DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Office of Science Coordination & Communication

Science Board to the Food and Drug Administration

April 21, 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, April 21, 2000, a meeting was convened at FDA Bldg: 5630 Fishers Lane, Rockville, MD. The public meeting was called to order at 8:30 a.m. by Robert S. Langer, Chair. The meeting was adjourned at approximately 4:00 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
Linda A. Suydam, D.P.A., Senior Associate Commissioner, FDA
Joseph Levitt, Esq., Director, CFSAN, FDA
Stephen F. Sundlof, D.V.M., Director, CVM
Dan Casciano, Ph.D., Acting Director, NCTR
David W. Feigle, Jr. , M.D., M.P.H., Director, CDRH
Dennis Baker, Director, ORA
Mary Babcock, Director, OHRM, FDA
Margaret Miller, Ph.D., Manager, Scientific Programs, Office of Women's Health
Robert Buchanan, Ph.D., Senior Science Advisor, CFSAN
Alan M. Rulis, Ph.D., CFSAN
Dennis Keefe, Ph.D., CFSAN

Office of Science Coordination & Communication
Bernard A. Schwetz, D.V.M., Ph.D., Acting Deputy Commissioner, FDA and Senior Advisor for Science
Susan Mackie Bond, M.S., Executive Secretariat to the Science Board
Suzy Fitzpatrick, Ph.D.
Hung Trinh
Susan A. Homire, D.V.M.
Donna Mentch
Brenda Gomez

Purpose

The Science Board met to discuss the following issues:

- Report on the Review of Research at the Center for Food Safety and Applied Nutrition
- FDA CFSAN Response
- CFSAN's Dietary Supplement Strategic Plan
- Overview of Office of Women's Health Scientific Research Program
- Joint FDA & Industry Training
- Strategies for Maintaining Quality of Science at FDA

Reports/Presentations

Introductory Remarks

Dr. Schwetz provided introductory remarks on behalf of the Commissioner, who was unable to attend. Dr. Schwetz announced changes since the last meeting of the Science Board (October 21, 1998), including that Dr. Elkan Blout is no longer Senior Advisor to the Agency and that Dr. Schwetz now serves in that role and as Acting Deputy Commissioner, FDA. He discussed Dr. Henney's priorities including strengthening the science base; engaging in leveraged and collaborative activities; and, emphasizing outreach and stakeholder involvement. Dr. Schwetz closed with a charge to the Board to assist FDA in assuring high quality science at the Agency through peer review, recruitment and retention activities, and maintaining a high quality workforce with the ability to adapt to rapidly changing technology. Dr. Schwetz also asked the Board to provide advice on general science policy matters and serve as "ambassadors" of the science of the Agency.

Report on the Review of Research at the Center for Food Safety and Applied Nutrition

The Science Board Subcommittee conducted the review of research programs at the Center for Food Safety and Applied Nutrition (CFSAN) on April 13 – 16, 1999 and presented the report for review by the Board. The review addressed quality, appropriateness, balance, personnel, and management of research programs in food and nutritional sciences. The quality of the CFSAN research program was judged quite good with considerable variability among research groups. All research groups were deemed appropriate but barely adequate in their type of activity and support to accomplish CFSAN's mission. To improve in the area of appropriateness, CFSAN must maintain mission-related research programs of world class quality and size commensurate with its mission. Because the Food Safety Initiative (FSI) mandate has created a funding imbalance for the six CFSAN research programs, it was recommended that the programs in toxicology and applied nutrition to be strengthened. With regard to personnel, CFSAN has high quality scientists but some specific recommendations include: making greater use of postdoctoral and student personnel; increasing the number of support personnel per scientist; improving performance review procedures; and, strengthening and expanding the professional development programs. Finally, in the context of management, the subcommittee noted that improvements are being instituted at CFSAN through the management transition and the Science Board recommended that a strategic plan be developed soon. The Science Board and CFSAN management should consider this review the first of three steps, to be followed by development of a management/strategic plan and subsequent evaluation of how CFSAN research activities correspond to the plan. In a final evaluation of the review procedure itself, the review committee recommended that the Board should prepare guidelines on "How to Prepare for a Review" before further FDA reviews take place.

