ENGELBERG CENTER for
Health Care Reform
at BROOKINGS

Reinvigorating the Oral Antibacterial Drug Development Pipeline

The Brookings Institution • Washington, DC
Thursday, November 20, 2014

Biographies


Helen Boucher

Helen Boucher, MD, is the director of the infectious diseases fellowship program, staff physician in the Division of Geographic Medicine and Infectious Diseases at Tufts Medical Center, and associate professor of medicine at Tufts University School of Medicine in Boston, Massachusetts. Dr. Boucher received her medical degree from the University of Texas Medical School at Houston. She completed her internship, residency, and Chief Residency in Internal Medicine at the New England Deaconess Hospital and her clinical and research fellowships in infectious diseases at the Beth Israel Deaconess Medical Center. Dr. Boucher is board certified in internal medicine and Infectious diseases.

Dr. Boucher's clinical interests include infections in immunocompromised patients with an emphasis on transplant-related bacterial and fungal infections and human immunodeficiency virus as well as *S. aureus* infections. Her research interests focus on *S. aureus* and the development of new anti-infective agents. She is the author or coauthor of numerous abstracts, chapters, and peer-reviewed articles, which have been published in such journals as *The New England Journal of Medicine, Antimicrobial Agents and Chemotherapy, Clinical Infectious Diseases*, and *Drugs*.

Dr. Boucher is a member of several professional organizations, among them the Infectious Diseases Society of America, the American Society for Microbiology, and the American Medical Association. In 1998, the Massachusetts Infectious Diseases Society awarded Dr. Boucher the Edward H. Kass Award for Clinical Excellence. In May 2006, she was elected to the Antimicrobial Availability Task Force (AATF) of the Infectious Diseases Society of America (IDSA) and in October, 2007, she was elected to the Research Committee of the IDSA. Dr. Boucher was elected a Fellow in the American College of Physicians in 2008. In 2009, she was appointed to the Steering Committee of the Mycoses Study Group. She was included in Best Doctors in America 2009, 2010, 2011, 2012, and 2013. In 2011, Dr. Boucher was elected Fellow and Member of the Board of Directors of the Infectious Diseases Society of America. In 2012, she was elected to the American Board of Internal Medicine Infectious Disease Board.

Dr. Edward Cox is Director of the Office of Antimicrobial Products, where he has served since 2007. As Director for the Office of Antimicrobial Products, Dr. Cox oversees the review, approval and safety of antimicrobial (antibacterial, antiviral, antifungal, and antiparasitic) drugs, ophthalmic drugs, and immunosuppressive agents for patients who have received solid organ transplants.

Dr. Cox has worked extensively on the science and design of clinical trials for evaluating antimicrobial drugs. He serves on the U.S. Government's Inter-Agency Task Force on Antimicrobial Resistance and the Transatlantic Task Force on Antimicrobial Resistance.

Dr. Cox received his M.D. from the University of North Carolina School of Medicine. He completed an internship and residency in Internal Medicine at the Hospital of the University of Pennsylvania and an Infectious Disease fellowship at the National Institute of Allergy and Infectious Diseases of the National Institutes of Health. He also holds a Masters of Public Health Degree from the Johns Hopkins School of Hygiene and Public Health. He joined FDA in 1998.

Gregory Daniel, PhD, MPH is a Fellow in Economic Studies and Managing Director for Evidence Development and Innovation in the Engelberg Center for Health Care Reform at the Brookings Institution. In this position, Dr. Daniel leads the Engelberg Center's pharmaceutical and medical device policy portfolio that includes developing strategies for better post-market safety surveillance and comparative effectiveness research, improving regulatory science, fostering practical steps for implementing expedited drug development and review tools, improving biomedical innovation, and supporting payment reform. Dr. Daniel is also a senior advisor to the Reagan-Udall Foundation for the FDA.

