

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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THURSDAY,  
FEBRUARY 26, 2009

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The meeting convened at 8:00 a.m. in the NTSB Conference Center, 429 L'Enfant Plaza, S.W., Washington, DC, 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

DRUG SAFETY AND RISK MANAGEMENT ADVISORY  
COMMITTEE MEMBERS:

- TERRY C. DAVIS, Ph.D.
- TIMOTHY S. LESAR, Pharm.D.
- SIDNEY M. WOLFE, M.D., Consumer Representative

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## FDA PARTICIPANTS:

LEE L. ZWANZIGER, Ph.D., Designated Federal  
Officer/Executive Secretary  
JODI DUCKHORN, M.A., Team Leader,  
Division of Risk Management, Office of  
Surveillance and Epidemiology, CDER  
DEBORAH HENDERSON, Director, Office of  
Executive Programs, CDER  
NANCY M. OSTROVE, Ph.D., Director for Risk  
Communication, Office of the  
Commissioner

## GUEST SPEAKERS:

CAROLE L. KIMBERLIN, Ph.D., Professor,  
Pharmaceutical Outcomes and Policy, University  
of Florida College of Pharmacy  
ALMUT WINTERSTEIN, Ph.D., Associate  
Professor, Pharmaceutical Outcomes and Policy,  
College of Pharmacy, and Epidemiology  
and Biostatistics, College of Public  
Health and Health Professions,  
University of Florida

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EXPERT AND CONSUMER EVALUATION OF  
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Carol L. Kimberlin, Ph.D., Professor,  
Pharmaceutical Outcomes and Policy  
University of Florida College of  
Pharmacy

Almut Winterstein, Ph.D.,  
Associate Professor,  
Pharmaceutical Outcomes and Policy  
College of Pharmacy, and  
Epidemiology and Biostatistics  
College of Public Health and Health  
Professions, University of Florida

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Adjourn

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P R O C E E D I N G S

(8:16 a.m.)

CHAIRMAN FISCHHOFF: My name is Baruch Fischhoff. I'm the Chair of the FDA's Risk Communication Advisory Committee, and I hereby call us to order, and transfer the gavel to Dr. Lee Zwanziger, the Designated Federal Official for this meeting.

DR. ZWANZIGER: Thank you, Dr. Fischhoff. And good morning to all the members and consultants of the Risk Communication Advisory Committee, and the Drug Safety and Risk Management Advisory Committee, to members of the public, and the FDA Staff. Welcome to this meeting.

The following announcement addresses the issue of conflict of interest with respect to the meeting, and is made a part of the public record to preclude even the appearance of such at the meeting. Today the Risk Communication Advisory Committee, and members of the Drug Safety and Risk

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1 Management Advisory Committee will discuss  
2 points the FDA should consider regarding the  
3 appropriate next steps to improve the  
4 communication of information about  
5 prescription drugs to patients, including  
6 different types of prescription drug  
7 information currently available to patients  
8 in the form of medication guides, patient  
9 package inserts, and consumer medication  
10 information. Based on the submitted agenda  
11 for the meeting, and all financial interests  
12 reported by the Committee participants, it's  
13 been determined that no interests in the  
14 firms regulated by the Food and Drug  
15 Administration present potential for conflict  
16 or appearance of a conflict of interest at  
17 this meeting.

18 We'd like to note that Dr. Bruce  
19 Burlington, Industry Representative on the  
20 Drug Safety and Risk Management Advisory  
21 Committee will be participating as Industry  
22 Representative in accord with the charter of

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1 the Risk Communication Advisory Committee.  
2 He was unable to be present today due to a  
3 family matter.

4 Risk Communication Advisory  
5 Committee members, Dr. Jacob DeLaRosa, Sally  
6 Greenberg, and Dr. Michael Wolf were unable  
7 to attend this meeting due to urgent  
8 scheduling patient and family matters.

9 We also note an item that does not  
10 present a financial conflict of interest, but  
11 we believe should be disclosed. Dr. Betsy  
12 Sleath was involved in data collection in one  
13 part of the material in the report that will  
14 be presented this morning by its principal  
15 investigators. One part of the reported  
16 study included asking experts to review  
17 samples of consumer medication information,  
18 score them on the basis of the criteria  
19 developed by a different set of experts, but  
20 including attention to the standards set  
21 forth in the Agency's guidance. Dr. Sleath  
22 was one of these experts. She was not a

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1 designer of the study, or the evaluation  
2 criteria, nor is she an author of the report.

3

4           The design and execution of the  
5 study, itself, is not a question before the  
6 Committee at this meeting, but it's possible  
7 that it may be mentioned in the discussion.  
8 She received a small honorarium, but there is  
9 no ongoing entity. There's no possibility of  
10 an ongoing or future arrangement to influence  
11 her. We're disclosing this connection so  
12 that any comments she does make can be  
13 interpreted in context.

14           In general, the Committee  
15 participants are aware of the need to exclude  
16 themselves from involvement in discussion of  
17 topics if their interest would be affected,  
18 and their exclusion will be noted for the  
19 record. With respect to all other  
20 participants, we ask in the interest of  
21 fairness that they address any current or  
22 previous financial involvement with any firm

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1 whose product they may wish to comment upon.

2 We have a period for open public  
3 comment each day, as listed in the agenda.  
4 It's fairly fully subscribed, but if persons  
5 not already signed up wish to speak, please  
6 see one of my colleagues in the back of the  
7 room, or at the registration table outside,  
8 and we will do the best we can.

9 This entire meeting is being  
10 transcribed, and the transcript will be  
11 posted on the FDA website, but it will only  
12 contain what the transcriber could hear, so I  
13 remind us all to please turn on and speak  
14 into your microphones when you're recognized  
15 to speak, and then turn them off when you're  
16 not speaking.

17 Also, I'd suggest that we all take  
18 an opportunity to turn cell phones and other  
19 communications to silent mode, just in case  
20 you're able to get a signal. If you cannot  
21 get a signal in here, you might want to step  
22 out to the parking garage or upstairs by the

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1 plate glass windows. Thanks very much.

2 CHAIRMAN FISCHHOFF: Thank you,  
3 Lee. And let me thank you all for coming,  
4 and we thank the Committee members for  
5 joining us here, and the members of the  
6 Staff, and hope we'll use your time well  
7 today.

8 I thought that I'd give a little  
9 bit of background to the Committee for those  
10 of us who are either new to the Committee.  
11 We're fortunate to welcome some new members,  
12 as well as those who are not familiar with  
13 our work. So the Committee Members are  
14 people concerned with these issues. They're  
15 interested in providing service to the  
16 American public so that they get the best  
17 possible products to help with their -- to  
18 get along with their lives, with trying to  
19 help the pharmaceutical industry fulfill its  
20 role in there, and to make the system work as  
21 well as we can.

22 Members of the Committee are

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1 uncompensated. They go through quite a bit  
2 of hassle in order to ensure that if there  
3 are any conflicts of interest, that they're  
4 revealed. And you could see in Dr.  
5 Zwanziger's introduction, the level of detail  
6 that goes into it.

7 This is the fourth meeting of this  
8 Committee. The Committee is chartered under  
9 the FDA Amendment Acts of 2007. We make no  
10 obligatory decisions, all of our advice is  
11 just advice, providing guidance to the Food  
12 and Drug Administration. As a result, I feel  
13 like we need to prove our value to FDA in  
14 helping it to fulfill its mission.

15 Although, our Committee name is  
16 Risk Communication Advisory Committee, one  
17 wouldn't be communicating about risks if  
18 there weren't benefits associated with the  
19 regulated products, so we, and FDA, envision  
20 the task as insuring that people have the  
21 information that they need in order to make  
22 wise decisions. And then with the

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1 understanding that the public will be making  
2 wise decisions, that manufacturers will be  
3 providing them with the products that will be  
4 attractive to well-inform the patients, and  
5 consumers, and will provide the information  
6 that people need in order to do that; taking  
7 advantage of the science of communication,  
8 which is represented here on this Committee,  
9 as well as the people concerned with other  
10 parts of the communication system.

11 We have expertise here, as you'll  
12 hear, in mass communications, and patient  
13 advocacy, and, of course, in the science of  
14 the products that are regulated.

15 So we've had four meetings up to  
16 now. The first of them, and kind of an  
17 underlying theme of all of these meetings is  
18 to familiarize ourselves with the -- we're  
19 not lawyers, and not public administrators,  
20 with the work of FDA, and the arena within  
21 which it works. And we'll be getting some  
22 more of that background today.

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1           Each of our meetings has had a  
2 focal topic. The first one dealt with  
3 opportunities for standardizing the wording  
4 on food recalls. The second meeting focused  
5 on direct-to-consumer advertising, where we  
6 had two foci; one was, how does direct-to-  
7 consumer advertising work with diverse and  
8 under-served populations. And, secondly,  
9 what were the -- how could FDA go about  
10 conducting a mandated study of the  
11 possibilities of providing an 800 number on  
12 TV, direct-to-consumer advertising that would  
13 allow people to report problems that they  
14 had.

15           Our third meeting dealt with the  
16 science that's concerned with how to  
17 communicate uncertain information. And by  
18 that we meant that -- those of us who work on  
19 the science here perhaps have reasonable  
20 confidence in our ability to communicate  
21 well-characterized risks, and well-  
22 characterized benefits. But what happens

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1 when the evidence is not as good as we would  
2 like it to be, where we're relying on post-  
3 licensing surveillance, and we don't know  
4 quite how well that system is, or we've  
5 changed our inspection system, and we're  
6 getting a different signal-to-noise pattern,  
7 and the public needs to understand the  
8 context within which information is produced  
9 in order to make good use of the best  
10 information that we're able to provide. So  
11 we talked about the science there, and  
12 produced a set of -- came up with a set of  
13 advisory recommendations.

14           If people are interested in the  
15 results of -- actually, any details about  
16 previous meetings, you could go to the  
17 Committee's website. You'll find the charge,  
18 you'll find PDF's of the presentations that  
19 were given, you'll find summaries of the  
20 conclusions and recommendations that we had,  
21 as well as the full transcripts that are  
22 being provided.

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1           As you know, the topic of today's  
2 meeting is how well FDA and those within this  
3 work are succeeding in providing useful  
4 consumer medical information in line with its  
5 charge, which we will get in authoritative  
6 detail in the next two speakers.

