

–SPEAKER BIOGRAPHIES



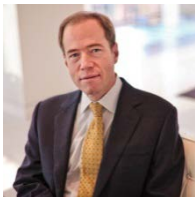
H. Eric Cannon

Pharm.D., FAMCP, Chief of Pharmacy, SelectHealth; Director, Academy of Managed Care Pharmacy

H. Eric Cannon is chief of Pharmacy for SelectHealth, an Intermountain Healthcare company and has responsibility for SelectHealth Prescriptions, a full-service pharmacy benefit management group.

Dr. Cannon has worked in pharmacy for more than twenty years. He received his Doctor of Pharmacy degree from Idaho State University. Eric has pharmacy experience in hospital, retail, long-term care and home health areas. Eric is an active member of the Academy of Managed Care Pharmacy, where he has chaired the legislative committee and is currently serving on the board of directors. Dr. Cannon was recently awarded the recognition of Fellow of the Academy of Managed Care Pharmacy. Dr. Cannon is on the board of directors for the Utah Lung Association.

At SelectHealth Prescriptions, Dr. Cannon works to develop, implement and administer many first-of-their-kind programs that improve clinical quality, control costs and optimize outcomes in the Intermountain system. He has published numerous articles and research studies in the peer-reviewed literature, and he has been involved in projects to reduce medication errors and adverse events. Dr. Cannon served on the Institute of Medicine of the National Academies Committee, Preventing Medication Errors.



Allan Coukell

Deputy Director, Medical Programs, The Pew Charitable Trusts

Allan Coukell oversees medical programs, including the Pew Prescription Project, the Drug Safety Project, the Antibiotics and Innovation Project, the Medical Device Initiative and Innovate FDA, as well as other activities related to medical products and services.

He leads the Drug Safety Project's advocacy around the need for reforms to address the risks of the global pharmaceutical manufacturing and distribution supply chain. He has also contributed to the development of federal and state legislation to foster transparency of physician-industry relationships and in the creation of programs to encourage evidence-based prescribing. He has worked closely with medical schools and medical centers, developing new industry relations policies, and he was co-creator of the American Medical Student Association PharmFree Scorecard, a national assessment of such policies at U.S. medical schools.

Mr. Coukell practiced as a clinical pharmacist in oncology at the Victoria Hospital and London Regional Cancer Center in London, Ontario, and was subsequently a senior medical writer and editor with Adis International, publisher of the peer-reviewed journals *Drugs*, *Drugs & Aging*, and *PharmacoEconomics*, among others.

He also spent a decade in journalism, ultimately as health and science reporter for WBUR, Boston's NPR news station. He was the founding producer and host of the weekly *Eureka!* science program on Radio New Zealand, and he has written for *The Economist*, the *New York Times*, *New Scientist* and *Discover*, among other publications. He is the recipient of an Edward R. Murrow award for hard news reporting.

Mr. Coukell serves as the consumer representative on the FDA Cardiovascular and Renal Drugs Advisory Committee.



Edward Cox

M.D., M.P.H., Director, Office of Antimicrobial Products, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Edward Cox received his undergraduate degree in chemistry from the University of North Carolina at Chapel Hill and his medical degree from the University of North Carolina School of

■ A New Pathway for Antibiotic Innovation: Exploring Drug Development for Limited Populations

Medicine. He completed an internship and residency in internal medicine at the Hospital of the University of Pennsylvania in Philadelphia, and he went on to complete a fellowship in infectious diseases at the National Institute of Allergy and Infectious Diseases at the National Institutes of Health in Bethesda, MD. Dr. Cox is board certified in internal medicine and infectious diseases.



Michael N. Dudley

Pharm.D., FIDSA, Senior Vice President, Research and Development and Chief Scientific Officer, Rempex Pharmaceuticals

Michael Dudley has more than 30 years of experience in anti-infective drug research and development, with experience in the discovery, preclinical and clinical stages in both academia and industry. He currently serves as senior vice president, Research and Development, and chief scientific officer for Rempex Pharmaceuticals in San Diego. Prior to co-founding Rempex, he held a similar position in Mpx Pharmaceuticals and was vice president of Preclinical and Clinical Sciences at Diversa Corp and vice president of Pharmacology and Microbiology at

Essential Therapeutics/Microcide Pharmaceuticals.

