Duke | MARGOLIS CENTER *for* Health Policy

Evaluating the Pressor Effects of Drugs & Ambulatory Blood Pressure Monitoring Studies

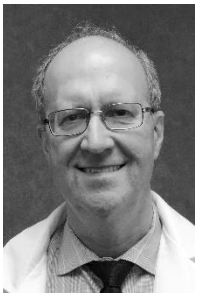
Conference Center at 1777 F Street NW • Washington, DC
February 4th, 2019

Biographies

G. Brandon Atkins is currently a Senior Principal Scientist at Merck Research Laboratories in Rahway, NJ. Dr. Atkins joined Merck in June 2015 as part of the Merck Drug Development And Leadership Pathway (MEDDAL Program). Upon starting at Merck he worked in Global Clinical Development-Cardiovascular supporting the late stage clinical development of Merck's cardiovascular drugs including ezetimibe and vericiguat. In August 2016, he transitioned to Translational Pharmacology where he currently leads teams to support the early stage development of drugs in Merck's cardiovascular and thrombosis pipeline. Dr. Atkins received a B.A. in Biochemistry from the University of Virginia and M.D. and Ph.D. degrees in Molecular Biology from the University of Pennsylvania. He completed his Internal Medicine Residency at Brigham and Women's Hospital and his Cardiology Fellowship at Massachusetts General Hospital. Prior to joining Merck, Dr. Atkins was an Assistant Professor of Medicine (Cardiovascular Division) at Case Western Reserve School of Medicine and University Hospitals Case Medical Center, where he also served as Assistant Program Director of the Internal Medicine Residency Program. In addition to his patient care responsibilities, Dr. Atkins had an independently supported laboratory research program focusing on vascular biology and the basic molecular mechanisms of cardiovascular and cerebrovascular disease. He is board-certified in Cardiology.

George Bakris has published over 800 peer-reviewed articles and book chapters in the areas of diabetic kidney disease, hypertension and progression of nephropathy. He is the Editor or Co-Editor of 20 books, in the areas of Kidney Disease Progression and Diabetes as well as the new 3rd edition of Hypertension: A Companion to Braunwald's The Heart. Additionally, he is an Associate Editor of the International Textbook of Cardiology. He served as a special government expert to the Cardio-renal Advisory Board of the FDA and to CMS (1994-2008). He was a co-principal investigator on the NIH Clinical Research training grant for clinical research (K30) (1999-2004). He chaired the first National Kidney Foundation Consensus report on blood pressure and impact on renal disease progression (2000). He has also served on many national guideline committees including: The Joint National Committee Writing Groups VI & 7 (1997, 2003), the JNC 7 executive committee (2003), the American Diabetes Association Clinical Practice Guideline Committee (2002-2004 and 2019-present), the National Kidney Foundation (K-DOQI) Blood Pressure Guideline committee (2002-2004 & 2013), (K-DOQI) Diabetes Guideline committee (2003-2005 & 2014), Chair, ADA BP Consensus Report (2016) and writing committee ACC/AHA Resistant Hypertension Consensus report (2016-2017). Dr. Bakris is the past-president of the American College of Clinical Pharmacology (2000-2002) and the American Society of Hypertension (ASH). He is the current Editor-in-Chief, Am J Nephrology, Editor-in-Chief- Up-to-Date, Nephrology section, Hypertension Section Editor Up-to-Date and Assoc. Ed of Diabetes Care.

Charles Benson is a Senior Medical Director of Clinical Pharmacology, Diabetes with Eli Lilly & Co., where he has worked for 18+ years. He received a B.S. from Massachusetts Institute of Technology (M.I.T.) before attending Indiana University, where he received a M.D. and a Ph.D., the latter in Physiology and Biophysics. He then completed a residency in Internal Medicine at the Scripps Clinic, La Jolla, California prior to joining Lilly. He is recognized for his leadership and expertise in quantitative approaches to early drug development, including work on advancing the field of use of biomarkers in prediction of cardiovascular safety.