FDA CFSAN Response

Mr. Levitt stated that CFSAN found the process to be very helpful. Dr. Buchanan consented agreement to almost everything in the review and responded with what CFSAN has done in the past year to deal with the issues raised in the report as well as additional issues. CFSAN broadened the Food Safety Initiative (FSI) to include other things not previously mandated to better manage scientific resources and upgrade equipment. Other improvements included the formation of the CFSAN Senior Science Council and appointment of a Senior Science Advisor to CFSAN (Dr. Buchanan). In response to toxicology, an office is being established at JIFSAN to recruit for senior toxicologists and program directors. With regard to nutrition, CFSAN has begun review of their nutrition research programs and developed the ten-year dietary supplement strategic plan. In response to the recommendation that CFSAN collaborate, where appropriate, with industry and academia, Dr. Buchanan gave examples of leveraging including JIFSAN, NCTR, University of Mississippi, and the Moffett Center in Illinois. He noted that leveraging has enabled CFSAN to address their technology transfer goals and become a world class organization in microbiological risk assessments. Regarding the productivity of scientists, Dr. Buchanan announced the formation of the CFSAN Staff College, the competitive intramural lab support program, and the review of the peer review process for scientific career advancement. Other initiatives included the development of a CFSAN strategic plan, priority setting program for all equipment purchases, the use of JFSAN to assisting in setting research priorities with the Food Safety Initiative, and the support of the laboratory accreditation program.

Dr. Fennema thought the CFSAN's response was excellent and addressed all of the Board's recommendations. The Science Board voted to accept the report. There was general discussion between the Board and CFSAN on specific issues and action items followed.

CFSAN's Dietary Supplement Strategic Plan

Mr. Levitt presented CFSAN's Dietary Supplement 10 Year Strategic Plan to build a world class organization with three components: (1) strong science-based program for decision making; (2) operational capacity to implement decisions; and, (3) culture of accountability, cooperation, and respect. He summarized the plan and explained why it was created, described the public outreach process and outlined the next steps. The framework for the plan was based on feedback from two public meetings in Washington, D.C. and Chicago, IL held in 1999. The overall program goal is that by the year 2010, FDA will have a science-based regulatory program that fully implements the Dietary Supplement Health and Education Act of 1994, thereby providing consumers with a high level of confidence in the safety, composition, and labeling of dietary supplement products. Following the presentation, there was general discussion between the Board and CFSAN and some specific action items followed.

Overview of Office of Women's Health Scientific Research Program

Dr. Miller presented the Office of Women's Health Research Program and asked the Board how the program could be improved, how to build for the future, how to identify priorities, and how leveraging can help. The program, established in 1994, has awarded over $8 million to fund 86 projects to address the gaps in scientific knowledge in areas where regulatory decisions have to be made. The Board was confused about the program's priorities and asked whether the goal was to improve women's health in general or to improve FDA's ability to make regulatory decisions regarding women's health. The Science Board also asked if they could assist in the peer review and provide objectivity in selecting projects. Action items followed.

Joint FDA & Industry Training

Dr. Fitzpatrick described the joint FDA and industry training program, established in 1999 through a series of co-sponsorship agreements between the FDA and industry. The program is intended to educate FDA reviewers and inspectors about new technology. The program will facilitate scientific review. Training programs were outlined and include (1) Merck – Barrier Isolation Technology, (2) General Mills - Elisa Rapid Screening Methods for field investigations, (3) Bay Area Bioscience Center, microarray technology, (4) Nucleic Acid Amplification Testing, and (5) future training - New Trends in Sterilization Technology by Johnson & Johnson. The Board felt this was a forward thinking and exciting program.

Strategies for Maintaining Quality of Science at FDA

Dr. Suydam presented FDA leveraging initiatives including why FDA should leverage now, what it is, and what FDA wants to accomplish. She also gave examples of current FDA leveraging efforts including the Moffett Center in Illinois, the Mammography Quality Assurance Program, the Product Quality Research Institute (PQRI), the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), and the Take Time to Care (TTTC) program. She also mentioned leveraging activities within the Agency including the development of an action plan, vision, and guiding principles, a handbook for all FDA employees, a leveraging website, a taskforce to build a leveraging infrastructure at each Center, and the incorporation of leveraging into performance plans and budgets. Dr. Suydam mentioned the two stakeholders meetings regarding leveraging at Stanford and Duke Universities.

Mary Babcock presented the human resource issues regarding scientists including recruitment and retention, training, peer review promotion system, and profile of scientific workforce. The overall onboard strength of FDA includes 78% positions that are scientific and scientific support. The FDA attrition level is normal for a government agency but includes an especially high turnover rate for drug reviewers and pharmacokineticists who learn the drug review process and can command larger salaries from industry later. She noted that the younger workforce coming in does not generally stay at one organization for up to 30 years as the previous generation and last major hiring bulge did. One challenge the Agency faces is that 1/3 of the senior staff and Senior Executive Service level employees are eligible to retire in the next two years; and, 1/3 of the whole FDA workforce is eligible in the next 5 years. FDA is contracting strategic workforce planning to address this and many other human resource challenges. With regard to retention, FDA has new hiring authorities (Titles 38 and 42) that allow flexibility in recruitment, better salary structures, and less paperwork/faster process. Stipends and internships are also mechanisms to offer students and postdoctoral graduates a few months of experience at the Agency. To assist in the retention of its workforce, FDA has implemented the Quality of Worklife Initiative that includes family friendly workplace initiatives, support for a learning environment, improving communication, and appreciating diversity. Some of the family friendly practices include the ANY 80 program, telecommuting and work-at-home, alternative work schedules, and flextime. Other initiatives include sabbaticals as part of a review reward system, creation of a "virtual university," and Center staff colleges that bring in speakers from industry and academia. The profile of recently hired FDA scientists was given to the Board to review the backgrounds and universities from which they were recruited. Ms. Babcock outlined the peer review promotion process for scientists and described the level of research and responsibility that the Agency looks for when preparing to promote a scientist to the next level. This presentation generated a lot of discussion and action items. The Board was asked their ideas for places to recruit, to review the profile to see if we are targeting the right schools and getting the quality of science we need in the organization, and for feedback on how to face the challenges for the next 20 years given the Agency's impending situation.