7           We have been asked by FDA to  
8 answer a number of specific questions. These  
9 questions have been developed by Dr.  
10 Zwanziger and Dr. Ostrove, and their  
11 colleagues in consultation with other FDA  
12 Staff, as well as with FDA's Risk  
13 Communication Strategic Plan Working Group,  
14 which is an informal FDA body that was  
15 created, in part, in response to a  
16 recommendation from our Committee, that FDA  
17 needed some sort of strategic plan for  
18 coordinating its activity, taking best  
19 advantage of us, and taking advantage of the  
20 science that is out there, and could be  
21 applied to FDA's needs.

22           So I'd like -- you all have the

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1 questions, but I'd like to spend two minutes  
2 just reading through them. I think that will  
3 get them all on our agenda, get everybody  
4 thinking on them. I think it's good  
5 communication practice to show your client,  
6 which is FDA, that you're listening to them.

7 So the five questions, and I'm sure you can  
8 all read even faster than even I can talk,  
9 but let me just go through them. Okay.

10 Question One - "Is there  
11 scientific evidence that supports the  
12 continued use of multiple communication  
13 tools, or that supports the development of a  
14 single tool to be used to convey prescription  
15 drug information to patients? If so, please  
16 describe."

17 Second - "In addition to published  
18 studies, what other types of scientific  
19 research should be conducted to insure that  
20 FDA is effectively communicating prescription  
21 drug information to patients?"

22 Third - "Based on what you've

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1 heard at this meeting, and your knowledge of  
2 the literature, what is the best format for  
3 written patient information? For example, is  
4 there evidence supporting use of unstructured  
5 narrative, question and answer, tabular,  
6 listing of top ten risks, or another format?"

7 Fourth - "How should FDA evaluate  
8 the effectiveness of different communication  
9 tools? Further, what are the most important  
10 parts of a complete assessment of a  
11 communication tool? For example, did the  
12 patient receive the tool? Did the patient  
13 read the tool? Did the patient understand  
14 the tool?"

15 And, fifth - "Please prioritize  
16 the types of research relating to patient  
17 information, what projects are most important  
18 for moving ahead expeditiously, and please  
19 include consideration of the following, plus  
20 other factors you think are important; the  
21 amount of information patients receive from  
22 the pharmacy, the appropriate balance of risk

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1 and benefit information, most effective order  
2 in which to present information, whether  
3 information should be in a standard format,  
4 or an as-appropriate for that product  
5 format, most credible source of the  
6 information, and, finally, how to communicate  
7 effectively with patients at different  
8 literacy levels, primary language skills  
9 other than English, or other served patient  
10 populations."

11 So these are the questions that  
12 the Staff has directed to us. I'll be taking  
13 notes, Lee will be taking notes, Nancy will  
14 be taking notes. At the end of the meeting,  
15 we will try to organize what's been said  
16 along those questions, but if you can help  
17 us, if you keep those questions before you.

18 And for those who haven't been at  
19 one of these meetings, I hope never to  
20 understand the Federal Advisory Committee  
21 Act, as well as Lee does, so she is empowered  
22 to interrupt me at any time if I've missed

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1 something.

2 So not to take -- it would be my  
3 pleasure to ask the Members of the Committee  
4 to briefly introduce themselves. So, I'm  
5 Baruch Fischhoff. I'm at Carnegie Mellon  
6 University. I'm a Cognitive Psychologist,  
7 Decision Scientist, and I study risk under  
8 various guises. Let's start with Christine.

9 DR. BRUHN: Good morning. I'm  
10 Christine Bruhn with the University of  
11 California at Davis. I'm in the Department  
12 of Food Science and Technology. I'm the  
13 Director of the Center for Consumer Research.

14 My academic work focuses on doing consumer  
15 attitude research on knowledge and practices  
16 related to food handling, and food safety,  
17 and understanding of new opportunities to  
18 enhance safety.

19 MS. DeSALVA: Good morning. I'm  
20 Anna Maria DeSalva, and I lead the Worldwide  
21 Healthcare Practice at Hill and Knowlton,  
22 which is a global public affairs and public

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1 relations firm. And our clients are really  
2 active all throughout healthcare, so we do a  
3 lot of work, on the one hand, with  
4 manufacturers who, obviously, are dealing in  
5 products that are regulated by FDA, but also  
6 with major health systems, and non-profits  
7 active in healthcare.

8 My primary role, I think, both in  
9 working with client organizations and in the  
10 industry, and here as part of this Committee  
11 is to, obviously, focus on the application of  
12 risk communication principles in a real world  
13 setting on a daily basis in the communication  
14 of risk and benefits of products, but also in  
15 certain urgent situations when products are  
16 recalled, or otherwise have major issues.

17 DR. WOLFE: I'm Sid Wolfe. I am  
18 professionally a General Internist. I have  
19 been the Director of the Health Research  
20 Group Public Citizen for 37-1/2 years. We  
21 have been very interested in this issue for  
22 roughly 30 plus years, when we became

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1 involved in the final regulation that would  
2 have, had it not been cancelled, caused  
3 patient package inserts to be mandatory FDA-  
4 approved patient package information to be  
5 there for a large proportion, not the  
6 majority, but large proportion of drugs, so  
7 we have followed this issue very closely.  
8 I'm pleased to be here to engage in a  
9 discussion about where it is in 2009.

10 MS. FINCH: Okay. Good morning.  
11 My name is Sokoya Finch, and I'm with Florida  
12 Family Network. As it relates to work in  
13 this area, we do work with pretty much rural  
14 counties focused on infant mortality,  
15 cardiovascular, HIV/AIDS, and Diabetes. The  
16 other thing that we do is just make sure that  
17 information is culturally competent as it  
18 relates to the different ethnic groups that  
19 are throughout the State of Florida. And  
20 it's a pleasure to be here. I am a new  
21 Committee member.

22 DR. SLEATH: Good morning. My

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1 name is Betsy Sleath, and I'm a Pharmacist  
2 and a Sociologist, Professor of  
3 Pharmaceutical Outcomes and Policy at the  
4 University of North Carolina-Chapel Hill. And  
5 a lot of my research actually focuses on  
6 audio taping providers and patients, and  
7 looking at how the communication that is  
8 provided is related to patient knowledge,  
9 and, also, patient adherence, and other  
10 health outcomes.

11 DR. KHANNA: Good morning. My  
12 name is Prerna Mona Khanna. I'm a Board  
13 Certified Physician in General Internal  
14 Medicine, Public Health, and Occupational  
15 Medicine. I've been a full-time medical  
16 journalist for about seven years, raising  
17 health literacy in particularly the area of  
18 health disparities. I'm also an Emergency  
19 Medical Aid Volunteer with the National  
20 Disaster Medical System, and NGOs, as well as  
21 a Lieutenant Colonel with the Texas State  
22 Guard.

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1 DR. LESAR: Good morning. My name  
2 is Timothy Lesar. I'm the Director of  
3 Clinical Pharmacy Services at the Albany  
4 Medical Center in Albany, New York. I have a  
5 background in medication safety, delivery of  
6 safe medication practices, as well as  
7 managing the endpoint delivery of patient  
8 information at the point of care by a  
9 pharmacist. I'm a member of the Drug Safety  
10 and Risk Management Committee.

11 DR. PETERS: Good morning. My  
12 name is Ellen Peters. I'm a Research  
13 Psychologist out of Decision Research in  
14 Eugene, Oregon. I study how people process  
15 information as they perceive risks in the  
16 world, and as they make decisions. I'm  
17 particularly interested in issues around how  
18 people who differ in number ability will  
19 perceive numeric information differently, and  
20 how that makes a difference to how they judge  
21 and decide. I'm also interested in issues of  
22 how we present numbers, in order to help

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1 people comprehend them, and use them better,  
2 as well as issues around adult aging. As we  
3 age from younger adulthood into older  
4 adulthood, how do these processes change, and  
5 how does that make a difference as to how  
6 people comprehend and use information? Thank  
7 you.

8 DR. ANDREWS: Good morning. I'm  
9 Craig Andrews from Marquette University. I'm  
10 a Professor and Kellstadt Chair in Marketing  
11 at Marquette. It's in Milwaukee, Wisconsin.  
12 I'm also a new Committee member, although I  
13 did present on direct-to-consumer advertising  
14 to vulnerable populations back in May.

15 My area is primarily marketing  
16 communications, consumer research, and  
17 advertising research. I also was involved as  
18 a consumer research specialist on coffee  
19 testing with the Federal Trade Commission. I  
20 also was involved on measurement evaluation  
21 issues with the National Youth Anti-Drug  
22 Media Campaign. And it's a pleasure to be

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1 part of the Committee.

2 DR. DAVIS: Good morning. I'm  
3 Terry Davis from LSU Health Sciences Center  
4 in Shreveport, Louisiana. I'm a member of  
5 the Drug Safety and Risk Management, I get  
6 all these names mixed up. But, at any rate,  
7 in a previous life, I was a psychologist  
8 studying depression, when I realized that  
9 patients couldn't understand the questions  
10 that we were asking them, so I began to study  
11 patients' ability to understand and act on  
12 health information. And my expertise is  
13 health literacy, which I see as the  
14 intersection and the gap between patients'  
15 ability to understand and act on oral and  
16 written health information in the  
17 unnecessarily complex information that we  
18 give them, and services that we're offering.

19 MS. LAWSON: Good morning. I'm  
20 Madeline Lawson, President and CEO for the  
21 Institute for Multicultural and Minority  
22 Medicine based in Washington, D.C. I am a

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1 member of the Risk Communication Advisory  
2 Committee. And the Institute's primary focus  
3 is on addressing health disparities. We work  
4 in collaboration with the National Health and  
5 Consumer organizations, academic institutions  
6 in developing education and training  
7 initiatives for the community.

8 DR. PALING: Good morning. My  
9 name is John Paling. I represent the Risk  
10 Communication Institute, a very small  
11 organization consulting with doctors and  
12 hospitals about various ways of helping  
13 patients understand risks. Since this is my  
14 second year, and since I view the purpose of  
15 an introduction to try and help you evaluate  
16 any slim chance that what I say might be  
17 helpful, let me please give you very briefly  
18 my five lessons from my first year.

19 First of all, and very generally,  
20 for someone who tends to be very critical, I  
21 would tell you that it is not only my own  
22 view that the FDA Staff at all levels seem

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1 the most committed, the most dedicated, and  
2 the most generally open-minded of any  
3 government agency I've worked with. That's a  
4 very sincere comment that I've shared  
5 socially, and many feel the same thing.

