MINUTES OF THE

RISK COMMUNICATION ADVISORY COMMITTEE, FDA

5630 Fishers Lane, Room 1066, Rockville, MD, 20857
Thursday, April 30, and Friday, May 1, 2009

Executive Summary

The Risk Communication Advisory Committee (RCAC) met April 30 and May 1, 2009.

One person spoke during the Open Public Hearing on both the first and second day, and two additional persons spoke on the second day (see below for more detail).

Discussion Topic

On both days the Committee discussed the agency's draft risk communication strategic plan, and provided comment and advice on different parts of the plan and on strategic priorities for research on effective risk communication.

Summary Results

After hearing and discussing the presentations listed in the agenda and presented at the open public hearing, members turned to a set of draft recommendations proposed by the chairman. After discussion of modifications, and acknowledgment of the committee's advisory role, the following set of final recommendations was voted upon (in accord with procedures in the recent guidance on voting). The recommendations were supported unanimously by the 13 voting members present on Friday, listed in the roster and below.

- The Committee applauds the Strategic Plan for Risk Communication at the Food and Drug Administration, as a major step forward in enabling FDA to meet its mission of service to the American public. The Committee recommends continuing these efforts to make scientifically sound communication central to the production, summary, and dissemination of evidence regarding FDA's regulated products. An important part of that strategic planning is identifying the outcomes that communications are intended to achieve. An outcomes-focused planning process can further define the key priorities for improving capacity, policy, and science.

- The Committee applauds FDA's commitment to creating the in-house scientific work force necessary to execute its strategic communication plan. The Committee recommends that FDA develop an organizational structure that ensures that individuals with the needed expertise are recruited, retained, and effectively integrated with its operations.

- The Committee applauds FDA's efforts to create partnerships with other public and private organizations that produce and use studies relevant to the effectiveness of its communications. The Committee recommends expansion of these efforts to achieve full leverage of FDA's expertise and resources. The Committee offers itself as a resource for developing those plans.

- The Committee applauds FDA's commitment to producing and evaluating its communications to a scientific standard. The Committee recommends that, as part of its continuing efforts, FDA develop a work-flow system for ensuring that communication needs are integrated into its operations. That system will ensure that its subject-matter experts and communication scientists work together to create, summarize, refine, and deliver needed information, in time to allow proper evaluation.

- The Committee recommends that FDA use the Strategic Communication initiative to reaffirm its commitment to help the public make informed choices regarding FDA-regulated products. Promoting awareness of the initiative will ensure that full benefit is derived from these efforts.

- The Committee recognizes that current interpretations of the Paperwork Reduction Act of 1990 hamper FDA's ability to evaluate its communications, to a scientific standard, in a timely fashion, and with adequately diverse samples. The Committee makes two recommendations to address this problem. First, FDA should identify the public welfare implications of *not* testing its communications. Second, FDA should submit a proposal to the Office of Management and Budget, for a communication evaluation protocol that balances the public welfare needs of FDA's mandate with those of the Paperwork Reduction Act.

RCAC Members Present

Baruch Fischhoff, Ph.D., *Chair*
Craig Andrews, Ph.D. (May 1 only)
Christine M. Bruhn, Ph.D.
AnnaMaria DeSalva, B.A.
Jacob DeLaRosa, M.D. (April 30 only)
Sokoya Finch, M.A.
Michael Goldstein, M.D.
Sally Greenberg, J.D. (April 30 only)
Prerna Mona Khanna, M.D., M.P.H.
Madeline Y. Lawson, M.A.
Musa Mayer, M.S., M.A.
John E. Paling, Ph.D.
Ellen M. Peters, Ph.D.
Betsy Lynn Sleath, Ph.D.
Michael Wolf, Ph.D., M.P.H.

Executive Secretary
Lee L. Zwanziger, Ph.D.

Open Public Hearing Speakers

April 30, 2009
Jeffrey Secunda, AdvaMed

May 1, 2009
Julie L. Aker, Concentrics Research
Jim Paul, Corvallis Group
Jeffrey Secunda, AdvaMed

Presentations, Thursday, April 30, 2009

- Strategic Planning at FDA
  Malcolm J. Bertoni, M.S., Assistant Commissioner for Planning

- Goal: Expand FDA's Capacity to Generate and Oversee Risk Communication
  Susan C. Winckler, RPh, Esq., Chief of Staff

- Goal: Optimize FDA's Policies on Communicating Product Risks and Benefits
  Jeffrey Shuren, M.D., J.D., Associate Commissioner for Policy and Planning

- Goal: Strengthen the Science Supporting Effective Risk Communication
  Nancy M. Ostrove, Ph.D., Director for Risk Communication

