

**Development of Non-Traditional Therapies for Bacterial Infections; Public Workshop—August 21-22, 2018**

**Speakers and Panelists**

**Paul Ambrose, Pharm.D.**

President  
Institute for Clinical Pharmacodynamics, Inc.  
New York, NY

**Michael Bevilacqua, MD, PhD**

Chief Scientific Officer/Chief Executive Officer  
Amicrobe, Inc.  
Carlsbad, CA

**Todd Black, PhD**

Director of Infectious Diseases-Drug Discovery  
Merck  
New York, NY

**Helen Boucher, MD**

Professor of Medicine,  
Tufts Medical Center, Tufts University School of Medicine  
Boston, MA

**Edward Burd, PhD**

Head of Regulatory Affairs  
Rebiotix, Inc.  
Roseville, MN

**Cara Cassino, MD**

EVP, Research and Development  
Chief Medical Officer  
ContraFect Corporation  
Yonkers, NY

**Edward Cox, MD, MPH**

Director  
Office of Antimicrobial Products (OAP)  
OND, CDER, FDA, Silver Spring, MD

**Wayne Dankner, MD**

Chief Medical Officer  
Atox Bio  
Carrboro, North Carolina

**Shampa Das, PhD**

Senior Lecturer, Antimicrobial Pharmacodynamics and Therapeutics  
University of Liverpool  
Liverpool, UK

**Mary Beth Dorr, PhD**

Director, Clinical Research, Infectious Diseases  
Merck  
Kenilworth, NJ

**Filip Dubovsky, MD**

Vice President of Clinical Development, Infectious Disease  
MedImmune  
Gaithersburg, MD

**Ann Eakin, PhD**

Senior Scientific Officer, Concept Acceleration Program  
Office of Biodefense, Research Resources & Translational Research/DMID/NIAID/NIH  
Rockville, MD

**Scott Evans, PhD**

Professor of Epidemiology and Biostatistics  
Director of the George Washington Biostatistics Center  
George Washington University  
Washington, DC

**Mayurika Ghosh, MD**

Medical Officer  
Division of Anti-Infective Products (DAIP), OAP  
OND, CDER, FDA  
Silver Spring, MD

**Ramya Gopinath, MD**

Medical Officer  
Division of Anti-Infective Products (DAIP), OAP  
OND, CDER, FDA  
Silver Spring, MD

**William Hope, PhD**

Professor of Therapeutics and Infectious Diseases  
University of Liverpool  
Liverpool, UK

**Dmitri Iarikov, MD**

Deputy Director  
DAIP, OAP  
OND, CDER, FDA  
Silver Spring, MD

**Michael Kaleko, MD, PhD**

Senior Vice President, Research and Development  
Synthetic Biologics, Inc.  
Rockville, MD

**Wes Kim, PhD**

Senior Officer, Innovation; Antibiotic Resistance Project  
The Pew Charitable Trusts  
Washington, DC

**Joe Larsen, PhD**

Senior Vice President for Life Sciences  
Strategic Marketing Innovations  
Washington, DC

**Elizabeth Leininger, PhD**

Vice President of Regulatory Affairs  
Aridis Pharmaceuticals  
San Jose, CA

**Owen McMaster, PhD**

Pharmacologist  
OND, CDER, FDA  
Silver Spring, MD

**David Melnick, MD**

Chief Medical Officer  
Spero Therapeutics  
Cambridge, MA

**Sumati Nambiar, MD, MPH**

Director  
DAIP, OAP  
OND, CDER, FDA  
Silver Spring, MD

**Kevin Outterson, JD**

Executive Director  
CARB-X  
Boston, MA

**Toni Perez, MD, PhD**

Chief Medical Officer  
Combioxin  
Geneva, Switzerland

**Peter Potgieter, MD, PhD**

VP, Medical Affairs  
Locus Biosciences, Inc.  
Research Triangle Park, NC

**John Rex, MD**

Chief Medical Officer & Director  
F2G, Ltd  
Manchester, UK

**Dan Rubin, PhD**

Statistician  
Division of Biometrics IV, Office of Translational Sciences (OTS), CDER, FDA  
Silver Spring, MD