Prior to his career in the pharmaceutical industry, he held full-time academic appointments that included professor of pharmacy and chairman of the Department of Pharmacy Practice at the University of Rhode Island College of Pharmacy, and adjunct professor of medicine, Brown University School of Medicine and was based at Roger Williams Medical Center in Providence, RI. As an academic researcher, he conducted research in infectious disease, including important clinical studies (Phase I-IV) and pioneering work in describing PK-PD approaches and studies in several classes of antibacterial, antifungal and antiviral agents.

Dr. Dudley has published more than 100 scientific papers and book chapters describing the evaluation and clinical use of anti-infective agents and treatment of infectious diseases. He has served as a consultant on several advisory boards for pharmaceutical industry on anti-infective use and development, and as an editor for *Antimicrobial Agents and Chemotherapy* (1995–2002), where he remains on its editorial board. He has served as voting member and advisor of the Antimicrobial Susceptibility Testing Subcommittee of the Clinical Laboratory Standards Institute since 1996. He completed undergraduate work at Pepperdine University and his Doctor of Pharmacy from the University of California San Francisco (UCSF) in 1980, completed at residency at UCSF, and a fellowship in infectious diseases at Hartford Hospital.



Steven C. Ebert

Pharm.D., FCCP, FIDSA, Clinical Pharmacy Specialist, Clinical Supervisor, Meriter Hospital, Clinical Professor of Pharmacy, University of Wisconsin, Madison

Steven Ebert is clinical manager in Infectious Diseases at Meriter Hospital and Clinical Professor of Pharmacy, University of Wisconsin, Madison. He received his B.S. in Pharmacy from the University of Wisconsin in 1979. He subsequently received his Pharm.D at the University of Texas-Austin and completed a residency in infectious diseases at the University of

Texas Health Sciences Center at San Antonio. His practice and research interests are antimicrobial resistance; antimicrobial pharmacokinetics/pharmacodynamics; and appropriate utilization of health care resources. Dr. Ebert has served as a member of the board of directors of the Pharmacy Society of Wisconsin; as chairman of WARN (Wisconsin Antibiotic Resistance Network); and as president of the Society of Infectious Diseases Pharmacists. He also served as a member of the FDA Anti-Infective Drug Advisory Committee. Dr. Ebert has published more than 50 original research articles, review articles and book chapters on optimizing antimicrobial use and administration.



Matthew Bidwell Goetz

M.D., Chief of Infectious Diseases, Veterans Affairs Greater Los Angeles Healthcare System; Professor of Clinical Medicine, David Geffen School of Medicine at UCLA

Matthew Goetz is professor of clinical medicine at the David Geffen School of Medicine at

■ A New Pathway for Antibiotic Innovation: Exploring Drug Development for Limited Populations

UCLA, and chief of Infectious Diseases at the Veterans Affairs (VA) Greater Los Angeles Healthcare System. In addition, he is a member of the VA National HIV/AIDS Technical Advisory Group, the VA National Hepatitis C Technical Advisory Group, the VA National Medical Advisory Panel, the VA Infectious Diseases Field Advisory Committee and the VA Antimicrobial Stewardship Task Force. He is also a former member of the FDA Anti-Infective Drug Advisory Committee. Dr. Goetz is currently actively engaged in projects related to antimicrobial stewardship that are sponsored by the VA and the Centers for Disease Control and Prevention. He is the author of more than 100 peer-reviewed publications.