6           Secondly, I think the Risk  
7 Communication Advisory Committee can have a  
8 tremendous value bringing in all sorts of  
9 opinions from all sorts of sources at a time  
10 when clearly new ideas should be valued and  
11 embraced.

12           Thirdly, I'm aware, very much  
13 aware, that the world of the FDA is  
14 circumscribed, in part, by politics,  
15 internally and externally.

16           Fourthly, it is my personal  
17 opinion that very frequently in the past,  
18 we've been asked to talk about specifics  
19 before we've ever really defined the general.

20           And by that I mean trying to give advice on  
21 topics of how to deal with a relatively  
22 complicated risk communication topic to a

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1 MS. MAYER: You're a hard act to  
2 follow, John.

3 My name is Musa Mayer. I'm a  
4 Breast Cancer Advocate. I work  
5 independently, but consult with many  
6 organizations, and I've worked extensively  
7 with FDA before, and with the Institute of  
8 Medicine, and a number of others.

9 My focus as an advocate, as a  
10 patient advocate, is on working with women  
11 and their families who are living with  
12 advanced or metastatic breast cancer. And  
13 over the years, I've become increasingly  
14 interested in the challenge of communicating  
15 accurate risk-benefit information to  
16 patients, so that they can make informed  
17 decisions.

18 I'm also a writer, and more  
19 recently I've become, sort of by default, a  
20 website developer, all with the intention of  
21 communicating more clearly to patients about  
22 the drugs, often very toxic drugs they must

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1 take.

2 DR. GOLDSTEIN: Hello, everyone.  
3 I'm Michael Goldstein. I'm an Internist and  
4 a Psychiatrist, and I currently am the Chief  
5 of Mental Health and Behavioral Sciences at  
6 the Providence VA Medical Center, part of the  
7 Veterans Affairs system of care. And my  
8 interest is in clinician-patient  
9 communication, like others on this Committee.

10 I'm particularly interested in not only what  
11 has to be in the setting of that  
12 communication to make it effective, but how  
13 we can train health professionals to do a  
14 better job of improving the way they work  
15 with patients, and empower them to  
16 participate in care.

17 I'm also at Brown University  
18 Medical School. I have a chance to do some  
19 teaching there. And I also want to say that  
20 I've learned a tremendous amount just coming  
21 to these meetings, and hearing from the  
22 diverse experiences, and expertise of members

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1 of this Committee. And that's a message, I  
2 think, about the importance of communication  
3 skills, communication training, and different  
4 perspectives and levels of influence on the  
5 outcomes we're looking for.

6 MS. HENDERSON: Good morning. I'm  
7 Debbie Henderson. I'm the Director of the  
8 Office of Executive Programs at the Center  
9 for Drug Evaluation and Research. I know  
10 many on this Committee are used to seeing Dr.  
11 Paul Seligman in this role, representing the  
12 Center for these sorts of risk communication  
13 issues. For those of you that don't know,  
14 Dr. Seligman has left the Center for Drugs,  
15 and has gone on to work in our international  
16 offices, and I believe as we speak, is  
17 probably sitting in Costa Rica, so let's all  
18 take a moment to feel really sorry for Dr.  
19 Seligman. And I have taken on the role of  
20 leading this effort in the Center for Drugs  
21 to try to figure out where we should go in  
22 this arena of patient information.

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1 DR. OSTROVE: Good morning. I'm  
2 Nancy Ostrove. I'm Director for Risk  
3 Communications in FDA's Office of Planning in  
4 the Commissioner's Office. And thank you all  
5 for being here. It's great to see you again.

6 CHAIRMAN FISCHHOFF: Thank you  
7 all. Again, my first introduction to this  
8 topic was on those PPIs in the late 1970s,  
9 when FDA has always had some behavioral  
10 scientist on its staff. And they asked -  
11 there was Lou Morris, and somebody else's  
12 name I've forgotten, asked for our advice,  
13 from me and from Paul Slovic, a mutual  
14 friend. And I think it makes a tremendous  
15 difference for an agency to have that  
16 expertise on its staff when the time comes to  
17 take a set of issues seriously. And I think  
18 that the -- I just commend the staff who has  
19 been working directly serving this Committee,  
20 and through the Agency, more in helping us to  
21 come up to speed on these issues, and kind of  
22 hitting the ground running, in addition to

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1 having the excellent taste to have assembled  
2 such a wonderful Committee, which I'm just  
3 really pleased to be chairing. And I will  
4 take my job seriously to use your time well.

5 So our first speaker now will be  
6 Debbie Henderson.

7 MS. HENDERSON: That was a very  
8 long trek over here, and I will be able to  
9 tell you something immediately about the  
10 importance of font size as the patient gets a  
11 little older, as I put on my specs here.

12 Let me just add the voice of the  
13 Center for Drugs to welcoming you, and  
14 thanking all of you, Dr. Fishhoff and other  
15 members of the Committee, profusely for being  
16 here. In my office in CDER, we house the  
17 organization, the CDER organization, the  
18 advisors and consultant staff who actually  
19 manage our CDER, the Center for Drugs  
20 Advisory Committees, and so I well appreciate  
21 the enormous hassle, paperwork, all of the  
22 other things that you guys experience in

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1 serving the Agency in the roles that you do.

2 We know that it's a burden. We know we're  
3 not making millionaires out any of you, as  
4 you serve on our committees, and we truly,  
5 truly appreciate your commitment to help us  
6 to serve the public health, and to serve the  
7 best interests of the public. It's just  
8 enormously appreciated, so let me just start  
9 by thanking you very much.

10 You've heard a little bit from  
11 some of the people around the table who have  
12 been involved in this issue for many, many  
13 years now, and so I want to just do a few  
14 very brief opening remarks, which I have  
15 entitled, "Patient Information: The Long and  
16 Winding Road". And you're going to hear a  
17 good bit more about this, much more detail in  
18 the next two presentations. But I'm going to  
19 go very, very briefly just through how long a  
20 journey this has been, and continues, and why  
21 we have you here now, and what we're hoping  
22 to accomplish over the next, hopefully, not

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1 40 years.

2 I think we could start with what  
3 we all agree on, that long gone are the days  
4 that some of us in the room remember where  
5 the doctor basically said to the patient  
6 here, take these little yellow pills because  
7 they're good for you, and that's really all  
8 you need to know about your drugs. Those  
9 were the days of the practice of medicine.  
10 That was the healthcare system that some of  
11 us in this room actually remember, but I  
12 think those days are long gone, and that, in  
13 fact, it's no huge leap, I think, to suggest  
14 that everyone in this room agrees with the  
15 assertion that patients not only have the  
16 right to information about the drugs that  
17 they're taking, but that having the  
18 information they need enhances their care.  
19 There's huge literature now that suggest it  
20 improves adherence to medication regimens,  
21 and so forth. So I thought I would start  
22 with what we can all agree with, is that

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1 access to useful written patient information  
2 is important to assure the safe and  
3 appropriate use of prescription medicines.

4 So if that's the case, why don't  
5 we just move on with it? Well, again, as  
6 mentioned, we have a long history here about  
7 patient medication information in the United  
8 States, beginning, as someone noted, in 1968.

9 I can't believe that was 40 years ago, when  
10 the Food and Drug Administration first  
11 required that there be some prescription  
12 patient labeling for estrogens and oral  
13 contraceptives. Those are known as patient  
14 package inserts. You're going to hear a lot  
15 of acronyms during the day. You will hear  
16 those referred to as PPIs, or patient package  
17 inserts.

18 In 1996, and I am skipping way  
19 ahead, you're going to hear a lot more, there  
20 was Public Law 104-180 passed, which dealt  
21 with consumer medication information. We  
22 were told by the Congress that this was to be

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1 a private sector initiative, but that the FDA  
2 was to participate in a collaborative long-  
3 range action plan for implementing consumer  
4 medication information. And in that law,  
5 you're going to hear much more about the law,  
6 but it articulated how many patients should  
7 receive useful information, and we were to  
8 work collaboratively to determine what that  
9 ought to look like.

10 So, in 1998, just, again, some of  
11 the highlights of our history, we published  
12 the Medical Guide Final Rule, another piece  
13 of patient information now came into being  
14 called Medication Guides, known by some as  
15 Med Guides. And in 2006, as directed by the  
16 legislation, we published a guidance on what  
17 was useful Consumer Medication Information,  
18 or CMI.

19 As part of the law that I just  
20 mentioned, the FDA, although we were told  
21 quite clearly that this was to be a private  
22 sector initiative, we were given the task of

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1 evaluating how it was working, and so we did  
2 the first evaluation some years ago. And the  
3 springboard that really brings us here today  
4 is that late last year, we did the final  
5 evaluation of the Consumer Medication  
6 Initiative. And what we found is that 94  
7 percent of patients actually do walk away  
8 from the pharmacy with written medication  
9 information for their prescription products,  
10 but that only about 75 percent met the  
11 minimal criteria for usefulness. And, again,  
12 you're going to hear much more about this in  
13 the following presentations. As an overview,  
14 this is really what brought us here today.

15 In addition to some of these big  
16 milestones, all along the way FDA has been  
17 engaging our stakeholders. This is not an  
18 FDA problem, or an FDA issue. We recognize  
19 that this is an issue that needs to be taken  
20 up by the entirety of the healthcare system.

21 So as early as 2002, some of our members of  
22 the DSARM are here, we had a Drug Safety and

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1 Risk Management Advisory Committee meeting  
2 about CMI. We had a public meeting in 2003,  
3 and a whole series of stakeholder meetings.  
4 We have had Part 15 hearings, which are  
5 hearings where the public comes forward and  
6 tells us what they think. We had one in 2005  
7 about the entirety of communicating drug  
8 safety information. We also had a Part 15  
9 hearing in 2007, specifically about how the  
10 Med Guide program was going. And, in  
11 addition to us engaging our stakeholders all  
12 along the way, we have our stakeholders  
13 engaging us. We have Congress, of course,  
14 engaging us most recently with the passage of  
15 the FDA Amendments Act, in which they very  
16 strongly took up this issue of how we manage  
17 the risks of prescription drug products,  
18 including mentioning Med Guides now as part  
19 of what's called a REMS, Risk Evaluation and  
20 Mitigation Strategies that the FDA now has  
21 clear authority to require of the drug  
22 sponsors.

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1           We have numerous letters all of  
2 the time, and most recently, probably some in  
3 this room were even involved in, but most  
4 probably know that we have something in the  
5 Agency called a Citizen Petition Process,  
6 where the Agency can be petitioned by members  
7 of the public to take certain regulatory  
8 actions.

