

MINUTES OF THE
RISK COMMUNICATION ADVISORY COMMITTEE, FDA
Hilton Washington DC/Rockville, 1750 Rockville Pike, Rockville, MD
Thursday, May 15, and Friday, May 16, 2008

Executive Summary

The Risk Communication Advisory Committee (RCAC) met May 15-16, 2008.

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

Discussion Topic May 15: On the first day, the Committee heard presentations from FDA staff members, two SGE Consultants (Craig Andrews and Cheryl Holt), and a guest speaker relating to points the FDA should consider in preparing a report to Congress, as mandated in FDAAA 901, about how direct-to-consumer (DTC) advertising relates to communicating to subsets of the general population, such as the elderly, children, and racial and ethnic minority communities, and increased access to health information and decreased health disparities for these populations. See below for a listing of participants (aside from the public audience), and for details on the presentations.

The RCAC commended FDA offices for their ability to develop extensive communications programs with few resources, and offered several specific suggestions on the topic of the report, including the following.

- Communication research provides a scientific foundation for predicting and empirically assessing a message's impacts. The research base remains incomplete, however, and more is needed.
- Members recommended:
 - Involving target audiences in the development of messages,
 - Empirical testing of messages for understandability and effect,
 - Segmenting the audience, for example according to levels of health literacy, for most effective communication,
 - Considering whether to look at impact of DTC on children or their caregivers,
 - Consulting existing surveys on the elderly, and
 - Making languages other than English available.

Discussion Topic May 16: On the second day, May 16, 2008, the Committee heard a presentation from a staff member about plans for studying the appropriateness of including in televised DTC ads a statement encouraging consumers to report negative side effects of prescription drugs to MedWatch, as is currently required for print DTC prescription drug ads (as mandated by FDAAA 906). See below for a listing of participants (aside from the public audience), and for details on the presentations.

- The RCAC members offered many specific suggestions or points to consider regarding sampling, design, and proposed stimuli for the study.
- Members also recommended that
 - The FDA identify one or a few spokespersons who can give MedWatch a human face, and
 - Consider a separate program to develop Public Service Announcements (PSAs) to publicize MedWatch while waiting for results of the mandated study. Possible messages for dissemination might include the following: that all drugs have “side” effects, all drugs have risks, and that adverse events perceived as unwanted side effects can be reported to MedWatch.

Members Present

Baruch Fischhoff, Ph.D., *Chair*
 Christine M. Bruhn, Ph.D.
 Jacob DeLaRosa, M.D.
 AnnaMaria DeSalva
 Sally Greenberg (5/15 only)
 Michael Goldstein, M.D.
 Prerna Mona Khanna, M.D., M.P.H.
 Madeline Y. Lawson, M.A.
 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

Craig Andrews, Ph.D.
 Cheryl Holt, Ph.D.
 Gavin Huntley-Fenner, Ph.D.
 Elaine Morrato, Ph.D.

 Andreas Lord, M.S., *Guest Speaker*

 Theodore Reiss, M.D., *Guest Industry Representative (5/15 only)*

Executive Secretary

Lee L. Zwanziger, Ph.D.

Open Public Hearing Speakers

May 15, 2008

Ellen Liversidge, Board member of Alliance for Human Research Protection
 Peter Pitts, President, Center for Medicine in the Public Interest

May 16, 2008

Elizabeth Foley, Consumers Union (CU)
 Kim Witczak
 Peter Pitts, President, Center for Medicine in the Public Interest

Presentations

Thursday, May 15, 2008

Overview of Direct-to-Consumer (DTC) Advertising Regulation at FDA

Nancy M. Ostrove, Ph.D., Senior Advisor for Risk Communication

FDAAA – Report on DTC Advertising

Kristin Davis, J.D., Deputy Director, Division of Drug Marketing, Advertising and Communications, Center for Drug Evaluation and Research

Literature Review: Underserved Populations and DTCA

Excerpt from Draft Scientific Literature on Direct-to-Consumer Advertising of Prescription Pharmaceuticals, 2004-2008, prepared for the FDA by Eastern Research Group, John Eyraud, Charles Goodhue, Andreas Lord, and Cynthia Whitman