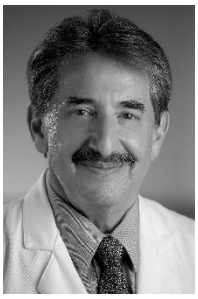


Robert Blankfield is a Clinical Professor of Family Medicine at Case Western Reserve University, Cleveland, Ohio. He graduated from Swarthmore College, Swarthmore, Pennsylvania. He received his medical degree from Case Western Reserve University School of Medicine, Cleveland, Ohio. He did his residency training at Fairview General Hospital, Cleveland, Ohio, and he completed a research fellowship in Family Medicine at Case Western Reserve University. Dr. Blankfield works for Southwest General Medical Group, Middleburg Heights, Ohio. He practices family medicine and he is a Senior Aviation Medical Examiner. He has served as the Chairman of the Institutional Review Board, Southwest General Health Center. He has been a peer reviewer for several medical journals. Dr. Blankfield's research interests include the cardiovascular complications of obstructive sleep apnea; and the effect of fluid retention upon the velocity and turbulence of blood flow.

Jeffrey S. Borer is Professor of Medicine, Cell Biology, Radiology, Surgery and Public Health at the State University of New York Downstate Medical Center and Adjunct Professor of Cardiovascular Medicine in Cardiothoracic Surgery at Weill Medical College of Cornell University. For many years he served as Chief, Division of Cardiovascular Medicine and Chairman, Department of Medicine, at SUNY Downstate, positions he has relinquished to direct two research institutes (Gilman Institute for Heart Valve Disease and Schiavone Institute of Cardiovascular Translational Research) at Downstate. Dr. Borer received a BA from Harvard, M.D. from Cornell, trained at the Massachusetts General Hospital, spent 7 years in the Cardiology Branch, NHLBI, and a year at Guy's Hospital (London) as Senior Fullbright Hays Scholar and Glorney-Raisbeck Fellow in the Medical Sciences, completing the first clinical demonstration of nitroglycerin's utility in acute MI following his preclinical studies at NIH. Upon returning to NIH, he developed stress radionuclide cineangiography, enabling the first non-invasive assessment of cardiac function with exercise and importantly changing the practice of cardiology. He then returned to Cornell for 30 years as Gladys and Roland Harriman Professor of Cardiovascular Medicine and Chief, Division of Cardiovascular Pathophysiology. He has been an Advisor to the USFDA for 42 years, chaired the CardioRenal Drugs Advisory Committee for 3 terms and the Circulatory Devices Advisory Panel for one term. He has published more than 500 full-length scientific papers and chapters, 8 books, and has received the Lifetime Achievement Award of the American and European Heart Valve Societies (2014), the Albert Nelson Marquis Lifetime Achievement Award (2017), and the Kanu Chatterjee Lifetime Achievement Award (2018) from the International Academy of Cardiology.

William C. Cushman is Chief of the Preventive Medicine Section at the Memphis Veterans Affairs (VA) Medical Center, Co-Chair of the National VA Hypertension-Lipid Field Advisory Committee (FAC), and Professor of Preventive Medicine, Medicine, and Physiology at the University of Tennessee Health Science Center. Dr. Cushman graduated from the University of Mississippi School of Medicine in 1974 and completed his residency training there in 1977. He served on the faculty at the University of Mississippi and was on the staff at the VA there from 1977-1988, then moved to the University of Tennessee and VA in Memphis, TN. He has been VA champion for the 2014 and 2019 VA-DoD Hypertension Clinical Practice Guideline committees and was on the JNC 7 and JNC 8 U.S. hypertension guideline committees. He has been an investigator and/or on the leadership for many clinical trials in hypertension, diabetes, and lipid therapy, including many VA Cooperative Studies, NHLBI trials (ALLHAT, ACCORD, and SPRINT), and industry trials. He is currently co-chair of the Diuretic Comparison Project, a VA Cooperative Study, comparing the effect on MACE of the thiazide-type diuretics chlorthalidone and hydrochlorothiazide. He has received more than $60 million in research grant funding, has nearly 300 journal article and book chapter publications, and has received several awards, including the 2010 the VA Clinical Science Research and Development Barnwell Award, the 2017 Inter-American Society of Hypertension Lifetime Achievement Award, and the 2018 American Heart Association's Council on Hypertension Irvine Page-Alva Bradley Lifetime Achievement Award.

