

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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FOOD AND DRUG ADMINISTRATION

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RISK COMMUNICATION ADVISORY COMMITTEE

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FRIDAY, MAY 1, 2009

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The meeting convened at 8:00 a.m. in Room 1066 at 5630 Fishers Lane, Rockville, Maryland, Baruch Fischhoff, Ph.D., Chair, presiding.

COMMITTEE MEMBERS:

- BARUCH FISCHHOFF, Ph.D., Chair
- CRAIG ANDREWS, Ph.D., Member
- CHRISTINE M. BRUHN, Ph.D., Member
- ANNAMARIA DESALVA, Member
- SOKOYA FINCH, M.A., Member
- MICHAEL GOLDSTEIN, M.D., Member
- PRERNA MONA KHANNA, M.D., M.P.H., Member
- MADELINE Y. LAWSON, M.S., Member
- MUSA MAYER, M.S., M.F.A., Member
- JOHN E. PALING, Ph.D., Member
- ELLEN M. PETERS, Ph.D., Member
- BETSY LYNN SLEATH, Ph.D., Member
- MICHAEL S. WOLF, Ph.D., M.P.H., Member

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FDA PARTICIPANTS:

LEE L. ZWANZIGER, Ph.D., Designated Federal  
Officer/Executive Secretary

NANCY M. OSTROVE, Ph.D., Director for Risk  
Communication

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Adjourn

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P-R-O-C-E-E-D-I-N-G-S

8:00 a.m.

CHAIRMAN FISCHHOFF: Okay. Let me welcome all of you to the second day of the fifth meeting of the FDA's Risk Communication Advisory Committee and turn the floor to Lee Zwanziger who will get us going.

DR. ZWANZIGER: Good morning, everyone. Welcome to the members of the public, the press, the FDA staff and of course the members of the Risk Communication Advisory Committee.

As was read in full yesterday, let me just briefly reconfirm that based on the submitted agenda for the meeting and all financial interests reported by the committee participants, it's been determined that no interest in firms regulated by the Food and Drug Administration present potential for conflict or appearance of a conflict of interest to this meeting.

Should the discussion to any area

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1 not already on the agenda, there may be  
2 possible financial conflict for which we have  
3 not screened, so participants are aware of the  
4 need to identify any conflicts pertaining to  
5 them and refrain from participating  
6 accordingly and their statement and recusal  
7 would be noted for the record.

8 Ms. Greenberg and Dr. DeLaRosa are  
9 not participating today, but this is because  
10 of unforeseen schedule emergencies, not  
11 conflict recusal.

12 If persons not already signed up to  
13 speak at today's open public hearing session  
14 wish to request time, please see one of my  
15 colleagues out at the sign in table that's  
16 outside the door. Thanks very much.

17 CHAIRMAN FISCHHOFF: Thank you,  
18 Lee.

19 And we'll now introduce ourselves.  
20 I'm Baruch Fischhoff, the chair of the  
21 committee and I'm a professor of social and  
22 decision sciences and engineering and public

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1 policy at Carnegie Mellon University.

2 MEMBER KHANNA: Good morning. My  
3 name is Mona Khanna. I am a physician by  
4 training, board certified in internal  
5 medicine, public health and occupational  
6 medicine, medical journalist, full time for  
7 the last seven years. I currently work as the  
8 medical editor for a social media site for  
9 health where we bring communities of patients  
10 together. It's called ICYou.com. And I am a  
11 lieutenant colonel with the Texas State Guard  
12 in emergency preparedness and disaster  
13 deployments.

14 MEMBER LAWSON: Good morning. I'm  
15 Madeline Lawson and I'm the president and CEO  
16 of the Institute for the Advancement of  
17 Multicultural and Minority Medicine based on  
18 Washington, D.C.

19 MEMBER MAYER: Good morning. I'm  
20 Musa Mayer. I'm a breast cancer advocate from  
21 New York City and a writer and have an  
22 enduring interest in communication of the

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1 risks and benefits of treatments to patients.

2 MEMBER SLEATH: I'm Betsy Sleath.  
3 I'm a professor of pharmaceutical outcomes and  
4 policy at the University of North Carolina.  
5 And I primarily study how providers and  
6 patients talk about medications and how that  
7 impacts their health outcomes.

8 MEMBER PALING: Good morning. I'm  
9 John Paling. I run a small organization, the  
10 Risk Communication Institute, that helps  
11 medical professionals understand risks. I  
12 have a very circuitous track coming here. I  
13 started off as a junior professor of biology.

14 Then I became a wildlife film maker, which  
15 gave me a great appreciation of the power of  
16 visual communications and I got hooked into  
17 the world of risk communication and developed  
18 visual aids and then became a keynote speaker  
19 at many conferences, both chemical,  
20 environmental and finally medical. I wish you  
21 to know that I use the information that the  
22 researchers that preponderantly occupy these

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1 seats have found and try and communicate that  
2 to audience of all sorts, particularly medical  
3 audiences.

4 I have the same problem that the  
5 FDA has, which is getting an audience for a  
6 message that I think is very important. And  
7 I've done my very best to prepare to optimize  
8 acceptance. I, however, have the personal  
9 benefits of being able to embellish my  
10 communications by using two things. One is  
11 small excerpts of my little wildlife films  
12 which I use as metaphors. And also the  
13 occasional gentle English humor. For example,  
14 the very last and best presentation was to an  
15 organization calling itself DAM, which stands  
16 for Mothers Against Dyslexia.

17 MEMBER PETERS: John is always a  
18 hard act to follow, so I won't even attempt to  
19 try.

20 My name is Ellen Peters. I'm a  
21 senior research scientist at Decision Research  
22 in Eugene, Oregon. I'm a research

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1 psychologist by training and I study how  
2 people process different sources of  
3 information and how that makes a difference to  
4 judgments and decisions that they make in our  
5 complex world.

6 MEMBER WOLF: My name is Michael  
7 Wolf. I am an associate professor of medicine  
8 and learning sciences at Northwestern  
9 University and director of the Center for  
10 Communication and Health Care there and my  
11 research has been primarily focused on health  
12 literacy medication safety and adult learning  
13 issues.

14 MEMBER FINCH: Good morning. My  
15 name is Sokoya Finch, executive director of  
16 Florida Family Network. We basically work in  
17 the areas of health disparity, social justice  
18 and advocacy.

19 MEMBER BRUHN: I'm Christine Bruhn  
20 with University of California at Davis. I'm  
21 the director of the Center for Consumer  
22 Research, which is in the Department of Food

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1 Science and Technology. And my focus of my  
2 research and education is on consumer  
3 attitudes and behavior regarding food safety.

4 MEMBER ANDREWS: Good morning. I'm  
5 Craig Andrews from Marquette University. I'm  
6 a professor in Charles Kellstadt Chair in  
7 Marketing. My expertise is on consumer  
8 research, advertising research. Formerly in a  
9 previous life I was at the Federal Trade  
10 Commission on evaluation of different and copy  
11 testing, the National Youth Anti-Drug Media  
12 Campaign as well. Thank you.

13 MEMBER DeSALVA: Good morning. I'm  
14 AnnaMaria DeSalva and I lead the global health  
15 care practice at Hill & Knowlton, and that is  
16 a public relations and public affairs firm.  
17 And our health care business serves many  
18 different kinds of organizations focused on  
19 health care in the public and private sector  
20 and we're very involved in helping those  
21 organizations better communicate risk and  
22 benefit.

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1                   MEMBER GOLDSTEIN:     Good morning,  
2     everybody.     I'm Michael Goldstein.     I'm a  
3     physician and chief of the Mental Health and  
4     Behavioral Sciences Service at the Providence  
5     VA Medical Center and I'm also a professor of  
6     psychiatry and human behavior at Brown  
7     University. My area of interest and expertise  
8     is in health behavior change and medical  
9     settings as well as helping clinicians  
10    communicate more effectively with their  
11    patients, to engage them in making the right  
12    decisions for them. Thank you

13                   CHAIRMAN FISCHHOFF:     Thank you.  
14    And for those of you weren't here yesterday,  
15    we had a really intense and enlightening  
16    discussion of FDA's draft strategic  
17    communication plan which is noteworthy for its  
18    call for science-based approach to  
19    communication. That is, the communication  
20    process will be scientifically done as well as  
21    the content being scientifically sound.

22                   And what we've asked to do today is

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1 to comment on the kind of research that would  
2 be needed to, you know, build on what we  
3 already have and support this communication  
4 plan. FDA has conducted an internal exercise  
5 in the topics that people are most interested  
6 in. And so Nancy Ostrove will kick off the  
7 discussion by talking to that.

8 And our objection today is to  
9 provide sort of free-flowing advice as we've  
10 done on the details of this plan and then  
11 think about whether we have some either  
12 conclusions or recommendations on the two  
13 day's meetings that we'd like to, you know,  
14 put in the record and as non-binding as advice  
15 to FDA.

16 So, Nancy?

17 DR. OSTROVE: Good morning,  
18 everyone. I'm here to talk about kind of the  
19 draft, the research topics that we had put  
20 together, as Baruch said. Internally we did a  
21 small set of reviews among many of the  
22 researchers and the members of the

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1 Communications Council at FDA. And this is  
2 kind of the result of that. We really want to  
3 hear from the Committee about your opinions  
4 about this, whether there's anything missing.

5 Well, we'll go into that in a minute.

6 As you all know, FDA's objective is  
7 to help get the public the accurate  
8 science-based information that they need to  
9 use the products that we regulate to improve  
10 their health. We've heard that, you know,  
11 time and time again.

12 As you've also all heard, probably  
13 many more times than once, our mission is  
14 complicated by the breadth of the products  
15 that we regulate, the variety of laws and  
16 regulations that form the basis of our  
17 authority, the types of actions that we can  
18 and cannot take, both on our own and in  
19 conjunction with industry and the various  
20 audiences with whom we communicate, ranging  
21 from of course consumers through patients,  
22 health care providers, health care plans. I

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1 mean, it's just a huge number.

2 Further, at least at present our  
3 communications are often product-focused.  
4 They often come out of different parts of the  
5 Agency. There are lots of them. Many of them  
6 bear similar messages, but they may have  
7 different specific content, different formats,  
8 different titles. And part of this kind of  
9 variability across the Agency is a function of  
10 a commitment that we made a few years ago to  
11 greater transparency and earlier communication  
12 about emerging issues.

13 In looking at whether we feel that  
14 we're communicating effectively, well, there's  
15 a couple of points that I think we all agree  
16 on. One is that we don't consistently test  
17 the communications that we use prior to use.  
18 As I mentioned yesterday, there's one  
19 particular organization within FDA, the Office  
20 of Women's Health, that does consistently  
21 pretest its communications, its messages, its  
22 tools before they go out and that office also

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1 translates its information into a number of  
2 different languages. But generally, across  
3 the Agency that is not something that we  
4 consistently do.