Robert Guidos

J.D., Vice President, Public Policy and Government Relations, Infectious Diseases Society of America

Robert Guidos serves as the Infectious Diseases Society of America's (IDSA) vice president of public policy and government relations. IDSA represents more than 10,000 infectious diseases physicians and scientists in the United States and abroad who are devoted to patient care, research, education, disease prevention, and public health. Mr. Guidos works with infectious diseases and other health care experts/organizations to develop sound, science-based legislative and regulatory policy. His team activates advocacy campaigns to carry IDSA's messages to the public as well as to policymakers in the U.S. Congress, Food and Drug Administration, Centers for Disease Control and Prevention, National Institutes of Health, and in other countries. Prior to coming to IDSA, Mr. Guidos did legislative work for FDA's commissioner and for the secretary, U.S. Health and Human Services. He served as a Brookings Institute Congressional Fellow in 1998. He earned his J.D. from the University of Pittsburgh School of Law (Pittsburgh, Pennsylvania), his B.S. in chemistry from Gannon University (Erie, Pennsylvania), and served as a U.S. Peace Corp volunteer in Kampala, Uganda. Mr. Guidos' scientific, legal, legislative and health policy experience has enabled him to work effectively with policy leaders in government; the medical, scientific, public health and international health communities; representatives from the pharmaceutical, biotechnology and diagnostic industries; patient advocates and the media.



Saira A. Jan

M.S., Pharm.D., Director of Clinical Pharmacy Management, Horizon Blue Cross Blue Shield of New Jersey; Clinical Professor, Ernest Mario School of Pharmacy, Rutgers State University of New Jersey

Saira Azimuddin Jan serves dual roles as director of Clinical Pharmacy Management at Horizon Blue Cross Blue Shield of New Jersey (BCBSNJ) and Clinical Professor at the Ernest Mario School of Pharmacy at Rutgers, the State University of New Jersey, and has led a wide array of administrative, clinical, academic, and research programs, using a collaborative approach to medication utilization for more than 15 years.

Dr. Jan's leadership and clinical influence at Horizon BCBSNJ has resulted in a variety of cross-divisional medical policies, utilization management programs and pharmacy-based disease state management programs. She directs clinical initiatives in formulary management, is the chair of the Horizon BCBSNJ Pharmacy and Therapeutics Committee, and works closely with the organization's business units and clinical quality and medical management divisions to deliver integrated services. Dr. Jan also leads Horizon's medication therapy management program for Medicare Part D and Special Needs Populations and serves on several national committees focused on evidence-based medication management, including MEDCAC, AHIP, AMCP, and the Blue Cross Blue Shield Association MAP.

Dr. Jan spearheads Horizon's research initiatives, collaborating with a network of leading academic institutions throughout the county. Additionally, she has been instrumental in securing pharmaceutical industry cooperation in research and program development initiatives targeting patient safety and improved medication compliance, among other critical clinical issues.

■ A New Pathway for Antibiotic Innovation: Exploring Drug Development for Limited Populations

Dr. Jan has published articles and manuscripts on those topics in several peer-reviewed journals. She has a master's in Pharmacology from St. John's University, NY, and a doctorate in Pharmacy from Rutgers, the State University of New Jersey.



Nicole Mahoney

Ph.D., Senior Officer, Antibiotics and Innovation Project, The Pew Charitable Trusts

Nicole Mahoney is the senior officer for Pew Charitable Trusts' Antibiotics and Innovation Project, which addresses the growing public health challenge of multidrug-resistant infections by supporting policies that stimulate and encourage the development of antibiotics to treat life-threatening illnesses.

Before joining Pew, Dr. Mahoney served as a U.S. Food and Drug Administration Commissioner's Fellow in the FDA's Office of Antimicrobial Products, analyzing the regulatory pathway for all new antibacterial drugs reviewed by the agency between 1980 and 2011. Prior to that, she was a technology development associate at the National Institute for Allergy and Infectious Diseases, providing patentability and marketability assessments for new technologies and negotiating agreements for research and the exchange of resources (equipment, funds, reagents) between the institute and partner organizations. She also served as an American Association for the Advancement of Science policy fellow at both the National Institutes of Health and the National Science Foundation.

Dr. Mahoney earned her Ph.D. in biochemistry from the Albert Einstein College of Medicine and completed postdoctoral training at the University of California, San Francisco.

