Duke | Robert J. Margolis, MD Center for Health Policy

Implementation of Signal Detection Capabilities in the Sentinel System

Bethesda Hyatt Regency • Bethesda, MD
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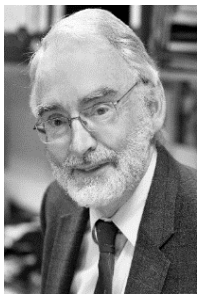
Biographies

Andrew Bate is Senior Director, Epidemiology Group Lead for Analytics, Worldwide Safety & Regulatory at Pfizer and oversees the provision of methodological and analytic expertise to the Epidemiology group in support of Regulatory & Safety activities worldwide. Prior to joining Pfizer in 2009, Andrew was at the WHO Collaborating Centre for International Drug Monitoring, Uppsala, Sweden for more than 12 years, where he headed the Centre's Research function.
Andrew has an extensive research record focused on the development and assessment of a range of methods and tools for signal detection and healthcare database analysis. He has published extensively including serving as Editor of a book on Pharmacovigilance. Ten of his original research publications focus on methods for hypothesis-free signal detection in healthcare databases, and he has presented at international symposia since 2004. Andrew has contributed to several international initiatives and partnerships associated with signal detection including membership of the FDA Science Board Subcommittee on Pharmacovigilance (2010-2011), membership of the CIOMS Working Group VIII on "Practical Aspects of Signal Detection in Pharmacovigilance" published in 2010 and as a member of the Advisory Board of OMOP (2009-2013). Andrew was more recently a co-PI for the IMEDS Evaluation Pilot, the first use of the US Food and Drug Administration's (FDA's) Sentinel System data and analytic tools by a non-FDA stakeholder.
Andrew holds a Masters' degree in Chemistry from Oxford University, and a PhD in Clinical Pharmacology from Umea University in Sweden. His doctorate, awarded in 2003, was on "The use of a Bayesian Confidence Propagation Neural Network in Pharmacovigilance". He was a Visiting Professor in Information Systems and Computing, at Brunel University, London, UK and is an Adjunct Associate Professor in Clinical Pharmacology at NYU School of Medicine and formerly affiliate faculty of the NYU Center for Health Informatics and Bioinformatics. He has served on both the Executive Committee of the International Society of Pharmacovigilance and the Board of the International Society of Pharmacoepidemiology.

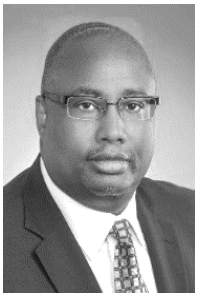
William H. Crown is Chief Scientific Officer of OptumLabs. In this role, he is responsible for research activities of the Labs. From 2004-2013, Dr. Crown was President of the health economics, late phase research, data products, and epidemiology business units at Optum Life Sciences. He was Vice President of Outcomes Research and Econometrics at Thomson Reuters Medstat from 1994-2004. From 1982-1995, Dr. Crown was a faculty member of the Florence Heller Graduate School, Brandeis University, where he taught graduate courses in statistics and conducted research on the economics of aging and long-term care policy. He received his doctorate degree in urban and regional studies from the Massachusetts Institute of Technology, and a master of arts in economics from Boston University. The author of two books and co-author of two

others, Dr. Crown has published over 160 peer-reviewed journal articles, book chapters, and other scholarly papers. Known for his early application of sample selection bias models in the pharmaceutical outcomes research literature, he is a frequent speaker on statistical methods for the analysis of observational data at professional meetings and conferences. In addition to his CSO role within Optum Labs, Dr. Crown is Affiliate Faculty, Mongon Institute for Health Policy, Harvard University. He was also 2013-14 President of the International Society of Pharmacoeconomics and Outcomes Research.

William DuMouchel is Chief Statistical Scientist at Oracle Health Sciences. His current research focuses on statistical computing and Bayesian hierarchical models, including applications to meta-analysis and data mining. Dr. DuMouchel has developed data mining algorithms for drug adverse event associations in spontaneous reports and in clinical research data that have been used widely within regulatory agencies and industry. Dr. DuMouchel received the Ph.D. in Statistics from Yale University and has been a member of the faculties of the University of California at Berkeley, the University of Michigan, MIT, and Columbia University.

