MINUTES OF THE

RISK COMMUNICATION ADVISORY COMMITTEE, FDA

Washington DC North/Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, MD

Thursday, February 28, and Friday, February 29, 2008

Executive Summary

The Risk Communication Advisory Committee (RCAC) met for the first time on February 28-29, 2008.

Four people spoke during the Open Public Hearing on the first day, and four on the second day (see below for summaries).

On the first day, the Committee members introduced themselves, and the Commissioner welcomed the new Committee. The Committee then heard from FDA staff members about existing risk communication programs, and about the legal and regulatory conditions that affect how the FDA communicates. See below for a listing of participants (aside from the public audience), and for details on the presentations.

Following the presentations, the Committee brainstormed areas of interest and suggested topics for further consideration, including:

- Designing programs with their communication implications in mind from the start in order to improve their overall effectiveness, rather than adding communications considerations on at the end of the process
- Systematically tracking response to the FDA's communication products among health care professionals and the general public
- Empirically testing the FDA's messages to make sure they are understandable, before publishing them
- Reaching people who have less scientific background, who speak languages other than English, or who have difficulty accessing the information
- Communicating information about benefits as well as risks
- Getting information about possible new risks to the public early, explicitly addressing the uncertainty in the data, in a scientifically sound way

On the second day, February 29, 2008, the Committee heard about how the FDA announces product recalls. The Committee discussed a working draft template for press releases about recalls. The members said that the template was a good start, and suggested some improvements, including the following.

- Using shorter section titles
- Letting the public know that people at FDA are human and care about the worry that recalls can cause for members of the public
- Letting the public know the limits to FDA's authority and resources, so that it has realistic expectations.
- Using the same, identifiable, spokesperson(s), so that FDA's messages have a human face

- As mentioned above, testing the messages to make sure they are understandable before releasing them to the public

Members Present
Baruch Fischhoff, Ph.D., *Chair*
Christine M. Bruhn, Ph.D.
Jacob DeLaRosa, M.D.
AnnaMaria DeSalva
Michael Goldstein, M.D.
Prerna Mona Khanna, M.D., M.P.H.
Madeline Y. Lawson, M.A. (2/28 only)
Musa Mayer, M.S., M.A.
David Moxley, M.S.W., Ph.D., D.P.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.

Consultants and Guests
Gregory Baird,
Steven Gorelick, Ph.D.
Daniel Q. Haney
Michael Wogalter, Ph.D.
Marcia Yaross, Ph.D., *Guest Industry Representative*

Executive Secretary
Lee L. Zwanziger, PhD.

Open Public Hearing Speakers
February 28, 2008
Kathryn Foxhall, Freelance reporter
Michael J. Negrete, Pharm. D., Pharmacy Foundation of California
Jeffrey Secunda, AdvaMed
Jennifer Wilmes, National Fisheries Institute

February 29, 2008
Donna Goldberg and Joel Harder, Heart Rhythm Society
Lisa Weddig, National Fisheries Industry
Marcela Gaitan, National Alliance for Hispanic Health

Presentations
Thursday, February 28, 2008
FDA Welcome
Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs

Overview of Risk Communication at FDA
Nancy M. Ostrove, Ph.D., Senior Advisor for Risk Communication

Legal Authorities and Protections Relevant to Risk Communication
Speech FDA regulates
Speech FDA generates
William A. McConagha, Assistant Commissioner for Accountability and Integrity

New in FDA Amendments Act
Jarilyn Dupont, Director of Regulatory Policy, Office of Policy

FDA Research: Clearance Requirements and Implications
Steven L. Bradbard, Ph.D., Team Leader for Consumer Studies, Center for Food Safety and Applied Nutrition

Existing Risk Communications Programs – Overview

Panel Representing FDA Component Organizations

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

Friday, February 29, 2008
Communication about Product Recalls
Capt. David Elder, Director, Office of Enforcement, FDA Office of Regulatory Affairs

