Duke UNIVERSITY | Duke-Margolis Center *for* Health Policy

Advancing Drug Development for the Prevention and Treatment of Respiratory Syncytial Virus Infections

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Biographies

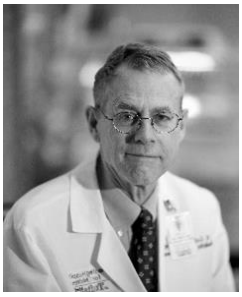
Michael Boeckh, MD, PhD, is a Full Member of the Vaccine and Infectious Disease division at Fred Hutch Cancer Research Center and a Professor of Medicine at the University of Washington. He heads a clinical research program focused on infectious diseases in immunocompromised patients. He conducts laboratory research, observational studies, as well as clinical trials of all phases. His major areas of interest are cytomegalovirus (CMV), HHV-6, respiratory viruses, and the genetic basis of infectious diseases. Most of these projects are bench-to-clinic translational research. Dr. Boeckh's lab is focused on pathogen-specific immune reconstitution. One major area of research is CMV, including the immune reconstitution after transplantation, transmission of CMV, and disease management in the immunocompromised patient population. Recently, he also initiated studies to determine the role of CMV and HHV-6 reactivation in the outcome of immunocompetent patients with sepsis and acute lung injury. Another active area of research is in respiratory viruses. Studies in immunocompromised patients are focused on the association of respiratory viruses and airflow obstruction, the adaptive immune response to respiratory viruses, viral dissemination and gene expression signatures as biomarkers for disease severity, and management strategies.

Jason Chien, MD, MSc, is a Director of Clinical Research in the Inflammation/Respiratory Therapeutics Area at Gilead Sciences, Inc. During his tenure at Gilead, Jason has focused on developing therapeutics targeted at the infectious etiologies and inflammatory processes that cause respiratory disease progression. He currently oversees Gilead development activities for respiratory viruses, including presatovir (GS-5806), a novel small molecule for treatment of RSV infections. Prior to joining Gilead, he was an Associate Professor of Medicine in the Division of Pulmonary and Critical Care Medicine at the University of Washington and an Associate Member in the Clinical Research Division at the Fred Hutchinson Cancer Research Center. During his 7 years on faculty as a translational epidemiologist, his NIH funded research team utilized genome wide approaches to identify clinical and molecular markers for risk stratification models. His scientific contributions in the field of bone marrow transplantation has guided the development of clinical management guidelines and remains accepted by the clinical community as standard of care for treatment of pulmonary complications such as bronchiolitis obliterans syndrome. Jason received his BA from University of Michigan, his MD from New Jersey Medical School, and an MS in Genetic Epidemiology from University of Washington. He completed clinical and research fellowships in infectious diseases at Case Western University Hospital and pulmonary and critical care medicine at the University of Washington.

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.

Selena Daniels, PharmD, is currently serving as acting Team Lead for the Clinical Outcome Assessments (COA) Staff in the Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). The COA Staff advises OND review divisions in matters of regulatory policy pertaining to the development and validation of clinical outcome assessments and related endpoints. This advice addresses matters of clinical study protocol design, analysis, and interpretation of clinical outcome assessments to support drug development, labeling, and promotion. Before joining the COA Staff, Selena was a Senior Manager in the Global Health Outcomes Strategy and Research department at Allergan, Inc. where she was responsible for developing and executing pharmacoeconomic and health outcome strategies to support Allergan's programs in Dermatology, Aesthetics, and Plastics. She has over 5 years of experience in health outcomes research including developing and implementing innovative patient-reported outcome strategies and endpoints for clinical trials. Selena earned her Bachelor of Science degree in Sports Medicine from Pepperdine University and her Doctor of Pharmacy degree from Loma Linda University. After completing pharmacy school, she completed a hospital pharmacy residency at the Medical Center of Central Georgia and earned her Master's in Pharmaceutical Sciences (emphasis in Pharmacoeconomics, Policy, and Outcomes) from the University of Arizona (through University of Arizona/Allergan Inc. Health Outcomes fellowship).

Filip Dubovsky, MD, MPH, joined MedImmune in 2006 and serves as Vice President Clinical Biologics and the Therapeutic Area Head of Infectious Disease and Vaccines. In this capacity, he leads the clinical development from candidate selection through demonstration of clinical efficacy for anti-infective biologics as well as prophylactic and therapeutic vaccines. He is responsible for the clinical support of the life-cycle management of Synagis and the FluMist franchise. Prior to joining MedImmune, Dr. Dubovsky served as the Scientific Director of the Malaria Vaccine Initiative, PATH, where he created and managed a portfolio of 25 malaria vaccine candidates spanning from early candidate optimization to Phase 3 clinical trial preparation. He also previously served in a clinical capacity at Stanford University, University of Maryland and John's Hopkins University hospitals. Dr. Dubovsky received a bachelor's degree in cell biology from Cornell University, a medical degree from the University of Alabama and a master's of public health degree from John's Hopkins University. He completed his pediatric training at Stanford University, Pediatric Infectious Disease fellowship at the Center for Vaccine Development at the University of Maryland and Preventive Medicine training at Johns Hopkins University.