**Mary Shatzoff, MS**

Senior Director of Regulatory Affairs  
Target Health Inc.  
New York, NY

**Kalavati Suvarna, PhD**

Microbiologist  
DAIP, OAP  
OND, CDER, FDA  
Silver Spring, MD

**Vu Truong, PhD**

Chief Executive Officer and Director  
Aridis Pharmaceuticals  
San Jose, CA

**Brian Tse, PhD**

Health Scientist  
Division of Chemical, Biological, Radiological, & Nuclear Countermeasures (CBRN)  
Biomedical Advanced Research & Development Authority (BARDA)  
Washington, DC

**Xiaohui (Tracey) Wei, PhD**

Pharmacologist  
OTS, Office of Clinical Pharmacology, CDER, FDA  
Silver Spring, MD

**Edward Weinstein, MD**

Medical Officer  
DAIP, OAP  
OND, CDER, FDA  
Silver Spring, MD

**Disclosures**

Dr. Paul Ambrose is employed by and have equity in ICPD, a company that provides pharmacometric services to industry.

Dr. Todd Black is a full-time employee of Merck.

Dr. Helen Boucher has the following disclosures:

- Data Monitoring Committee: Shire
- Scientific Advisory Board: Merck
- Editor: ID Clinics of North America; Antimicrobial Agents and Chemotherapy
- Treasurer: Infectious Diseases Society of America
- Member: ID Board and ID Test Writing Committee, American Board of Internal Medicine
- Voting Member: Presidential Advisory Council on Combating Antibiotic Resistant Bacteria (PACCARB)

Dr. Burd is a full-time employee of Rebiotix.

Dr. Cara Cassino is Chief Medical Officer at ContraFect Corp and is a full-time employee of the company.

Dr. Wayne M Dankner is a full-time employee of Atox Bio.

Dr. Shampa Das holds research grants with Spero Therapeutics, Allegra, Antabio, Bugworks, NAEJA-RGM and AMR Centre. Shampa Das is also working or has previously worked as a consultant with Pfizer, TenNor, Macrolide and Italfarmaco. She is also a former employee and holder of Astrazeneca shares.

Dr. Mary Beth Dorr is a full-time employee of Merck & Co., Inc, Kenilworth, NJ.

Dr Filip Dubovsky is a full-time employee and shareholder of MedImmune/AstraZeneca.

Dr. Evans reports grants from NIAID/NIH; personal fees from the FDA, NIH, The American Statistical Association, The Society for Clinical Trials, the Clinical Trials Transformation Initiative, the American Society for Microbiology, The Infectious Disease Society for America, ACTION, PPRECISE, the Huntington's Study Group, the Muscle Study Group, Osaka University, the National Cerebral and Cardiovascular Center of Japan, University of Rhode Island, NJMS / Rutgers, Statistical Communications in Infectious Diseases (Journal), Taylor and Francis, the City of Hope, the Austrian Breast & Colorectal Cancer Study Group (ABCSCG)/Breast International Group (BIG) and the Alliance Foundation Trials (AFT) , Takeda / Millennium, Pfizer, Roche, Novartis, Achaogen, Auspex, Alcon, Merck, Chelsea, Mannkind, QRx Pharma, Genentech, Affymax, FzioMed, Amgen, GSK, Boehringer-Ingelheim, the Drug Information Association, Cubist, AstraZeneca, Teva, Repros, Zeiss, Dexcom, Claret Medical, Vir, Arrebus, Five Prime, Shire, Alexion, Gilead, Spark, Nuvelution, Syndax, Advantagene, Tracon.