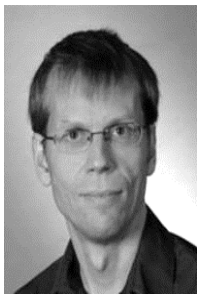


Stephen Evans is Professor of Pharmacoepidemiology at the London School of Hygiene and Tropical Medicine (LSHTM) and is a medical statistician. Stephen was at the UK Medicines Control Agency (now the MHRA) from 1995 to 1999, and 2000-2002. While at the MCA he dealt with major safety issues such as HRT and breast cancer; vitamin K and childhood cancer; MMR and autism. After training in Physics and Computing, he joined The London Hospital in 1970 becoming Professor of Medical Statistics in 1990. He is or has been on various editorial boards, including the British Journal of Clinical Pharmacology and wass an Associate Editor of Pharmaco-epidemiology and Drug Safety. He has been a statistical advisor to the British Medical Journal and a member of its editorial review committee for over 15 years. He was an independent expert member of the European Medicines Agency's committee that deals with drug safety (PRAC, 2012-18), and was a member of the WHO Global Advisory Committee on Vaccine Safety. He is an Honorary fellow of The Royal College of Physicians of London.



Kenneth Hornbuckle is a Research Fellow in the Pharmacoepidemiology Group which is a component within the Global Patient Safety Organization at Eli Lilly and Company. He has over 20 years of experience in pharmacovigilance, drug safety surveillance, pharmacoepidemiology, benefit-risk assessment and risk management. In his current role, Dr. Hornbuckle provides scientific support and consultation to risk management efforts, including risk identification, risk evaluation, risk minimization activities across the Company's portfolio. He is an adjunct professor at Indiana University Purdue University – Indianapolis, Fairbanks School of Public Health, Department of Epidemiology. Dr. Hornbuckle received a Doctor of Veterinary Medicine (DVM) from Tuskegee University and a MPH, PhD (epidemiologic science) from the University of Michigan.

Juhaeri Juhaeri is Vice President and Head of Epidemiology and Benefit-Risk at Sanofi. Juhaeri is an Epidemiologist and Statistician with over 20 year experience in epidemiologic research in academia and in pharmaceutical industry. He joined Sanofi in 2001 where he established a Real World Data system for epidemiologic research and signal detection. He has been leading various public-private partnership projects in the fields of Pharmacovigilance and Epidemiology, as well as quantitative Benefit-Risk Methods and signal detection. He was a member of the Steering Committee of IMI PROTECT Project, a European Consortium on Pharmacovigilance and Pharmacoepidemiology, and a leader of one of the case studies to evaluate various Benefit-Risk methods. He is Industry Lead of Methods Working Group in IMI-PREFER, a project on patient preferences in Benefit-Risk Assessments during the Drug Life Cycle. Juhaeri is an Adjunct Faculty at the Gillings School of Global Public Health, University of North Carolina Chapel Hill, North Carolina. He received his Ph.D. in Epidemiology from the same university.



Martin Kulldorff is a biostatistician in the Division of Pharmacoepidemiology and Pharmacoeconomics at the Brigham and Women's Hospital. His current research centers on developing new statistical methods for post-market drug and vaccine safety surveillance. He has developed new sequential statistical methods for near real-time post-market drug and vaccine safety surveillance, where the purpose is to use weekly, monthly or other frequent data feeds to find potential safety problems as soon as possible. He has developed a tree-based scan statistic for post-market drug and vaccine safety surveillance. Keeping the outcome definitions flexible, the method simultaneously evaluates thousands of potential adverse events and groups of related events, adjusting for the multiple testing inherent in such an approach. Another more recent area of methodological work is the development of new statistical methods for evaluating the comparative safety of different childhood vaccine schedules. A fourth major area of methodological research is spatial and spatio-temporal disease surveillance, for which Dr. Kulldorff has developed various scan statistics for disease cluster detection and investigation; and for the early detection of infectious disease outbreaks. As a biostatistician, Dr. Kulldorff also does collaborative and consulting work with epidemiologists and clinicians, using a wide variety of study designs and methods for many different types of diseases. Dr. Kulldorff received his bachelor's degree in mathematical statistics from Umeå University in Sweden, and his doctorate in operations research from Cornell University.