H. Cody Meissner, MD, is Professor of Pediatrics at Tufts University School of Medicine and Chief of the Pediatric Infectious Disease Service at Tufts Medical Center in Boston. He is a Consultant to the Committee on Infectious Disease (Red Book Committee) for the American Academy of Pediatrics. He was a member of the Advisory Committee on Infectious Diseases (ACIP) at the Centers for Disease Control and Prevention (CDC) until July 2012. Dr. Meissner is the author of over 200 original reports, reviews, book chapters and AAP and CDC Policy Statements.

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.

Flor M. Munoz, MD, MSc, is Associate Professor of Pediatrics and Molecular Virology and Microbiology at Baylor College of Medicine (BCM) in Houston, Texas. Dr. Munoz is a pediatric infectious diseases specialist interested in the epidemiology and prevention of infections in young infants through pediatric and maternal immunization. She has over 18 years of experience in clinical research, conducting NIH and industry sponsored phase I to IV infant and maternal immunization studies, and clinical trials of antiviral drugs for infants and children with respiratory infections. Dr. Munoz is involved in CDC pandemic preparedness influenza projects that focus on surveillance, vaccine and antiviral effectiveness in hospitalized and ambulatory patients and pregnant women, and in the CDC NVSN ARI Surveillance Network. Dr. Munoz is a member of the Committee of Infectious Diseases of the American Academy of Pediatrics, and COID liaison to the ACIP influenza working group. She is a member of special interest groups on maternal immunization at NIH, CDC, WHO, NVAC, BM-Gates Foundation, and the Brighton Collaboration GAIA Project, which aims to achieve harmonization of definitions for the assessment of safety of vaccines in pregnancy. She is IRB Chair at BCM, Director of the Solid Organ Transplant Infectious Diseases program and Infectious Diseases Consultant at Texas Children's Hospital in Houston, TX.

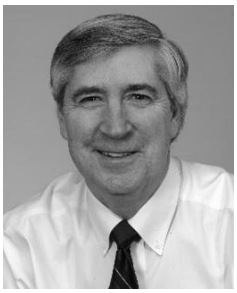
Jeffrey S. Murray, MD, MPH, is Deputy Director of the Division of Antiviral Products (DAVP) at the US Food and Drug Administration. He has worked in the Division in various capacities for over 20 years. At DAVP, Dr. Murray has reviewed and approved marketing applications for drugs to treat and/or prevent HIV, influenza, herpes viruses, hepatitis B and C. He has co-authored publications and FDA guidance documents for HIV drug development, HIV fixed dose combinations for the President's Emergency Plan for AIDS Relief (PEPFAR) and the development of drugs for the treatment of Influenza and Chronic Hepatitis C. Dr. Murray received his MD from The Ohio State University and his MPH in Epidemiology and Biostatistics from George Washington University in Washington, DC. He completed his internship, residency and chief residency in Internal Medicine at Riverside Methodist Hospitals in Columbus, followed by a fellowship in Infectious Diseases at the University of Cincinnati Medical Center. Dr. Murray is board certified in Internal Medicine and Infectious Diseases.

Barbara A. Rath, **MD, PhD,** has 20 years experience in phase 1-4 clinical trials and infectious diseases research in the US, Latin America and Europe. Dr. Rath has received her medical degree from the University of Erlangen-Nuremberg in Germany and her doctoral degrees from the University of Basel, Switzerland and the University of Besançon, France. In addition to a post-doctoral fellowship at the Stanford Center for AIDS Research, she has received pediatric residency and infectious disease subspecialty training at Duke and Tulane Universities, USA. As a former general coordinator for the Brighton Collaboration in Switzerland she is well familiar with international standards in vaccine safety. At Charité University with one of the largest pediatric emergency rooms in Europe and in close collaboration with the adjacent Robert-Koch-Institute in Berlin, Germany, she has established extensive real-time surveillance programs for the monitoring of influenza-like illness and drug safety in over 6000 infants and children. Recent research focuses on defining a precision medicine approach to managing children with infectious diseases. To this end, Dr. Rath has cofounded the Vienna Vaccine Safety Initiative (www.vi-vi.org), an international think tank and non-profit focused on vaccine safety and infectious disease research. In collaboration with the School of Design Thinking at the Hasso-Plattner-Institute in Potsdam, Germany (http://hpi.de/en/school-of-design-thinking.html) and CDISC (www.cdisc.org) in Austin, TX, USA, her team has worked intensely on developing innovative mobile health applications designed to standardize clinical endpoints and to improve the monitoring of adverse events and our understanding of disease burden associated with acute respiratory infections.

