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

Science Board to the Food and Drug Administration

November 17, 2000

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, November 17, 2000, 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.

FDA Participants

Jane E. Henney, M.D, Commissioner of Food and Drugs
Bernard A. Schwetz, D.V.M., Ph.D., Acting Deputy Commissioner, FDA
Elizabeth D. Jacobson, Ph.D., Acting Senior Advisor for Science
Susan Mackie Bond, M.S., Executive Secretary to the Science Board
Christy Foreman, M.B.E., Executive Secretary to the Science Board (Detail)
Stephen F. Sundlof, D.V.M., Director, Center for Veterinary Medicine (CVM)
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)
Alan M. Rulis, Ph.D., Director, Office of Pre-Marketing Approval, CFSAN
Dennis Keefe, Ph.D., Special Assistant to the Director, Office of Pre-Marketing Approval CFSAN

Purpose

The Science Board met to discuss the following issues:

- Emerging Science Issues Facing the Agency
- Programmatic Peer Review: Center for Devices & Radiological Health
- Hiring Update to support the Science Base of the CFSAN Food Ingredient Safety Program

Reports/Presentations

Introductory Remarks

Dr. Henney provided introductory remarks regarding scientific issues facing the agency. Dr. Henney also discussed recent efforts to fill both a human subjects protection position and an anti-bioterrorism position in the Office of the Commissioner and asked for the Board's help in identifying qualified candidates. She announced that Dr. Bernard Schwetz is now the Acting Deputy Commissioner and Dr. Elizabeth Jacobson is the Acting Senior Advisor for Science.

Dr. Schwetz explained that Dr. Jacobson would provide an overview of emerging science issues to provide context for anticipating FDA's future needs in terms of scientific expertise. He asked the Board to consider the relative priority of the issues and the implications for developing the appropriate profile of scientific & medical expertise.

Emerging Science Issues at FDA

Dr. Jacobson discussed the challenges that FDA faces in terms of these emerging science issues. She stressed that FDA's ability to make quality and timely decisions is strained partly due to the rapid advancements in science and technology. The Agency has to be prepared for rapidly changing technology, for an increase in volume of new information, for rapid response to public health questions, for a flexible workforce, and for patient and consumer needs. Dr. Jacobson introduced a number of emerging science issues at that were then expanded upon by the Centers and ORA. These topics will provide the basis for future in depth discussions at future Science Board meetings.

Several Board members commented that the Center presentations seemed to have some common, cross-cutting issues such as bioinformatics, bioterrorism, and anti microbial resistance. They are interested in the Agency's strategies for combination products and inter-center research. The Board was also interested in the number of researchers in each Center (e.g. the percentage that research plays into each Center) as well as how the Agency sets priorities for research across the Agency when some Centers have more research than others. They felt this was important to understand before they could help in strategies to attract and recruit a scientific workforce. Collaboration and leveraging with outside groups was encouraged as a means to address serious budget problems.

Public Comments

Doris Haire, President of the American Foundation for Maternal and child Health, provided the only public comment. She spoke to the Board about the effects of drugs used in labor and birth on the mother and the fetus. She encouraged the Board to recommend to the agency that an Interdisciplinary Obstetric Advisory Board, comprised of pediatricians, pediatric neurologists, behavioral scientists, midwives, obstetric nurses and obstetricians, be created to evaluate the safety of drugs that are intended to be administered to pregnant and parturient women. The Board will receive the comments in writing along with an Agency response before making an analysis.

Programmatic Peer Review: Center for Devices & Radiological Health

Dr. Feigal presented the proposed peer review process for CDRH including the completion of both an internal and external review by April 2002. The Board felt that this time frame may be too short and recommended that the internal review be completed and scheduled for presentation at the April meeting with the external review scheduled later that summer.

Hiring Update to Support the Science Base of the CFSAN Food Ingredient Safety Program

Drs. Alan Rulis and Dennis Keefe provided an update on the hiring initiative at CFSAN to support the science base of the food ingredient safety program. Their goal is to recruit scientists to do regulatory work in foods, target EEO goals, leverage FDA scientific expertise with non-FDA resources, and ensure a long-term approach and effectiveness in this hiring process. The Board would like an analysis of the number of applicants, where the applicants came from, the ranking process, and the number that accepted FDA as their first choice, in order to make an overall assessment of CFSAN's recruitment strategy. They suggested hiring temporary clerical help before hiring permanent administrative positions. They also suggested having minority candidates help in the recruiting process by campaigning at minority schools. The Board commended CFSAN's process for looking for recruits through personal interaction, job fairs, and chemical society meetings.

Update on Remaining Action Items from April Meeting

Dr. Jacobson provided an update to the board on the status of the remaining action items from the April meeting:

- The Office of Women's Health (OWH) update will occur at April 2001 meeting. This will allow Dr. Susan Wood, the newly appointed Director, OWH, the opportunity to present her priorities to the board.
- The agency is utilizing the internet to disseminate information on genetically modified foods rather than embark on a "Fight Bac" style campaign (as was originally recommended by the Board). This was decided since the industry itself has initiated a high profile public education campaign with the position that the agency needs to be the arbiters of safety, not the advocates of the technology with respect to this issue.
- Following a human resource presentation at the April 2000 meeting, the Board had recommended establishing relationships and networks with more universities, expanding outside the Beltway area, and utilizing more diverse sources such as Historically Black Colleges and Universities (HBCUs). Dr. Jacobson gave an update on how the Board recommendations were considered and implemented.
- To fulfill the Board's request for publications, FDA is expanding their Science FIRST (FDA Information Retrieval System) intranet site so that it may be accessed through the internet. This searchable site contains a listing of publications with abstracts for agency employees. The Agency plans to move this system to the internet sometime next year.

Science Board Discussion/Closing Remarks/Future Direction

Dr. Langer summarized three action items from the meeting:

(1) Follow-up with NSF (and DoD, NIH, or other areas of resource) for possible partnerships/collaboration.
(2) Public Comments: The Board will receive the full transcripts by Doris Haire and the Agency's comments before making any recommendations.
(3) CDRH Internal Review should go forth as planned. External review will follow sometime after April 2001.

The Board began closing discussions regarding the crisis state of the FDA budget and the subsequent impact on public health. They are interested in making a written statement on the issue and also wish to take subsequent actions. They will discuss as a collective group outside of the FDA and update FDA at the April 2002 meeting.

At the next meeting, FDA will present the "FDA Corporate University" which we hope will address recruitment/retention issues by providing job contentment and satisfaction by supporting professional development for onboard staff. The Board suggested the "corporate" be left out of the title of the initiative.

The FDA will also being to present the emerging science issues in more depth and begin with tissue engineering at the April 2002 meeting.

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

Summary prepared by Christy Foreman, M.B.E., and Susan M. Bond, M.S., Office of Science Coordination and Communication, Food and Drug Administration