Literature Review: What do we know about the public's awareness, understanding, and perception of recalls concerning FDA-regulated Products?
Amy Lando, M.P.P., Consumer Science Specialist, Center for Food Safety and Applied Nutrition

Comments from Consultants
Michael Wogalter, Ph.D., Professor of Psychology, North Carolina State University
Gregory Baird, President, Baird Edge Consulting
Steven Gorelick, Ph.D., Professor of Media Studies, Hunter College, CUNY
Daniel Q. Haney, Medical Journalist, Bloomberg Markets, Physician's First Watch

Risk Communication Advisory Committee Meeting, February 28, 2008

The Risk Communication Advisory Committee (RCAC) meeting was convened at approximately 8:30 a.m., Thursday, February 28, 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 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, February 28, 2008

Baruch Fischhoff, Committee Chair, called the meeting to order, welcomed all attendees, and began committee introductions, asking members to comment on specific items they saw as important in the work of the Committee.

Dr. Fischhoff summarized his academic and research background and previous (non-HHS) advisory committee experience. He observed that adequate risk communication requires a complex skill set including specialists in the scientific field of the identified

risk, risk and decision analysis, behavioral science, and communications process ranging from website and broadcast technology to community organization.

Dr. Bruhn, a specialist in food science and nutrition, focused on applying principles of risk communication to facilitate daily decision making about food and health, such as working with focus groups to identify consumer perceptions of information needs.

Dr. DeLaRosa, a heart surgeon, noted the importance of communicating specific risks between physicians and patients especially the elderly.

Ms. DeSalva, a specialist in public relations, focused on healthcare delivery systems and products, and emphasized the importance of communication in health decision making, including attending to international health promotion and women's health.

Dr. Goldstein, a psychiatrist and internist, develops educational programs to improve clinicians' communication with patients, and hoped that the Committee might help develop resources to facilitate better communication with the public.

Dr. Khanna, certified in internal and occupational and environmental medicine and public health and preventive medicine, is also a medical broadcaster, focusing on health communication as an essential part of medical care.

Ms. Lawson, a patient and consumer advocate, emphasized collaboration with national health and consumer organizations to address health disparities (e.g., chronic diseases disproportionately affecting people of color), and for improved quality of care for all.

Ms. Mayer, a writer and advocate for breast cancer patients and for research, emphasized communication about evidence-based healthcare in supporting complex treatment decision making by patients.

Dr. Moxley, a professor of social work and community development, focused on health disparities, small communities facing weak or inadequate healthcare coverage, and the interaction of poor health or healthcare with other aspects of poverty.

Dr. Neuhauser, a clinical professor of public health, focused on the problem of how to apply results of research about communication to specific situations of need, including barriers relating to literacy, language, disability, or culture.

Dr. Paling, a film maker and independent contractor in risk communication, addressed the importance of the audience and the potential for communicating even highly technical and specialized information with creative use of visual media.

Dr. Peters, a research scientist focusing on decision analysis, spoke to the use of numerical information in decision making, and variations with age and other individual characteristics in the perception of numerical information.

Dr. Sleath, a professor of pharmaceutical outcomes and policy, emphasized the importance of communication with patients of low literacy or whose first language is not English.

Ms. Vega, a research nurse, noted the importance of communications of health and risk to the Hispanic and Latino public.

Dr. Yaross, guest industry representative from the Circulatory System Devices Panel, observed that risk-benefit decision making and risk communication are critical concerns that industry also faces.

The consultants were also invited to comment.

Mr. Baird, a communications consultant for medical products, stressed the importance for industry of good risk communication, such that a clear expression of expectations from FDA would facilitate their better incorporation of communications expertise.

Mr. Haney, a career medical journalist and retired editor of the Associated Press, noted the role of the press in communication with medical professionals and with the public regarding risk and benefit of medical therapies.

Dr. Gorelick, a professor of media and sociology, focused on risk and crisis communication with communities following catastrophic events, and the importance of incorporating emerging technologies along with mainstream media in communication.