Prior to joining Brookings, Dr. Daniel was the Vice President of Government and Academic Research at HealthCore, Inc., a research subsidiary of WellPoint, Inc. At HealthCore, he led a division responsible for providing research services in the areas of pharmacoepidemiology, drug, vaccine, and biologic safety evaluations, comparative effectiveness research, and health economics and outcomes research. His research has utilized electronic health insurance claims data integrated with clinical data including laboratory results, electronic hospital data, paper-based and electronic medical record data, and registries. Dr. Daniel is a registered pharmacist and holds a PhD in Pharmaceutical Economics, Policy, and Outcomes with a minor in Epidemiology from the University of Arizona, an MPH specializing in biostatistics, an MS in Pharmaceutical Administration, and a BS in Pharmacy, all from The Ohio State University.

Dr. Michael Dudley leads Health Sciences research and development in the Infectious Disease Care Global Innovation Group of The Medicines Company, where he is overseeing the discovery and development programs for new anti-infectives. He has more than 30 years of experience in the discovery, pre-clinical and clinical development of anti-infectives. Prior to joining The Medicines Company, he co-founded Rempex Pharmaceuticals where he was Chief Scientific Officer. Prior to Rempex, he served in positions of increasing responsibility at Mpex Pharmaceuticals, Diversa Corp, and Essential Therapeutics/Microcide Pharmaceuticals. Before launching his career in industry, he held full-time academic appointments as professor and chairman at the University of Rhode Island College of Pharmacy and Brown University School of Medicine while based at Roger Williams Medical Center in Providence, R.I. Dr. Dudley has served on several government advisory boards and consensus committees, notably the CDC's Antimicrobial Resistance Working Group, the Clinical Laboratory Standards Institute, FDA and NIAID workshops, and he was an editor for the journal *Antimicrobial Agents and Chemotherapy*. He did his undergraduate work at Pepperdine University, completed his PharmD and residency at the University of California San Francisco, followed by a fellowship in infectious diseases at Hartford Hospital.

Michael W. Dunne, MD has been the Chief Medical Officer at Durata Therapeutics since December 2009, providing leadership to the development of dalbavancin. He sits on the Scientific Advisory Board of the Global Alliance for TB Drug Development as well as the Medicines for Malaria Venture. From 1992 to 2009, Dr. Dunne served in a variety of roles at Pfizer in connection with the clinical development of numerous anti-bacterial, anti-viral and antifungal compounds and ultimately as the Vice President and Therapeutic Head of Development for Infectious Disease from 2001 to 2009. Dr. Dunne holds a B.A. in Economics from Northwestern University and an M.D. from the State University of New York Health Sciences Center. He completed his internal medicine residency and fellowships in infectious diseases and pulmonary medicine at Yale University School of Medicine.

Christine C. Ginocchio, PhD, is the Vice President of Global Microbiology Affairs, bioMérieux, NC. Dr. Ginocchio is a Professor of Medicine, Hofstra North Shore-LIJ School of Medicine, N.Y. Previously, she was Senior Medical Director and Chief, Division of Infectious Disease Diagnostics, North Shore-LIJ Health System Laboratories, N.Y. She has 40 years experience in Clinical Diagnostics and Pharmaceutical Clinical Trials. She received her Ph.D. in Molecular Microbiology and Genetics at the State University of NY at Stony Brook. Dr. Ginocchio received a Sarber Fellowship from the American Society for Microbiology. Her awards include the President's Award and the Irving Abrahams Award for outstanding basic science research, the PASCV 2012 award in Diagnostic Virology and the ASM 2013 BD Award for Research in Clinical Microbiology. Dr. Ginocchio's areas of extra-mural funded research have included HIV, CMV, respiratory viruses, HPV, antibiotic resistance and molecular diagnostics for Infectious Diseases. She has received government funding from the NIH/NIAID, Department of Defense and the NY State Department of Health. She has been the principal investigator for more than 60 industry and pharmaceutical clinical trials, which include 24 studies of in vitro diagnostic devices for US FDA clearance. Dr. Ginocchio is a member of the ASM (Delegate, Laboratory Practices Committee), PASCV (President 2012-2014), ASCP, AMP, IDSA (Research Committee and Diagnostics Task Force), CLSI, JCAHO Influenza Pandemic Preparedness and Response Task Force, CDC Infectious Disease Working Group, Board of Scientific Counselors, Office of Infectious Diseases (BSC/OID) and formerly the College of American Pathologists Microbiology Resource Committee (2005-2012). She has been a member of National/International Advisory panels for the CDC, NIH, NIAID, FDA, IDSA, and European Union. She has been a clinical trial/diagnostics consultant for 6 Pharmaceutical Companies and has served on scientific advisory boards for 14 biotechnology companies. She is currently the Co-Editor-in-Chief for the Journal of Clinical Virology, Section Editor, 11th edition Manual of Clinical Microbiology, and on the Editorial Board for Clinical Microbiology Reviews. Dr. Ginocchio has published 9 book chapters, over 225 peer-reviewed articles/abstracts and has been an invited speaker at over 200 national and international conferences.

