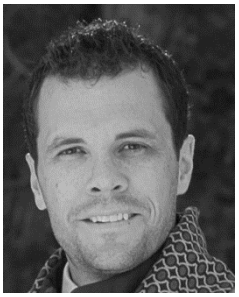
Duke | Robert J. Margolis, MD Center for Health Policy

Assessing Strategies to Improve the Market for Rapid Diagnostics for Bacterial Diseases

1100 New York Ave NW, Room 3DE, Washington, DC 20005

April 18, 2017

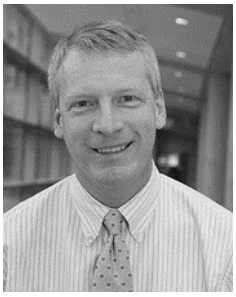
Biographies



Nicholas Anderson, MA, MBA, is a health economist and current Director of Market Access for PolarityTE, a regenerative medicine company based in Salt Lake sCity, UT. Previous to this appointment he was a Payer determining which medical technologies are paid for by Intermountain Healthcare. He is also a consultant to Venture Capitalists and start-ups who are working on new life science products helping them identify what health insurance companies and hospitals want in a technology and for what they're willing to pay. Nic is also a Strategic Advisor to a number of medical technology companies. He is a guest lecturer at UCSF School of Medicine, University of Utah and at conferences and symposiums where he speaks on clinical trials, HEOR and reimbursement. In February 2017, Nic was the Expert in Residence at the Dubai 100, a digital health accelerator located in Dubai. He received his BA in Behavioral Neuroscience from Purdue University, MA in Biomedical Imaging from Boston University School of Medicine, and MBA from the University of Utah.

Chris Bernard has 24 years of diagnostic and life science experience. He was appointed President & CEO of Curetis USA in July 2016 with a mandate to lead the company's U.S. sales, marketing and commercial operations expansion. Prior to Curetis, Mr. Bernard served as Chief Commercial Officer at Epic Sciences and as Senior Vice President, Sales and Marketing at Metabolon. Additionally, he was responsible for sales and marketing of Piccolo Xpress, a point-of-care diagnostic, at Abaxis Inc. Earlier in his career, Mr. Bernard served as regional business director at Cytyc Corporation, acquired by Hologic, where he was responsible for managing a portfolio of diagnostic products including ThinPrep and NovaSure. He received his BA in psychobiology from Hiram College and started his diagnostic career at the lab level in the early 1990's as a cytologist at Mt Sinai hospital in Cleveland, OH.

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.



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.

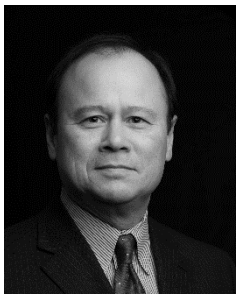
Gregory Daniel, PhD, MPH, is a Clinical Professor in Duke's Fuqua School of Business and Deputy Director in the Duke-Robert J. Margolis Center for Health Policy at Duke University. Dr. Daniel directs the DC-based office of the Center and leads the Center's pharmaceutical and medical device policy portfolio 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.

Andrew Fish, JD, is the Chief Strategy Officer of AdvaMed, the leading trade association advancing medical technology in the U.S. and around the world. As chief strategy officer, Mr. Fish leads the association's strategic planning, oversees AdvaMed's global, regulatory, and payment departments, and coordinates the development and operations of AdvaMed's membership divisions and sectors. Mr. Fish also serves as Executive Director of AdvaMedDx, AdvaMed's diagnostics division that operates as the U.S. trade association representing leading manufacturers of medical diagnostic tests. Mr. Fish joined AdvaMedDx upon its founding in 2010 and led the development of AdvaMedDx into a globally influential advocacy organization. Mr. Fish has extensive experience navigating the complex intersections of business, science, media, law, regulation, and politics. Prior to joining AdvaMedDx, Mr. Fish was Senior Vice President of Legal and Government Affairs, General Counsel, and Secretary for the Consumer Healthcare Products Association (CHPA), representing manufacturers of non-prescription medicines. Mr. Fish also led the American Cancer Society's federal lobbying team as the Senior Director of Federal Government Relations. Earlier in Mr. Fish's career, he served in the Senate-confirmed post of Assistant Secretary of Agriculture for Congressional and Intergovernmental Affairs. Prior to that position, he worked twice for the U.S. Senate Agriculture Committee, first as a professional staff member and later as deputy chief counsel. In his legal practice, Mr. Fish focused on biotechnology regulation, as well as on a wide range of food, drug and agriculture issues. Mr. Fish is a graduate of Yale University and Stanford Law School.