Mark Levenson is the Director of the Division of Biometrics 7 in the Office of Biostatistics/Office of Translational Sciences/Center for Drug Evaluation and Research of FDA. At FDA, he has been the primary reviewer or secondary reviewer on many major pre-market and post-market drug safety problems. He has contributed to the methodology of the application of meta-analysis and propensity score analysis to the regulatory setting. He is active in CDER's efforts in the Sentinel Initiative, reducing prescription opioid abuse, and real-world evidence.

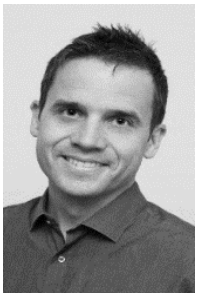
Judith C. Maro is an Assistant Professor in the Department of Population Medicine at Harvard Medical School and the Harvard Pilgrim Health Care Institute. She received her doctorate in Engineering Systems at the Massachusetts Institute of Technology (MIT). Her doctoral work examined practical implementation of prospective sequential database surveillance activities in the Sentinel System using modeling and simulation. She works with the Therapeutics Research and Infectious Disease Epidemiology group and acts as the Sentinel Operations Center Operations Lead. Dr. Maro's main research interest is the modeling and simulation of large-scale engineering systems (e.g., observational database networks) with the aim to improve the efficiency of public health activities. She is currently focusing on the implementation of pharmacovigilance techniques, particularly continuous near-real time sequential statistical analysis methods and data-mining. She is also interested in developing these system-based models into teaching tools as simulation-based in silico "microworlds" in which users "practice" testing, adapting, and honing policy/implementation strategies to manage complex public health systems prior to actual implementation in the real world.

Monica Muñoz is the Deputy Director of the Division of Pharmacovigilance I (DPV-I) in the Office of Surveillance and Epidemiology within the FDA's Center for Drug Evaluation and Research. In this role she provides scientific oversight for pharmacovigilance activities and initiatives executed by the Division. Prior to her current position, she served as safety evaluator team leader for cardiology and renal products and safety evaluator for neurology products in DPV-I. Monica received her Bachelor of Science degree in biology from Texas A&M University-Kingsville, her Doctor of Pharmacy from Texas Tech University, and a Master of Science in Pharmacoepidemiology from the University of Florida.

Jennifer Clark Nelson is Director of Biostatistics and a Senior Investigator at Kaiser Permanente Washington Health Research Institute and an Affiliate Professor of Biostatistics at the University of Washington. Dr. Nelson's research focuses on methods to quantify post-market safety and effectiveness for drugs and vaccines. She is particularly interested in addressing the statistical challenges of multi-site safety studies that use electronic health record data from large health care systems. She has authored over 80 publications, primarily in this area. Since 2009, Dr. Nelson has provided national leadership as Methods Core Lead and Senior Statistician for the Food and Drug Administration's (FDA's) Sentinel Network that is designed to facilitate active and rapid safety surveillance for FDA-regulated medical products. She has also led the Methodology Committee for the Centers for Disease Control and Prevention sponsored Vaccine Safety Datalink (VSD) project, a national collaboration that has involved 10 health care systems and monitored vaccine safety in the U.S. since 1990. Dr. Nelson earned the 2009 VSD Margarette Kolczak Award for outstanding biostatistical and epidemiological contributions in the field of vaccine safety. Her 2013 paper that adapted group sequential monitoring methods to a real-world observational vaccine safety data setting was one of the

American Journal of Epidemiology's Articles of the Year. She received her PhD in Biostatistics at the University of Washington in 1999.

Michael D. Nguyen is the FDA Sentinel Program Lead and Deputy Director of the Regulatory Science Staff in the Office of Surveillance and Epidemiology at the Center for Drug Evaluation and Research (CDER). He oversees the day-to-day management of the Sentinel Program for the Agency and coordinates scientific operations, routine safety analyses, and data infrastructure development. He previously served as the Acting Director and Deputy Director of the Division of Epidemiology in the Center for Biologics Evaluation and Research (CBER), where he led CBER's Sentinel Program and was involved in postmarketing safety surveillance of vaccines, blood components, and blood-derived products. Prior to working at the FDA, he completed his training in pediatrics at Washington University in St. Louis, and served as an officer in the Epidemic Intelligence Service at the Centers for Disease Control and Prevention.



