

1 less resources and less manpower but as we
2 like to say internally, we are a small but
3 mighty center. We regulate, just like my
4 colleagues, a diverse and oftentimes
5 controversial range of products. Items such
6 as cloning, BSE, and genetically engineered
7 animals. And what we hear time and again from
8 both industry and the public is that they had
9 no idea we even existed.

10 Some examples of how CVM
11 communicates non-persuasive information are
12 through our website. We have pages on topics
13 such as cloning, pet food, NSAIDS for dogs,
14 which the acronym stands for non-steroidal
15 anti-inflammatory drugs for dogs and that
16 includes a downloadable brochure. It is a
17 public education campaign in place. We put
18 out a newsletter six times a year entitled The
19 FDA and the Veterinarian and we have over a
20 thousands subscribers to that. We put out an
21 annual report. Unlike some of the other
22 centers' annual reports, ours not only

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1 discusses our successes but also our failures
2 and puts things into context.

3 We issue CVM updates, which are
4 similar to press releases but are tailored
5 more towards our stakeholders. We also put
6 out consumer articles. We exhibit at over a
7 dozen conferences a year. And we hold public
8 meetings which not only keep our stakeholders
9 and the public informed but it provides a
10 forum for participation and comment.

11 Examples of persuasive
12 communication, what we consider persuasive
13 communication, where an action is required are
14 recall notices, warning letters and untitled
15 letters which are geared towards advertising
16 and promotion.

17 And some of the criteria that we
18 consider before issuing a persuasive
19 communication are surveillance. We monitor
20 approved drugs post-marketing. We look for
21 trends and patterns in the reports. How
22 confident are we in the information? And in

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1 the absence of confidence, how do we balance
2 the need to protect public health with the
3 need to provide accurate information? And as
4 my colleagues said previously, this is
5 something we struggle with all the time and it
6 is kind of a risk-benefit ratio we try to
7 apply. And typically these types of
8 communications are targeted towards industry.

9 So, how can we best serve our
10 stakeholders in providing timely and important
11 information? What vehicle provides the
12 optimum exposure? Again, these are questions
13 that we would like the committee to consider.

14 Does the target audience determine the type
15 of document we provide? And how can we
16 utilize outside groups to participate in
17 disseminating our message?

18 And finally questions that we
19 continuously ask ourselves and again that we
20 would like the committee to consider are how
21 do we balance the need to communicate early
22 while issues are still emerging, without

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1 causing undue alarm in the public or damage to
2 a business or industry? We have to consider
3 that as well.

4 And what are the best techniques
5 for conveying an emerging or uncertain issue?

6 In the case of melamine in pet food, we were
7 faced with no definitive cause for many weeks
8 of what was causing the illness in animals.
9 Yet, we had an audience that wanted and
10 demanded information on an almost daily basis.

11 We decided to hold press briefings, even when
12 we had no new information to report. And that
13 is kind of how we handled that issue until we
14 did find the definitive cause. We said as
15 much as we could at each press briefing.

16 And then finally, how do you
17 practice follow-up as the issue unfolds? And
18 how often do you communicate? And how do you
19 come to closure? How do you announce to the
20 public the investigation is over and, you
21 know, no more new information will be emerging
22 after this. And again, this echoes what my

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1 colleagues have said in their previous
2 presentations.

3 So, I thank you for the opportunity
4 to present today. Thanks.

5 CHAIR FISCHHOFF: Thank you. And
6 our next speaker will be Marjorie Davidson
7 from the Center for Food Safety and Applied
8 Nutrition.

9 DR. DAVIDSON: Good morning. I am
10 Marjorie Davidson from the Center for Food
11 Safety and Applied Nutrition and I didn't put
12 our acronym down here but we are called CFSAN,
13 just to keep a similar process as everyone
14 else.

15 I wanted to go over a little bit
16 about our different kinds of communication.
17 Some of the risk communication challenges that
18 we have. As well as I would like to highlight
19 just a little bit of the evaluations that we
20 have done in our various kinds of
21 communication. It is a quick and dirty
22 presentation, if you will but sometimes we are

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1 successful and sometimes we are not. And I
2 just wanted to give you a little sense of how
3 we are doing.

4 Examples of our non-persuasive
5 communication, our public meetings on
6 regulatory proposals, issuance of plans,
7 guidances. We have fact sheets on our
8 different products, web pages on a variety of
9 also issues and products concerning food,
10 constituent updates about CFSAN activities, a
11 toll free hotline, email inquires and EdNet
12 list serves.

13 Other non-persuasive communication
14 factors that we have at CFSAN are package
15 labeling, where we provide information on
16 regulated products such as weight statements
17 on food products, ingredients lists,
18 manufacturer contact information, nutrition
19 facts panels. We also have safe handling
20 labels on egg cartons, warning labels on
21 unpasteurized fruit juices.

22 Persuasive communication, an

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1 example of that are consumer education
2 campaigns. They are primarily used for
3 preventing illness from unsafe food handling
4 practices. Examples that I have presented
5 earlier to the committee are Be Food Safe or
6 Fight BAC! campaigns which focus on the four
7 safe food handling practices, behaviors that
8 scientists had determined were the most
9 effective in preventing illness, if followed.

10 Other examples are how to safely handle fish
11 and seafood, safe handling of fruits and
12 vegetables, just handling practices under many
13 products.

14 The risk communication challenges
15 that we have confronted in our consumer
16 education is how do you persuade consumers who
17 have life-long experiences with handling food
18 to change their unsafe food handling
19 behaviors. If there is a product that
20 everyone in this room is familiar with, it is
21 food because everyone has to deal with it.

22 To that end, we want to alarm

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1 consumers about the risks in foods
2 sufficiently to persuade them to change these
3 practices but, at the same time, not to cause
4 a lack of confidence in the safety of the food
5 supply. Some of the evaluation we have had on
6 that challenge is we have seen large
7 improvements in food safety practices, in safe
8 handling practices between 1993 and 1998 when
9 we first started evaluating these trends. In
10 our 2001 survey, the gains were maintained.

11 In our 2007 survey, we found that
12 the youngest age group showed better practices
13 than a similar age group did in 1993. So we
14 are showing generational improvement.

15 As far as keeping the confidence in
16 the safety of the food supply, this is the
17 Food Marketing Institute trends show that in
18 2006 there was 82 percent confidence in the
19 safety of the food supply. In 2007, it went
20 down to 66 percent. That was taken right
21 after spinach recall. Then in 2008, it came
22 back up to an 81 percent confidence rate.

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1 Persuasive communication. One of
2 the methods of our persuasive communication is
3 our consumer advisories where we advise
4 consumers about emerging food safety risks. A
5 couple of examples are about the risks from
6 listeriosis in certain refrigerated food
7 products. This was advice for pregnant women,
8 older Americans, young children, and people
9 with weakened immune systems. Other examples
10 are advice to pregnant women, mothers of young
11 children, nursing women, and women planning to
12 become pregnant about the risks of
13 methylmercury in fish to their young child's
14 developing nervous system.

15 We find these advisories
16 particularly challenging. For example, some
17 of the questions we ask ourselves is what do
18 you do in disparate scientific belief and
19 risks. One of the examples in methylmercury
20 risk. There is very sound and strong views on
21 both sides of the scientists, how significant
22 that risk is and how it contributes to

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1 confounding the message delivery when we get
2 our advisories out there.

3 Also, how do you mitigate the
4 impact of your message to one segment of the
5 population, such as many of our advisories are
6 to those at-risk categories, pregnant women,
7 older Americans, people with weakened immune
8 systems, how do you prevent the spillover to
9 the general population that doesn't need to be
10 worried about the issue?

11 And also how do you effectively
12 balance advice to avoid a food and eat the
13 same food for the health benefits at the same
14 time?

15 I just wanted to talk a little bit
16 about some of the evaluation that we had done,
17 for example, on the risk communication
18 advisory on fish, which shows how these
19 challenges show up in the evaluation as well.

20 Most U.S. adult consumers have eaten seafood
21 in the past year, which is good, and they are
22 aware of the health benefits and health

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1 concerns related to eating seafood. At the
2 same time, most consumers have heard of
3 methylmercury as a problem in some seafood but
4 few of them know the specific details. So
5 that is a continuing challenge we have in the
6 complexity of the message about methylmercury
7 in fish.

8 Nearly all pregnant women report
9 that they limit or do not eat the fish as
10 highest risk of methylmercury, which is what
11 our goal is. And at the same time, some
12 report limiting their eating of other fish as
13 well.

14 Another persuasive or explanatory
15 crisis communication is another type of
16 communication we have, which is warnings and
17 recalls. And these are issued for an
18 immediate threat to the public health. Recent
19 examples are spinach contaminated with E.
20 coli, melamine in pet food, botulism poisoning
21 in Castleberry brand can foods, and Salmonella
22 Saintpaul, which we are undergoing right now

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1 in tomatoes, jalapenos, and Serrano peppers.

2 Here again we have the challenges,
3 how do you characterize the risk in an
4 emergency, Others have talked about that one,
5 when there is so much uncertainty. Sometimes
6 we don't know what the product is. Sometimes
7 we don't know where the product is coming
8 from.

9 And then also how do you balance
10 the scientific desire, as mentioned earlier
11 today, to speak precisely about a risk with
12 the development of a comprehensible consumer
13 message? And then how do you manage rapidly
14 changing consumer advice during an outbreak to
15 effectively impact consumer behavior? As we
16 go through the process of an outbreak, we will
17 narrow to products, we will narrow it to
18 geographic locations and then also, how do you
19 effectively tell consumers when the emergency
20 event is over?

21 And also how do you reconcile the
22 characterization of a risk in a product such

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1 as raw spinach during an outbreak and the
2 continuing risk from the same product when it
3 is in an outbreak? There is continuing issues
4 with the safety of the food supply that are
5 inherent in eating food, in some instances,
6 and we need to concern ourselves with how we
7 balance those messages.

