

MINUTES OF THE
SCIENCE BOARD TO THE FDA

Washington DC North/Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, MD 20877

Friday, October 31st, 2008

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

Members

Barbara McNeil, M.D., Ph.D. Chair
Rhona Applebaum, Ph.D.
Garret FitzGerald, M.D. (via phone)
Erik Hewlett, M.D.
Lonnie King, D.V.M., M.P.A.
John H. Linehan, Ph.D.
David R. Parkinson, M.D.
Martin Philbert, Ph.D.
Larry Sasich, Pharm.D., M.P.H., F.A.S.H.P.

Executive Secretary

Carlos Peña, Ph.D., M.S., Office of the Commissioner (OC)

FDA Participants

David Acheson, M.D., Associate Commissioner for Foods, OC
Bernadette Dunham, D.V.M., Ph.D., Director, Center for Veterinary Medicine (CVM)
Randall Lutter, Ph.D., Deputy Commissioner for Policy, OC
Subhas Malghan, Ph.D., Deputy Director, Office of Science and Engineering Laboratories, Center for Devices and Radiological Health (CDRH)
Steven Musser, Ph.D., Director, Office of Regulatory Science, Center for Food Safety and Applied Nutrition (CFSAN)
George Salem, Office of Regulatory Affairs (ORA)
Daniel Schultz, M.D., Director, CDRH
William Slikker, Jr., Ph.D., Director, National Center for Toxicological Research (NCTR)
Stephen Sundlof, D.V.M., Ph.D., Director, CFSAN
Douglas Throckmorton, M.D., Center for Drug Evaluation and Research (CDER)
Frank M. Torti, M.D., M.P.H., Principal Deputy Commissioner and Chief Scientist, OC
Andrew von Eschenbach, M.D., Commissioner of Food and Drugs
Carolyn Wilson, Ph.D., Center for Biologics Evaluation and Research (CBER)

Open Public Hearing Speakers

The following individuals and organizations who submitted comments to the Science Board were acknowledged during the open public hearing session.

- Environmental Working Group

- Ms. Rachael Rawlins and Breast Cancer Action
- Natural Resources Defense Council
- American Chemistry Council's Polycarbonate/BPA Global Group
- Dr. David Epel, Stanford University Hopkins Marine Station

Presentations and Discussions

Commissioner's Report

Andrew von Eschenbach, M.D., Commissioner of Food and Drugs

Science at the FDA: Update

Frank M. Torti, M.D., M.P.H., Principal Deputy Commissioner and Chief Scientist, OC

Strategy for 2009 Science Board Topics

Barbara McNeil, M.D., Ph.D., Chair

Overview of Current Methods for Detection of Contaminants in FDA Regulated Products

David Acheson, M.D., Associate Commissioner for Foods, OC

Steven Musser, Ph.D., Director, Office of Regulatory Science, CFSAN

Randall Lutter, Ph.D., Deputy Commissioner for Policy, OC

Stephen Sundlof, D.V.M., Ph.D., Director, CFSAN

Report from the Science Board BPA (Bisphenol A) Subcommittee

Martin Philbert, Ph.D., Subcommittee Chair

Comments from the Science Board Chair

Barbara McNeil, M.D., Ph.D., Chair

Summary of Committee Discussions and Recommendations

Opening Comments

Barbara McNeil, M.D., Ph.D. Chair

- Dr. McNeil welcomed Science Board (Board) members, FDA staff, and all meeting attendees. She summarized the agenda, including a review of the draft assessment of BPA (Bisphenol A) for use in food contact applications by the Science Board BPA Subcommittee. She mentioned that the Commissioner increased the size of the Science Board to 21 members, and vacancies exist on the Science Board. Science Board members as well as members of the public were encouraged to submit potential nominations to the Science Board to FDA.

Commissioner's Report

Andrew von Eschenbach, M.D., Commissioner of Food and Drugs

- The Commissioner of Food and Drugs presented an update to the Science Board on the state of FDA. He discussed the importance of the FDA being a science-based and science-led agency, as the essential foundation for its public health decisions. He identified peer-review as a cornerstone of how the agency meets its public health mission, and emphasized that decisions must be based in science, law, and regulations. He also discussed how important the role of science is to the agency's ability to promote medical innovation, enhance its food protection capacities, and keep pace with rapid and radical changes in science and technology.