5 We also don't consistently assess  
6 the effectiveness of the communications that  
7 we put out once they are in the public domain.

8 We try to do that from time to time, but the  
9 truth of the matter is that there has been  
10 little support for doing that in the past.  
11 That is changing. And on top of the fact that  
12 we don't get a lot of that information, we do  
13 get feedback from many of our stakeholders and  
14 from the media that we're not communicating  
15 effectively. For instance, there is some  
16 research that has demonstrated the lack of  
17 effectiveness of highlighting  
18 contraindications in black boxes, on changing  
19 physician prescribing behavior with regard to  
20 concomitant use of specific medications. So  
21 we do have that kind of research-based  
22 feedback and we hear on an anecdotal basis as

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1 well from many, many different people and  
2 groups that there's room for improvement in  
3 terms of FDA's communications.

4           So in going through this process  
5 where we identified a number of areas that we  
6 could use better information, they basically  
7 fell into five different general arenas. When  
8 and what to communicate. How you best reach  
9 the audience, you know, the whole issue of  
10 dissemination, which Michael Goldstein talked  
11 about pretty extensively yesterday kind of  
12 when we were discussing things at the broader  
13 level. Assuring audience understanding; that  
14 is, assuring that basically the messages that  
15 we're trying to get across are getting across  
16 are in fact getting across. Motivating  
17 audiences to take action. I think we heard  
18 yesterday that -- well, for instance, a recent  
19 Rutgers report came out that looked at the  
20 impact of food recalls over time. And that  
21 report very clearly shows that although people  
22 seem to be aware of a lot of the recalls, in

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1 many cases they really didn't do anything  
2 about having heard that a product was being  
3 recalled. They didn't necessarily check their  
4 shelves, for instance. And they also have  
5 this kind of sense, which is pretty consistent  
6 with some of the psychological literature,  
7 this personal sense of invulnerability, that,  
8 you know, yes, it may be affecting other  
9 people, but it's not going to affect me. And  
10 many of them reported in fact that they ate or  
11 consumed products that had been recalled. And  
12 that's consistent with some other research  
13 that we've seen in the past.\*\*And then final  
14 kind of general area is that of evaluating  
15 effectiveness.

16 I have not put the actual questions  
17 up on the slides because your web site had the  
18 list of many of the specific research  
19 questions and the Committee has that  
20 information as well to look at.

21 In terms of prioritizing the  
22 questions, the exercise that we went through

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1 with a very small number of people, because I  
2 have to say that at the Agency I think there  
3 is so much awareness of the need to get more  
4 information about all of these questions that  
5 it was very difficult for people to actually  
6 prioritize them, so there was not a whole lot  
7 of agreement with regard to that. So I think  
8 that was one of the other reasons we decided  
9 to not kind of make a big deal out of what was  
10 essentially a very small and informal exercise  
11 in an attempt to prioritize.

12 But getting to our discussion  
13 topics, what we're asking is after having  
14 reviewed the proposed research need, that  
15 small document, the questions that we've asked  
16 is, you know, what research questions could be  
17 further clarified to support the strategic  
18 goals as we've described them in our draft  
19 plan, what types of research or research  
20 questions might we consider adding to the ones  
21 that are already there, given your knowledge  
22 and understanding of FDA and what FDA

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1 communicates with the public, what types of  
2 research or research questions that we've  
3 currently listed could be informed or  
4 potentially even answered by research that  
5 already exists, and we've asked for as much  
6 detail as possible on that.

7           There's one particular question  
8 that we kind of brought up again as I  
9 mentioned yesterday as a way to kind of spark  
10 conversation about specific questions in this  
11 particular instance, but is not meant to imply  
12 that this is the only question that we're  
13 interested in. And we heard this yesterday as  
14 well a number of times. We know that people  
15 may perceive the meaning of words that we use  
16 that are essentially term of art words that  
17 may also have legal implications. For  
18 instance in the past we've talked about the  
19 kind of phrase safety and effectiveness. That  
20 they may hear those words and take away  
21 something from them that's very different from  
22 than what is actually meant by the way that

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1 the Agency is using it; for instance, that  
2 often arises in this legal context. And we  
3 recognize the need to test how people  
4 understand some of these key terms.

5 The question that we're asking on  
6 this particular one here is what existing  
7 research would inform the decision of whether  
8 to provide public education about such terms  
9 or whether we should change the terms that we  
10 use where change is legally possible, for  
11 instance. In some cases we may have to use  
12 them whether we like them or not. But, you  
13 know, is there existing research out there  
14 that would kind of inform this kind of  
15 decision. And again, these questions are not  
16 meant at all to restrict this morning's  
17 conversation, but simply to provide, you know,  
18 both the general and the specific and to let  
19 you know kind of, you know, our interests here  
20 are very wide and deep in terms of getting  
21 your feedback. Thank you.

22 CHAIRMAN FISCHHOFF: Thanks, Nancy.

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1 I'd like to maybe kick off the  
2 discussion because I've been struggling with  
3 how best to use, you know, our collective time  
4 on the topic and I've been at sort of, you  
5 know, research needs forums and you end up  
6 with a large undifferentiated list which gets  
7 everybody happy because their topic is up  
8 there in the short run. And in the long run  
9 nobody's happy because there's no real  
10 priorities and it doesn't really get done, but  
11 then you've moved off to the next group that  
12 you're giving your sagacious advice on the  
13 research that needs to be done.

14 So let me offer a suggestion here.

15 So one problem with lists of research needs  
16 is it's starting to take that forum  
17 mission-oriented agency that can often lead to  
18 paralysis. That having a list of things that  
19 we'd like to know more about could inform  
20 people, could suggest to people who are  
21 unfamiliar with the research base that we  
22 don't know anything. And, you know, depending

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1 on the area that you're looking for, there's,  
2 you know, 10 to 100 years of research that one  
3 could draw on, you know, for the topics that  
4 are up here. So I would hate for us to  
5 produce a list of things that we'd like to  
6 know about that would in any way enable people  
7 to say, well, we're not ready to act here. So  
8 I think that's a risk that, you know, I'd like  
9 to see us avoid.

10 A second thing that can contribute  
11 to paralysis is the feeling that we need to  
12 solve these problems, that these problems are  
13 solvable in some absolute way. That is, you  
14 know, as you were saying, we can get everybody  
15 to wash their hands to a professional  
16 standard. The slow eating movement would  
17 thank us because it would keep anybody from,  
18 you know, snacking very quickly. But where as  
19 what we're looking at -- you know, this came  
20 up yesterday, you know, in your comments.  
21 We're trying to figure out what's the best way  
22 that we can achieve these problems, taking

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1 advantage of the science that we already have  
2 or the science that could be produced on short  
3 order. And we have an obligation to the  
4 American public to produce to do the best that  
5 we can. And we have an obligation to our  
6 policy makers to say just how good that best  
7 is. Which sort of takes us back, you know, to  
8 the point that AnnaMaria said. You know, the  
9 discussion that AnnaMaria led us through  
10 yesterday is that the objectives of the  
11 organization, they need to drive the  
12 priorities for the research. Until we know  
13 what we're achieving, there's really no point  
14 in doing research. You can't define  
15 importance in the absence of objectives and in  
16 the absence of knowing what your alternatives  
17 are. I mean, I think you and your colleagues  
18 are legitimately, you know, putting my  
19 decision theory hat -- you are legitimately  
20 flustered by trying to come up with an overall  
21 definition of importance, because it doesn't  
22 really exist.

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1                   And what strikes me is that  
2 researchers ought to be secondary to what  
3 you're thinking about now, that what FDA  
4 really needs is development. That is to say,  
5 if you think of R&D, you do research in order  
6 to develop some kind of products. Well  
7 there's, you know, thousands and thousands of  
8 person years, you know, of research that's  
9 already out there, thousands and thousands of  
10 papers out there. And we know a lot about the  
11 principles that govern people's behavior.  
12 That good numbers are better than verbal  
13 quantifiers. Badly presented numbers are  
14 worse than well-presented numbers. We know  
15 that emotions have a proper orienting  
16 function, but we know that emotions can also  
17 confuse people and make them not want to list.

18                   The late Herb Simon had -- well,  
19 he's no longer around to contradict me, but he  
20 had a way of thinking about the social  
21 sciences, which I hope that he would do that,  
22 he says that people are governed by very

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1 simple rules so that when, you know, you do  
2 good psychological or sociological or  
3 anthropological research, that people resonate  
4 to that. Yes, sometimes I am kind of  
5 paralyzed and sometimes I really want to know  
6 more about that and wish they weren't hiding  
7 it from me. But those simple principles,  
8 there's a lot of those simple principles. We  
9 don't know which of them are triggered in any  
10 natural situation. That's part of our  
11 research in generalizing from the lab to the  
12 world. And they interact in complicated ways  
13 so that there isn't going to be a general  
14 predictive social and behavioral science of  
15 how this works. What we want to know is  
16 what's the best that we can do in some  
17 specific situation? So what's the best we can  
18 do with, you know, windows of opportunity of  
19 three levels, for food recalls, for, you know,  
20 processed products. I'm guessing it might be  
21 different for processed products where, you  
22 know, peanut butter is kind of an industrial

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1 chemical as opposed to places where you get  
2 the lettuce and you think you can wash it  
3 yourself.

4 So seems to me that I would be more  
5 comfortable, you know, continuing the  
6 discussion that we had at the end of  
7 yesterday, which is, you know, how do we help  
8 FDA to do the development? And how do you,  
9 you know, produce things that will help people  
10 do their job. And the research questions in  
11 some sort of general sense are relevant to  
12 thinking of what are the kinds of FDA  
13 scientific expertise that FDA absolutely has  
14 to have on staff or on tap in order to be able  
15 to do this. So we know that, you know,  
16 literate health, nutritional literacy is  
17 absolutely essential because it tells you  
18 what, you know, kind of mental models, what  
19 information people bring to it so that you can  
20 do a first draft of a communication on a  
21 food-related product that gets in the ballpark  
22 of one that you could then refine through

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1 iterative testing. So clearly, you know, I  
2 would say you need to know people who have  
3 those kinds of expertise here, In order to get  
4 those kinds of people with those kinds of  
5 expertise, you may very well need to have an  
6 intramural research program which is pushing  
7 the frontiers of literacy, numeracy research,  
8 emotions research, whatever it is, so that  
9 you'll get people who really love science,  
10 really are on top of the literature, have  
11 incentives for staying on top of the  
12 literature because they want to continue  
13 publish -- or willing to deal with some of the  
14 day to day drudgery, you know, that goes with  
15 being in a regulatory agency, but see these  
16 great opportunities not only to help the  
17 American people, but also to say we're going  
18 to collect all of this data and some of it's  
19 going to be publishable and I won't get  
20 exactly the study I want, but I will get an  
21 enormous diverse sample that I could never get  
22 a university. So if you have a strong

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1 intramural research program on the areas that  
2 were most important, you could get in some of  
3 the top people, you know, who are well  
4 networked and can call up their former  
5 advisors or former students and say, you know,  
6 what do we know about this specific topic?