- Continuum of Risk and Framework for Planning Desired Outcomes and Behaviors
  AnnaMaria DeSalva (added to agenda)

- Perspective: Select Models for Conducting Research Needed by Government Agencies
  Baruch Fischhoff, Ph.D., Professor, Carnegie Mellon University

Presentation, Friday, May 1, 2009

- Prioritization of Risk Communication Research
  Nancy M. Ostrove, Ph.D., Director for Risk Communication

Risk Communication Advisory Committee Meeting,

April 30, 2009

The Risk Communication Advisory Committee (RCAC) meeting was called to order by Baruch Fischhoff, Committee Chair, at approximately 8:00 a.m., Thursday, April 30, 2009. One member, Craig Andrews, could not be present due to a schedule conflict. The conflict of interest statement was read into the record, noting that, based on the agenda and financial information reported by participants, no members had conflicts of interest, but that all participants were aware of the need to address conflicts of interest should any arise. All participants introduced themselves.

In his opening remarks, Dr. Fischhoff noted that the committee deliberates and develops recommendations in a purely advisory capacity, and that meetings typically include both informational presentations by FDA staff members and others, and committee recommendations to FDA. Dr. Fischhoff presented a summary of the past meetings of the RCAC, referring attendees to the committee website for detailed records including minutes, slides shown, and transcripts (see the following address http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/default.htm). In conclusion, he said that FDA is fortunate in having a professional diverse staff including social scientists, and is in a good position to undertake steps to improve communication.

Summary of Presentations and Committee Discussions, April 30, 2009

Please see the slides and transcript for further details.

Strategic Planning at FDA

Malcolm J. Bertoni, M.S., Assistant Commissioner for Planning, presented a brief overview of theories of strategic planning and highlights of strategic planning in the federal government. He then focused on strategic planning at FDA, both for general agency goals and for risk communication in particular. While different schools of thought on strategy formation emphasize different aspects of the planning process, the process in general aims to incorporate information broadly, explore alternatives, develop plans for decisions and actions to produce the desired outcomes, and measure the outcomes. Measuring success is challenging, especially for the government, as the military and business models informing much previous strategic planning theory don't directly apply. Measurement of success in public organizations depends on articulating the goals of the organization and then reflecting them throughout organizational levels, as, for example, mandated in the Government Performance and Results Act of 1983 and OMB Circular A-11. FDA strategic planning is aligned with the goals of the Department of Health and Human Services, and revised as needed to accommodate new events like the H1N1 virus. The agency named producing a Strategic Plan for Risk Communication (SP-RC) as part of its commitments for receiving the Fiscal Year 2008 Budget Supplement. The draft plan, which is the focus of this meeting, was developed in alignment with recommendations from the Risk Communication Advisory Committee as well as cross-agency working groups and internal councils. The plan's three strategic goals will be presented separately for discussion later in this meeting. After the committee's review, the plan will be revised and integrated with other agency strategic planning. The final version of the plan will be submitted to Congress by the end of Fiscal Year 2009, with further specific development of action items expected during implementation.

Committee Questions and Discussion Following Presentation

- A member asked about the relation between the goals of the draft SP-RC and the FDA Strategic Plan. Mr. Bertoni showed multiple crosscutting connections. A member commented further that, as communication is integral to product performance, and also to observations of performance (e.g., not knowing what to look for, people may observe less of either bad or good outcomes), overall outcomes might improve with crosscutting efforts to integrate communication into product regulatory processes. Another member inquired about plans to communicate to the public about the draft SP-RC, and Mr. Bertoni replied that a roll-out plan was not yet complete. Finally, a member observed that one connection to examine may lie between communications and bioinformatics. Specifically, as the opportunities for two-way communication increase, the agency should prepare for changes in the quality and quantity of signals it receives, for example from adverse event reports.

- A member commended the idea of developing a panel of internal message testers, but also asked about other internal processes for gleaning data from one event to inform action on the next, and partnering with other agencies. Another member also pursued the theme of partnerships; Mr. Bertoni generally agreed about the importance of partnerships, pointing to partnership elements in the SP-RC as well as improvements in information technology infrastructure.

- Returning to the interrelations of the strategic goals, a member asked about the use of behavioral or public health outcomes in strategic planning. Mr. Bertoni pointed out that strategic planning can be an exercise in organizational transformation. Incorporating long-term outcomes measures into planning and analyzing processes for cross-agency commonality have been highlighted at the FDA mainly since about 2002. The transformation in agency thinking is still underway. While the majority of the work was done internally, it was and continues to be informed by many interactions with industry, consumer and patient groups, and with the public in general. One member suggested that while great change has been made, for example in product approval times, the time needed for change overall suggests that the agency's size may be unwieldy. Mr. Bertoni replied that FDA's size is a perennial question, along with the benefits of integrating rather than splitting FDA's various activities. Following up on the question of speed, another member noted that speed must be balanced with caution for safety.