Lars Johannesen is a clinical analyst in the Division of Cardiovascular and Renal Products in the Office of New Drugs in CDER/FDA. He received his PhD in 2015 in Medical Science from Karolinska Institutet (Stockholm, Sweden), which focused on the evaluation of ECG data quality metrics and the development of new ECG biomarkers to improve proarrhythmic risk assessment of new drugs.



Mitchell Krucoff graduated Yale University in 1976 Magna Cum Laude with a degree in religious studies. He earned his M.D. from George Washington University in 1980, where he was elected to the Alpha Omega Alpha Medical Honor Society. He trained in angioplasty with Dr. Kenneth Kent at Georgetown University in 1983, and in 1988 moved to Duke University Medical Center where he is currently fully tenured as a Professor of Medicine/Cardiology and a member of the Senior Interventional Cardiology faculty, teaching live trans-radial, stent and coronary device cases in India, China, the Middle East and across the United States. With 30 years of clinical research he serves as Director of the Cardiovascular Devices Unit at the Duke Clinical Research Institute (DCRI) and is a special government employee of the United States FDA, from which he received a Distinguished Service Award in 2007. Through two memos of understanding between Duke and FDA, Dr. Krucoff directs both the Critical Path Cardiac Safety Research Consortium and the Medical Device Epidemiology Network (MDEpiNet) Coordinating Center. Internationally he is the co-Director of the Japan-USA Harmonization By Doing international regulatory affairs group, a founding member of the Global Harmonization Task Force Working Group 5. Dr. Krucoff is also the founder and Director DCRI eECG Core Laboratories. In 2008 he was awarded the honorary Hein JJ Wellens Professorship by the University of

Maastricht in the Netherlands. Dr. Krucoff has published more than 200 peer review papers in addition to several books, and was the lead author of the National Medical Device Registry Task Force recommendations to FDA for a National Medical Device Evaluation System.

Rajnikanth Madabushi is a Team Lead for Guidance and Policy Team in the Office of Clinical Pharmacology, Center for Drug Evaluation and Research, FDA, Silver Springs, MD. Dr. Madabushi has 10 years of regulatory review experience as Pharmacometrics Review and as Team Leader in the Office of Clinical Pharmacology. He was predominantly involved in the application of quantitative clinical pharmacology approaches for regulatory decision making and addressing various drug development issues in the areas of Cardio-Renal, Hematology and Endocrinology drug products. In 2016, Dr. Madabushi became the Team Lead for the new formed Guidance and Policy Team in the Immediate Office of the Office of Clinical Pharmacology. Since then, he has been involved in the drug development, regulation, research and policy from a clinical pharmacology perspective. He is also the CDER Point-of-Contact for the PDUFA VI MIDD Pilot Meeting Program.

Tzu-Yun McDowell is currently a clinical reviewer in the Division of Cardiovascular and Renal Products (DCRP), Office of New Drug (OND), Center of Drug Evaluation and Research (CDER), FDA. She received her Ph.D. from the Department of Epidemiology and Public Health, at University of Maryland, Baltimore. She first joined FDA as a Commissioner's Fellow in 2010 and has worked across different offices within CDER. Since joining DCRP in 2013, she has performed safety reviews of many important drug products and participated in division- and center-wide activities with respect to developing and streamlining quantitative review methodologies. She is additionally interested in regulatory research to promote cardiovascular safety and drug development.

Vasilios Papademetriou is a professor of medicine at Georgetown University School of Medicine, and staff cardiologists at the VA medical center in Washington DC, where he pursues his interests in interventional cardiology and hypertension. He is the head of hypertension, interventional hypertension and vascular medicine program and co-director of the cardiac catheterization laboratory. In recent years he developed expertise in interventional/device based treatment of Resistant Hypertension. He has performed a series of studies in interventional cardiology, Renal Denervation, Baroreceptor stimulation, Coronary disease, diabetes, hypertension and dyslipidemia. He has published over 290 peer-reviewed research papers, review articles, editorials, and book chapters and presented over 600 abstracts at national and international meetings . He served as a local PI for many national and international studies. He serve is a reviewer of several prestigious journals such as Circulation, JAMA, American Journal of Cardiology, American Heart Journal, American Journal of Hypertension, and the New England Journal of Medicine. He served for five years as a member of the Cardio-renal Panel of the Food and Drug Administration. Dr. Papademetriou received his medical degree from Athens University School of Medicine and completed his training at the NIH, Georgetown University and the Department of Veterans Affairs in Washington DC. Dr. Papademetriou is board-certified by the American Board of Internal Medicine and the American Board of Cardiovascular Disease.