Sheila Farnham
Global Marketing Manager, bioMerieux

Vance Fowler, MD, MHS, Professor, Departments of Medicine and Molecular Genetics & Microbiology, Duke University Medical Center. Dr. Fowler has extensive expertise in clinical and translational research in bacterial infections. Dr. Fowler created the S. aureus Bacteremia Group and co-founded the International Collaboration on Endocarditis. He is a project PI in the Clinical Trials Transformation Initiative (CTTI; total value 37 million), the Communicating PI of the Antibacterial Resistance Leadership Group (ARLG; total value >100 million); and PI of a multinational NIH-funded trial of staphylococcal bacteremia (total value 20 million). He has over 225 publications, has been cited over 13,000 times, and has an h-index of 58.

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.



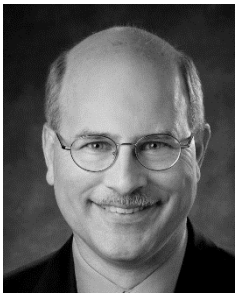
Louis Jacques, MD, is Chief Clinical Officer and a Senior Vice President at ADVI, a health care advisory services firm, where he is also a partner. He also serves on several institutional boards and advisory panels. Before joining ADVI in 2014, Dr. Jacques was the Director of the Coverage and Analysis Group (CAG) in the Centers for Medicare & Medicaid Services (CMS) from 2009 - 2014, where he managed Medicare fee for service coverage policy development on technologies as diverse as molecular diagnostic testing, implanted cardiac devices, advanced imaging, chemotherapeutics, wound care, and screening and preventive services. From 2004 – 2009 he was a division director within CAG, focusing on Part B drugs and diagnostic tests. Before joining CMS in 2003, he served as the Associate Dean for Curriculum at Georgetown University School of Medicine; where he also saw patients at the Lombardi Cancer Center in his practice of hospice and palliative medicine.

Evan Jones is the Chairman and CEO of OpGen and also is the Managing Member of jVen Capital, LLC, a life sciences investment company. Prior to forming jVen Capital, he was co-founder, Chairman and CEO of Digene Corporation, a publicly traded biotechnology company focused on women's health and molecular diagnostic testing. He is a Board Member of Fluidigm, Inc., Foundation Medicine, Inc., and Veracyte, Inc. Mr. Jones is Vice-Chairman of the Board of the Children's National Medical Center and a Board Member of the Children's Research Institute.

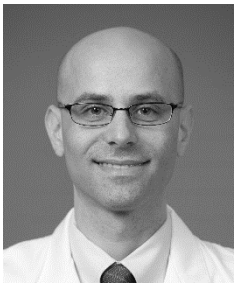
Tobi B. Karchmer, MD, MS, is Senior Vice President, Global Medical Affairs and Clinical Development for BD. As SVP, Dr. Karchmer is responsible for product safety and efficacy, medical input to business strategy and innovation, development and execution of clinical evidence generation plans for new products and solutions for all of the BD businesses. Dr. Karchmer joined BD in 2007 as a Medical Director for BD Diagnostics and became WW VP, Medical Affairs for BD Diagnostics in 2011. In 2014, Dr. Karchmer became VP, Corporate Clinical Development with responsibility for the design and execution of clinical trials to support evidence generation for new products and solutions across all of the BD businessses. Her expanded responsibilities as SVP, Global Medical Affairs and Clinical Development began in Oct 2015. Prior to joining BD, Dr. Karchmer was Assistant Professor of Medicine in the Section of Infectious Diseases at Wake Forest University School of Medicine and the Medical Director for the Department of Infection Control and Hospital Epidemiology at Wake Forest University Baptist Medical Center in Winston-Salem, North Carolina from 2000 - 2007. During her time at WFUBMC, Dr. Karchmer expanded the institution's program for prevention of Healthcare Associated Infections, provided in-patient consultative care and conducted clinical research. Dr. Karchmer received her Medical Degree from Harvard Medical School and Master of Science from the University of Virginia. She completed an internship and residency in internal medicine at the University of Washington in Seattle. Dr. Karchmer then completed a fellowship in Infectious Diseases at the University of Virginia Health System in Charlottesville.

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.

John McInnes, MD, JD, is the Director of the Division of Outpatient Care within the Hospital and Ambulatory Policy Group, Center for Medicare at the Centers for Medicare and Medicaid Services. His division is responsible for Medicare hospital outpatient and ambulatory surgery center payment policy. Currently he is on a detail in CMMI where he is working on a variety of Alternative Payment Models. Prior to joining CMS in 2010, Dr. McInnes was an attorney at Arnold and Porter, LLP where he worked on a wide variety of Medicare and Medicaid payment issues and FDA regulatory issues. Prior to practicing law Dr. McInnes practiced ophthalmology in Illinois and Pennsylvania. He is cornea fellowship trained, received his law degree from the University of Texas at Austin and his medical degree from Duke University.



