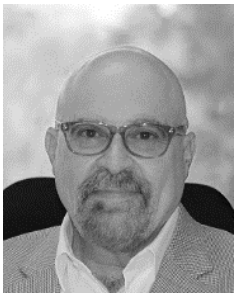
Duke | Robert J. Margolis, MD Center *for* Health Policy

Exploring Practical Implementation of Economic Incentives for Antimicrobial Development in the U.S.

Marriott Marquis • Washington, DC
July 20-21, 2016

Biographies

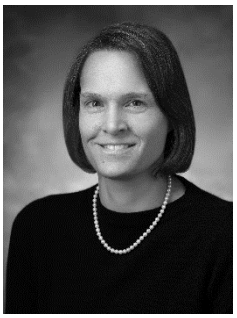
Helen Boucher, MD, FACP, FIDSA is Director of the Infectious Diseases Fellowship Program at Tufts Medical Center and Associate Professor of Medicine at Tufts University School of Medicine. Dr. Boucher's clinical interests include infections in immunocompromised patients and S. aureus infections. Her 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, and Clinical Infectious Diseases; she is Associate Editor of Antimicrobial Agents and Chemotherapy. She has been included in Best Doctors in America since 2009. 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 Exam Writing Committee and in 2014, to the American Board of Internal Medicine Infectious Diseases Subspecialty Board. In 2015 she was appointed to the Presidential Advisory Council on Combating Antibiotic-resistant Bacteria, and elected Treasurer of the Infectious Diseases Society of America. She was awarded the IDSA Society Citation Award in October, 2015. Dr. Boucher serves on the Board of Trustees of the Physicians of Tufts Medical Center and The College of the Holy Cross.



Sam Bozzette, MD, PhD, currently serves as Vice-President, Medical Affairs-Americas/East Asia for bioMerieux, a leading diagnostics company where he also heads global health economics/outcomes efforts. Previously, he was Senior Natural Scientist at the RAND Corporation and Professor of Medicine and of International Relations at the University of California San Diego. There he led an internationally recognized program of clinical, services, economic, outcomes, and policy investigations resulting in over 175 publications, including over a dozen in the New England Journal of Medicine. He retains an Adjunct appointment at UCSD and is also Adjunct Professor of Health Management and Policy at the University of North Carolina. Dr. Bozzette holds a B.S. from Georgetown University, an M.D. from the University of Rochester, and a Ph.D. in Policy Studies with Distinction in Economics and Quantitative Methods from the RAND Pardee Graduate School. He is certified in Internal Medicine and Infectious Diseases. He is a fellow of the American College of Physicians and the Infectious Diseases Society of America, and an elected member of American Society for Clinical Investigation, the Association of American Physicians, and the Pacific Council on International Policy.

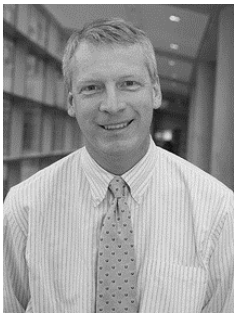
Jason Brown, PhD, is currently the Director of the Office of Microeconomic Analysis at the U.S. Department of the Treasury, where he directs a team of economists who analyze a range of domestic economic issues to inform policymaking. Prior to assuming his current position in 2011, he was an economist in the Office of Microeconomic Analysis. His research focuses on health policy, with a specific interest in long-term care and Medicare. At Treasury he has contributed to the policy development and analysis of a wide range of health and retirement issues, including the Affordable Care Act, Social Security reform, and health care spending growth. He holds a Ph.D. in Economics from Stanford University.

