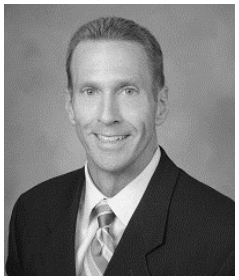
Duke-Margolis Center for Health Policy

Enhancing the Application of Real-World Evidence In Regulatory Decision-Making

Washington Plaza Hotel • Washington, DC
March 3-4, 2016

Biographies

Marc L. Berger, MD is Vice President, Real World Data and Analytics (RWDnA) in the Global Health & Value group at Pfizer, Inc. Marc has held senior-level positions in industry including Executive Vice President and Senior Scientist at OptumInsight; Vice President, Global Health Outcomes at Eli Lilly and Company; and Vice President, Outcomes Research and Management at Merck & Co., Inc. Marc has served on the Medicare Evidence Development & Coverage Advisory Committee (MedCAC) for CMS, the steering committee for the AHRQ Centers for Research and Education on Therapeutics (CERTs), the board of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), the Advisory Council for North America (ACNA) of the DIA, and the editorial advisory board of Value in Health. Currently, he serves as chair of the Innovative Technology Advocacy Committee of PhRMA. Marc has written or co-written more than 100 peer-reviewed articles, book chapters, and other publications on a range of topics including health services research, outcomes research, health economics, and health policy. He co-edited "Health Care, Cost, Quality, and Outcomes – ISPOR Book of Terms" which was published in 2003 and was subsequently translated into nine languages. His current research interests focus on rapid cycle analytics of real world data including electronic medical records to provide timely insights into the outcomes associated with alternative therapeutic strategies and the use of big data and advanced analytics (including machine learning) to develop predictive models in support of precision medicine drug development.



Marc M. Boutin, JD is the chief executive officer of the National Health Council, the only organization that brings together all segments of the health community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers. Boutin has been a leading voice for greater patient involvement at every stage of the continuum, starting with the development of new drugs, to regulatory oversight of health care delivery, to shared decision-making at the point of care. Under his leadership, the NHC has convened a broad range of stakeholders to create and effectively implement pragmatic strategies and public policy that address diverse issues, such as enhancing patient engagement, advancing the development of new treatments, and developing a better health delivery system to meet the needs of people with chronic conditions.

Bill Capra, PhD is Senior Director and Global Head of Oncology for the Real World Data Science function at Roche/Genentech. Prior to this role he held various roles within Biostatistics in the pharmaceutical industry over 20 years with a focus primarily on the oncology and infectious disease therapeutic areas. Bill has a B.S in Mathematics from Drexel University and a Ph.D. in Statistics from the University of California, Davis.

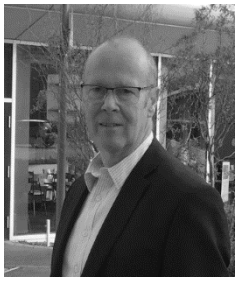
William W. Chin, MD is the Executive Vice President for Science and Regulatory Advocacy and Chief Medical Officer at PhRMA where he leads PhRMA's continuing efforts in science advocacy in the drug discovery and development ecosystem. He was the Executive Dean for Research, Bertarelli Professor of Translational Medical Science and Professor of Medicine at Harvard Medical School (HMS). In this role, Dr. Chin spearheaded efforts to design and implement the vision for research at HMS, with special emphasis on interdisciplinary and translational research that crosses departmental and institutional boundaries. Chin is a Harvard-trained endocrinologist and longstanding faculty member. His impressive career is exemplified in part by his extensive bibliography of nearly 300 papers, chapters and books, most of which were generated during his 25 years on the Harvard Medical School faculty. During his tenure as a faculty member in the Department of Medicine at Brigham and Women's Hospital, he became chief of the Genetics Division and a Howard Hughes Medical Institute investigator, advancing to professor of Medicine, and Obstetrics, Gynecology and Reproductive Biology at HMS. As a pioneering molecular endocrinologist at HMS, Dr. Chin embraced the early use of emerging DNA technology to make important discoveries regarding the structure, function and regulation of hormone genes. His investigations often demonstrated a translational research theme, connecting basic laboratory discoveries to their physiologic relevance in animal models and humans. He has been honored with numerous awards for research, mentorship and leadership. Prior to HMS, Dr. Chin was at Eli Lilly and Company, where he had worked for the last decade, most recently as senior vice president for Discovery Research and Clinical Investigation. He received his AB (Chemistry; summa cum laude) from Columbia University and his MD from Harvard Medical School.