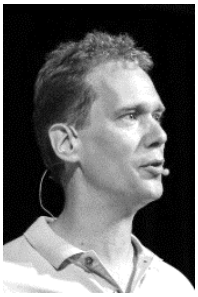
Niklas Norén is Chief Science Officer and Head of Research at the Uppsala Monitoring Centre. He is responsible for the scientific direction of the center and oversees 25 pharmacists, data scientists and medical doctors engaged in scientific development, safety signal detection and capacity building. He has published extensively on statistical pattern discovery in observational medical data, primarily adverse event reports and electronic medical records. His research on duplicate detection and subgroup discovery has been internationally awarded. In Europe, he has led collaborative projects in pharmacovigilance funded by the European Commission including: the signal detection work-package in PROTECT; the work-packages on detecting substandard medicines and drug dependence from adverse event reports in Monitoring Medicines; and the social media analytics work-package in WEB-RADR. Internationally, he led Uppsala Monitoring Centre's contributions to the Observational Medical Outcomes Partnership and is a member of the editorial board for Drug Safety. Dr. Norén holds a PhD in Mathematical Statistics from Stockholm University in 2007 and a Master's degree in Engineering Physics from Chalmers University of Technology in 2002. He has worked in various positions at the Uppsala Monitoring Centre and affiliated organizations since 2003.

Simone Pinheiro joined the FDA in 2009 and is currently the director of the Division of Epidemiology-1 (DEPI-1), in the Office of Surveillance and Epidemiology (OSE), in the Center of Drug Evaluation and Research (CDER), at the Food and Drug Administration (FDA). Together with the Division of Epidemiology-2 (DEPI-2), The Divisions of Epidemiology (DEPIs) are composed of over 60 pharmaco-epidemiologists and drug use analysts primarily responsible for the evaluation of use and safety of drugs and biologics post-approval. In the pre-approval space, the DEPIs are involved in determining strategies for the safety surveillance and evaluation after approval and in

the use of real-world evidence in regulatory decision-making. Dr. Pinheiro obtained her Doctoral and Master's Degrees in Epidemiology from the Harvard T.H. Chan School of Public Health.

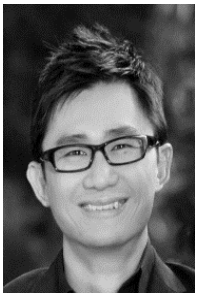
Mary Beth Ritchey is the Director, Epidemiology, Medical Devices & Real-World Evidence at RTI-HS. In her role, Dr. Ritchey performs and oversees the scientific, technical, and logistic aspects of projects including prospective and retrospective noninterventional safety, effectiveness, and utilization studies, registry governance and implementation, analyses of the regulatory landscape for novel therapeutics and rare diseases, and consults on timing, design, and practical application of methods for real-world studies. Prior to joining RTI-HS, Dr. Ritchey's career spanned government and industry. During her tenure at the US FDA, she managed the device Postmarket Surveillance Studies program and was involved with the Medical Device Epidemiology Network and Sentinel initiatives. At Merck, she developed data strategy tools, collaborations, and a continuous learning organization for Comparative and Outcomes Evidence. At Procter & Gamble, she enhanced the signal and risk management programs to include synthesis and interpretation across multiple disparate data sources. She obtained her masters and doctorate degrees in Epidemiology from the UNC Gillings School of Global Public Health and holds an adjunct faculty appointment in the Center for Pharmacoepidemiology and Treatment Science at Rutgers University.

Mary Frances Schubert is Vice President, Clinical Safety and Risk Management at Merck which is part of the Global Regulatory Affairs and Clinical Safety Organization (GRACS). She received a B.S. in Biology from Villanova University, an M.D. from Hahnemann University School of Medicine, and completed an internship and internal medicine residency at the New York Hospital/Cornell Medical Center. Prior to joining Merck and Co. in 2001, her faculty appointments included Clinical Assistant Professor of Medicine, University of Pennsylvania and Assistant Professor of Medicine at Temple University. Her industry roles at Merck and Co. have included extensive experience as a regulatory lead in the therapeutic areas of neuroscience and gastrointestinal products. She also was the product development team chair for a late stage neuroscience compound. Following those roles she transitioned to the clinical safety group where she took increasing responsibility for safety activities in support of a broad range of therapeutics areas, including Associate Vice President, Clinical Safety and Risk Management serving as the therapeutic area lead for products in oncology and bone. As Vice President of Regulatory Affairs – US and Global Functions, Mary Frances worked across GRACS to oversee two global functions (Worldwide Product Labeling, Medical Device/Combination Product Center of Excellence) and managed key US-focused regulatory functions which included the U.S. Regulatory Subsidiary and the Office of Promotion and Advertising Review. She returned to Clinical Safety and Risk Management early in 2018 to lead the department.



