

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

**FDA Science Board Meeting
November 16, 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, November 16, 2001, a meeting was convened at 5630 Fishers Lane, Conference room 1066, Rockville, MD. The public meeting was called to order at 9:00 a.m. by the FDA Science Board Chair, Robert S. Langer, Sc.D.

Members in Attendance *(names in alphabetical order, affiliation information attached)*

Marion W. Anders, D.V.M., Ph.D.
Michael P. Doyle, Ph.D.
Owen Fennema, Ph.D.
Robert S. Langer, Sc.D., Chair
Robert M. Nerem, Ph.D.
Cecil M. Pickett, Ph.D.
José Principe, Ph.D.

FDA Participants *(alphabetical order)*

Norris E. Alderson, Ph.D., Acting Senior Advisor for Science, FDA
Dennis Baker, Associate Commissioner for Regulatory Affairs, FDA
Celeste F. Bové, CCC-A, Acting Executive Secretary, Office of Coordination & Communication
David W. Feigal, Jr., M.D., M.P.H., Director, Center for Devices & Radiological Health (CDRH)
Ajaz Hussain, Ph.D., Deputy Director, Office of Pharmaceutical Science, CDER
David Lepay, M.D., Senior Advisor for Clinical Science, FDA
Joe Levitt, Director, Center for Food Safety and Nutrition (CFSAN)
Murray Lumpkin, M.D., Acting Deputy Commissioner, FDA
Bernard A. Schwetz, D.V.M., Ph.D., Acting Principal Deputy Commissioner, FDA
Steven Sundlof, Director, Center for Veterinary Medicine (CVM)
Linda Suydam, D.P.A., Sr. Assoc. Commissioner for Communications & Constituent Relations
Janet Woodcock, M.D., Director, Center for Drug Evaluation & Research (CDER)
Kathryn Zoon, Ph.D., Director, Center for Biologics Evaluation & Research (CBER)

Invited Guests and Speakers *(alphabetical order)*

Frances Bruttin, PricewaterhouseCoopers, Pharmaceutical Sector Team
Alexa I. Canady, M.D., Co-Chair, CDRH External Science Review Committee
Doug Dean, Ph.D., PricewaterhouseCoopers, Pharmaceutical Sector Team
Steve Hammond, Manager, Process Analytical Group, Pfizer
G.K. Raju, Ph.D., Executive Director, MIT Pharmaceutical Manufacturing Initiative
Norman Winskill, Ph.D., Vice President, Manufacturing, Pfizer, Inc.

Public Comment Speakers *(alphabetical order)*

Robert Chisholm, International Technology Manager, AstraZeneca
Mats Josefson, AstraZeneca (AZ) Sweden (with Umetrics group)
Gideon Kantor, Ph.D, personal statement.
Nouna Kettaneh-Wold, Umetrics
Gabi Levin, Ph.D., Brimrose Corporation of America
John Parsons, Umetrics (alternate)
Scott C. Ratzan, MD, MPA, MA, Editor, Journal of Health Communication
Svante Wold, Ph.D., Umetrics

Major Topics:

The Science Board convened to consider the following scientific topics:

- Emerging Science Issues: Pharmaceutical Manufacturing
- The Center for Devices and Radiological Health's External Science Review
- Emerging Issues in FDA's Oversight of Clinical Research

Introductory Remarks

After brief introductions from the participants, Bernard A. Schwetz, D.V.M., Ph.D., Acting Principal Deputy Commissioner, began the session by introducing Norris E. Alderson, the Acting FDA Senior Advisor for Science, who is new to the position since the last FDA Science Board meeting. Dr. Schwetz also announced another staff change and introduced Dr. Mac Lumpkin, M.D., as the new Acting Deputy Commissioner. Next Dr. Schwetz welcomed the two new FDA Science Board members, Dr. Cecil Pickett and Dr. José Principe.

Dr. Schwetz updated the group on recent activities of the agency including counter-terrorism, the review of emergency preparedness plans, the review of product security, and the review of food security. In addition, he discussed the recent anthrax events at the agency, the five presumptive positives findings in the mail rooms and the final confirmed negatives. Dr. Schwetz further related that at a time when everyone wants to be protected, the agency has developed a new Crisis Management Center. Janet Woodcock, M.D. has taken the lead to develop this new center that will help us communicate and sort out the more routine variety of emergencies from those that the whole agency needs to address and to be prepared to work with other agencies such as the Centers for Disease Control, the United States Department of Agriculture, and the Environmental Protection Agency.

Regarding a peer review update, Dr. Schwetz indicated that the Center for Devices and Radiological Health (CDRH) has been completed and Drs. Nerem and Canady will report today along with comments from Dr. Feigal, Director of CDRH. The science within the field operation, Office of Regulatory Affairs (ORA), is scheduled for the next peer review. In addition, Dr. Schwetz gave brief comments on the 2002 budget regarding coverage for the pay increase and a supplemental request.

Lastly, Dr. Schwetz thanked two board members that are here for the last time because their term is expiring the end of this year, Drs. Anders and Nestle. Dr. Schwetz stated that over the course of the next year, FDA will need five new Science Board members as current terms expire and he asked members to send recommendations for replacements.