- In discussing FDA's potential impact, one member stressed the importance of the specific communication needs of different communities. Another noted the importance of trust in effective communication. Mr. Bertoni agreed with the former. On the later, he observed that surveys indicate more confidence in the FDA than may be suggested in some reports, and that the agency is trying to develop better ways to measure and to maintain its credibility. Another member suggested that the FDA appoint spokespersons who are good communicators because one trusts persons rather than institutions, and that the spokespersons should make a point of distinguishing legal or technical use of words like "safe and effective" from common use of the terms.

<u>Goal: Expand FDA's Capacity to Generate and Oversee Risk Communication</u>

Susan C. Winckler, RPh, Esq., Chief of Staff, presented the goal of expanding FDA's capacity to generate and oversee risk communication, along with proposed strategies supporting the goal:

- Streamline/coordinate development of communication messages and activities
- Plan for crisis communications
- Streamline research and testing
- Clarify staff roles/responsibilities in creating and clearing messages
- Increase involvement of decision/behavioral science expert staff, by having more staff, and involving more staff in message development
- Improve effectiveness of Web site, including use of new web tools
- Enhance partnering to improve two-way communication

FDA has already moved toward increasing efficiency through clarifying roles by experimenting with rapid response teams for quickly developing messages.

> *The agency provided the following discussion topics to the committee for this goal.*
>
> After reviewing the Capacity Goal of the draft RC Strategic Plan,
> (a) What strategies could be further clarified to better support this goal?
> (b) What strategies might we consider adding for this goal?

(c) What additional scientific questions need to be addressed to meet this goal?

Several Capacity Goal strategies address streamlining processes for research and testing (e.g., pilot testing a subset of cases, and/or testing messages with FDA staff not involved in the topic). This reflects the need to balance getting timely results against getting data we are confident will be reliable and can be extrapolated to critical population segments. FDA can most expeditiously get answers by using in-house "surrogate" audiences. A second level of rapidity can be obtained through standard-question customer satisfaction surveys or focus groups. The longest time frames occur in conducting surveys or experiments with larger or more representative samples.

Please discuss the types of questions FDA can reasonably answer using different research/testing methodologies. Provide suggestions or examples about approaches to optimally address issues of reliability and validity.

Committee Questions and Discussion Following Presentation

- Members discussed the challenges of learning about target audience responses to FDA's messages, including practical matters such as short timeframes. One suggestion for streamlining envisioned a panel of non-technical special government employees. Another was to develop a sizable longitudinal panel, perhaps of SGEs, to assess changes over time. On the other hand, others pointed out, the members of such a panel would likely learn about the subject matter and quickly become more expert, and less representative of the general public, so at a minimum the time they serve on the panel would have to be short. Another approach suggested for exploration called for developing, and discussing clearance with the Office of Management and Budget, some standard protocols for testing messages. A member noted that while the Paperwork Reduction Act aims to reduce burden on the public, for a patient to receive untested and badly worded messages about an important product would be another sort of burden.

- Members also discussed further the potential benefits of partnerships for complementing FDA capacity. One possibility to explore, though not without difficulties, is partnering with industry, for example, in examining different contexts of communicating about such different types of products as prescription medical products or food ingredients. Another possibility would be partnering with other agencies, particularly those experienced in the challenges of disseminating and encouraging uptake of evidence-based guidelines. The Agency for Healthcare Research and Quality (AHRQ) was mentioned in this context. Another member observed that FDA may need access to experts in systems analysis for considering dissemination.

- A member suggested that the draft SP-RC, while a step forward, is not yet sufficiently outcomes-oriented, and that more focus on outcomes would help refine and focus other questions about priorities for limited time and resources. Another member pointed to the current news on the spread of H1N1 virus as an illustration of multiple conflicting messages coming from political and other governmental leaders,

often without actionable advice, and suggested that one strategy in an urgent outbreak would include briefing such leaders to facilitate consistent communication.

- In summing up the discussion to that point, a member noted suggestions that the FDA compile categories of types of risks, where the type of risk is recurrent, even though each incident is unique. After identifying such categories, the FDA should explore agreeing with the Office of Management and Budget (OMB) on standard testing protocols for different types, and seek blanket clearances.