Martijn Schuemie is a research fellow and director at Janssen R&D, and is a visiting scholar at the Biostatistics department at UCLA. Martijn is one of the founders of Observational Health Data Science and Informatics (OHDSI), and a leader of the OHDSI Population-Level Estimation workgroup. After receiving his Master's degree in Economics Martijn obtained his PhD in Computer Science on the topic of human-computer interaction in virtual reality systems for phobia treatment. Later, Martijn started research on the application of text-mining the scientific literature in support of molecular biology. He then moved to pharmacoepidemiology, and became one of the lead investigators in the EU-ADR project tasked with building a prototype drug safety signal detection system using population-level observational data. In 2012 he received a one-year fellowship of the FDA and became an active Observational Medical Outcomes Partnership (OMOP) investigator. In 2013 Martijn joined Janssen R&D, where he continued his research in OMOP and later OHDSI. Martijn's primary interest is improving the science of observational research through open science, empirical evaluation and calibration, and large-scale observational studies to improve reproducibility.

Miriam Sturkenboom is a pharmacoepidemiologist, currently working at the Julius Global Health group of University Medical Center Utrecht in the Netherlands. She worked 20 years in the department of Medical Informatics at Erasmus MC, where she was a full professor in Observational Data Analysis. She is past president of the International Society for Pharmacoepidemiology. She serves as expert to EMA, FDA, WHO and many other organizations. Her research interests focus on knowledge discovery from data collected in routine health care to improve evidence on drug and vaccine safety in particular in vulnerable populations (children, pregnancy and elderly). She initiate the EU-ADR project, which tested methods for signal detection on longitudinal health care records in 2008. She has coordinated multiple distributed drug safety and is coordinator of the European commission funded ADVANCE project aiming to establish a tested system for the monitoring of benefits and risks of vaccines. She pioneered and implemented the data management and data sharing infrastructures for large collaborative distributed data network studies to allow for European vaccines safety studies during the pandemic VAESCO) and global vaccine and drug studies (SOMNIA, GVS-MCC). In terms of quantitative research outputs: she supervises/d more than 50 PhD students, has more than 380 peer reviewed papers in the area of pharmacovigilance, pharmacoepidemiology and medical informatics and an h-index of 72.



Darren Toh is an Associate Professor in the Department of Population Medicine at Harvard Medical School and Harvard Pilgrim Health Care Institute. He is a pharmacoepidemiologist with an interest in the comparative safety and effectiveness research of medical products. His research has been focused on 1) assessing the risks and benefits of medical products using electronic data collected as part of routine healthcare delivery, and 2) developing and applying privacy-protecting analytic methods to conduct multi-center studies in distributed data networks.

Darren is Director of Applied Surveillance at the Operations Center of the FDA-funded Sentinel System, a congressionally mandated national medical product safety surveillance system. He is Principal Investigator of projects funded by the National Institutes of Health (U01EB023683), the Agency for Healthcare Research and Quality (R01HS026214), the Patient-Centered Outcomes Research Institute (ME-1403-11305), and the Food and Drug Administration. Darren received his doctoral degree in Epidemiology from the Harvard School of Public Health.

Theresa (Terry) Toigo is Associate Director for Drug Safety Operations, Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA). She is responsible for the operational management of significant and timely drug safety issues and the creation and oversight of CDER processes for management of cross-office and cross-center safety issues. Immediately prior to returning to CDER in October 2010, Ms. Toigo served as Director, Office of Special Health Issues for 15 years, working with patients, their advocates, and health professionals to encourage and support their active participation in FDA regulatory decision-making. Ms. Toigo joined FDA in 1984, working as a Consumer Safety Officer in CDER. She held various FDA positions in CDER, the Center for Biologics Evaluation and Research, and the Commissioner's office. Ms. Toigo received her pharmacy (BS) and business (MBA) degrees from Rutgers University.