Andreas Lord, M.S., Eastern Research Group

Comments from Consultants

Craig Andrews, Ph.D., Professor and Kellstadt Chair in Marketing, Marquette University
Cheryl L. Holt, Ph.D., Assistant Professor, School of Medicine, University of Alabama
in Birmingham

Other FDA Presentations

Ellen Frank, Director, Division of Public Affairs, Office of Training and
Communications, Center for Drug Evaluation and Research

Mary Hitch, Senior Policy Advisor, Office of External Relations,
Office of the Commissioner

Catherine McDermott, Director, Public Affairs/Information Branch,
Division of Federal and State Relations, Office of Regulatory Affairs

Karen Feibus, M.D., Medical Officer, Office of New Drugs,
Center for Drug Evaluation and Research

Friday, May 16, 2008

Overview of MedWatch Statement in DTC Print Ads & Presentation of Proposed
Experimental Study

Amie O'Donoghue, Ph.D. (substituting for Kathryn J. Aikin, Ph.D.), Social Science
Analyst, Division of Drug Marketing, Advertising and Communications, Center
for Drug Evaluation and Research

Risk Communication Advisory Committee Meeting, May 15, 2008

The Risk Communication Advisory Committee (RCAC) meeting was convened at approximately 8:00 a.m., Thursday, May 15, 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, May 15, 2008

Baruch Fischhoff, Committee Chair, called the meeting to order, and welcomed all attendees. This was the first meeting attended by newly appointed member Sally Greenberg. Dr. Theodore Reiss participated as the guest Industry Representative.

The Committee was asked to comment on points the FDA should consider in preparing a report to Congress as mandated in section 901 of the FDA Amendments Act of 2007, about how direct-to-consumer (DTC) advertising relates to communicating to subsets of

the general population, such as the elderly, children, and racial and ethnic minority communities, and increased access to health information and decreased health disparities for these populations.

Summary of Open Public Hearing Presentations, May 15, 2008

- Ellen Liversidge, board member of Alliance for Human Research Protection – Since the death of her son as a result of extreme hyperglycemia while he was taking Zyprexa, has been pressing for stronger warnings on drugs, especially antipsychotics. She also calls for restraint on broadcast advertising either directed toward children, or aired during times when children might be exposed to topics that are not age-appropriate.
- Peter Pitts, President, Center for Medicine in the Public Interest – Referring to poll results that the elderly are more distrustful of FDA than the general population, he suggested as an explanation that until recently they did not have access to the health information now available to the all public. Referring to research supporting positive effects of DTC advertising on Americans, including its ability to motivate patients to visit a physician and to discuss a medical condition for the first time, he suggested an educational effect of DTC ads.

Summary of Presentations and Committee Discussions, May 15, 2008 (see slides for more detail on presentations)

Overview of Direct-to-Consumer (DTC) Advertising Regulation at FDA

Nancy M. Ostrove, Ph.D., Senior Advisor for Risk Communication, summarized DTC advertising regulation authorities, which are divided between the FDA (for labeling and promotion of prescription products and the labeling over-the-counter products) and the Federal Trade Commission (for the over-the-counter product advertising). Law and regulation about DTC advertising have not changed (though there have been changes in advertising practices), and until the FDA Amendments Act, did not recognize any differences between advertising directed to consumers and advertising that directed to healthcare professionals. FDA recognizes different classes of promotional materials (reminder ads, help seeking ads, and product claim ads) with different requirements about what can be claimed and must be disclosed. If an ad is out of compliance, the FDA can inform the advertiser of the observed violations. This interaction is often enough, as firms tend to follow FDA's requests. If more is needed, the FDA can issue a formal warning letter, which may be a prelude to more serious legal actions. If necessary, the FDA can seize products for bring injunctions and prosecutions.

FDAAA – Report on DTC Advertising

Kristin Davis, J.D., Deputy Director, Division of Drug Marketing, Advertising and Communications, Center for Drug Evaluation and Research, presented a summary of the requirements for the report as set out in the FDA Amendments Act (FDAAA) of 2007, noting also that the act gives the FDA the new authority to require that proposed

television DTC ads be submitted to the Agency for pre-review and recommendations. She also discussed some other provisions of the Act.