Update On Action Items From April 2001 Meeting

Norris E. Alderson, Ph.D., Acting Senior Advisor for Science, FDA, related that the FDA has established a list of ethicists in response to the Science Board's suggestion for FDA to have an Ethics Advisory Committee. This list of ethicists will be maintained in the Office of Science Coordination and Communication for FDA's use. At the last meeting, Dr. Scolnick recommended that FDA consider institutionalizing its peer review system. Because Dr. Scolnick could not join us today, we will defer this topic to a future meeting.

Dr. Alderson reported that the Science Board members will soon be receiving the nominations for FDA's 2002 Scientific Achievement Awards. The Board members vote and is the final recommending body in determining these important recognition awards. Based on earlier correspondence, arrangements have been made for the Science Board members to tour FDA laboratories this Spring to learn about how we establish research priorities at the agency.

Emerging Science Issues: Pharmaceutical Manufacturing

Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research (CDER), FDA, explained that this topic relates to science issues in the regulation of pharmaceutical quality. She reported that at FDA we are seeing an increasing trend toward manufacturing-related problems which are a real health care issue because a lack of efficiency contributes to the cost of drugs. Dr. Woodcock related that it's a huge challenge for FDA to enable the introduction of new technologies while maintaining quality standards. The speakers from industry and academia (refer to list above) presented a broad view of the problem and some of the various approaches that may be used to facilitate the introduction of modern process analytical technologies and pharmaceutical engineering principles into practice. Dr. Ajaz Hussain, CDER, related that this issue has been discussed at the FDA's Advisory Committee for Pharmaceutical Science and the committee recommended FDA form a subcommittee on Process Analytical Technology (PAT). The Federal Register notice has been published and the end of November is the deadline to apply. He encouraged attendees from industry to consider being part of the PAT subcommittee. The Science Board agreed by consensus that the FDA should move forward to act on this issue and supported CDER's approach to start with some pilots on small pieces.

Open Public Comment

The FDA received five requests to speak during the open comment period (refer to above list of public comment speakers). The speakers commented on topics to include: real-time quality control, enhancement of regulatory science animal research, risk communication, real-time process control, and Total Quality Management Strategy.

Note: Copies of the public comment presentations are available on the FDA Advisory Committee website, <http://www.fda.gov/oc/advisory/sciboard111601.html>

Update on CDRH External Science Review

Robert M. Nerem, Ph.D., Science Board Member was Chair for the CDRH External Science Review Committee. Dr. Nerem reported for the committee and also introduced Dr. Alexa Canady, the co-chair, who was present as an invited guest. The objective of the External Science Review was to assess the quality of science across the organization and its relevance to the organization's regulatory mission.

This internal review process was initiated in February 2001 with the field of electrostimulation devices chosen as a representative technology. The review was not an evaluation of individual decisions, but rather an evaluation of the overall role of science. The external review process built on the foundation of knowledge provided by the internal review. The findings addressed: science and the regulatory decision-making process; the present level of scientific expertise in the CDRH; the increasing complexity of applications; science and the long-term regulatory role; the leveraging of external and internal expertise for the Office of Device Evaluation; metrics for quantity, timeliness, and the quality of decision making; and, scientific expertise for the newer, breakthrough technologies. Finally, the subcommittee appreciates the fact that these recommendations, if accepted, cannot be put into place overnight; the subcommittee suggests that these recommendations be incorporated as explicit components of the CDRH strategic plan.

In response to the external review findings, David W. Feigal, Jr., M.D., M.P.H., Director of CDRH, discussed a "Top 10 list" of the greatest challenges and problems for science-based regulation at CDRH and a "Top 10 list" of recommendations for science-based regulation at CDRH. For next steps, the center has established a CDRH Recommendations Committee to go over the review and make recommendations to the senior management and division directors. The final report is posted at <http://www.fda.gov/cdrh/science/science-work-CDRH.html>

The Science Board members unanimously accepted the CDRH external science review report as presented. Overall, comments emphasized that the internal review was the most beneficial part of the process, with the external review being an additive benefit for the center.

Note: These presentations are available on the FDA Advisory Committee website, <http://www.fda.gov/oc/advisory/sciboard111601.html>

Emerging Issues in FDA's Oversight of Clinical Research

David A. Lepay, M.D., Senior Advisor for Clinical Science, Office for Good Clinical Practice (OGCP) in the Office of Science Coordination and Communication. Dr. Lepay talked about clinical trials, the conduct of clinical trials, the oversight of clinical trials, and some of the events taking place in this arena. First he presented a brief history to the underpinnings of our current models. He explained that FDA's mission in clinical research is broad and includes: ensuring the implementation of Good Clinical Practice (GCP) standards with human subject protection is one facet of GCP. Dr. Lepay also described OGCP operations and functions as well as its challenges. Additional information is available online, <http://www.fda.gov/oc/gcp/default.htm>

Note: This presentation is available on the FDA Advisory Committee website, <http://www.fda.gov/oc/advisory/sciboard111601.html>

Recommendations/Action Items

1. In response to Dr. Anders request, FDA will provide information on the magnitude of the drug recall problem, i.e., the relationship of recall to manufacturing problems.
2. Dr. Langer will work with Dr. Raju on presenting seminars at universities and chemical engineering schools to help address the lack of available scientific expertise in the newer technologies as opportunities may arise.

Adjournment - The meeting was adjourned at approximately 4:00 p.m.

Note: Refer to the complete official transcript for additional information: <http://www.fda.gov/ohrms/dockets/ac/01/transcripts/3799t1.htm>

**Science Board Member Affiliations
FDA Science Board Meeting
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