Angela M. Caliendo, MD, PhD, is Professor, Executive Vice Chair of the Department of Medicine, and Director of the Division of General Internal Medicine at the Warren Alpert Medical School of Brown University. Dr. Caliendo received a PhD (Biochemistry) and MD from Case Western Reserve University School of Medicine and completed an internship and residency in Internal Medicine at Brigham and Women's Hospital in Boston, MA and an Infectious Diseases fellowship at Massachusetts General Hospital, Boston MA. Dr. Caliendo's research has focused on the development of molecular diagnostic tests for the detection and quantification of infectious diseases and assessment of their clinical utility; molecular testing in transplantation; standardization of viral load testing; and evaluation of HIV-1 RNA burden and the development of antiretroviral resistance in HIV-1 seropositive women. Dr. Caliendo is an Editor for the Journal of Clinical Microbiology, Chair of the Microbiology Medical Devices Panel for the FDA and Chair of the Diagnostics Task Force for the Infectious Diseases Society of America. She served as the President of the Association of Molecular Pathology (2004), President of the Pan-American Society for Clinical Virology (2010 -2012). Dr. Caliendo has published over 135 peer-reviewed manuscripts covering various topics in clinical and diagnostic virology and microbiology and was a recent recipient of the Ed Nowakowski Senior Memorial Clinical Virology Award from the Pan American Society for Clinical Virology and the BD Award for Research in Clinical Microbiology from the American Society for Microbiology.



Sara E. Cosgrove, MD, MS, is a Professor of Medicine in the Division of Infectious Disease at Johns Hopkins University School of Medicine and has a joint appointment in the Department of Epidemiology at the Johns Hopkins Bloomberg School of Public Health. She serves as the Director of the Antimicrobial Stewardship Program and the Associate Hospital Epidemiologist at The Johns Hopkins Hospital. Dr. Cosgrove's research interests the epidemiology and outcomes of antimicrobial resistance, the development of tools and programs to promote the rational use of antimicrobials, the prevention of hospital-acquired infections and the epidemiology and management of S. aureus bacteremia. Dr. Cosgrove currently serves as President-Elect on the Society for Healthcare Epidemiology of America's Board of Directors. She is Assistant Deputy Editor of Clinical Infectious Diseases. She was member of the President's Council of Advisors on Science and Technology Working Group on Antimicrobial Resistance and is a voting member to the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. Dr. Cosgrove received her undergraduate degree from Columbia College in New York, New York, her medical degree from Baylor College of Medicine in Houston, Texas, and her Master of Science degree in epidemiology from Harvard School of Public Health in Boston, Massachusetts. She completed her postgraduate training in internal medicine at The Johns Hopkins Hospital and underwent subsequent training in infectious disease at Beth Israel Deaconess Medical Center in Boston.

Patrick Courneya, MD, is the Executive Vice President of Hospitals, Quality and Care Delivery Excellence and Chief Medical Officer of Medicare Advantage, 1876 Cost, and Part D Pharmacy Plans at Kaiser Foundation Hospitals and Health Plan, Inc. in Oakland, CA. In this role, Dr. Courneya oversees Kaiser Permanente's national quality agenda, helps ensure the organization's members and communities receive the best quality and service Kaiser Permanente offers, and advocates for the advancement of evidence-based medicine and proven innovation for the industry. Dr. Courneya previously served 10 years as Medical Director and Associate Medical Director for HealthPartners Health Plan. Additionally, he has played a significant role in advancing health care quality and innovation on a national level. Dr. Courneya is the former Chair of the America's Health Insurance Plans' Chief Medical Officer Leadership Council, and in 2014, finished serving as Chair of the Medical Directors Council of the Alliance of Community Health Plans. Dr. Courneya received his undergraduate degree from the University of St. Thomas, St. Paul, Minnesota and his medical degree from the University of Minnesota. He completed his Family Practice Residency at Methodist Hospital in St. Louis Park, Minnesota in 1988, and remains board certified in that specialty. He has served as medical leader in various roles at medical group, hospital, and health plan levels. He has had 25 years of experience in active clinical practice.

