Duke UNIVERSITY | Duke-Margolis Center *for* Health Policy

**Biologic Variability to Drug Response: Sex Differences in Clinical Trials**

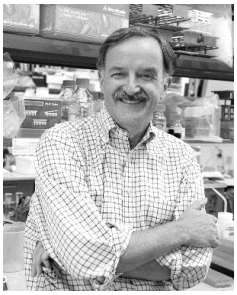
Marriott Renaissance • Washington, DC

May 16, 2016

**Biographies**

**Gregory Daniel, PhD, MPH**, is a Clinical Professor in Duke's Fuqua School of Business and Deputy Director in the Duke-Robert J. Margolis Center for Health Policy at Duke University. Dr. Daniel directs the DC-based office of the Center and leads the Center's pharmaceutical and medical device policy portfolio which includes developing policy and data strategies for improving development and access to innovative pharmaceutical and medical device technologies. This includes post-market evidence development to support increased value, improving regulatory science and drug development tools, optimizing biomedical innovation, and supporting drug and device payment reform. Dr. Daniel is also a Senior Advisor to the Reagan-Udall Foundation for the FDA and Adjunct Associate Professor in the Division of Pharmaceutical Outcomes and Policy at the UNC Eshelman School of Pharmacy. Previously, he was Managing Director for Evidence Development & Biomedical Innovation in the Center for Health Policy and Fellow in Economic Studies at the Brookings Institution and Vice President, Government and Academic Research at HealthCore (subsidiary of Anthem, Inc). Dr. Daniel's research expertise includes utilizing electronic health data in designing research in health outcomes and pharmacoeconomics, comparative effectiveness, and drug safety and pharmacoepidemiology. Dr. Daniel received a PhD in pharmaceutical economics, policy and outcomes form the University of Arizona, as well as an MPH, MS, and BS in Pharmacy all from The Ohio State University.

**Ruthanna Davi, PhD**, is a Statistician and Deputy Division Director in the Office of Biostatistics in the Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA) and has been working in the area of clinical trials and pharmaceutical product development since 1996. Ruthie has experience designing and analyzing clinical trials across a number of therapeutic areas and has particular interest in pediatric studies, development of biosimilars, and analysis of subgroups. Ruthie is a member of FDA's Pediatric Evaluation and Research Committee (PeRC), a multidisciplinary team guiding the design of FDA-requested studies in pediatrics. She has contributed to the development of standards for biosimilars, particularly in the area of rheumatoid arthritis. More recently, Ruthie has become involved in FDA's Drug Snapshot Initiative and has developed both statistical approaches and procedural methods to examine the effects of new molecular entities and original biologics by age, sex, and race, for use in the Drug Snapshot postings. This work has an emphasis on description and transparency of information rather than traditional statistical hypothesis testing. Ruthie holds a Ph.D. in biostatistics from George Washington University. Ruthie is passionate about teaching and is well-known in CDER for providing formal and informal statistics training to non-statisticians in easy to understand language.



**Garret FitzGerald, MD**, is the McNeil Professor in Translational Medicine and Therapeutics at the University of Pennsylvania in Philadelphia, where he chairs the Department of Pharmacology and directs the Institute for Translational Medicine and Therapeutics. Dr. FitzGerald's research has been characterized by an integrative approach to elucidating the mechanisms of drug action, drawing on work in cells, model organisms and humans. His work contributed substantially to the development of low-dose aspirin for cardioprotection. FitzGerald's group was the first to predict and then mechanistically explain the cardiovascular hazard from NSAIDs. He has also discovered many products of lipid peroxidation and established their utility as indices of oxidant stress in vivo. His laboratory was the first to discover a molecular clock in the cardiovascular system and has studied the importance of peripheral clocks in the regulation of cardiovascular and metabolic function. Dr. FitzGerald has received the Boyle, Coakley, Harvey and St. Patrick's Day medals, the Lucian, Scheele and Hunter Awards and the Cameron, Taylor, Herz, Lefoulon-Delalande, and Schottstein Prizes. He is a member of the Institute of Medicine and a Fellow of the American Academy of the Arts and Sciences and of the Royal Society.