Drs. Alan Rulis and Dennis Keefe described the hiring initiative at CFSAN to support the science base of the food ingredient safety program. The Office of Premarket Approval at CFSAN is the largest office in the Center. Due to two new Congressional appropriations ($6m to run pre-market notification program for food contact substances, $5.4m to enhance and increase effectiveness of direct food and color additive petitions), the office has an opportunity to hire fifty science based positions. 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. They asked the Board for ideas on how to make this work long-term. Discussion and recommendations followed.

Public Comments

There were no public comments.

Recommendations/Action Items

- The report on the review of CFSAN's research programs was accepted with minor changes to the recommendation for future programmatic reviews of other Agency components. These changes will ensure flexibility for future reviews (e.g. review of research versus regulatory function). Changes in the report will be developed and agreed upon by Drs. Bernard Schwetz and Owen Fennema.

- The Science Board will form a small subcommittee to assist CFSAN with the DSHEA ten-year plan. The subcommittee will include Joe Levitt, Bernard Schwetz, Marion Nestle, and Rita Colwell. A conference call will be the first step in follow-up for this action item.

- The Science Board recommended that CFSAN pursue a public education campaign for genetically modified foods similar to the successful "Fight Bac" campaign.

- The OWH will present again at the next Science Board meeting to further define areas of their scientific research/grant program and how they ensure objectivity in the peer review of the proposed grants. Furthermore, OWH will report on how the program focuses on needs of the Agency versus broad public health issues. Finally, OWH will provide statistical information on the outcomes and success stories of funded research programs.

- Edward Scolnick will make a presentation at the next Science Board meeting on global information gathering in terms of the review process.

- Human resource management at FDA will be revisited at future Science Board meetings. The Science Board will deliberate at the next meeting on what it would do if it were responsible for recruitment and retention over the next twenty years at FDA. Initial recommendations from the Board included establishing relationships and networks with more universities (and getting outside the Beltway area), with more diverse sources (Historically Black Colleges and Universities (HBCUs), et al), and improving our internship opportunities with them. In addition, the Board recommended "talking science" to prospective employees versus the usual government services pitch—and using scientists to recruit. They defined recruiting as not just a filling a job but as a lifelong process of establishing relationships with science departments and making a presence on the university campuses. Another suggestion was that the FDA recruit either from the regulated industry or find out where the regulated industry recruits and use that source. One suggestion including recruiting for bioengineering and biosciences fields, the up and coming program for many young people. The Board suggested that job contentment and satisfaction is also taken into consideration for recruitment/retention issues and emphasized the need to support professional development and sabbaticals for onboard staff.

- Edward Scolnick agreed to look into tapping FDA into Merck's existing foster fellowship for minorities. He will follow-up with Mary Babcock.

- The Board recommended that Drs. Alan Rulis and Dennis Keefe follow the above recommendations in their 50+ hiring initiative but added that a well-designed "traveling road show" be considered to focus on the science and value of public service when we visit target universities. They also recommend that with a 50+ hiring scenario the Agency should consider this as a relatively rare opportunity to use this significant headcount to attract one or more recognized/established scientist(s). This would help increase the scientific credential of the Agency and concomitantly allow attraction of higher quality junior staff to these groups (thereby also impacting on the HR concerns regarding high retirement).

- The Science Board wants to help the FDA in all aspects presented to them and made recommendations to assist in that process. The FDA agreed that they would benefit from the Science Board's help in focusing the Agency's priorities given all its responsibilities, mandates, and current budgetary constraints. The Board suggested that they receive CVs of all new recruits to the Agency, a record or copies of published materials from Agency personnel, and examples of impact.

- Topics of future discussion for the Board: Programmatic Peer Review; Presentations on how FDA interacts between Centers versus and FDA 101; Focus on priorities and research outcomes or discoveries versus a list of projects.

Adjournment - The meeting was adjourned at approximately 3:40 p.m.

Summary prepared by Susan Mackie Bond, M.S., Office of Science Coordination and Communication, Food and Drug Administration