MINUTES OF THE

RISK COMMUNICATION ADVISORY COMMITTEE, FDA

5630 Fishers Lane, Room 1066, Rockville, MD

Thursday, August 14, and Friday, August 15, 2008

Executive Summary

The Risk Communication Advisory Committee (RCAC) met August 14-15, 2008.

Three people spoke during the Open Public Hearing on the first day, and two people on the second day (see below for more detail).

Discussion Topic: The Committee heard and discussed presentations from committee members on the scientific basis for translating principles of risk communication into practice in situations of emerging and uncertain risk. The Committee also heard from and interacted with FDA staff members regarding considerations and open questions at the FDA about developing risk communication and management strategies. See below for a listing of active participants in the discussions. For more detail, see below and the presentation slides available on the FDA's Web site (http://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4377s1-00-index-for-1and2days.html).

The Committee proposed and adopted the following resolutions. All voting was simultaneous. The voting members present supported the first four unanimously, and unanimously less one in the last case.

- FDA should consider risk communication as a strategic function, to be considered in designing its core processes.

- FDA should engage in strategic planning of its risk communication activities.

- FDA should find ways to do risk communication research efficiently, ensuring that communications are designed in a timely fashion to a scientific standard.

- FDA should routinely present quantitative risk and benefit information, in formats consistent with its regulatory constraints.

- FDA should develop a participatory design and testing process for FDA consumer communication. The process should include vulnerable groups with barriers to understanding and access.

Members Present

Baruch Fischhoff, Ph.D., *Chair*
Christine M. Bruhn, Ph.D.
Jacob DeLaRosa, M.D. (8/14 only)
AnnaMaria DeSalva
Michael Goldstein, M.D.
Prerna Mona Khanna, M.D., M.P.H.
Madeline Y. Lawson, M.A.
Musa Mayer, M.S., M.A.
Linda Neuhauser, Dr. P.H., M.P.H.
John E. Paling, Ph.D.
Ellen M. Peters, Ph.D.
Betsy Lynn Sleath, Ph.D.
Marielos L. Vega, B.S.N., R.N.

David Smith, Ph.D., *Guest Industry Representative*

Executive Secretary
Lee L. Zwanziger, Ph.D.

Open Public Hearing Speakers

August 14, 2008
William Maisel, M.D., M.P.H.
Jennifer Wilmes, National Fisheries Institute
Ronald Barnett, Ph.D. NIH

August 15, 2008
Cindy Evans, M.Sc., Health Canada
Jeffrey Secunda, AdvaMed

Presentations (see roster for titles and affiliations of committee members)
Thursday, August 14, 2008

Introductory Remarks: Objective of Meeting
Baruch Fischhoff, Ph.D.
Introductory Remarks: FDA's Communication and Concerns
Nancy M. Ostrove, Ph.D., Senior Advisor for Risk Communication

Existing Risk Communications Programs – Overview

Panel Representing FDA Component Organizations

Lynne Rice
Paul Seligman, M.D., M.P.H.
Lorrie McNeill
Laura Alvey
Marjorie Davidson, Ph.D.

Introductory Remarks on Science at the FDA
Frank M. Torti, M.D., M.P.H., Principal Deputy Commissioner and Chief Scientist, FDA

Presentations from Committee Members
Non-Persuasive Communication: What do we know? How do we know it?
Baruch Fischhoff, Ph.D.
Ellen Peters, Ph.D.

Persuasive Communication: What do we know? How do we know it?
Christine Bruhn, Ph.D.
Linda Neuhauser, Dr.P.H., M.P.H.

Friday, August 15, 2008
Presentations from Committee Members
Urgent, Crisis or other Explanatory Communication in Practice: How is it done and how is it evaluated?
AnnaMaria DeSalva
John Paling, Ph.D.

FDA Press: Factors in Decisions on Communication about FDA Actions
Heidi Rebello, Deputy Assistant Commissioner for Public Affairs

Risk Communication Advisory Committee Meeting, August 14, 2008

The Risk Communication Advisory Committee (RCAC) meeting was convened at approximately 8:00 a.m., Thursday, August 14, 2008. The conflict of interest statement was read into the record, noting that, based on the agenda and financial information reported by participants, the meeting affected no particular firms and thus no potential conflicts arose, but that all participants were aware of the need to address conflicts of interest should any arise.

Summary of Committee's Opening Comments and Discussion, August 14, 2008

Baruch Fischhoff, Committee Chair, called the meeting to order, and welcomed all attendees. One member, Sally Greenberg, could not be present due to a schedule conflict, and another, David Moxley, due to illness. Dr. David Smith participated as the guest Industry Representative.

The Committee was asked to discuss and comment on the scientific basis for translating principles of risk communication into practice in situations of emerging and uncertain risk.