Dr. Wogalter, a professor of psychology specializing in cognitive ergonomics, highlighted the study of warnings in risk communication and methods for evaluating both existing beliefs and the actual effects of warnings on them.

In additional Committee discussion, members commented on important opportunities and hopes for good outcomes of the Risk Communication Advisory Committee, including the following.

- Better communication about risk may improve communication with patients and the public, including those of lower literacy or less access to information, about health and science more generally.
- Improved communication might address the complexity and ambiguity in knowledge of medical products, including communicating about benefits as well as risks.
- The FDA might take a leading role in communication, among government organizations.
- Present an identifiable human face and voice explaining the FDA's actions, similar to what is being done by the CDC.
- Industry is very interested in learning from the Committee about how better to incorporate results of basic research in risk communication.
- Improvements in communication should be incorporated into standard operating procedures and implemented throughout the risk management process.

See the meeting roster and the transcript for details of affiliation and comments.

Summary of Open Public Hearing Presentations, February 28, 2008

- Kathryn Foxhall, Freelance reporter: expressed concern that agencies, including FDA, restrict access by reporters to Agency personnel, with detrimental effect on media's ability to provide full coverage.

- Michael J. Negrete, Pharm. D., Pharmacy Foundation of California: wanted to raise awareness of preventable communication-mediated medication errors, referring to an IOM report.

- Jeffrey Secunda, AdvaMed: suggested that, rather than borrowing industry representatives from product-focused FDA advisory committees, the Agency should consider a procedure for selecting a pool of industry communication experts to serve as guest industry representatives similar to the approach used for other advisory committees.

- Jennifer Wilmes, National Fisheries Institute: commented on unintended consequences of reduced total fish consumption following FDA announcements on mercury in certain species.

Summary of Presentations and Committee Discussions, February 28, 2008

<u>FDA Welcome</u>
Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs, welcomed the members and thanked them for their willingness to serve. He observed that the Risk Communication Advisory Committee is a different sort of committee than other FDA advisory committees. He emphasized the importance of good communication on health and medicine in building relationships and trust leading to good outcomes for patients and the public. The FDA wants to improve communication, thereby leading to safer, better informed use of regulated products, and to rebuilt trust. It welcomes the Committee's advice in this crucial area.

In questions and discussion, members asked about current FDA communication challenges and initiatives, including communication that takes account of ensuring access to Hispanics, to people with different reading levels, and to those with limited internet access. The Commissioner summarized some current FDA efforts, for example redesigning the website. He also noted that other efforts, such as community-level involvement, would be good and are needed. However, such efforts require resources not presently available, so the FDA hopes to work in partnership with external organizations to further its communication.

<u>Overview of Risk Communication at FDA</u>
Nancy M. Ostrove, Ph.D., Senior Advisor for Risk Communication, presented an overview of risk communication at the FDA, starting with the FDA's mission to protect

and advance the public health, and including the complex range of regulated products. She summarized how the communication environment has changed, from a style of avoiding lay language to actively seeking engagement with the lay public in medical and health decision making. The current Committee structure and function is an expression of the FDA's recognition of its need to communicate more effectively.

Legal Authorities and Protections Relevant to Risk Communication

William A. McConagha, Assistant Commissioner for Accountability and Integrity, presented background information on how the FDA regulates communication about products, focusing first on FDA regulation of speech by product sponsors and, then, on the speech the FDA itself generates.

Speech FDA regulates

Mr. McConagha explained that the FDA regulates the labeling (including the actual information on labels and also the packaging, including package inserts) of products, and the advertising about some classes of products including prescription drugs and some devices. In general, constitutional protection of freedom of speech is paramount in how we regulate in this area. This freedom, however, is not absolute, and commercial speech may be regulated more than political or scientific speech. Commercial speech is not protected if it is false or misleading, and that is what the FDA monitors. For example, FDA assesses claims about a product in light of evidence supporting its intended use. Case law has further established the limits of government authority in regulating commercial speech; the government must be able to show that its interest in restricting certain speech is substantial and directly advances its mission in a way that is minimally restrictive.

