

Characterizing FDA's Approach to Benefit-Risk Assessment throughout the Medical Product Life Cycle

Tommy Douglas Conference Center • Silver Spring, MD
May 16, 2019

Participant Biographies



Conny Berlin is Global Head of Quantitative Safety and Epidemiology at Novartis Pharma AG. Her responsibilities include promoting a quantitative safety and epidemiology culture which enables evaluation, understanding and communication of safety data and benefit-risk to support decision-making at all stages of the drug life-cycle. Her team of epidemiologists, quantitative safety scientists and analysts provides quantitative safety and epidemiology support for the whole product portfolio of Novartis with the focus on development, submission and early postmarketing activities, which are relevant for regulatory decision-making. Conny is the project leader of IMI-PREFER, a 5 year (2016-2021) IMI project to develop expert and evidence-based recommendations with the aim to guide industry, regulatory authorities and HTA bodies and reimbursement agencies on how patient preferences can be assessed and used to inform medical product decision making. Conny holds a degree in mathematics from the University of Rostock, Germany. Since joining Novartis in 2007, she has led several initiatives to improve signal detection, safety and benefit-risk evaluation. She is a member of the Novartis's Medical Safety Review Board and of the Benefit-Risk Steering Committee, which drives the implementation of structured benefit-risk and further enhancements like patient preferences in the company. Prior to joining Novartis Pharma, Conny held various statistician roles at Bayer AG, Germany between 1992 and 2007. Conny is an active member of the councils of the Basel Biometric Section and of the Basel Epidemiology Seminar.



Laura Bloss is the Global Regulatory Therapeutic Area Head at Amgen for the inflammation, metabolic, and endocrine product portfolio and the department head at Amgen for the Global Regulatory Writing and Clinical Trial Disclosure groups. Laura has been with Amgen since 1998. She has worked in several leadership roles in Global Development and Global Regulatory Affairs, across most Amgen therapeutic areas (Oncology, Inflammation, Nephrology, Cardiovascular, Bone). She also played a key role in designing and implementing Amgen's internal benefit-risk assessment process. Laura received her doctorate in biochemistry from the University of Wisconsin-Madison and received her bachelor's degree in chemistry from the University of Virginia.



John Crowley is the Chairman and CEO of Amicus Therapeutics, a global biotechnology company focusing on developing treatments for rare genetic diseases. John has been Amicus CEO since 2005 and has overseen the company's growth from a four person start-up to one with operations in more than 30 countries, with 550+ employees and a market value of nearly \$3 Billion. John's involvement with biotechnology stems from the 1998 diagnosis of two of his children with Pompe disease—a severe and often fatal neuromuscular disorder. In his drive to find a cure for them, he left his position at Bristol-Myers Squibb and became an entrepreneur as the Co-founder, President and CEO of Novazyme Pharmaceuticals, a biotech start-up conducting research on a new experimental treatment for Pompe disease (which he credits as ultimately saving his children's lives). In 2001, Novazyme was acquired by Genzyme Corporation and John continued to play a lead role in the development of a drug for Pompe disease as Senior Vice President, Genzyme Therapeutics. John and his family have been profiled on the front page of The Wall Street Journal and are the subjects of a book by Pulitzer prize-winning journalist Geeta Anand, "The Cure: How a Father Raised \$100 Million-And Bucked the Medical Establishment-In a Quest to Save His Children." The major motion picture, Extraordinary Measures, starring Brendan Fraser and Harrison Ford, is inspired by the Crowley family journey. John is the author of a personal memoir: Chasing Miracles: The Crowley Family Journey of Strength, Hope, and Joy.



Sara Eggers supports FDA's Center for Drug Evaluation and Research in the areas of decision support and analysis, contributing to the development and implementation of initiatives regarding human drug benefit-risk assessment, patient-focused drug development, risk evaluation and mitigation strategies, and other efforts. Before joining FDA in 2011, she conducted research and consulting in the area of decision science, stakeholder engagement, and risk communication. She has a PhD in engineering and public policy, with an emphasis on decision science, from Carnegie Mellon University.