Jeffrey A. Kelman, MD, MMSc is the Chief Medical Officer for the Center for Medicare at the Centers for Medicare & Medicaid Services. Dr. Kelman received his A.B. in 1969 and M.M.Sc. in 1971 from Brown University and his Doctorate of Medicine in 1973 from Harvard Medical School. He is board certified in Internal Medicine, Pulmonary Medicine, Geriatrics, and Medical Direction LTC. Dr. Kelman trained at The Peter Bent Brigham Hospital and the National Heart, Lung, and Blood Institute of the National Institutes of Health. He served as Medical Director for Collington Episcopal Life Care Center, and as Senior Medical Consultant, Congressional Budget Office, before joining CMS.

Mark B. McClellan is director of the Health Care Innovation and Value Initiative and senior fellow at the Brookings Institution. His work at Brookings focuses on promoting quality and value in patient centered health care. A doctor and economist by training, McClellan also has a highly distinguished record in public service and in academic research. He 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, the FDA's Critical Path Initiative, and public-private initiatives to develop better information on the quality and cost of care. Dr. McClellan chairs the FDA's Reagan-Udall Foundation, is co-chair of the Quality Alliance Steering Committee, sits on the National Quality Forum's Board of Directors, is a member of the Institute of Medicine, and is a research associate at the National Bureau of Economic Research. He previously served as a member of the President's Council of Economic Advisers and senior director for health care policy at the White House. He was also an associate professor of economics and medicine at Stanford University. McClellan holds an MD and an MPA from Harvard University and a PhD in economics from MIT.

Dr. Steve Miller joined Express Scripts in 2005. An international speaker and author of more than 80 scientific articles, Dr. Miller is recognized for his research in the areas of acute renal failure, transplantation, hypertension, and healthcare economics. Dr. Miller has been actively involved in the development of Express Scripts clinical programs supporting the use of generic pharmaceuticals and specialty medications. He serves as a leader in the promotion of legislation to create a pathway at the FDA for regulation of biosimilars. Dr. Miller earned his medical degree from the University of Missouri-Kansas City. He received additional training in the Pathology and Research Fellowship at the University of Alabama at Birmingham and in cardiology at the University of California, San Francisco. In 1988 he joined Washington University School of Medicine as a fellow in Nephrology/Hypertension and Transplantation. He remained on the faculty, becoming the Vice President and Chief Medical Officer for the institution. In addition to his medical education, Dr. Miller earned his MBA at the Olin School of Business at Washington University in St. Louis.

Dr. Sumathi Nambiar is the Director of the Division of Anti-Infective Products, Office of Antimicrobial Products, since July 2013. Dr. Nambiar joined the Division of Anti-Infective Products in 2002. In her current role, Dr. Nambiar provides regulatory oversight for anti-infective products, including antibacterial, antifungal, and antiparasitic drugs. Dr. Nambiar is board-certified in pediatrics and pediatric infectious diseases. She completed her pediatric residency at the Inova Fairfax Hospital for Children, V.A. and her fellowship in pediatric infectious diseases at Children's National Medical Center, Washington D.C. She received her MPH from The George Washington University School of Public Health.