Summary of Open Public Hearing Presentations, August 14, 2008

- William H. Maisel, M.D., M.P.H., Director of the Medical Device Safety Institute of Beth Israel Deaconess Medical Center, spoke on behalf of the Heath Rhythm Society. He emphasized that devices are diverse and communicating about implantable devices presents special problems in that patients may interpret the word "recall" as requiring surgical removal of their cardiac device. His recommendations include that the word "recall" not be used for implantable device (slide set associated with statement is on the FDA's Web site).

- Jennifer Wilmes of the National Fisheries Institute commented on possible inconsistency between agencies regarding safety messages. She highlighted messages about mercury in certain fish, contrasting the EPA's website Fish Kids and the FDA's site, arguing that the former provides information about risk inadequately balanced with benefit. Members inquired about testing of the site, and she said she

was not aware of any. Members commented other evidence suggests that children can understand and use well-designed risk and benefit information.

- Ronald Barnett, Ph.D., from the NIH, commented on the value of visual presentations as well as text in conveying information, inviting comment from Committee and also suggesting as useful references the work of Dr. Hans Rosling of Sweden, and the book *Made to Stick: Why Some Ideas Survive and Others Die*. Several members agreed that visual presentation can be helpful both instead of text for conveying information, and to encourage the reading of text. Ms. Mayer recommended Dr. Paling's tools, and Dr. Peters recommended the research of Peter Ubel, Angela Fagerlin and Brian Zikmund-Fisher.

Summary of Presentations and Committee Discussions, August 14, 2008 (Note that these descriptions are succinct summaries. The slide presentations on FDA's Web site provide additional detail.)

Introductory Remarks: Objective of Meeting

Baruch Fischhoff, Ph.D., presented a synopsis of the Committee's purpose to help the FDA with better risk communication. He proposed 4 different types of expertise that an organization needs for effective risk communication and explained the different roles that each expertise plays. The four are expertise in (a) the subject matter of the product and its risk and benefits; (b) decision analysis for extracting the facts most important to audience members' decisions; (c) behavioral science for formulating scientifically sound communications and testing them rigorously; and (d) system design, for disseminating messages and incorporating feedback. He also suggested considering a model recommended by the Canadian Standards Association and adopted by some government agencies (and institutions working with them, including Health Canada). It requires two-way communication between risk managers and stakeholder representatives throughout the development and implementation of a program.

Introductory Remarks: FDA's Communication and Concerns

Nancy M. Ostrove, Ph.D., Senior Advisor for Risk Communication, presented an overview of the history of the Committee, including a summary of some committee recommendations and Agency responses: (1) the FDA supplemental budget includes some funding specifically for risk communication; (2) the FDA has started an internal Communication Council to facilitate and coordinate developing risk communication processes; (3) the FDA has taken steps toward some message testing with internal review for the press release template discussed in February, and: (4) the FDA obtained OMB clearance for customer satisfaction surveys, including the ability to get feedback about specific Web sites with tailored questions.

Existing Risk Communications Programs – Overview

Panel Representing FDA Component Organizations

Lynne Rice (Center for Devices and Radiological Health)
Paul Seligman, M.D., M.P.H. (Center for Drug Evaluation and Research)
Lorrie McNeill (Center for Biologics Evaluation and Research)
Laura Alvey (Center for Veterinary Medicine)
Marjorie Davidson, Ph.D. (Center for Food Safety and Applied Nutrition)

The panelists from the product regulation centers presented an overview of communications that their Centers produce, and highlighted common themes. These common themes include the:

- substantial diversity of regulated products within and between centers;
- will to communicate promptly and with transparency, with varied audiences;
- difficulty of assessing or even estimating communication effectiveness;
- difficulty in communicating numerical risk information.

Introductory Remarks on Science at the FDA

Frank M. Torti, M.D., M.P.H., Principal Deputy Commissioner and Chief Scientist, FDA, thanked the committee for help with risk communication, and shared insights about FDA communication, including that: the FDA cannot communicate successfully without interaction and advice; the FDA needs to build internal expert capacity, and; while it is particularly difficult for a regulatory agency to be proactive about emerging science, that the FDA needs to do more than it has.

Presentations from Committee Members

Non-Persuasive Communication: What do we know? How do we know it?

- Baruch Fischhoff, Ph.D. presented four cases illustrating how sound risk communication is founded on sound risk analysis. He emphasized that the analysis and the evaluation to improve communications would not be unfeasibly difficult, especially as FDA already has some staff with requisite expertise.

- Ellen Peters, Ph.D. presented an overview of barriers to effective communication supporting informed decision-making and how behavioral research can be used to overcome them. These barriers include the intuitive difficulty of understanding uncertain information and the potentially biasing effects of pre-existing beliefs. Addressing these barriers requires overcoming communicators' tendency to overestimate their own effectiveness, leading them to release messages without consulting or conducting the relevant science.