- In further discussion, a member observed that broadcast news organizations are facing a great deal of airtime with fewer reporters to help fill it. FDA could take advantage of periods of relative quiet to develop relations with reporters and facilitate or develop educational footage, thus improving FDA's chances of getting its messages on the air. Later, a member reemphasized that part of FDA's problem is mistaken assumptions by many audiences, for example, that an FDA approved product is already known to be absolutely safe. In a similar vein, a member asked how much information is available to FDA about who is using what products; Ms. Winckler replied that the FDA has access to very little information at the level of individual patients and consumers.

- Several members reemphasized the importance of having a diverse array of partnerships for message evaluation, with the caveat that institutions have particular defining characteristics (e.g., military organizations have more men and relatively young average age) and so may not be representative of the general population. One member observed that the most effective way to start change may be by example, recounting previous experience that if members of a target group (of businesses, healthcare professionals etc) take even small steps, others may then follow that peer example.

- A member suggested personalizing the decision about when to communicate information that is emerging or uncertain: communicate to the public when you would communicate the information to a friend or relative to whom it could be relevant. An FDA comment noted that we also are learning who to address; for example, during an outbreak of salmonella associated with some peanut butters, FDA learned that emergency room health professionals should be targeted.

- Speaking to the final question regarding the quality of results the FDA might reasonably expect with the time-saving methods mentioned, one member supported the idea of testing with in-house volunteers, as any non-represented segments of target audiences could be accounted for. The same member also observed that customer satisfaction surveys probably cannot return the type of information needed (such as whether people both received and understood the message). Finally, the member emphasized that focus groups are well known to be good ways to generate ideas but are not rigorous testing venues. Others concurred about focus groups and re-emphasized the importance of testing in the target audience.

Summary of Open Public Hearing Presentation, April 30, 2009

Please see the transcript for further details.

- Jeffrey Secunda, Vice President for Policy and Regulatory Affairs at AdvaMed, commended the draft plan. He suggested that the capacity goal strategies should include partnering with manufacturers, so that FDA explicitly acknowledges manufacturers as risk communicators. He also recommended that the agency avoid the word "recall" in communications about possible problems with implantable devices.

Continued Summary of Presentations and Committee Discussions, April 30, 2009

Please see the slides and transcript for further details.

Continuum of Risk and Framework for Planning Desired Outcomes and Behaviors

AnnaMaria DeSalva (added to agenda), Worldwide Director of Healthcare at Hill and Knowlton and a committee member, presented a graphic sketch of how an organization might approach a continuum of risks, and a framework for planning communications based on desired outcomes and identified gaps in current communication programs. Her remarks built on her August 2008 presentation to the committee of a fictionalized composite case of developing crisis communications by a medical products company. Conceptualizing a spectrum of risks in relation to desired outcomes helps show gaps, and suggests priorities in addressing them.

Committee Questions and Discussion Following Presentation

- A member commented that the risk categorization seems in line with that used by the World Health Organization (WHO). Another member observed that the two-dimensional spectrum might need an additional axis, to represent factors such as the number of people affected, and others suggested an axis for the severity of the condition.

- FDA employees, invited by the Dr. Fischhoff and Dr. Ostrove to comment on their agency experience in relation to the suggested spectrum of risks, generally agreed with the presentation, but also suggested that it would likely need some modification for application in different product areas, and might have the effect of minimizing apparent risk at the time products were first marketed.

- Both a member and an FDA employee observed that the spectrum-of-risk sketch and planning framework as presented reflect thinking about the absolute risks of a specific product, but do not address multiple product comparisons.

- Several members discussed the value of the approach to sharpen concepts in overall strategic planning and to facilitate learning from experience to communicate changing risks in evolving situations. Ms. DeSalva noted in conclusion that an outcomes-focused communication strategy necessitates locating and addressing potential problems early in the development of both the matter to be communicated and the planning of the communication.

Goal: Optimize FDA's Policies on Communicating Product Risks and Benefits

Jeffrey Shuren, M.D., J.D., Associate Commissioner for Policy and Planning, presented the goal of optimizing FDA's policies related to communicating product risks and benefits. He noted first that this work is ongoing, rather like renovating a fire station at the same time as fighting fires and providing fire safety education. FDA's proposed strategies to achieve this goal include:

- Develop principles to guide consistent & easily understood FDA communications, such as what information to include routinely
- Identify consistent criteria for when and how to communicate emerging risk information
- Re-evaluate and optimize policies for using partnerships and other leveraging activities to facilitate effective communication about regulated product, including sharing information and addressing needs of medical professionals
- Assess and improve FDA communication policies in areas of high public health impact, such as modernizing effective communication during recalls, ensuring that patients get useful written information about the prescription drugs they use and that medical professionals get useful information about FDA-regulated products when and in the form they need it, and updating the regulation of prescription drug promotion

The agency provided the following discussion topics to the committee for this goal.