John Powers

M.D., FACP, FIDSA, Associate Clinical Professor of Medicine, George Washington University School of Medicine and University of Maryland School of Medicine

John Powers is a physician/investigator on faculty as an associate clinical professor of medicine at the George Washington University School of Medicine. Prior to his current position, Dr. Powers was the lead medical officer for Antimicrobial Drug Development and Resistance Initiatives at the FDA. Dr. Powers was co-chair for the US Federal Inter-Agency Task Force on Antimicrobial Resistance. Prior to joining the FDA, Dr. Powers was assistant professor in the Division of Infectious Diseases at the University of Maryland School of Medicine, and he still is on the faculty there. Dr. Powers also actively cares for patients weekly in clinic and attends on the infectious diseases inpatient service.

Dr. Powers has been an investigator on more than 50 clinical trials. He has particular expertise in the design, conduct and analysis of clinical trials and has published on various aspects of clinical trial design.

Dr. Powers received his bachelor's degree and graduated magna cum laude from the University of Pennsylvania. He received his medical degree and residency training from Temple University School of Medicine, where he also served as chief resident. He completed his infectious diseases training at the University of Virginia School of Medicine.



John H. Rex

M.D., FIDSA, FACP, Infection Clinical Vice President, Infection Therapy Area, AstraZeneca Pharmaceuticals LP

John H. Rex received his medical degree from Baylor College of Medicine, trained in internal medicine at Stanford University Hospital and trained in infectious diseases at the National Institute of Allergy and Infectious Diseases. Dr. Rex served on the faculty of the University of

Texas Medical School at Houston from 1992–2002, during which time his work focused on laboratory studies of novel antifungal agents, clinical trials of novel antifungal agents and hospital epidemiology.

In 2003, Dr. Rex moved to AstraZeneca Pharmaceuticals where he currently serves as vice president and head of Infection, Global Medicines Development. Driven by a focused goal of *Build Infection*, Dr. Rex and his colleagues

■ A New Pathway for Antibiotic Innovation: Exploring Drug Development for Limited Populations

undertook collaborative team and program building for AstraZeneca via multiple approaches to partnership, creative risk sharing, three licensing deals, three acquisitions, and internal program progression. With these activities, the AstraZeneca Infection program has gone from having only one product in late life-cycle management to become a strongly supported and diversified program featuring products in all phases of clinical development, registration and post-approval commercialization.

In addition, Dr. Rex has been the industry representative on the FDA Anti-Infective Drug Advisory Committee, is chair of the Area Committee on Microbiology for the Clinical Laboratory Standards Institute, is a highlights advisor for *Nature Reviews Microbiology*, is a member of the Wellcome Trust Seeding Drug Discovery Committee, serves on several editorial boards, was formerly an editor for *Antimicrobial Agents and Chemotherapy*, and is an emeritus editor for www.doctorfungus.org, a nonprofit website devoted to dissemination of information about medical mycology.



James Scott

J.D., President and CEO, Applied Policy

James Scott, president and CEO of Applied Policy, founded the company to apply his in-depth and insider knowledge of federal health policy to help health care providers and companies succeed. Immediately prior to founding Applied Policy, Mr. Scott was charged with obtaining optimal Medicare coding, coverage and payment for all pharmaceutical products manufactured by Hoffmann-La Roche, Inc. While at Roche, he also worked to resolve Medicare and Medicaid reimbursement issues at the federal level and served as the company's principal point of contact with the Centers for Medicare & Medicaid Services (CMS).

Mr. Scott served as the senior legislative advisor at CMS, advising the CMS administrator on congressional intent in implementing the Medicare Modernization Act of 2003 and engaging members of Congress in the implementation of the Act. Prior to his service with CMS, Mr. Scott was an assistant counsel with the Office of the Legislative Counsel of the U.S. Senate, where he was a principal drafter of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 and other Medicare legislation.

Mr. Scott received a Bachelor of Science in Political Science from James Madison University in Harrisonburg, VA, and received his juris doctor, magna cum laude, from the Catholic University of America, Columbus School of Law, in Washington, DC.