7           So anyway, and I kind of sort of  
8 hate to preempt the discussion, but I was  
9 trying to think of where do I say this? You  
10 know, well let's all talk about it, and I say,  
11 nah, none of that. Wait to the end of the  
12 discussion and say, nah, I think this was  
13 going in the wrong direction. Or just to put  
14 it out there that I think that FDA most needs  
15 to help in organizing and in bringing on staff  
16 or on tap the people who know these topics  
17 that you all had a gut feeling were absolutely  
18 essential.

19           DR. OSTROVE: Okay. We knew that  
20 this was going to be difficult and I do  
21 appreciate, you know, that notion about moving  
22 forward on this.

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1 I would like to hear what the  
2 Committee as a whole has to say about that. I  
3 like that approach. I would like to ask that  
4 there be a focus on kind of the internal piece  
5 of it because I think we heard a lot yesterday  
6 about partnerships with other groups. And I  
7 think that we do need to talk more about what  
8 we need internally and not just about, you  
9 know, having people internally who can partner  
10 with others that are working externally.

11 CHAIRMAN FISCHHOFF: Yes. So in  
12 that spirit let me say that, one, if nobody is  
13 doing anything, then FDA needs to start. And  
14 I think actually on the question of  
15 partnerships, of distribution, of how do you  
16 reach people, I think that that work isn't  
17 being done. So there would be a case where  
18 there would be a void that FDA could do. So  
19 we're not resolving this question of whether  
20 you want a research or a development focus, if  
21 we use that terminology. You know, we can  
22 sort of talk about topics that would be really

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1 nice to know more about. The things that are  
2 most pertinent FDA may be places, there may be  
3 specific topics where it would be nice to do  
4 that work internally, but we can say these are  
5 areas of expertise where FDA needs to staff  
6 up. And let's say we can think about these  
7 topics in both senses, both specific research  
8 and general areas of expertise. And then, you  
9 know, you all will go off and, you know,  
10 resolve, you know, I'll let you guys do it.

11 DR. OSTROVE: Yes. No, that sounds  
12 good. And I should clarify what I meant by  
13 partnership. I meant research.

14 CHAIRMAN FISCHHOFF: Oh, okay.

15 DR. OSTROVE: I meant partnerships  
16 with external research.

17 CHAIRMAN FISCHHOFF: Oh, okay.

18 DR. OSTROVE: You know, the AHRQ  
19 and NIH, NCI, CDC. That's what I meant.

20 CHAIRMAN FISCHHOFF: Okay.

21 DR. OSTROVE: I mean, I absolutely  
22 believe that the other partnership, I mean --

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1 CHAIRMAN FISCHHOFF: Yes.

2 DR. OSTROVE: That's the problem  
3 with having the same word for two very  
4 different things.

5 CHAIRMAN FISCHHOFF: Yes. Okay.  
6 Yes, I was thinking about the other kind of  
7 partner. And from what we learned yesterday,  
8 that Mona is on everybody's list, but there's  
9 lot of people who are nobody's list, and then  
10 how do we find them.

11 So, Michael?

12 MEMBER WOLF: I'm just going to  
13 comment, I mean, I really do appreciate the  
14 workload that the FDA has to kind of overcome  
15 and I do agree that, you know, talking about  
16 development versus research, but when you  
17 really think about it, the FDA is really kind  
18 of the quintessential like learning  
19 environment where you have this opportunity  
20 for being this kind of open source system  
21 where you definitely need something internal  
22 to be able to like see through a series of

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1 natural experiments how you're learning and  
2 how you can build off of the last piece. So  
3 having that kind of risk communications core  
4 within your group to identify, I mean I don't  
5 know if you can really go through and looking  
6 at the discussion topics -- I mean, you could  
7 go in for an endless list of what the research  
8 topics should be and those are going to be  
9 continually changing. And you just need to  
10 have that infrastructure in place, but I guess  
11 the question to ask you is, you know, thinking  
12 back to the research literature that I know  
13 and the work that I do, I mean, the FDA has  
14 had a fairly strong presence with regards to  
15 both having -- I mean, I'm thinking of people  
16 working on everything from the Med Guides to  
17 the information sheets and going back. And I  
18 thought there was a lot the people, the  
19 coauthors on publications partnering with the  
20 University of Wisconsin Pharma School,  
21 pharmacy and the like. They've always had a  
22 very strong presence in that regard.

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1           So I guess I'm not really sure I  
2 know exactly what currently exists internally  
3 as far as what kind of core that would be  
4 pulled in. I mean, clearly you're going to  
5 need your communications, cognitive behavioral  
6 scientists being able to pull into it.  
7 There's always going to be people like many of  
8 us here that are academics, whether there is  
9 funding up to -- directly through the FDA or  
10 through somewhere else, or just on our regard,  
11 or are we going to be doing work that's  
12 relevant probably to the FDA in which you're  
13 going to be able to be pulled in and informed  
14 on.

15           So I guess I don't know what you  
16 currently have to really kind of say what you  
17 need to add onto it and I don't know if you  
18 have a moment to speak on that.

19           DR. OSTROVE: I can tell you what I  
20 know and what we currently have is we have a  
21 consumer studies team in the Center for Food  
22 Safety and Applied Nutrition. And that team

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1 is focused on consumer studies around  
2 food-related issues. And it is composed of a  
3 variety of individuals. There's a social  
4 psychologist in there. We've got  
5 sociologists. We've got economists, people  
6 who have a public health and food-oriented  
7 public health perspective. We also have a  
8 separate set of economists who tend to work  
9 more on regulatory issues, but also do  
10 research, but their research is really more  
11 focused on regulations.

12 Also in that center we have what  
13 has been an expanded communications group with  
14 an education team and an outreach team that  
15 deals more with crises. And if there's anyone  
16 on the audience from FDA and I'm completely  
17 getting this wrong, they should let me know.  
18 So there's that research, that oriented team  
19 that is really very multidisciplinary in our  
20 food center.

21 We then have a team of three; count  
22 them, three psychologists in the Division of

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1 Drug Marketing, Advertising and Communications  
2 within the Center for Drug Evaluation and  
3 Research. And it's three now. It used to be  
4 two and they just recently got a new person  
5 and at least two of them, possibly all three,  
6 are social psychologists.

7 And that is the group that I  
8 started in at FDA and Baruch knows Lou Morris  
9 basically started that and Craig also knows  
10 that Lou started that group. And that is the  
11 group that's done the research around direct  
12 to consumer advertising, patient labeling.  
13 When I was there we were doing work with  
14 physician labeling that ended up supporting  
15 the revision to the current prescribing  
16 information. So there's that group.

17 We have someone who is kind of a  
18 new researcher in the Office of  
19 Nonprescription Drug Products who mostly does  
20 review of label comprehension and actual use  
21 studies, and provides policy input into that.

22 And then there's me. And we are getting a

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1 couple of new survey, mostly survey, people  
2 with survey background into my little staff.

3 And we also, in the Center for Drug  
4 Evaluation and Research, have a group of  
5 individuals with like survey statistician  
6 background who review patient labeling,  
7 medication guides, patient package inserts.  
8 Their focus is not on research, although one  
9 of them, Jodi Duckhorn, was the lead on and  
10 spoke to this Committee the last time around,  
11 kind of the project officer for the study that  
12 evaluated the CMI program.

13 MEMBER WOLF: Okay.

14 DR. OSTROVE: Okay? But again,  
15 they're not focused on research. They really  
16 are focused more on applying what we know to  
17 reviewing the prescription drug labeling for  
18 patients and consumers.

19 MEMBER WOLF: You identified them  
20 in multiple different departments, so they're  
21 dissipated.

22 DR. OSTROVE: Yes.

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1                   MEMBER WOLF:   And the capacity is  
2 maybe questionable, too, whether or not you're  
3 at capacity to cover everything you need to?

4                   DR. OSTROVE:   Right.   No, I would  
5 say we're definitely not.   I mean, we do also  
6 have a group called the Social Science Forum,  
7 of which these people are part of, and we meet  
8 quarterly to discuss the research that we're  
9 doing.   So we have been trying to do a better  
10 job of kind of making sure that everyone kind  
11 of talks to everybody else and we learn from  
12 each other's work.   But it is very small and  
13 fairly fragmented in the sense that there is  
14 like, you know, a few groups across mostly the  
15 Center for Foods and the Center for Drugs  
16 within the Agency.   And again, there are some  
17 people who are focused on the communications  
18 in the Office of Women's Health and they  
19 contract out the focus group testing that they  
20 do of the materials that they put together.  
21 But, you know, their focus is on education and  
22 communication.   And each of the centers has

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1 its own communications group which oftentimes  
2 it's combined with the public affairs  
3 function.

4 MEMBER BRUHN: Nancy, forgive me  
5 for not being current on the contemporary  
6 acronyms. How closely are you able to work  
7 with USDA. I think of Susan Welsh who's in  
8 the nutrition area. I have a regional  
9 research project that looks at nutrition and  
10 we have an administrator who is our contact.  
11 And thinking of the area of research with  
12 motivation, Susan and others like her are the  
13 contact person for a number of projects that  
14 are being done across the country in the  
15 nutrition arena, many of which address  
16 obesity, but not all, and many have a common  
17 component of communication and motivation that  
18 are part of them. And I think that the  
19 findings could feed the research needs that  
20 you are addressing.

21 And then of course in USDA, the  
22 CSREES program leader in food safety is Jan

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1 Singleton and she is the contact person the  
2 numerous USDA grants, some of which pertain to  
3 consumer issues and food safety.

4 DR. OSTROVE: I would say that  
5 actually our people in CFSAN are very well  
6 connected with USDA. I don't know about the  
7 specific individuals because I'm just not on  
8 the ground there. But they're fairly well  
9 connected with USDA. And actually, the people  
10 in the foods group are the most well connected  
11 -- well, the people in the foods group and the  
12 DDMAC, the drug advertising people, are the  
13 most well connected with the academic  
14 community in general. As Craig can tell you,  
15 they generally appear at the annual conference  
16 of the public -- what is that Craig?