Speech FDA generates

In the second part of his presentation, Mr. McConagha summarized the FDA's own communication initiatives. The FDA works to communicate to healthcare professionals and to the general public, but also must consider factors like protecting confidential commercial information and whether disseminating information or advice might, or might appear to, interfere with the practice of medicine or pharmacy.

New in the FDA Amendments Act

Jarilyn Dupont, Director of Regulatory Policy, Office of Policy, summarized some provisions in the FDA Amendments Act of 2007 that particularly affect risk communication. The law includes not only the reauthorization of several existing statutes affecting the FDA, but also new provisions on pediatric medical devices, clinical trial databases, conflicts of interest and advisory committees, postmarket safety of drugs, and food safety. The FDA is mandated to consult the Risk Communication Advisory Committee on several matters, including the preparation of a report on the relation of direct-to-consumer advertising and access to health information and reduction of health disparities, and the design of a study on the appropriateness of including in TV advertisements a statement about reporting adverse events to the FDA.

FDA research: Clearance requirements and implications

Steven L. Bradbard, Ph.D., Team Leader for Consumer Studies, Center for Food Safety and Applied Nutrition, provided an overview of how federal government agencies do social science research, with methods like surveys, experiments, and focus groups. In particular, the Paperwork Reduction Act of 1980 requires that any time the federal government proposes to cause data to be collected from ten or more persons, the Agency must first formally seek public comment and must receive clearance from the Office of Management and Budget. This process has a substantial impact on how the FDA may conduct research to evaluate its communication initiatives. Dr. Bradbard also addressed the process of obtaining Institutional Review Board clearance for studies using human participants.

Committee Discussion

In Committee discussion of FDA presentations (above), Committee members suggested that the Agency might work to streamline the Paperwork Reduction Act process to allow pre-testing some protocols for evaluating messages, so that there could be more rapid and limited testing of specific messages in concrete situations. The FDA replied that this might be possible within the current framework. Regarding FDA regulation of advertising, members requested clarification on the extent of application to off-label uses, to advertising in non-English markets, and to public and private airwaves. Dr. Ostrove explained that the FDA's position is that advertising should not promote off-label use (though some have argued that there maybe substantial evidence for some off-label uses), and that its jurisdiction includes non-English advertising and all broadcast airwaves, though action may be limited by resources.

Existing Risk Communication Programs - Overview

Representatives (listed above) from each of FDA's product regulation centers and from the Office of the Commissioner presented summaries of communication initiatives in various FDA components. All the product regulation centers, and several components of the Office of the Commissioner, issue statements to communicate emerging or newly identified risk information, and all maintain one or more websites to make additional information continuously available to the public. A wealth of information is thus available, but is presented under different titles and at present may be difficult for the public to locate on the FDA's website – though the website is undergoing gradual re-design to enhance usability (see slides for titles and examples of publications and websites).

Committee Discussion

Members thanked the panelists for the extensive though briefly presented information. Further discussion began with the question of languages other than English. The FDA is aware of this challenge and attempting to respond within resource constraints. Susana Perry (Office of Women's Health) described her office's partnership with national organizations to promote translations into different languages, which are then verified for accuracy and cleared through the Department of Health and Human Services. Regarding the question of when to issue communications, center representatives referred to the magnitude of risk and numbers of persons potentially affected. Members asked about

communication channels other than the internet. Print newsletters are no longer used due to resource constraints, and FDA components try to partner with interested organizations to increase dissemination of messages. Members observed that, despite efforts, FDA programs like MedWatch are not as well-known as would be desirable. Regarding questions of how the FDA receives and tracks the effect of its announcements, except for certain programs on nutrition labeling, systematic tracking and evaluation is usually not available, especially for particular breaking issues, but the FDA considers any feedback it receives in email comments.

Summary of Committee's Further Comments and Discussion, February 28, 2008

- RCAC members suggested that *communications considerations should be designed into programs from the start to improve effectiveness*, not added on afterwards. Members requested more information on Sentinel Project as a possible example.