Literature Review: Underserved Populations and DTCA

Excerpt from “Draft Scientific Literature on Direct-to-Consumer Advertising of Prescription Pharmaceuticals, 2004-2008,” prepared for the FDA by Eastern Research Group, John Eyraud, Charles Goodhue, Andreas Lord, and Cynthia Whitman

Andreas Lord, M.S., Eastern Research Group, presented a selection from the results of a literature survey done under contract for the FDA. In results focusing on the literature addressing the population subsets mentioned for the required report, he noted that these population subsets see as much advertising as others, but differ in how they respond; for example, older people tend to request prescriptions less often, but when they do, are likely to be referred for further treatment. African-Americans, on the other hand, tend to request prescriptions more often, but do not receive requested prescriptions as often as other groups. People with high school or less education were more likely to agree that DTC advertising provides enough information to decide if drug benefits outweigh the risks. Physicians may provide treatment and prescriptions more frequently to patients who request drugs than to those who do not. Finally, consumers may overestimate their own likelihood of suffering a side effect, both when the risk information given was vague or was specific.

Comments from Consultants

Craig Andrews, Ph.D., Professor and Kellstadt Chair in Marketing, Marquette University, presented both practical and theoretical points to consider for the FDA’s report. Practical considerations from his experience at the Federal Trade Commission and in the Wisconsin Anti-Tobacco and the National Youth Anti-drug Media Campaigns demonstrate that there are many different though overlapping perspectives on how to assess communication, and that therefore all must strive to listen to one another. Theoretical considerations are captured in the Elaboration Likelihood Model of how people are persuaded to take an action, and the Consumer Information Processing Model of depicting stages in considering information and deciding to act. Although research on some of the subpopulations mentioned is limited, the results show that the groups do differ significantly in how they respond to communications in general.

Cheryl L. Holt, Ph.D., Assistant Professor, School of Medicine, Univ. Alabama in Birmingham, presented suggestions for the FDA’s report, starting with recommending attention to basic components of communication (source, message, channel of delivery, and receive characteristics), and noting that the subpopulations named for the report are quite distinct audiences. Therefore, if DTC advertising is to provide communication to reduce health disparities, she advised targeting the specific audiences, involving the relevant communities at all stages, and pre-testing messages in target groups.

Other FDA Presentations

Ellen Frank, Director, Division of Public Affairs, Office of Training and Communications, Center for Drug Evaluation and Research, presented samples of FDA communications (www.fda.gov/usemedicinesafely), often by necessity designed and

disseminated with external partners. The communications presented focused on the subpopulations to be considered in the required report. All were general (not product-specific) education campaigns for safe and informed use of medicines.

Mary Hitch, Senior Policy Advisor, Office of External Relations, Office of the Commissioner, presented an overview of the FDA's communications and impacts on ethnic, racial, and underserved subpopulations, noting how the use of information sources and health status vary among different groups. She concluded with an overview of challenges for better communication on health matters, including considering differences in cultures, assumptions and practices, levels of health literacy, and primary language.

Catherine McDermott, Director, Public Affairs/Information Branch, Division of Federal and State Relations, Office of Regulatory Affairs, discussed activities conducted by the field Public Affairs Specialists. These thirty communication professionals are spread across the ORA's five regions of operations, throughout the country and Puerto Rico, and serve as our community-base educators on many FDA topics and especially for outreach to groups representing the subpopulations for consideration in the required report.

Karen Feibus, M.D., Medical Officer, Office of New Drugs, Center for Drug Evaluation and Research, presented "Medicines in my Home," an educational campaign directed toward children for safe and correct use of medicines (www.fda.gov/medsinmyhome), which was pilot tested in several middle school classrooms and launched on the web in June 2006. Key concepts introduced include the information to look for in the Drug Facts label, the importance of reading and following the directions under adult supervision, being careful to measure the medicine and not combine two products with the same ingredients, and recommendations to ask a doctor or pharmacist any questions about medicines.

