MINUTES OF THE
SCIENCE BOARD TO THE FDA

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

Friday, May 30th, 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.
Gail Cassell, Ph.D., D.Sc.(hon)
Lonnie King, D.V.M., M.P.A.
John Linehan, Ph.D.
David R. Parkinson, M.D.
Martin Philbert, Ph.D.
Larry Sasich, Pharm.D., M.P.H., F.A.S.H.P.
Catherine Woteki, Ph.D., R.D.

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

FDA Participants
Norris Alderson, Ph.D., Associate Commissioner for Science
Jesse Goodman, M.D., M.P.H., Director, Center for Biologics Evaluation and Research (CBER)
Larry Kessler, Sc.D., Center for Devices and Radiological Health (CDRH)
Margaret Glavin, Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs (ORA)
William Slikker, Jr., Ph.D., Director, National Center for Toxicological Research (NCTR)
Bernadette Dunham, D.V.M., Ph.D., Director, Center for Veterinary Medicine (CVM)
Stephen Sundlof, D.V.M., Ph.D., Director, Center for Food Safety and Applied Nutrition (CFSAN)
Douglas Throckmorton, M.D., Deputy Director, Center for Drug Evaluation and Research (CDER)
Frank M. Torti, MD, MPH, Principal Deputy Commissioner and Chief Scientist
Andrew von Eschenbach, M.D., Commissioner of Food and Drugs
Janet Woodcock, M.D., Director, CDER

Open Public Hearing Speakers
A public letter to the FDA from Sherry L. Ward, PhD, MBA, President, BioTred Solutions, was acknowledged during the open public hearing session.

Presentations and Discussions
Commissioner's Report
Andrew von Eschenbach, M.D., Commissioner of Food and Drugs
Science at the FDA: Vision, Plans, and Timetable

Frank M. Torti, MD, MPH, Principal Deputy Commissioner and Chief Scientist
Report from the Science Board Subcommittee Review of the National Center for Toxicological Research (NCTR)
Larry Sasich, Pharm.D., M.P.H., F.A.S.H.P.
Report from the Science Board Subcommittee Review of the Office of Regulatory Affairs (ORA)
David R. Parkinson, M.D.
Center Director's Input on Future Science Board Support of Agency Activities
FDA Directors & Science Board Members
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 meeting attendees. She summarized the agenda including updates from the June 14, 2007 and December 3, 2007 Board meetings. She also mentioned the Board's report on science and technology that was transmitted to the agency January 22, 2008.

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

- The Commissioner of Food and Drugs presented an update to the Board on the state of FDA, including the role of the Board to the agency, the increase in Board membership from 12 to 21 members, and increase in meeting frequency to four times per year. He thanked the Board for its review of FDA science. He identified upcoming challenges to FDA science such as globalization of FDA regulated products and evolving areas of science and technology. He also discussed planned enhancements to the agency such as the fellowship program, updates to the information technology infrastructure and tools, and the agency's on-going consolidation to the White Oak campus.

Science at the FDA: Vision, Plans, and Timetable
Frank M. Torti, MD, MPH, Principal Deputy Commissioner and Chief Scientist

- Dr. Torti presented his views on science at FDA and reviewed three principles guiding the Chief Scientist position: 1) the FDA cannot do it alone, 2) FDA must maintain its core expertise, and 3) the FDA scientific strategy must be preemptive. He discussed the importance of partnerships with external organizations, the value of intra-agency collaborations, and enhancing scientific capacity to successfully carry out the mission of FDA. He also discussed future steps for the agency, including the establishment of an overall scientific vision for the agency and development of process for vetting cross-cutting scientific initiatives. Dr. Torti closed with a discussion of his 100 day plan, including several proposed initiatives and opportunities for the Board to assist the agency in the near future.

Committee Discussion

- The Board discussed several topics including organizational changes to the agency (including creation of the Chief Scientist position), the cross-center collaborative grant opportunities for FDA staff, the need for a definition of regulatory science, plans for a fellowship program, and updates to the Science Board Charter. The Board recommended exploring partnerships with the National

Institute of Health's Clinical and Translational Science Centers of Excellence and leveraging opportunities outside the agency.

Report from the Science Board Subcommittee Review of the National Center for Toxicological Research
Larry Sasich, Pharm.D., M.P.H., F.A.S.H.P.

- Dr. Sasich opened his presentation with the charge to the NCTR subcommittee, including 1) to review the coordination between NCTR and FDA Product Centers, 2) to review the process of how projects are prioritized at the NCTR, and 3) to review utilization of resources at the NCTR. He discussed the process of how the subcommittee performed its review and its observations, such as the need to increase communication between NCTR and other components of the agency, the value of direct collaboration between NCTR and other components of the agency, and enhancing the science prioritization process. He presented the NCTR reporting structure within the agency and the subcommittee's preliminary findings and recommendations. Preliminary findings focused upon the NCTR's location, the process of research prioritization, safety pharmacology studies, and support of FDA Product Centers.