8 People have spoken to the
9 difficulty of getting research and evaluation
10 through OMB, processes we also use evaluations
11 as I have shown from other organizations.
12 Rutgers University, for example, had told us
13 after the spinach recall, these are just some
14 of the highlights of their research, that most
15 people, we were successful in most people had
16 heard about the outbreak. However, large
17 percentages of people thought the recall was
18 still in effect and thought it was still
19 ongoing or didn't know if it was still
20 ongoing.

21 And as the process of our risk
22 communication went on during the spinach

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1 recall, the news coverage was more about the
2 investigation and didn't re-emphasize the
3 consumer advice about what to do.

4 So, that is my quick overview of
5 CFSAN risk communication challenges. And I
6 appreciate your time and I truly welcome your
7 advice.

8 CHAIR FISCHHOFF: Thank you very
9 much. We have seven minutes. I am sure the
10 other panelists have been sitting on their
11 hands waiting to ask some questions. So,
12 let's ask questions until 10:15. And since we
13 are expecting Dr. Torti at 10:30, we will take
14 a break right then.

15 Okay, Mona.

16 DR. KHANNA: I have a question for
17 Lorrie McNeill. My question is about your
18 information that it took three weeks to get
19 the information out for one particular
20 example. What I would like to know from you
21 is why. And you could probably explain that
22 by telling us what the approval process is

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1 like to get information out from the FDA.

2 MS. MCNEILL: That is a really good
3 question. I think part of the issue here is I
4 don't believe it would have taken that long
5 had we just been dealing with one agency. We
6 have our own internal process where we work
7 with, my office works with the subject matter
8 experts, in this case two different offices,
9 the office of vaccines research and review
10 that know the product and the office of
11 biostatistics and epidemiology, which are the
12 folks who review the adverse experience
13 reports.

14 So, we work with those two offices
15 in developing the message and we clear it
16 within the Center and with our center
17 director's office. And then we have to, in
18 this case, is we decided that we would have a
19 more powerful message if it were a joint
20 message from both agencies, again, since we
21 both had a role in vaccine safety, we worked
22 with CDC. And within CDC, we were dealing

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1 with several institutes and I don't know all
2 of their acronyms very well but I believe the
3 National Institute for Childhood and
4 Respiratory Diseases, if I have got that one
5 correct, the Immunization Safety Office, the
6 STD people, and the cancer people. And so,
7 they are not all in one place. And so they
8 have their own process for getting something
9 cleared and there was a lot of back and forth
10 on how much we should include in the message,
11 how detailed we should be about some of the
12 information. We included an overview of the
13 serious events that we have seen to date. We
14 talked about Guillian-Barre Syndrome. We have
15 talked about fatalities that had been reported
16 and the fact that we had not been able to
17 associate any of those with the vaccine. But
18 there was much debate on how much detail
19 should we provide about those deaths. And so
20 it was a lot of back and forth and
21 negotiation. And honestly, I thought that
22 within a few days, we had a really good

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1 message within my center that we were ready to
2 go with. And so I think that was the added
3 challenge in this case. Normally, doing
4 something like this doesn't take that long.
5 So it was just a very unique situation.

6 MS. DESALVA: I first wanted to
7 thank the panel for all of your comments. And
8 it is very interesting to hear how you are
9 struggling with very similar issues across the
10 centers. So, I just have a couple of overall
11 comments in response to some of your
12 questions. And one common theme you had was
13 how do we deal with an emerging issue where
14 there is a lot of uncertainty or something
15 that is changing quickly? And this is a
16 simple response and an untested response but I
17 would suggest that maybe one way to deal with
18 this is not to run from uncertainty and to
19 embrace it because one of the foundations of
20 risk communication is transparency.

21 So, if you were to say something
22 like, I'm just thinking of a quick template

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1 here, what do we know, and equally, what don't
2 we know? What should you do right now? And
3 the answer may be nothing. And what are doing
4 to find out more? How can you get updated?
5 So much like you commented about the daily
6 press releases when the information on the
7 food contamination was unknown, that is a
8 great approach, saying we are here, we are
9 telling you what we know, what we don't know,
10 what you should do right now, and we will be
11 back to tell you more.

12 So, I think this will go along way
13 to establishing trust about issues that are
14 uncertain and very frightening to people. The
15 caveat would be I am just doing this off the
16 top of my head as a template but all of this
17 would have to be tested with the kinds of
18 audiences that you might want to impact.

19 Another general comment was that I
20 had some questions about how do we get the
21 information out through various channels. And
22 one channel that I think is quite underused

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1 are the public information officers that are
2 at every state and in many localities. And I
3 know some of your centers are working on pilot
4 projects with what we call PIOs. So these
5 folks' job is to get out information to the
6 public about health risks, benefits, and so
7 on. And if you could somehow work with them
8 through their national organization to have a
9 formalized relationship, I think it will go a
10 long way to helping with what you would like
11 to do.

12 We have, in past meetings, brought
13 up the issue of having an identifiable
14 humanized spokesperson for FDA, it could be
15 the Commissioner or someone else, who would
16 become a household name. And that could go a
17 long way, too, to being someone who could
18 appear on television and say here is where we
19 are with various issues. And that would,
20 again, respond to one of the other basic
21 foundations of risk communication, which is to
22 acknowledge emotional and human connection

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1 that is needed for trust.

2 CHAIR FISCHHOFF: Thank you. We
3 are going to take a break in one second. I
4 have on my EPA's Homeland Security Advisory
5 Committee, one of the members is a wonderful
6 guy named L. D. McMullen, who is head of the
7 Des Moines, Iowa Water Works. And I think he
8 validates your theory that prior, I guess it
9 was in '93 they had the largest loss of water
10 in sort of modern American history, pre-
11 Katrina, in those previous big floods on the
12 Mississippi, Missouri system. And he followed
13 your strategy. Every 12 hours he had a press
14 conference, whether he had news or not. He
15 said this is what we promised to do. This is
16 what we have done. By the time it was done,
17 people had, you know, like a mental model of
18 how Water Works worked. He became a local
19 hero and he even has a country and western
20 song dedicated to him. So, perhaps that is
21 our aspiration and evaluation.

22 So, let's break now and we will

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1 meet again at 10:30.

2 (Whereupon, the meeting went off the record at
3 10:16 a.m. and resumed at 10:32
4 a.m.)

5 CHAIR FISCHHOFF: Let me welcome
6 you all back. And we are very fortunate and
7 honored to have a visit from FDA's new and I
8 think first Chief Scientist, Dr. Frank Torti.
9 And Dr. Torti will come and give us some
10 introductory remarks, entertain a few
11 questions, and then we will move on to some
12 presentations and then he will get to ask the
13 questions. Please. Thank you for coming.

14 DR. TORTI: I need all the
15 communications help I can get. So, I am
16 really glad to be here. You know, Nancy came
17 and oriented me a little bit toward the risk
18 communications efforts at the FDA and told me
19 a little bit about this meeting. And I said,
20 gee, I would just like a chance to sort of
21 dialogue a little bit because this is actually
22 very important to me and I would like to sort

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1 of be here just first to say that, and to
2 understand the dialogue that is ongoing, and
3 to help in any way that I can to facilitate
4 and implement the recommendations made from
5 this committee and from the FDA leadership in
6 risk communications.

7 And even in the few minutes that I
8 have been here, I have learned some things
9 that are important. You know, I have been
10 here now almost three months and have already
11 been thrust into an area of science that is
12 relatively new for me but in some ways,
13 therefore, really exciting for me, and that is
14 the issues of scientific risk assessment, risk
15 management, and, as part of that, risk
16 communications.

17 And I have already learned from Dr.
18 Fischhoff that risk communications comes at
19 the beginning as well as the end of that
20 adventure. And I respect that and understand
21 that and want to work with you to being sure
22 that we are able to provide that communication

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1 at the beginning as well as at the end of
2 these issues because they come before us in
3 an interesting way, from my perception. And
4 what I will do is give you just sort of one
5 example of that and one issue that the FDA is
6 wrestling with now. And then from there, sort
7 of step back and give you a little bit broader
8 sense of where I think the science and the FDA
9 is going, needs to go, and to engage all of
10 you to help me with that.

11 But you know, I came here really to
12 confront a number but I will just choose one
13 issue in risk assessment and that is with the
14 issue of BPA and its presence in infant
15 formula and the relationships there to
16 potential toxicities that had to be sort of
17 examined, and explored, and studied, and
18 analyzed. And an enormous team of FDA
19 scientists are in the process and will, very
20 soon in the next days, be issuing a report to
21 try and clarify if and what toxicities might
22 be expected from such a product that is in

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1 many of the devices and foods that we are
2 exposed to.

3 Well, you know, without going in to
4 the details, and I am certainly not an expert
5 in any of the details, it struck me that in a
6 broad sense, this was a dialogue that was
7 incredibly complex scientifically. Very hard
8 to wrap around even for a scientist who is not
9 in that field, let alone for a lay person, let
10 alone for a nursing mother who is confronted
11 with the issue of potential product in
12 formula.

13 So, how do we approach this? Well
14 of course, we approach this scientifically in
15 trying to as clearly as possible understand
16 what that risk actually is. We must
17 understand it scientifically. But then the
18 next steps are how to communicate this risk.
19 To everything there is probably some risk, at
20 some dose, at some level. And you all as
21 scientists yourselves understand that but the
22 question is at exposures that happen in the

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1 human environment, what kind of risk is there
2 and defining that and exploring that.

3 So, we will be challenged with BPA
4 and with many other issues about how to
5 communicate our decisions, our findings, our
6 collaborative findings with sciences outside
7 of the Agency to the broader community how to
8 take an incredibly complex scientific issue
9 and bring it, and distill it to a way that
10 people can understand and be advised
11 appropriately.

12 So, we need you help. We truly do
13 in such kinds of issues. And I am really
14 looking to this group to help advise us and
15 guide us as to what kinds of approaches and
16 how in the future we can build our efforts in
17 this area to even more deeply and completely
18 communicate with the American public.