Carrie D'Andrea, RN currently works as the Nurse Navigator for the Carol Franc Buck Breast Care Center at the University of California, San Francisco. In this position, she serves both the medical and surgical oncology teams by coordinating the care of new patients. Carrie previously worked at the Breast Care Center as the lead Clinical Research Coordinator for the I-SPY 2 TRIAL. Through each of these positions, Carrie has developed a strong interest in breast cancer research and the practice of nursing in improving quality of life for patients. Carrie has a BA in Political Science from Saint Mary's College of California and received her BSN from the Duke University School of Nursing in 2014.

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.

Nancy Dreyer, PhD, MPH is Global Chief of Scientific Affairs and Senior Vice President at Quintiles Real-World and Late-Phase Research where she leads an international team in the design, conduct, and interpretation of "real-world" health research, including effectiveness, safety, quality improvement activities and sports injuries. Among other activities, she is a senior editor of "Registries for Evaluating Patient Outcomes: A User's Guide," now in its third edition and leads the GRACE Initiative for developing Good Research Practices for Observational Studies of Comparative Effectiveness (www.graceprinciples.org). She is a member of the FDA's National Medical Device Evaluation System Planning Board and is an advisor to Center of Postmarketing Safety Evaluation at Peking University. She was co-lead investigator with the European Medicines for a direct-to-patient study evaluating new methodologies for pharmacovigilance. She is a fellow of the International Society of Pharmacoepidemiology (ISPE) and a former director, also having served on the board of the Drug Information Association through 2015. In addition to her work at Quintiles, Dreyer is an Adjunct Professor of Epidemiology at the UNC-Chapel Hill. Prior to joining Quintiles, she was CEO of an independent research firm for 20 years, where she founded the journal, Epidemiology.

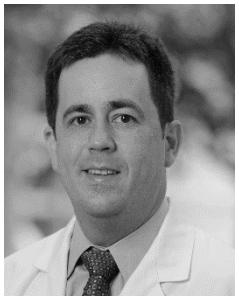
Rachael Fleurence, PhD is Program Director of the Research Infrastructure Program at the Patient-Centered Outcomes Research Institute (PCORI). In this role, she leads the research prioritization initiative to help identify important patient- and stakeholder-generated questions and establish a rigorous research prioritization process to rank these questions. A methodologist with experience in systematic reviews and evidence synthesis, health technology assessment, and research prioritization methods, Fleurence has 15 years of experience in the field of health outcomes research, including seven years in the life sciences consulting industry, where she held senior leadership positions at United BioSource Corporation and ICON plc. From 1995 to 1999, she was a program officer at the World Health Organization for the revision of the International Classification of Disabilities. Fleurence co-chaired the 2011 ISPOR issue panel review committee for the 16th annual meeting and was an associate editor for the journal Health Outcomes Research in Medicine in 2011 and 2012. She is currently co-editing a volume on Comparative Effectiveness for Springer's upcoming handbook on health services research. Fleurence received a BA from Cambridge University, an MA in business management from the Ecole Superieure des Sciences Economiques et Commerciales (ESSEC)-Paris, and an MSc and PhD in health economics from the University of York in the United Kingdom.



Martin Gibson, MD, PhD is Director of the NIHR Clinical Research Network for Greater Manchester and Clinical Director for Business Development for NIHR CRN. He is also Research and Informatics Director for the Greater Manchester Academic Health Science Network and Chief Executive of Northwest EHealth. Martin is a consultant physician specialising in diabetes and lipid disorders at Salford Royal NHS Foundation Trust where he was formerly R&D Director of both the acute and primary care Trusts. Martin is an active clinical trialist and has had a long-term interest in the use of electronic clinical data systems to improve healthcare and facilitate research.

