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Designing Economic Incentives for Antimicrobials: Implementation in the U.S. Context

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Biographies

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.

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.

Andrea Gelzer, MD, MS, FACP, is the senior vice president and corporate chief medical officer for AmeriHealth Caritas. She is responsible for setting and overseeing the organization's overall population health management, informatics, quality and provider network contracting strategies, as well as clinical policy development and data analytics oversight for all AmeriHealth Caritas' health plans and ancillary businesses. Prior to joining AmeriHealth Caritas, Dr. Gelzer served as the Chief Medical Officer for Boston Medical Center HealthNet Plan and Senior Vice President of Clinical Public Affairs at CIGNA Corporation, and spent 16 years practicing internal medicine. Dr. Gelzer serves on several national committees including the Health Care Payment Learning and Action Network's (HCP-LAN) Alternative Payment Model Framework & Progress Tracking Workgroup, Core Quality Measures Collaborative, and the CMS Technical Expert Panel on the National Impact Assessment of CMS Quality Measures. She also chairs the Chief Medical Officer Leadership Council of America's Health Insurance Plans (AHIP). Dr. Gelzer earned her undergraduate degree from Tufts University and her doctor of medicine from St. George's University. She also received a master's degree in preventive medicine/administrative medicine at the University of Wisconsin Madison. She is a board certified by the American Board of Internal Medicine and by the American Board of Preventive Medicine in clinical informatics.

Vikas Goyal, MBA, joined SR One in January 2011, after interning with SR One since 2009. Prior to joining SR One, Vikas was a consultant at McKinsey and Co, a co-founder of Extera Partners, and a business development manager at Infinity Pharmaceuticals. Over his career, Vikas has supported business and corporate development activities for nearly 50 large and small public, venture-backed, and angel funded life science companies. Vikas received his BA in Neurobiology from Harvard University, and his MBA in Health Care Management from the Wharton School of the University of Pennsylvania. He is a member of Class 17 of the Kauffman Fellows Society.

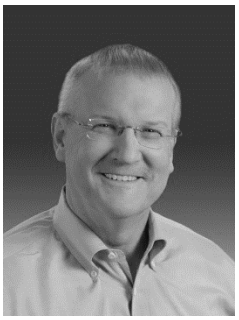
Robert J. Guidos, JD, serves as the Associate Director for Legislative Affairs of the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER). As a health policy executive with more than 25 years of experience with FDA, Congress and the private sector, Mr. Guidos has successfully led strategic policy/advocacy initiatives across multidisciplinary teams of experts from the fields of medicine, science, public health, law, regulation, government relations and communications. As a member of CDER's senior leadership team, Mr. Guidos manages CDER's congressional relations and legislative policy portfolio (e.g., 21st Century Cures Initiative, Innovation for Healthier Americans, drug access, etc.), while engaging with key stakeholders and providing strategic advice to CDER's Director and Executive Committee. Before returning to FDA in 2013, Mr. Guidos served for 13 years as vice president of public policy and government relations with the Infectious Diseases Society of America (IDSA)—a medical society representing U.S. and international infectious diseases physicians and scientists—where he developed policy expertise in antibacterial resistance and development. Mr. Guidos also has held leadership positions in health policy and legislative affairs in HHS' Secretary's Office, FDA's Commissioner's Office, and FDA's Center for Veterinary Medicine; and also served as a Brookings Institution Congressional Fellow with the offices of U.S. Senators Richard Durbin (D-IL) and Richard Lugar (R-IN). He received his juris doctor degree from the University of Pittsburgh School of Law and Bachelors of Science degree in chemistry and business from Gannon University in Erie, Pennsylvania. Mr. Guidos served as a U.S. Peace Corp volunteer in Kampala, Uganda in the early 1990's and is an avid traveler (38 countries visited to date).