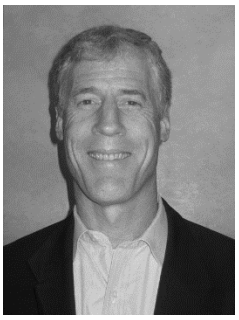


Edward Cox, MD, MPH, is Director of the Office of Antimicrobial Products, where he has served since 2007. As Director for the Office of Antimicrobial Products, Dr. Cox oversees the review, approval and safety of antimicrobial (antibacterial, antiviral, antifungal, and antiparasitic) drugs, ophthalmic 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 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 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.

Prabhavathi Fernandes, PhD, has been President and Chief Executive Officer of Cempra, Inc. since its inception in January 2006. In 2012 she led the public offering on Nasdaq for Cempra, and has successfully raised over half a billion dollars to date for Cempra, building value for its investors and taking its first antibacterial product, solithromycin from the bench to the NDA with the plan to launch the product in the US. She has licensed solithromycin in Japan to Toyama/Fujifilm. In addition she has successfully obtained funding from BARDA, the biodefense arm of Health and Human Services in the US for the development of solithromycin for use in pediatrics and for biodefense. She has also developed partnerships with the NIAID for the development of solithromycin. Her career, of more than four decades, has been focused on anti-infectives, first in clinical microbiology and infectious diseases and then in pharmaceutical anti-infective discovery and development. Prior to this, Dr. Fernandes held executive leadership positions at pharmaceutical corporations, having worked at Bristol-Myers Squibb, Pharmaceutical Research Institute, Abbott Laboratories and The Squibb Institute for Medical Research. During these years she was directly involved in the development of antibiotics, four of which have been approved and one, Clarithromycin, achieving sales over a billion dollars. After leaving Bristol Myers Squibb in 1997 she has founded and led three biotechnology and CRO companies and was President and Chief Executive Officer of DarPharma, Ricerca and Small Molecule Therapeutics. Dr. Fernandes has served on the U.S. Congressional Panel for Assessment of Impact of Antibiotic Resistant Bacteria and on the American Society for Microbiology Advisory Panel for Antibiotic Resistance. She has continued to work on policy matters to help in combating antibiotic resistance with IDSA and the Anti-infective Working Group. She serves on the editorial board of journals, was a member of the Product Development working group for Biodefense for the NIAID, and was an Advisory Board Member of Optimer Pharmaceuticals, Inc. as well as the Supervisory Board of GPC biotech. She has over 250 publications and has authored numerous reviews and book chapters. She received her Ph.D. in Microbiology from Thomas Jefferson University, Philadelphia.

Steven Gitterman, MD, PhD is currently Deputy Director of the Division of Microbiology Devices, Office of In Vitro Diagnostics and Radiological Health at the Food and Drug Administration (FDA). He is board-certified in both Internal Medicine and Infectious Disease. In addition to his work at FDA, he is an attending physician in Infectious Diseases at the Washington, DC, Veterans Administration Medical Center, Assistant Professor of Medicine at the Uniformed Services University of the Health Sciences, and Assistant Clinical Professor of Medicine at the University of Maryland and at George Washington University.

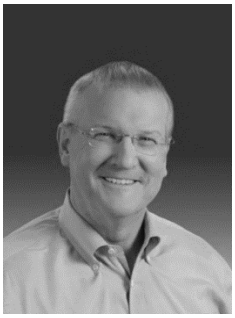


Patrick Holmes is currently on assignment as Strategic Policy Development Lead, Pfizer Global Policy and International Public Affairs. His role is focused on working across the organization and other critical stakeholders to develop policy positions that can help drive positive impact. He brings the ability to integrate experiences across multiple aspects of the biopharma business. Previously, Patrick was Vice President, Strategy and Portfolio Support, within Pfizer's Strategy, Portfolio, and Commercial Operations Group (SPCO). Strategy and Portfolio Support provides comprehensive insights and identifies key emerging trends for Pfizer leaders. Patrick joined Pfizer as a marketing associate in 1990. Through the end of 2005, Patrick held positions of increasing responsibility in both US and global marketing. His responsibilities have included products for hypertension, lipid lowering, arrhythmia, diabetes, erectile dysfunction, and allergies. In 2006, Patrick assumed the role of Senior Director, US New Product Planning, leading a team that was responsible for evaluating new product opportunities and providing strategic input on behalf of the US commercial organization. At the end of 2008, Patrick assumed leadership for Portfolio and Decision Analysis, a group which supports strategic decisions and investment tradeoffs across Pfizer's development portfolio. Patrick has a BA in biology from Middlebury College and an MS in management from the Massachusetts Institute of Technology Sloan School of Management. He is a lifelong skier and soccer player.