17 MEMBER ANDREWS: Marketing and  
18 Public Policy.

19 DR. OSTROVE: Marketing and Public  
20 Policy Conference. And are out there kind of  
21 encouraging academics to be active in this  
22 area as well. So, I mean, I'll pass the names

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1 on, but my suspicion is that our researchers  
2 in CFSAN who are really quite active probably  
3 do have those, yes.

4 MEMBER ANDREWS: I had a quick  
5 question, Nancy. Is there any coordination  
6 among, for example, DDMAC, CDER, the food  
7 side, where they might get together on some  
8 research issues? Has that occurred, or do we  
9 have, you know, really separate areas and  
10 separate issues?

11 DR. OSTROVE: In some ways that  
12 would be kind of more what I'm trying to do.  
13 You know, it's more of the cross-cutting  
14 issues, should they happen. Generally, the  
15 foods and the drugs people, I mean, they're so  
16 overwhelmed as it is, you know, that they  
17 really do need to have a focus on their own  
18 stuff. But they will work together. We had a  
19 couple of focus group studies, for instance,  
20 looking at some of the communication materials  
21 that are up on our website regarding emerging  
22 risks, where we brought in people from, you

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1 know, as kind of a capacity issue, brought in  
2 people from foods who had an interest. So  
3 there is some interaction there, but they  
4 still, you know, tend to be -- the actual  
5 research tends to be product-focused.

6 MEMBER ANDREWS: There are many  
7 best practices out there, and sometimes it's  
8 tough, and reinventing the wheel, so to speak.

9 One practice I've been familiar with, and we  
10 had a discussion about this a few minutes ago,  
11 was the National Youth Anti-Drug Media  
12 Campaign with ONDCP, which we really felt was  
13 really the gold standard on communication, at  
14 least on the process. But the developmental  
15 issues are very, very important.

16 So for example, the objectives.  
17 Theirs are very clear, almost too clear, on  
18 belief change. At that time, it was regarding  
19 various drugs, marijuana, and intent to use.  
20 And all the communication was eventually copy  
21 tested and tracked on those particular  
22 objectives.

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1           But going back on the process, we  
2 had a behavioral change expert panel with a  
3 lot of stakeholders feeding into a creative  
4 brief. And from that, a lot of focus groups  
5 on various areas, much like, let's say, if you  
6 have health literacy issues, other  
7 populations, which fed into copy testing, and  
8 the campaign and the ads never aired unless  
9 they passed those objectives, and being  
10 significantly moving those particular  
11 objectives versus control groups. And then  
12 finally, tracking. So it was really a gold  
13 standard. But you needed the expertise,  
14 including media specialists. For example, you  
15 were talking about testing various  
16 communication. I don't know to the extent  
17 that you get involved with media specialists  
18 at all. But consumer research folks, you  
19 know, behavioral scientists, just the whole  
20 group.

21           And so I just thought I would put  
22 in a plug for them because, you know, you do

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1 have agencies out there where maybe they've --  
2 and it's not exactly the same thing as far as  
3 what they're doing. But certainly there is  
4 that expertise out there.

5 MEMBER LAWSON: I'm just throwing  
6 this out for maybe for us to look at. It  
7 sounds to me that you would like, Nancy, you  
8 would like for us to kind of look at the  
9 research capability, internal capability, and  
10 that maybe there is a need for us to do that.

11 And you have cited where some of the staff  
12 experiences are within the centers, but when  
13 you talk about risk communication, you're it,  
14 it sounds like. That's it. And so maybe, and  
15 I'm throwing this out for -- because research  
16 is not my level of expertise, but maybe we  
17 should be looking at what recommendations  
18 could be made to build up the Office of Risk  
19 Communications within FDA.

20 MEMBER PETERS: Just to sort of  
21 continue what Madeline's saying, it sounds to  
22 me from this conversation that, as we were

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1 talking about yesterday, capacity is a huge  
2 issue here. And really in terms of everything  
3 we've talked about, that capacity in a variety  
4 of ways is the big issue. And I guess the  
5 question that I'd ask back to you is, what can  
6 we as a committee do to help provide you with  
7 justification that will allow you to get that  
8 additional capacity, potentially?

9 DR. OSTROVE: Yes, this is kind of  
10 uncomfortable. I mean, because the purpose of  
11 the Committee, you know, and I appreciate all  
12 of this, but the Committee's purpose -- I  
13 doubt that it would be well received, you  
14 know, for me to come back and say, well, the  
15 Committee said you need to have me build up my  
16 staff. It's just, you know, there's too much  
17 of a vested-interest-kind of looking thing  
18 there. It's just not going to fly.

19 Plus, so I guess, you know, from a  
20 strategic standpoint, I guess, you know, it  
21 would be useful to know what the different  
22 varieties are of the expertise that we need.

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1 It doesn't necessarily need to be, you know,  
2 at the Office of the Commissioner level. I  
3 mean, that's something I think that the Agency  
4 needs to decide as to where that capacity  
5 should be located. But certainly, you know,  
6 what we need, the kind of expertise that we  
7 need would be welcome. Does that kind of  
8 help?

9 MEMBER PETERS: Yes. Could I  
10 follow up? Okay. So it sounds like part of  
11 what we can do is talk about what the research  
12 needs are that we see, and that comes very  
13 much from the various expertises that we have  
14 around the table. There are two different  
15 ways of looking at that, and I guess we can  
16 maybe think about it both ways. One is, in a  
17 more global sense, what are the kind of  
18 research needs that we see the FDA as having,  
19 whether or not the capacity exists. And then  
20 a second level of that question is, given the  
21 capacity that we at least understand exists,  
22 are there ways of sort of asking for less that

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1 maybe your system can handle. You know, so we  
2 can kind of look at it more globally, or we  
3 can look at more in terms of what actually  
4 exists there. Does that sound --

5 DR. OSTROVE: Yes. Yes. That's  
6 sounds -- were you asking me to make a choice?

7 I didn't think there was a choice there. But  
8 it all sounded good.

9 MEMBER PETERS: Yes, not a choice,  
10 but just I guess really the question is, I  
11 think as a committee what we would want to do  
12 is look at it in terms of an absolute level.  
13 From what we've seen in terms of the risk  
14 communication needs, what we believe the FDA  
15 needs in terms of the science, and therefore,  
16 there's capacity that needs to go with that.  
17 That's probably where we would go as a  
18 committee.

19 You have more pragmatic needs on a  
20 day-to-day basis, and so I guess my question  
21 to you is, do you want us to also try to deal  
22 somewhat with that more pragmatic level?

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1 DR. OSTROVE: I think the first  
2 piece is the most important, from what we can  
3 get from you all. The pragmatic stuff, we're  
4 going to have to deal with the pragmatic stuff  
5 ourselves.

6 CHAIRMAN FISCHHOFF: So let me  
7 suggest as possible nomenclature that we use  
8 expertise needed in terms of the kind of  
9 people that need to be at the table who, you  
10 know, you can't guess what somebody who'd --  
11 you know, somebody who deals with social  
12 disparities, they have to be at the table.  
13 They have to tell you how they see the world  
14 through their eyes, just like you need  
15 somebody who does decision analysis, or  
16 whatever needs to be at the table. Because  
17 you just don't know what they are. So maybe  
18 we ought to think about expertise needed in  
19 terms of the staffing, and it's something  
20 that's none of our business. We can't really  
21 offer an informed opinion where that should go  
22 in the organization. We can just tell you

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1 what the expertise is, and then research  
2 needed. So the people who have the expertise  
3 who'll be capable of doing certain kinds of  
4 research. And then we have the separate topic  
5 of research that FDA needs to do because  
6 nobody else is doing it.

7 And then to go back to my previous  
8 -- you know my opening statement, that there  
9 may be research that's already being done, but  
10 FDA needs to do it in order to get people with  
11 the requisite expertise on its staff, because  
12 they'll only come if they get a chance to do  
13 research as well as being in it. So that  
14 might be a way of -- let me just say that from  
15 the top. So I kind of was thinking out loud  
16 that FDA needs certain kinds of expertise. It  
17 may only be able to get that expertise in part  
18 by doing research that is part of research  
19 that's done elsewhere, but it may be there's  
20 some kind of research that FDA needs to do  
21 because nobody else is doing it.

22 Okay. Betsy?

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1                   MEMBER SLEATH:        One area of  
2 expertise I thought of while you were talking  
3 about the recall example where people knew  
4 there was a problem but didn't do anything, is  
5 I think you need someone with expertise in  
6 theories of health behavior and health  
7 education, because there's different  
8 theoretical frameworks out there, like the  
9 health belief model, the theory of planned  
10 behavior, as to why people do or don't do  
11 stuff. And that could help ground some of  
12 your, you know, messages out to the public,  
13 and also evaluations of what people get and  
14 what they don't get. Like maybe you  
15 emphasized one area too much and didn't talk  
16 about their possible perceived susceptibility  
17 to it or that kind of thing.

18                   Then another thought, I agree with  
19 Baruch about attracting people. Because for  
20 example, I had an excellent colleague at UNC  
21 who left and went to AHRQ, and part of why he  
22 went is he got to work with people on projects

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1 across the country, but he also got to have  
2 his own research program, exactly what he's  
3 talking about.

4 And another idea I thought of,  
5 because colleagues of mine in pharmacy schools  
6 that are more basic science sometimes do  
7 sabbaticals I know with you at the FDA is  
8 maybe starting a program in the behavioral  
9 area. And then I wondered if there's other  
10 regulatory bodies similar to you in other  
11 countries that maybe you can see what they do,  
12 because, you know, with Theo Raynor at the  
13 last meeting from the United Kingdom, and I  
14 know Australia is doing stuff on communication  
15 about medications. So those were just some  
16 thoughts that I had.

17 MEMBER GOLDSTEIN: So I would agree  
18 that it's really important for us to think  
19 about the strategy along with the discussion  
20 about the research priorities. And my only  
21 concern about putting aside the work that the  
22 FDA can't do by themselves, the whole area of

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1 the dissemination research agenda, is that if  
2 we don't also include those aspects in at  
3 least our discussion, then there will be no  
4 way for that work to ever get done. So that  
5 would be my concern from a strategic  
6 standpoint. If we focus only on what FDA can  
7 potentially do themselves, and maybe  
8 commission themselves, and don't talk about  
9 the larger questions about how we change, not  
10 just the behavior of individual people when  
11 they receive a message, but get that message  
12 out to populations and talk about the health  
13 care system, and how we could integrate it  
14 with the health care system, then who's going  
15 to do that research? So it's important that  
16 we still -- you know, I agree we need to be  
17 focused on what's possible and achievable, but  
18 if we're giving a message as a committee about  
19 where the research needs are, and we don't  
20 say, we need a huge large scale study that  
21 AHRQ has to do and commission with FDA, that's  
22 going to cost millions of dollars all by

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1       itself to do, because that's what it would  
2       cost, then nobody's every going to fund it.  
3       So that's my concern.