19 Let's start back from the issues of
20 risk communication to the broader issues of
21 FDA science and I think you will see why I
22 started with the specifics and wanted to then

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1 go to the general because it is really the
2 specifics that define, sort of the general
3 issues that we face at the FDA. There is an
4 extraordinary amount of absolutely superb
5 cutting edge science at the FDA. I think very
6 little of it is recognized by the public and
7 we are doing some things to change that. But
8 we are also very cognizant of you know, other
9 advisory groups, such as the Science Board who
10 have advised on the science of the FDA and in
11 some of the areas where we need to grow and we
12 need to modernize and we need to improve. And
13 part of what I have tried to do is work with
14 the center directors at the FDA and others to
15 begin to build a program to address the
16 modernization of the science of the FDA in
17 ways that will directly impact on the quality
18 of the regulatory decisions that are being
19 made by the Agency.

20 Well how do we do that? What
21 principals guide the implementation of that
22 strategy? The first is that the FDA cannot do

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1 it alone, that the FDA needs to seek advice
2 broadly from all its constituencies and do
3 that even in a more, and we do that now, you
4 are testament to that being here but we even
5 need to do that in a broader and more complete
6 way than we have done in the past. And I
7 particularly want to be sure that we engage
8 the academic community in thinking about some
9 of the major problems that we face and looking
10 to solutions. But I wouldn't limit it there,
11 I think, even the industries that we regulate
12 have things that they can teach us at a basic
13 level and we need to listen very carefully to
14 their thoughts, their stakeholders in this
15 process as well. And we need to engage them
16 on FDA-related issues where appropriate at the
17 FDA.

18 The second thing we need to do, and
19 again it relates, I think, directly to this
20 committee, is for those things that we need to
21 do in-house ourselves, because we are a
22 regulatory agency and we can't contract out

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1 our mission. We need to build and grow in
2 those areas that are most critical to the
3 Agency. And the Science Board defined many of
4 those but the area of risk assessment, risk
5 management, risk communication is one that I
6 feel very strongly about and that we need to
7 see growth in those areas building on the
8 expertise. So, we are looking to your advice
9 to help us think through what the right
10 approaches are to do that.

11 Finally, I think it is a challenge
12 for a regulatory Agency to be pre-emptive
13 scientifically but I think that is where we
14 need to be. We need to be out there and
15 looking at where the risks are and placing our
16 resources in areas of greatest risk. And that
17 is what I mean by preemption, preemptive
18 strategy for the FDA. So, in all three of
19 those general principals, the FDA needs to
20 move forward in the scientific arena and I
21 think we are making great strides to do so.

22 So, that just gives you a little

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1 flavor of where we are going, how we are
2 thinking about things, how we are putting
3 things together in a broad sense and some of
4 the specific challenges that I think we face.

5 But I would be glad to answer any questions
6 that you have and also to sit back and learn a
7 little bit about what you have to teach us.
8 So, thanks for your attention.

9 CHAIR FISCHHOFF: Thank you. Mona?

10 DR. KHANNA: Thank you very much,
11 Dr. Torti. Did I pronounce your name
12 correctly?

13 DR. TORTI: Yes, you did.

14 DR. KHANNA: Okay. I am intrigued
15 by when you said there is some extraordinary
16 cutting edge medicine and science going on at
17 the FDA. I would like to know why is it
18 unrecognized? I would think it would be a
19 tremendous strategy to build a credibility and
20 expertise of the FDA in times of non-emergent
21 conditions by raising the profile of some of
22 that cutting edge science and I would like to

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1 know what efforts have been made to bring
2 these accomplishments into the spotlight
3 publicly.

4 DR. TORTI: Well, that is a
5 wonderful comment, so we agree entirely on
6 that strategy. So, I will just give you one
7 example of our strategy in this regard. We
8 are reaching out to science writers to
9 actually engage them in some of this cutting
10 edge science that occurs at the FDA. And it
11 is extraordinary and it is different than the
12 other science that they will find because it
13 is regulatory science but it is no less
14 intriguing. So that in November of this year,
15 we will hold the first ever symposia just for
16 science writers, where they will have an
17 opportunity for a full day to hear maybe six
18 to ten of the most cutting edge and novel
19 approaches that the FDA has taken in the
20 scientific arena.

21 But I don't mean scientific only in
22 the sense of laboratory. So I think you know,

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1 science in the sense of epidemiology. Science
2 in the sense of the anatomy of an epidemic.
3 Science in the sense of some of the
4 nanotechnology kinds of things which we do, in
5 terms of biomedical engineering, as well as
6 the biological and clinical sciences.

7 So, you know, we could fill many
8 days with these kinds of stories. But I think
9 we just want to whet their appetite to some of
10 these issues and hopefully they will be
11 engaged and come back and learn more about
12 some of these issues. But it is something
13 that has been done in the past but never in
14 such a formal way. So, my intent is to do it
15 formally and consistently. That meeting in
16 November will not be the end of our efforts.
17 They will be the beginning of those efforts.

18 DR. SMITH: Just a little more
19 clarification on your comment. Do you see
20 this sort of committee as a prototype for more
21 of an outreach approach by FDA and a little
22 less isolationism and reaching out to consumer

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1 groups, and reaching out to industry, and sort
2 of engaging in a high level discussion, as
3 opposed to just dictating?

4 DR. TORTI: Well, I think these are
5 the kind of committees that give us an
6 opportunity to do that. I don't think, you
7 know, I don't think the FDA has been
8 isolationist. I think it has been difficult
9 for the FDA sometimes to communicate its
10 messages and we need partners in that
11 communication. And groups like this would be
12 very effective partners in advising us on how
13 to communicate.

14 But it is constituencies that you
15 can engage and raise to help us that will
16 really make this committee, to my mind, go
17 beyond, take the next step. So yes, I think
18 is the answer.

19 DR. SMITH: Okay, Thank you.

20 DR. TORTI: Okay. Thank you.

21 CHAIR FISCHHOFF: Thank you very
22 much.

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1 So the program here is, I guess all
2 you have, is we are going to now have four and
3 perhaps five talks distributed between this
4 morning and this afternoon, the fifth is
5 dependent on how well David Moxley feels,
6 trying to show you some of the science that
7 might be applied or, to some extent, has been
8 applied to answering the kind of challenges
9 that we heard from Dr. Torti and from FDA this
10 morning.

11 So, we are going to hear, first
12 about two talks on non-persuasive
13 communication from myself and Ellen Peters.
14 Ellen and I have divided this up. I will be
15 talking more about the interface between the
16 communication and the risk analysis, risk
17 management, trying to figure out what it is
18 that you want to say. And then Ellen will be
19 talking more about some of the basic science
20 on how you say it.

21 But I thought the best way to
22 organize my own was, rather than to give a

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1 discourse on general methods, was to take four
2 case studies of projects out of our research
3 group, but you can certainly find other ones,
4 and I think they are very much in the spirit
5 of what a couple of, several of the speakers
6 said this morning. There are lots and lots of
7 different problems out there. There is one
8 size doesn't fit all. And so we will give
9 some examples of what the tailoring process
10 would be that would take advantage of general
11 capabilities that we have in risk analysis and
12 in risk communication.

13 So, again, non-persuasive
14 communication is addressing people's decision-
15 making needs with in situations where you say
16 it is, well I don't know if it is none of our
17 business -- well, perhaps it is none of our
18 business to tell you what to do. It is our
19 business to put you in a position where you
20 can make the best informed decision, given the
21 limitations on the data that we have now.

22 One can think of this process of

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1 non-persuasive communications having three
2 elements. One is analysis. That is,
3 determining what people need to know in order
4 to make sound choices. In many of these
5 situations, we could easily give them the fire
6 hose treatment of all of the data that we have
7 got but there is a limited window of
8 opportunity.

9 Second, how do we design
10 communications to effectively bridge critical
11 gaps? And there we take advantage both of
12 descriptive research, finding out where people
13 are on a particular issue and the basic
14 research saying well how do you get across
15 issues of uncertainty or of conflicting
16 opinions?

17 And then finally, how do you
18 evaluate how well we have done? And as we
19 heard this morning, the evaluation has rather
20 different faces in different tasks.

21 So, I will talk about four
22 examples, examples from these four domains.

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1 If I could presage one of my last slides, this
2 is going to look complicated and expensive.
3 And you all are clearly overworked and I'm
4 pretty sure under- budgeted. But I think most
5 of this is actually, once somebody has done
6 the basic science to adapt it to new
7 situations or to do a fundamental work in an
8 area and then to adapt it to specific
9 settings, it is much more attractive than it
10 may look. Most of these problems were
11 dissertations but usually with a new problem,
12 it takes a dissertation then somebody can
13 confirm it with a masters thesis. Then you
14 have a couple of undergraduate honors thesis
15 and then anybody could do it.

16 And first a case in medical
17 informed consent. This particular example,
18 this is an older paper. This is John Merz's
19 dissertation, along with Dennis Mazur at the
20 University of Oregon Health Center. And Paul
21 Fischbeck was a risk analyst in our group.
22 And so John was, John is a lawyer and a risk

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1 analyst. He actually worked in nuclear power.

2 And he was interested in how is it that you -
3 - basically, he was interested in how
4 physicians can protect themselves against
5 malpractice by showing that they have given
6 patients the appropriate information.

7 For his masters, he reviewed the
8 case record and found it really doesn't tell
9 you what to do. Just hope nothing big goes
10 wrong. So he said, well maybe as an
11 analytical question, we can figure out what
12 are the most important things to do. He
13 picked carotid endarterectomy, which is a very
14 well understood surgery. A very well
15 understood surgery for which there was a lot
16 of information about the risks. That is the
17 surgery that probably half the audience knows
18 more about this than I do. But this is the
19 carotid artery and if it is hardening of the
20 arteries, you scrape it out. It can extend
21 your life. But they have got something sharp
22 in your neck and lots of things can go wrong.