David M. Shlaes

M.D., Ph.D., Owner, Anti-Infectives Consulting

David Shlaes has had a thirty-year career in anti-infectives spanning academia and industry with a long-standing scientific interest in antimicrobial resistance. In 1991, he was appointed professor of medicine at Case Western Reserve University. In 1996, Dr. Shlaes became vice president for Infectious Diseases at Wyeth Research for six years, assuming responsibility for the strategic direction for infectious diseases within Wyeth. He also was a member of the Forum for Emerging Infections of the National Academy of Sciences for seven years. In 2002, Dr. Shlaes became executive vice president, Research and Development for Idenix, Pharmaceuticals, a company located in Cambridge, MA, focused on the discovery and development of antivirals. In 2005, he left Idenix to form a consulting company for the pharmaceutical industry, Anti-Infectives Consulting, LLC. He was an independent director for Novexel, S.A, an anti-infectives biotech in Paris recently sold to AstraZeneca, and he consults for a number of other anti-infective focused biotechs, including Nabriva in Vienna, Austria, and Actelion in Basel, SW, as well as several large pharma companies. Dr. Shlaes frequently works with venture capital firms in the evaluation of anti-infective companies. He is now an editor for *Antimicrobial Agents and Chemotherapy*, a member of the NIH Drug Discovery and Mechanisms of Antimicrobial Resistance Study Section and the Antibacterial Drug Development Task Force of the Brookings Institution.

■ A New Pathway for Antibiotic Innovation: Exploring Drug Development for Limited Populations



Pranita Tamma

M.D., M.H.S., Director of Pediatric Antimicrobial Stewardship, Johns Hopkins Hospital

Pranita Tamma is faculty at Johns Hopkins in the Division of Pediatric Infectious Diseases and is the director of the Pediatric Antimicrobial Stewardship Program at Hopkins. She completed medical school at SUNY Downstate in Brooklyn, NY, and her pediatrics residency and infectious diseases fellowship at Johns Hopkins Hospital. She has a master's degree in public health from the Bloomberg School of Public Health. As director of the Pediatric Antimicrobial Stewardship Program at Johns Hopkins Hospital, Dr. Tamma spends a fair portion of her day actively educating prescribers about optimizing selection, route, dose, interval and frequency of antibiotics; developing guidelines to guide appropriate and judicious use of antibiotics; and monitoring patient outcomes after implementation of these practices. Her research focuses on comparative effectiveness studies related to antibiotic use.



Kavita K. Trivedi

M.D., Medical Epidemiologist and Lead, California Antimicrobial Stewardship Program Initiative, Healthcare Associated Infections Program, California Department of Public Health

Kavita Trivedi, a medical epidemiologist, created, manages and leads the California Antimicrobial Stewardship Program Initiative at the California Department of Public Health. She also leads the California Department of Public Health in investigating outbreaks and enquiries regarding infection control and prevention in health care settings in California. Prior to joining the California Department of Public Health, Dr. Trivedi was the medical director of the Downtown Clinic, a multidisciplinary clinic for homeless veterans in San Francisco. Thereafter, she served as an epidemic intelligence service officer in the United States Public Health Service with the Centers for Disease Control and Prevention (CDC) in Atlanta, GA. Dr. Trivedi received her medical degree from Stanford University School of Medicine and completed residency in internal medicine at the University of California, San Francisco.



Christine Welch

M.S., RAC, Vice President, Regulatory Affairs, Achaogen, Inc.

Chris Welch is the vice president of Regulatory Affairs at Achaogen, Inc, a small biotech company focused on the discovery and development of new antibiotics for the treatment of serious Gram-negative bacterial infections. Chris has more than 20 years industry experience in global regulatory affairs and drug development gained in both large pharma and small biotech companies, including SmithKline Beecham Pharmaceuticals, Gilead Sciences and Alexza Pharmaceuticals. She has been involved in a wide range of regulatory affairs activities from investigational new drug filings to global marketing approvals across a variety of products in the infectious diseases, respiratory, psychiatry and neurology therapeutic areas. Ms. Welch was previously an independent regulatory affairs consultant in the UK, specializing in providing global regulatory and filing strategies. Her early career was spent as clinical biochemist at the Western General Hospital in Edinburgh and Yorkhill Hospital in Glasgow, UK. Chris has a B.S. degree in Biochemistry from the University of Liverpool (UK), a MS degree in Clinical Biochemistry from the University of Newcastle-upon-Tyne (UK), and Regulatory Affairs certification from the University of California, Santa Cruz. She also holds the regulatory affairs certification (US).