Summary of Committee's Further Comments and Discussion, May 15, 2008

In further discussion, members addressed the issues suggested in the discussion topics below, regarding points to consider for the proposed FDA report. 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.

Discussion Topic: DTC Advertising's Impact on Subsets of the General Population; Report (FDA Amendments Act Section 901)

1. Please provide suggestions or points to consider for the FDA to keep in mind as we prepare a report regarding the relation of DTC advertising to increasing access to health information and decreasing health disparities for subsets of the general population, including elderly populations, children, and racial and ethnic minority communities. In your response, please try to address at least one of the following groups:

- a. elderly
- b. children (including teenagers)
- c. racial minorities
- d. ethnic minorities

2. Please provide suggestions about effective ways to communicate information to subsets of the general populations, including those listed above.

- Committee members maintained that communications about a product can affect when it is chosen and how it is used. As a result, communications should be considered as an intrinsic part of the product. If communications change (e.g., from a clinical trial to commercial distribution, from prescription to OTC), then the product and its impacts may have changed.
- Committee members commented that communication research provides a scientific foundation for predicting and empirically assessing the impact of a message. Based on that research, ads must be considered as a whole, including visuals and sound tracks, when assessing impact. The impact of a finished ad could be different than that predicted on the basis of scripts and storyboards, in how both risks and benefits are perceived. Communication research also finds that ads should be considered as part of the overall communication programs in which they are embedded.
- Members also noted that, while the research base affords guidance, it is still incomplete. As a result, impacts cannot be predicted with sufficient confidence to remove the need for direct empirical testing. Members discussed how the research agenda could be developed and funded.
- Members made specific comments regarding some subgroups. These include:
 - *Children*: The meaning of the subgroup “children,” is ambiguous in the context of DTC advertising of prescription drugs. Are we to consider the effects of ads on children or on the caregivers of children? Should communication with teens be considered separately?
 - *Elderly*: Consult resources, such as the Health Information National Trends Survey (HINTS), for information on use of the internet by older Americans; also look at reports from the Pew Trust.
 - *Minorities*: Many toll-free numbers offered for follow-up on FDA materials lead to messages only in English, even when the materials are in Spanish.
- Members offered many suggestions for effective ways to communicate to these subpopulations, including:
 - Involving target audiences in the development of messages,
 - Empirical testing of messages for understandability and effect,
 - Segmenting the audience, for example according to levels of health literacy, for most effective communication,
 - Making languages other than English available.

Members commended the FDA offices that made presentations, for their ability to develop extensive communications programs with few resources. Public Affairs Specialists were especially mentioned as important communicators, whose work could be more effective if they were able to attend more regional conferences. Recognizing that the FDA has stretched resources in part by the thoughtful development of partnerships, members suggested other possible partners, such as AHRQ and its CERTS, NIH, CDC, educational institutions, and grass roots organizations.

Members also noted that industry should be involved in assessing the communication impacts of DTC ads, and that with proper disclosure and transparency, good research could result from partnering with industry or an industry consortium. They raised the specific possibility that companies that evaluate ads for commercial purposes could also collect data that will allow the FDA to assess the ads' health impacts. Members suggested that doing so could cost little, while allowing advertisers to refine ads so that they more effectively meet FDA's objectives, and while still meeting their own commercial needs.

Finally, members requested more background and context for future discussions. They also requested more feedback about the FDA's response to RCAC advice, given that their advice and the FDA's response lack the discrete, immediate response of advice from product-focused advisory committees. Nancy Ostrove provided a publicly disclosable summary update of work within the Agency that is ongoing and relevant to the recommendations from the previous meeting.

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

Risk Communication Advisory Committee Meeting, May 16, 2008

The Risk Communication Advisory Committee (RCAC) meeting was reconvened at approximately 8:00 a.m., Friday, May 16, 2008. The same conflict of interest statement was read into the record as described for the prior day.