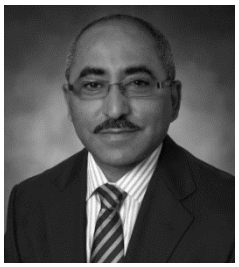
Clifford Goodman, PhD, MS is Senior Vice President and Director of the Center for Comparative Effectiveness Research at The Lewin Group. Cliff joined The Lewin Group in 1996. He has 30 years of experience working with government, industry and nonprofit organizations in such areas as health technology assessment, comparative effectiveness research, health economics, and studies pertaining to health care innovation, regulation, and payment for pharmaceuticals, biologics, medical devices, and other interventions. Other recent areas include pharmacogenomics, diagnostic testing, personalized medicine, organ donation and transplantation, and policy applications of cost-effectiveness analysis. He served as Chair of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) for the Centers for Medicare & Medicaid Services (2009-2012). Dr. Goodman is Past President of the professional society, Health Technology Assessment International (HTAi), and is a Fellow of the American Institute for Medical and Biological Engineering. A compelling public speaker on these topics, Cliff is also a nationally recognized health policy issues moderator and expert panel facilitator. He received a Doctor of Philosophy from The Wharton School, University of Pennsylvania, a Master of Science from The Georgia Institute of Technology, and a Bachelor of Arts from Cornell University.

Jennifer Graff, PharmD is the National Pharmaceutical Council's (NPC) vice president of comparative effectiveness research. Dr. Graff works to advance NPC's comparative effectiveness research (CER) and evidence-based medicine policy research initiatives assessing the methods, interpretation and application of CER. Most recently, Dr. Graff served as associate director of health outcomes and pharmacoeconomics at MedImmune, where she was responsible for health outcomes and pharmacoeconomics for 10 products in clinical development for the respiratory and inflammation therapy areas. She also developed strategic research and case studies to identify market challenges and enhance product differentiation. Prior to MedImmune, she held several positions at the Pfizer Pharmaceuticals Group, most recently as the associate director for worldwide outcomes research. Dr. Graff holds a Doctorate of Pharmacy from the University of Nebraska Medical Center, and completed a Health Outcomes and Pharmacoeconomics fellowship at the University of Michigan.



Adrian Hernandez, MD, MHS is a cardiologist with extensive experience in clinical research ranging from clinical trials to outcomes and health services research. He is the Faculty Associate Director of the Duke Clinical Research Institute and Director of the Health Services and Outcomes Research Domain. He has led several research grants funded to address issues in clinical care, health policy, quality of care, and outcomes. He is the PI of multiple large studies including the NHLBI's Heart Failure Research Network, PCORI funded study, PROSPER, on comparative effectiveness in stroke and AHA's Get With the Guidelines Registry. He is also the Coordinating Center PI for PCORI's PCORNet and the NIH's Collaboratory, both of which aim to transform clinical research using electronic health records and health system data. He is the PI of the coordinating center for several large clinical trials including ASCEND-HF (nesiritide/heart failure), EXSCEL (exenatide/diabetes) and HARMONY-Outcomes (albiglutide/diabetes). Dr. Hernandez has over 300 published articles in high-tier journals on cardiovascular outcomes including the *New England Journal of Medicine, Journal of the American Medical Association*, and *Lancet.* He serves on the leadership of several national committees such as AHA's Scientific Sessions, AHA's Heart Failure Committee, ACCF Task Force on Clinical Expert Consensus Committee, and HFSA Guidelines Committee. He has been recognized for his research through numerous awards and was elected to the American Society of Clinical Investigation in 2012. He has mentored over 25 students, residents, fellows and faculty and has been a recipient of the Robert M. Califf Mentorship Award.

Michael Hogarth, MD has a degree in Biomedical Engineering from Texas A&M, and a medical degree from the University of Texas Southwestern Medical School. He completed Internal Medicine training at the UC Davis Medical Center in 1995 and a Fellowship in Medical Informatics in the UC Davis Department of Pathology in 1997. He has been a faculty at UC Davis since 1997. Dr. Hogarth has led a number of large-scale informatics initiatives. Since 2004, Dr. Hogarth has led the development and on-going technical operation of the California Electronic Death Registration System (http://www.edrs.us), the largest electronic death registration system in the U.S. today. His team also developed the Maryland EDRS, which went live in 2015. Since 2010, he has been the Chief Medical Information Officer and informatics lead for the UC-wide Athena Breast Health Network project (http://www.athenacarenetwork.org), which involves electronic patient, reported information from over 100,000 women in California. Dr. Hogarth is the UC Davis site informatics lead for the pSCANNER network, a PCORI funded distributed clinical research data network (CDRN) with access to over 30 million patient records. Additionally, he serves as the Medical Director of the UCDHS "Clinical Registries" group, which manages over a dozen clinical registries used for quality improvement and clinical outcomes research within UC Davis.



