost his cookies? He vomited. He became sick. It was the second Mr. Bush? And of course he had a stomach flu. Whichever one it was. He had the stomach flu. Was it in Japan? In Asia.

And then just last night, we had one of our swimmers who has been having stomach flu for the last three days and was

not performing to their normal standard. Well you know what stomach flu is? It is foodborne illness. And maybe if we could have the media call it what it really is, we might let people know that this is something that can occur frequently.

You know, I try to tell people that it is not just a moment of being upset, an upset stomach, that it can have very serious ramifications. And I describe all of those. I go to the far fear. Oh, and the far fear is really quite bad. And there is also just feeling bad for a day or two. But there is a lot of in between and it needs to all be mentioned.

DR. KHANNA: Just a quick follow-up. The reason it is not mentioned as foodborne illness is because they don't know. Producers don't know that stomach flu is foodborne illness. They see it written somewhere or it comes across somewhere.

DR. BRUHN: Yes, of course. The

media doesn't know.

DR. KHANNA: Yes, they don't know that it is foodborne illness. Otherwise, I believe they would call it that.

CHAIR FISCHHOFF: Thank you. I promised John the last word on this discussion that he kicked off.

DR. PALING: I, too, have a dream.

(Laughter.)

DR. PALING: I thank you for your input. I tend to be contrary in though wishing the very best for the public and for the healthcare professionals to whom the FDA speaks.

And with my deepest respect to Nancy, I am by no means sure that the FDA does simple things as effectively as it might right now. I would give an example in your fifth of the slides which I will read to you. You were talking about information to be communicated and the one thing that does not appear there is any reference to the FDA's responsibility

to communicate probabilities in numbers.

You will find, if you go through the patient information sheets, that there are often six to ten side effects that are listed with no indication at all of their probabilities. I view that as a huge deficiency.

Tomorrow -- I am not saying that I am right. Because one of the things that I have learned from Ellen and I have learned many things from Ellen, is a phrase that most certainly applies to me. I am not impeded by the curse of knowledge.

And so what I am saying comes from own impressions. And when I speak tomorrow, I will try and offer suggestions that I think could be done and are not being done. And it is to the deficiency of the efficacy of FDA's communications.

And since I seem to be the last person, one of the other lessons I have learned from the day is this. It is crucial

that someone in risk communication to first listen, then to learn, and then to communicate with those two experiences in mind. So I would like to finish up by apologizing to the audience for my front.

DR. SELIGMAN: Could I say just a quick comment, John? Actually in the last couple of years, there are a couple of things we have been doing by way of providing the actual numbers.

In the product that I describe that is called the healthcare professional information sheet, the last section of that is called a data summary. And it is the basis for why we are issuing the alert or the recommendation. Was it five cases? Was it 15 cases? Was it a meta-analysis? Was it an observational study or a series of clinical trials? What was it that was the basis for that recommendation?

And we have used actually all of those kinds of sources of information. And we

have also learned that when we portray the numbers, we describe them in a variety of ways. We will not only talk about the relative risk, we will also talk about he absolute risk. Because there are people who prefer the relative versus the absolute.

And the other thing that we are doing, another product that I mentioned, which is the drug safety news letter, again, it is really meant to provide the data that formed the post-marketing review that we covered. How many cases? What were the demographic characteristics of those cases? And then actually providing something which we find the medical literature just doesn't do as well anymore, we just give case studies. Because so many journals aren't just publishing those individual case studies that we find to be so illustrative of not only where we think a relationship can be demonstrated between a drug and an adverse event but also very illustrative, more often, of the complexity

that we face in trying to tease out complicated patients taking multiple drugs with multiple morbidities and trying to define an association between a drug and a side effect.

So, we are making some progress in that area, but I still second your point.

DR. PALING: I am very heartened by that. Thank you.

CHAIR FISCHHOFF: Let me thank everyone. First of all, let me thank our guests for having given the presentations this morning and having kept us going. I thank the panel for their presentations and contributions.

We will start again tomorrow at 8:00. We will be doing urgent crises communications. So come in and get ready to buckle your seatbelts.

(Whereupon, the meeting was adjourned to reconvene on Friday, August 15, 2008 at 8:00 a.m.)