9           We currently have a Citizen  
10 Petition in-house about this very issue, with  
11 very strong suggestions about how we ought to  
12 be communicating with patients around  
13 prescription drug information. Because we  
14 are in the process of just now developing an  
15 answer to that petition, much of which will  
16 be influenced by some of the things we hear  
17 from our advisors today, we cannot talk  
18 specifically today about an answer to that  
19 petition. But since many people know it's  
20 in, I think it's important to mention that we  
21 are working on it, and that this meeting  
22 serves partially as input to where we think

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1 we ought to go in this area.

2           So where has all of this history  
3 led us? Really, where are we today? We've  
4 had 40 years worth of work in the arena of  
5 how to communicate with patients about their  
6 drugs, and what we've ended up with are  
7 multiple forms and sources of written patient  
8 information. And today I think you're going  
9 to hear primarily about the following three;  
10 we have patient package inserts, which are  
11 mandatory. The patient package inserts are  
12 part of the product labeling, and they go out  
13 to -- the ones for oral contraceptives and  
14 the estrogen products go out -- they are  
15 mandatory to be included with the product.  
16 There are also any number of voluntary  
17 patient package inserts, and you'll, again,  
18 hear about all of this in greater detail, so  
19 we have PPIs.

20           We have Medication Guides, which  
21 are also a mandatory form of patient  
22 communication. However, we have heard very

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1 much over the last couple of years that not  
2 only are they too long, and there are too  
3 many of them, and they are inconsistent in  
4 some in their format, some are about a single  
5 issue, so we have Med Guides that speak only  
6 to the suicidality issue, for example, with  
7 the SSRIs. Some of them, which tell the  
8 whole story, or give complete information.  
9 So they are inconsistent in their format,  
10 many have told us that they're too long, and  
11 I think most importantly, we're learning that  
12 even though they're mandatory, patients  
13 aren't getting them. It is required of the  
14 manufacturers to be sure they go out with the  
15 products that require Med Guides, but we know  
16 that patients aren't getting them. We hear  
17 this.

18                   And then, finally, we have CMI.  
19 And we have just learned from our most recent  
20 study that the CMI is not meeting its  
21 statutory goals, so we have the Med Guides,  
22 which may or may not communicate well, which

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1 aren't getting there. And then we've got the  
2 CMI, which is getting there, but not entirely  
3 useful.

4 We have a couple of other  
5 challenges as we try to figure out how to  
6 move forward. One is, of course, we are not  
7 unaware of the burden to the healthcare  
8 system in having so many pieces of paper. We  
9 have heard vehemently from the pharmacy  
10 community that -- we just heard from a couple  
11 of people yesterday that you go your  
12 pharmacy, and they, basically, in some cases,  
13 if they're giving you everything you're  
14 supposed to get, you have a shopping bag  
15 that's more full of the paperwork that you're  
16 required to take home and read, and you can  
17 hardly find your drugs in there. So in very  
18 busy pharmacies that are tight in financial  
19 times, just like every other part of our  
20 industry, this isn't working for them. This  
21 is a real burden to them.

22 There are challenges, of course,

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1 of electronic distribution. We know that all  
2 patients don't have access to computers, and  
3 aren't able to use them. And, of course,  
4 our, we think, most important challenge is to  
5 assure that whatever information we're  
6 providing to patients has value to them, that  
7 they are able to read it and understand it,  
8 and that it's actually making a difference in  
9 a positive way as to how they're using their  
10 drugs.

11 What we've heard then as we've  
12 listened to all of our stakeholders is, we  
13 have heard from a lot of patients who don't  
14 believe they're being informed of risks  
15 properly, and that too much paper is leading  
16 to confusion, at best, and at worst, the  
17 stories we hear is that when you have that  
18 much paper, you just throw it away before you  
19 ever even leave the pharmacy.

20 Again, we hear from the  
21 pharmacists that they are too overwhelmed  
22 with paperwork requirements, and that there

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1 is not -- in addition to the cost I  
2 mentioned, there are logistical concerns  
3 about where they even store these Med Guides,  
4 if they get them from the manufacturers. And  
5 we believe, and we've heard from everyone,  
6 that more research is needed to focus on the  
7 utility, balance, and comprehension of  
8 prescription drug information with an eye  
9 toward reaching the broadest audience  
10 possible.

11 And, so, how can you help us? I  
12 think that ought to be really clear, is we  
13 need you to help us answer the question, all  
14 of our specific questions, but more broadly,  
15 we are trying to determine how we, the FDA,  
16 what we can do alone, and what we can do in  
17 partnership with the rest of the healthcare  
18 system to insure that prescription drug  
19 information is effectively communicated to  
20 our target audiences.

21 I heard Dr. Wolfe in his opening  
22 comments talk about his interest in hearing

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1 where we are in 2009, 40 years later. And I  
2 think you will hear that. What we are hoping  
3 for is that we will have some idea at the end  
4 of this meeting where we should be not only  
5 in 2009, but, certainly, where we should be  
6 as we go forward into 2010, and over the  
7 upcoming years.

8 I loved to hear from Dr. Paling  
9 that new ideas are valued and embraced. We  
10 are really looking for your new ideas. We do  
11 have a few Social Scientists. We don't have  
12 nearly enough. It hasn't been a big part of  
13 the FDA's staffing, and so we are really  
14 counting on the folks around this table to  
15 help us answer this question.

16 We recognize that what we have now  
17 is a problem, a system-wide problem. We came  
18 here because of the results of what we  
19 learned from the most recent CMI study that  
20 brought us here, but we have heard over the  
21 years, and I think that just highlighted,  
22 that we are just in a bit of a quandary now,

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1 and we hope really at a crossroads where we  
2 can figure out now what is the very best  
3 thing for us to do in the next upcoming short  
4 and long term. So, again, thank you so much  
5 for your time. I am honored to be in the  
6 presence of so many people knowledgeable  
7 about these very issues.

8 CHAIRMAN FISCHHOFF: Thanks for  
9 asking. And to continue our education, we'll  
10 hear from Nancy Ostrove.

11 DR. OSTROVE: Okay. Good morning,  
12 again.

13 All right. Having been in my  
14 previous incarnation at FDA one of the  
15 behavioral scientists in CDER, they let me  
16 talk about the history, because I've been  
17 involved in this process, I guess Part II of  
18 it. But let's start a little bit further  
19 back than that. I'm also giving homage to  
20 some of the past lives that Dr. Kessler used  
21 when we started kind of Part II of this whole  
22 effort.

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1           In the 1500s, if a physician was  
2 caught teaching a patient about medicines, he  
3 could be fined 40 shillings, because it was  
4 considered to be a bad thing for them to  
5 learn about this, and might actually harm  
6 them. Four centuries later, an FDA notice  
7 published for the public instructed drug  
8 manufacturers to write the labeling for the  
9 products so that non-medical experts couldn't  
10 understand the information. So, four  
11 centuries later not a whole lot had changed.

12       But, at least - well, think of it this way,  
13 at least they weren't being fined for giving  
14 the patient some information if they could  
15 understand it. So, I mean, there was some  
16 movement forward by 1938.

17           Things changed a lot between 1938  
18 and the latter half of the 20<sup>th</sup> century. And  
19 as Debbie mentioned, actually, in 1968, FDA  
20 required a short warning to be put on the  
21 labeling for isoproterenol products,  
22 sometimes -- I think the brand name was

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1 Isuprel. And the warning was about  
2 paradoxical bronchoconstriction, because, in  
3 fact, the product could cause the same  
4 problem that it was being used to treat,  
5 which is difficulty breathing.

6 And, in addition to that, in  
7 1970s, FDA required manufacturers to write  
8 and distribute information about oral  
9 contraceptives, and estrogen. Now, these  
10 were kind of an interesting change,  
11 interesting case. And these products were  
12 different from many others in the sense that  
13 they were being used by healthy women. They  
14 carried risks associated with them, and the  
15 women had other options, so there was really  
16 kind of an informed consent process involved  
17 in this particular area. But FDA was still  
18 interested in continuing, and expanding the  
19 use of patient information, of written  
20 patient information.

21 Now, in 1980, and, basically, what  
22 I'm doing here is giving you a little bit

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1 more detail, and we'll get even more into the  
2 details when the next speaker is up. In  
3 1980, FDA issued regulations for a pilot  
4 project, and that project was for 10 drugs  
5 that are commonly used, to include FDA-  
6 approved patient information, written patient  
7 information. But in 1982, the sense was that  
8 there was a lot going on in the private  
9 sector, and that FDA did not want to stand in  
10 the way of potential innovation. So FDA  
11 withdrew that regulation in favor of  
12 encouraging the private sector initiatives  
13 that were going on.

14 At that point, Cyba Geigy gave  
15 about a million dollars to form the National  
16 Council on Patient Information and Education.

17 AMA, the American Medical Association,  
18 committed to providing leaflets to their  
19 physicians at a relatively low cost, so that  
20 they could give them to the patients, because  
21 the thought was, after all, rather than  
22 getting the information in the pharmacies

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1 after the prescriptions had already been  
2 written, and patients had, in some ways,  
3 already given implied consent by trying to  
4 fill the prescriptions, the sense was that  
5 really physicians should be doing this. So  
6 there were a few -- AARP was involved, as  
7 well. There were a number of private sector  
8 initiatives, but what FDA did is commit to  
9 monitoring the process of how well this  
10 information, information about prescription  
11 drugs, was being given to patients.

12 And, at that point, starting in  
13 1982, FDA started conducting national surveys  
14 of patients looking at the information they  
15 were being given, both orally, and in  
16 writing, at both physician's offices, and at  
17 pharmacies.

18 In that period of time, and going  
19 forward from there, there also were patient  
20 package inserts, which were essentially  
21 voluntary in nature, as opposed to the  
22 estrogen and the oral contraceptives ones,

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1 which were mandated by regulation. These  
2 voluntary ones kind of kept moving forward.  
3 Some people wanted them, some manufacturers  
4 wanted them, so they continued to be issued.