4                   CHAIRMAN FISCHHOFF: Describe that  
5       study.

6                   MEMBER GOLDSTEIN: Well, it would  
7       be in a particular area, say risk  
8       communication about drugs for diabetes, and we  
9       do it in a number of health care settings  
10      where we test different strategies of helping  
11      clinicians, patients and the system to get  
12      messages about risk out to their patients, and  
13      we test not just the message, but also the  
14      system for delivering that message, whether  
15      it's an expert system, or it's a training  
16      program, or a combination of those. And the  
17      outcome is change in health behavior, the use  
18      of medication safely by the patient  
19      population. That's going to cost a lot of  
20      money. It's going to require thousands of  
21      patients, teams across -- delivering  
22      interventions, designing interventions. It's

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1 a big study.

2 And we do that for smoking  
3 cessation interventions. I was part of the  
4 group of studies that was funded by NCI, the  
5 physician- delivered smoking cessation  
6 interventions. We were just testing simply  
7 how to deliver a message to patients about the  
8 value and the importance of smoking cessation.

9 That was in the late 1980s, and each project  
10 in the RFA that NCI funded got \$5 million over  
11 five years. That's \$25 million for that one  
12 effort to try and disseminate smoking  
13 cessation interventions within primary care  
14 settings. That became the basis for  
15 subsequent research, and the whole AHRQ  
16 guideline on smoking cessation was based on  
17 that. It had tremendous impact over the  
18 subsequent course, but it cost \$25 million in  
19 1985 to fund that. That's not going to happen  
20 without somebody deciding this is a priority,  
21 and we need to fund dissemination research at  
22 that level.

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1                   CHAIRMAN FISCHHOFF: Can I offer a  
2 bit of a paraphrase and then a question to  
3 Nancy?

4                   My guess is that you're saying some  
5 of that's none of our business, and would  
6 argue that this would be -- that is, there's  
7 some of the doctor/patient stuff. So ensuring  
8 that doctors understand I'm guessing might be  
9 FDA's, but some of the things are not FDA's,  
10 without trying to understand the law. But  
11 what Mike is saying, you know, so sort of an  
12 amendment of that, or maybe an implication of  
13 that, if this is done so that FDA, I'm  
14 guessing, has an interest in seeing that  
15 there's appropriate communications and use  
16 about regulated products, that the  
17 communication part of that, you know,  
18 particularly the on-label communication part  
19 of that, is squarely in FDA's thing. And FDA  
20 is interested in communicating to patients and  
21 to physicians how patients then transfer that,  
22 or how other intermediaries in the community

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1 do that. That might be a little fuzzier about  
2 whether that's FDA's job, but this might be  
3 the job of a partner, like AHRQ or somebody  
4 else.

5           And that in Mike's kind of think  
6 big spirit, that one or two landmark studies  
7 that took a couple of drugs where we've got,  
8 say a drug or two where we've got the  
9 potential, you know, and the potential isn't  
10 being realized because people don't adhere to  
11 it, or they don't do whatever else. Or we've  
12 got the potential, but we don't know how to  
13 control the risks, because there are other  
14 populations that got to it, and actually  
15 demonstrated what it took to really work that  
16 problem. Not little lab studies, but actually  
17 in situ with diverse populations, you know,  
18 working the full, you know, Web 2.0, or  
19 whatever. You know, the full kind of social  
20 -- you know, all that we know that there would  
21 be, you know, just like as people have  
22 learned, people in other areas who haven't had

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1 the resources to do the smoking cessation,  
2 have learned behavioral principles that then  
3 could be applied other places.

4 So you know, that I think would be  
5 the spirit. Because the resources have been  
6 so constrained here, you know, we're thinking  
7 very small, and that maybe, you know, we as a  
8 committee ought to take Mike's spirit and  
9 think big about what it would take to really  
10 address these problems. And you know, we'd  
11 have a lot of winners, including the regulated  
12 industries might support this.

13 DR. OSTROVE: And I would not  
14 discourage that, you know, in terms of  
15 thinking big. I think that, you know, the  
16 issue is ultimately going to be where the  
17 Agency's priorities are.

18 Now with a new administration  
19 coming in, and you know, potentially lots of  
20 changes on the horizon, clearly there's been a  
21 lot of funding that's gone to various places,  
22 not to us, but to various places from the

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1 Recovery Act, I would say that it's definitely  
2 worth getting on the public record that that  
3 is something that the Committee believes is  
4 important for FDA to consider.

5 Being completely honest, I'm not  
6 sure that it would take priority over, you  
7 know, some of the things that are more  
8 directly applicable to our day-to-day  
9 functioning and our putting out the various  
10 fires that need to be put out in hopefully the  
11 most effective fashion, you know, and dealing  
12 specifically with the things for which we have  
13 oversight, you know, for which we have a  
14 mandate, basically, that we need to do. Which  
15 is not to say that we shouldn't be working on  
16 these other things, as well. It's just a  
17 matter of where they stand in terms of  
18 priorities. I have no objection to it being  
19 discussed. I think it's important to get all  
20 that out here. I wish there was a better  
21 forum in some ways, you know, that it was not  
22 an FDA-focused forum for you to be able to

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1 talk about this, because I think it is  
2 important.

3 MEMBER GOLDSTEIN: Can I just  
4 respond? And this leads to, you know, we can  
5 table this kind of a conversation. Say we  
6 need a different forum for this, because I do  
7 agree, we can't even fully have this  
8 conversation without, I would suggest, the  
9 strategic piece where, within FDA and higher  
10 even, a decision is made, yes, this is  
11 important enough that we want to take a next  
12 step. And a next step might be to sit down  
13 with AHRQ, for instance, and talk about how  
14 does what's our priority fit with your  
15 priority, and how could we design together a  
16 study that will work for us that we can't do,  
17 but you guys could do. And that would be the  
18 right forum probably. But we first have to  
19 put it on the agenda as being something that's  
20 important enough so that it gets taken to the  
21 next level as, not a priority for day-to-day,  
22 but a priority to answer questions that we

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1 need to answer in order to meet our mission,  
2 which is to make sure that people use drugs  
3 safely and effectively.

4 DR. OSTROVE: And I guess I would  
5 kind of throw that back to the Committee to  
6 decide whether, you know, is that something  
7 that, you know, they feel that should be a  
8 high priority for FDA to do.

9 MEMBER PALING: This has been a  
10 most revealing discussion. When Baruch, our  
11 chair, started his introduction, he used the  
12 word "sagacious," which is in fact what I  
13 found it to be. I was going to make a  
14 flippant comment. Almost everything he said I  
15 felt myself saying, gosh, I hadn't thought of  
16 that, but I do agree with it. That's really  
17 true.

18 And then I looked across at Nancy,  
19 and I thought of the personal elements of  
20 this. One of the things I said yesterday  
21 morning early on is how impressed I, and I  
22 know other Committee members are, with the

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1 document that you've produced. I'm also  
2 empathetic enough to know how exhausting the  
3 work has been for you and your colleagues, and  
4 you sort of pushed this great thing up the  
5 mountain with huge effort. And now there's  
6 another big set of steps that are going to be  
7 required of you, which if it were me, would  
8 certainly be overwhelming. And so I'm very  
9 sympathetic to that, and I want our advice to  
10 be practical. And at the end of perhaps two  
11 other remarks, I'm going to think small and  
12 try to address the specific that you asked.

13 The general comments are that I  
14 think, in the way that I really do empathize,  
15 it wouldn't look good us recommending that our  
16 good friend and colleague Nancy gets more  
17 staff. I do think it is inherently crucial  
18 that, since we're dedicated to trying to  
19 improve risk communication in the FDA, and  
20 this document is being produced, at the end of  
21 this meeting somewhere, we put a motion on the  
22 table acknowledging it, stating our

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1 recognition of how much work is involved, and  
2 stressing how important we think it to be. I  
3 don't think that's a platitude. I think the  
4 Department needs to know that, because really  
5 they've done a huge amount. This is in no way  
6 intended as flattery, as I know you know I can  
7 be very critical at times. But I really think  
8 that's one positive simple thing that we can  
9 do to make it realistic.

10 The next thing is I think there are  
11 other important things that we're not  
12 discussing today that also should go as a top  
13 priority for FDA, and I won't digress to do  
14 those.

15 Now my small thing. I don't know  
16 the literature as well as colleagues around  
17 the table, but to my mind, the least  
18 researched and most important of the various  
19 strategies that you list was improving our  
20 ability to both see when there is effective  
21 understanding, and to evaluate effectiveness.

22 So of all of those lists, I think all of

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1 those items on the list, to my mind,  
2 intuitively I'd suggest those are by far the  
3 two topics that should be prioritized of those  
4 that you put on the table.

5 MEMBER KHANNA: I would just like  
6 to make a comment about an item that I don't  
7 think that the FDA needs to be involved in,  
8 and I'll give you my rationale.

9 And that is, if you look -- on your  
10 talk today, Nancy, where you said, what are  
11 the questions, motivating audiences is  
12 specifically the topic that I'm arguing  
13 against investing a significant amount of time  
14 and resources in. And the reason is this:  
15 There's I think a significant body of social  
16 science literature about how do you motivate  
17 people, and I'm going to give you an example  
18 of what's happening in the private industry  
19 right now with corporations. They're looking  
20 at their health care costs and they're saying,  
21 boy, if our own employee body was able to  
22 reduce their blood pressure on an average by

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1 four millimeters of mercury systolically, that  
2 would possibly save X amount of money. If on  
3 a population level we were able to reduce our  
4 cholesterol, or reduce our weight, et cetera,  
5 et cetera, we have all this modeling that can  
6 be done, we could save significantly on health  
7 care costs, on insurance premiums of employees  
8 on an individual level can save on co-  
9 payments, prescription medication, et cetera,  
10 et cetera. Why aren't people doing it?

11 So when folks have their health  
12 status, which is at risk, when they can prove  
13 a good example for their children, when there  
14 are social advantages to being healthier, when  
15 they can save money from not smoking, we still  
16 have problems with motivating people as  
17 patients to do the right thing, despite the  
18 significant body of literature that we have,  
19 and despite the fact that there's direct and  
20 indirect financial costs to all these  
21 unhealthy behaviors. So I would suggest that  
22 that be taken off of the FDA's plate in terms

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1 of strategic interventions, or when we talk  
2 about capacity, just because it is so big, and  
3 there is so much out there, and you know, at  
4 this point, it's still a difficult question.

