<u>Facilitating Anti-infective Drug Development for Neonates and Young Infants</u> — September 15, 2016

Speakers and Panelists

John Alexander, MD, MPH

Deputy Director

Division of Pediatric and Maternal Health (DPMH), Office of Drug Evaluation IV (ODEIV), CDER

Food and Drug Administration, Silver Spring, Maryland

Danny Benjamin, MD, PhD, MPH

Kiser-Arena Distinguished Professor of Pediatrics

Chair, Pediatric Trials Network

Faculty Associate Director, Duke Clinical Research Institute

Duke University, Durham, North Carolina

John Bradley, MD

Professor and Chief of the Division of Infectious Diseases in the Department of Pediatrics University of California, San Diego

John Farley, MD, MPH

Deputy Director

Office of Antimicrobial Products (OAP), CDER

Food and Drug Administration, Silver Spring, Maryland

William Hope, PhD

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

Laura Kovanda

Director, Global Development Project Leader

Astellas Pharma Global Development, Inc., Northbrook, IL

Susan McCune, MD, M.A.Ed.

Deputy Director

Office of Translational Sciences, CDER

Food and Drug Administration, Silver Spring, Maryland

Lily Mulugeta, Pharm.D.

Lead Scientist for Pediatrics

Division of Pharmacometrics, Office of Clinical Pharmacology, CDER

Food and Drug Administration, Silver Spring, Maryland

Sumathi Nambiar, MD, MPH

Director

Division of Anti-infective Products (DAIP), OAP, CDER

Food and Drug Administration, Silver Spring, Maryland

Gary Noel, MD

Senior Director in the Child Health Innovation Leadership Department (CHILD) Johnson and Johnson, Raritan, New Jersey

Christopher Rubino, Pharm.D.

Executive Vice President of Pharmacometrics Institute for Clinical Pharmacodynamics, Inc., Schenectady, New York

Brian Smith, MD, MHS, MPH

Professor of Pediatrics Steering Committee Member, Pediatric Trials Network Duke Clinical Research Institute Duke University, Durham, North Carolina

Thomas Smith, MD

Clinical Team Leader, Division of Anti-Infective Products OAP, CDER, FDA

Mark Turner, PhD

Senior Lecturer in Neonatology (Clinical) University of Liverpool, Liverpool, UK

Yuliva Yasinskava, MD

Medical Officer, Division of Anti-Infective Products OAP, CDER, FDA

Anne Zajicek, MD, Pharm.D.

Chief, Obstetric and Pediatric Pharmacology and Therapeutics Branch Eunice Kennedy Shriver National Institute of Child Health and Human Development National Institutes of Health, Bethesda, Maryland

Disclosures

Dr. Bradley's employer, the Regents of the University of California, receives research grant support from AstraZeneca, Alios, Cubist/Merck, Allergan, Cempra, The Medicines Company, Theravance, as well as the NICHD, and the RCHSD Foundation. The Regents provide consultation to Allergan, Alios, AstraZeneca, Nabriva and Zavante. The University of California may have other interactions with regulated industry of which Dr. Bradley is not aware.

Dr. Hope has received research funding from Pfizer, Gilead, Astellas, AiCuris, Amplyx, Spero Therapeutics and F2G, and acted as a consultant and/or given talks for Pfizer, Basilea, Astellas, F2G, Nordic Pharma, Medicines Company, Amplyx, Mayne Pharma, Spero Therapeutics, Auspherix, Cardeas and Pulmocide.

Dr. Rubino is a full time employee of the Institute for Clinical Pharmacodynamics and is currently the Executive Vice President of Pharmacometrics at ICPD.

Dr. Noel is a full-time employee of Johnson & Johnson.

Dr. Kovanda is a full-time employee of Astellas Pharma Global Development, Inc.