



**DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
Office of Science Coordination & Communication**

Science Board to the Food and Drug Administration

April 13, 2001

Executive Summary

Administration

The agenda and meeting arrangements of the Science Board to the Food and Drug Administration (FDA) were administered by FDA's Office of Science Coordination and Communication (OSCC). On Friday, April 13, 2001, a meeting was convened at FDA Bldg: 5630 Fishers Lane, Rockville, MD. The public meeting was called to order at 9:00 a.m. by Robert S. Langer, Chair. The meeting was adjourned at approximately 3:30 p.m.

Members in Attendance (member/affiliation list attached)

Robert S. Langer, Sc.D., Chair
Rita Colwell, Ph.D., D.Sc. (Hon)
Marion Nestle, Ph.D., M.P.H.
Owen Fennema, Ph.D.
Martin Rosenberg, Ph.D.
Edward M. Scolnick, M.D.
Robert M. Nerem, Ph.D.
Harold Davis, D.V.M., Ph.D.
Marion W. Anders, D.V.M., Ph.D.
Michael P. Doyle, Ph.D.

Invited Participant

Cecil M. Pickett, Ph.D., (NCTR Science Advisory Board)

FDA Participants

Bernard A. Schwetz, D.V.M., Ph.D., Acting Principal Deputy Commissioner, FDA
Elizabeth D. Jacobson, Ph.D., Acting Senior Advisor for Science
Susan Mackie Bond, M.S., Executive Secretary to the Science Board
Dan Casciano, Ph.D., Director, National Center for Toxicological Research (NCTR)
David W. Feigal, Jr., M.D., M.P.H., Director, Center for Devices & Radiological Health (CDRH)
Dennis Baker, Associate Commissioner for Regulatory Affairs
Kathryn Zoon, Ph.D., Director, Center for Biologics Evaluation & Research (CBER)
Robert Buchanan, Ph.D., Senior Science Advisor, Center for Food Safety & Applied Nutrition (CFSAN)
Janet Woodcock, M.D., Director, Center for Drug Evaluation & Research (CDER)
Andrew Beaulieu, D.V.M., Associate Director for Animal Health Policy & Operations, Center for Veterinary Medicine (CVM)
Susan Wood, Ph.D., Director, Office of Women's Health (OWH)
Jim Heslin, FDA Training Officer

Purpose

The Science Board met to discuss the following issues:

- External Peer Review:
 - Center for Devices & Radiological Health
 - Office of Regulatory Affairs
- Emerging Science Issue: Tissue and Tissue Engineered Products
- Office of Women's Health Research Program
- Preparing to Meet Scientific Workforce Challenges:
 - How Scientists in a Non-Academic Institution Keep Up with Cutting Edge Science
 - FDA University

Reports/Presentations

Introductory Remarks

Dr. Schwetz provided introductory remarks regarding scientific issues facing the agency. Dr. Jacobson gave an update of action items from the November 17, 2000 meeting of the Science Board. She also mentioned new leveraging opportunities the FDA is participating in with the National Science Foundation, the National Science Teachers Association, and the Department of Defense's Telemedicine and Advance Technology Research Center.

External Peer Review

Dr. Feigal presented the proposed plan for an external science review of CDRH. He described the vision to focus on the total product lifecycle. The Science review will extend beyond the review of research programs to more broadly review science-based regulation in the Center. The review will examine the Center's scientific decision-making process, the impact of those decisions, resources required, processes and feedback mechanisms, and preparedness to address future science-based decisions. CDRH will complete an internal review in June 2001 followed by an external review by a sub-committee of the Science Board chaired by Dr. Robert Nerem, visiting the Center in July 2001.

Science Board members applauded the efforts but encouraged initiating reviews on a regular basis. They suggested that CDRH create "Top Ten" lists prior to the review that include ten best, worst, most difficult, and most controversial decisions. This process was described as a necessary self-critical process that further opens the Center up for external review.

Mr. Baker presented the proposed plan for an external science review of ORA. He described the three main organizational components to be reviewed: inspection & investigation, lab sciences, and compliance & enforcement. The main thrust of their review is to assess actions at ORA to determine if the regulatory science was fit for its intended use. He described this fitness for use concept further including 1) how the science is being used; 2) customer interaction and to what extent the customers will use their data; 3) potential outcomes.

Science Board members again applauded the peer review efforts. Furthermore, ORA should take one issue every two years and so forth to institutionalize the external review process since the scope of ORA's responsibilities are so large. The Board is also interested in a timeline for the review process.