5 And, basically, the culture  
6 continued to change, as well. And we've been  
7 part of the changes. Despite the fact that  
8 low health literacy remains a significant  
9 issue, as has already been discussed by Dr.  
10 Davis, the population has gotten more  
11 sophisticated, and educated. There's been a  
12 real movement for consumer empowerment, and  
13 people wanting to be involved in making  
14 decisions about their own healthcare.  
15 There's the whole issue, especially in  
16 America, of a fairly litigious environment,  
17 where something goes wrong, people really  
18 want to find someone to blame for it, greater  
19 attention to improving outcomes, and reducing  
20 risk, and an aging baby-boomer population.  
21 Notice I left out the baby-boomer part, but  
22 I'm allowed to talk about that, since I'm

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1 part of it.

2 So, by 1993, the requirements of  
3 the 1990 Omnibus Budget Reconciliation Act,  
4 that's the OBRA, those requirements changed  
5 the pharmacy environment. It required drug  
6 utilization review, which really starting  
7 moving pharmacies toward electronics, and a  
8 little bit away from being purely paper-  
9 based. And, in addition to that, the OBRA  
10 '90 also required that pharmacists make an  
11 offer to counsel patients who are Medicaid  
12 patients. And many State Boards of Pharmacy  
13 expanded that requirement to include that  
14 pharmacists should offer to counsel all  
15 patients.

16 Now, that has been kind of  
17 inconsistently implemented. And, in some  
18 cases, patients kind of sign something that  
19 really is their offer to counsel that they're  
20 not necessarily aware is their offer to  
21 counsel. They think they're signing for the  
22 prescription. Now, that's kind of an

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1 anecdotal report. We don't have solid data  
2 on that, but we certainly heard that a lot.  
3 So, sometimes there is, sometimes there  
4 isn't, but that was kind of all started by  
5 OBRA '90.

6 FDA, as I said, continued to do  
7 these surveys of patients as to what kind of  
8 information they were getting, both orally  
9 and in written form, at doctor's offices, and  
10 at the pharmacies. And what we found in 1992  
11 and 1994 is that a third or fewer of the  
12 patients who were surveyed had been orally  
13 counseled by their physicians, and about a  
14 quarter or fewer had been orally counseled by  
15 pharmacists about the risks of the medicines  
16 that they were being prescribed and  
17 dispensed.

18 In looking at written information,  
19 only 15 percent or fewer of the patients who  
20 were surveyed had gotten any written  
21 information from their physicians. And, in  
22 addition, between 1992 and 1994, those who

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1 got written information from their  
2 pharmacists that went from about 32 percent  
3 of the patients to about 59 percent between  
4 1992 and 1994. Recall that OBRA `90 went  
5 into effect in 1993, so it did appear that  
6 there was a considerable effect on the  
7 provision of written information by OBRA  
8 `90's requirements. And we postulated  
9 internally, of course, we speculated that  
10 that requirement was facilitating giving out  
11 written information, as opposed to actually  
12 orally counseling the patients. So, again,  
13 speculation, but it seems to be somewhat  
14 supported by the coincidental increase from  
15 32 to 59 percent.

16 We did a small analysis  
17 internally, and found out that, in fact,  
18 while there was more written information  
19 being given out at the pharmacy, the quality  
20 of the information was still highly variable.

21 So, in 1995, the FDA proposed that it would  
22 set goals and time frames for the private

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1 sector to meet these goals to guide more  
2 consistent private sector effects, because we  
3 were seeing this increase in written  
4 information that's being given out to  
5 supplement and reinforce whatever oral  
6 information patients were getting from their  
7 doctors and their pharmacists, but we felt  
8 that it would be helpful to actually have  
9 goals for that program to meet. So those  
10 were set in the Medication Guide proposed  
11 regulations that we issued in 1995.

12 At the same time, as part of those  
13 regulations, we proposed that for certain  
14 drugs that were considered especially risky  
15 for one reason or another, that there also be  
16 manufacturer-drafted, FDA-approved written  
17 information for those products, and that that  
18 be required to be given out to patients.  
19 Again, this was a proposal.

20 Now, while that proposal was out  
21 for public comment, Congress kind of took the  
22 issue into its own hands, and passed Public

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1 Law 104-180, which Debbie has already  
2 mentioned. And what that Public Law did, is  
3 that it adopted the goals and the time frames  
4 that we had put in the proposed rule for the  
5 private sector to meet in order to be insured  
6 that they were providing useful written  
7 information. It mandated a process to  
8 develop a long-range action plan through  
9 collaboration of all of the interested  
10 stakeholders, pharmacy, medicine, patients,  
11 consumers, information providers, to set up  
12 this action plan. And it limited FDA's  
13 ability to take any further regulatory action  
14 to require a comprehensive program of FDA-  
15 mandated, and FDA-approved written patient  
16 information about prescription drugs. In  
17 1997, the Secretary of the Department of  
18 Health and Human Services accepted that  
19 action plan, sometimes known as the Keystone  
20 Report.

21 Now, in 1998, FDA published the  
22 final regulations that required Medication

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1 Guides for products that pose a serious and  
2 significant public health concern that  
3 necessitated distribution of information to  
4 patients, written information to patients, so  
5 that they would be able to use their products  
6 in an appropriate -- the products they were  
7 being prescribed in an appropriate fashion.  
8 And in 1999, those regulations became  
9 effective. And since then, more and more  
10 products have been getting Medication Guides.  
11 Initially, there were relatively few, and  
12 over the last few years there's been kind of  
13 an exponential increase.

14 In 1999, in response to the Public  
15 Law, we sponsored a limited valuation. It  
16 was restricted to eight states of the  
17 information that patients were being given  
18 under this private sector program, that was  
19 being guided by the long-range action plan,  
20 and the goals in Public Law 104-180. That  
21 was to give the information providers some  
22 feedback about how they were doing at that

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1 point, because their first goal was set up  
2 for 2001. And Jodi Duckhorn is going to talk  
3 more about that, so I'm not going to go into  
4 detail. But in 2001, FDA sponsored a  
5 national evaluation of the progress toward  
6 meeting that initial goal. And then in 2005,  
7 to provide additional information to the  
8 information vendors, and to, basically, the  
9 public about kind of how we were -- because  
10 even though we were not responsible for  
11 regulating this information, we were  
12 responsible, we are responsible for  
13 evaluating it. So, the guidance that we put  
14 out basically let the public know how we were  
15 interpreting the criteria for useful  
16 information that were in the long-range  
17 action plan, and how we were evaluating  
18 those.

19 So that draft guidance went out in  
20 2006. We issued the final guidance for that,  
21 that's part of our guidance process. And in  
22 2008, we sponsored the evaluation of the kind

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1 of the private sector programs' success at  
2 meeting the final goal in the Public Law,  
3 which was set out actually for 2006. So it  
4 was a couple of years after that goal was  
5 supposed to be reached, but we had provided  
6 more information to the public about how to  
7 kind of go about doing that, and did not feel  
8 that it was inappropriate to give them a  
9 little bit more time to get to those goals.

10 So, that's where we are kind of  
11 right now, and I think you'll -- it's part of  
12 the teaching thing. Tell them what you're  
13 going to tell them, tell them what it is, and  
14 then tell them again, so you're going to be  
15 hearing, I think, the same thing a few times.

16 But, basically, we have three different  
17 varieties of prescription drug information  
18 out there; FDA-approved patient labeling,  
19 either PPIs, which are, in most cases,  
20 voluntary, but in a couple of cases  
21 mandatory, Medication Guides, which are  
22 mandatory under the Medication Guide

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1 regulations. Then we have Consumer  
2 Medication Information, which FDA does not  
3 regulate, which is not produced by  
4 manufacturers. It's produced by independent  
5 private sector information vendors. And then  
6 there's promotional materials, which we're  
7 not going to talk about at all today, but  
8 figured for the purpose of comprehensiveness,  
9 we would make sure that you've got all those  
10 out there. So, thank you for your attention,  
11 and, again, looking forward to the rest of  
12 the day.

13 CHAIRMAN FISCHHOFF: Thank you.  
14 We'll go on now to Jodi Duckhorn.

15 MS. DUCKHORN: Hi. I'm Jodi  
16 Duckhorn. I am the Team Leader for the very  
17 expanding group of patient labeling  
18 reviewers, who review this patient labeling  
19 that's received by the Agency. I also lead  
20 what will hopefully be a group of, but  
21 currently just one social scientist, who is  
22 responsible for evaluating the effectiveness

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1 of medication guides as a tool used to  
2 mitigate risk. I, myself, am a social  
3 scientist, and one of only a handful in CDER,  
4 so it's very nice to be in kind of a group of  
5 social scientists who have more experience  
6 than me.

7           There are, I guess in the spirit  
8 of what Nancy was saying, I'm now telling you  
9 for the third time there are three types of  
10 written information patients might receive  
11 with their prescription; FDA approves and  
12 regulates Medication Guides, Patient Package  
13 Inserts, and we do not review or regulate  
14 Consumer Medication Information. You've  
15 heard about the longstanding interest in  
16 assuring that patients receive useful  
17 information with their prescription  
18 medicines, so I'm going to start by talking  
19 about Medication Guides.

20           Products must have a serious and  
21 significant public health concern for which  
22 patient information is necessary to insure

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1 the safe and effective use. Medication  
2 Guides are primarily for outpatient  
3 prescription products, and there are three  
4 triggering criteria for Medication Guides.  
5 So, a Medication Guide is required if FDA  
6 determines that one or more of these exist  
7 for a particular product. Patient labeling  
8 could help prevent serious adverse effects,  
9 the product has serious risks that could  
10 affect patient's decision to use, or to  
11 continue to use, and patient adherence to  
12 directions is crucial to the effectiveness of  
13 the product.

14 Medication Guides are written, for  
15 the most part, by manufacturers. They're  
16 reviewed and approved by FDA by patient  
17 labeling reviewers, and then they become part  
18 of the professional labeling. The details of  
19 this are not as important as just to  
20 understand that there are -- I'm going to go  
21 through each of these, and you're going to  
22 see kind of why we are where we are today,

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1 that there's all this craziness in the  
2 differences.

3 Medication Guides have  
4 distribution requirements according to the  
5 regulations. Manufacturers are responsible  
6 for providing "sufficient numbers" of the  
7 Medication Guides so that enough can be  
8 disseminated to patients receiving either new  
9 prescriptions or refills. And the dispenser  
10 is actually required to provide the  
11 Medication Guide with each prescription when  
12 the product is dispensed.