Professor Kevin Outterson teaches health law and corporate law at Boston University, where he co-directs the Health Law Program. His research work focuses on the organization and finance of the health sector. Areas of specialization include global pharmaceutical markets, particularly antibiotics and other antimicrobials that can degrade in usefulness over time through resistance. He leads an interdisciplinary project on the legal ecology of antimicrobial resistance, originally funded by the Robert Wood Johnson Foundation program on public health law. He is an Associate Fellow at the Royal Institute of International Affairs (Chatham House) and a founding member of the Antimicrobial Resistance Working Group at the CDC. He was a senior consultant on the Eastern Research Group study on antibiotic markets for FDA/HHS. Starting in October 2014, he joined DRIVE-AB, a three-year €9 million project on antibiotic business models sponsored by the European Union's Innovative Medicines Initiative. Professor Outterson also serves on the Advisory Panel for the Longitude Prize for an inexpensive rapid point-of-care antibiotic diagnostic. He serves as the Editor-in-Chief of the *Journal of Law, Medicine & Ethics*; faculty co-advisor to the *American Journal of Law & Medicine*; past chair of the Section on Law, Medicine & Health Care of the AALS; and a member of the Board of the American Society of Law, Medicine & Ethics. Professor Outterson is an occasional author for the *New England Journal of Medicine* on health law topics.

John Powers, MD, is the Senior Medical Scientist at Leidos Biomedical Research in support of the Division of Clinical Research, National Institute of Allergy and Infectious Diseases, National Institutes of Health and an Associate Clinical Professor of Medicine at George Washington University School of Medicine in Washington, D.C. Dr. Powers' research interests are in clinical trials in a variety of infectious diseases with a focus on research methodology and patient centered outcomes, and measuring the safety and effectiveness of medical interventions. Dr. Powers also has a research interest in antimicrobial resistance and appropriate antimicrobial use. He was the co-chair of the United States Inter-Agency Task Force on Antimicrobial Resistance and is a member of the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance. He received medical training in Internal Medicine at Temple University School of Medicine and sub-specialty training in Infectious Diseases at the University of Virginia.

John H. Rex, MD is Senior Vice President and Head of Infection, Global Medicines Development at AstraZeneca Pharmaceuticals. Via multiple approaches to partnership, creative risk sharing, three licensing deals, three acquisitions, and internal program progression, Dr. Rex and his team have worked since 2003 to move AZ from having only one product in late life-cycle management to having a diversified program featuring products in all phases of clinical development, registration, and post-approval commercialization. During his time in Industry, Dr. Rex has led multiple Industry interactions with FDA, EMA, and other external groups with a focus on enhancing available development pathways and the approaches to value for antimicrobial agents. His key activities have included lead authorship of a publication describing an updated approach to regulatory paradigms for antibacterial agents, co-authorship of other publications on the challenge of antimicrobial resistance, founding and ongoing participation in creation and implementation of the New Drugs For Bad Bugs (ND4BB) program within the Innovative Medicines Initiative (IMI) in Europe (including founding participation in the design of a new ND4BB topic focused on evaluation and implementation of novel business models for antibiotics), a 4-year term as Industry Representative on the FDA Anti-Infective Drugs Advisory Committee (AIDAC, 2007-2011), ongoing active leadership within the antimicrobial working groups for EFPIA and PhRMA, ongoing roles (currently Vice-Chair of the Area Committee on Microbiology) with the Clinical Laboratory Standards Institutes (CLSI), and membership in the Brookings Council on Antimicrobial Drug Development. Dr. Rex has an MD from Baylor College of Medicine and is board-certified in Internal Medicine and Infectious Diseases. Before moving to Industry in 2003, Dr. Rex was Professor of Medicine at UT Medical School-Houston with a focus on translational studies of novel antifungal agents and hospital epidemiology.