MINUTES OF THE
SCIENCE BOARD TO THE FDA

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

Tuesday, February 24th, 2009

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.
James Broach, Ph.D.
Garret FitzGerald, M.D.
Erik Hewlett, M.D.
Sangtae Kim, Ph.D.
Lonnie King, D.V.M., M.P.A.
John H. Linehan, Ph.D.
Joseph Pagano, M.D.
David R. Parkinson, M.D.
Alan Russell, Ph.D.
Stephen Spielberg, M.D.
Catherine Woteki, Ph.D.

Consultants (Temporary Voting Members)
Frederick Kushner, M.D.

Executive Secretary
Carlos Peña, Ph.D., M.S., Office of Science and Health Coordination, Office of the Commissioner (OC)

FDA Participants
Frank M. Torti, M.D., MPH, Acting Commissioner of Food and Drugs
David Acheson, M.D., Assistant Commissioner for Food Protection, OC
Norris Alderson, Ph.D., Associate Commissioner for Science, Office of Science and Health Coordination, OC
Michael A. Chappell, Acting Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs (ORA)
Mitchell Cheeseman Ph.D., Deputy Director, Office of Food Additives Safety, Center for Food Safety and Applied Nutrition (CFSAN)
Jesse Goodman, M.D., Director Center for Biologics Evaluation and Research (CBER)
Randall W. Lutter, Ph.D., Deputy Commissioner for Policy, OC
Jonathan Sackner-Bernstein, M.D., Associate Director, Post Market Operations, Center for Devices and Radiological Health (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., Deputy Director, Center for Drug Evaluation and Research (CDER)
David White, Ph.D., Director, Office of Research, Center for Veterinary Medicine (CVM)
Carolyn Wilson, Ph.D., Center for Biologics Evaluation and Research (CBER)

Open Public Hearing Speakers
The following individuals presented to the Science Board during the open public hearing session.

- Dr. Nancy Beck, Physicians Committee for Responsible Medicine
- Brandel France de Bravo, National Research Center for Women and Families
- Dr. Urvashi Rangan, Consumer Reports
- Dr. Anila Jacob, Environmental Working Group
- Ms. Lisa M. Weddig, National Fisheries Institute
- Stephen Hentges, Ph.D., American Chemistry Council Polycarbonate/BPA Global Group
- Mr. Robert Weiss, Hooper & Weiss, LLC

Presentations and Discussions
Acting Commissioner's Report
Frank M. Torti, M.D., MPH, Acting Commissioner of Food and Drugs
Rapid Detection of Contaminants in Food: Update
David Acheson, M.D., Assistant Commissioner for Food Protection, OC
Economically Motivated Adulteration of FDA Regulated Products: Update
Randall W. Lutter, Ph.D., Deputy Commissioner for Policy, OC
Subcommittee Report on FDA's Projects in Scientific Priority Areas
David R. Parkinson, M.D.
Plan for the Annual Review of FDA Research Programs
Norris Alderson, Ph.D., Associate Commissioner for Science, Office of Science and Health Coordination, OC
Biospecimens for Genomic and Proteomic Analyses
Frank M. Torti, M.D., MPH, Acting Commissioner of Food and Drugs
Update to the Science Board on Bisphenol A (BPA)
Mitchell Cheeseman Ph.D., Deputy Director, Office of Food Additives Safety, CFSAN
Jonathan Sackner-Bernstein, M.D., Associate Director, Post Market Operations, CDRH
Comments from the Science Board Chair
Barbara McNeil, M.D., Ph.D., Chair

Summary of Committee Discussions and Recommendations
Introductions
Barbara McNeil, M.D., Ph.D., Chair

- Dr. McNeil welcomed Science Board members, FDA staff, and all meeting attendees. She introduced new members and summarized the agenda.