Summary of Opening Comments, May 16, 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 was asked to provide comment on design considerations for studying the appropriateness of including, in televised DTC ads, a statement encouraging consumers to report negative side effects of prescription drugs to MedWatch, as is currently required for print DTC prescription drug ads. It was explained that FDA would seek public comment in accord with the Paperwork Reduction Act, as well as seeking peer review of the study protocol. The study in question is mandated in section 906 of the FDA Amendments Act of 2007.

Summary of Open Public Hearing Presentations, May 16, 2008

- Elizabeth Foley, Consumers Union (CU) – CU supports including the MedWatch number in broadcast DTC ads and has already submitted a Citizens’ Petition signed by approximately 56,000 members of the public.¹ The organization urges the FDA to move faster on the mandated evaluation research.
- Kim Witzzak – Since the suicide of her husband while he was taking Zoloft, she has been pressing for stronger warnings on drugs, and supports the inclusion of the MedWatch number in broadcast DTC ads. She also urges speed in completing the research and regulations, and suggested that, in the meantime, FDA should disseminate a Public Service Announcement about reporting adverse drug experiences to MedWatch.
- Peter Pitts – Suggested that the FDA is becoming “the victim of its own success,” in that the relative safety of approved drugs fosters unrealistic expectations of perfect safety, but that actual regulation should be based on data rather than anecdote. He noted that the terms “side effects” and “adverse events” are not synonymous, but as long as that remains unclear to many in the public, and assuming that a more robust adverse event reporting system can be put in place, there may be unintended consequences of FDA gathering significantly more adverse event reports from consumers and issuing early alerts based on this information.

Summary of Presentations and Committee Discussions, May 16, 2008

Overview of MedWatch Statement in DTC Print Ads & Presentation of Proposed Experimental Study

Amie O’Donoghue, Ph.D. (substituting for Kathryn J. Aikin, Ph.D.), Social Science Analyst, Division of Drug Marketing, Advertising and Communications, Center for Drug Evaluation and Research, presented a review of the process of clearing proposed research projects, and an overview of the FDA’s suggested study design that responds to the mandate in the FDA Amendments Act section 906. The proposed research protocol will be reviewed by the FDA’s Committee on Research Involving Human Subjects and by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act. The latter review process results in at least two opportunities for public comment. Following OMB clearance, the protocol may be implemented as a research project.

From focus groups assembled during the study of a similar statement in labeling required under the Best Pharmaceuticals for Children Act of 2002, the FDA has learned that some people think a statement on reporting adverse events to MedWatch tells them where to get medical advice, some understand that the number is for reporting only but would not

¹ The organization suggested to signatories of the Citizen’s Petition that they also email the advisory committee, including a message of support for including the MedWatch number. These emails were counted and summarized by the executive secretary, and made available to the committee.

be motivated to call, while others said they would call. Subsequent quantitative research on statement wording is now being analyzed. The proposed FDA research, and the RCAC advice, should help answer the questions: Does the inclusion of a toll-free number for reporting side effects in DTC television advertisements detract from the communication of important risk information in the ad? And if the statement does not detract from the communication of important risk information, what is the optimal length of time this statement should be displayed in the ad? The proposed design also would test the placement of the statement before, during, or after the major statement of product risks, and would also compare short and longer times of showing the statement, with subjects of varied education levels, age, and sex.

Summary of Committee's Closing Comments and Discussion, May 16, 2008

After the presentation, Dr. Fischhoff first asked whether the time required for proposing and carrying out a study in compliance with the Paperwork Reduction Act is indeed substantially greater than the time mandated in the more recent FDA Amendments Act for completing the study under discussion. After receiving confirmation from FDA personnel, the Committee turned to the discussion topics, below, on the proposed study. 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.

Discussion Topic: Adverse Event Reporting Number Statement Study (FDA Amendments Act, Section 906)

1. Are you aware of research that is relevant to the task set before us by Congress in Section 906 of FDAAA? If so, please provide the research or alternatively, a bibliography.
 2. Does the approach reflected in the materials provided seem like a reasonable approach to address the task set before FDA by Congress? In your answer, please address:
 - a. Sampling
 - b. Design
 - c. Proposed stimuli.
- Members pointed to many research resources the FDA might consider, including:
 - FCC and FTC rules and guidelines,
 - The NCI Special Population Networks, to facilitate recruitment among the named subpopulations,
 - Various published studies, such as Hoy MG and Andrews JC. "Adherence of Prime-Time Television Advertising Disclosures to the "Clear and Conspicuous Standard": 1990 vs. 2002, *Journal of Public Policy & Marketing*, (2004) 23: 170-182.