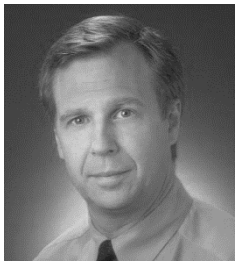
Solomon Iyasu, MD, MPH joined Merck in August of 2015 as head of the Pharmacoepidemiology department in MRL. Prior to joining Merck, Dr. Iyasu was Director of the Office of Pharmacovigilance and Epidemiology (OPE) in the Office of Surveillance and Evaluation (OSE) for the Center for Drug Evaluation and Research. As the Director of OPE, Dr. Iyasu was responsible for the Divisions of Pharmacovigilance, the Divisions of Epidemiology, and CDER's participation in Sentinel Surveillance Program as well as all related drug safety epidemiology research programs. Prior to his position in OPE, he served as the director of the newly created Division of Epidemiology in OSE and is largely credited with building the regulatory epidemiology program and vastly increasing the role of epidemiological data in regulatory decision making. During his 13 year career with the FDA, Solomon has had leadership positions on various committees and workgroups including guidance development workgroups and CDER's Drug Safety Oversight Board. Prior to the FDA, Solomon was at the Centers for Disease Control and Prevention conducting perinatal and pediatric epidemiology studies to evaluate pregnancy and infant outcomes. Dr. Iyasu has published numerous scientific research papers and book chapters pertaining to pharmacoepidemiology, the epidemiology of pregnancy and newborn outcomes, medical product safety, regulatory policy and public health. Dr. Iyasu received his medical training at the University of Delhi, India and his Master of Public Health at the Johns Hopkins University. He subsequently completed a 2-year fellowship training in Applied Epidemiology with the Epidemic Intelligence Service and a Residency Program in Preventive Medicine at the Centers for Disease Control and Prevention in Atlanta, Georgia.

Jonathan P. Jarow, MD is currently the senior medical advisor to the Center Director and chair of the medical policy council in CDER at FDA. Jonathan previously served as the director of CDER's Office of Medical Policy and as deputy director of the Office of Hematology and Oncology Products. He is a Board Certified Urologist and prior to joining the FDA he was in academic medicine for over 20 years. His last academic appointment was Professor of Urology, Pathology, Radiology, and Molecular Biology & Biochemistry at Johns Hopkins University.

Lisa LaVange, PhD is Director of the Office of Biostatistics in the Office of Translational Sciences, Center for Drug Evaluation and Research, U.S. Food and Drug Administration (FDA). As Director, she oversees approximately 170 statistical reviewers and staff members involved in the development and application of statistical methodology for drug regulation. She is a member of the PDUFA V steering committee and serves on the CDER Antibacterial Drug Development Task Force. Prior to joining the FDA, Dr. LaVange was a professor and Director of the Collaborative Studies Coordinating Center (CSCC) in the Department of Biostatistics, Gillings School of Global Public Health at the University of North Carolina at Chapel Hill, where she served as principal investigator of the coordinating centers for several large-scale multi-center clinical trials, epidemiology studies, and patient registries. Before joining academia, Dr. LaVange spent ten years in the pharmaceutical industry and 16 years in non-profit research. She is a fellow of the American Statistical Association, served as President of the Eastern North American Region of the International Biometric Society (IBS, 2007), and currently serves on the IBS Executive Board. She is co-editor of the Journal of Pharmaceutical Statistics and editor-in-chief of the ASA-SIAM book series.

K. Kimberly McCleary is Managing Director at *FasterCures*, a center of the Milken Institute determined to remove barriers to medical progress. As a member of the senior management team, Kim helps define, scope and initiate new programmatic activities and strengthen existing programs for the benefit of diverse stakeholders across the medical research and healthcare ecosystem. Kim leads the Patients Count: Science of Patient Input program through which *FasterCures* aims to improve health by expanding opportunities for patients' perspectives to shape the processes by which new therapies are discovered, developed and delivered. This includes advancing patient-focused drug development, expanding patient input into regulatory decision-making and fostering shared definitions of value to improve healthcare quality, efficiency, and effectiveness while rewarding innovation in medical products and services. McCleary serves on numerous advisory and planning committees and speaks regularly on topics including patient-centered benefit-risk assessment, patient-focused medical product development, and the 21st Century Cures Act. Kim is a member of PCORI's Patient Engagement Advisory Panel, DIA's Advisory Committee for North America, and the steering committee for the Medical Device Innovation Consortium's Patient-Centered Benefit Risk project. Prior to joining *FasterCures'* staff in October 2013, Kim was President & CEO of the CFIDS Association of America (now the Solve ME/CFS Initiative) from 1991 until June 2013. Kim is a graduate of the University of North Carolina at Chapel Hill.