**David J. Greenblatt, MD**, has been on the Faculty of Tufts University School of Medicine and the Staff of Tufts Medical Center since 1979. He holds the Louis Lasagna, M. D., Endowed Professorship in the Department of Integrative Physiology and Pathobiology at Tufts University School of Medicine, and is a senior faculty member in the Graduate Program in Pharmacology & Experimental Therapeutics at the Sackler School of Graduate Biomedical Sciences at Tufts University. He also holds appointments as Professor of Psychiatry, Medicine, and Anesthesia, Tufts University School of Medicine. He has previously served as Chair of the Department of Pharmacology and Experimental Therapeutics at Tufts University School of Medicine, Program Director and Associate Program Director of the institution's Clinical/Translational Research Center (formerly the General Clinical Research Center), and Chair of the Institutional Review Board. He is Editor-in-Chief of *Clinical Pharmacology in Drug Development*, operated by the American College of Clinical Pharmacology. He also is Co-Editor-in-Chief, with Dr. Richard I. Shader, of the *Journal of Clinical Psychopharmacology*. A native of Newton, Massachusetts, Dr. Greenblatt is a Magna Cum Laude graduate of Amherst College (1966), where he was senior class president and co-captain of the varsity football team. After college he attended Harvard Medical School, graduating in 1970. Thereafter he trained in internal medicine at the Montefiore Hospital, New York City (1970-1971), and on the Harvard Medical Service at Boston City Hospital (1971-1972). Following a Fellowship in Clinical Pharmacology at Massachusetts General Hospital under the mentorship of Dr. Jan Koch-Weser (1972-1974), he stayed on to head the Clinical Pharmacology Unit at Mass. General from 1975 to 1979, at which time he moved to Tufts. Dr. Greenblatt has been an active investigator in the area of molecular and clinical pharmacology going back to the late 1960s. His PubMed listing includes more than 1000 publications; more than 760 of these represent original research reports. His work has been supported by the National Institutes of Health for more than 35 years.

**Mark McClellan, MD, PhD**, is the Robert J. Margolis Professor of Business, Medicine, and Policy, and Director of the Duke-Margolis Center for Health Policy at Duke University with offices at Duke and in Washington DC. The new Center will support and conduct research, evaluation, implementation, and educational activities to improve health policy and health, through collaboration across Duke University and Health System, and through partnerships between the public and private sectors. It integrates the social, clinical, and analytical sciences to integrate technical expertise and practical capabilities to develop and apply policy solutions that improve health and the value of health care locally, nationally, and worldwide. Dr. McClellan is a doctor and an economist, and his work has addressed a wide range of strategies and policy reforms to improve health care, including such areas as payment reform to promote better outcomes and lower costs, methods for development and use of real-world evidence, and more effective drug and device innovation. Before coming to Duke, he served as a Senior Fellow in Economic Studies at the Brookings Institution, where he was Director of the Health Care Innovation and Value Initiatives and led the Richard Merkin Initiative on Payment Reform and Clinical Leadership. He also has a highly distinguished record in public service and in academic research. Dr. McClellan is a former administrator of the Centers for Medicare & Medicaid Services (CMS) and former commissioner of the U.S. Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy. These include the Medicare prescription drug benefit, Medicare and Medicaid payment reforms, the FDA's Critical Path Initiative, and public-private initiatives to develop better information on the quality and cost of care. Dr. McClellan is the founding chair and a current board member of the Reagan-Udall Foundation for the FDA, is a member of the National Academy of Medicine and chairs the Academy's Leadership Council for Value and Science-Driven Health care, co-chairs the guiding committee of the Health Care Payment Learning and Action Network, and is a research associate at the National Bureau of Economic Research. He has also previously served as a member of the President's Council of Economic Advisers and senior director for health care policy at the White House, and as Deputy Assistant Secretary for Economic Policy at the Department of the Treasury. He was previously an associate professor of economics and medicine with tenure at Stanford University, and has twice received the Kenneth Arrow Award for Outstanding Research in Health Economics.

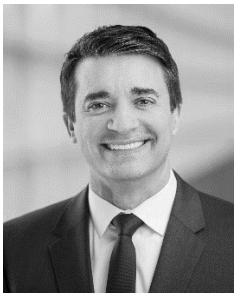
**Virginia M. Miller, MBA, PhD**, is Professor of Surgery and Physiology and Director of the Women's Health Research Center at the Mayo Clinic. Dr. Miller received her PhD in Physiology from the University of Missouri, Columbia, MO. Her research for the last 25 years has focused on how sex steroids affect vascular function. In addition to her basic science work, she was principal investigator for the Mayo site for the Kronos Early Estrogen Prevention Study (KEEPS), a double blind, placebo controlled clinical trial. She currently serves as principal investigator for Mayo Clinic's Specialized Center of Research on Sex Differences and Research Director of the Mayo Clinic's Building Interdisciplinary Careers in Women's Health (BIRCWH). She has authored over 200 original publications and reviews. She was the 2014 recipient of the Bernadine Healy Award for Visionary Leadership in Women's Health from the Women's Health Congress and a 2015 recipient of Women's Day Magazine Red Dress Award for her work in research and advocacy for women's health. She has worked with international groups in the promotion of sex and gender education and research including the web-based program Genderedinnovations.com, International Society of Gender Medicine and Sex and Gender Women's Health Collaborative. In addition to service on various grant review panels and editorial boards for scientific journals, she served as a member of the governing council for the American Physiological Society (APS) and as President of the Organization for the Study of Sex Differences (OSSD).