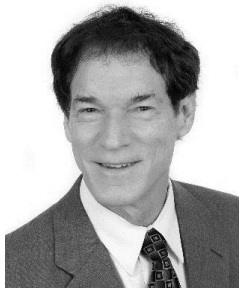
Jeff Roberts, MD, joined the FDA in 2008, where he now serves as Chief of Clinical Review Branch 1 in the Division of Vaccines at the Center for Biologics Evaluation and Research. Dr. Roberts attended medical school at the University of Alabama School of Medicine and trained in Obstetrics and Gynecology at the University of Colorado Health Sciences Center. In a fellowship at the National Institutes of Health prior to joining the FDA, Dr. Roberts conducted basic research on human papillomavirus, focusing on animal modeling of HPV infection. During his initial tenure at FDA, Dr. Roberts reviewed HPV vaccine applications at all phases of development. He now oversees the clinical review of a wide variety of vaccines, including the RSV vaccine candidates.

Alan Murray Shapiro, MD, PhD, FAAP, is a Pediatrician Infectious Diseases Specialist working in the Office of Computational Sciences at the Center for Drug Evaluation and Research (CDER) at FDA. Alan Shapiro received his BS in Life Sciences from the Massachusetts Institute of Technology (1985). He was a member of the Medical Scientist Training Program (MSTP) and received his Ph.D. in Biochemistry (1993) and his M.D. (1994) from the University of California San Francisco. His PhD thesis work involved studies of B lymphocyte development focusing on the regulation of heavy chain and light chain rearrangement. He completed his residency in Pediatrics at University of California Los Angeles (UCLA) Medical Center and continued his fellowship training in Pediatric Infectious Diseases. Dr. Shapiro is certified by the American Board of Pediatrics in General Pediatrics and Pediatric Infectious Diseases. Dr. Shapiro has been a medical officer at the Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration since 2003. Prior to his current position, he was a member of the Divisions of Pediatric Drug Development and Antiviral Products.

Prabha Viswanathan, MD, is a Pediatric Infectious Diseases specialist in the Division of Antiviral Products, Center for Drug Evaluation and Research (CDER), FDA. She earned her undergraduate degrees in Biology and Art History at Duke University and her MD degree from the University of Kansas. She completed General Pediatrics residency at the Children's Hospital of Philadelphia, where she subsequently worked as a pediatric hospitalist, and then continued her post-graduate training as a Pediatric Infectious Diseases fellow at Children's National Medical Center. Dr. Viswanathan has been serving as a Medical Officer in CDER since 2010 and has been a member of the Division of Antiviral Products since 2012. She is certified by the American Board of Pediatrics in General Pediatrics and Pediatric Infectious Diseases.



Edward Walsh, MD, is Professor of Medicine at the University of Rochester, and Head of Infectious Diseases at the Rochester General Hospital. His research activities since 1980 have revolved around many aspects of RSV infection. These include characterizing the function and antigenic characteristics of the viral proteins, primarily the F and G glycoproteins. This work also involved study of their role as potential vaccines in animal models of RSV infection. Dr. Walsh's clinical work has centered on describing the epidemiology an clinical characteristics of RSV infection in adult populations with an emphasis on high risk and elderly populations. In addition, laboratory work has attempted to describe immune correlates of protection in these groups. Currently, he is completing a three year study of the pathogenesis of disease severity in infants with primary RSV infection.



Robert C. Welliver, Sr, MD, is the Hobbs-Recknagel Endowed Chair in Pediatrics, Professor in the Department of Pediatrics at the Children's Hospital of Oklahoma, and Chief of Pediatric Infectious Diseases at Oklahoma University Health Sciences Center (OUHSC). Dr Welliver received his medical degree from the University of Florida College of Medicine in Gainesville, FL, and completed residency training in Pediatrics as well as a fellowship in Pediatric Infectious Diseases at UCLA Center for the Health Sciences in Los Angeles. A Fellow of the American Academy of Pediatrics and the Infectious Diseases Society of America, Dr Welliver is a member of the American Association of Immunologists, the American Pediatric Society, the American Society for Microbiology, and the American Thoracic Society. He is a past member of the Research Affairs Committee of the Pediatric Infectious Diseases Society. Dr Welliver serves on numerus hospital and university committees at OUHSC. He has received the Louis A. and Ruth Siegal Award for Excellence in Teaching from the State University of New York at Buffalo School of Medicine and Biomedical Sciences and the Frederick B. Wilkes Award for Teaching from the Pediatric Residents at Women and Children's Hospital of Buffalo, as well as the Outstanding Faculty Teaching Award in Pediatrics at OUHSC. In addition, Dr Welliver has been listed in The Best Doctors in America since 1998. He is a reviewer for more than 20 journals, including *Journal of Immunology, Journal of Infectious Diseases, Journal of Pediatrics*, *Pediatric Infectious Disease*, *Pediatric Pulmonology, New England Journal of Medicine,* and *The Lancet*. His career interest is in respiratory syncytial virus (RSV) and influenza virus infections. Dr Welliver has authored more than 230 articles (147 peer-reviewed) in such journals as *Journal of Immunology, Journal of Infectious Disease, Journal of Pediatrics,* and *New England Journal of Medicine*. He has received funding for research from the NIH, Oklahoma Center for Science and Technology, and various pharmaceutical companies including Merck, MedImmune and Novavax. His current research efforts are to develop an RSV vaccine, working both with pharmaceutical companies, as well as developing a proprietary RSV vaccine candidate. He is also currently studying an animal model of Zika virus infection.