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1 The analytical approach that we
2 took was to say, well, imagine you have
3 patients who are candidates for this surgery
4 and you told them about the different things
5 that could go wrong. Which things were
6 important enough, in the sense of severe
7 enough and frequent enough, that their
8 decision would flip? We did this with
9 hypothetical patients. This was more of an
10 analytical than a behavioral exercise.

11 So, here are some of the possible
12 side effects. And if you believe our
13 methodology, what we did is we said, you took
14 a population of hypothetical patients and said
15 imagine you said them what the probability of
16 death was. In this population, again a
17 hypothetical population, 15 percent of them,
18 the benefit of doing the surgery now would be
19 sufficiently low and hearing the risk of death
20 would be enough for them to say that is not
21 for me right now. The possibility of stroke
22 would affect another five percent and then

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1 facial paralysis. Well you could tell
2 everything. You wouldn't want to hide any of
3 these things, but there clearly were three
4 things that were at the top. This is in the
5 common term, the supply curve.

6 If you wanted to design a
7 communication, then we would say, well,
8 shouldn't we just assume that people have no
9 valid prior knowledge? There is no reason for
10 anybody -- they may have beliefs but there is
11 no reason to trust. So you need to assume
12 that they need to be told everything.

13 Second, you would want to focus
14 your communications on the few most critical
15 facts. And you could think of these risks,
16 each risk has a probability and an event
17 associated -- has an event and a probability
18 associated with it. You have to tell people
19 the probabilities of death, stroke, and facial
20 paralysis. People probably know what -- well,
21 they know what death is as well as you are
22 going to tell them. Stroke many people in

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1 this population would know because it has been
2 on their mind. And maybe you would want to
3 tell them about the facial paralysis. There
4 would be four facts that you might want to get
5 across.

6 And then critically, it turns out,
7 in this situation, as in many, people keep
8 going after the facts but the real
9 uncertainties are in themselves what kind of
10 decisions they want to make. And you would
11 want to legitimate that kind of value
12 uncertainty and help people to think that
13 through. And we didn't do any evaluation at
14 all.

15 So, we think we would know how to
16 do it. We think this is practical but John
17 was a risk analyst an a lawyer and didn't want
18 to do the work. But that would be the
19 process. You could imagine how you might
20 empirically evaluate it but you want be very
21 careful in dealing. You would probably do it
22 with a non-clinical population than an actual

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1 population.

2 Second kind of task. There are
3 also some parallels that, well, actually this
4 was something that was brought to our
5 attention by somebody at FDA, although the
6 work is neither endorsed nor sponsored by FDA.

7 So, as many of you, I think at least some of
8 you probably have suffered through or dealt
9 with is a court-mandated warning label a
10 court-mandated disclaimer for dietary
11 supplements.

12 And one of the interesting cases
13 that we looked at, this was Sarah Eggers'
14 master thesis was looking at saw palmetto.
15 So, the top shows a kind of claim that might
16 be made, might be legal under the law for saw
17 palmetto for a dietary supplement. This is
18 where you are allowed to make structure and
19 function claims. And the bottom is the court-
20 mandated disclaimer. So, the question is, is
21 this good enough. Does this make it possible
22 to sell this, to make this dietary supplement

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1 available?

2 So, our form of analysis here was
3 we decided to determine how sensitive
4 consumers decisions are to the kind of
5 information that would be provided with or
6 without this disclaimer with other kinds of
7 information. What we did is, we drew a
8 decision tree, which is the point of departure
9 for many of these studies. And if you have
10 ever seen a decision tree, this is just a
11 decision tree. If you have never seen a
12 decision tree, it is just on the left are the
13 different things you could do.

14 So, if you were a male concerned
15 with benign prostatic hyperplasia, you might
16 take saw palmetto, you might seek your
17 doctor's advice, or you might do nothing.
18 This is one of the dietary supplements where
19 the evidence is relatively good. And if you
20 believe our analysis, the critical question is
21 whether people self-medicate, rather than
22 going to a physician for a condition that

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1 should be treated. So the real risks here are
2 the opportunity costs of self-treating, rather
3 than not being treated.

4 Here we did collect, we thought
5 about how to collect some evidence. So we
6 took a typical label, we took the disclaimer,
7 and then we designed what we thought might be
8 an ideal label. We think that an ideal label
9 for somebody for facing this class of
10 decision, in fact many classes of decision,
11 would be you want to give them both the risk
12 and the benefit information. You want to
13 provide the information in quantitative terms.

14 There is very large literature, which some of
15 you may have seen, showing that people vary
16 all over the place in how they interpret
17 verbal quantifiers like common side effect,
18 rarely causes a problem.

19 We want to give some indication of
20 the data quality so people know how much you
21 know what you are talking about. And you want
22 to present the alternative options so people

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1 know, well that is the trade-offs here, but I
2 would like to know the trade-offs with other
3 things that I could do.

4 Our vehicle for doing this was the
5 kind of drug box that Gil Welch, Lisa
6 Schwartz, and Steve Woloshin, some of you may
7 be familiar with, they gave us some help in
8 designing that.

9 So, our evaluation process was
10 pretty straight forward. We just asked
11 potential users. Actually, for those who know
12 Pittsburgh, Sarah interviewed men at Ritter's,
13 which is the classic Pittsburgh diner. And
14 went through human subjects. It was okay.
15 But she showed them the different labels and
16 asked them what they would do with it and gave
17 them as much coffee as they wanted, which was
18 perhaps the stimulant of choice for this
19 particular product. And then, based on what
20 they told her, try to predict whether they
21 would make the decisions that seemed to be
22 appropriate for them.

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1 So, the nature of the data are, you
2 can imagine, you know, you could imagine there
3 are some people for whom saw palmetto is right
4 and some people for whom it is wrong. I
5 imagine you could do this discretely, it is a
6 little murkier than that. Some people who
7 should consume it, some people who shouldn't
8 consume it. You could ask whether they would
9 consume it or whether they wouldn't consume
10 it, based on different kinds of information.
11 And then you can get a pattern like that and
12 then that creates a regulatory decision or you
13 are saying, well, how much do I value having
14 people in each of these different cells? It
15 could be false negatives and false positives
16 might be weighted differently in different
17 situations. Getting a few true positives
18 might be worth a bunch of -- it depends on the
19 decision. That is a regulator's decision not
20 ours. We can just characterize it
21 scientifically.

22 But, trying to guess what the

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1 regulatory decision might be in this
2 situation, we concluded that this was a
3 terrible warning label, that people understood
4 less with the disclaimer than without it.
5 Some people read the disclaimer and said oh,
6 they wouldn't put a disclaimer if this stuff
7 didn't really work. So they exaggerated the
8 benefits. Some of them said, oh, of course,
9 FDA doesn't believe in alternative medicine,
10 so the warning means nothing. They are just
11 trying to divert us into traditional. But
12 they also told us that they didn't really
13 believe in dietary supplements enough that
14 they would take it for very long.

15 So, it doesn't have much risk. It
16 hardly costs anything and they wouldn't have
17 the opportunity cost of self-medicating. So,
18 in this situation, lousy label probably good
19 enough.

20 Third example. Emergency alert. I
21 think the example is outside of your domain,
22 but we have several examples here, if you are

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1 trying to get after people with information.
2 We were asked a few years ago by the, actually
3 about ten years ago by the American Water
4 Works Research Foundation, when there was
5 press, remember, to produce consumer
6 confidence reports, if you pay your own water
7 bill, you get them annually, talking about
8 contaminants in your water, and they wanted to
9 design the perfect boil water notice. How do
10 you tell people if they have got a crypto
11 intrusion that they should be worrying about
12 it.

13 We did some formative interviews
14 and we found that people actually wanted to
15 know why this was their problem. They wanted
16 to know more than just how to boil water but
17 whether they should take this seriously,
18 because there is lots of people trying to
19 cover themselves by presenting information.

20 So, what we did is we created, Liz
21 Casman is a microbiologist in our group,
22 created a computational model to determine the

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1 sensitivity of choices about whether or not to
2 boil water as a function of how soon they got
3 them and how comprehensible they were.

4 Her model looks a little better on
5 a Mac than on a PC but it is in risk analysis,
6 if you are interested. Try to take into
7 consideration the whole public health system.

8 So, the uncertainties that come from is it
9 detected. Does the message get through? Is
10 it interpreted appropriately? We made a
11 distinction between people who are on public
12 water and are not. Somebody said in the last
13 session, you could have spillover from people.

14 It could be the municipal water supply and
15 people who are on wells or think that it has
16 to do with them.

17 And this is a complicated model but
18 the stakes were high enough so we thought it
19 was worthwhile running the numbers. This is
20 MM -- it turns out some of these, people if
21 you want to do the modeling, the risk
22 modeling, sometimes you have got hard data.

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1 So there had been an MMWR report on people's
2 response to notices. Other places, all you
3 have is expert judgment we know a trick or
4 two, in the literature found a trick or two
5 about how to elicit expert judgment for
6 modeling purposes.

7 We thought that the conclusion that
8 we came from doing interviews with people
9 about this situation was that it was important
10 to establish communicator's credibility as
11 part of any communication so people know why
12 they were being asked to do this and whether
13 this was just somebody in covering themselves.

14 And in order to have credibility, people
15 wanted to know where this problem came from,
16 as best you understood. With crypto, it turns
17 out a set of suspects in a local water supply
18 is relatively small. It is perhaps feedlots
19 or perhaps a breakdown in an aging system,
20 like our area.

21 Second, they needed to know that
22 they couldn't test by themselves because this

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1 is a very hard test to do but you can probably
2 buy test kits. You could think that you are
3 testing. You could be testing for something
4 else. So we needed to see that they couldn't
5 really protect themselves and then they needed
6 to know how they could decontaminate their
7 water.