5 So when we talk about including  
6 things, I just wanted to make a suggestion of  
7 something we could possibly exclude. And when  
8 you think about the purpose of this committee  
9 to communicate risk, we want to make sure that  
10 we put the information out there about  
11 medications, and devices, and biologics, and  
12 that we want to ensure that audiences  
13 understand that. So I can see putting the  
14 research towards studies and focus groups that  
15 make sure that that information is given and  
16 understood. But as to that next step of what  
17 the audiences do with it, that would be an  
18 area I think that we could let go.

19 MEMBER PETERS: I think, Mona, that  
20 it depends on what they mean by motivating.  
21 Because for example, in some of the research  
22 that I do in number processing, I can ask

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1 people to locate the number six percent in a  
2 table and repeat it back to me. And that's a  
3 very simple version of understanding of  
4 information. It's comprehension. But  
5 depending upon what other information I  
6 present around it, the meaning of that six  
7 percent is very different. Whether it's good  
8 or bad depends upon whether it's in the  
9 context of the average risk is 12 percent and  
10 yours is six percent, or the average risk is  
11 three percent and yours is six percent. And  
12 so I'd argue that the definitions of  
13 comprehension and motivation have to be looked  
14 at carefully. So it's not just comprehension  
15 of a fact. It's comprehension of the meaning  
16 of information, and comprehending that meaning  
17 of information changes how motivated people  
18 are to do something. And so I'm not quite  
19 sure what your definition of motivation is.  
20 My definition of motivation would include this  
21 information processing level where you help  
22 people to understand, not just the facts, but

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1 also the meaning behind the facts.

2 And just in that vein, some of the  
3 expertise that I think is needed here at the  
4 FDA perhaps a bit more are some people who  
5 understand more about information processing.

6 Information processing in terms of how  
7 different formats of information or different  
8 contexts of information will change  
9 comprehension of facts as well as meaning.  
10 But also information processing in terms of  
11 health literacy issues, whether it's reading  
12 literacy or numeracy.

13 But in addition, and we've talked  
14 about this a little bit before, because a lot  
15 of pharmaceuticals are used by older adults,  
16 and a lot of the research is based on younger  
17 adults, I think you need some expertise in  
18 terms of how information processing changes  
19 across the life span, because that's critical  
20 to the people who are using the bulk of the  
21 pharmaceuticals.

22 MEMBER BRUHN: I appreciate your

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1 efforts to narrow the list of things to do,  
2 but I'm also going to defend the need for more  
3 research on motivation.

4 We see so often when people know  
5 the correct behavior but don't follow it. You  
6 know, for me, how to move people to adopt what  
7 I would consider a doable behavior is most  
8 important. We haven't cracked that shell.  
9 But I concur that maybe it's not what we  
10 should ask the FDA to do. In fact, I would  
11 suggest that we keep the request for FDA to do  
12 research in these various areas to a bare  
13 minimum. It is too cumbersome. It is just  
14 plain too cumbersome for them to do anything  
15 in the area of research because of all their  
16 OMB restraints. I suggest, however, that they  
17 should let others know this is really an  
18 important area where research is needed, so  
19 that they can then pursue those partnerships  
20 we discussed yesterday and have been discussed  
21 before.

22 So my recommendation would be to

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1 keep the research that is actually conducted  
2 by FDA to a minimum, but for them to say these  
3 are critical areas where additional  
4 information is needed so that we can be more  
5 successful.

6 And I really do embrace the  
7 suggestions that Michael Goldstein had  
8 provided about partnership with other groups  
9 that have dollars to initiate a change, and I  
10 don't go to NIH. That's not where I go. But  
11 would that be an area where they might be  
12 appropriate? So you know, talking about it,  
13 urging from FDA's side and from other  
14 professionals, organizations and individuals  
15 who can say, this is really an important area  
16 to look at, and the research can have  
17 implications in many health-related behaviors.

18 The diabetes is when they're in -- diabetes  
19 is growing, you know, weight control, physical  
20 fitness. I mean, some of this motivational  
21 work can be applied in so many different  
22 areas. But that need should be elevated.

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1                   MEMBER KHANNA: Just very quickly,  
2 and that's what I was speaking to was, given  
3 the limited resources of the FDA, I wasn't  
4 suggesting that all research come to a  
5 grinding halt. Just what was on their radar  
6 screen and what they were able to do  
7 internally.

8                   MEMBER FINCH: I want to also  
9 support the notion of keeping the motivation  
10 audiences involved. We've seen on many  
11 levels, for example, infant mortality, that  
12 out of educating comes comprehension, and  
13 comprehension has fallen out to be, well,  
14 women don't douche anymore because that  
15 impacts the fetus. So learning that has  
16 motivated them to stop douching. Diabetes,  
17 learning the causes of diabetes has helped  
18 people to put in components of exercises and  
19 watching a diet.

20                   So I think motivation based upon  
21 education and comprehending those levels, of  
22 different levels of education that's out

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1 there. The health literacy information has  
2 been effective. So I would recommend that we  
3 keep this portion in the FDA work.

4 And I agree with Michael that maybe  
5 there needs to be some level of partnership  
6 with other agencies that are doing that well  
7 where the bulk of the work doesn't fall upon  
8 the small staff that you have.

9 MEMBER WOLF: Yes, I just want to  
10 make sure to get on the record that I  
11 completely support the direction that  
12 Christine had mentioned that this is something  
13 that you need to maybe more downsize. But at  
14 the same time, speaking to Ellen, and I think  
15 Ellen well articulated that the areas of  
16 expertise that you need to have on staff to  
17 engage with the academic community, and those  
18 doing research in other federal agencies and  
19 what not to learn what is going, what is  
20 cutting edge, what is best practice. And also  
21 a point that I think Christine made that was  
22 again just -- I'm just underlining here, not

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1 really adding much more, but that the idea  
2 that, as much as you can be in a position to  
3 inform the directions, the program  
4 announcements, the RFAs, the research agenda  
5 that should be put forth that supports the FDA  
6 needs, that that is probably the best way you  
7 can position yourself to engage in it. I  
8 mean, again, it's just too large of a scope.  
9 You've already got too much on your plate.  
10 It's almost like, I differentiate you from  
11 AHRQ and many other members of HHS, maybe  
12 similar to seeing what you have as a service,  
13 a public service, public good and a commodity  
14 that you have to maintain and that's ever  
15 changing, versus kind of a more slow-paced  
16 research agenda, like NIH, that can engage in  
17 that.

18 So I think it's a great idea to  
19 have the capacity to engage, but not to have  
20 to lead it yourself.

21 MEMBER GOLDSTEIN: So I have a  
22 concrete suggestion. I think it's concrete.

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1 Maybe it's not. And let me preface it by  
2 saying the Office of Cancer Communications at  
3 NCI, when they developed their strategic plan,  
4 developed a model for the different levels of  
5 research that they might support. And we  
6 already have seen a couple of examples during  
7 previous meetings of wonderful models for risk  
8 communication research. Baruch, you presented  
9 a model. Craig, you presented a model. And  
10 we could look at that model as a way of saying  
11 here's where the questions that we have, which  
12 are really good questions, fit within that  
13 model. That would be one step. And then  
14 seeing if maybe there are other areas that we  
15 haven't hit when we look at the whole model of  
16 what has to happen in risk communication. We  
17 can fill out that list, and then we could  
18 prioritize it, and we can also look at where  
19 that research would take place. Some of it  
20 would take place potentially right here at  
21 FDA. Some of the more basic questions perhaps  
22 about message framing might take place right

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1 here. Whereas some of other downstream kinds  
2 of research, looking at how to disseminate  
3 effective communication framing within health  
4 care systems, would be done as a partnership  
5 with other organizations. And it would help,  
6 not only to map out what the research  
7 questions are and where they fit within the  
8 bigger model, but also the strategy for who to  
9 partner with, how to track also success in  
10 meeting that agenda. And it would be a really  
11 good way, I think, to over time see how the  
12 agenda has shifted, perhaps, or where there's  
13 still gaps, and where the success has been  
14 achieved.

15 CHAIRMAN FISCHHOFF: In terms of  
16 terminology, sounds like you're suggesting a  
17 task analysis of, you know, we have these  
18 models, and what are the skills that you need  
19 to bring off these models? And I think even  
20 though they disagree theoretically, I think  
21 you'd find that most of the models basically  
22 have the same elements in them, or shame on

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1       them if they've ignored them.       And then I  
2       think you're talking about, you know, what  
3       might be called a production systems analysis  
4       that, you know, what is the flow of  
5       information, the pacing of things?       Because  
6       you do have -- they're producing a large  
7       volume of things, and you know, how do you  
8       make certain that the information comes out of  
9       CDER in the form at the time that you need to  
10      be able to do the evaluation, and that you've  
11      got the evaluation platform ready to be able  
12      to do it?       So maybe there's a recommendation  
13      there of a kind of task analysis as a way of  
14      identifying the expertise that FDA needs, and  
15      this production system analysis of making  
16      certain that, in the day-to-day operation of  
17      FDA, the communication function is -- you  
18      know, if it really is strategic, then it needs  
19      to be part of the day-to-day operation, and it  
20      can't, you know, be waiting for handouts on  
21      information at a time when it's already too  
22      late to get the system to produce the

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1 information that consumers or physicians need,  
2 or you know, as well as waiting for handouts  
3 for resources to do. I was thinking it's not  
4 matrix organization when Nancy talks to  
5 everybody.

6 So let's see, it was Craig and then  
7 Ellen.

8 MEMBER ANDREWS: I totally concur  
9 with what Baruch just said, and Michael,  
10 especially on trying to track and integrate  
11 the objectives with various models, with  
12 measures, with the effectiveness. We went  
13 through this in the National Youth Anti-Drug  
14 Media Campaign. It was difficult, but there  
15 is some glue and common issues across those  
16 theoretical models. So I think this can be  
17 done.

18 When I was looking at what are the  
19 questions, I thought there were a few things  
20 that were missing, and I had a question for  
21 Nancy on that.

22 On one and two, the when and what,

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1 and two was really the who, we also think in  
2 the media area about the where and how often.

3 And I was just going to ask, just quickly,  
4 Nancy, about that on media placement, on what  
5 expertise the Agency has on that.

6 And then I had another little point  
7 or beef I wanted to raise.

8 DR. OSTROVE: Well, I'm not  
9 necessarily the best person to ask about what  
10 expertise we have in media placement. We have  
11 I think expanding expertise in that area.  
12 There has been an effort to move that along.