Acting Commissioner's Report
Frank M. Torti, M.D., MPH, Acting Commissioner of Food and Drugs

- Dr. Torti welcomed the Science Board members. In his opening remarks he noted that FDA had prepared a report for the Science Board: "Status of regulatory Science at FDA" that highlights the progress FDA has made in developing its scientific base. He noted that FDA needed to

develop partnerships with the scientific, academic, and regulated industry communities. He identified the agency's overarching scientific priority areas: rapid methods, biomarkers for safety and efficacy, adverse event detection and analysis, clinical trial design and analysis, personalized medicine and nutrition, microbial ecology and contamination mitigation strategies, and manufacturing science. He discussed the role the Science Board will have to enhance specific activities in these selected areas. He discussed initiatives and progress in career development and training, including the Commissioner's Fellowship Program, a two year program of course work and regulatory research conducted under the guidance of a FDA scientist preceptor. He updated the committee on genomics at FDA including the creation of a position for a genomics coordinator. The committee was requested to create a sub-committee to oversee information technology initiatives at FDA. In his closing remarks Dr. Torti provided an overview of future engagement with the Science Board in specific regulatory assessments.

Committee Discussion

- The Science Board commented upon the importance of the Commissioner's Fellowship Program to the FDA and noted the scope of the fellows research proposals. They noted that it was important that the public is aware of this activity. The Science Board also discussed the investment needed to support FDA scientists. The Science Board discussed the importance of communication with the public to enhance consumer confidence and noted that investment would be needed for risk communication..

Rapid Detection of Contaminants in Food: Update

David Acheson, M.D., Assistant Commissioner for Food Protection, OC

- Dr. Acheson summarized how rapid detection tools could identify microbial contamination earlier, eliminate false positives faster, and thus result in public health gains. He reviewed the challenges of detection in outbreak and routine situations, the speed of detection systems, and the importance of "field" capable detection systems as well as the need to address regulatory requirements. He reviewed the process FDA was following to get input from other government agencies, academia, industry and states/local interests.

Committee Discussion

- The Science Board commented on the importance of identifying and enhancing collaborations with other government agencies as well as developing closer ties and greater interaction with the other stakeholders, including state and local governments. The Science Board noted the value of this endeavor in preparation for future outbreaks, the significance of developing test kits, and establishing measures of success.

Economically Motivated Adulteration of FDA Regulated Products: Update

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

- Dr. Lutter presented the challenge of preemptively identifying products purposefully adulterated for economic gain. He stated that FDA had created an internal workgroup to develop a strategy to anticipate future adulterated products and prevent or control risk associated with such products. He noted that the workgroup has developed a set of questions pertaining to economically motivated adulteration to ask federal, state, and international partners and industry. These questions were presented to the Science Board. He reported that a public meeting to solicit public input will be held. He noted that evaluation of adulteration requires identification of high risk products, substances that could be used as adulterants, assays which were not optimal for identification of adulterants or were not very sensitive, and potential signals which

may indicate economically motivated adulteration. . He noted that FDA had a site on its website for people to report suspected criminal activity (www.fda.gov/oci/contact.html). FDA would be consulting with partners, holding a public meeting, and consulting with outside stakeholders.

Committee Discussion

- The Science Board noted that the recent economically motivated adulterated products had the most damaging effects among the pediatric population which may seem contrary to the perceived relatively small market place. This observation also illustrated the importance of engaging international organizations in this activity. The Science Board also highlighted the importance of this topic for the prevention of future adulterated products and the significance of shared responsibility, especially during current economic challenges.

Subcommittee Report on FDA's Projects in Scientific Priority Areas

David Parkinson, M.D.

- Dr. Parkinson discussed the process of establishing a Science Board Science Projects Subcommittee; he also presented the charge to the subcommittee, agency science priority areas, and projects within these areas as organized by FDA Center. He reviewed each of the priority areas including rapid, sensitive, high throughput detection of contaminants, biomarkers for safety and efficacy, adverse event detection and analysis, clinical trial design and analysis, personalized medicine and nutrition, microbial ecology and contamination mitigation strategies, and manufacturing science, and provided examples in each topic area.