- Members inquired how the FDA as a whole or the various centers *systematically track responses* to communication products among health care professionals and the general public.

- There was strong support among Committee members for *empirically evaluating communications prior to their dissemination.*

- There was strong support among Committee members for *reaching diverse populations*, with particular reference to different language and cultural groups, as well as people outside the FDA's normal communication channels (e.g., the homeless).

- Members returned several times to the topic of how to communication benefit as well as risk, recognizing that there may be different challenges for communicating each – but that both must be understood, if decisions are to be made well.

- Members discussed whether "FDA Approved" adequately conveys what might be called *FDA's "brand,"* given that many regulated products are not pre-approved and that the public may not understand that approval does not indicate absence of risk.

- Members are interested in further consideration of *the tension between communicating when there is enough certainty to provide specific recommendations, vs. early notice of emerging, uncertain, information for which no FDA recommendations are yet available.*

- More generally, understanding FDA's communications on specific topics *requires understanding FDA's regulatory authority and the risk management practices employed by the industries that FDA regulates.* Members suggested providing that sort of background information together with FDA communications, in order to promote better stakeholder understanding and decision making, and fairer evaluation of FDA's performance.

- Members expressed interest in the overall plans and distribution of resources for communication programs in FDA's centers and offices. The sheer volume of FDA communications, many with vital consequences for public health (and for public trust in the FDA), prompted the *suggestion of a daily press conference, which would give FDA an identifiable face and immediate, centralized feedback* on these aspects of its communications.

- Members expressed *encouragement for leveraging common interests and complementary resources both across the Agency and between the Agency and external partners* to capitalize on opportunities for better communication. Many industries are elevating communication to a central role in corporate strategy, and might provide models for FDA– while others might follow leadership from FDA.

- Members are anxious to help with FDAAA mandates and current communications, and to get started as soon as possible. Providing feedback on FDA's responses to the Committee's advice will help to maintain the momentum.

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

Risk Communication Advisory Committee Meeting, February 29, 2008

The Risk Communication Advisory Committee (RCAC) meeting was reconvened at approximately 8:00 a.m., Friday, February 29, 2008. The same conflict of interest statement was read into the record as described for the prior day.

Summary of Opening Comments, February 29, 2008

Baruch Fischhoff, Committee Chair, called the meeting to order, welcomed all attendees, and, after members quickly introduced themselves, opened the discussion of the day. He observed that effective communication about product recalls has important health implications, as well as economic implications for producers and distributors, and social implications for public trust in public and private institutions. The Committee was asked to provide comment and advice on a draft template for press releases about product recalls.

Summary of Open Public Hearing Presentations, February 29, 2008

- Donna Goldberg and Joel Harder, Heart Rhythm Society: asserted that communication about implantable devices should be sensitive to concerns about whether recalls need surgery; made additional specific comments in response to questions the FDA had posed to the Committee.

- Lisa Weddig, National Fisheries Industry: provided examples of FDA press releases related to seafood where the title or the timing may have caused confusion in the public.

- Marcela Gaitan, National Alliance for Hispanic Health: described their collaborative relationship with FDA, and their organization's message-amplification outreach.

Summary of Presentations and Committee Discussions, February 29, 2008

Communication about Product Recalls

Capt. David Elder, Director, Office of Enforcement, FDA Office of Regulatory Affairs, first provided an overview of the range of responsibilities of the Office of Regulatory Affairs, the Agency-wide field organization that supports the FDA's mission to advance and protect the public health. In regard to recalls specifically, he noted that FDA is not only a scientific but also a law enforcement agency, and the definition of terms like "recall" are codified and specific. He summarized the usual stages of a recall, from initiation, through notification and execution, and finally verification of recall effectiveness. Firms usually undertake recall communications voluntarily, often in consultation with the FDA. The FDA inspects firms, gathers information, and when a problem is identified, conducts health hazard evaluations leading to classification of the recall according to the potential for harm due to the problem. FDA and firms communicate regarding the problem and, as noted, firms often agree to conduct recalls as voluntary actions. In the most serious situations, Class One Recalls, the Agency and firms issue press releases and use other channels to get the information to potential stakeholders. He highlighted the Washington Post Business section's recall list as a possible model for consistent but brief communications. Noting that how consumers actually receive the recall message remains problematic, he asked the Committee to comment on the draft press release template in regard to format and organization for good communication.