Adam Kroetsch, MSPPM, advises senior staff at FDA's Center for Drug Evaluation and Research on key issues related to policy and informatics. For the past several years, he has led numerous efforts within the agency to improve the effectiveness of FDA's drug safety programs and better measure their impact. He has also helped manage the work and research of CDER's economics staff, which provides expert advice to the center on a wide range of economic issues.

Joseph Larsen, PhD, is acting Deputy Director of the Biomedical Advanced Research Development Authority (BARDA). In that role, he oversees a $2.8B fund for the development and procurement of medical products for use during public health emergencies. From 2014-2016, Joe served as the Deputy Director of BARDA's Chemical, Biological, Radiological, and Nuclear Medical Countermeasure Division. He is also the BARDA lead for the Obama Administration's Initiative on combating antibiotic resistant bacteria and has chaired intergovernmental working groups on research and development and economic incentives for antibacterial drug development. Previously Dr. Larsen served as Chief of the Broad Spectrum Antimicrobials program at BARDA. The goal of BARDA's Broad Spectrum Antimicrobials program is to develop additional antimicrobial treatment options needed to counter the growing threat of antimicrobial resistance. In that role, he oversaw a portfolio of approximately $1.2B in programs that support the development of novel antibacterial and antiviral drugs. Dr. Larsen also serves as the BARDA representative on the U.S. Transatlantic Task Force on Antimicrobial Resistance. Dr. Larsen received his PhD in Microbiology from the Uniformed Services University of the Health Sciences and his BA with honors from the University of Kansas.

Shari M. Ling, MD, currently serves as the Deputy Chief Medical Officer for the Centers for Medicare and Medicaid Services (CMS), and Medical Officer in the Center for Clinical Standards and Quality (CCSQ). She assists the CMS Chief Medical Officer in the Agency's pursuit of better health care, healthier populations, and smarter spending. Dr. Ling's committed focus is on the achievement of meaningful health outcomes for patients and families through the delivery of high quality, person-centered care, across all care settings. Her clinical focus and scientific interest is in the care of persons with dementia, multiple chronic conditions, and functional limitations. Dr. Ling represents CMS on several Health and Human Services (HHS) efforts. She leads the Clinical Services federal workgroup for the National Alzheimer's Project Plan, and represents CMS on the workgroups to eliminate and prevent Healthcare Associated Infections (HAIs) and the National Strategy to Combat Antimicrobial Resistance. Dr. Ling is a board certified Geriatrician, Rheumatologist and Internist who received her medical training at Georgetown University School of Medicine and received her clinical training in Internal Medicine and Rheumatology at Georgetown University Medical Center, and Geriatric Medicine training at Johns Hopkins University. She served on the faculty of the Johns Hopkins School of Medicine for 5 years before joining the Intramural Research Program of the National Institutes of Health at the National Institute on Aging as a Staff Clinician to study human aging and age-associated chronic diseases with attention to musculoskeletal conditions and mobility function for 8 years Dr. Ling is also a Gerontologist who served as the Clinical Services Co-director of the Andrus Older Adult Counseling Center after receiving her training in Direct Service from the Leonard Davis School at the University of Southern California.



