

Janet Woodcock, M.D.

Janet Woodcock is the Director of the Center for Drug Evaluation and Research at FDA. She previously served as FDA Deputy Commissioner and Chief Medical Officer.

Dr. Woodcock has close interactions with diverse constituencies, including the clinical and scientific communities, members of Congress and the Administration, national media, patient and consumer advocacy groups, the international drug regulatory community, the regulated industry, and representatives of the Federal and State agencies. She frequently appears in or is quoted by the national media and has testified repeatedly before Congress.

Dr. Woodcock has led many cross-Agency initiatives while at FDA. She introduced the concept of pharmaceutical risk management in 2000 as a new approach to drug safety. She has led the “Pharmaceutical Quality for the 21<sup>st</sup> Century Initiative” since 2002. This effort, to modernize pharmaceutical manufacturing and its regulation through the application of modern science and quality management techniques, has been highly successful in meeting its objectives. She has spearheaded an initiative on pharmacogenomics that has led to unprecedented agency-industry interactions on pharmacogenomics use in drug development. In 2004, she introduced FDA’s “Critical Path” Initiative, which is designed to improve the scientific basis for medical product development. Most recently, she launched the “Safety First” and “Safe Use” initiatives that are designed to improve drug safety management within and outside the FDA, respectively.

Dr. Woodcock was director of the Center for Drug Evaluation and Research (CDER) from 1994 – 2005. During this period, review processes for new and generic drugs were streamlined, while the standards for quality, safety and effectiveness were improved. Dr. Woodcock also oversaw initiatives to automate submission and review of applications and adverse event reports. Under Dr. Woodcock’s leadership, CDER’s regulatory decision-making was made more open and transparent to the public. Changes included publishing CDER’s regulatory procedures and policies, developing over 100 technical “guidances” that describe regulatory standards, providing an unprecedented degree of participation of consumer and patient representatives in FDA processes, and creating an extensive Center web site which includes drug reviews and consumer information.

Prior to joining CDER, Dr. Woodcock was director of the Office of Therapeutics Research and Review, Center for Biologics Evaluation and Research (CBER). There she oversaw approval of the first biotechnology-based treatments for multiple sclerosis and cystic fibrosis. She also served as Acting Deputy Director of CBER for several years.

Dr. Woodcock has earned numerous awards, including a Presidential Rank Meritorious Executive Award, the Nathan Davis Award from the American Medical Association (1999), the Roger W. Jones Award for Executive Leadership from American University (2000) the Public Health Leadership Award (2004) from the National Organization for Rare Disorders (NORD), the VIDA Award from The National Alliance for Hispanic Health (2005), the Leadership Award in Personalized Medicine from the Personalized Medicine Coalition (2005), the Public Service Award from the American Association for Cancer Research (2006), the “indispensable person of the year award” from the Alliance for Aging Research (2007), the Distinguished Service and Leadership Award from the Food and Drug Law Institute (2008), the Distinguished Career Award from the Drug Information Association (2008) and the Neal Prize for Innovation in Drug Development from the ASCPT (2009).. She has also received three HHS Secretary’s

Distinguished Service Awards and the HHS Asian-Pacific Network achievement award (2001) and six FDA Commissioner's Special Citations. She has authored over 60 publications.

Dr. Woodcock received her M.D. from Northwestern University Medical School in 1977. She received her undergraduate degree from Bucknell University. She has held teaching appointments at Pennsylvania State University and the University of California at San Francisco. She lives in Maryland with her husband and is the mother of two daughters.