Scott Evans is a Professor of Epidemiology and Biostatistics and the Director of the George Washington Biostatistics Center. Professor Evans interests include benefit:risk assessment and the design, monitoring, analyses, and reporting of and education in clinical trials and diagnostic studies. He is the author of more than 100 peer-reviewed publications and three textbooks on clinical trials including Fundamentals for New Clinical Trialists. He is the Director of the Statistical and Data Management Center (SDMC) for the Antibacterial Resistance Leadership Group (ARLG). Professor Evans is a member of the Board of Directors for the American Statistical Association (ASA) and the Society for Clinical Trials (SCT) and is a former member of the Board for the Mu Sigma Rho, the National Honorary Society for Statistics. He is a member of an FDA Advisory Committee, the Steering Committee of the Clinical Trials Transformation Initiative (CTTI), and serves as the Chair of the Trial of the Year Committee of the SCT. Professor Evans is the Editor-in-Chief of CHANCE and Statistical Communications in Infectious Diseases (SCID), and the Co-Editor of a Special Section of Clinical Infectious Diseases (CID) entitled Innovations in Design, Education, and Analysis (IDEA). Professor Evans has served on numerous DMCs including as Chair for the Adolescent Trials Network (ATN) and a clinical trial of microbial restoration

in Clostridium difficile associated disease. Dr. Evans is a recipient of the Mosteller Statistician of the Year Award, the Robert Zackin Distinguished Collaborative Statistician Award, and is a Fellow of the ASA and the SCT.



Richard (Rich) Forshee leads the Analytics and Benefit-Risk Assessment Team for the Office of Biostatistics and Epidemiology in the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration. He works on a wide range of issues related to the risks and benefits of blood and blood products, vaccines, and human cell and tissue products. Dr. Forshee has won numerous awards including the FDA Service Award and the CBER Hope Hopps Memorial Award, and he has published more than 70 scientific articles. Before joining the FDA, he was the Director of the Center for Food, Nutrition, and Agriculture Policy at the University of Maryland, College Park.



Brett Hauber is Senior Economist and Vice President of Health Preference Assessment at RTI Health Solutions and Affiliate Associate Professor in the School of Pharmacy at the University of Washington. He is an expert in stated-preference methods. He was principal investigator for the Catalog of Methods for the Medical Device Innovation Consortium. He is a member of the Scientific Advisory Board for IMI-PREFER and co-chair of the Benefit-Risk Assessment, Communication, and Evaluation special interest group at the international Society for Pharmacoepidemiology (ISPE). He was chair of the ISPOR Good Research Practices Task Force for the statistical analysis of DCE data and was a member of the ISPOR Task Force on the ISPOR Checklist for Good Research Practices in Conjoint Analysis.



Richard (Rick) Hermann is a Safety Science Physician at AstraZeneca. He is a physician trained in dual specialties of Rehabilitation Medicine and in Clinical Pathology. He has specialized in caring for infants, children and adolescents with a broad range of disabilities, both common and rare. He is a senior physician in the AstraZeneca Patient Safety Center of Excellence and specializes in Safety Decision Management enabling more robust decisions and process around key topic in Safety Surveillance, Signal Detection and Risk Mitigation. Areas of expertise include formal Benefit-Risk analysis, Causality algorithms, AE-to-ADR methodology, Risk scoring, and advanced surveillance techniques. He also holds a master's in public health and has a passion for patient advocacy issues at the individual and societal level.



Juhaeri Juhaeri is Head of Epidemiology and Benefit-Risk at Sanofi. Juhaeri is an Epidemiologist and Statistician with over 20 years' 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 PhD in epidemiology from the same university.



Veronique Kugener completed her medical training and medical Degree at the Victor Segalen School of Medicine, University of Bordeaux, France. Dr. Kugener has received a Master Degree in Advanced Studies (DEA) in Epidemiology from the University of Bordeaux, France; a Master Degree in Pharmacology from the Pierre and Marie Curie University in Paris, France and a Master of Business Administration (MBA) from the Institut of Administration des Entreprises, University of Bordeaux, France. Dr. Kugener has been working at Takeda Pharmaceuticals for more than 10 years leading Global Patient Safety Evaluation (GPSE), a global function responsible for medical and operational pharmacovigilance activities in the pre and post-marketing setting worldwide. Dr. Kugener has more than 25 years of experience in pharmaceutical industry in Europe and in the USA in leading roles in clinical drug safety, Medical Affairs and Pharmacovigilance across multiple therapeutic areas. Dr. Kugener is also the Chair of the North America Chapter of the International Society of Pharmacovigilance (NASoP).