Dr. William Hope holds or has recently held research grants with F2G, AiCuris, Astellas Pharma, Spero Therapeutics, Matinas Biosciences, Antabio, Amplyx, Allecra, Bugworks, NAEJA-RGM, AMR Centre, and Pfizer. He holds awards from the National Institutes of Health, Medical Research Council, National Institute of Health Research, FDA and the European Commission (FP7 and IMI). William Hope has received personal fees in his capacity as a consultant for F2G, Amplyx, Auspex, Spero Therapeutics and BLC/TAZ. Dr. Hope is an Ordinary Council Member for the British Society of Antimicrobial Chemotherapy.

Dr. Michael Kaleko is a full-time employee of Synthetic Biologics, Inc., a public company pursuing strategies to protect the gut microbiome from antibiotic exposure.

Dr. Joe Larsen is Senior Vice President, Life Sciences at Strategic Marketing Innovations, a government relations firm. Locus Biosciences is a current client.

Dr. Leininger is currently Vice President and Head of Regulatory at Aridis Pharmaceuticals.

Dr. Melnick is a full-time employee of Spero Therapeutics, Cambridge, MA.

Professor Outtersson is a professor at Boston University and the Executive Director of CARB-X. He has no financial conflicts of interest with any drug company. His research is funded by the US Government, the Wellcome Trust, the UK Government, and the Bill and Melinda Gates Foundation.

Dr. Perez is the Chief Medical Officer of Combiouxin, member of GARDP (REVIVE), ESCMID Study Groups (Critically Ill Patients and Nosocomial Infections) and adviser of Abionic, Debiopharm, FP7-HEALTH-2010, Horizon 2020, EUREKA and Innovation Fund Denmark projects.

Dr. Potgieter is a full-time employee of Locus Biosciences.

Dr. John H. Rex is Chief Medical Officer & Director, F2G, Ltd.; Non-Executive Director & Consultant, Adenium Biotech ApS; Operating Partner & Consultant, Advent Life Sciences; and Expert-in-Residence, Wellcome Trust; He sits on the scientific advisory boards of Macrolide Pharmaceuticals; Bugworks Research, Inc.; Basilea Pharmaceutica; Forge Therapeutics, Inc.; and Novo Holdings; He is a shareholder in AstraZeneca Pharmaceuticals; F2G, Ltd; Adenium Biotech ApS; Advent Life Sciences; Macrolide Pharmaceuticals; and Bugworks Research, Inc.; He has received consulting fees from Phico Therapeutics; ABAC Therapeutics; Polyphor, Ltd.; Heptares Therapeutics, Ltd.; Gangagen, Ltd.; Meiji Seika Pharma; Basilea Pharmaceutica International Ltd.; Allecra Therapeutics GmbH; Forge Therapeutics, Inc.; SinSa Labs; AtoxBio; Peptilogics; F. Hoffmann-LaRoche, Ltd.; and Novo Holdings.

Mary Shatzoff is a Regulatory Affairs Executive and has been working in the pharmaceutical industry in clinical drug development for the past 20 years. She has been a Director of Regulatory Affairs at Target Health Inc. since 2006. Before she joined Target Health she worked as a Manager of Regulatory Affairs at Sanofi Aventis and a Quality Control Microbiologist at Pfizer. She is an active member of The Regulatory Affairs Professional Society (RAPS) as well as the Drug Information Association (DIA). Two of her articles have been published in Applied Clinical Trials Magazine and RAPS Focus Magazine. She received a Bachelor of Science in Biology from Northeastern University, and a Master of Science in Regulatory Affairs from Long Island University, Arnold & Marie Schwartz College of Pharmacy and Health Sciences. Certificates: Regulatory Affairs Certification (RAC-US), Certified Quality Auditor (CQA).

Dr. Vu Truong is a full-time employee of Aridis Pharmaceuticals, Inc.

Dr. Tse is a full-time employee of ASPR/BARDA. The division in which he works supports the development of new antibiotics by pharmaceutical companies, including non-traditional therapies. The pharmaceutical companies often provide cost-share in these development programs.