Lynn Marks, MD, is Senior Clinical Advisor for Infectious Diseases with a particular focus on antimicrobial drug development, economic incentive models and the growing global challenge of antimicrobial resistance. He directs a clinical phase antibiotic development program for an agent targeted against multidrug resistant gram negative pathogens in hospitalized patients. He joined GSK in 1993 in the Infectious Diseases organization with increasing accountability. Ultimately he led the Infectious Diseases Therapy area globally. Over the next 10 years, his focus was antivirals, including a large portfolio of anti-HIV medications, diseases of the developing world in particular malaria and tuberculosis as well as antibacterials. Subsequently, he transitioned to lead Projects, Clinical Platforms & Sciences. In this role, he had operational accountability for clinical trials over a broad range of disease and therapeutic areas on a global scale ranging across the Phase I to IV development landscape. In addition, he helped create TransCelerate BioPharma which is comprised of more than 15 biopharmaceutical companies focusing on collaboration in an effort to improve the efficiency and effectiveness of drug development globally. He is the Corporate Secretary and Chair of the Oversight Committee. Dr. Marks is Board Certified in Internal Medicine and Infectious Diseases.

Anthony McDonnell is head of economic research for the Independent Review into Antimicrobial Resistance, established by then British Prime Minister David Cameron in 2014 and chaired by Economist Jim O'Neill, as well as this he has set up a working group to examine how Clinical Trial Networks can be created to improve the investment case for new antimicrobials. Anthony has a master's degree in public and economic policy at the London School of Economics, where his dissertation assessed the effect electoral competition had on the quality of services in UK local government. He has previously worked on a project for the Greater London Authority analysing how shale gas could impact the UK's gas prices and how this in turn might impact London's green energy plans. He has also worked as an assistant editor for LSE's review of books blogs as well as undertaking several different research roles within the LSE.

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.

Kevin Outterson, JD, LLM, teaches health law and corporate law at Boston University, where he co-directs the Health Law Program. His research work focuses on the law and economics of antimicrobial resistance. He leads interdisciplinary projects on the legal ecology of antimicrobial resistance. 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. Professor Outterson was given the 2015 Leadership Award by the Alliance for the Prudent Use of Antibiotics for his research and advocacy work. 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 and had publishing extensively in medical, legal and health policy journals.

Edmund Pezalla, MD, MPH, is National Medical Director for Pharmaceutical Policy and Strategy. He is responsible for the integration of pharmacy policy and activities into Aetna's overall strategy and operations. Dr. Pezalla also serves as the lead clinical spokesperson for Aetna in pharmacy related issues and represents Aetna on industry work groups and conferences. He has recently been named a Scholar-in-Residence at the Duke-Margolis Center for Health Policy in Washington, DC and serves on the Board of Directors of the Pharmacy Quality Alliance and the Connecticut Biosciences Innovation Fund. Dr. Pezalla received his medical degree from Georgetown University and trained in general medicine and pediatrics at the Bethesda Naval Hospital. He also holds an MPH from the University of California at Berkeley and was a health services research fellow at the University of Michigan where he completed all but the dissertation in the doctoral program in Health Services Organization and Policy.

John Rex, MD, is a physician and drug developer with ~30 years of development and policy experience focused on antimicrobial agents. His experience includes moving compounds from early preclinical development thru all development phases in the context of (a) academic positions (NIH, Bethesda, MD; Univ. of Texas Medical School-Houston), (b) VP-level role at a multinational pharmaceutical firm (AstraZeneca), (c) board-level roles in two biotechs (F2G Ltd, Adenium Biotech ApS, and (d) an operating partner role with a venture capital group (Advent Life Sciences). His activities have also included advancing novel regulatory paradigms for antibacterial agents, publications on novel reimbursement models for antibiotics, founding of the New Drugs For Bad Bugs (ND4BB) program of Europe's Innovative Medicines Initiative (IMI), a 4-year term as Industry Representative on the FDA Anti-Infective Drugs Advisory Committee (AIDAC, 2007-2011), a current role as an Expert-in-Residence at Wellcome Trust (London, UK), and current voting membership on the US Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria.