Committee Discussion

- The Science Board discussed the establishment of the Science Board Science Projects Subcommittee and the process involved in this review including meeting with Center Directors and staff, with the acknowledgement that a report would be presented to the Science Board in the spring and fall.

Plan for the Annual Review of FDA Research Programs

Norris Alderson, Ph.D., Associate Commissioner for Science, Office of Science and Health Coordination, OC

- Dr. Alderson provided an overview of the Science Board review of FDA intramural research programs. He presented the basis for initiating this review, including the Chief Scientist's responsibilities as provided in FDAAA 2007. He reviewed the process for establishing a subcommittee and the proposed five year review cycle for FDA intramural research. Dr. Alderson discussed the first two planned reviews of the intramural science programs of the Center for Veterinary Medicine and the Center for Food Safety and Applied Nutrition. He described the mission of each center, their key regulatory activities, and the timeline for review. He also outlined the importance of the Science Board review to FDA.

Committee Discussion

- The Science Board discussed the membership on the subcommittee, subcommittee resources, and the need to tailor specific Center reviews to their intramural research program. The Science Board also identified potential Science Board members for the establishment of the CVM, CFSAN, Information Technology, and CDER subcommittees.

Biospecimens for Genomic and Proteomic Analyses

Frank M. Torti, M.D., MPH, Acting Commissioner of Food and Drugs

- Dr. Torti summarized the agency's approach to ensuring biospecimen quality in regulatory decision-making including consideration of patient preparation, sample collection, handling, and storage. He invited the Science Board to share with the agency their advice in this field and upcoming events. He also noted plans to hold a public meeting and formulate a process on next steps for developing standards for tissue acquisition and manipulations.

Committee Discussion

- The Science Board discussed the applicability of biospecimens to regulatory submissions and importance of standards for specimens because of the value afforded to other government agencies when using such specimens. The Science Board unanimously agreed with FDA on the need for strategic collaboration with other government components as well as outside parties.

Update to the Science Board on Bisphenol A (BPA)

Mitchell Cheeseman Ph.D., Deputy Director, Office of Food Additives Safety, CFSAN

- Dr. Cheeseman discussed the progress the FDA has made in addressing the Science Board's comments on FDA's draft assessment of BPA in food contact applications. He reviewed the point of departure studies and benchmark dose analyses. He discussed uncertainty factors with specific reference to repeated dose toxicity studies and developmental and reproductive toxicity analyses. He presented results of ongoing assessment of infant formula and a questionnaire to assess infant feeding practices. He also mentioned ongoing activities to assess infant exposure, to engage with industry, and to plan toxicity and epidemiological studies.

Committee Discussion

- The Science Board discussed the new infant formula data, including detection values and degree of variability in outcomes, methods to analyze future studies, collaboration with other agencies on health effects, and how BPA is regulated in the United States and other countries.

Jonathan Sackner-Bernstein, M.D., Associate Director, Office of Surveillance and Biometrics, CDRH

- Dr. Sackner-Bernstein presented an introduction to the Agency's approach for evaluating BPA in medical products and compared the assessments of BPA in food contact applications and medical products. He discussed methods to assess safety, toxicity and risk characterization including literature review and data gathering efforts, as well as exposure assessment and risk characterization. He reviewed BPA sources from a number of products, the importance of prioritizing assessment based on exposure, and studies being initiated to measure exposure in specific settings.

Committee Discussion

- The Science Board discussed the value of accurate measures of exposure, including systemic exposure and the difficulty in interpreting and extrapolating data from animal studies to humans. The Science Board also commented upon additional collaboration with other agencies for subsequent analyses of exposure and the consequence of human exposure.

Comments from the Science Board Chair

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

- Dr. McNeil closed the meeting with final remarks, including the following statements:
  - The Science Board unanimously agreed to establish the Information Technology subcommittee.
  - The Science Board encouraged further interaction with the FDA Fellowship program fellows and program activities.

The meeting adjourned at approximately 3:00 p.m.

Please see transcript for details

I certify that I attended the February 24th, 2009 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