Kerry Jo Lee is a graduate of Princeton University and of the New York University School of Medicine with an honors degree conferred in microbiology. She completed her residency in pediatrics at the Children’s Hospital of Los Angeles followed by a post-doctoral clinical fellowship in Pediatric Gastroenterology, Hepatology, and Nutrition at Columbia University College of Physicians and Surgeons. During this time, she completed research involving the microbiome and viral pathogens at the Center for Infection and Immunity of Columbia University Medical Center. Dr. Lee worked for several years in bioethics with the National Bioethics Advisory Commission on reports that advised on ethical and policy issues in both international and domestic clinical trials and interned at the World Health Organization. She has served on multiple institutional and organizational ethics committees throughout her career. Upon joining the FDA, Dr. Lee was a clinical reviewer in the Division of Gastroenterology and Inborn Errors Products where she contributed to papers published on pediatric trial design in inflammatory bowel disease and pediatric drug development. Currently she works as a medical officer on the Clinical Advisors Team for the Office of New Drugs, Immediate Office-Policy Staff where she serves as a team lead for benefit-risk assessment and the modernization of the marketing application review.



Bennett Levitan is Senior Director, Benefit-risk Assessment, Department of Epidemiology at Janssen R&D, Pharmaceutical Companies of Johnson & Johnson. He introduced state of the art patient-focused benefit-risk assessment to Johnson & Johnson and his group has led numerous clinical teams in preparation of benefit-risk assessments and patient preference studies for regulatory submissions and health authority advisory meetings. He has co-led cross-disciplinary teams to implement processes to support growing regulatory requirements for patient-focused benefit-risk

assessment both during development and post-approval. Bennett has published widely on both theoretical and pragmatic aspects in benefit-risk and patient preference studies and is a frequent speaker on these topics in national and international conferences. He co-lead development of the PhRMA Benefit Risk Action Team (BRAT) Framework for drug benefit-risk assessment and the Medical Device Innovation Consortium (MDIC) Patient Centered Benefit-Risk Framework. Bennett serves on several committees that inform policy on benefit-risk methods including the IMI PREFER project on patient preference studies, the ISPE Benefit-Risk Assessment, Communication and Evaluation (BRACE) team, the CTTI Patient Groups & Clinical Trials work stream and the PhRMA Patient-Focused Drug Development Work Group. Bennett received his B.Sc. (Electrical Engineering) from Columbia University in New York and his MD-PhD (Bioengineering) from the University of Pennsylvania and was a postdoctoral fellow at the Santa Fe Institute.



Elaine Morrato is a professor in Health Systems, Management and Policy and Associate Dean for Public Health Practice at the Colorado School of Public Health, University of Colorado Anschutz Medical Campus. Trained as an epidemiologist and board-certified in public health, her passion is accelerating the translation of evidence into practice with a particular focus on drug safety. She directs the Innovation-Bioentrepreneurism and Dissemination Science programs for the NIH-supported Colorado Clinical & Translational Sciences Institute. She advises the U.S. Food and Drug Administration on issues of risk communication and management and is currently a visiting scientist on sabbatical with FDA in the Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research. Her past experience as an R&D manager at Procter & Gamble with responsibility for commercializing new OTC and prescription drugs informs her research and public health practice.



