MINUTES OF THE
SCIENCE BOARD TO THE FDA

Holiday Inn, 2 Montgomery Village Avenue, Gaithersburg, Maryland

Thursday, June 14th, 2007

The Science Board to the FDA (Science Board) meeting was convened at approximately 8:00 a.m.

Members Present for June 14th, 2007
Kenneth I. Shine, M.D., *Chair*
Gail H. Cassell, Ph.D., D.Sc.(hon)
Susan Kay Harlander, Ph.D.
Lonnie King, D.V.M., M.P.A.
David R. Parkinson, M.D.
Allen D. Roses, M.D.
Larry Sasich, Pharm.D., M.P.H., F.A.S.H.P.

Executive Secretary
Carlos Peña, Ph.D., M.S.

FDA Participants
David Acheson, M.D., Assistant Commissioner for Food Protection
Norris Alderson, Ph.D., Associate Commissioner for Science
Robert Brackett, M.D., Director, Center for Food Safety and Applied Nutrition
Steven Galson, M.D., Director, Center for Drug Evaluation and Research
David Hattan, Ph.D., Center for Food Safety and Applied Nutrition
Carlos Pena, Ph.D., M.S., Executive Secretary, Office of Science and Health Coordination
Daniel Schultz, M.D., Director, Center for Devices and Radiological Health
William Slikker, Jr., Ph.D., Director, National Center for Toxicological Research
Stephen Sundlof, D.V.M., Ph.D., Director, Center for Veterinary Medicine
Andrew von Eschenbach, M.D., Commissioner of Food and Drugs
Janet Woodcock, M.D., Deputy Commissioner and Chief Medical Officer

Presentations
Commissioner's Report
Andrew von Eschenbach, M.D., Commissioner of Food and Drugs
Report to the Science Board: Bioinformatics, FDA Fellowship Program
Janet Woodcock, M.D., Deputy Commissioner and Chief Medical Officer
Report to the Science Board: Melamine Overview
David Acheson, M.D., Assistant Commissioner for Food Protection
Report to the Science Board: Presentation of the Interim Melamine Safety/Risk Assessment & Conclusions, Summary of Interim Melamine Safety/Risk Assessment Peer Review
David Hattan, Ph.D., Center for Food Safety and Applied Nutrition

Report of the Science Board Subcommittee Review of the National Antimicrobial Resistance Monitoring System (NARMS) Program
Lonnie King, D.V.M., M.P.A., Subcommittee Chair, Science Board
Progress Report of the Science Board Subcommittee Review of FDA Science
Gail Cassell, Ph.D., D.Sc.(hon), Subcommittee Chair, Science Board
Comments from the Science Board Chair
Kenneth I. Shine, M.D., Chair, Science Board

Summary of Committee Discussions and Recommendations
Commissioner's Report
Presentation Summary

- The Commissioner of Food and Drugs presented the Science Board an update on the state of FDA, current review of science programs and infrastructure, critical path initiative, pandemic strategic plan, food protection activities, strategic objectives, and future challenges of the agency.

Committee Discussion

- The Science Board discussed enhancing the coordination among Centers and Offices, opportunities for interdisciplinary research, science programs and infrastructure oversight and review, public recognition of the importance of FDA, risk communication, and research and resource needs of the agency;

Report to the Science Board: FDA Fellowship Program, Bioinformatics
Presentation Summary

- Dr. Janet Woodcock presented an overview of the agency's FDA fellowship program, including its current state of scientific and administrative fellows, a description of how fellows are administered at the Center level, and future goals of a cross agency two year fellowship program administered through a foundation targeting specific areas of scientific need. She discussed expectations for the fellowship program, including the exposure of fellows to regulatory science and career opportunities. She also provided an update to FDA's automation/bioinformatics strategies. Dr. Woodcock discussed existing challenges within the agency such as data access, standards, and interfaces, and strategies for improvement. She discussed the Bioinformatics Board (BiB) and Business Review Boards (BRBs) and their role in updating the agency's business planning through information technology. She also described ongoing projects related to information management and technology.

Committee Discussion

- The Science Board discussed the importance of a fellowship program, including a role in educating the public. The Science Board also commented on the importance for a strategic bioinformatics plan to help collect, standardize, and review data;

Report to the Science Board: Melamine Overview

- Dr. David Acheson presented an overview of the agency's activities associated with melamine, including a timeline of events and steps taken by the agency in the evaluation of adverse event reports associated with animals. He also presented upon the agency's investigation into food manufacturers and cooperation with other agencies including USDA in evaluating data associated with the Interim Melamine Safety/Risk Assessment (S/RA).