Emerging Science Issue: Tissue & Tissue Engineered Products

Dr. Zoon gave an overview of the emerging technology of tissues, cells, and related products. She discussed the framework at FDA to address this emerging issue and CBER's proposed approach to cellular and tissue based product regulation through the Public Health Service Law 361. Dr. Zoon gave an update on the status of tissue regulation and the Final Rule on Establishment Registration & Listing. Dr. Feigal added comments on how the Agency is looking at bioengineered tissues in terms of regulation and determining how to develop a science-based framework.

Science Board members recommended that FDA consider creating an external committee of ethicists or to utilize the consumer representatives on current advisory committees to look at these types of issues so that the Agency is not linked to the ethical considerations when making science-based decisions. They also expressed concern for the product jurisdiction issues that will arise at FDA as a result of the increase in hybrid products and technologies.

Office of Women's Health (OWH) Program

Dr. Susan Wood updated the Board on activities and programs at OWH that have occurred since the April 2000 presentation to the Board. OWH is working on several activities including 1) working with the Department's Centers of Excellence for specific projects; 2) sponsoring a five-year Women's Health Initiative with the National Center for Toxicological Research; 3) sponsoring a Women's Health Dialogue; and 4) continuing their intramural research program. Dr. Wood addressed some of the outstanding questions the Board had including the use of both internal and external peer review in the selection of projects funded by the intramural research program. The outcomes of these programs were mailed to the Board last November as they were updated.

The Board is interested in continued updates from OWH on their research program and specifically would like the Agency to address what they consider the most important issues, products, or problems in women's health as they relate to FDA. The Board suggested that FDA consider an integrated, interdisciplinary approach to research at FDA versus the current concept of pockets of research in various Centers and Offices. They suggested the FDA University could facilitate this top-down priority setting approach.

Public Comments

There were no public comments.

Preparing To Meet Scientific Workforce Challenges

Jim Heslin presented the "FDA University" concept to provide an Agency-wide system for learning. Mr. Heslin described the current needs for this broad focus, the proposed components to the University, and outlined ten steps for implementation. He asked the Board members for feedback on the development of this initiative including: 1) who needs to be involved; 2) what programs should be included; 3) and how the University should be structured and led.

Science Board members applauded FDA's efforts with this new initiative but urged the Agency to focus on the scientific training or "science academy" aspect of the University. They recommended centrally structuring scientific courses through broad spending across the Agency. Board members would like to receive an update on the progress of the University at the next meeting and, asked specifically that FDA address such as issues as the science academy, the reward to employees other than the obvious promotion/career advancement, and the feedback the Agency receives from its employees regarding this concept.

Dr. Scolnick presented suggestions for scientists in a non-academic environment to keep pace with rapidly changing technologies. He urged the Agency to reach out to the global world of science and to institutionalize the programmatic peer review process at FDA.

Science Board Discussion/Closing Remarks/Future Direction

Dr. Langer summarized four action items from the meeting:

- (1) The Board will make final recommendations regarding public comments made at the November 17, 2000 meeting and forward their response to FDA. The comments were made by Doris Haire, President, Maternal & Child Health Foundation.
- (2) CDRH External Review: Dr. Feigal and Dr. Nerem will present the results of the external review at the next Science Board meeting. CDRH will consider the "Top Ten" lists as part of their review. CDRH will consider looking at gender differences as part of review.
- (3) ORA External Review: ORA will consider changing the scope of their planned review to smaller, programmatic reviews held on a continual basis. ORA will consider the "Top Ten" lists and also how data gaps in science are handled as part of the review. They will also review CFSAN's recent review to address any comments pertaining to ORA.
- (4) The Board will receive an update on the progress of the FDA University at the next meeting.

The Board held closing discussions regarding the rapid change of technology in the world and the need for FDA to keep up with a strong scientific excellence so critical to FDA's regulatory decision-making. FDA leaders were asked to digest this concept and possibly discuss at next meeting. Specifically, FDA should discuss Dr. Scolnick's presentation regarding institutionalizing peer review in order to keep scientists updated and trained.

Next Meeting- The next meeting of the Science Board to the FDA will be held on Friday, November 16, 2001 at 5630 Fishers Lane, Rockville, MD. The time has been tentatively set for 9:00 a.m. to 4:30 p.m.

Adjournment - The meeting was adjourned at approximately 3:30 p.m.