13 There are several Medication Guide  
14 requirements in the regulations. One is that  
15 they're written in non-technical,  
16 understandable language. It actually  
17 specifies sixth to eighth grade reading  
18 level. We do check that. That's our aim,  
19 sometimes it's just not possible. They're  
20 supposed to be non-promotional in tone and  
21 content, specific in comprehensive content  
22 that is consistent with the professional

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1 labeling, and not conflicting with the  
2 professional labeling. Ten point minimum  
3 type size, they have to be legible and  
4 clearly presented, using appropriate use of  
5 highlighting techniques, bolding or  
6 underlining, not in Italics or any fanciful  
7 fonts, use of white space, as I said,  
8 bolding, headers, the idea of chunking,  
9 having like information together. And then  
10 there's a uniform order of headings or  
11 information with specified section headers in  
12 the question and answer format. This is the  
13 question and answer format that we use, and  
14 it's actually specified in the regulations.  
15 They're used as-appropriate. What is the  
16 most important information I should know  
17 about drug? What is drug? Who should not  
18 take drug? How should I take drug? What  
19 should I avoid while taking drug? What are  
20 the possible side effects of drug? And then  
21 some specific verbatim statements that are  
22 more a disclaimer than anything else. And,

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1 again, these are just as they apply. We  
2 don't always have what should I avoid while  
3 taking drug section, or if there are no  
4 contraindications, then that section is not  
5 in there.

6           The Food and Drug Administration  
7 Amendments Act of 2007 stated that Medication  
8 Guides developed after March 25<sup>th</sup>, 2008 will  
9 be considered part of a risk evaluation and  
10 mitigation strategy, as we call REMS, for  
11 purposes of development and evaluation. This  
12 means that the effectiveness of a Medication  
13 Guide as a tool to mitigate the risks  
14 associated with the drug must be evaluated,  
15 which is why, as I was saying, we have social  
16 scientists, also.

17           Those assessments are an  
18 evaluation, again, used to assess the  
19 effectiveness of the Medication Guide as a  
20 tool to mitigate the risks associated with  
21 the product. The manufacturer develops a  
22 survey, or other mechanism to evaluate at 18

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1 months, three years, and seven years, and  
2 sometimes at the Agency's discretion, more  
3 often.

4           Some of our better assessments  
5 have included questions about patient's  
6 receipt of the Medication Guide, and  
7 patient's understanding of the specific risks  
8 in the Medication Guide. Do they understand  
9 the information? Do they demonstrate  
10 knowledge about what to do if they experience  
11 the event?

12           So, some of the proposals where  
13 we've - I'm saying this lightly - recommended  
14 revisions, they're not as good, have included  
15 patient attestation of receipt and  
16 understanding. So one sponsor, for example,  
17 proposed a business reply card that simply  
18 had check boxes, yes, I received it; yes, I  
19 understood it. And, in our opinion, it  
20 simply meant that the patient was able to  
21 check boxes, and they found a mailbox. They  
22 didn't demonstrate, or necessarily even

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1 receive anything.

2           Proposals have included recruiting  
3 selected physician's offices or pharmacies to  
4 survey patients. We felt that sponsors could  
5 actually recruit physicians who they knew  
6 were providing better education, essentially,  
7 cherry-picking patients to participate in  
8 these surveys. Use of approved Medication  
9 Guide as a reference during the survey, so  
10 one of the -- actually, several of the  
11 proposals we've received have requested that  
12 during the survey, the patient actually has  
13 as a reference the Medication Guide, so it's  
14 not how effective was this tool in terms of  
15 your understanding, it was can you read from  
16 this piece of paper to take an open-book  
17 test, essentially.

18           Something else that we've seen is  
19 using the general population and not,  
20 necessarily, patients to test materials. So,  
21 again, if they haven't received the  
22 Medication Guide, and you're not taking into

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1 account the other education that they've  
2 received, what they know about their disease,  
3 we didn't feel like that was a good  
4 assessment.

5           Additionally, we have seen  
6 proposals for not just using the general  
7 population, but using patients of competitor  
8 products, what they're calling potential  
9 patients. So, again, they may understand the  
10 disease, but they don't use that product.

11           Something else we've seen is re-  
12 educating patients prior to survey by  
13 providing a Medication Guide at the time they  
14 are recruited to take the survey, but not at  
15 the time of the survey. So what that means  
16 is, when a patient is recruited to  
17 participate in the survey, they are sent the  
18 Medication Guide, which, if it was an ideal  
19 situation, they received it when they picked  
20 up their prescription, then they receive it  
21 again when they're recruited to participate,  
22 and then they're told in a week we're going

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1 to survey you. So it's a re-education prior  
2 to survey, which we felt like it wasn't  
3 actual use setting.

4 Another scenario was allowing  
5 respondents to be eligible to participate in  
6 multiple waves of evaluations. So they  
7 participate in the evaluation, they're then  
8 educated on what they've answered  
9 incorrectly, and then they get to participate  
10 again. So I'm just kind of showing you some  
11 of the bias we've seen, and what we've  
12 recommended changes to, as opposed to some of  
13 the better which ones, which I showed you on  
14 the slide prior to this.

15 Questions under consideration to  
16 facilitate consistency. These questions, in  
17 addition to the specific risk questions, we  
18 wanted to facilitate consistency, because  
19 these questions would be used to evaluate the  
20 Medication Guide for a particular product,  
21 but then across all products, also. So any  
22 product that has a Medication Guide that's

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1 being assessed for the effectiveness of that  
2 tool, would have the same set of questions.  
3 These are the kinds of questions that we are  
4 considering.

5 Now, we're still very early in  
6 this process. Obviously, we're looking for  
7 advice from you guys on both the methodology,  
8 and the actual specific questions, so some of  
9 these are probably more nice to know, than  
10 need to know. I haven't separated them. We  
11 haven't even spent a whole lot of time  
12 differentiating between which ones are nice  
13 to know, versus need to know. But the  
14 questions that we've been thinking about,  
15 that we want to consider to facilitate  
16 consistency, who gave you the Medication  
17 Guide? And, again, I'm not providing to you  
18 all the possible answers, just because for  
19 the interest of time. Did you read the  
20 Medication Guide? Did you understand what  
21 you read in the Medication Guide? Did  
22 someone offer to explain to you the

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1 information in the Medication Guide? Did you  
2 accept the offer? Did you understand the  
3 explanation that was given to you? Did, or  
4 do you have, any questions about the  
5 Medication Guide? How long did you keep your  
6 Medication Guide for a drug? And, other than  
7 the first time you received the Medication  
8 Guide for a drug, did you refer back to it  
9 for any reason? And then, finally, where did  
10 you fill your prescription for drug? And  
11 then, in addition to those, there would be  
12 actually the specific questions about if you  
13 had this side effect, which of the following  
14 things would you do, or something about more  
15 specific risk. But these are the more  
16 general questions that we would like to see  
17 across in assessments.

18 So, we talked about Medication  
19 Guides, and assessment of Medication Guides.

20 Now we're going to talk about Patient  
21 Package Inserts. Again, in the spirit of  
22 telling you again for the third time, there

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1 are two kinds of Patient Package Inserts.  
2 There are required Patient Package Inserts  
3 for two drug categories, the oral  
4 contraceptives, and the estrogen-containing  
5 products. And then there are the voluntary  
6 PPIs for the other products.

7           While we call them voluntary, once  
8 the Agency has asked for a Patient Package  
9 Insert, or once one has been submitted to the  
10 Agency for review, it becomes part of patient  
11 labeling. And, so, it's not voluntary in  
12 that it's not part of labeling. It's part of  
13 labeling. It's just voluntary in terms of  
14 dissemination. The content and the format  
15 are not covered in the regulation the way  
16 that the Medication Guide content and format  
17 is covered in regulation. It's also -- the  
18 dissemination is not covered in regulation,  
19 so manufacturers are not required to provide  
20 it to dispensers, and dispensers are not  
21 required to disseminate it with each  
22 prescription. So that's how it very much

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1 differs from Medication Guides, but the  
2 language that's used is still reviewed and  
3 approved by the Food and Drug Administration,  
4 and it is still part of labeling.

5           Again, for now the fourth time,  
6 it's considered to be FDA-approved labeling.

7       Generally, when FDA or the manufacturer  
8 considers it necessary for the appropriate  
9 use, and it can include patient instructions  
10 for use, which I want to also kind of just  
11 take one quick step out of my slides and say,  
12 patient instructions for use are sort of a  
13 unique problem, if you will, in this whole  
14 mess of communicating to patients. Patient  
15 instructions for use, we recommend as patient  
16 labeling reviewers for instructions for use  
17 to actually be appended to the patient  
18 labeling. And even though it increases the  
19 length of the patient labeling, we're hoping  
20 that if there's one thing that patients are  
21 going to look at, it's usually the  
22 instructions for use. If you're going to

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1 have an insulin pen, you want to know how to  
2 use that pen. So if it's appended to the  
3 stuff that we want you to know, hopefully,  
4 while you have that instructions for use in  
5 your hand, you're also going to maybe look at  
6 the Patient Package Insert, or the Medication  
7 Guide. So we're in sort of between a rock  
8 and a hard place, in that it adds length to  
9 the patient labeling, but, hopefully, by  
10 having these things together in one sort of  
11 document, we're increasing the likelihood  
12 that a patient will actually, maybe, read it.

13  
14 Let me also take this opportunity  
15 to say that products don't have a Medication  
16 Guide and a Patient Package Insert. You  
17 don't have one that's required, and one  
18 that's sort of voluntary. You have one or  
19 the other, or neither. You don't have to  
20 have a PPI, as we have covered. And if a  
21 Medication Guide isn't required, then you  
22 don't have to have that. So there are

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1 situations where you would have a Patient  
2 Package Insert, and an instructions for use,  
3 and consumer medication information, or a  
4 Medication Guide, instructions for use, and  
5 consumer medication information, or just  
6 consumer medication information.

7 So, as of June 30<sup>th</sup>, 2006, any FDA-  
8 approved patient labeling must be reprinted  
9 with or accompany professional labeling. Any  
10 printed patient information required to be  
11 distributed to the patient shall be reprinted  
12 at the end of labeling. There's no way for  
13 us to know if patients are actually receiving  
14 or understanding the information, which,  
15 again, gets us back to why we need to assess  
16 the effectiveness of that information. So now  
17 we've talked about Medication Guides, Patient  
18 Package Inserts, now we're going to talk  
19 about Consumer Medication Information.

20 CMI is the printed information  
21 that's typically stapled to the outside of or  
22 put inside the pharmacy bag. It's not

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1 reviewed or regulated by FDA. It's developed  
2 by commercial vendors, and then usually sold  
3 to pharmacies. It's not developed by drug  
4 manufacturers, either.