Committee Discussion

- The Science Board discussed the rapid pace of technology development and the ability of the agency to recruit and retain top scientists. Committee discussion focused upon ensuring a strong workforce and the Commissioner's Fellowship Program. The Science Board also commented on the importance of a plan for career development for FDA staff.

Science at the FDA: Update

Frank M. Torti, M.D., M.P.H., Principal Deputy Commissioner and Chief Scientist, OC

- Dr. Torti presented his views on science at FDA and stated quality regulatory science will improve regulatory decisions, regulatory consistency and speed the approval of new products. He discussed three scientific focus areas: scientific investment in partnerships, recruitment and retention of a strong FDA workforce, and information technology (IT) infrastructure. He stated the importance of an overarching scientific vision, identifying critical problems and roadblocks to achieving science priorities, and developing hypothesis driven research to solve problems. Dr. Torti discussed the FDA Commissioner's Fellowship program, including the application process and research and career development for fellows. He discussed future steps towards establishing agency task forces to tackle urgent problems confronting the agency using state of the art scientific approaches. Dr. Torti closed with a discussion of evaluating the entire life cycle of products, and identifying problems at the source, risk-based assessment/inspections, and enhancing and product tracking methodologies and field-ready techniques of rapid identification of contaminants in FDA regulated products.

Committee Discussion

- The Science Board discussed the FDA Commissioner's Fellowship program and process for matching fellows to FDA responsibilities. The Science Board discussed the life cycle of FDA regulated products and how the agency can better identify potential problems before they arise. The Science Board commented that increasing commerce and globalization will place increasing demands upon the agency. FDA staff agreed, and noted that harmonization of product development processes globally is one important solution to addressing challenges in commercialization. The Science Board also discussed the importance of a plan to bridge the gap between scientific findings and regulation. The Science Board also inquired about the international field offices. FDA staff responded that the agency is in the process of staffing offices in China, India, the Middle East, Europe, and Latin America.

Strategy for 2009 Science Board Topics

Barbara McNeil, M.D., Ph.D., Chair

- Dr. McNeil identified topic areas to come before the Science Board in 2009. These include reports from two FDA Task Forces on rapid detection of contaminants in FDA Regulated Products: (1) rapid detection of contaminants in foods and (2) intentionally and economically motivated adulteration of foods. She also identified the Center-by-Center review of science programs (one Center per year), and additional review of BPA exposure from other FDA-regulated products.

Committee Discussion

- The Science Board discussed how its review of FDA Science Programs can best help the agency. FDA staff commented that a plan would be presented at the next Science Board meeting, including a schedule for Center reviews. The Science Board also discussed the upcoming review of BPA exposure from other FDA-regulated products and the importance of relating the various BPA assessments to each other. Additional discussion focused on future updates on modernizing the information technology structure at FDA, an overview of FDAAA, and risk communication.

Overview of Current Methods for Detection of Contaminants in FDA Regulated Products

David Acheson, M.D., Associate Commissioner for Foods, OC

- Dr. Acheson opened his presentation with a discussion of detection challenges during outbreak situations, including problems analyzing different types of samples, and issues with the slow speed of detection methods and the ease of detection methods for use in the field. Dr. Acheson mapped out the timeline of an outbreak, from consumer illness, through case findings and gathering additional case information. He described FDA's role, including discussions with the product sponsor(s), product tracing, product testing, and source determination, consumer communication, and reoccurrence prevention. He also identified the sequence of events during the 2008 salmonella saintpaul outbreak. He closed by describing key factors for improved rapid detection, such as rapidly identifying pathogens, eliminating negatives faster, and enabling greater availability of products not implicated in an outbreak.

Steven Musser, Ph.D., Director, Office of Regulatory Science, CFSAN

- Dr. Musser presented methods and approaches in rapid detection for an outbreak, including routine surveillance, tracking/identifying sources of outbreaks, and assessing and validating new and novel technology, protocols and methods. He discussed the importance of specificity and sensitivity in rapid detection assays, and explained that not all pathogens present the same level of difficulty in detection methodologies. He reviewed the challenges in testing for microbial contamination and the need for enrichment of samples. He also briefed the Science Board on pulse field gel electrophoresis and other assessment techniques for foodborne, disease-causing pathogens. He closed with a discussion of important factors for rapid detection, including identification of technology appropriate for use in foods and the need for reproducible and comparable results across laboratories.