Committee Discussion

- The Board discussed better coordination of NCTR activities with those of the agency. Several Board members noted that Recommendation 3 addresses agency-wide prioritization of science, not NCTR processes, and thus is outside the scope of the subcommittee's charge. Board members further noted that the December 3, 2007 report already addresses the need for better agency-wide prioritization of science in detail. The Board unanimously recommended accepting recommendations 1 and 2 as written. The Board also requested that the subcommittee re-characterize recommendation 3 as "additional information" rather than as a "recommendation." The Board asked the subcommittee to resubmit its revised report to the Chair, who will then transmit the report to the agency.

Report from the Science Board Subcommittee Review of the Office of Regulatory Affairs
David R. Parkinson, M.D.

- Dr. Parkinson opened with the recommendations from the December 3, 2007 Board meeting, requesting a review of ORA. He reviewed how the subcommittee executed its charge, including a series of teleconferences, site visits, and review of background literature. Characteristics of ORA were highlighted, including inspection and enforcement activities, its increase in workload, and public expectations. A summary of observations was presented from the subcommittee's visits to ORA District Office and Laboratories. He presented findings and recommendations of the ORA subcommittee including the increasing scope of the organization's responsibilities, decreasing resources, support for the results of a recent internal review of ORA (the "Revitalization report"), and need for organizational change to meet future challenges. The subcommittee also supported a greater emphasis upon regulatory science.

Committee Discussion

- The Board discussed the need for new tools and technologies to meet future ORA challenges, the appropriations process, import and inspection challenges, the use of capacity indexing-an approach to assess lost capital. The Board unanimously accepted the report, endorsed a phased in approach to rebuilding ORA, and concurred on the ORA challenges identified in the December 2007 Board report on science and technology. The Board also acknowledged testimony before the house

Committee on Energy and Commerce, Subcommittee on Oversight and Investigations by Dr. Porter regarding decreasing agency resources compared with its statutory responsibilities.

Center Director's Input on Future Science Board Support of Agency Activities

FDA Directors & Board Members

- Each of the Directors discussed how the Board could help his/her own Center's scientific and technologic activities.
    - Dr. Goodman, CBER, discussed emerging sciences challenges in the areas of biomarkers, gene expression, vaccines, and data quality control. The recruitment of experts, evolving regulatory sciences, regenerative medicine, blood research, and the ability to nurture scientific capacity were all identified as areas that the Board could help cultivate.
    - Dr. Woodcock, CDER, discussed the challenge of updating regulatory policy as science evolves, and the value of Board input into potential science-based changes in regulatory policy. She cited several such initiatives on which the Board had provided valuable input (product quality for the 21st century, the pharmacogenomics initiative, and the bioresearch monitoring initiatives), and indicated that CDER would benefit from Board input on the new Sentinel Program.
    - Dr. Kessler, CDRH, discussed areas for targeted advice by the Board, including the FDA fellowships program, mechanisms and approaches to recruiting and retaining students, involvement of the Board in the periodic review of intramural research programs and workshops focused on specific emerging science topics.
    - Dr. Sundlof, CFSAN, discussed external review of intramural research science programs, the importance of allergenicity and threshold determination studies, biomarkers for good health and nutrition, increasing the transparency of industry and public sectors, and nutritional labeling as areas for Board input.
    - Dr. Dunham, CVM, discussed enhancing the training of staff in emerging sciences, risk assessment and management from an inspectional approach, and further peer-review of CVM programs, including the National Antimicrobial Resistance Monitoring Program, as areas where the Board could help.
    - Dr. Slikker, NCTR, discussed the need to build capacity in emerging areas of science such as nanotechnology, bioimaging, and nutrition safety. The importance of identifying further cross-cutting emerging science areas and increasing collaborations was also identified as an area for Board focus.
    - Ms. Glavin, ORA, discussed the areas of counterfeit products and associated analytical needs where greater investments and expertise by the Board could provide useful input. She also identified ORA methods development and validation for emerging sciences as areas for potential Board involvement.

Committee Discussion

- The Board discussed the importance of partnerships with academic sites, scientific collaborations, and defining regulatory science. The Board recommended targeting ongoing review of different components of the agency and further evaluating emerging sciences. The Board proposed rapid diagnostic test kits as an agenda item for the Fall meeting. The Board also agreed to establish a subcommittee to work with the agency as it narrows its priorities for Board input.

Comments from the Science Board Chair

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

- Dr. McNeil presented closing remarks, including the following statements:
  - The Board unanimously recommended accepting recommendations 1 and 2 in the NCTR Subcommittee report, and asked the subcommittee to re-characterize recommendation 3 as additional information, since it was outside the charge of the subcommittee. The Board recommended the subcommittee resubmit its report to the Chair, who will then transmit the report to the agency.
  - The Board unanimously accepted the ORA Subcommittee report and transmitted the report to the agency; and
  - The Board created a small subcommittee to work with FDA as it determines its priorities for Science Board Activities.

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

Please see transcript for details

I certify that I attended the May 30, 2008 meeting of the 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