**Rita F. Redberg, MD, MSc**, is a cardiologist and Professor of Medicine at the University of California, San Francisco since 1990 and Core Faculty, Philip R Lee Institute for Health Policy Studies. Dr. Redberg is the Chief Editor of JAMA Internal Medicine (formerly Archives of ) and has spearheaded the journal's new focus on health care reform and "less is more", which highlights areas of health care with no known benefit and definite risks. Her research interests are in the area of health policy and technology assessment, and how to promote high value care, focusing on high risk medical devices as well as the need for inclusion of women in clinical trials of such devices. Dr. Redberg is a member of the Medicare Payment Advisory Commission, which advises Congress on Medicare payment issues. She also served on the Medicare Evidence, Development and Coverage Advisory Committee from 2003-2006 and was reappointed in 2012 as Chairwoman of MEDCAC. Dr Redberg is a member of the California Technology Assessment Forum, the Medical Policy Technology and Advisory Committee, and the Food and Drug Administration Cardiovascular Devices Expert Panel, and is a consultant for the Center for Medical Technology Policy. She has given Congressional testimony multiple times in hearings related to the issue of balancing safety and innovation in medical device approvals. Dr. Redberg worked in the office of Senator Hatch and with the Senate Judiciary Committee on FDA-related matters during her tenure as a Robert Wood Johnson Health Policy Fellow, 2003-2006. Dr. Redberg was a member of the Institute of Medicine's Learning Health Care Committee, which produced the report Best Care at Lower Cost in September 2012. She is currently a member of the National Academy of Medicine Committee on A Learning System for Military Trauma Care. She chaired the AHA/ACC Writing Group on Primary Prevention Performance Measures and is a member of the American College of Cardiology's (ACC) Clinical Quality Committee and serves on the Quality in Technology Work Group. She is on multiple technology assessment boards, including the Blue Cross Blue Shield Medical Advisory Panel and the California Technology Assessment Forum, as well as the Institute of Clinical and Economic Review Advisory Board. Dr. Redberg has authored several books, including *You Can Be a Woman Cardiologist*, *Heart Healthy: The Step-by-Step Guide to Preventing and Healing Heart Disease*, and *Betty Crocker Cookbook for Women: the Complete Guide to Women's Health and Wellness at Every Stage of Life*. Dr. Redberg graduated from Cornell University and the University of Pennsylvania Medical School and has a Master of Science in Health Policy and Administration from the London School of Economics.

**Rick Sax, MD**, is Senior Vice-President and Managing Director of Quintiles Advisor Services. Rick is a 25-year veteran of the pharmaceutical industry, having held senior positions in Clinical Development at Merck & Co. and AstraZeneca. His career has included leading cardiovascular drug development at Merck, and leadership roles in the U.S. Business, Global Medical Sciences, and New Opportunities at AstraZeneca. At AstraZeneca he also helped lead their efforts to transform Clinical Development, focusing on improving program and protocol design. Rick joined Quintiles in 2011, where he oversaw the Biostatistics/Medical Writing/Global Regulatory Affairs group (Clinical Analysis & Reporting Services), Safety Knowledge & Reporting, and the Center for Integrated Drug Development – Quintile's home for clinical program and trial design and its enabling technology platform, Infosario Design®. He now is a Senior Vice-President in Advisory Services, focused on supporting biopharma companies to design integrated development, regulatory, and commercial strategies for their assets.

**Jerald S. Schindler, DrPH**, is Head, Translational Applied Statistics at Merck Research Laboratories and Adjunct Professor, Biostatistics at the Harvard T.H. Chan School of Public Health. This group is responsible for the application of innovative statistical methodology across the entire development process, from early drug discovery through post marketing. Previously, Dr. Schindler was VP, Global Late Development Statistics at Merck Research Laboratories. This global group of 140 statisticians is responsible for the experimental design and statistical analysis of all clinical trials for all therapeutic areas at Merck. Dr. Schindler is also Adjunct Professor of Biostatistics at the Harvard T.H. Chan School of Public Health and is on the faculty of the Post Graduate Course in Pharmacology at the Tufts University Center for the Study of Drug Development. He is also on the advisory committees for the Department of Biostatistics at Duke University and for the Department of Statistics at George Mason University. Prior to joining Merck, Dr Schindler was President of the Pharmaceutical Research Division at Cytel. And earlier, he was the Chief Biostatistician and Global Head of Biostatistics and Clinical Technology at Wyeth Research, where he led 120 staff in the quantitative science groups at Wyeth responsible for drug development. Dr. Schindler received undergraduate and master's degrees from Georgetown University and a doctorate in Biostatistics from the University of North Carolina, Chapel Hill.