After reviewing the Policy Goal of the draft RC Strategic Plan,

(a) What strategies could be further clarified to support the goal?
(b) What strategies might we consider adding to the goal?
(c) What additional scientific questions need to be addressed to meet this goal?

Policy Strategy 2 focuses on identifying consistent criteria for when and how to communicate emerging risk information. Currently, FDA does not have a comprehensive, science-based set of principles about when and how to communicate this information.

Please identify and discuss any principles or recommendations, derived from existing research, for when it is most appropriate to communicate with different audiences about still-uncertain (emerging) risks of FDA regulated products. Assuming that FDA would at least pilot such principles, what kinds of testing or evaluation would be most effective to address the question of when to communicate to maximize public health outcomes? In your comments, please consider that emerging risks may be previously unknown and may (or may not) be clinically relevant for most patients or consumers – also, that the relevant information may reflect poor quality date and thereby contribute to the indeterminacy of the risk.

Committee Questions and Discussion Following Presentation

- One member suggested tying FDA-issued information for healthcare professionals to other online practice guidelines. Another member brought up the question of what to do about off-label uses. Dr. Shuren clarified that the FDA does not regulate off-label

use, but can affect what information is presented about a product. Specifically, such information must be in accord with the approved product labeling.

- A member pointed out that with the use of barcode reading at grocery store checkouts to track inventory, a retail company can tie recall messages to particular barcodes. Thus, even if some product remains on the shelves, no consumer will mistakenly purchase it. Further, some retailers could contact consumers who had made a purchase before the recall message was disseminated.

- Members reemphasized several recurring themes, including the importance of: better communication when the legal terms used by the FDA may not be understood by the public; supplying quantitative information with useful comparisons and with consistency (for example, not permitting relative and absolute risks to be mixed); and evaluating, and correcting where necessary, the literacy level of communication materials. Further comments included consideration of locating, and forming partnerships for communication with, influential healthcare professionals and their organizations, and developing ways to highlight communication success stories to provide both encouragement and examples for successful and potential communicators.

- Responding to the FDA's specific discussion questions:
    - Several members highlighted the still unfilled need for longitudinal research and for comparative studies to identify more successful risk communication approaches.
    - A member suggested that science-based policy setting for risk communication should have FDA, first, use terms that are well-characterized. Second, FDA should sample audience perceptions of the importance of different risks and benefits to check whether the FDA's communication strategizers are incorporating realistic assumptions. Third, FDA should test the communication model by developing predictions about its effects and testing them.
    - A member commented, on the question about communicating risks of not using some product, that the FDA might consider communicating about other health choices not under its regulatory purview, including perhaps lifestyle approaches to managing certain conditions.
    - A member stressed two practical suggestions for the FDA to consider. First, FDA should consider developing tiered communication vehicles, starting with the simplest and most essential information, to reach audiences with varied levels of health literacy and need for information. Second, FDA should develop templates for communication vehicles to increase consistency and reduce confusion about FDA messages.
    - In regard to FDA's effort to improve policy in areas of high public health impact such as food recalls, a member observed that the agency should consider that consumers not immediately resuming purchasing a recalled food item may indicate deliberate caution by consumers rather than communication failure.
    - Finally, a member suggested that the agency consider in its strategic planning the tension between public affairs communication (focused on the agency) and public health communication (focused on the public), noting that while the agency's mission is the latter, the former is important for building credibility so that public health messages will be heeded.

Goal: Strengthen the Science Supporting Effective Risk Communication

Nancy M. Ostrove, Ph.D., Director for Risk Communication, presented the goal of strengthening the science supporting effective risk communication at FDA, emphasizing that, as FDA is a science-based and science-led agency, the commitment to using scientific methods extends to the design and assessment of communications activities. FDA's proposed strategies to achieve this goal include:

- Identify gaps in key areas of risk communication knowledge and implementation and work toward filling those gaps
- Evaluate the effectiveness of FDA's risk communication and related activities and monitor those of other stakeholders
- Translate and integrate knowledge gained through research/evaluation into practice

The agency also compiled a draft selection of research gaps and needs, for discussion on the second day of the meeting.

> *The agency provided the following discussion topics to the committee for this goal:*
>
> After reviewing Science Goal of the draft RC Strategic Plan,
>
> (a) What strategies could be further clarified to support the goal?
> (b) What strategies might we consider adding to the goal?
> (c) What additional scientific questions need to be addressed to meet this goal?
>
> In addition to the list of research categories and priorities for FDA, we hope researchers outside FDA will also help fill gaps in key areas of risk communication knowledge. Please provide suggestions or examples of ways to encourage researchers outside of FDA to pursue the proposed research ideas (with non-FDA funding).