Literature Review: What do we know about the public's awareness, understanding, and perception of recalls concerning FDA-regulated Products?

Amy Lando, M.P.P., Consumer Science Specialist, Center for Food Safety and Applied Nutrition, presented results of her literature review, which revealed few articles specifically addressing awareness of FDA recalls, in contrast to a substantial literature about warnings in general, which was reviewed in 2003 for the US Consumer Product Safety Commission. The most relevant literature specific to FDA relates to food-borne illness outbreaks. The somewhat limited evidence on these cases reveals such difficulties as convincing consumers not to use a product that appears to be in good condition and identifying the specific products involved.

Comments from Consultants

Michael Wogalter, Ph.D., Professor of Psychology, North Carolina State University, gave an overview of cognitive ergonomics as it relates to warnings (e.g., what features best attract attention and communicate what to do), and then summarized a research project carried out by NCSU graduate student Jennifer Cowley. The project assessed participants' responses to different possible names for recall notifications, and different words. The study concluded that terms like "FDA urgent recall notice" or "FDA public safety warning" were rated more attention-worthy than terms like "advisory" or

"bulletin." The project also addressed communication about recalls of surgically implanted medical devices, with participants generally preferring a term other than "recall," so that it would be clearer that such devices do not always have to be surgically removed and replaced, when already implanted.

Gregory Baird, President, Baird Edge Consulting, presented an overview from his experience in risk communication for the medical products industry. He first summarized events in recent years that have undermined confidence in marketed products. He then identified ten important challenges to good risk communication originating from industry; they range from the role of money and the emotional connection of patients to medical therapies, to ambiguities in assessments of when, what, and how much to communicate. He asserted that such problems might be managed better if FDA worked more closely with industry and collaborated with healthcare providers, and if all concerned sought better risk and benefit balance in marketing efforts. He concluded by recommending that the financial sector could be a model for corporate risk communication and that the public be educated at a younger age about assessing health and risk.

Steven Gorelick, Professor of Media Studies, CUNY, presented a series of points. First, while people rate their trust in traditional media fairly low, they actually use them extensively. Second, it is important to attend to emerging information consumption patterns with new media. Third, the FDA should consider the impacts of both what it is and what image it projects on public confidence in the FDA and responses to the information it provides. Fourth, research supports the usefulness of checklists to help promote quality performance in a variety of safety-related activities and should be considered for developing communications. Fifth, any risk communication message will be projected into an information environment crowded with rumor; as a result, unofficial comment on the issue should be monitored as well as formal communications. Finally, message crafters should realize that no matter how much expertise goes into message development, the crucial point is the decision by each individual member of the public about whether to attend to an issue and, if so, how to act on it. The desired outcome can never be presumed.

Daniel Q. Haney, medical journalist and editor, addressed comments specifically to the draft press release template for recalls, noting first that the template would be a step in the right direction. He also pointed out that the use and function of press releases has changed significantly with the Internet, as they now are received directly by the reading public and not just by journalists. The draft press release appears to recognize this dual role, and its promotion of consistency of content and organization will facilitate better use of recall information by both types of audience. He commented further that journalists covering a recall will need to know, for example, the size of the recall, the number of people at risk, and the magnitude of potential harm. The sections of the template titled "What is the Problem?" and "Who is at Risk" should, therefore, include those facts, in addition to information such as how the problem was identified and other actions that have been taken. For drugs, common uses should be given.

Summary of Committee's Closing Comments and Discussion, February 29, 2008

After listening to presentations from FDA staff and consultants and asking questions, Dr. Fischhoff first observed that the topics so far have involved consideration on three levels. First was the general environment in which FDA carries out its mission, and how that is changing. Second was the role assigned to risk communications in the risk-management process; adding them only at the very end means that they cannot fulfill their potential. Third was, what are the opportunities to improve communications about product recalls, given different visions of their role?