Theresa Mullin is the CDER Associate Director for Strategic Initiatives. She oversees areas of strategic interest to both the Center and external stakeholders. She leads a variety of CDER efforts including the FDA Patient-Focused Drug Development (PFDD) initiative, which includes work related to the FDA Reauthorization Act (FDARA) and implementation of the 21st Century Cures Act. She also leads CDER's International Program, including the FDA delegation to the International Council on Harmonization (ICH), where she led recent reforms to expand ICH global regulatory membership, and is currently Chair of the ICH Management Committee. Dr. Mullin previously served as director of CDER's Office of Strategic Program (OSP) for almost a decade. Under her leadership, the office became a critical part of CDER's sustained effort to modernize drug regulatory operations. She led FDA negotiations with industry and public consultations to support the 2017 reauthorization of the Prescription Drug User Fee Act (PDUFA) and Biosimilar User Fee Act and led the previous 3 cycles of negotiation for the 2002, 2007 and 2012 reauthorizations of PDUFA, now providing \$1B in annual funding. Before joining CDER in 2007, Dr. Mullin was Assistant Commissioner for Planning in FDA's Office of the Commissioner. Dr. Mullin received the Senior Executive Service Presidential Rank Award for Distinguished Service in 2011, Presidential Rank Award for Meritorious Service in 2006, and the FDLI Distinguished Service and Leadership Award in 2017. She received her bachelor's degree, magna cum laude, in economics from Boston College, and she has a PhD in public policy analysis from Carnegie-Mellon University.



Adora Ndu is Executive Director and Head of Global Regulatory Policy, Research, & Engagement (PRE) as well as International Regulatory Affairs at BioMarin Pharmaceutical, Inc. She provides strategic oversight to BioMarin’s regulatory policy, research and intelligence, patient engagement and outcomes research functions, as well as international regulatory affairs activities in LATAM, APAC and MEACIS. Adora serves as the chair of the Alliance for Regenerative Medicine (ARM) Regulatory Committee and chair for the American Society for Gene and Cell Therapy (ASGCT) Clinical Trials and Regulatory Affairs Committee. Adora is a member of DIA’s North American Advisory Board as well as DIA’s editorial board for the Global Forum publication. Prior to BioMarin, she served in multiple roles at the Food and Drug Administration, including as Commander in the United States Public Health Service, and Director for FDA’s Division of Medical Policy Development where she led the development of a broad range of FDA guidances and regulations. At FDA she also held leadership roles in the Office of Prescription Drug Promotion (OPDP), and was involved in FDA’s pharmacovigilance program. Prior to FDA, Adora worked at Procter & Gamble Pharmaceuticals. Adora received her Doctor of Pharmacy degree from Howard University and her JD from the University of Maryland.



Rebecca (Becky) Noel is the Global Benefit-Risk Leader at Eli Lilly and Company, where she and her team are responsible for providing benefit-risk assessment support across the Lilly portfolio. Since 2005, Becky has been extensively involved in developing and promoting systematic methods for benefit-risk assessment, both internally at Lilly and externally via the PhRMA Benefit-Risk Action Team (BRAT), the PhRMA Benefit-Risk Global Convergence issues team, the Center for Innovation in Regulatory Science (CIRS) Benefit-Risk Task Force, and Innovative Medicines Initiative projects (PROTECT and PREFER) devoted to benefit-risk assessment and the development and use of patient preference information in benefit-risk decision making. Becky recently served as the PhRMA Deputy for the ICH Expert Working Group responsible for the update of benefit-risk guidance in the Clinical Overview (M4ER2) as well as a lead and discussant on multiple panels, workshops, and professional societies including IOM, DIA, ISPOR, and ISPE. She recently joined the CIOMS Working Group XI on Patient Involvement in the Development and Safe Use of Medicines. Along with other Lilly colleagues, Becky also recently edited and contributed to the book, *Benefit-Risk Assessment in Pharmaceutical Research and Development*. Becky graduated from the University of Kentucky School of Public Health with a Master of Science in Public Health (MSPH) and from the University of Alabama at Birmingham School of Public Health, with a Doctorate of Public Health (DrPH), where she had a dual focus on international health and epidemiology. She joined Eli Lilly and Company in 2002.