Perspective: Select Models for Conducting Research Needed by Government Agencies

Baruch Fischhoff, Ph.D., Professor, Carnegie Mellon University, presented on models for including communication expertise in the government. He noted first that strategic communication planning should include attention to both processes of integrating communication with analysis and regulation, and staffing. Strategic staffing should include domain specialists in the science of the risks (and benefits) of the product, risk and decision analysts to sort out which information is critical for informed choices, behavioral scientists with knowledge of designing and evaluating messages, and system specialists, to create and use communication channels to disseminate messages. All these types of expertise should be distinct and each set of experts should take on only the tasks specific to their expertise. He summarized several organizational models that might address aspects of the strategic needs. Two models included internal agency social science research expertise, located either in the various product-focused centers or centrally. Three models focused on using externally-based expertise through competitive grants, designated centers of excellence, and contracting for services. Each model has positive and negative features. Dr. Fischhoff concluded by suggesting a hybrid model to include a both an internal core group of experts to provide strategic

coordination and facilitate organizational learning, and external programs using competitive grants and contracts to provide the agency with rapidly conducted, cutting edge work, as well as flexibility.

Committee Questions and Discussion Following Presentations

- A member and Dr. Ostrove explored further some of the positive and negative aspects of competitive grants and centers for excellence. On one hand, research not federally performed could be easier to initiate, but on the other hand, it still would be far from timely for FDA's day-to-day communication needs.

- A member reminded the FDA to include research into unintended (adverse) effects of communications in plans for research.

- A member commended the FDA for the specific strategies mentioned in the draft strategic plan, and reemphasized the importance of effectiveness research into concrete behavior change.

- Several members made comments and suggestions regarding partnering with other agencies, especially the AHRQ and National Cancer Institute (NCI) along with other NIH programs, noting that AHRQ has some funding for comparative effectiveness research and communication would be part of what accounts for effectiveness. Another added that effective communication contributes to cost containment as well. A member observed that some foundations, like Robert Woods Johnson (RWJ), have substantial experience funding and carrying out large public health campaigns. Other possible partners are medical and other healthcare professional schools. Several members urged additional consideration of developing partnerships through hosting interns and visiting professionals, either on-site or working remotely from their regular locations.

The meeting was adjourned at approximately 4:35 p.m. for the evening, to reconvene the next day.

Risk Communication Advisory Committee Meeting,

May 1, 2009

Dr. Fischhoff called the meeting back to order at approximately 8:00 a.m., Friday, May 1, 2009. Two members, Jacob DeLaRosa and Sally Greenberg could not be present due to schedule conflicts. The conflict of interest statement was read into the record. The Chairman welcomed all attendees and, after Committee members quickly reintroduced themselves, he opened the presentations and discussions of the day. The Committee returned to discussion of the topics listed above and heard an additional presentation listed on the agenda and summarized below.

Summary of Presentation and Committee Discussion, May 1, 2009

Prioritization of Risk Communication Research

Nancy M. Ostrove, Ph.D., Director for Risk Communication discussed some of FDA's research needs in striving toward the overarching agency goal of helping the public get the accurate, science-based information they need to use FDA-regulated products to improve their health. She noted that the agency is working in a complex context that includes a wide breadth of products, regulations, actions, and audiences. Further, FDA already has in existence multiple product-focused communications bearing similar messages but with different content, formats, and titles. This can be confusing even though it is partly a result of FDA's public commitment to greater transparency and earlier communication about emerging issues. What we do know at this point is that FDA does not consistently test communications prior to use, nor assess the effectiveness of a communication after releasing it. We consistently receive feedback from stakeholders and media that we're not communicating effectively; for example we have received some research reports demonstrating lack of effect on physician prescribing choices of changes made to labeling to highlight contraindications in boxed warnings. FDA staff concluded that the agency needs additional research about topics including the following, but would greatly appreciate further comment and suggestions from the Committee.

- When and what to communicate
- Reaching the audience (dissemination)
- Ensuring audience understanding
- Motivating audiences
- Evaluating effectiveness

The agency provided the following discussion questions to the committee for this topic.

After reviewing the proposed FDA Risk Communication Research Needs appended to the draft RC Strategic Plan,

(a) What research questions could be further clarified to support FDA's Risk Communication Strategic Goals as described in the draft plan?
(b) What types of research or research questions might we consider adding to this listing?
(c) What types of research or research questions currently listed could be informed (or even answered) by existing research? Please provide as much detail as possible.

The RCAC has noted that members of the public may perceive the meaning of "term of art" words and phrases very differently from either the legal context from which they arise or FDA's intended meaning. FDA recognizes the need to test how people do in fact understand several key terms. What existing research would inform the decision of whether to provide public education about such terms or change terms (where change is legally possible)?