Persuasive Communication: What do we know? How do we know it?

- Christine Bruhn, Ph.D. presented examples illustrating principles of, and barriers to, communication designed to educate audiences about safe handling of food, especially

produce, to persuade them to adopt safe practices, and to inform them about the safety benefits of unfamiliar technologies. She used food irradiation as an example.

- Linda Neuhauser, Dr.P.H., M.P.H. presented recommendations for improving FDA risk communication by taking account of insights from the study of health literacy and processes for involving target audiences in the development process, so that their information needs are identified and the resultant messages are understandable and actionable.

Summary of Committee's Further Comments and Discussion, August 14, 2008
In further discussion, members addressed a variety of issues, including ones prompted by the discussion topics circulated prior to the meeting and inserted below. Neither voting nor consensus was requested, but the Committee provided comments that suggested a shared sense of the issues, and was summarized as such by the Chair.

Topics for Committee Discussion

- In light of information presented by the RCAC members and the FDA panelists, please discuss what scientifically supportable, empirically-based, steps FDA should take to improve the effectiveness of communications.

- As noted in the FDA presentations, FDA's communications may be drafted for a range of objectives and for a range of audiences. Please discuss how the success of a communication may be evaluated for different objectives.

- FDA has adopted, especially in regard to drug products, a policy of increased transparency about early or emerging (possibly still uncertain) risk information. From the perspective of your communities and experience, what might be the effects of this policy? How might the FDA learn more about such effects, if necessary?

- FDA uses certain terms that have special regulatory meaning and importance (example: product X has been shown ***safe and effective*** for its intended use). From the perspective of your communities and experience, what might be conveyed by such terms? How might the FDA learn more about such key terms, if necessary?

Regarding the *first* topic, members strongly emphasized the importance of creating and implementing standard protocols for testing communications empirically. Given the time constraints of emergencies, prototypical messages must be tested in advanced, then adopted to the specific circumstances. Drawing on the research literature, members also made specific design suggestions: They encouraged using quantitative expressions of numerical results rather than ambiguous verbal descriptions (e.g., "rare" or "common"), and using visual depictions of quantitative information rather than (or in addition to)

tables. They also encouraged assessing the reading levels of existing FDA communications with validated tools. Both members and FDA panelists suggested possible research collaborations the FDA might pursue or expand upon, including having academicians work temporarily at the FDA (under the Intergovernmental Personnel Act – IPA) and partnering with groups like the Veterans' Administration and third-party payers that collect data, such as HMOs and Blue Cross/Blue Shield. Some members also suggested paying attention to experientially-based as well as research-based practices. This included considering targeting women even for messages about family members because women are most likely to act as the primary family health care provider, and using celebrity figures for more emotional engagement.

Regarding the *second* topic, members observed that the success of an FDA communication would have to be evaluated differently depending on whether its objective was to persuade people to take some action or only to inform them about the range of possible actions. Members emphasized that sound communication must be supported by sound analysis of the situation facing people, sound design, and sound evaluation after release.

Regarding the *third* topic, members discussed the difficulties of communicating early about information that is still emerging and of uncertain implications, and noted that there can be risks from not using a product as well as risks from using it. Some members commented that the industry, like the FDA, is learning with time but has as yet no clear pattern of practice. Some members encouraged FDA to communicate both what we know and what we don't know, as well as when and where updated information will be available. As elsewhere, they stressed the need to test messages empirically. Members mentioned several times the possibility of FDA holding a workshop on a specific topic such as the communication of uncertain information, and emphasized the committee's willingness to help to plan such an event.

Regarding the *fourth* topic, several members commented that experience suggests that FDA staff may interpret particular terms such as "safe" and "effective" differently than do members of the public. Some suggested that empirical tests be designed to determine whether there are systematic differences and, if so, what interpretations are most common among the public. One member emphasized that the choice of specific words, such as "recall," should be evaluated empirically, rather than relying on claims, however well-intended, made by professional and patient associations, which can be one-sided.

The meeting was adjourned at approximately 5:00 p.m. for the evening, to reconvene the next day.

Risk Communication Advisory Committee Meeting, August 15, 2008

The Risk Communication Advisory Committee (RCAC) meeting was reconvened at approximately 8:00 a.m., Friday, August 15, 2008. The conflict of interest statement was read into the record, summarized from the prior day.

Summary of Opening Comments, August 15, 2008
Baruch Fischhoff, Committee Chair, called the meeting to order, welcomed all attendees, and, after Committee members quickly reintroduced themselves, opened the discussion of the day.

The Committee returned to discussion of the topics listed above and heard additional presentations as below.