Joanne Waldstreicher is Chief Medical Officer, Johnson & Johnson. In this role, she has oversight across pharmaceuticals, devices and consumer products for safety, epidemiology, clinical and regulatory operations transformation, collaborations on ethical science, and technology and R&D policies, including those related to trial transparency and compassionate access. She chairs the Development Committee for Janssen R&D, the pharmaceuticals group of Johnson & Johnson, and supports Device and Consumer Development committees. Joanne is also a Faculty Affiliate of the Division of Medical Ethics, Department of Population Health, New York University School of Medicine. Among her prior roles, Joanne was responsible for late-stage development in neuroscience, cardiovascular disease and metabolism at Janssen. Before joining Johnson & Johnson in 2002, she headed Endocrinology and Metabolism clinical research at Merck Research Laboratories, overseeing development programs in atherosclerosis, obesity, diabetes, urology and dermatology. She was honored with the Key Innovator Award, among other distinctions. Joanne received both the Jonas Salk and Belle Zeller scholarships from the City University of New York, and graduated Summa Cum Laude from Brooklyn College. She graduated Cum Laude from Harvard Medical School, completed her internship and residency at Beth Israel Hospital, and her endocrinology fellowship at Massachusetts General Hospital. She has received numerous awards and scholarships, and is an active scientific author. In 2016, the National Association of Female Executives named her Healthcare Champion of the Year. Joanne combines broad experience in science and medicine with a passion for advancing transparency and ethics, with a goal of improving the lives of patients and consumers worldwide.

Diana Zuckerman is President of the National Center for Health Research, a nonprofit think tank that conducts and analyzes research, and uses the results to improve policies and programs affecting the health of adults and children. The Center's largest program is its Cancer Prevention and Treatment Fund. She has testified about the safety and efficacy of medical and consumer products dozens of time before Congress, federal agencies, state legislative committees, and the Canadian Parliament. She has also been interviewed on all major news media in the U.S. and numerous other countries. After serving on the faculty of Vassar and Yale and as a researcher at Harvard, Dr. Zuckerman went to Capitol Hill as a AAAS Congressional Science Fellow. Trained in epidemiology and public health at Yale Medical School, she worked for a dozen years as a Congressional staffer and was a senior policy advisor to First Lady Hillary Rodham Clinton. While in her current position at the National Center for Health Research, she was also a fellow at the University of Pennsylvania Center for Bioethics, and was the first non-physician elected to the Women in Medicine International Hall of Fame. She previously chaired Maryland's Women's Health Promotion Council and until recently served on the Medicare Evidence Development & Coverage Advisory Committee. She currently serves on the Board of Directors of the Reagan-Udall Foundation and Alliance for a Stronger FDA. She serves as a peer reviewer for numerous medical and public health journals and is the author of five books and dozens of book chapters and articles in medical and academic journals and newspapers.

Duke-Margolis Moderators:

Mark McClellan is the Robert J. Margolis Professor of Business, Medicine, and Health Policy, and founding Director of the Duke-Margolis Center for Health Policy at Duke University. With offices in Durham, NC and Washington, DC, the Duke-Margolis Center is a university-wide, interdisciplinary initiative that is nationally and internationally recognized for its research, evaluation, implementation, and educational initiatives to improve health and health policy. The Center integrates Duke's expertise in the social, clinical, and analytical sciences with health care leader and stakeholder engagement to develop and apply policy solutions that improve health and the value of health care locally, nationally, and worldwide. Dr. McClellan is a physician and an economist who has informed and improved a wide range of strategies and policy reforms to advance health care, including payment reform to promote better outcomes and lower costs, methods for development and use of real-world evidence, and strategies for more effective biomedical 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. With highly distinguished record in public service and academic research, Dr. McClellan is a former administrator of the Centers for Medicare & Medicaid Services and former commissioner of the U.S. Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy. These reforms 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. He previously served as a member of the

President's Council of Economic Advisers, senior director for health care policy at the White House, and Deputy Assistant Secretary for Economic Policy at the Department of the Treasury. Dr. McClellan is the founding chair and a current board member of the Reagan-Udall Foundation for the FDA and a member of the National Academy of Medicine (NAM), where he chairs the 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 is also a Senior Advisor on the faculty of the University of Texas Dell Medical School and co-chair of the Accountable Care Learning Collaborative. Dr. McClellan is an independent director on the boards of Johnson & Johnson, Cigna, and Alignment Healthcare. 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.