Milton L. Pressler is Vice President, Clinical Development and Operations, Pfizer Global Product Development, New York, NY. Dr Pressler graduated with highest distinction from Northwestern University Medical School and is board-certified in Internal Medicine and Cardiology. Prior to joining industry, he was Associate Professor of Medicine and Physiology and Director of the Heart Failure Clinic at Indiana University School of Medicine. His academic publications involved cellular electrophysiology, gap junctions, and molecular mechanisms of cardiac arrhythmias. During his 23 years at Pfizer, he has participated in the clinical development of over 25 unique drugs and drug candidates including quinapril, atorvastatin, eplerenone, apixaban, tofacitinib and celecoxib.

Frank Rockhold is a fulltime Professor of Biostatistics and Bioinformatics at Duke University Medical Center and The Duke Clinical Research Institute. His career includes senior positions at Lilly, Merck, and GlaxoSmithKline, where he retired as Chief Safety Officer. Frank has previously held faculty appointments at Butler University, Indiana University, Penn State University, Virginia Commonwealth University, The University of Pennsylvania as well as Duke. He served as Chairman of board of CDISC, and is past president of the Society for Clinical Trials. He holds a BA in Statistics, and an ScM and PhD in Biostatistics. Frank is a Fellow of the American Statistical Association, The Royal Statistical Society, and the Society for Clinical Trials and is as an Accredited Professional Statistician (US) and a Chartered Statistician (UK). He serves on and chairs numerous data monitoring committees and is widely published across a wide variety of research topics.

Philip Sager is an Adjunct Professor of Medicine at the Stanford University School of Medicine, the previous chair of the FDA Cardiovascular and Renal Drugs Advisory Committee, and an Executive Committee member of the FDA-Sponsored Cardiac Safety Research Consortium. He has played a major leadership role in CV safety issues in drug development. He was the ICH E14 ("the QT Guidance") PhARMA Expert Working Group Topic Leader and is a Steering Committee Member of the FDA Comprehensive In Vitro Proarrhythmia Assay (CIPA) effort. Previous roles have included tenured faculty member at the UCLA School of Medicine, senior leadership roles in the pharmaceutical industry, including Vice President, CV/Metabolic Development at Gilead Sciences and Executive Director at AstraZeneca. He has major development leadership on multiple drugs including Zetia®, Vytorin®, Crestor®, Ranexa®, Letairis®, and Brilinta. He holds an M.D. from Yale University School of Medicine, B.S. degrees in biology and chemistry from the Massachusetts Institute of Technology, trained in internal medicine and cardiology at the Yale School of Medicine, and has published more than 200 original manuscripts and abstracts.

Daichi Shimbo is Associate Professor of Medicine and Ewig Clinical Scholar at the Columbia University Herbert and Florence Irving Medical Center. He received a B.S. from the Johns Hopkins University in Biomedical Engineering and a M.D. from the Albany Medical College. After completing an Internal Medicine residency, Dr. Shimbo went on to complete Chief Medical residency in Internal Medicine and fellowship in Cardiovascular Medicine at the Mount Sinai Hospital in New York, before joining the faculty at Columbia University in 2003. At Columbia, Dr. Shimbo is the Director of the Hypertension Center, Director of the Translational Lab at the Center of Behavioral Cardiovascular Health, and Director of the Cardiovascular Physiology Research in the Cardiovascular Ultrasound Laboratories. He is a preventive cardiologist who has expertise in the area of hypertension diagnosis and management. His primary area of interest in blood pressure measurement, and in the blood pressure phenotypes based in the discordance of hypertension inside and outside of the clinic setting including white coat and masked hypertension. His research has been continuously funded as a Principal Investigator by the NIH/NHLBI for over 15 years.