**Robert Temple, MD**, has been Deputy Center Director for Clinical Science at FDA's Center for Drug Evaluation and Research since 2009, participating in the direction of the Center's operations. He is also Acting Deputy Director of the Office of Drug Evaluation I (ODE-I). ODE-I is responsible for the regulation of cardio-renal, neuropharmacologic, and psychopharmacologic drug products. Dr. Temple served as Director, Office of Medical Policy from 1999-2009. The Office of Medical Policy is responsible for regulation of promotion through the Office of Prescription Drug Products (formerly, Division of Drug Marketing, Advertising, and Communication) and for assessing quality of clinical trials. Dr. Temple has a long-standing interest in the design and conduct of clinical trials and has written extensively on this subject, especially on choice of control group in clinical trials, evaluation of active control and non-inferiority trials, trials to evaluate dose-response, and trials using "enrichment" designs.



**John J. Whyte, MD, MPH**, is the Director of Professional Affairs and Stakeholder Engagement at the Center for Drugs Evaluation and Research at the U.S. Food and Drug Administration. In this role, Dr. Whyte works with health care professionals, patients, patient advocates, and others involved in the use of medicines. He also oversees the Safe Use program and supports the ongoing partnerships and activities under the Safe Use Initiative. Previously, Dr. Whyte served as the Chief Medical Expert and Vice President, Health and Medical Education at Discovery Channel, the leading non-fiction television network. In this role, Dr. Whyte developed, designed and delivered educational programming that appeals to both a medical and lay audience. Prior to Discovery, Dr. Whyte was in the Immediate Office of the Director at the Agency for Healthcare Research Quality. He served as Medical Advisor/Director of the Council on Private Sector Initiatives to Improve the Safety, Security, and Quality of Healthcare. Prior to this assignment, Dr. Whyte was the Acting Director, Division of Medical Items and Devices in the Coverage and Analysis Group in the Centers for Medicare & Medicaid Services (CMS). In his role at CMS, Dr.Whyte made recommendations as to whether or not the Medicare program should pay for certain procedures, equipment, or services. Dr. Whyte is a board-certified internist and continues to see patients. He completed an internal medicine residency at Duke University Medical Center as well as earned a Masters of Public Health (MPH) in Health Policy and Management at Harvard University School of Public Health. He has written extensively in the medical and lay press on health policy issues. His book *Is This Normal? The Essential Guide to Middle Age and Beyond* has won numerous awards. His most recent book, *AARP New American Diet: Lose Weight, Live Longer* is a national best-seller.

**Janet Woodcock, MD**, is Director of the Center for Drug Evaluation and Research (CDER), at the Food and Drug Administration (FDA). In 2015, Dr. Woodcock also assumed the role of Acting Director of CDER's newly formed Office of Pharmaceutical Quality, (OPQ). Dr. Woodcock first joined CDER in 1994. For three years, from 2005 until 2008, she served FDA's Commissioner, holding several positions, including as Deputy Commissioner and Chief Medical Officer, Deputy Commissioner for Operations, and Chief Operating Officer. Her responsibilities involved oversight of various aspects of scientific and medical regulatory operations. Before joining CDER, Dr. Woodcock served as Director, Office of Therapeutics Research and Review, and Acting Deputy Director in FDA's Center for Biologics Evaluation and Research. Dr. Woodcock received her M.D. from Northwestern Medical School and completed further training and held teaching appointments at the Pennsylvania State University and the University of California in San Francisco. She joined FDA in 1986.

**Issam Zineh, PharmD, MPH**, is Director of the Office of Clinical Pharmacology (OCP) at the U.S Food and Drug Administration (FDA). From 2008-2012, Dr. Zineh was the Associate Director for Genomics in OCP. He also served as Co-Director of the CDER Biomarker Qualification Program until 2015. He is an experienced applied clinical pharmacologist who was formerly on the faculty of the University of Florida (UF) Colleges of Pharmacy and Medicine and Associate Director of the UF Center for Pharmacogenomics. Dr. Zineh received his PharmD from Northeastern University and completed his residency at Duke University Medical Center. He completed a fellowship in cardiovascular pharmacogenomics at UF where he also obtained his MPH in Health Policy and Management. He is a recognized expert in the fields of drug development and evaluation, clinical pharmacology, pharmacotherapy, and precision medicine. As Director of OCP, Dr. Zineh leads a staff of 240 regulatory, research, project management, and administrative staff in FDA's efforts to enhance drug development and promote regulatory innovation through clinical pharmacology and experimental medicine.