Fred Tenover, PhD, D(ABMM), is Vice President of Scientific Affairs at Cepheid, Consulting Professor of Pathology at Stanford University School of Medicine, and Adjunct Professor of Epidemiology in the Rollins School of Public Health at Emory University. After being awarded his PhD in Microbiology at the University of Rochester, he completed a 2 year post-doctoral fellowship in Clinical Microbiology and Public Health at the University of Washington. He then served as Associate Chief of the Microbiology Laboratory at the Seattle Veterans Affairs Medical Center and Associate Professor of Laboratory Medicine at the University of Washington. He joined the Centers for Disease Control and Prevention in Atlanta in 1990 and served for 18 years as Associate Director for Laboratory Science in the Division of Healthcare Quality Promotion and then as Director of the Office of Antimicrobial Resistance for CDC. He joined Cepheid, a molecular diagnostics company, in California in 2008 where he focused his research studies on the evolution of antimicrobial resistance in Staphylococcus aureus and Clostridium difficile, and the epidemiology of carbapenem resistance mechanisms globally. He has contributed to the design and development of a number of molecular diagnostic assays. He is a Diplomate of the American Board of Medical Microbiology and a Fellow of both the American Academy of Microbiology and the Infectious Disease Society of America. He has been an author of over 320 peer-reviewed journal articles and has written or edited 10 books.



Ephraim L. Tsalik, MD, MHS, PhD, is an Associate Professor of Medicine in the Center for Applied Genomics & Precision Medicine and the Division of Infectious Diseases at Duke University School of Medicine. He is also a Staff Physician in the Emergency Department Service Line at the Durham VA Health Care System. Dr. Tsalik's research has focused on the development, evaluation, and promotion of diagnostics for acute infectious disease. In particular, he has made use of systems biology approaches to characterize the host response to infection, using these findings to drive the development of diagnostic and prognostic assays. Specific areas of interest include the differentiation of infectious from non-infectious disease; bacterial vs. viral infection; and using molecular data to better diagnose and stratify sepsis. Dr. Tsalik serves in the Antibacterial Resistance Leadership Group where he interfaces with industry and academic partners to advance diagnostics development. Included in this effort is the Rapid Diagnostics in Categorizing Acute Lung Infections (RADICAL) study. Dr. Tsalik also leads the Master Diagnostics Protocol, which advances diagnostics development under the principle that one patient can inform multiple research questions.

Jorge Villacian, **MD,** is Chief Medical Officer at Janssen Diagnostics, developing diagnostic solutions spanning across companion diagnostics as well as novel diagnostics in the areas of focus for Johnson & Johnson, including infectious, metabolic, immunologic, neurologic, oncologic diseases and global public health. Previously, Jorge worked for Tibotec-Virco developing solutions to manage HIV and other infectious diseases. He established the Medical Department at Virco, including a diagnostic biostatistics and clinical virology groups as well as a the management of a diagnostic laboratory performing collaborative work with multiple pharmaceutical companies for clinical development of compounds in hepatitis C and HIV. Before this, Jorge lead international clinical development studies of a new protease inhibitor for treatment of HIV with Boehringer Ingelheim. Before joining pharmaceutical industry, Jorge worked in the clinical setting in Asia in the infectious diseases and public health areas. He obtained his MD Degree in Mexico, trained in Internal Medicine at Mount Sinai Medical Center, Miami, Florida, and specialized in Infectious Diseases at the Mayo Clinic, Rochester, Minnesota. He certified by the American Board of Internal Medicine in Internal Medicine and Infectious Diseases.

Hui-Hsing Wong, **MD, JD**, is the Chief Medical Officer in the Division of Science Policy, in the Office of Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation (ASPE), at the U.S. Department of Health and Human Services. Dr. Wong oversees a broad range of policy, clinical, and data analyses related to FDA's Center for Drug Evaluation and Research, medical product development (especially antibacterial), medical product safety, clinical trials, healthcare-associated infections, opioid use in the Medicare population, organ transplantation, hepatitis, and pediatric health. While at ASPE, she has been the contracting officer's representative on several projects relating to medical product development (drugs, devices, and partnership formation), clinical trials, and using CMS data for policy analysis. Prior to working at ASPE, she was a primary reviewer at FDA focusing on the review of organ transplant drugs and worked at HRSA's Division of Transplantation on organ transplantation policy. Dr. Wong holds a BS in Biology from Yale University, a JD from Columbia School of Law, and an MD from Baylor College of Medicine. She is board-certified in Pediatrics and trained at the Johns Hopkins Hospital. She is currently a Captain in the U.S. Public Health Service and maintains her clinical skills by seeing pediatric patients at the Walter Reed Pediatric Clinic.