Biography for Wendy R. Sanhai, Ph.D.

As Senior Scientific Advisor, Immediate Office of the Commissioner, FDA, Dr. Sanhai is responsible for leading, and in some cases assisting in, the development and implementation of scientific initiatives and strategic alliances under the agency's Critical Path Initiative. Dr. Sanhai serves as FDA's Federal Liaison on a number of consortia and committees. She has received numerous awards and commendations, including the Commissioner's Leveraging/Collaboration Award, FDA (2005) and again in 2006 for "Tireless Commitment to the FDA's Critical Path Initiative." Some of the initiatives (with positions) Dr. Sanhai has helped develop or participated in include:

- FDA Chair, Nanotechnology Sub-Committee of the Interagency Oncology Task Force (IOTF) between FDA and NCI (since 2004)
- Member, Board of Directors, Critical Path Institute, Tucson, Az., working on the following: (since 2005)
  - Predictive Safety Testing Consortium
  - Molecular Assays and Targeted Therapeutics (MATT) Consortium
  - Collaborative Cardiovascular Drug Safety and Biomarker Research Program (as Chief Program Manager)
- Federal Liaison and Member, Executive Committee, Cardiac Safety Research Consortium: FDA/Duke University (since 2006)
- Committee Member (Office of the Commissioner), FDA Grants and Contracts Program (since 2007)
- Federal Liaison, Severe Adverse Events (SAE) Consortium: IP/Business Committee (since 2007)
- The Biomarker Consortium (FDA Liaison to Business Committee, Manager for Internal FDA Coordination: for all FDA Liaisons to all Steering Committees and Special Assistant to Dr. Janet Woodcock, since 2006)
- Chief FDA Liaison to NIH's Clinical Translational Science Award (CTSA) Program (since 2006)

Prior to her current appointment, Dr. Sanhai was the Director of Public-Private Partnerships at the Foundation for the National Institutes of Health (FNIH) and was the senior Foundation officer responsible for creating, implementing, managing and evaluating all new and existing programs in clinical research, education and training. In this role, she served as the chief scientific liaison to the NIH, other Federal agencies, including the FDA and the CDC, academia, industry and non-profit organizations. Her program portfolio budget was approximately $113M, notwithstanding the FNIH's $200M Grand Challenges in Global Health Initiative.

Dr. Sanhai's dedication to the advancement of biomedical research and public health started in academia as a clinical chemistry fellow, scientific researcher and faculty member in the Departments of Pathology and Medical and Research Technology at the University of Maryland, School of Medicine. Dr. Sanhai left academia at the level of Assistant Professor to join the National Institutes of Health (NIH), Office of Technology Transfer (OTT) as a Technology Licensing Specialist and Patent Advisor. In that capacity, she managed a license and intellectual property portfolio of more than 200 NIH invention families from across the 27 Institutes and Centers of the NIH, with special emphasis on the National Cancer Institute. Dr. Sanhai worked extensively with the NIH, industry, academic and international organizations on behalf of the NIH and the FDA, conducting a full range of activities associated with technology development: intramural program assessment, securing appropriate intellectual property protection and negotiating the transfer those patent rights to the private sector to promote the research, development and commercialization of medical products.

Dr. Sanhai is not new to the FDA as she was the first official hire under the Director's Total Product Life Cycle (TPLC) Initiative, Center for Devices and Radiological Health (CDRH), FDA. As such, she is in trained in all aspects of regulatory and scientific review at that Center, as well as compliance/enforcement procedures. She left the FDA to join the FNIH.

Dr. Sanhai has a Ph.D. in biochemistry and structural biology from the School of Medicine, State University of New York at Buffalo and a baccalaureate degree in chemistry from the University of Florida, Gainesville.