Clarifying questions sought detail on FDA's inspection operations and how information is made publicly available on an ongoing basis. Captain Elder explained that, similar to other areas of law enforcement, it is not possible to publicize ongoing investigations at the FDA. Regarding food distribution centers like community pantries, he affirmed that the FDA does attempt to get word to these organizations, and gladly adds to its distribution lists any such organization for which contact information is provided. It was also observed for possible exploration that several large chain retailers maintain information about customers and have, in the past, sometimes amplified recall messages. Michael Verdi of the FDA's Center for Devices and Radiological Health summarized some history regarding the term "recall," noting that the word is used because uniformity helps avoid confusion and because that word gets attention. There was discussion of how well it fit the special case of surgically implantable medical devices, where visions of "exchanging" implanted devices may cause undue worry for patients, as more surgery may not actually be needed, possible, or advisable.

In further discussion, members addressed the four specific topics that the Committee was asked to discuss (see immediately below). The Committee was supportive of the template, characterizing it as a "good start," and members offered careful and specific suggestions for improving it. Neither voting nor consensus was requested, but the members provided comments that suggested a shared sense of the issues, and was summarized as such by the Chair.

> Topic 1. What are the pros and cons of standardizing different parts of the press release template, especially with respect to the title, format and how the content is expressed? Specifically, how and to what degree will standardization improve or interfere with effective communication?

Response: the Committee generally *appreciated standardization of terminology but noted that it is unlikely that truly uniform terms could cover all situations,* such as those concerning implanted cardiac devices.

> Topic 2. Please comment on the degree to which the current proposed template incorporates currently recommended risk communication practices, including but not necessarily limited to
>
> a. wording of the current title and subtitle

b. amount of information to be included in announcement
c. tailoring to specific audiences
d. use of subsections, highlighting and boxing
e. clarity of message, including directions for what to do

Response: Members *offered specific suggestions*, such as using short titles with only one theme each, providing numbers with context rather than verbal quantifiers like "rare," adding a summary (or abstract) at the beginning, and revising the section on "what to do."

> Topic 3. Please comment on any additional recommended risk communication practices that could be better incorporated into the template.

Response: Members suggested *considering how to include more emotive content and concern for the affected audience*, noting that this is a widely accepted practice in good communication but that the mention of sympathy for cat owners whose pets were injured was the only example of FDA communications doing this.

> Topic 4. Please comment on ways, in addition to press releases, that FDA could effectively communicate to the public about recalls.

Response: Members suggested that the FDA consider using *one or a few recognizable spokespersons to communicate urgent messages* in a way that is both more humanly engaging and more accessible to audiences who get information in ways other than text.

More broadly, members emphasized that *expert opinion is no substitute for data, and encouraged the Agency to redouble efforts to carry out or stimulate research on the effect and use of its messages*. Members further emphasized that this would be cost-effective, by showing how to streamline existing programs for greater efficiency of communication – in addition to increasing the chances of protecting consumers and FDA's reputation.

In addition to the need for empirical evaluation, the discussion echoed a number of themes from the general discussion of February 28. These included the need to reach diverse populations, the importance of communicating the risk management practices whose results are the topics of recall notices, and the importance of making communication integral to the risk management process from its beginning.

Dr. Fischhoff summed up main themes of comment on the draft press release template, including

- Broad support for the idea of a template for press releases, and for the proposed draft as a good start, including standardization of terms with possible exceptions (e.g., for implants) drawing on studies like those presented by Dr. Wogalter;
- Suggestions on making content more accessible, ranging from simplifying the reading level to providing context about the meaning for the public of the regulatory action;

- Ideas for establishing trust between the FDA and the public, both as a general good an as an essential element for effective recall announcements; and finally,
- Empirical testing and internal analysis of how the FDA can build communication planning into its procedures.

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 February 28 and 29, 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