Norman Stockbridge joined what is now the Division of Cardiovascular and Renal Products in FDA/CDER in 1991, and he has served as the Division Director since 2004.

Douglas Throckmorton is Deputy Director for Regulatory Programs and shares responsibility for overseeing the regulation of research, development, manufacture and marketing of prescription, over-the-counter, and generic drugs in the United States. He is committed to ensuring that the benefits of approved drugs outweigh their known risks. Dr. Throckmorton received his medical degree from the University of Nebraska Medical School and completed his residency and fellowship at Case Western Reserve University and Yale University, respectively. Prior to coming to the FDA in 1997, he conducted basic science research and practiced medicine at the Medical College of Georgia, Augusta, Georgia and Augusta Veterans Administration Hospital.

Raymond R. Townsend is a Professor of Medicine and an Associate Director of the Clinical and Translational Research Center at the University of Pennsylvania. He is currently a Principal Investigator on a 7-center U01 grant (DK-060984) studying factors in the progression of chronic kidney disease and the development and progression of cardiovascular disease in patients with CKD. His formal certifications are in internal medicine (ABIM), nephrology (ABIM), clinical pharmacology (ASCP) and hypertension (ASH). He is a fellow in the American Heart Association and the Council for High Blood Pressure Research. Research interests include role of vascular dynamics in CKD progression and the incidence/development of CVD in CKD. He was an empaneled member of JNC 8, and the co-chair of the 8th AHA Hypertension Summer School and an Investigator in SPRINT. He was

also the AHA Physician of the Year awardee for 2016. His ABPM experience began in Pittsburgh in 1986 using the Spacelabs Analysis Station. In the intervening years he has done industry-sponsored and NIH-sponsored ABPM-based research. He has consulted with several pharmaceutical manufacturs regarindg ABPM data in the fields of Cardiology, Endocrinology and Nephrology. His most recent ABPM publications are in the CRIC (NIDDK) and SPRINT (NHLBI and others) studies.

Patrick Twomey is currently transitioning to Medical Director in the oncology branch of Licensing and Early Development Safety Science at Genentech. For the past 1.5 years, he has been a senior scientist in clinical pharmacology at Genentech working primarily on immuno-oncology therapeutics. Prior to joining Genentech, Patrick was an active duty officer in the US Army Medical Corps where he served as the director of the clinical trial center and chief of clinical pharmacology both at the Walter Reed Army Institute of Research (WRAIR). During his time at the WRAIR, Patrick was a principal and associate investigator on over fifteen clinical protocols for vaccines and small molecules combating or preventing infectious diseases such as malaria, ebola, and dengue. Patrick received his Bachelor's degree in Chemistry and Biochemistry from College of the Holy Cross, his Master's degree in Business Administration from University of North Carolina at Chapel Hill, and his Medical Doctorate from Georgetown University. He completed residency training in internal medicine and fellowship training in clinical pharmacology and has maintained an active clinical practice in internal medicine for the past 12 years.

Ellis Unger is the Director, Office of Drug Evaluation-I, Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER), U.S. FDA. His office oversees the regulation of drugs for cardiovascular, renal, neurological, and psychiatric disorders. Dr. Unger obtained his medical degree from the University of Cincinnati. He completed a fellowship in Cardiovascular Diseases at Johns Hopkins. Dr. Unger was a Senior Investigator in the Cardiology Branch, National Heart, Lung, and Blood Institute, National Institutes of Health, from 1983 to 1997 where he led efforts in translational science on experimental promotion of angiogenesis. From 1997 to 2003, Dr. Unger served as a Medical Officer, Team Leader, and subsequently Branch Chief in the Center for Biologics Evaluation and Research (CBER), FDA. When regulatory authority for therapeutic biologics was transferred to the Center for Drug Evaluation and Research (CDER) in 2003, Dr. Unger joined CDER as Deputy Director of the Division of Cardiovascular and Renal Products. Dr. Unger assumed the role of Deputy Director, Office of Drug Evaluation-I in July 2009, and was promoted to Director in July 2012. He has served on numerous guidance-writing groups at FDA, the Council for International Sciences (CIOMS), and International Conference on Harmonization Expert Working Groups E2F, E2C(R2), M4E(R2), and E19. Dr. Unger has authored and co-authored many scientific articles, and is a co-holder of two patents.