13 And in terms of the where, I guess  
14 part of the where, and I guess it's because  
15 I'm not thinking in terms of the model, is  
16 under kind of the dissemination piece of it,  
17 so that for instance one of the things that  
18 we're looking at right now is with regard to  
19 the use of social media tools. And the web  
20 has become a much bigger piece of the where  
21 than it ever has been in the past. In the  
22 past, really, you know, our focus historically

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1 was on health care providers, not for the  
2 foods area, but for the medical products. And  
3 again, here's the complication. You know,  
4 it's different as a function of what the  
5 product is, so that there have been, you know,  
6 different ways of communicating with health  
7 care providers, partly as a function of whether  
8 it's a drug you're talking about, or whether  
9 it's a biologic, or whether it's a device. I  
10 really like the idea of putting together a  
11 model, and in some ways I kind of despair of  
12 ever being able to put together one that's not  
13 so complex that you need to go into different  
14 rooms to kind of figure out what it is.

15 But I'm sorry, that's getting off  
16 the point of your question.

17 I agree that, you know, the where  
18 is a piece, and I guess we were thinking about  
19 it in terms of the dissemination piece. Does  
20 that answer the question?

21 MEMBER ANDREWS: Absolutely. I  
22 totally agree, especially on digital

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1 expertise, online expertise. And it's  
2 interesting, especially with skewing of  
3 younger audiences and what's going on there.  
4 And sometimes you don't have a control.  
5 Control for the dissemination of that  
6 information, if you look at all of the  
7 blogging, and if you ask physicians, and  
8 misinformation I guess over the Internet as  
9 far as the interaction. So anyway, I thought  
10 I'd point out the need for expertise certainly  
11 in that area.

12 Also, I apologize not being here  
13 yesterday, but I guess there was some  
14 discussion on OMB. And I just recall decades  
15 ago being so happy at the FDC that we didn't  
16 have that sort of problem. And it was just  
17 amazing how quickly things could be done.  
18 Obviously that was under litigation. But  
19 anyway, I just wanted to emphasize the need to  
20 tackle that, I guess, for researchers at the  
21 FDA.

22 MEMBER PETERS: I wanted to just

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1 continue what Michael and Baruch were talking  
2 about in terms of a task analysis. One of the  
3 things that occurred to me when Michael  
4 earlier had mentioned the dissemination  
5 project that he did is that that's potentially  
6 a way to start. If you think back to what's  
7 the main goal of the FDA, the main goal of the  
8 FDA is to promote and protect human health.  
9 And if you start with that goal and think  
10 about that in terms of Michael's dissemination  
11 project even, with the idea that in the end,  
12 to meet that goal, you really do have to  
13 disseminate. But then what are all the  
14 different expertises that would have to go  
15 into a dissemination project? It was a big  
16 project, because there are a bunch of  
17 different people all bringing in very  
18 different expertises to something that  
19 ultimately was a dissemination project, but  
20 really it was also a message framing project.  
21 I mean, I don't even know all the different  
22 expertises that went into it, but it had to

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1 have been a bunch of them, and you probably  
2 missed some. But you know, given the limits  
3 of \$6 million, I suppose, you can only do so  
4 much. But to think about the task analysis  
5 potentially as starting with the major goal  
6 that the FDA has, and kind of work back from  
7 there. And it's not as if the FDA, as other  
8 people have been emphasizing, it's not as if  
9 the FDA can themselves do all of the research  
10 that's necessary, or you know, have all the  
11 internal expertise that's necessary. But it  
12 can start to outline - along with being guided  
13 by different models, perhaps - it can start to  
14 outline what does it take to get to that goal,  
15 and what pieces now that we can kind of see  
16 that as a whole, what pieces do we have, what  
17 pieces do we want to take, and therefore need  
18 to get this internal expertise, and where can  
19 we partner? And maybe even in some cases the  
20 expertise already exists and you just need a  
21 review of the state of the art at the moment.

22 CHAIRMAN FISCHHOFF: Here's an OMB

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1 question. Maybe you don't want to reveal the  
2 answer. How does the Office of Women's Health  
3 get away with evaluating its communications?

4 DR. OSTROVE: Focus groups.  
5 There's a generic clearance for focus groups  
6 as done by the FDA focus groups. So that kind  
7 of has streamlined the process. And we have  
8 these generic clearances for a few things.  
9 Basically, OMB's sense is that focus groups  
10 are only used in a very limited way. They're  
11 not supposed to be for making policy or making  
12 regulatory decisions. But, you know, in terms  
13 of guiding communications, whether people --  
14 you know, whether the message seems to be  
15 generally getting out, they're okay with using  
16 it for those purposes, and sometimes for  
17 developmental purposes. So, you know,  
18 developing more quantitative research.

19 So as a result, we went through a  
20 process where we got kind of this overall  
21 clearance for focus groups for a period of  
22 time and told OMB that we would be doing X

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1 number of focus groups, we think, you know,  
2 over this period of time. And then that  
3 allows us to submit a memorandum to OMB and  
4 with all of the information about the focus  
5 groups, the moderator guide, the sample, you  
6 know, how we're selecting participants, that  
7 kind of thing. And then OMB has set a time  
8 frame wherein they're supposed to be getting  
9 back to us, which is much shorter than the  
10 time frame that is necessary because you've  
11 kind of theoretically already gone through the  
12 process. So that's why you can actually do  
13 focus group work across the Agency a lot more  
14 quickly.

15 CHAIRMAN FISCHHOFF: But you said  
16 that the Office of Women's Health does do some  
17 kind of focus group-based activity routinely.  
18 Is that because there's a commitment? Why is  
19 that?

20 DR. OSTROVE: Because they have  
21 their own kind of funding stream and they  
22 believe that if they're going to put out

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1 information that it should be tested, which we  
2 all believe. It's just a matter of having the  
3 necessary will and resources to do it.  
4 They're set up. That's part of their  
5 foundational understanding and beliefs.  
6 They're set up to do that.

7 MEMBER WOLF: So how well -- is  
8 that work for you then, too? I'm sorry. That  
9 it's for you, too, focus groups then? You can  
10 use focus groups? How clearly defined is  
11 focus group?

12 DR. OSTROVE: It's fairly well,  
13 it's fairly clearly defined. I mean, you're  
14 thinking about trying to expand the definition  
15 of focus groups? That might be difficult.

16 (Off-mic comment.)

17 DR. OSTROVE: Yes. Well, yes, you  
18 could do a lot of focus groups, but you know  
19 and I know that, you know, what you can take  
20 out of even lots and lots of focus groups is  
21 still limited. And then the issue is, you  
22 know, whether you can actually use that to

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1 make important regulatory or policy decisions.

2 PARTICIPANT: Are you thinking  
3 focus groups of one?

4 MEMBER WOLF: Well, no, no, no.  
5 Well, I mean, this is completely and aside,  
6 but we got around a little bit of an issue at  
7 my own institution by we called them cognitive  
8 discussion groups. So basically, we don't  
9 really need an hour-and-a-half. We'll take 45  
10 minutes and the 45 minutes while you're  
11 waiting we'll give you some food and, hey, why  
12 don't you feel out questionnaire and we'll do  
13 a little interview with you.

14 DR. OSTROVE: Yes, that would not  
15 work.

16 MEMBER ANDREWS: I suspect the  
17 focus groups had a magic number of nine,  
18 maybe.

19 DR. OSTROVE: You know, it has  
20 changed over the years. They no longer have  
21 that. Years ago we thought actually that we  
22 did not need OMB clearance for focus groups as

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1 long as we kept the magic number at nine or  
2 less. In the last decade OMB has clarified  
3 its position on that and has made it clear  
4 that, you know, if you do more than one, you  
5 know, if you're looking at something  
6 regularly, even the nine does not count in  
7 that circumstance.

8 MEMBER ANDREWS: Yes, most of us  
9 know the dangers of focus groups. Great for  
10 insights. I'm thinking back to the National  
11 Anti-Drug Media Campaign, all the sorts of  
12 marketing research events I've been involved  
13 with, including FDA on the food side. I've  
14 been part of some of those focus groups and  
15 it's fascinating, you know, on labeling,  
16 various diseases I recall in the past.

17 DR. OSTROVE: Yes, iron  
18 supplements, for instance.

19 MEMBER ANDREWS: Right.

20 DR. OSTROVE: And perceptions of  
21 that.

22 MEMBER ANDREWS: But the problem is

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1 that, you know, you've got bandwagon effects,  
2 you've got, you know, biasing, you've got a  
3 lot of things. And it's just one key element  
4 in the process and you hate to see the process  
5 kind of cut in a way as you go through and  
6 what you really need to do in testing the  
7 effectiveness. And I'm sure there's  
8 agreement, you know, in all of that.

9 CHAIRMAN FISCHHOFF: Could you tell  
10 us what was the case, what was the suit that  
11 gave FDC the freedom to do this?

12 MEMBER ANDREWS: That's before my  
13 time. Maybe Nancy knows. It was under  
14 litigation, the issue on litigation.

15 DR. OSTROVE: There are certain  
16 exceptions. There are certain exceptions to  
17 the Paperwork Reduction Act clearance  
18 requirements. There's a whole list of them,  
19 including clinical trials. For instance,  
20 that's one of the biggest exceptions, clinical  
21 trials. They don't have to go through OMB  
22 clearance. Well, one of them is if there is

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1 an active investigation, you know, or some  
2 kind of litigation, some kind of a compliance  
3 action, then because the whole issue behind  
4 the Paperwork Reduction Act is not the  
5 implementation of it in any case. It's all  
6 about public disclosure and asking the public  
7 for input as to whether the burdens posed by  
8 the information collection are worth the  
9 utility of the information that will come out  
10 of that. And if you have litigation or, you  
11 know, you're investigating something, well you  
12 can't do it. You know, it's kind of  
13 completely antithetical. So it's written into  
14 the regs that that's an exception.

15 MEMBER PETERS: Not to beat the OMB  
16 bandwagon, but it's in part the more space we  
17 take up with this the more important it  
18 appears to the public. The issue of OMB  
19 clearance is not only a science issue, it's  
20 also a capacity issue. It will influence, has  
21 influenced I'm sure, your ability to attract  
22 and retain people who know the literature, who

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1 are motivated to continue knowing the  
2 literature and to develop the literature.  
3 Minus the ability to do research, I know a  
4 couple of cases right now where NIH is losing  
5 people. So there's also the potential for  
6 cross-institute will and motivation perhaps to  
7 try to change this in terms of the OMB issues.