Summary of Open Public Hearing Presentations, August 15, 2008

- Cindy Evans, M.Sc., Director, Therapeutic Effectiveness and Policy Bureau, Marketed Health Products Directorate, Health Canada, introduced herself as an observer at the meeting. She provided an overview of Health Canada's risk communication outreach initiatives, such as MedEffect TM Canada, which includes a website for both disseminating information about health and medication advisories and recalls, and for receiving adverse event reports, and the MedEffect E-Notice listserv for pushing out advisory information. She also noted that her office and FDA's Senior Advisor for Risk Communication, Nancy Ostrove, maintain regular contact, for example on meetings of Health Canada's Expert Advisory Committee on the Vigilance of Health Products (EAC-VHP) and the FDA's RCAC.

- Jeffrey Secunda of AdvaMed observed that Ms. DeSalva's presentation represents an admirable standard of industry practice, but one well beyond the means of the small firms that constitute most of the manufacturers of devices. He said that the FDA has a responsibility to shape communications, including educating the media and financial communities. Finally, he agreed with Dr. Maisel that use of the word "recall" for implantable devices should be reconsidered.

Summary of Presentations and Committee Discussions, August 15, 2008

<u>Presentations from Committee Members</u>
Urgent, Crisis or other Explanatory Communication in Practice:
How is it done and how is it evaluated?

- AnnaMaria DeSalva presented a fictional composite case to illustrate an ideal example of how a medical device firm might carry out communication about the decision to recall and later re-introduce a surgically-implanted device. She emphasized that an effective communication strategy should be designed early in the decision-making process regarding whether to recall the device, concluding that systems for communication development must be in place, with the foundations laid before there is an ongoing crisis.

- John Paling, Ph.D., presented a series of suggestions, especially focused on communicating numerical information, derived from his experience as a practitioner in communicating risks. These suggestions included using visual aids in presenting both risks and benefits, reporting risks with a common denominator (e.g., X per million), and that the FDA should consider preparing a short educational summary of

basic principles about understanding risk in general, to precede public communications of specific risks.

Summary of Committee's Closing Comments and Discussion, August 15, 2008

Members decided to propose resolutions and vote on them. All voting was simultaneous by raised hand. Those present supported unanimously (or unanimously less one in the last case) the following:

- FDA should consider risk communication as a strategic function, to be considered in designing its core processes.

- FDA should engage in strategic planning of its risk communication activities.

- FDA should find ways to do risk communication research efficiently, ensuring that communications are designed in a timely fashion to a scientific standard.

- FDA should routinely present quantitative risk and benefit information, in formats consistent with its regulatory constraints.

- FDA should develop a participatory design and testing process for FDA consumer communication. The process should include vulnerable groups with barriers to understanding and access.

Regarding the *first and second* resolutions, members discussed how developing a research agenda should be included in internal strategic planning for communication. They suggested that possible research agenda priorities could include research on specific word choices, how to present numerical information to individuals who differ in age and in numeric ability, and how to compare the risks and benefits of using and not using a product.

Regarding the *third* resolution, discussion before voting established that the intent of the resolution language was on the logistics and needed processes associated with the FDA conducting research, not on the prioritization of research topics, which would be considered during strategic planning (resolution 2). Members emphasized that they did not intend the call for efficiency as a criticism of FDA social science researchers. Regarding logistics and process, members encouraged that the FDA consider pursuing additional blanket pre-clearances of research methods and topics through the Office of Management and Budget, analogous to the existing agreements on Web customer surveys. Several members also encouraged the FDA to explore making research priorities better known to academic researchers, who might then work, individually and collaboratively, to investigate questions of importance to the FDA's communication functions.

Regarding the *fourth* resolution, members emphasized the importance of providing a balance of risk and benefit information to inform judgments about whether to use a product. However, they also noted that members of the public may appropriately get information and advice from sources other than the FDA. In particular, individuals who have difficulty using numerical information can turn to intermediaries such as healthcare professionals or family members. As a result, communications with essential information can assist even individuals uncomfortable with using them directly.

Regarding the *fifth* resolution, several members re-emphasized the principle that the information needs of, and actual effects of communications on, diverse stakeholder groups (especially those with lower literacy) must be investigated and taken into consideration. That cannot be done without engaging such groups on designing and testing communication.

The meeting was adjourned at approximately 2:30 p.m.

For further details of presentations and discussions, please see transcript and slides, both posted at http://www.fda.gov/ohrms/dockets/ac/oc08.html#RCAC.

I certify that I attended the August 14 and 15, 2008, meeting of the Risk Communication Advisory Committee and that the minutes reflect what transpired.

//s//.
Lee L. Zwanziger, Ph.D.
Executive Secretary

//s//.
Baruch Fischhoff, Ph.D.
Chair