Bray Patrick-Lake is Director of Stakeholder Engagement and Research Together Program Lead at the Duke Clinical Research Institute. Bray supports efforts to facilitate partnerships between patients, health advocacy organizations, sponsors and investigators across Duke Clinical Research Institute’s portfolio of research activities, which includes a broad spectrum of industry sponsored trials and federally-funded research. She has led extensive efforts through the Clinical Trials Transformation Initiative to incorporate patient voice into clinical trial design, conduct, oversight, and

regulatory frameworks, as well as improvement of the clinical trial enterprise. She currently serves as the DCRI Coordinating Center's engagement lead for the Project Baseline study, is a stakeholder advisor for the Digital Therapeutics Alliance, and recently served on the National Academies of Science, Engineering, and Medicine (NASEM) committee that developed recommendations and a framework for the Return of Individual Research Results. In 2015 – 2016, she co-chaired the Advisory Committee to the NIH Director's Working Group responsible for authoring the vision and roadmap to launch the Precision Medicine Initiative Cohort Program, now All of Us Research Program. She served as the Interim Director of Engagement for several months after program launch. She currently serves on NASEM Board on Health Sciences Policy, the All of Us National Advisory Panel, and leads engagement work at Duke's Coordinating Center for NIH's Environmental Influences on Child Health Outcomes (ECHO) program.



Robert (Bob) Ratner is a Professor of Medicine at Georgetown University Medical School in Washington, DC, and recently stepped down after serving 5 years as Chief Scientific & Medical Officer for the American Diabetes Association from 2012-2017. At the Association, Dr. Ratner provided leadership of scientific and medical activities including research, clinical affairs, program recognition and certification, medical information, and professional education. In this capacity, he oversaw the development of the ADA Clinical Practice Recommendations, clinical consensus reports, and expert opinions. He completed a sabbatical as a Robert Wood Johnson Foundation Health

Policy Fellow, serving as the study director for the Institute of Medicine Comparative Effectiveness Research Priorities Committee, and a program examiner for health reform in the Health Division of the US Office of Management and Budget. He received his MD from Baylor College of Medicine in Houston, Texas where he also completed his Internal Medicine training. He underwent fellowship training in Endocrinology and Metabolism at Harvard Medical School and the Joslin Diabetes Center in Boston. He was a Principle Investigator for the Diabetes Prevention Program (DPP) and DPP Outcomes Study of the National Institutes of Health (NIH) and served on the Steering Committee for the project nationwide. At Georgetown University, he served on the University Research Committee, and co-chaired the Joint Oversight Committee for Clinical Research. His research interests include diabetes prevention, therapeutics and complications, with an emphasis on translational efforts from controlled trials into community-based practice. He is the author of more than 190 original scientific articles and 20 book chapters.



James (Jim) Smith is a medical officer in the Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER), at the FDA. In his current capacity as a member of the OND Policy Staff within the OND Immediate Office, he primarily works on clinical and scientific policy priorities of OND. He was previously responsible for overseeing development programs targeting lipid disorders and obesity as the deputy division director of the Division of Metabolism and Endocrinology Products. Prior to joining FDA in February 2011, he was a faculty member in the Division of Nephrology of the University of Michigan Health System. Dr. Smith is a graduate of the University of

Michigan Medical School, and he completed his residency in Internal Medicine at the same institution. Subsequently, he completed fellowships in both nephrology and clinical pharmacology at Vanderbilt

University Medical Center, as well as a master's degree in Clinical Research Design and Statistical Analysis at the University of Michigan School of Public Health.



Peter Stein is Deputy Director, Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA). Peter earned his medical degree from University of Pennsylvania and trained at Yale-New Haven Hospital in internal medicine, and in endocrinology and metabolism. He was on faculty at Yale in the Section of Endocrinology and served as the associate program director for the Primary Care Residency Program. Subsequently, Peter was the section chief for endocrinology and the program director for internal medicine residency program at the Medical College of Georgia. Peter joined Bristol-Myers Squibb in 1999, subsequently working at Merck, Janssen, and finishing his career in industry at Merck as Vice-president for late-stage development in Diabetes and Endocrinology. During his industry career, Peter led development programs for several currently approved diabetes medications, and has worked on a wide range of programs from discovery through early and late clinical development. He is a clinical associate professor at the Robert Wood Johnson Medical School, where he maintained a practice in endocrinology for many years. Peter joined FDA in late 2016 as the Deputy Director, Office of New Drugs, CDER.