The agency also suggested the following overall discussion topics to the committee:

After reviewing and discussing our draft RC Strategic Plan,

(a) What further clarifications would you recommend that we consider?

(b) What further strategies would you suggest we consider adding to the plan?

(c) What further comments, examples, or references to published research, would you suggest to us, regarding this draft strategic plan and research agenda on risk communication at the FDA?

Committee Questions and Discussion Following Presentation

Members discussed the draft research needs document and the overall draft risk communication strategic plan document, highlighting points as follows.

- A member observed that, in considering the research needs document, two sorts of paralysis should be avoided. First, we should avoid producing a long list of desirable research that creates an overall impression that we at present know nothing and cannot act, when in fact we do have a research base. Second, we should avoid creating an impression that the general problems must be or can be addressed with absolute solutions. In terms of research and development, the FDA's communication efforts may actually stand more in need of development than research.

- Members asked about research groups in the FDA and their interactions. Dr. Ostrove summarized the missions of CFSAN's teams on consumer studies and on consumer education, economists, CDER's marketing, labeling and communications experts on both prescription and nonprescription drugs, and the Risk Communication staff in the Office of Policy and Planning. All the groups are busy in their respective areas, but also interact through the quarterly Social Science Forum.

- Members agreed to separate considerations about the type of expertise needed at FDA (with no comment on where it should be located), and the type of research that should be done at FDA's initiative, either because it is a type not done elsewhere or because some research must be available to be done at FDA in order to attract to FDA experts who would likely maintain their interest in research. Members noted and reemphasized that FDA should recognize and capitalize on its position as a great learning environment to: attract research experts; develop internal agency capacity to evaluate and apply research with professional expertise; and glean valuable evidence from the "natural experiments" that make up much of FDA's work in communication.

- Several members emphasized the importance of research into health behavior and behavior change, including research in settings of real-world healthcare systems of message dissemination, medication use, and health monitoring, observing actual health behavior as outcomes. Members recognized that while not all aspects of healthcare fall under FDA purview, FDA's mission overlaps with many aspects, and that to mention explicitly "big" ideas, such as this one, may help the FDA to discuss them with other agencies.

- Several members commented on whether one way to narrow FDA's research needs might center around understanding motivation better. The emerging consensus was

that the FDA should encourage such research on motivation in health behavior, perhaps by outside parties or even partners, but that FDA should keep its own research in this area to a minimum.

- Several members discussed a task analysis approach to risk communication at FDA, starting either from (1) considering areas of overlap between different research operations models (such as those presented by Dr. Fischhoff the previous day), or (2) from a desired endpoint action such as dissemination, and working back. A member noted that dissemination might deserve greater attention in the research needs document, for example, FDA needs more information about media placement of its communications of risk information. Members added that FDA clearly need not be the one to do every element in a task analysis, but should start from a clear conception of the needed steps and roles.

- Members inquired about the extent of use of focus groups at the FDA and discussed some strengths and weaknesses of this research method. Members also considered the importance of FDA's relationship with OMB about social science research and the Paperwork Reduction Act (PRA), observing that interpretations about the balance of doing social science research and complying with the PRA depend in part on the political climate and are not immutable.

- Members emphasized that, just as the strategic plan reiterates FDA's long-term commitment to communication with the public and to giving information adequate for informed decision-making about FDA regulated products, so FDA should redouble efforts to integrate considerations of communication science throughout its scientific product review process. This consideration should include user testing under real-world conditions. Members recognized that some aspects of communication at FDA are legally mandated to be done in certain ways, but suggested there probably are some matters of convention where modification would be possible. Another member pointed out that one aspect of the pre-marketing approval process is well controlled clinical trials under necessarily artificial conditions in order to decrease time to marketing, suggesting that the agency should consider building more communication study into its post-marketing activities rather than its pre-marketing reviews.

Summary of Open Public Hearing Presentations, February 27, 2009

Please see the slides (where applicable) and transcript for further details.

- Julie L. Aker, President and CEO of Concentrics Research stressed the importance of keeping messages simple and targeted, and of testing communications materials in target user groups, noting also that methods for comprehension testing have been well-developed in nonprescription drugs (please see slides).

- Jim Paul of the Corvallis Group highlighted concerns about the complexity of textual and quantitative risk information in communications intended for patients, noting that understanding risk information requires training which may not be in the backgrounds of all physicians and is unlikely to be available to most patients.

- Jeffrey Secunda of AdvaMed first reemphasized the point he noted yesterday that it is important to plan explicitly to involve industry in partnership for risk

communication. He then urged public health agencies generally to acknowledge the difficulties humans have in assessing and using risk information.