5 We've, again, talked about this  
6 several times. Public Law 104-180 required  
7 that an action plan be developed, and I'll  
8 talk about that action plan in just a minute.

9 It also specified goals for the receipt of  
10 useful written information with new  
11 prescriptions. By the year 2000, 75 percent  
12 of people receiving new prescriptions would  
13 receive useful written patient information  
14 with their prescription. The legislation  
15 called for FDA to assess the distribution and  
16 quality of the patient information to assure  
17 that the goals are met within the specified  
18 time frames. The law prohibited FDA from  
19 taking regulatory action specifying uniform  
20 content or format for CMI, provided that the  
21 private sector initiatives met the goals  
22 within the specified time frames.

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1           The action plan for the provision  
2 of useful prescription medicine information  
3 was pulled together by the Keystone Center.  
4 The Keystone Center is an independent  
5 organization that facilitates consensus-  
6 building processes. They convened a group  
7 that consists of healthcare providers,  
8 consumer organizations, voluntary health  
9 agencies, pharmaceutical manufacturers,  
10 prescription drug wholesalers, drug  
11 information database companies, CMI  
12 developers, and others, a lot of people. And  
13 they came up with what's termed the Keystone  
14 Criteria, and that is that information is CMI  
15 should be scientifically accurate, unbiased  
16 in content and tone, sufficiently specific  
17 and comprehensive, presented in  
18 understandable and legible format that is  
19 readily comprehensible to consumers, timely  
20 and up-to-date, and the catch-all, useful;  
21 "useful", meaning that it enables patients to  
22 use the medicine properly and appropriately,

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1 and receive maximum benefit, and avoid harm.

2 So that was `97.

3 In 1998, as Nancy started to talk  
4 about, we contracted an independent  
5 assessment of the proposed program and  
6 methodology. The eight-state study was just  
7 to test the methodology for collecting CMI.  
8 There was an expert panel, and they evaluated  
9 the materials, and then developed eight  
10 categories of useful, by combing the action  
11 plan criteria and components.

12 The eight categories listed were  
13 developed by this expert panel for the 2000  
14 study by combining the action plan criteria  
15 and components, and then they were  
16 operationalized in the two national  
17 evaluations in 2001 and 2008. So the eight  
18 criteria to be considered useful that were  
19 ultimately used in those two studies were  
20 that the drug name, indication for use, and  
21 how to monitor for improvement should be  
22 there. Contraindications and what to do if

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1 they apply, specific directions about storage  
2 and overdose, specific precautions and  
3 warnings, symptoms of serious and frequent  
4 adverse effects, and what to do, certain  
5 general information, including encouraging  
6 patients to communicate with healthcare  
7 professionals, and disclaimer statements,  
8 information that is scientifically accurate,  
9 unbiased in tone and content, and up-to-date,  
10 and information should be in understandable  
11 and legible format that is readily  
12 comprehensible to consumers. So you can sort  
13 of see the overlap between what they  
14 ultimately ended up with, and what was  
15 starting.

16           The results of the 2001 evaluation  
17 of the year 2000 goal, so in the -- just sort  
18 of as a side note, in the 2001 evaluation,  
19 they also added a consumer evaluation, which  
20 was one of the complaints about the 1998  
21 pilot study. So, in addition to having an  
22 expert panel, they also added a consumer

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1 panel.

2                   What they found in the 2001  
3 evaluation of the year 2000 goal is that  
4 almost 90 percent of patients were receiving  
5 new prescription information with their --  
6                   were receiving written patient information  
7 with their prescriptions, but after assessing  
8 it, only 50 percent of that met the minimum  
9 criteria for usefulness. And, therefore, the  
10 year 2000 goal of 75 percent was not met.

11                   After that evaluation, the  
12 National Council on Patient Information and  
13 Education, NCPIE, convened CMI stakeholders  
14 because we wanted to know what we can do to  
15 improve CMI so that the 2006 goal of 95  
16 percent can be met. And what came out of  
17 that is a request for FDA to provide advice,  
18 which put FDA in a unique situation to  
19 provide advice for something that we don't  
20 regulate. So, as Nancy showed you in her  
21 presentation, in 2005, FDA published guidance  
22 for Consumer Medication Information, in 2006

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1 we published the final guidance.

2           Having said that, the goal was for  
3 2006, so we still left some time for all this  
4 to be implemented. What we found in the 2008  
5 evaluation of the year 2006 goal is that  
6 almost 94 percent of patients received  
7 written Consumer Medication Information, but  
8 only about 75 percent of that met the minimum  
9 criteria for usefulness; and, therefore, the  
10 year 2006 goal of 95 percent was not met.  
11 You'll hear Drs. Kimberlin and Winterstein  
12 present the details of the 2008 evaluation.

13           Thank you for your attention.

14           CHAIRMAN FISCHHOFF: Thank you.  
15 We have now, I think, just as a comment, a  
16 sort of remark, that we'll be talking about  
17 whether this was the right study, and how  
18 good is the evidence, and so on. But, I  
19 think, I find it really noteworthy that FDA  
20 has collected evidence, and we have a basis  
21 to start the discussion. There are plenty of  
22 agencies that communicate without any

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1 evidence at all, and have sort of chosen to  
2 fly blind. So you'll probably get some  
3 criticism now, but I think you've put us in a  
4 position for this to be constructive  
5 criticism, rather than starting from scratch.  
6

7                   So we have 45 minutes for  
8 discussion. For the audience, by the rules,  
9 you're invited to speak during the public  
10 comment, but the actual discussion is  
11 restricted to people at the table, and to  
12 presenters who we direct questions to. And  
13 what I'd like to do is invite the members of  
14 the Committee to let me know if they're like  
15 to speak. I'll just take people in the order  
16 that their hands go up. We have pretty good  
17 peripheral vision between Lee and myself, and  
18 I will have a -- we'll probably just go  
19 around the table. And then we'll give --  
20 I'll keep a running list, giving some  
21 priority to people who haven't spoken yet.  
22 So let's start with Ellen, Sid, Mona, Anna

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1 Maria, Paul, Terry, Craig, rather. I'm  
2 sorry. Okay. Ellen?

3 DR. PETERS: So I was curious --  
4 thank you, by the way, for those  
5 presentations. It really helps to sort of  
6 clarify the structure of these different  
7 guides for patients in understanding  
8 information.

9 The question that I had is - and,  
10 to be honest, I'm not sure you're going to  
11 have an exact answer for this - but what is  
12 the purpose of having all three? Is the idea  
13 that we're headed towards a single one? Is  
14 the idea that they've just sort of emerged  
15 through history?

16 MS. HENDERSON: I'll take a stab  
17 at it. It was not purposeful. I think you  
18 have it just right. This is really a system  
19 that has grown through accretion, for want of  
20 a better word. You know, Nancy is more  
21 familiar with the history, but I think you've  
22 identified exactly where we find ourselves.

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1 One thing has led to the other. We were  
2 working to do something different, when it  
3 was determined that the CMI would be a  
4 private sector initiative, and so they've  
5 sort of grown separately and together. And  
6 what is our ideal? We are looking for an  
7 ideal. I think we hear that there's too much  
8 paperwork. And while the Agency has made no  
9 decision yet as to exactly where we need to  
10 go, it would be fair to say we think there's  
11 too many pieces of paper, and that this is  
12 quite confusing. And that we need to develop  
13 something simpler out of this.

14 DR. PETERS: If I could just  
15 follow-up on that. Do you have the ability  
16 now, given that the private sector hasn't met  
17 the standards, do you have the ability now to  
18 regulate something?

19 MS. HENDERSON: We have not gone  
20 all the way down the road yet to determine  
21 exactly what regulatory authority we would  
22 need, if we wanted to put one piece of paper,

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1 make up a system that we're going to require  
2 manufacturers to put one piece of patient  
3 labeling with every drug. But it was very  
4 clear from the law that there is language in  
5 the law that says if this has not succeeded,  
6 the FDA has to go out and get input from the  
7 various stakeholders, and figure out what to  
8 do. So we haven't gone all the way down the  
9 road of figuring out exactly what kind of  
10 regulatory authority we have, or think we  
11 might need, but I think it's fair to say we  
12 are looking at all options. And we'll pursue  
13 whatever we need to do to do this right for  
14 the American people.

15 DR. OSTROVE: If I can add one  
16 thing. Basically, the law says that if the  
17 private sector program does not reach the  
18 goals, that the restriction that it had laid  
19 on FDA about taking further action then no  
20 longer applies. So, it's basically opened  
21 things up. We still have to figure out kind  
22 of what we can do, but that restriction,

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1 which basically said you can't put anything  
2 in place, would be lifted if the goals were  
3 not met.

4 DR. WOLFE: Two things. One is  
5 just information that I dug up when I went  
6 through our files going back 30 plus years.  
7 The FDA actually commissioned a study, which  
8 was done by the Rand Corporation in 1979 and  
9 1980, to answer a number of questions, such  
10 as the role of educational background on  
11 being able to understand the inserts, whether  
12 people would be frightened by the inserts,  
13 and not take drugs, and so forth. And I  
14 would just like to -- I'm sure there are  
15 people in the FDA that know about this, but  
16 many of them who were around at that time are  
17 not around. There was a study by Kanouse, K-  
18 A-N-O-U-S-E. It was called, "Informing  
19 Patients About Drugs", the topic we're  
20 talking about here. It was an FDA contract,  
21 and the report was handed in in August of  
22 '91. We found that very useful just in terms

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1 of some of the claims that were being made  
2 about giving too much information to  
3 patients, and so forth.

4 The other comment is just really  
5 on the question that was just raised, is that  
6 aside from PL 104-180, that says if the  
7 private sector doesn't do what it's supposed  
8 to, meet the goals, the FDA can regulate.  
9 The Medication Guide regulation itself, if  
10 construed not broadly, but just accurately,  
11 there are many more drugs, possibly most, if  
12 not all drugs, where at least one of these  
13 three triggering criteria that you showed in  
14 the slide can be met. Since all drugs have  
15 risks, not just benefits, more information  
16 about how to use the drug, the third  
17 criteria, adherence to directions is crucial  
18 to effectiveness, I think that one can easily  
19 see that the number of drugs that could be  
20 covered just under the Medication Guide,  
21 combined with this PL law that now has  
22 failed, I think the FDA probably does have

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1 enough authority without going to Congress to  
2 greatly broaden, if not include for everyone,  
3 some sort of uniform FDA regulated guide.