Committee Discussion

- The Science Board discussed response vs. prevention approaches to rapid detection methods and technologies, the importance of partnerships between different agencies (i.e. FDA and the Center for Disease Control), and the importance of keeping state and local governments involved in any outbreak investigation. FDA staff commented that the establishment of a task force to strengthen partnerships and evaluate outbreaks could enhance FDA prevention and response activities.

Stephen Sundlof, D.V.M., Ph.D., Director, CFSAN

- Dr. Sundlof opened his presentation with a discussion of how the agency first learned about the melamine contamination of milk-derived ingredients and finished food products containing milk, what have we learned about melamine and melamine + cyanuric acid, and current information needs. He discussed consumer calls to FDA related to melamine and FDA action in response to consumer interest. He discussed the discovery of melamine, industrial use of melamine, and methods used to detect its presence in FDA regulated products. He reviewed the risk assessment of melamine developed by the FDA and its presentation to the Science Board (June 14, 2007 Science Board meeting). He also presented current activities on melamine at FDA, lessons learned on the cause of injury, including recent published literature, and requested the Science Board's ongoing scientific advice as we continue to address issues related to contamination of food and ingredients with melamine and its analogues.

Randall Lutter, Ph.D., Deputy Commissioner for Policy, OC

- Dr. Lutter opened his presentation with an account of recent cases of intentional, economically motivated product adulteration, and congressional actions to address intentional adulteration. He stated that economically motivated adulteration is becoming a key target of FDA's efforts to protect and promote public health. He noted the volume of imported "lines" of FDA-regulated products has grown 14% annually since 1997 and identified ongoing efforts at strengthening

protection, and the need to understand economic systems in other countries. Dr. Lutter explained that large-scale economically motivated contamination is likely where the expected reward from adulteration is greater than the expected cost of being discovered and penalized. He closed with notice to the Science Board of the establishment of a science and policy workgroup tasked with soliciting information about factors that may lead to economically motivated product adulteration from within the agency, from industry, and from other governments.

Committee Discussion

- The Science Board discussed other products that could be at risk for adulteration and how the public might provide input to FDA on potential adulterated products. The Science Board inquired about the role of other agencies in identifying economically motivated adulteration of FDA regulated products. FDA staff commented that greatest priority is placed on economically motivated adulteration of FDA regulated products that pose a risk to humans.

Report from the Science Board BPA (Bisphenol A) Subcommittee

Martin Philbert, Ph.D., Subcommittee Chair

- Dr. Philbert discussed the process of the BPA subcommittee peer-review, including the subcommittee's internal process, the public meeting, and additional discussions between the subcommittee and the invited panel at the public meeting. Dr. Philbert discussed the scope of the report and subcommittee findings. He also presented limitations to the report. Dr. Philbert closed with a review of future directions and recommendations contained in the BPA subcommittee report.

Committee Discussion

- The Science Board discussed the differences between Good Laboratory Practice (GLP) studies and other studies, access to raw data from non-GLP investigations, additional risk analyses, and exposure assessments from other products containing BPA. The Science Board also discussed the importance of epidemiological data, biomonitoring studies, and pharmacogenomics as additional factors to consider in an assessment. The Science Board unanimously agreed to accept the subcommittee report, with additional revisions to the last two bullets in the Executive Summary of the report. The Science Board transmitted the report to the agency on Friday, October 31, 2008. Any Science Board members who wish to submit additional written comments to the FDA were requested do so separately. A final Science Board report will be made available online at FDA.GOV.

Comments from the Science Board Chair

Barbara McNeil, M.D., Ph.D. Chair

- Dr. McNeil presented closing remarks, including the following statements:
 - The Science Board unanimously agreed to accept the BPA subcommittee report. The Science Board transmitted the Science Board report to the agency on Friday, October 31, 2008. Any Science Board members who wish to submit additional written comments to the FDA were requested do so separately. A final Science Board report would be made available online at FDA.GOV.
 - Dr. McNeil identified four areas to come before the Science Board in 2009, including reports from two FDA Task Forces on rapid detection of contaminants in FDA Regulated Products: (1) rapid detection of contaminants in foods and (2) intentionally and economically motivated adulteration of foods. She also identified the upcoming Center-

by-Center review of science programs (one Center per year) and additional reviews on BPA exposure from other FDA-regulated products.

The meeting adjourned at approximately 3:30 p.m.

Please see transcript for details

I certify that I attended the October 31st, 2008 meeting of the Science Board and that these minutes accurately reflect what transpired.


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


Barbara McNeil, M.D., Ph.D. Chair
Chair