8 And what we found and we
9 interviewed deliberately in Pittsburgh area
10 communities that had had crypto intrusions and
11 found no local memory at all that this had
12 happened. But we also interviewed people who
13 were recruited to the Pittsburgh AIDS task
14 force and found that people who were
15 immunocompromised were generally quite
16 knowledgeable about this. So generally
17 speaking, nothing that they could do about
18 this but they were generally quite
19 knowledgeable.

20 Independently, we found that people
21 were immunocompromised for other reasons are
22 often like people on chemotherapy and so on,

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1 are not routinely told about water borne
2 contaminants but that was coincidental to this
3 project.

4 So the evaluation that we did, we
5 felt that we had good, based on the interviews
6 and other work that had done, a lot of people
7 in food safety and elsewhere, we had a pretty
8 good estimate of how many people would boil
9 their water in a way that made themselves safe
10 if they got a message. And you could think of
11 how well if you got the message to everybody
12 and everybody boiled their water right, what
13 difference would it make. And when we ran the
14 numbers, to our surprise, it made no
15 difference whatsoever.

16 That is, the best available
17 information has no practical value, however
18 clearly it is presented because of the system
19 properties with cryptosporidium, which take a
20 week to culture. And the test is quite
21 specific but not that sensitive. And by that
22 time, it is only really useful for forensic

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1 purposes. You want to know why. If you
2 haven't otherwise why people have gotten sick
3 or perhaps have died, then the test.

4 So, we had a communication system
5 that was set up that could not work. This was
6 a problem in risk management, not a problem in
7 risk communication. But thinking
8 systematically about the communication
9 provided leverage into figuring out what kind
10 of information the system was producing.

11 So, if they wanted, an example for
12 making the case, if you had to start with the
13 communication needs as a matter of strategy.
14 It could be that for E. coli, you can test it
15 quickly, get the message out, you might be
16 able to save people by testing. And
17 particularly for the people who cannot protect
18 themselves, like the people who are
19 immunocompromised, if you have got a
20 vulnerable water system, it suggests you need
21 an engineering solution rather than a
22 communication one. And this is some of our

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1 modeling.

2 And the final example would be one
3 of health communication. Once again, we have
4 heard that is part of what you all do to put
5 people in a position that they can take care
6 of themselves, perhaps not need some of your
7 regulated products, or to understand why those
8 products might be necessary.

9 So, the example I have here is a
10 project that we had done with sponsorship from
11 the National Institutes of Allergies and
12 Infectious Disease trying to improve young
13 women's behavior in STI prevention and
14 treatment. We ended up we had the resources
15 to do a randomized controlled trial with a
16 group of high-risk adolescents. I think 17
17 percent of them had Chlamydia on our initial
18 testing. So those that work in this area, you
19 can characterize the population by that.

20 And again, the process was to
21 analyze. The analysis that we did here was to
22 try to figure out what young women's intuitive

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1 framing was of the decisions that could
2 conceivably expose them to sexually
3 transmitted infection. So we particularly
4 looked at what are the options that they see
5 available to them and what are the options
6 that they care about? And so clearly, they
7 care about not getting STIs but they also care
8 about having relationships, having fun,
9 maintaining trust with young men in their
10 lives, and so on. And then using that to
11 identify the critical facts. And it turned
12 out that some of the critical facts were -- oh
13 I meant, it should be missing options. I will
14 cover that in just a second.

15 So we had, here is, we made a
16 couple of different models. I will just, here
17 is a decision tree relative to choice of
18 contraceptive methods. And you could think
19 about how those decisions affected them. And
20 then we sort of do what we typically, what
21 many people typically do, is to have
22 interviews with people asking them about this

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1 decision and gradually getting more and more
2 explicit.

3 So from this we had the resources
4 to make and test an intervention. So, first
5 thing we realized is you needed to reduce the
6 complexity of the topic. Young people in
7 Southwestern Pennsylvania, but I think this is
8 generally true, they actually know a lot about
9 HIV/AIDS and they know almost nothing about
10 any of the other STIs. And then it is just a
11 blur of different diseases. If you think of
12 the matrix of diseases with treatment,
13 prevention, detection, it is more than -- so,
14 how do you make this comprehensible to them?

15 Secondly, we found that a recurrent
16 theme in many of these interviews, the kind of
17 information that was missing was that they,
18 young women, naturally, wanted to preserve,
19 believed that they could trust young men.
20 Young men would often assert to them that they
21 were clean. And conceivably, both the young
22 man, that the young man exaggerates his

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1 ability to tell whether he is disease free or
2 not, even though there are some things where
3 men are legitimately asymptomatic when they
4 are carriers, and other places where they are
5 symptomatic but it takes a physician, a
6 healthcare professional to tell it. So we
7 actually, this is an X-rated DVD because we
8 thought we couldn't get this across any other
9 way other than showing diseased genitalia, to
10 show that you couldn't really -- only a couple
11 of pictures but enough to make it X-rated.

12 The third thing, we thought that,
13 we did this with the head of Adolescent
14 Medicine at Children's Hospital of Pittsburgh,
15 Pam Murray, that one critical issue was that
16 it is just difficult to talk about many of
17 these issues for many people, both for
18 healthcare providers and the other side. So,
19 we ended up with a DVD that simulated
20 conversations.

21 And then finally and maybe most
22 importantly of all of these things from the

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1 perspective of making decisions, it doesn't
2 matter if you don't feel like you have got
3 decisions to make. And as people found, as we
4 found and as people have found in other
5 places, an awful lot of sex at this age in
6 particular is coerced in one way or another.
7 So, helping young women to see and create
8 choice options was part of our intervention.

9 So, oh, no. But let me tell you
10 what you are missing. I guess this worked
11 better on the PC. I have three screen shots
12 here, I thought. One shows how we tried to
13 organize the world of STIs into basically
14 viruses, bacteria, and parasites, for which
15 most people have some kind of a mental model
16 and if you are interested in Chlamydia or
17 whatever, you could use that as basic. And we
18 sort of broke it down into detection --
19 prevention, detection, and treatment. So, if
20 there was something on your mind, you could
21 quickly find it. It is on a -- I would be
22 happy to send it if anybody is interested. It

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1 is on a DVD.

2 Second, we had a dramatized pelvic
3 exam to show how both for physicians and for
4 kids, to sort of, to show how to talk about
5 these sensitive issues. And the third, about
6 half of it was choose your own adventure. You
7 could pick a young woman that you wanted to
8 follow and you could, there was a young man,
9 either a steady or a pickup who was trying to
10 get her to go as far as possible and you could
11 stop it and say, like, "Mark would like you to
12 go upstairs." Imagine you didn't want to go
13 upstairs, what could you do? And this
14 cognitive rehearsal. It is not from our
15 literature but it is a field term, technique
16 that is know what to do. And then had an
17 actress demonstrating different ways of
18 stopping it.

19 So, our evaluation here sort of
20 compared to a print version of these materials
21 and commercially available leaflets matched
22 for topics, this DVD but the greater reported

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1 condom use, less reported condom failure, less
2 Chlamydia we did the test for, and less
3 reported sex. This may actually be the only
4 program that has reduced. You know, despite
5 being sometimes very accepting, we think that
6 it reduced the coerced sex. So you know, not
7 everybody would want this, but in some sense
8 the tone was, you know, this will help you to
9 get the sex that you want. If you don't want
10 any, then this will help you to reduce the
11 pressure, and if you want, only under certain
12 conditions. Okay, not everybody would want
13 this but this was what the science was here.

14 So finally, so these are bigger
15 projects, the last one was a really big
16 project, the others were, you know, basically
17 done by underpaid graduate students or people
18 that -- anyways, underpaid graduate students.

19 But it is not that hard or expensive to do.
20 So first of all, there are many examples in
21 the literature you could say, yes, mine, yes,
22 the crypto one, that is kind of like mine.

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1 Here is a set of things that we have done.
2 Most of these have published papers, if you
3 are interested in one of these topics or
4 something that you think has the same
5 properties, you know, I could be happy to talk
6 to you. I think actually the analytical part
7 tends to be the hardest and then once you see
8 the analysis it is kind of straight forward.

9 Second, that the basic kind of
10 analysis, even if nobody has done something
11 like this, is not particularly -- anybody can
12 draw a decision tree. Anybody can sketch out
13 an influence diagram like we had in the model
14 and the cryptosporidium, the discipline, it is
15 mostly discipline common sense. Running
16 numbers, doing computations, that takes
17 special training. But actually sketching
18 somebody's decision tree, having them check
19 your work, not particularly hard.

20 Third, many of the design
21 principals, in order to make this work, can be
22 found in the basic research in the next talk,

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1 Ellen Peters' talk, which will be next, will
2 give you a bunch a those. And then finally,
3 the FDA has individuals with a requisite
4 expertise in order to do these things. And I
5 think, you know, I think it makes an enormous
6 difference in terms of institutional change
7 having even a few people on staff who have
8 this kind of expertise because you say, gee, I
9 need behavioral sciences. You really don't
10 know what you look for. You put out the word
11 on the street that you are looking for
12 behavioral sciences and lots of people will
13 hang out a shingle asking whether it is
14 spelled with or without a U or will claim to
15 do the work. But having people internally and
16 fortunately we do have some excellent
17 behavioral scientists and so on, you know,
18 enables you to build up a program, gives you
19 what the economists call absorptive capacity
20 to build up a program. And I think that FDA
21 is really poised to do some really important
22 work here. Thank you.

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1 And maybe we should have the two
2 talks and then we can sort of like have
3 questions, rather than structure -- let's do
4 that. Okay? We are making our audience sit a
5 lot. Well, I guess this part of the audience
6 mostly has to sit but this part of the
7 audience. Let me just say I believe that that
8 part of the audience can asked to be
9 recognized. Right?