- Members offered a range of suggestions regarding the proposed study approach.
 - *Sampling:*
 - Ensure sufficient sample sizes to be able to identify the needs of special populations.
 - Include both high school and non-high school graduates, who may differ in ways not captured by literacy measures.
 - Ensure sampling of the subpopulations mentioned in the previous day’s discussion, recognizing that their recruitment often requires an extra effort.
 - Consider that mall-intercept recruitment may not result in a representative sample.
 - When screening for health literacy, use the S-TOFHLA (short form of the Test of Functional Health Literacy in Adults) as the instrument rather than the REALM (Rapid Estimate of Adult Literacy in Medicine).
 - *Design:*
 - Conduct intensive qualitative research with individuals drawn from the target populations in order to ensure the appropriateness of the design and materials, before conducting quantitative research with larger samples.
 - Rely on published literature as much as possible to reduce the number of experimental conditions and increase sample size (and statistical power) for each. For example, it was noted that the effects of the duration of message exposure have been extensively studied, and need not be reexamined.
 - Note that the public will actually experience the MedWatch message in many ads, scattered throughout programming. The proposed design, focused on a single exposure, does not capture this experience, which could change perceptions of both risks and benefits. For example, in a single ad, the message might increase perceived risks by suggesting possible problems, while in multiple ads it might reduce perceived risks by suggesting additional safety as a result of ongoing monitoring. One suggestion was for the test to embed ads within a half hour TV segment.
 - *Proposed Stimuli:*
 - Consider testing only the condition of simultaneous voice and text presentation of the MedWatch information, described in the proposed study presentation as the “extra prominent” stimulus. Research has found that messages delivered consistently in multiple modalities are more likely to be understood. Using them will also increase access for hearing- and vision-impaired individuals.
 - Because motivation affects both attention and comprehension, the study should look separately at effects on viewers who have direct and/or indirect experience with the condition associated with the drug or advertisement-mentioned side effects, viewers who have been affected by any adverse drug events, and other viewers.
- Members also made the following suggestions for improving the MedWatch system, to which individuals are being encouraged to report adverse drug experiences.

- The FDA currently gets information from many different sources, including physicians, manufacturers, and the general public. Those sources provide data of varying quality and quantity that can be represented in terms of the ratio of signal to noise. These sources can provide potentially useful input to an early warning hazard detection system. However, increasing the sampling of a subset of sources could make it more difficult to detect problems, especially if the subset is relatively "noisy." Therefore, the agency should
 - Consider alternative approaches to assessing how the manner of encouraging side effect reporting affects various input sources (e.g., signal detection or “mean squared error analyses” that consider both bias and variance);
 - Investigate how to design ad messages so that the quality of new data improves on current inputs from these sources.
- Ensure that messages reach individuals who have experienced reportable adverse events, and convey the value of reporting.
- Play the MedWatch number more slowly, and add a Spanish version.
- Identify one or a few spokespersons who can give MedWatch a human face. These individuals might be the recognizable spokespeople for FDA suggested by the Committee at the February RCAC meeting.
- Develop Public Service Announcements (PSAs) to publicize MedWatch while waiting for results of the mandated study. Messages to consider for dissemination might include the following: that all drugs have “side” effects, that all drugs have risks, and that adverse events perceived as unwanted side effects can be reported to MedWatch.

Members were enthusiastic about participating in study design, and requested the opportunity to discuss a later version of the draft study, perhaps in a telephone advisory committee meeting. Members would like to discuss how to improve communication with healthcare professionals regarding reporting adverse drug effects, and to assist the FDA in developing processes for evaluating its varied communication interventions.

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 May 15 and 16, 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