The New Frontiers in Science Distinguished Lectureship Program at the FDA

Objective of Program—This program aims to help strengthen scientific expertise at the FDA and foster interactions between the scientific community and the FDA by bringing outstanding scientific leaders to the FDA for short periods to serve as Distinguished Lecturers. In this capacity they will present their work and discuss advances and challenges in fields of particular relevance to the FDA such as stem cell therapies, nanotechnology, and innovative clinical trial designs appropriate for small patient populations. The New Frontiers in Science Distinguished Lectureship Program at the FDA is the first program in a new regulatory science initiative adopted by the HRA Board of Directors in the summer of 2011.

Rationale for Program—The potential for new path-breaking therapeutics, diagnostics and preventions for human diseases is extraordinary. However, the pace and breadth of scientific discovery today makes it particularly challenging to ensure that there are sufficient FDA staff knowledgeable in the numerous complex and highly specialized areas that the agency regulates. Providing opportunities for FDA staff to work with and access the expertise of scientists who are working in the quickly changing cutting-edge fields that FDA is regulating will help fill this knowledge gap. The HRA-sponsored New Frontiers in Science Distinguished Lectureship Program at the FDA is one approach for facilitating interactions between FDA staff and the scientific community.

The FDA published a strategic plan for regulatory science in August, 2011 that lists the following priority areas:

1. Modernize toxicology to enhance product safety
2. Stimulate innovation in clinical evaluations and personalized medicine to improve product development and patient outcomes
3. Support new approaches to improve product manufacturing and quality
4. Ensure FDA readiness to evaluate innovative emerging technologies
5. Harness diverse data through information sciences to improve health outcomes
6. Implement a new prevention-focused food safety system to protect public health
7. Facilitate development of medical countermeasures to protect against threats to US and global health and security
8. Strengthen social and behavioral science to help consumers and professionals make informed decisions about regulated products.


These eight priority areas are informing the selection of topics for the lectures.
**Funding and progress to date** - A lead gift from the Burroughs Wellcome Fund and additional funding from JDRF International and the Doris Duke Charitable Foundation enabled HRA to proceed to work with FDA to plan the program. An HRA-FDA Joint Planning Committee was appointed to identify potential speakers (see list of Committee members below).

**2012 offerings:**

- On September 17, 2012, Sanjiv Gambhir, M.D., Ph.D., Virginia and D. K. Ludwig Professor of Cancer Research, Stanford University, presented "Emerging Strategies for the Early Detection of Cancer," the inaugural lecture in the New Frontiers program. The lecture, which was introduced by FDA Commissioner Margaret Hamburg and FDA Chief Scientist Jesse Goodman, was well-attended by FDA staff. Several representatives from HRA member organizations were also in attendance. Following the lecture, Dr. Gambhir met with staff members at the Center for Devices and Radiological Health (CDRH) and the Office of the Commissioner. The full recording of the lecture is available at the following link (Dr. Gambhir’s presentation starts at the 10:30 minute mark): [https://collaboration.fda.gov/p43535904/](https://collaboration.fda.gov/p43535904/)

- On December 5, 2012, the second lecture under the New Frontiers program, “Ethics, Compassion and Evidence,” was presented by Arthur L. Caplan, Ph.D., Drs. William F. and Virginia Connolly Mitty Professor and Department Chair, Department of Bioethics, New York University, Langone Medical Center. The full recording of the lecture is available at the following link: [https://collaboration.fda.gov/p38552110/](https://collaboration.fda.gov/p38552110/).

**2013 offerings:**

- The first 2013 lecture in the New Frontiers program was held on March 20, 2013 at the FDA White Oak campus. Leroy Hood, M.D., Ph.D., of the Institute for Systems Biology presented “Systems Medicine, the Emergence of Transformational Technologies and Proactive P4 Medicine.” A recording of the lecture can be viewed at [https://collaboration.fda.gov/p84154042/](https://collaboration.fda.gov/p84154042/). Following his lecture, Dr. Hood visited with staff in the Office of Cellular Tissues and Gene Therapies and the Office of Biostatistics and Epidemiology in the Center for Biologics Evaluation and Research (CBER); in the Office of Translational Sciences, the Office of New Drugs and the Office of Pharmaceutical Science in the Center for Drug Evaluation and Research (CDER); and in the Office of the Chief Scientist.

- The next lecture in 2013 will be given on November 13, 2013 by Irving Weissman, M.D., Director, Institute for Stem Cell Biology & Regenerative Medicine at Stanford University, “Stem Cells and Cancer Stem Cells: From Discovery to the Clinic.”
Members of the HRA-FDA Joint Planning Committee:

The following individuals represent FDA on the Joint Planning Committee:

- Ross Filice, M.D., Medical Officer, Division of Medical Imaging Products, Center for Drug Evaluation and Research
- Francis Kalush, Ph.D., Senior Health Science Advisor, Center for Devices and Radiological Health
- Michelle McMurry-Heath, M.D., Ph.D., Associate Director for Science, Center for Devices and Radiological Health
- Carlos Pena, Ph.D., M.S., Director, Emerging Technologies, Office of the Commissioner
- Steven Pollack, Ph.D., Director, Office of Science and Engineering Laboratories, Center for Devices and Radiological Health
- Leslie Wheelock, M.S., R.N., Director, Office of Scientific Professional Development, Office of Chief Scientist
- Bernadette Williamson-Taylor, M.Ed., Lead Regulatory Health Education Specialist, Office of Scientific Professional Development, Office of Chief Scientist

The following individuals represent HRA on the Joint Planning Committee:

- Maria Carrillo, Ph.D., Vice President for Medical & Scientific Relations, Alzheimer’s Association
- Elaine Gallin, Ph.D., Principal, QE Philanthropic Advisors (Former HRA Board Member)
- Sharon Hesterlee, Ph.D., Vice President, Research, Parent Project Muscular Dystrophy
- Marc Hurlbert, Ph.D., Executive Director, Avon Foundation for Women (Past Chair of HRA Board of Directors)
- Rusty Kelley, Ph.D., Program Officer, Burroughs Wellcome Fund (effective 5/2013)
- Sally McNagny, M.D., M.P.H., Vice President, The Medical Foundation, a division of Health Resources in Action (Chair, HRA Board of Directors)
- Elizabeth (Betsy) Myers, Ph.D., Program Director for Medical Research, Doris Duke Charitable Foundation
- Concepcion (Marie) Nierras, Ph.D., Assistant Vice President, International Partnerships, JDRF International
- Kate Ahlport, Executive Director, Health Research Alliance