10 DR. ZWANZIGER: Normally we don't
11 do a lot of that.

12 CHAIR FISCHHOFF: In the open
13 public hearing.

14 DR. ZWANZIGER: Yes. Maybe you
15 could say if people want to speak at the open
16 public hearing.

17 CHAIR FISCHHOFF: Okay. So, if you
18 would like to speak in the open public
19 hearing, please come to Lee. And then please
20 come and talk to us on the break so maybe we
21 can just work your topics into our questions.

22 DR. PETERS: Good morning. Is this

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1 close enough so everybody can hear me?
2 Better? Okay, good. Thank you.

3 So my name is Ellen Peters and I am
4 going to take a slightly different tact in my
5 talk today compared to what Dr. Fischhoff was
6 doing. What I would like to do is I would
7 like to talk to you about anticipating some of
8 the barriers that exist to effective
9 communication. And I am focusing in part, and
10 in fact about half of my talk, will talk about
11 some of the barriers to effective
12 communication. Because by knowing those
13 barriers, we can understand better how to
14 motivate ourselves to work through them. And
15 we can understand better how we might begin to
16 start, how we might start to address those
17 barriers, in order to make communications more
18 effective.

19 So, I will talk briefly today about
20 what is needed to make a good decision. And
21 then I will start to address six barriers or
22 six potential barriers, I guess to effective

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1 communication of the kinds of critical
2 information that the FDA needs to communicate.

3 And then I will talk a little bit towards the
4 end about some ways that we can begin to
5 address those barriers.

6 First of all, to make decisions,
7 you have to have information, of course. It
8 has to be available. It has to be accurate
9 and it has to be given on a timely basis. You
10 also have to be able to understand that
11 information, though. This is one of the basic
12 building blocks of good decision making. In
13 informed choice, you have to have the informed
14 part. And so I am going to focus quite a bit
15 on comprehension in the talk I will give
16 today.

17 You have to be able to not only
18 understand the information but you have to be
19 able to understand its meaning as well. You
20 have to be able to determine meaningful
21 difference between options, if multiple
22 options exist, of course. And you have to be

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1 able to weight different factors in order to
2 match your own needs and values. And that of
3 course, by the way, means that you have to
4 know what your own needs and values are. You
5 have to be able to make tradeoffs. The FDA is
6 often faced with patients and consumers
7 needing to make tradeoffs between risks and
8 benefits. And I will focus on that a little
9 bit today, too.

10 Ultimately, the person has to
11 choose. The person has to choose multiple
12 options or has to choose to take a medication
13 or not take a medication, to look at the food
14 in their refrigerator and decide if it is part
15 of a lot that is contaminated or choose not to
16 do so.

17 So, I am going to talk today about
18 six potential barriers. I am going to go
19 through each of them in turn and I will
20 highlight them with a red type as I go through
21 each one.

22 There are a number of potential

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1 barriers. The first of course is just the
2 idea of the information that is available. It
3 can be insufficient, like not knowing the
4 source of a food contaminant. The information
5 can be uncertain and it can often change. And
6 these are barriers to effective communication.

7 The second barrier that I am going to spend a
8 little more time on is the idea that
9 communicators in general, and this is not just
10 the FDA, communicators, in general,
11 overestimate what others know.

12 So, studies have shown that
13 communicators overestimate what others know.
14 And this is important because we tend to adapt
15 what is said in order to communicate more
16 effectively. And the better we adapt to what
17 other people know, the more effective we are
18 as communicators. To be able to do this,
19 though, you need to have a model of what other
20 people know. And for the FDA in particular,
21 what they often need to have is a model of
22 what most people know because they are

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1 communicating about a wide variety of issues
2 to a very diverse population of people.

3 Research by Raymond Nickerson and
4 others suggest that the default model, the
5 model that people use about what other people
6 know, that the default model is ourselves. We
7 use ourselves and what we know as an initial
8 anchor to decide what other people know. And
9 that generally works pretty well because
10 people are often quite similar.

11 The problem that comes up though,
12 is that then we have to adjust. We have to
13 adjust for what the other person actually
14 knows. And we tend to insufficiently adjust
15 for what other people know, particularly,
16 other people who lack the same specialized
17 knowledge that we ourselves have.

18 When information is familiar, in
19 particular, and people who are working at the
20 FDA, for example, are quite familiar with some
21 of the information about the various devices
22 and the various medications that are out

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1 there. And when information is quite
2 familiar, it seems much simpler and it seems
3 much more straight forward than that same
4 information seems to somebody who is seeing it
5 for the first time or is seeing it for the
6 first time in a long time, maybe. And what
7 ends up happening is this cursive knowledge,
8 in a sense, leads us to over estimate what
9 other people know. And that can end up being
10 a barrier to good effective communication.

11 The third barrier I wanted to talk
12 about is simply a lack of comprehension of
13 information that you provide to other people.

14 And I wanted to show you an example from our
15 own work here. What we did, this was actually
16 work that was being done for the Centers for
17 Medicaid and Medicare Services, CMS. What we
18 did is we devised a comprehension index that
19 reflects the number of errors that were made
20 on 33 decision tasks and these are 33 very
21 simple decision tasks. I will show you an
22 example. And it simply involves

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1 interpretation of numbers from tables and
2 graphs. We had two study samples. We had an
3 elderly sample who ranged in age from 65 to I
4 think 98 and we had an employed age sample who
5 ranged in age from 18 to 64 because we were
6 interested in how well people would be able to
7 perform on these decision tasks across the
8 life span.

9 This is an example of one of the
10 decision tasks that we gave people. As you
11 can see, it is a really simple decision task.

12 We tell them, we actually gave them this
13 table. There are four different health plans
14 and we give them two pieces of information on
15 each of the four health plans. And we simply
16 ask, which health plan requires the lowest co-
17 payment for a visit with a primary care
18 doctor. Now, I know the answer, but I also
19 have seen this slide a million times. I'm
20 betting you know the answer but I will
21 highlight it for you, just in case you don't.

22 But the issue is that across the life span,

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1 and you can see age on the X axis down at the
2 bottom here, on the Y axis are the proportion
3 of errors in each of those age groups, just on
4 that one simple question. And what you can
5 see is that the number -- that errors exist
6 and the number of errors increase with age.
7 And in fact, if you look across all 33
8 decision tasks, this is the average proportion
9 of errors across the 33 tasks within each of
10 the age groups that are shown. And what you
11 can see are large problems with comprehension
12 and large age differences in addition to that.

13 People who are over 65 make many more errors
14 on even these very simple decision tasks
15 compared to people who are younger.

16 Oh, I'm sorry. And the
17 correlation, by the way, between age and the
18 number of errors made across 33 tasks was a
19 0.31, for those of you are interested.

20 The fourth barrier that I wanted to
21 talk about is the idea that communicators also
22 overestimate how effectively they do

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1 communicate. It turns out that we are not
2 really attuned to difference in the different
3 perspectives that people have.

4 So, communicators tend to speak
5 from their own perspective. We tend to
6 communicate from our own knowledge base, from
7 our own experiences. Remember the cursive
8 knowledge that I talked about a moment ago,
9 briefly. But listeners, as a listener, I also
10 interpret from my own perspective again. And
11 as communicators we are sensitive to these
12 difference in perspective, we know that they
13 exist and we do adjust for it, but not as much
14 as we could.

15 I wanted to show you just a simple
16 example that comes from a study by Boaz
17 Keysar. I hope I am saying his name
18 correctly. What he did is he gave subjects a
19 simple sentence. The sentence was "Angela
20 killed the man with the gun." And he told
21 them that he had two different meanings. And
22 then he said, okay, I am going to pick out

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1 this one meaning for you and I would like you
2 to speak it to the person across from you,
3 this is just a third party, so that they can
4 understand exactly which of the two meanings
5 you are tending to communicate.

6 Well, the two meanings of course of
7 this sentence are the man holding the gun is
8 the one that Angela killed. That is one of
9 the meanings. But the other meaning is she
10 killed the man with the gun that she, herself
11 was holding. So we have got two meanings
12 here. A really simple sentence. It is really
13 clear that there are two, people are told,
14 very clearly, there are two meaning here.
15 When the speakers were asked to be clear and
16 when the speakers really truly believed,
17 according to their reports that they had
18 communicated correctly, 50 percent of the time
19 they were not understood with that very simple
20 sentence.

21 Similar findings are found with
22 tapping a song. If you try to tap a song for

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1 someone and they are supposed to guess it, it
2 is very difficult for the listener to hear it
3 because they don't share that same internal
4 symphony of sounds that the speaker hears as
5 they are tapping a song. Similarly in email,
6 we think we can convey as well over email as
7 we do in person and we don't.

8 Let's see, let's go on to another -
9 - so basically, one of the ideas that comes
10 out of this study is the idea that using
11 intuition to clarify communication, using your
12 intuition to figure out how to use intonation
13 and tone in order to clarify communication
14 isn't always enough. And in fact that brings
15 us to another potential barrier to effective
16 communications because intuitions about how to
17 best provide information don't always lead to
18 comprehension of that information.

19 And I would like to share with you
20 an example that we have from a study in our
21 own group that just came out last year. What
22 we did, we were trying to help consumers to

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1 understand a fairly new health insurance plan.

2 It is a consumer directed health plan for
3 those of you who know, with a high deductible.

4 And it was a new product that consumers were
5 not very accustomed to hearing. And what we
6 wanted to do is we wanted to try to help them
7 better understand what is different about this
8 new kind of plan compared to other more
9 traditional plans. And so we thought, okay,
10 what if we were to provide them a framework.
11 Let's provide them with a framework of kind of
12 the overall gist of the differences, and then
13 we will provide them with the detailed
14 information afterwards. That should help them
15 to understand. And this is what we thought.

16 And so what we did, for half of our
17 consumers we gave them this overall framework
18 and then we provided them the detailed
19 information. For the second half of the
20 consumers, we provided them just with the
21 detailed information. And so we evaluated our
22 message. We wanted to know, does the

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1 framework really help or not?