Amber Jessup, PhD, is a Senior Economist in the Office of the Assistant Secretary for Planning and Evaluation (ASPE) in the U.S. Department of Health and Human Services. Amber Jessup acts as a senior advisor to the ASPE. In ASPE, she works on the intersection of economic analysis and policy development. Amber has a lead role in the Department on the development of economic methods for assessing the economic impact of regulations. She also is in the forefront of the development of new methods and standards for incorporating insights from behavioral economics into the evaluation and design of policy. In addition, she analyzes the economic impact of policies from the Affordable Care Act, including implementation of the Biologics Price Competition and Innovation Act, nutrition labeling, and policies facilitating access to preventive services. She has also worked extensively on the economic causes of drug shortages, incentives for spurring medical device and drug innovation, health care cost containment, food safety, and tobacco control. Previously, she worked as an economist at the Center for Food Safety and Applied Nutrition at FDA analyzing the benefits and costs of food safety and nutrition policies. She has a Ph.D. in economics from the University of North Carolina at Chapel Hill and a bachelor's degree from Florida State University.

Amanda Jezek is currently the Vice President for Public Policy and Government Relations at the Infectious Diseases Society of America (IDSA), which represents over 10,000 ID physicians and scientists. Amanda oversees IDSA's public policy and government relations department, with responsibility for policy development and advocacy on IDSA priority issues, including antimicrobial resistance, antimicrobial and diagnostics development, immunizations, preparedness, federal funding, and other issues relating to public health and research. Amanda has been with IDSA since 2011, previously serving as IDSA's Government Relations Director. Prior to joining IDSA, Amanda was the Deputy Director for Federal Affairs at the March of Dimes Foundation. In this capacity, Amanda led the March of Dimes' policy development and lobbying efforts on all issues related to access to healthcare for women of childbearing age, infants, and children, including the Foundation's work on the Affordable Care Act. Amanda also lobbied for Mental Health America, and worked as a legislative assistant and press secretary for U.S. Representative Grace Napolitano (D-CA). Amanda holds a B.A. in Political Science from Dartmouth College.

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.

Evan Loh, MD, was elected President of Paratek in June 2014. He was appointed Chief Medical Officer of Paratek in June 2012 and has served on Paratek's board of directors since May 2012, including as Executive Chairman from June 2012 until June 2014. From October 2009 to January 2012, Dr. Loh served as Senior Vice President, Development and Strategic Operations, Worldwide Research and Development, at Pfizer. While at Pfizer, Dr. Loh's responsibilities included scientific, operational, and strategic drug development oversight for all pre-proof of concept development phase programs and leading portfolio prioritization. Dr. Loh joined Pfizer from Wyeth Pharmaceuticals, where he was Vice President, Multiple Therapeutic Areas where he was responsible for global strategy and clinical operational deliverables. At Wyeth, he led the successful registration programs for Torisel and Tygacil. Dr. Loh served as a faculty member at both Harvard Medical School and the University of Pennsylvania School of Medicine. Dr. Loh received his A.B. from Harvard College and his M.D. from Harvard Medical School. He completed his Internal Medicine and Cardiovascular fellowship training at Brigham and Women's Hospital. Dr. Loh is currently a director at Nivalis Pharmaceuticals.



Lynn Marks, **MD,** is currently Senior Clinical Advisor for Infectious Diseases with a particular focus on antimicrobial drug development and the global challenge of antimicrobial resistance. 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, Inc. and currently is the Corporate Secretary and Chair of the Oversight Committee. Dr. Marks is Board Certified in Internal Medicine and Infectious Diseases.

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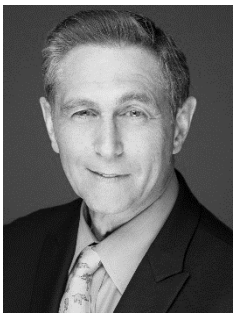
Mark McClellan, MD, PhD, is the Robert J. Margolis Professor of Business, Medicine, and Policy, and Director of the Duke-Margolis Center for Health Policy at Duke University with offices at Duke and in Washington DC. The new Center will support and conduct research, evaluation, implementation, and educational 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 and serves as the Executive Director and PI for CARB-X, a $350m international public-private partnership to fund preclinical R&D to combat antibiotic resistance. 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.