Hector Ventura attended medical school at National University of Buenos Aires School of Medicine and did his Internal Medicine training at Ochsner and cardiovascular disease Fellowship at Ochsner. He is currently Section Head, Advanced Heart Failure/Heart Transplant at the John Ochsner Heart and Vascular Institute, and Professor of Medicine, Ochsner Clinical School-The University of Queensland School of Medicine in New Orleans. He has co-authored more than 600 article, abstracts and book chapters and serves on 21 editorial boards, including the Journal of the American College of Cardiology and the American Journal of Cardiology, and is Associate Editor of Journal of Cardiac Failure, Current Hypertension Reviews and Journal of the American College of Cardiology: Heart Failure. He is also Editor-in-Chief of Current Problems in Cardiology.

Michael A. Weber is a Professor of Medicine at Downstate College of Medicine of the State University of New York. He received his medical degree from Sydney University in Australia. His career has focused largely on hypertension and preventive cardiology. He has been a leading part of several of the clinical trials that have helped define strategies for optimizing cardiovascular protection for patients with hypertension. He has also been very much involved with new drug development going back to the beta blockers and through to the contemporary angiotensin receptor blockers. He is an author of over 500 articles in the peer-reviewed literature and has authored or edited 16 books. He was a founder of the American Society of Hypertension (ASH) and the ASH Hypertension Clinical Specialists Accreditation Program and has served as President of both those organizations. Dr. Weber maintains a strong interest in global hypertension issues and is a member of the Executive Committee of the International Society of Hypertension. He was Chair of the Writing Committee of the 2014 ASH/ISH Hypertension Clinical Practice Guidelines. He is currently Editor in Chief of the Journal of Clinical Hypertension, the official Journal of the World Hypertension League. He is a Fellow of The American College of Physicians, The American College of Cardiology and The American Heart Association. He has served on the Cardiovascular and Renal Drugs Advisory Board of the Food and Drug Administration and continues as a consultant to that Agency. He has also served as Chairman of the Formulary Committee of a major pharmacy benefits provider serving many of the leading health plans in the United States. His main research interests are in clinical trials of patients at high risk of cardiovascular events or strokes. He is also participating actively in trials in patients with metabolic disorders such as diabetes and kidney disease. Dr. Weber currently serves on the Steering Committees of several national and international clinical outcomes trials.

William B. White is Professor of Medicine and Chief of the Division of Hypertension and Clinical Pharmacology in the Calhoun Cardiology Center at the University of Connecticut School of Medicine. He is a Fellow of the Council for High Blood Pressure Research of the American Heart Association (AHA) and was the President of the American Society of Hypertension from 2012-2014. The speaker has a longstanding interest in clinical hypertension and pharmacology, particularly in the areas of ambulatory blood pressure monitoring, clinical trials of antihypertensive drugs, and the impact of non-cardiac drugs on cardiovascular safety. He is the author of over 450 original articles and numerous book chapters in the field of cardiovascular medicine and pharmacology.

Dr. White has also published several textbooks, including Blood Pressure Monitoring in Cardiovascular Medicine and Therapeutics (Springer Verlag) and Hypertension and Related Disorders (CV Mosby Press). To support this work, Dr. White has been the recipient of competitive research funding from the NIH/NIA, the AHA, the Donaghue Research Foundation, and investigator-initiated grants from industry. During the past 2 decades, Dr. White has been part of the leadership of major clinical trials in cardiovascular medicine, including the CONVINCE trial which evaluated cardiovascular outcomes in at risk patients using chronotherapy, the CARES trial which evaluated the cardiovascular safety of xanthine oxidase inhibitors in gout, EXAMINE, which assessed the impact of the DPP-4 inhibitor aloglitpin in patients with type 2 diabetes and acute coronary syndromes, and the MIRCERA PASS trial which assessed mortality outcomes in patients with renal anemia.

Duke-Margolis Moderators:

Mark McClellan 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 & 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.

Gregory Daniel 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.