2 And it turned out that we were
3 partially correct. We help people like us.
4 What happened was, highly numerate, people who
5 are good with numbers, highly numerate
6 consumers who are very good with numbers were
7 helped by the framework. When we provided
8 them with the framework, they better
9 understood that detailed information that
10 followed, regardless of what the detail was
11 that followed. So the framework helped people
12 like us. We used our own perspective and we
13 helped people like us.

14 The framework also somewhat helped
15 consumers who were less numerate. It helped
16 them to better understand information that was
17 related to the framework because half of our
18 questions were related to the framework and
19 half of our questions were unrelated to the
20 framework. What happened though, providing
21 the framework actually hurt their
22 comprehension of other information. And so

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1 what that said to us was one, you can't always
2 count on your intuition. And two, if you are
3 going to use a framework because sometimes it
4 is quite helpful and you know that some of
5 your consumers are going to be less skilled
6 with numbers in particular, in this case, then
7 you might want to make sure that any important
8 information that you are providing shows up in
9 that framework. So, that is an important
10 thing for us to know because we didn't know
11 that that was going to happen.

12 So, why don't we just ask the
13 people receiving the information about what
14 they prefer? How do you prefer to get
15 information? Will that help? Can they use
16 their own intuitions in order to help us
17 figure out what to give to them? The problem
18 is, of course, if this doesn't work either,
19 studies have shown that preferences don't
20 necessarily lead to comprehension and use of
21 that information. Messages need to be tested.

22 The final barrier, though, that I

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1 want to mention has to do with perceptions,
2 risks, and benefits. We want consumers and
3 patients to be able to trade off the risks and
4 the benefits of pharmaceuticals and other
5 products. The problem is, though, is that
6 perceptions of those risks and benefits may be
7 linked together. And let me show you what I
8 mean.

9 In the real world, as well as in
10 this slide, risks and benefits are positively
11 correlated. For example, a medication with
12 serious side effects, something that was
13 highly risky, would have to have very high
14 benefits simply to stay on the market or it
15 just wouldn't exist. You are not going to get
16 things in that upper left-hand quadrant that
17 are high in risk and low in benefit. The
18 market is going to push them out. People
19 aren't going to purchase that product.
20 However, in people's minds, they are actually
21 negatively correlated. Perceptions of risks
22 and benefits are inversely related. Things

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1 that are perceived as high in benefit tend to
2 be perceived as low in risk. Things that are
3 perceived as highly risky, tend at the same
4 time to be perceived as low in benefit. And
5 the strength of that inverse or that negative
6 relationship between risk and benefit
7 judgments for a hazard or for a consumer good,
8 depends on its affect, it depends on how good
9 or bad it feels. Things that feel good to us
10 tend to be perceived as high in benefit and
11 low in risk. Things that feel bad to us tend
12 to be perceived as high in risk and low in
13 benefit.

14 An example of this is in chemical
15 sources. Medical sources of exposure to
16 chemicals like prescription drugs tend to be
17 perceived as good overall. People feel good
18 about prescription drugs overall. Whereas,
19 non-medical sources, like pesticides, tend to
20 be perceived as bad. Both are chemical but
21 the medical sources of exposure have much more
22 favorable benefit risk reading than do the

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1 non-medical sources.

2 This inverse relationship between
3 risk and benefit perceptions can be explained
4 by the affect heuristic. This is a model that
5 has been developed within the group at
6 Decision Research. And research in our group
7 as well as others, suggest that we use our
8 feelings or our affect as information to guide
9 perceptions of information and, ultimately to
10 guide decisions in some cases. The affect
11 heuristic predicts and explains how good and
12 bad feelings about nuclear waste repositories
13 or prescription drugs are associated with
14 perceptions of its risks and its benefits. It
15 predicts that we look to our feelings, we look
16 to our affect as information to judge how
17 risky and how beneficial something is.

18 Tests of the affect heuristic have
19 demonstrated that when decision-makers are
20 under time pressure and they have little time
21 to deliberate carefully, affect and the affect
22 heuristic play a larger role. And that

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1 inverse relationship between perceived risk
2 and perceived benefit grows. In other words,
3 time pressure strengthens reliance on the
4 affect heuristic.

5 The FDA and others sometimes choose
6 to provide only risk information in a
7 particular communication or to provide only
8 benefit information in a particular
9 communication. And the affect heuristic has
10 something to say about this as well. What is
11 also predicted by the model is that you can
12 provide information to change an overall
13 impression. So, for example, you can provide
14 information only about the risks of a
15 pharmaceutical drug that says the risks are
16 high, for example. And because just that
17 information is high, that alters the affect
18 that is felt towards that drug, for example,
19 increases negative affect in this case. And
20 an inference is made that the drug is less
21 beneficial. So there is this inverse
22 relationship between risk perceptions and

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1 benefit perceptions.

2 So, how can we disclose information
3 so that people can understand it and so that
4 people can use it? Because that is what we
5 want to do. We want to effectively
6 communicate. We can certainly do better than
7 the nutrition facts disclosed by this guy
8 selling fried stuff on a stick. For those of
9 you who can't see it, the nutrition facts are
10 it won't kill you, not right now anyway. We
11 can do better. The FDA already does much,
12 much, much better.

13 So, how can we address these? One
14 of the things we can do is we can provide both
15 risk and benefit information. We have been
16 talking about this in previous meetings. We
17 have been talking about this earlier today.
18 If you provide both risk and benefit
19 information in communications, what happens is
20 is that if the public draws an inference about
21 benefits when provided only risks, by
22 providing both of them together, you can

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1 actually better ensure that the tradeoff is
2 going to be evaluated between risks and
3 benefits. It also suggests, by the way, in
4 evaluations of your communications, you may
5 want to measure both risk perception and
6 benefit perception, even though you are only
7 providing one side of the coin.

8 What about providing it in numeric
9 ways or nonnumeric ways? People tend to trust
10 risk information more when provided numeric
11 information. Providing numeric risk
12 information, reduced fear of adverse events in
13 one study. Providing numeric benefit
14 information also reduced perceived benefit, by
15 the way, in another study.

16 There is one issue with the studies
17 that have been done on this so far, though and
18 there have been a variety of studies. Most of
19 them are hypothetical. Some of them have been
20 done with quite non-representative populations
21 like Stanford students, little non-
22 representative. The issue is that not

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1 everybody understands and uses numbers very
2 well. And in addition to that, not every
3 format of number communicates equally well to
4 different people. These are empirical issues
5 that need to be tested. And in fact, it needs
6 more study in the context of pharmaceuticals
7 to understand how to communicate these
8 important sources of numeric information best.

9 Another thing you can do is make
10 the information that you provide more usable.

11 It turns out that how information is
12 presented may matter as much as what
13 information is presented. So, it is very
14 important to get the information right, to get
15 it accurate, to get it timely. But in
16 addition to that, you also have to pay
17 attention to how it is communicated, if you
18 expect it to be understood and if you expect
19 it to be used.

20 And so one thing that we have
21 shown, one thing that we studied is the idea
22 of less is more. And this is something that

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1 the FDA is aware of and it shows up, in fact,
2 in some other documentation. But I want to
3 show you a specific example of it so that you
4 can actually see it and see that it makes a
5 difference when we did an evaluation of it.
6 And the example that I will show you is
7 showing only the most important information.

8 So in this study, we are actually
9 studying people's ability to understand and
10 use hospital quality information when choosing
11 a hospital. Subjects were given information
12 about three hospitals. They were given cost
13 information, quality and other non-quality
14 information. And we put subject in one of two
15 conditions so that they saw all of the
16 information in an unordered fashion or the
17 other half of the subjects saw just he cost
18 and quality information and the quality
19 information was highlighted. I will show you
20 what I mean.

21 So this is the condition for the
22 half of the subjects who got all of the

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1 information and it was unordered. It actually
2 is quite similar to what is often presented on
3 hospital quality websites. And in fact, I
4 stole this basic format from a website in
5 Minnesota that was presenting hospital quality
6 information. And what you can see is that
7 people get out of pocket costs. They get non-
8 quality information like the number of general
9 care beds. Jumping down a little bit, they
10 get quality information like the percent of
11 times that guidelines are followed. And then
12 on that same page as this table of
13 information, they answer question such as
14 which hospital followed guidelines for heart
15 attack care most often.

16 The other half of the subjects, we
17 take out the non-quality information and we
18 presented them only with the information that
19 we considered most relevant, the cost
20 information and the quality information
21 because we were trying to help them to better
22 understand the quality information. And we

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1 also, and then we asked them the same exact
2 questions that we asked the other group of
3 subjects. Are hypotheses were that including
4 less information would help comprehension.
5 And in addition to that, that it would
6 particularly true for more vulnerable
7 populations, like people who are lower in
8 number ability.

9 In terms of the evaluation itself,
10 the dependent variable that I am going to show
11 you is comprehension. We asked them three
12 comprehension questions and then simply
13 counted how many each person got correct.
14 What I am showing you here on the Y axis is
15 the average number of questions that subjects
16 scored correctly. The less numerate people
17 are on the left. The more numerate people are
18 on the right. And what you can see in the red
19 bars is that people who are given cost and
20 quality information only. So they were given
21 less information and actually understood more.
22 It was true whether they were less numerate

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1 or whether they were more numerate. But it
2 particularly helped people who were less able,
3 who had less skill with numbers.

4 So how information is presented may
5 matter as much as what information is
6 presented. These choices are judgments but
7 these choices are quite important and they
8 deserve study within the context of a
9 particular communication.

10 So, in some of the studies that we
11 have done, showing only the most important
12 information helps comprehension. It also
13 helps people to weight quality of care more in
14 the particular choices we were looking at.
15 Making key points easier to evaluate helps
16 comprehension, if you can help people by
17 ordering information, summarizing information,
18 interpreting that information for them. In
19 general, if you can require less cognitive
20 effort from the person you are communicating
21 with and require fewer inferences from them,
22 they are ultimately going to understand more

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1 of the key messages that you are trying to
2 communicate to them.