Summary of Committee's Further Comments and Discussion, May 1, 2009

After hearing and discussing the presentations listed in the agenda and presented at the Open Public Hearing, members turned to a set of draft summary statements proposed by Dr. Fischhoff to capture the sense of the meeting. The first draft set of statements follows.

Draft Recommendations

- The Committee applauds the Draft Strategic Risk Communication Guide, as a major step forward in enabling FDA to meet its mission of service to the American public. The Committee recommends continuing these efforts to make communication central to the production, summary, and dissemination of evidence regarding its regulated products. An important part of that strategic planning is identifying the outcomes that communications are to achieve.

- The Committee applauds FDA's efforts to create partnerships with other public and private organizations that produce and use studies regarding the efficacy of its communications. The Committee recommends expansion of these efforts to achieve full leverage of FDA's expertise and resources.

- The Committee applauds FDA's commitment to creating the scientific work force needed to execute its strategic communication plan. The Committee recommends that FDA develop and implement a plan that will identify the range of behavioral and decision science expertise that FDA must have on staff, in order to execute its mission, and develop the organizational structure needed to recruit and retain excellent bearers of that expertise.

- The Committee applauds FDA's commitment to producing and evaluating its communications to a scientific standard. The Committee recommends that, as part of its continuing efforts, develop a (work flow) system for ensuing that FDA's scientific staff create, summarize, and deliver the information that its communications researchers identify as needed, in time to allow proper evaluation.

- The Committee recognizes that current interpretations of the Paperwork Reduction Act hamper FDA's ability to evaluate its communication, to a scientific standard, in a timely fashion, with adequately diverse samples. The Committee recommends that FDA (a) undertake an analysis of the public welfare implications of not testing its communications and (b) submit a proposal to the Office of Management and Budget, for an evaluation protocol that balances the welfare concerns of FDA's mandate and the Paperwork Reduction Act.

Members then discussed the draft recommendations and considered many possible revisions. These included the addition of a new draft statement encouraging FDA to take the opportunity of its redesigned Web site and the draft risk communication strategic plan to renew its commitments to partnering with the public to improve

communication, and to continuing to strive to maintain the safety and effectiveness of regulated products. Later, the committee also considered a written suggestion for wording for the developing additional statement offered from the audience. The committee reworked the statement to its collective satisfaction. Finally, the members voted on the edited recommendations, resulting in the revised and re-ordered list of recommendations below. Each was separately subject to simultaneous voting, and each was passed unanimously.

Final Recommendations

- The Committee applauds the Strategic Plan for Risk Communication at the Food and Drug Administration, as a major step forward in enabling FDA to meet its mission of service to the American public. The Committee recommends continuing these efforts to make scientifically sound communication central to the production, summary, and dissemination of evidence regarding FDA's regulated products. An important part of that strategic planning is identifying the outcomes that communications are intended to achieve. An outcomes-focused planning process can further define the key priorities for improving capacity, policy, and science.

- The Committee applauds FDA's commitment to creating the in-house scientific work force necessary to execute its strategic communication plan. The Committee recommends that FDA develop an organizational structure that ensures that individuals with the needed expertise are recruited, retained, and effectively integrated with its operations.

- The Committee applauds FDA's efforts to create partnerships with other public and private organizations that produce and use studies relevant to the effectiveness of its communications. The Committee recommends expansion of these efforts to achieve full leverage of FDA's expertise and resources. The Committee offers itself as a resource for developing those plans.

- The Committee applauds FDA's commitment to producing and evaluating its communications to a scientific standard. The Committee recommends that, as part of its continuing efforts, FDA develop a work-flow system for ensuring that communication needs are integrated into its operations. That system will ensure that its subject-matter experts and communication scientists work together to create, summarize, refine, and deliver needed information, in time to allow proper evaluation.

- The Committee recommends that FDA use the Strategic Communication initiative to reaffirm its commitment to help the public make informed choices regarding FDA-regulated products. Promoting awareness of the initiative will ensure that full benefit is derived from these efforts.

- The Committee recognizes that current interpretations of the Paperwork Reduction Act of 1990 hamper FDA's ability to evaluate its communications, to a scientific standard, in a timely fashion, and with adequately diverse samples. The Committee makes two recommendations to address this problem. First, FDA should identify the public welfare implications of *not* testing its communications. Second, FDA should submit a proposal to the Office of Management and Budget, for a communication

evaluation protocol that balances the public welfare needs of FDA's mandate with those of the Paperwork Reduction Act.

The meeting was adjourned at 12:40 p.m.

For further details of presentations and discussions, please see transcript and slides, both posted at http://www.fda.gov/ohrms/dockets/ac/oc09.html#RCAC.

I certify that I attended the April 30 and May 1, 2009, 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