4 MS. HENDERSON: I would just add  
5 one more comment to that. Just to remember,  
6 and I'm sure everyone knows, of course, that  
7 our regulatory authority is over the drug  
8 manufacturers, so we have no regulatory  
9 authority over pharmacies, and doctors, and  
10 what they ought to do, so it is constrained  
11 in that way, of course.

12 DR. KHANNA: Okay. Thank you.  
13 Thank you very much, Debbie, and Nancy, and  
14 Jodi. This was tremendously helpful  
15 information for me.

16 First a comment, and then a  
17 question. The comment is that I'd be hard-  
18 pressed to say that the system isn't  
19 successful, or hasn't succeeded if the goal  
20 is to achieve health literacy, because  
21 whether you read one, or you read three  
22 pieces of this information, you'll learn.

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1 You'll learn more about the drug you're  
2 taking, you'll learn about the  
3 contraindications, why you shouldn't take it,  
4 et cetera. But I think it's not the most  
5 streamlined, or efficient, process. And I  
6 would actually be very much in favor of  
7 streamlining it, and having one piece of  
8 information out there that covers all the  
9 bases, that follows the law as it's written,  
10 or if we need to rewrite it, but achieves the  
11 goal of raising health literacy, which I  
12 think is the ultimate goal.

13 The question that I have is, the  
14 Patient Package Inserts in the '60s and '70s  
15 were originally created for oral  
16 contraceptives and estrogens. Why? I mean,  
17 why not benzodiazepines? Why not other  
18 medications? I figured Nancy would be the  
19 one to answer that one.

20 DR. OSTROVE: Well, I think  
21 probably a lot of us could. It really had to  
22 do with the issue of patient consent. Oral

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1       contraceptives were a product that women -  
2       well, obviously, women were using it for  
3       contraception, there were other alternatives.

4       At the time, especially, there were IUDs,  
5       there were condoms, there are different ways  
6       of protecting one's self from getting  
7       pregnant. So given that, and given that it  
8       had these risks of blood clots, the  
9       cardiovascular risks associated with it, it  
10      was felt that women needed to know about  
11      this, because it was an important factor in  
12      their making an informed decision as to  
13      whether this was the right type of  
14      contraceptive product to use.

15                 Similarly, for estrogens, because  
16      the long-term use was associated with  
17      problems, and it was being used by healthy  
18      women. So that was the crucial piece there,  
19      was these were products that are being used  
20      by healthy people. There were alternatives.

21      They didn't have to use them to deal with a  
22      particular condition, so there was an issue

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1 there of patient consent that I think was  
2 more compelling than just the general  
3 argument that you should be informed about  
4 the prescription drugs that you're taking.

5 DR. KHANNA: Okay. And just a  
6 quick follow-up. Given the spectrum of  
7 medications we have now, and you could argue  
8 that some other classes of medications are  
9 taken by people who are not sick, perhaps  
10 they have biomarkers that indicate that  
11 they're at risk for certain conditions and  
12 diseases, statins come to mind immediately,  
13 but they're not sick per se in the definition  
14 of being sick, do you think this argument  
15 still holds today to restrict, not to  
16 restrict, but to provide the guideline of  
17 PPIs specifically for contraceptives and  
18 estrogens?

19 DR. OSTROVE: Well, I welcome  
20 Debbie's perspective, as well. Obviously,  
21 the environment has changed. And since the  
22 late 1970s, the number of drugs in the

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1 armamentarium for healthy people has clearly  
2 increased.

3 I think though we've kind of gone  
4 passed that point in the sense that there has  
5 been an acceptance, that even for products  
6 that are used to treat a particular problem,  
7 that there is value for people learning about  
8 those products, so that they can use it most  
9 appropriately. So, the kind of that  
10 restricted notion, it's really more a  
11 holdover from the fact that we had  
12 regulations. In some ways, the Medication  
13 Guide regulations were put in place so that  
14 that would be able to be done more often,  
15 when it was felt that it was needed for  
16 patients. So I think we've kind of gone  
17 passed that.

18 CHAIRMAN FISCHHOFF: Anna Maria,  
19 then Craig, Terry, and then back to Sid. Oh,  
20 Mike, and then back to Sid. Okay.

21 MS. DeSALVA: Okay. Thanks.

22 I have two related questions that

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1 might be helpful for discussion later. I'm  
2 just wondering if you can characterize any  
3 trends with respect to the manufacturers'  
4 interest in voluntary PPIs, so you presented  
5 that there are both, of course, mandated PPI,  
6 and those that have been developed on a  
7 voluntary basis. And is it certain types of  
8 products, certain levels of risk, certain  
9 manufacturers? If there are any observable  
10 trends, that would be interesting to know.  
11 And then I have a related follow-up.

12 MS. HENDERSON: Jodi, do you have  
13 specific information? It's very clear that  
14 the number of PPIs has increased voluntarily  
15 over the years. I don't have that data.  
16 Jodi, you would at least have a perspective  
17 on it, if not the data. We can certainly get  
18 you that information, those data exist.

19 MS. DUCKHORN: I think the one  
20 thing I want to say about voluntary Patient  
21 Package Inserts, is that they can be used in  
22 lieu of brief summaries. In brief summaries,

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1 the information is sort of on the back of an  
2 advertisement, and so a lot of times what we  
3 see is that sponsors, or manufacturers are  
4 submitting to us Patient Package Inserts that  
5 they want to ultimately use as their brief  
6 summary.

7           Having said that, there are times  
8 that the Agency is actually requesting the  
9 Patient Package Insert, as opposed to the  
10 manufacturer submitting one on their own. In  
11 those cases, it's usually because we've seen  
12 something, we've seen maybe a slight signal,  
13 it's not to the point of requiring a  
14 Medication Guide, but it's almost like that  
15 first step. We think that nothing is not a  
16 good idea. We think patients should receive  
17 something, and so this is that first attempt.

18       So that's maybe a trend, I would say.

19           MS. DeSALVA: Okay. Thank you.

20           And I, also, was interested in  
21 your discussion of Medication Guide, and  
22 evaluation of effectiveness of Medication

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1 Guides. And I was just also wondering if  
2 it's possible to kind of probe a little more  
3 on the range of performance of Medication  
4 Guides, and their evaluation. You talked  
5 about assessments and certain things that  
6 you've seen come up with recommended  
7 evaluation programs that you think were  
8 problematic, and where the Agency has pushed  
9 back, which is interesting to know. I'm  
10 wondering if there are, conversely, any best  
11 practices, or, at this point, what you would  
12 say characterizes levels of performance in  
13 the Medication Guide development and  
14 evaluation? Do you know, are certain  
15 companies, I wouldn't expect you to name  
16 them, but are certain companies further along  
17 in that respect? It's difficult to ask you  
18 these questions, and look at -

19 MS. DUCKHORN: That's okay. So  
20 the Food and Drug Administration Amendments  
21 Act was enacted in 2007, and it's only with  
22 Medication Guides that were approved after

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1 September, I think it's 25<sup>th</sup>, or 21<sup>st</sup> of 2008,  
2 has this started. So the first assessments  
3 for most of these is not actually required  
4 until 18 months after that approval. So,  
5 frankly, we haven't seen any of these yet.  
6 We've only seen proposed methodology. And we  
7 haven't seen a whole lot that's what we would  
8 say is great.

9 I wasn't trying to be flippant or  
10 funny in showing you some of the things that  
11 we've seen, but I wanted you to see some of  
12 these proposals that almost feel like are  
13 intentional bias. That's what it feels like,  
14 as we review these.

15 The ones that are -- most of what  
16 we see is just we're going to do an  
17 assessment, and then we send back to them  
18 saying please provide all of your  
19 methodology, including sample size, and  
20 limitations associated with your methodology,  
21 et cetera. And we have a list of some  
22 questions that we ask. We haven't seen some

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1 really good solid methodology at this point,  
2 and so the question is, is if we could come  
3 up with something, should we be telling  
4 sponsors how to do it, or just let them  
5 propose -- right now, our thinking is let  
6 them propose, and we'll make comments from  
7 there. I mean, the methodology isn't really  
8 the required part of it, it's actually that  
9 they do the assessment. But it would be nice  
10 if we could standardize it in some way to  
11 know, especially patient selection.

12 The questions is probably the  
13 easier part of it. It's the methodology in  
14 terms of how they recruit the patients, those  
15 kinds of things that are really challenging  
16 for us.

17 MS. DeSALVA: Yes, and just a  
18 quick note, and then I'll pass the baton  
19 here. But I think that's a major  
20 opportunity. I just feel like the industry  
21 is very much finding its way in this new  
22 context, and in many cases really quite

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1 urgently wants to do the right thing, but  
2 brings varying levels of knowledge and  
3 expertise. And in my own professional life,  
4 this comes up with some frequency. And,  
5 also, there's interest in this Committee, and  
6 I know I've said this before, but there is  
7 interest in this Committee because of the  
8 tremendous expertise that all of you bring to  
9 bear on the subject, and perhaps playing a  
10 role in developing and providing some of that  
11 guidance. And maybe that's an opportunity for  
12 us going forward and identifying emerging  
13 best practices.

14 MS. HENDERSON: Yes, thank you for  
15 that comment. We would really agree with  
16 that. Not only is the industry struggling, we  
17 are, of course, struggling with what guidance  
18 to give the industry, as we move into this  
19 new territory of having to evaluate not only  
20 Med Guides, but really all of the risk  
21 management tools. I don't want to sidetrack  
22 the whole Committee, but really all of the

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1 risk management tools that are -- this is  
2 really new territory for all of us, and so we  
3 really welcome your input about especially  
4 how to evaluate these communication tools,  
5 because I think it will apply not only to how  
6 we evaluate Med Guides, which is what we have  
7 right now, but as we go forward in whatever  
8 communication tool it is that we end up  
9 having, as we go forward, what should we be  
10 doing from now on to be sure that whatever  
11 we're putting into place is continuing to  
12 work, is working, and is continuing to work.

13 So thank you for that.

14 CHAIRMAN FISCHHOFF: Okay. Craig,  
15 Terry, Mike, Sid, and then Baruch.

16 DR. ANDREWS: I just want to thank  
17 Debbie, Nancy, and Jodi for very helpful  
18 information in trying to better understand  
19 this mix of different patient information  
20 that's being provided.

21 Just a general comment from the  
22 field of integrated marketing communications,

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