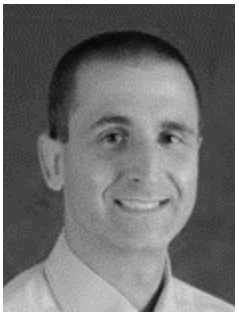
Manos Perros, PhD, was central to the establishment of Entasis Therapeutics, and led talks with AstraZeneca that resulted in the creation of the new company in 2015. Manos was Vice President of the Innovative medicines and Early Development unit of and Head of AstraZeneca's Infection Innovative Medicines organization for more than four years, and also served as Site Head, for AstraZeneca's Boston R&D research center and Gatehouse Park BioHub in Waltham, MA. In his role as the Infection Head, Manos was accountable for the Infection delivery from idea to clinical proof-of-concept of a portfolio of programs against serious bacterial infections, respiratory viruses, and neglected infectious diseases (tuberculosis and malaria in particular). Manos was also the executive sponsor for the Global Chemistry Leadership team at AstraZeneca, and led the evolution of the organizational and sourcing model, including the establishment of a strategic partnership with Pharmaron (China). A chemist by training, Manos conducted his PhD work in Belgium, France and Germany, and was Associate in the Biophysics department at Yale from 1993-1995. Prior to joining AstraZeneca, Manos served as Director of the Novartis Institute for Tropical Diseases in Singapore, and prior to that, as Vice-President and Chief Scientific Officer, Antivirals, at Pfizer. Manos has overseen a wide range of therapeutic areas, but his greatest contributions have been in the field of anti-infectives, where he is a distinguished and widely published scientist, having led research projects against HIV, Hepatitis C, influenza and fungal pathogens. Amongst a number of molecules still in development, Manos is a co-inventor of the first-in-class HIV treatment maraviroc (Celsentri/Selzentry) on which he worked from inception to launch. The medicine earned numerous accolades, including the 2008 Prix Galien USA. For his contributions to the discovery and development of maraviroc, Manos received the PhRMA Discoverer's Award in 2010.

Kevin Ronneberg, MD, joined HealthPartners in 2015 and is responsible for designing health solutions for employer groups, strengthening consumer partnerships, and building new services and programs. He works closely with multiple teams — including product development, health and care engagement, network management, sales and marketing — to connect consumer, employer and care delivery perspectives with a focus on improved health and well-being. Dr. Ronneberg has held multiple clinical and administrative leadership roles. Prior to HealthPartners, he was medical director at Target and led efforts to make high-quality health care more affordable and accessible in the retailer's in-store clinics and pharmacies. His areas of focus included brokering partnerships with health systems in key markets and developing new models of care to leverage the expanding role of the pharmacist and nurse practitioners. Dr. Ronneberg has also served as medical director for health management at Medica health plan, and was a medical director and founder of Fairview's Sports and Orthopedic Care clinics before that. He is a graduate of the University of Minnesota Medical School and completed residency training with Park Nicollet Health Services. He is board certified in family medicine.



Edward J. Septimus, MD, FIDSA, FACP, FSHEA, received his medical degree from Baylor College of Medicine in Houston in 1972. Dr. Septimus went on to complete his postgraduate training in internal medicine and infectious diseases at Baylor College of Medicine in Houston. Dr. Ed Septimus is board certified in both internal medicine and infectious diseases. His current position is Medical Director Infection Prevention and Epidemiology Hospital Corporation of America (HCA). He has served on the Board of Directors of the Infectious Diseases Society of America (IDSA) and is on the IDSA Antimicrobial Resistance Committee, the SHEA Antimicrobial Stewardship Committee, and the IDSA Quality Measurement Committee. He was the first recipient of the IDSA Annual Clinician Award. In 2011 he was appointed to the Healthcare-Associated Infections/Preventable Adverse Events Advisory Panel for the Texas Department of State Health Services. He was awarded the John S Dunn Sr. Outstanding Teacher Award in 2010, 2011, 2013 and 2014. He is on the FDA Anti-Infective Drug Advisory Group and is co-chair of the NQF Patient Safety Steering Committee. He holds a faculty position as Clinical Professor at Texas A&M Medical School and Professor, Distinguished Senior Fellow, School of Public Health, George Mason University. He has published over 100 articles and chapters.

John Rex, MD, is a physician and drug developer with ~30 years of development and policy experience focused on antimicrobial agents. His experience (figure) includes moving compounds from early preclinical development through all development phases in the context of (a) academic positions (NIH, Bethesda, MD; University of Texas Medical School-Houston); (b) VP-level roles at a multinational pharmaceutical firm (AstraZeneca), (c) board-level roles in two biotechs (F2G Ltd, Adenium Biotech ApS, (d) a charitable foundation (Wellcome Trust), (e) a public-private partnership (CARB-X), and (f) an operating partner role with a venture capital group (Advent Life Sciences). His activities have 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 Presidential Advisory Council on Combating Antibiotic Resistant Bacteria (PACCARB).