Arjun Srinivasan, MD, FSHEA, CAPT USPHS, is the Associate Director for Healthcare Associated Infection Prevention Programs in the Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention. He is board certified in Infectious Diseases. Before coming to CDC he was an Assistant Professor of Medicine in the Infectious Diseases Division at the Johns Hopkins School of Medicine where he was the founding director of the Johns Hopkins Antibiotic Management Program and the associate hospital epidemiologist. His primary responsibilities include oversight and coordination of efforts to eliminate healthcare associated infections. His research and investigative areas of concentration include outbreak investigations, infection control, multi-drug resistant gram negative pathogens and antimicrobial use. From 2006-2010, he led the CDC's healthcare outbreak investigations team. In 2008, he assumed the medical directorship of a new CDC campaign called "Get Smart for Healthcare" which is designed to improve the use of antimicrobials in in-patient healthcare facilities. Dr. Srinivasan has published more than 70 articles in peer-reviewed journals on his research in healthcare epidemiology, infection control and antimicrobial use and resistance.

Eugene Sun, MD, joined Melinta Therapeutics in April 2013 as executive vice president of R&D. Prior to Melinta, Dr. Sun held multiple positions over a 17-year career at Abbott Laboratories where he most recently served as corporate vice president, global pharmaceutical clinical development. In this role, he was responsible for global clinical development, medical affairs, clinical operations and clinical pharmacology for the company's pharmaceutical portfolio. Prior to 2005, he held various R&D leadership positions for several therapeutic areas, as well as pharmacovigilance, quality assurance, medical affairs and health economics and outcomes research. During his tenure at Abbott, Dr. Sun led the development and worldwide regulatory approval of the landmark HIV protease inhibitor Kaletra® and oversaw the development and approval of multiple indications for Humira®. He also had responsibility for the anti-infective development portfolio that included compounds in the quinolone, cephalosporin, macrolide and ketolide classes. Dr. Sun served on the FDA Antiviral Drugs Advisory Committee from 2001 to 2007, and was a director of TAP Pharmaceuticals from 2004 to 2008. He earned his M.D. from New York University School of Medicine. He completed his internship and residency in internal medicine, and his fellowship in infectious diseases, at the University of California, San Francisco, and was subsequently on the faculty at UCSF where he was an attending physician on the medical and infectious disease services. During his fellowship, Dr. Sun received a National Research Service Award and a Physician Scientist Award from the NIH. He earned his undergraduate degree from Harvard University.

Ursula Theuretzbacher, PhD, is founder and principal of the Center for Anti-Infective Agents in Vienna, Austria, since 1988. A microbiologist by training, she dedicated her professional life to antibacterial and antifungal drug R&D as well as appropriate and optimized usage of these drugs. She focuses on resistance and dosing issues from the early development phase to the use of old and new drugs in clinical practice. She currently focuses on R&D strategies and policies. Ursula Theuretzbacher is currently work package leader in the multinational collaborative EU funded project AIDA (Re-developing old antibiotics) and in the multinational public-private partnership project DRIVE-AB (Incentivizing antibacterial drug R&D, funded by the EU Innovative Medicines Initiative, IMI) and partner in the IMI project COMBACTE-MAGNET (Developing new molecules against Gram-Negative Infections). Ursula Theuretzbacher is currently President of the Society of Anti-Infective Pharmacology (ISAP) and Founding President of the ECMID (European Society of Clinical Microbiology and Infectious Diseases) PK/PD of Anti-Infectives Study Group (EPASG). She is chair of a policy and scientific study group of the International Society of Chemotherapy (ISC), Member of the Executive Committee of the International Society of Infectious Diseases (ISID) and member of the ECCMID Programme Committee. She has published widely read textbooks on clinical microbiology and authored and/or co-authored reviews, book chapters, research papers on resistance, PK/PD, and antibacterial and antifungal agents.