3 We need to test information
4 formats. This is the third addressing the
5 barriers that I wanted to discuss. We need to
6 test information formats. The intuition of
7 information providers isn't enough. Sometimes
8 we choose based on our own abilities and our
9 own perspectives and we hurt people who are
10 coming from a different perspective. Consumer
11 preferences also are not enough, as what is
12 preferred is not always what is understood
13 best and what is used best.

14 In conclusion, who information is
15 presented influences how well it is understood
16 and it seems to be particularly true for
17 people who are from more vulnerable
18 population, people who are less numerate,
19 people who are less literate. Careful choices
20 of communications and how those communications
21 are presented may promote wellness and
22 ultimately may reduce some of the health

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1 disparities in our country.

2 Risk and benefit information should
3 be communicated and probably in a numeric
4 format, although I would suggest that more
5 studies need to be done in order to evaluate
6 across people who differ in age and across
7 people who differ in numeric abilities, what
8 formats for presenting numeric information
9 will lead to the best comprehension.

10 In general, communications should
11 be tested. The FDA has done a remarkable job
12 communicating a vast array of information
13 across a wide variety of populations but they
14 need more resources in order to be able to do
15 this better. The science of communication
16 exists. The FDA is aware of this. The FDA
17 uses the science of communication and they
18 have some tremendous expertise within their
19 group. At the same time, they should be using
20 it more. And they should be in fact,
21 developing that science. They should be a
22 partner in developing some of the science of

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1 communication.

2 Thank you very much.

3 CHAIR FISCHHOFF: Socially defined,
4 dynamically defined social norm of clapping.
5 So, we have got jargon for everything.
6 Thanks, Ellen.

7 Let's open up the conversation. We
8 have about 20 minutes now and the conversation
9 should be between and within the two tables.
10 So let me invite people from there as well as
11 people from here to offer comments.

12 Well, while you are warming up, --
13 go ahead, Mike. I think the last point, while
14 Ellen was talking it occurred to me and I
15 think it is about how this partnership goes.
16 And I think it is probably unreasonable to
17 expect FDA at any point to be a sponsor of
18 basic research. And I think much of what we
19 have been thinking about is just how to make
20 what is out there more accessible to you, so
21 you know about its existence, it is in ready
22 form.

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1 But I think that, thinking about
2 some of the challenges that you all
3 particularly presented this morning, there are
4 issues that you are aware of that are on your
5 plate where I think that the research, the
6 literature is probably pretty thin. And there
7 ought to be some way to get us to work more on
8 it. And I don't know whether that is just to
9 put it out and for us to translate it into
10 terms that our colleagues will understand or
11 to talk to NSF or NIH about having, you know,
12 about sponsoring research that particularly
13 interests you. So this question of
14 uncertainty or what is the quality of the
15 information. I can think of things that are
16 kind of relevant but I think we don't have as
17 much to offer you as we might. So I put it
18 out sort of, you know, both for us and for you
19 to think about ways that we might get some of
20 that basic science that you need most
21 generally.

22 One of my colleagues, Alan Baddeley

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1 used to run the Medical Research Counsel's
2 Applied Psychology. And he made a
3 distinction. He described what he called, he
4 said that he thought that it was essential for
5 the health of any science, and maybe in any
6 society to have both basic applied psychology
7 and applied basic psychology, where the
8 applied basic psychology was taking things
9 that we think that we know and seeing how well
10 they work in the world. Do we even have
11 predictions and what auxiliary assumptions we
12 need to make it work. But conversely to see
13 things that are going on in the world that we
14 can then domesticate for systematic. So, I
15 think we would be better off in learning from
16 you, you know, as well as we hope that you
17 will be better off in learning from us.

18 Mike.

19 DR. GOLDSTEIN: I just have a
20 couple of general comments to make that are
21 going on inside my head. So, I apologize in
22 advance if they don't come out quite the way

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1 that I expect them to because I am not sure
2 how they are going to come out.

3 What I was hearing in these last
4 few presentations, which really got me
5 thinking was that it is really, really
6 important not to make assumptions about the
7 communication that we are trying to influence.

8 And this whole notion that there is non-
9 persuasive and persuasive communication to me
10 seems like false dichotomy. Because, in fact,
11 those last few presentations was all about
12 trying to understand the meaning and the
13 relevance of the communication to the audience
14 that it is intended for. And if that is not
15 an attempt to be persuasive, then it gives me
16 trouble as a concept.

17 And the other point that is related
18 to that is that both those presentations, both
19 of your presentations underline the importance
20 of seeking to understand the pre-existing
21 notions, ideas, beliefs, preferences of the
22 audiences that we are trying to reach. So, to

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1 answer some of the questions that were raised
2 earlier about how do we deal with uncertainty,
3 Dr. Neuhauser said before that we have to
4 embrace uncertainty, we have to understand
5 uncertainty, too, from the point of view of
6 the audience that we are trying to reach.
7 What is their need for information? What is
8 their comfort with knowing and not knowing?
9 And that will help us to craft the messages, I
10 think, that will address those needs. First,
11 we have to understand the needs and we can't
12 just divide information into facts and not
13 facts. We first have to know the meaning in
14 the audience that we are trying to reach, in
15 order to reach them effectively. And that
16 means we have to tailor our messages based on
17 the audiences that we are trying to reach.

18 So, I will have more to say later.

19 That is just a general comment about how we
20 are asking questions about communication.

21 CHAIR FISCHHOFF: I have Betsy,
22 Christine, Marielos, and Mona.

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1 You yield your time. Christine.

2 DR. BRUHN: Thank you very much.
3 Thank you. I have, you know, I think we all
4 enjoyed the presentations and benefited from
5 them and learned from them. I have a couple
6 of comments.

7 First of all, actually in regards
8 to the question of who should be doing the
9 research or who does the research that relates
10 to understanding and communication. I contend
11 that it is fine if FDA has some small projects
12 that they want to do and they want to handle
13 in-house but I was appalled by all the
14 restraints that you have on research that you
15 are involved in. It looks like it would take
16 one to two years to get through all of your
17 IRB and other regulatory groups that have to
18 approve what you do. I strongly urge that you
19 keep in mind, keep open the opportunity to ask
20 general questions and allow the academic and
21 other community to respond to research calls
22 to address these questions.

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1 One of the projects that I am going
2 to be reporting on this afternoon is actually
3 an FDA funded research project and I think we
4 did a great job with it. So, I am looking
5 forward to showing how we were able to
6 collaborate together to show the actualization
7 of some of the theory of communication.

8 And if I am thinking now of the
9 forthcoming project that you have got on
10 allergy labels and how people respond to some
11 of the comments, and you have called for
12 comments. That is good. That is appropriate.

13 But wouldn't it be wonderful if there was
14 someone who had done research with allergic
15 patients on how they interpret and respond to
16 the new allergy information so you are not
17 hearing from anecdotal two, three, five, ten
18 or fifteen folks, but you have a base of a
19 large number of individuals.

20 And how are we going to get monies
21 to do that, if not having a research call that
22 academics or others are responding to or

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1 perhaps a group like FAAN, the Food Allergy
2 and Anaphylaxis Network, might have had a
3 response from their members. But open the
4 doors so that others can provide information
5 to comment on effectiveness.

6 And in regards to the impact of
7 some of the messages, Marjorie, I agree that
8 the seafood advisory for pregnant women has
9 been effective in that women who are pregnant
10 or in child bearing age are limiting the
11 amount of seafood that they are consuming,
12 fish and seafood. But there is, as you
13 mentioned, there is controversy in this.
14 There is also the question of it appears as
15 though they have limited it so much that they
16 are now not going to have for their children
17 the benefits that eating from this food group
18 provides. There is very clear information
19 that for infants as well as through children,
20 and I believe it has been tested through nine
21 years, those who had seafood in their diet
22 have higher cognitive abilities.

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1 And it appears that with the group
2 of pregnant women, when you say benefits and
3 you say risk, and indeed in the FDA's
4 communication benefits are listed first and
5 then risks, and very reasonable and quite
6 specific guidelines on how much people should
7 be eating or rather how much, what their limit
8 should be, the response has been, if I am
9 pregnant and I hear risk, I am not eating it.

10 And that has been shown by focus groups in a
11 study that is in press, as well as by national
12 surveys.

13 So, risk and benefit might seem
14 balanced to us who are writing. But again,
15 there is benefit of going to that target group
16 because they don't see balance. They see risk
17 big and benefit little and they are going to
18 be protective.

19 Thank you.

20 CHAIR FISCHHOFF: Marielos and Mona.

21 MS. VEGA: This question is for
22 anyone on the panel, the panel who spoke

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1 earlier. What is the reason why there is so
2 many difficulties to do evaluation at the
3 Centers' level? Is it because of the
4 logistics or because there is lack of funding?

5 And I also want to reemphasize
6 something that Linda said earlier and is the
7 need to have a unified voice. It is, as I was
8 listening from all of the Centers, I mean,
9 they seem to have a lot of similar challenges
10 in terms of communicating with the public what
11 is the best ways to do it.

12 It kind of remind me about the
13 issues we are having with colorectal cancer
14 screening, then there are so many tests
15 offered for colorectal cancer screening, that
16 there is a difficulty for patients to make an
17 informed decision.

18 So, like for example mammography
19 that is only one test and so it is easier for
20 consumers to make decisions. I think there
21 should be a unified voice to speak on behalf
22 of all of the Centers. As a consumer and I

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1 feel like I am educated in terms of navigating
2 the web and it is difficult to go into a
3 website. And I suppose each Center has their
4 own website. It is cumbersome to search for
5 that information.

6 So, when it comes to emergency
7 communication, I think it will be very
8 beneficial to have a unified voice. Also, I
9 think it is important for institutions like
10 the FDA to work with state governments and
11 with organizations in each state that know how
12 to communicate with their communities. We
13 cannot expect the FDA to be able to get the
14 message across to every individual in this
15 country.

16 But I think that working with
17 government, I was happy to see one of the

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