Brad Spellberg, MD, FIDSA, FACP, is Chief Medical Officer at the Los Angeles County-University of Southern California (LAC+USC) Medical Center. He is also a Professor of Clinical Medicine and Associate Dean for Clinical Affairs at the Keck School of Medicine at USC. He received his BA in Molecular Cell Biology-Immunology from UC Berkeley. He then attended medical school at UCLA, where he received numerous academic honors, including serving as the UCLA AOA Chapter Co-President, and winning the prestigious Stafford Warren award for the topic academic performance in his graduating class. Dr. Spellberg completed his Residency in Internal Medicine and subspecialty fellowship in Infectious Diseases at Harbor-UCLA Medical Center. Dr. Spellberg has extensive administrative, patient care, and teaching activities. His NIH-funded research interests are diverse, ranging from basic immunology and vaccinology, to pure clinical and outcomes research, to process improvement work related to delivery of care, focusing on safety net hospitals. His laboratory research has focused on developing a vaccine that targets the bacterium Staphylococcus aureus and the fungus Candida; the vaccine is undergoing clinical development. Dr. Spellberg is currently working on the immunology, vaccinology, and host defense against highly resistant Gram negative bacilli, including Acinetobacter and carbapenem-resistant Enterobacteriaceae infections. Dr. Spellberg has worked extensively with the Infectious Diseases Society of America (IDSA) to attempt to bring attention to the problems of increasing drug resistance and decreasing new antibiotics. His research regarding new drug development was a cornerstone of the IDSA's white paper, Bad Bugs, No Drugs, and has been cited extensively in medical literature and on Capitol Hill. As a member and then co-chair of the IDSA's Antimicrobial Availability Task Force (AATF), he first-authored numerous IDSA position papers and review articles relating to public policy of antibiotic resistance and antibiotic development. Finally, Dr. Spellberg is the author of Rising Plague, which he wrote to inform and educate the public about the crisis in antibiotic resistant infections and lack of antibiotic development.

Barrett Thornhill, **JD,** is a Principal at the McManus Group and advises life sciences companies and provider clients on legislative issues before the U.S. Congress and on regulatory matters before the Centers for Medicare and Medicaid Services (CMS) and Food and Drug Administration (FDA). He is also the Executive Director of the Antimicrobial Innovation Alliance, a coalition of pharmaceutical innovators spanning from early development-stage to global R&D leaders, focused on addressing the unique challenges affecting new antimicrobial product development and commercialization. He received his BA from Dartmouth College and JD from Georgetown University Law Center.

Tatiana Chiprez Vargas My name is Tatiana Chiprez Vargas, I am 28 years old and I am married to a lovely man named Alex. I was born in Michoacan, Mexico and came to the United States at the age of 8 months. I was raised in San Jose, CA attended elementary and middle school there. I then moved to Stockton, CA with my family at the age of 14 and continued high school in Lodi, CA. I attended Tokay High school and was in their dance group for two years. I graduated from high school in May of 2006 and continued my education at San Joaquin Delta College, which is a junior college in Stockton, CA. I went to Delta for 3 years and played soccer my first and last year there. I graduated college in May 2010 with two associate's degrees, an associate's in early childhood teacher preparation and an associate's in general education. I continued on to Sacramento State University for my BA degree the following year and followed on two semesters. I took a break from college due to wedding preparations in late 2013 and was planning on attending college again in fall 2014. Unfortunately, MRSA happened to me and I was unable to attend college the following few semesters. Today I continue with a chronic cough but find myself better and will finally be attending college Spring of 2017 to achieve my BA degree in Social Work. Besides school and education I have 3 siblings, two sisters and a little brother. I don't have children of my own quite yet, but we do have a pet daughter who is a cat and is named Molly. I am also a family person and enjoy family events. Lastly, I love soccer and dancing to the max! I am currently in a cultural folkloric dance group in Sacramento, CA as well.