Committee Discussion

- The Science Board discussed the agency resources available to address future events, surveillance systems in place to respond to future issues, and the use of risk based approaches to carrying out the regulatory responsibilities of the agency. The Science Board also discussed the physical and chemical properties of the compound melamine, compounds similar in structure to melamine, and background exposure rates.

Report to the Science Board: Presentation of the Interim Melamine Safety/Risk Assessment & Conclusions, Summary of Interim Melamine Safety/Risk Assessment Peer Review

Presentation Summary

- Dr. Hattan presented on the melamine compounds S/RA, including compounds studied, intake scenarios, margins of safety and conclusions from the S/RA. He also discussed the peer-review process, their recommendations, and additional points to consider.

Committee Discussion

- The Science Board discussed the chemical properties of melamine, responsibilities of the agency when investigating imports or exports of regulated products, and the publication of analyses related to melamine conducted by the agency. The Science Board reported they concurred with the findings in the report, including the probability of risk to humans, analysis of risk to the food supply, and methods used in the analysis. The Science Board recommended greater evaluation of risk assessment and surveillance methods. The Science Board also reported they concurred with the findings in the peer-review, including the use of members of the Science Board, as well as recommendation for the need of additional research. The Science Board recommended the following topics for discussion at the next Science Board meeting:
    - Update on the progress in implementing the peer-review recommendations;
    - Update on the legality of pursuing manufacturers that produce harmful products;
    - Update on the food supply for animals;
    - Update on the agency's surveillance systems; and
    - Distribute S/RA report and peer-review to the Science Board Subcommittee review of FDA science.

Open Public Hearing

One speaker was identified in the public hearing session. The speaker commented upon the toxicological profile of the compound melamine.

Report of the Science Board Subcommittee Review of the National Antimicrobial Resistance Monitoring System (NARMS) Program

Presentation Summary

- Dr. Lonnie King presented the charge to the subcommittee, including four questions to be addressed by the subcommittee. He discussed the panel approach to their review and introduced the NARMS program to the Science Board. He discussed the goals of the NARMS program, general considerations, and common themes. He also discussed the final findings and suggestions for the Science Board to consider in preparing a report to the agency.

Committee Discussion

- The Science Board discussed stakeholders for the NARMS report, data collection and storage, reporting timelines for release of NARMS data and analyses, the highest priorities in the next 2-3 years for the NARMS program, and coordinating the agency's activities with international programs and efforts. The Science Board recommended the following:

- Accept report from the NARMS subcommittee;
- Submit NARMS report to the agency; and
- Update on the agency's efforts to address report findings at the next Science Board meeting.

Progress Report of the Science Board Subcommittee Review of FDA Science
Presentation Summary

- Dr. Gail Cassell presented the charge to the Science Board subcommittee for the review of FDA science, interaction of the subcommittee and FDA staff, and submission of the subcommittee review document to the parent Advisory Board. She presented the subcommittee roster, as well as a list of advisors assisting the subcommittee in its review. The subcommittee is divided into 6 center-focused groups and 3 groups focused on cross-cutting topics. A draft review in anticipated in mid July/early August, a report to the parent Science Board Advisory Committee is anticipated in October, 2007, and the Science Board is anticipated to submit a final report to the agency in December, 2007.

Open Public Hearing
No speakers were identified in the open public hearing session.

Comments from the Science Board Chair

- Dr. Kenneth Shine presented closing remarks, including the opportunity for the Science Board to become more involved in science programs important to the agency, oversight of reviews of the agency, anticipation of the upcoming Science Board Subcommittee review of FDA science, and enhancing the process by which subcommittees of the Science Board can be formed to help review science programs at FDA. Dr. Shine also reported the following statements:
  - The Science Board requests an update on food safety and related programs at the next Science Board meeting;
  - The Science Board officially submits the NARMS report to the agency for review and follow-up from the agency on steps to address the recommendations identified in the report;
  - The Science Board requests a NARMS report dissemination plan to the public;
  - The Science Board anticipates a preliminary report from the Science Board Subcommittee at the next Science Board meeting;
  - The Science Board requests a Science Board Subcommittee report dissemination plan to the public;
  - The Science Board will target reviews of the agency at future Science Board meetings.

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

Please see transcript for details

I certify that I attended the June 14, 2007 meeting of the Pediatric Advisory Committee and that these minutes accurately reflect what transpired.

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Carlos Peña, Ph.D., M.S.	Kenneth I. Shine, M.D.
Executive Secretary	Chair