8 DR. OSTROVE: We appreciate your  
9 appreciation of the challenges that we face.

10 CHAIRMAN FISCHHOFF: So I would add  
11 to that that, you know, OMB is an office of  
12 the White House. It's a political question.  
13 You know, if FDA is unable to communicate  
14 effectively with the public because of an  
15 interpretation of the Paperwork Reduction Act,  
16 which has legitimate purposes, then there will  
17 be a series of embarrassments that will be  
18 laid to FDA's door and that will ultimately  
19 laid at the door of whoever's at the White  
20 House. And, I mean, I suspect that, you know,  
21 this seems like really down in the weeds. You  
22 know, it takes two years to clear a social

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1 science study. You know, why would this be an  
2 issue of fundamental national importance? You  
3 know, if our political leadership is judged by  
4 its ability to inform the American public  
5 about things that are essential to their, you  
6 know, health and safety, their ability to make  
7 wise decisions for themselves and, you know,  
8 for their families, this is a really essential  
9 political thing. You know, we may have a  
10 major embarrassment unfolding around the  
11 communications on H1N1, you know, which, you  
12 know, rightly or wrongly will be laid at the  
13 doorstep of our political leadership. So it  
14 strikes me that a well-articulated case for  
15 the scientific need for doing this kind of  
16 testing, you know, couched politely in terms  
17 of what are the social and political  
18 ramifications of this, you know, would give  
19 OMB's leadership, which includes people who  
20 understand social science, you know, put them  
21 in the position of saying, you know, what is  
22 the correct interpretation of this and the

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1 kind of personal opinion -- well, all personal  
2 opinion I guess is that the kind of SGE-type  
3 work-arounds that we were talking about  
4 yesterday are just perpetuating the problem.  
5 And I guess I would like try to draft in the  
6 break for the group's consideration some of a  
7 strong statement suited to the role that we  
8 play here.

9 DR. OSTROVE: I should clarify  
10 though, two years is like off the whole  
11 process and if you look at the actual  
12 Paperwork Reduction Act requirements, you  
13 could get something through in six months, you  
14 know, or so if everything goes well, you know,  
15 everything goes perfectly and there's no  
16 comments from the public and there's no  
17 policy-related stuff, since that's often what  
18 kind of gets involved in the clearance. I  
19 mean, it's like the total --

20 CHAIRMAN FISCHHOFF: So that would  
21 be saying if the process is pointless of  
22 soliciting comments, then it worked really

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1 well.

2 DR. OSTROVE: Well, yes, I guess  
3 that's -- I hadn't thought about it that way.

4 MEMBER WOLF: I mean, I kind of  
5 feel like, you know, we do keep getting lost  
6 in the weeds a little bit. Like there's  
7 nothing that we can really do about this. We  
8 clearly have to be aware of that limitation  
9 with OMB, but I'm just curious to get back to  
10 this issue that we had. I mean, I don't know  
11 how you do this. If you can ask for a  
12 consensus. Does anybody on the panel disagree  
13 with the idea that the FDA should of course  
14 engage in an evidence-based strategy for risk  
15 communication that they of course need to be  
16 on top of the literature, that they should be  
17 actively pursuing to be involved and  
18 influential on the research agenda at the  
19 federal level with regard to risk  
20 communication, yet its secondary role should  
21 always be the initiation of its own research  
22 agenda in-house?

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1 I mean, I felt like that was  
2 raised, but I just want to see is anybody in  
3 disagreement with that?

4 CHAIRMAN FISCHHOFF: So it seems to  
5 me that some of that is already in the  
6 strategic plan.

7 MEMBER WOLF: I guess I'm looking  
8 at these trying to be responsive to the  
9 discussion topic. Maybe I'm a little bit  
10 misguided as far as how we're supposed to  
11 respond to these discussion topics here, that  
12 we can of course generate and talk about how  
13 should you deal with patient understanding,  
14 how you do risk communication. But I thought  
15 the earlier mention that I didn't know if it  
16 was as articulated in the strategic plan is  
17 that these initiatives, these activities  
18 should not be felt to be completely -- that  
19 the FDA cannot tackle everything and should  
20 not feel obliged to tackle everything.  
21 Instead, that they should just be aware and  
22 influence others. And I guess do you feel

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1 that that's adequately conveyed in the  
2 strategic plan?

3 CHAIRMAN FISCHHOFF: No, I think  
4 there's a refinement there. Let me think  
5 about it.

6 Let's ask Nancy. Would Nancy agree  
7 that this is a focusing of the strategic plan  
8 from what Michael suggested?

9 DR. OSTROVE: Mike, could you  
10 expand a little bit? I mean, maybe I'm having  
11 trouble figuring it out in terms of the  
12 negative part of it. Because you're asking if  
13 anyone disagrees that we should not tackle  
14 everything. I mean, we should be evidence-  
15 based, we should have people internally who  
16 are on top of the literature, and we should  
17 work with others where appropriate and should  
18 not be in the position of tackling everything.

19 MEMBER WOLF: You know, my  
20 cognitive psychology doctoral student would be  
21 really upset with me for using negation like  
22 that. However, I guess what I'm just trying

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1 to ground myself, and maybe I'm just again  
2 being kind of a redundant wheel here, is that  
3 I get concerned when we start talking about  
4 bigger picture work and realizing that well  
5 that work is happening already. We know a lot  
6 about it, but it's not necessarily FDA's role  
7 to be doing it in-house. And I guess someone  
8 that can have that notion that if you're  
9 starting to think about what more resources do  
10 we need to have within the FDA to engage in  
11 research, when in reality you should be doing  
12 program evaluation really. I mean, clearly  
13 you are going to generate new information, new  
14 knowledge. You're going to contribute to  
15 that. And it's coming back to a comment  
16 earlier I said, you should be an open-source  
17 system to academics, you know, to partnering  
18 with industry, to making sure that, you know,  
19 as you are rolling out communications and  
20 learning what works and what doesn't work that  
21 that information -- again, it's back to  
22 partnerships. It's not about whether or not

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1 internally you have the labs in place to do  
2 all of this work. It's just recognizing --  
3 and I'll use this term again, you're a  
4 learning environment for people, whether it be  
5 through post docs -- we've talked about all  
6 these and I don't think -- I mean, you've  
7 gotten probably all the feedback you need  
8 about it and you're already doing some great  
9 work and opportunities, and partnering with  
10 the academics and the like. But it's just  
11 making sure that the role really is to make  
12 yourself available and to evaluate what you're  
13 already doing. There are natural experiments  
14 that are continuously happening with H1N1,  
15 with, you know, going back to, you know, avian  
16 flu, whatever the experience that you have to  
17 deal with, pistachios. We've been talking  
18 about all sorts of great things. But as you  
19 make yourself open and available and inform  
20 what you want to do next, I kind of feel like  
21 that's what I'm trying to focus. I don't know  
22 if that's being clear or not.

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1 DR. OSTROVE: I think so. I think  
2 that, you know, one of the major reasons for  
3 getting this out is not just to inform our  
4 own, not just to say we want to do all this.  
5 If these are the questions that we want to  
6 make available to everybody, to say these are  
7 the things that we need to know, and I think  
8 that's what you're saying --

9 MEMBER WOLF: Exactly.

10 DR. OSTROVE: -- so I think that  
11 we're in agreement there.

12 MEMBER WOLF: Okay. Okay.

13 MEMBER ANDREWS: This is very  
14 valuable discussion on this. There are  
15 trade-offs having memory in another federal  
16 agency. So there are some issues that are  
17 very precise that might be of interest to you  
18 that may not be of interest to academics and  
19 some of the research that's funded.

20 The other little problem is  
21 accountability. So at the end of the day, you  
22 know, maybe they're looking at FDA on certain

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1 issues where that particular academic  
2 expertise may not be there at that particular  
3 point in time. But then you've got the  
4 resource issues, like we were talking about  
5 before. I see this as a series of trade-offs  
6 in the discussion.

7 CHAIRMAN FISCHHOFF: I have another  
8 question about the strategic plan. And maybe  
9 this is implicit there, but tell me whether  
10 you think it needs reinforcement, and maybe  
11 this is obvious.

12 So the strategic plan reiterates  
13 FDA's long term commitment to communication  
14 with the public. And in order to communicate  
15 you have to have the evidence that is relevant  
16 to people's decision. So in the drug area,  
17 there's a system that one has developed for  
18 looking at the risks and the benefits of the  
19 drugs. There is however a gap that's missing  
20 between -- so then the question is so somebody  
21 is producing that information. One hopes  
22 that, you know, CDER and whoever else that is

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1 done, you know, on drugs and advices and so  
2 on, that the information is being produced by  
3 FDA and then that if it's being produced, then  
4 it's available for sort of a handoff to the  
5 communication people, and how tight is that  
6 link? You know, say if CDER is producing kind  
7 of bulky complicated data that is not in a  
8 user-friendly form, as a regulator-friendly  
9 form, if there are requirements and so on, you  
10 haven't really served the -- you haven't  
11 gotten full value out of the work that the  
12 CDER staff has done in order to serve the  
13 communication function because it handed off a  
14 bunch of really complicated stuff.

15           Conversely, it may be that the  
16 protocols that CDER is using are not fully in  
17 sync with the needs that consumers have, that  
18 there may be other questions that need to be  
19 asked of the people who provide submissions in  
20 order to answer the communication needs. So  
21 just to a topic that I keep bringing up, we  
22 know how something about how well a drug

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1 performs in a clinical trial which has either  
2 typically a pretty good communication  
3 protocol. Ensure that people take their  
4 drugs, got somebody to call right away if  
5 they've got problems. But we're not all in  
6 clinical trial. We who might take the drugs  
7 aren't in the clinical trial. I want to know  
8 how well this drug works with people, with  
9 ordinary people like myself who sometimes miss  
10 a dose, sometimes don't have anybody to call  
11 about our problems, may not have health  
12 insurance to do it. So as somebody who's  
13 considering a drug, I would like to know how  
14 well this drug will perform under realistic  
15 conditions with a fallible human like myself.

16 So somebody who's going through all  
17 the work of looking at the drug protocols  
18 could say something about -- you know, could  
19 extract that information. If somebody who had  
20 the right eyes, you know, who understood  
21 issues of compliance, understood issues of  
22 drug interactions among people who are not in

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1 a clinical trial, they could tell me something  
2 about how robust this drug is likely to be  
3 with a different communication package. And  
4 so I could imagine, you know, it seems to me  
5 that if communication were central, then CDER  
6 or whoever the equivalents are for your other  
7 activities, that there would be a handoff to  
8 the communication people that did the  
9 translation and in as authoritative a way  
10 possible so that the communication people  
11 didn't have to go through all the stuff and  
12 figure out what it is.

13           Conversely, the communication  
14 people would say, you know, there's something  
15 missing. There are things that people want to  
16 know and we're not telling them. As you do  
17 your reviews, could you look at that? And  
18 maybe we need to, you know, staff up a little  
19 bit differently, allocate your resources a  
20 little differently.

21           So I want to know how, you know, is  
22 that concern that the process work with the

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