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.



Robert Metcalf, PhD is Vice President, Global Regulatory Affairs – US and Global Medical Quality – at Eli Lily and Company. He is responsible for interactions with the FDA supporting new drug development and marketed products, including US product labeling, advertising and promotion, and regulatory policy. Robert also has responsibility for, global label management, global submission management, and global Chemistry, Manufacturing and Control for Lilly. He also has responsibility for the Quality organizations supporting clinical development, regulatory, and product safety. After completing his Ph.D. in Pharmacology and Toxicology at Queen's University in Canada, Robert joined Eli Lilly Canada in the Regulatory Affairs organization where he led successful approval efforts, for neuroscience and anti-infective new chemical entities. His next opportunity led him to the Lilly Corporate Center in Indianapolis where, as a member of the Global Project Management organization, he led cross-functional teams in the global development and registration of new molecular entities in Lilly's diabetes and osteoporosis portfolios. Following this opportunity, Robert returned to Lilly Canada where he had leadership responsibility for Regulatory Affairs, Health Outcomes, and Quality. In 1998, Robert was transferred to Japan where he led the Project Management and Pharmaceutical Development organizations for Lilly Research Laboratories, Japan. Robert returned to Indianapolis in 2002 as a Director in Project Management with responsibility for the Project Management organizations supporting early and late stage drug development. In 2005, Robert was named Executive Director, Global Patient Safety with worldwide responsibility for adverse event case management, pharmacovigilance, and quality systems in support of product safety. In June of 2009, Robert was name Vice President, Global Ethics and Compliance where he had responsibility for providing Ethics and Compliance leadership to functional and geographic areas across Eli Lilly, included implementation of an effective compliance program. In February of 2011, Robert was named Vice President Global Regulatory Affairs-US and Global Medical Quality, responsible for the organization and activities noted above.

Sally Okun, RN, MMHS is the Vice President for Advocacy, Policy and Patient Safety at PatientsLikeMe, an online patient powered research network. She is responsible for bringing patient voice and insight to diverse advocacy and health policy discussions at the national and global level, and is the company's liaison with government and regulatory agencies. Sally joined the company in 2008 as the manager of Health Data Integrity and Patient Safety overseeing the site's medical ontology and the development of the PatientsLikeMe Drug Safety and Pharmacovigilance Platform. She is a member of the PCORI Patient Engagement Advisory Panel, the Scientific Advisory Committee for Reagan-Udall Foundation's IMEDS program and numerous expert panels for the Institute of Medicine, the National Quality Forum, Agency for Health Care Research and Quality, The Commonwealth Fund, and others. Okun, a Registered Nurse and palliative care specialist, received her Master's degree from The Heller School for Social Policy & Management at Brandeis University, was a 2010 fellow at the National Library of Medicine Program in Biomedical Informatics and a 2014 Salzburg Global Fellow.

Edmund J. Pezalla, MD, MPH is Vice President and National Medical Director for Pharmaceutical Policy and Strategy at Aetna. Dr. Pezalla is a recognized leader in the development of advanced coverage and payment systems for pharmaceuticals. Dr. Pezalla is Aetna's lead executive for public policy related to pharmaceuticals and is also responsible for public policy coordination and quality of care in the Office of the Chief Medical Officer, Aetna. Dr. Pezalla has consulted on projects related to technology development and coverage decisions for the President's Council of Advisors on Science and Technology, the American Academy of Pediatrics, the Institute for Clinical and Economic Review and the Brookings Institution. He is a member of the Board of Directors of the Pharmacy Quality Alliance and the Connecticut Biosciences Innovation Fund. Dr. Pezalla received his bachelor's degree in Biophysics and his degree in Medicine from Georgetown University, and Masters in Public Health from the University of California at Berkeley. He was as health services research fellow and PhD student at the University of Michigan in Ann Arbor where he completed all but the dissertation in the program in Health Services Organization and Policy.