Theresa Strong is a co-founder and Director of Research Programs at the Foundation for Prader-Willi Research (FPWR, www.fpwr.org), a nonprofit organization that supports research to advance the understanding and treatment of the rare neurodevelopmental disorder Prader-Willi syndrome (PWS). Theresa received her B.S. from Rutgers University, a PhD in Medical Genetics from the University of Alabama at Birmingham (UAB) and performed postdoctoral work at the University of Michigan. Prior to joining FPWR full time, she was a faculty member at UAB, working primarily in the area of cancer gene therapy, and remains an Adjunct Professor of Genetics at UAB. Her work at FPWR has included the development of an international consortium to advance clinical trials in PWS (www.pwsctc.org), and she is also a member of the FDA's Patient Engagement Collaborative. She has four children, including a young adult son with PWS.



Ellis Unger is the Director, Office of Drug Evaluation-I, Office of New Drugs (OND), CDER. 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, and he trained in internal medicine and cardiovascular diseases at the Medical College of Virginia and the Johns Hopkins Hospital, respectively. Dr. Unger was a Senior Investigator in the National Heart, Lung, and Blood Institute, NIH, from 1983 to 1997. From 1997 to 2003, Dr. Unger was as a Medical Officer in CBER. Dr. Unger joined CDER as Deputy Director of the Cardiorenal Division in 2003, and he subsequently became the Director of the Office of Drug Evaluation-I, in July 2012.



William (Bill) Wang is executive director, clinical safety statistics, Merck Research Laboratories. He has over 25 years of experience in the pharmaceutical industry, with 19 years at Merck & Co Inc. He is currently co-chairing the ASA safety working group, and is a deputy topics-leader in the ICH E17 implementation working group on multi-regional clinical trials. Dr Bill Wang received the DIA Inspire Global Connector Award in 2017 and was elected as a Fellow of American Statistical Association in 2018.



John Wong is a practicing general internist, Chief of the Division of Clinical Decision Making at Tufts Medical Center, and Professor of Medicine at Tufts University School of Medicine. A graduate of Haverford College, he received his MD from the University of Chicago followed by internal medicine residency and medical informatics fellowship in Clinical Decision Making at Tufts Medical Center. A past president of the Society for Medical Decision Making, he has participated in consensus conferences, guideline development, appropriateness use criteria assessment and expert panels for the World Health Organization, National Academy of Medicine, National Institutes of Health, Centers for Disease Control and Prevention, Agency for Healthcare Research and Quality, American Association for the Study of Liver Diseases, American College of Cardiology (ACC), American Heart Association, European League Against Rheumatism, Infectious Diseases Society of America, Patient-Centered Outcomes Research Institute, and the US Preventive Services Task Force. Besides translating guidelines into quality improvement and performance measures with the Physician Consortium for Performance Improvement Work Groups, he has developed award winning decision aids for shared decision making and co-authored the ACC Health Policy Statement on Patient-centered Care. Dr. Wong's research focuses on the application of decision analysis to help patients, clinicians, and policy-makers choose among alternative tests, treatments, and policies, thereby promoting rational evidence-based efficient and effective patient-centered care. Having over 200 publications, his research areas include clinical and diagnostic reasoning, decision sciences, quality of life, technology assessment, health economics, patient centeredness, shared decision making, and evidence-based medicine.



Judith (Judy) Zander is the Director of the Office of Pharmacovigilance and Epidemiology (OPE), in the Office of Surveillance and Epidemiology (OSE), in the Center for Drug Evaluation (CDER) at the U.S. Food and Drug Administration (FDA). She oversees the Divisions of Pharmacovigilance 1 and 2 and the Divisions of Epidemiology 1 and 2, drug safety epidemiologic activities and pharmacovigilance programs. Judy joined FDA in January 2017. She has more than 20 years of pharmaceutical industry in leadership roles in drug safety life cycle management and risk management.

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 pharmacoconomics, comparative effectiveness, and drug safety and pharmacoepidemiology. Dr. Daniel received a PhD in pharmaceutical economics, policy and outcomes from the University of Arizona, as well as an MPH, MS, and BS in Pharmacy all from The Ohio State University.