Richard Platt, MD, MSc is Professor and Chair of the Harvard Medical School Department of Population Medicine, at the Harvard Pilgrim Health Care Institute. He is Principal Investigator of the FDA Sentinel System. Dr. Platt is also co-principal investigator of PCORI's PCORnet coordinating center, a consortium of 34 networks focused on comparative effectiveness research. He co-leads the coordinating center of the NIH Health Care System Research Collaboratory and leads a CDC Prevention Epicenter. He co-chairs the CER Innovation Collaborative of the IOM Roundtable on Value and Science-Drive Healthcare, and is a member of the American Medical Colleges Advisory Panel on Research.

Commander (CDR) Melissa Robb is Associate Director for Regulatory Affairs in the Office of Medical Policy within the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). She is involved in various FDA programs and working groups to include leading programs related to expedited drug development, evidence generation, real world evidence, and postmarket surveillance. In 2002, CDR Robb began her career with the Agency as a project manager in CDER's Division of Cardiovascular and Renal Products. She then served as a senior program management officer in the Office of Critical Path Programs within the Office of the Commissioner. Prior to joining the FDA and the U.S. Public Health Service Commissioned Corps, CDR Robb was on active duty in the U.S. Air Force.

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.

Sean Tunis, MD, MSc is the Founder and Director of the Center for Medical Technology Policy in Baltimore, Maryland. CMTP's main objective is to improve the quality, relevance and efficiency of clinical research by providing a neutral forum for collaboration among experts, stakeholders and decision makers. Dr. Tunis was a member of the Institute of Medicine Committee on Initial National Priorities for Comparative Effectiveness Research. He advises a wide range of domestic and international public and private health care organizations on issues of comparative effectiveness, evidence based medicine, clinical research, reimbursement and health technology policy. Through September of 2005, Dr. Tunis was the Chief Medical Officer at the Centers for Medicare and Medicaid Services (CMS), where he had lead responsibility for clinical policy for the Medicare and Medicaid programs. Previously, he served as the Director of the Health Program at the Congressional Office of Technology Assessment and as a health policy advisor to the U.S. Senate, where he worked on pharmaceutical and device policy issues. Dr. Tunis trained at the University of California in Los Angeles and the University of Maryland in Internal Medicine and Emergency Medicine, and holds adjunct faculty positions at the Center for Health Policy at Stanford University, the Department of Internal Medicine at the Johns Hopkins School of Medicine, and the Department of Surgery at the University of California at San Francisco.

Marcus D. Wilson, PharmD is President of HealthCore, Anthem's wholly-owned outcomes research subsidiary. HealthCore utilizes Anthem's rich data and extensive provider network to meet the evidence development needs of a broad array of healthcare stakeholders including Anthem, State and Federal agencies and the Life Sciences industry. He has been extensively involved in efforts to utilize electronic healthcare data environments to accelerate healthcare evidence development and to facilitate clinical decision support for more than 20 years. Prior to co-founding HealthCore in 1996, Dr Wilson spent seven years within an integrated delivery system owned by BCBS of Delaware where he oversaw the physician and patient clinical decision support, pharmacy policy and clinical trials programs. Dr. Wilson serves as chair of the Innovations in Medical Evidence Development (IMEDS) Steering Committee, Reagan-Udall Foundation for the FDA, is chair of the Research Committee for the Academy of Managed Care Pharmacy (AMCP) & the AMCP Foundation, is a member of the FDA Sentinel Initiative Planning Board, the Green Park Collaborative Real World Evidence Project Advisory Committee, the Dean's Roundtable, College of Science, Virginia Tech and the Board of Visitors for the Mayes College of Healthcare Business & Policy at the University of Sciences in Philadelphia. He is a past member of the Board of Directors for the International Society of Pharmacoeconomics and Outcomes Research (ISPOR) and the eHealth Initiative and is a reviewer for multiple journals. Dr. Wilson received his Bachelor of Science in Biochemistry from Virginia Tech and his Doctor of Pharmacy degree from the Medical College of Virginia. He completed a residency in Family Medicine at the Medical University of South Carolina prior to joining the faculty at the Philadelphia College of Pharmacy where he taught didactic and experiential courses in therapeutics and clinical decision support. His experiential site within the HMO of Delaware eventually served as the foundational assets for HealthCore. HealthCore was eventually acquired by WellPoint in 2003 just prior to the WellPoint-Anthem merger.

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.