

Public Workshop

Pediatric Clinical Investigator Training

September 22, 2014

Speakers' Biographies

**Alphabetically ordered by last name*

JONATHAN DAVIS, M.D., Tufts Medical Center

Jonathan Davis is Vice-Chair of Pediatrics and Chief of Newborn Medicine at the Floating Hospital for Children at Tufts Medical Center and Professor of Pediatrics at Tufts University School of Medicine. His research has focused on breathing problems in newborn infants, causes of newborn brain injury, and neonatal drug development. He has authored over 150 manuscripts and book chapters and received numerous grant awards from the National Institutes of Health, the FDA, the March of Dimes, the American Lung Association and many others. Dr. Davis has lectured worldwide including the Vatican Children's Hospital in Rome, the Pasteur Research Institute in Paris, and the National Academy of Sciences in Washington.

Dr. Davis has conducted the basic science and animal studies to support human trials of exogenous surfactant, human recombinant antioxidants, human recombinant anti-inflammatory agents (rhCC10), and many other drugs and devices in newborn infants and has been intimately involved in trial design, data collection, data analyses, and peer-reviewed publications. He is currently funded by NIH and FDA to develop better biomarkers and outcome measures for clinical trials and new and existing therapeutics to improve neonatal outcome. Dr. Davis is Chair of the Neonatal Advisory Committee in the Office of Pediatric Therapeutics at FDA and was recently elected to the Leadership Council of the American Pediatric Society. He has been actively involved in the Clinical and Translational Science Award Program and the BPCA Prioritization Committee at NIH. These positions permit him to work closely with NIH, FDA, academic leaders, and Industry to promote the development of important pediatric therapeutics.

LISA KAMMERMAN, Ph.D., Advanced Analytics Center, AstraZeneca

Lisa Kammerman is a Senior Principal Scientist in the Statistical Innovations Group. She provides statistical and regulatory consultation on drug development projects across many therapeutic areas, focusing on challenging trial designs and clinical outcome assessments. Prior to joining AstraZeneca, Dr. Kammerman was a Master Reviewer in the Office of Biostatistics, CDER, FDA. Over her twenty-four year FDA career, she worked in numerous therapeutic areas and participated in many committees, including the Pediatrics Evaluation and Review Committee, Science Prioritization and Review Committee, and the Research in Human Subjects Committee. She helped develop statistical and clinical guidance documents, and presented at many advisory committee meetings and professional meetings.

SUSAN LEIBENHAUT, M.D., Center for Drug Evaluation and Research, FDA

Susan Leibenhaut received her B.S. from MIT and her MD from Albert Einstein college of Medicine. After internship and residency in Boston and Washington DC, Dr. Leibenhaut practiced Internal Medicine in the Washington, DC area for 15 years before joining the FDA in 2000. From 2000 to 2008, Dr. Leibenhaut was a medical reviewer in CBER for a wide variety of products including cell and gene therapies. She reviewed a portfolio of products with broad indications for adult and pediatric diseases including inborn errors of metabolism, cerebral palsy, atherosclerosis and osteoarthritis. Since 2008, Dr. Leibenhaut has been a medical officer in Office of Compliance, CDER where she has been active working with Office of New Drugs on clinical practice compliance issues concerning drug development and approval. She is also the OSI liaison with EMA concerning areas of good clinical practice.

LINDA LEWIS, M.D., Center for Drug Evaluation and Research, FDA

Linda Lewis is a Team Leader in the Division of Antiviral Products (DAVP) in CDER. Dr. Lewis joined DAVP as a Clinical Reviewer in 1999 after working on the Pediatric Infectious Diseases staffs of the National Cancer Institute, NIH, and the DuPont Hospital for Children, Wilmington DE. She is board certified in General Pediatrics and Pediatric Infectious Diseases with a special interest in the care and treatment of pediatric patients with HIV/AIDS. Currently, she is a Medical Team Leader and the senior pediatrician in DAVP where she supervises reviews of new products for treatment and prevention of a variety of acute and chronic viral infections. She also serves as the DAVP/FDA liaison to the HHS Panel on Antiretroviral Therapy and Medical Management of HIV-Infected Children which publishes consensus guidelines for the use of antiretroviral agents in pediatric HIV infection.

ANDREW MOSHOLDER, M.D., M.P.H., Center for Drug Evaluation and Research, FDA

Andrew Mosholder is a medical officer in the Office of Surveillance and Epidemiology in CDER. He is a child and adolescent psychiatrist who joined FDA in 1992 to work on the premarketing evaluation of new psychiatric drugs. After completing a master's degree in public health from John Hopkins in 2001, he transitioned into his current position and now works as an epidemiologist in the Division of Epidemiology 1.

LILY MULUGETA, Pharm.D., Center for Drug Evaluation and Research, FDA

Lily Mulugeta received her Pharm.D degree from the University of Kentucky College of Pharmacy. She completed a residency in clinical pharmacy with a focus in pediatrics at Inova Fairfax Hospital in Falls Church, Virginia. Prior to joining the FDA, Dr. Mulugeta was a Critical Care Specialist and later the Director of Clinical Services at Children's National Medical Center (CNMC) in Washington D.C. Her primary research area was sedation management of pediatric

patients supported on mechanical ventilation. Dr. Mulugeta also served as a faculty member in the Department of Pediatrics at the George Washington School of Medicine and in the Departments of Pharmacy at the University of Maryland College of Pharmacy and Howard University School of Pharmacy. During her 8 years of service at CNMC, Dr. Mulugeta chaired several committees including the Pharmacy and Therapeutics Committee and served on the Institutional Review Board (IRB). In 2008, Dr. Mulugeta joined the Office of Clinical Pharmacology (OCP) at the FDA as a clinical pharmacologist in the Pediatric Clinical Pharmacology Staff (PCPS). She engages in scientific and regulatory research related to pediatric drug development. She is also involved in the development of FDA guidance to industry related to pediatric drug development and works in close collaboration with the Pediatric Maternal Health Staff (PMHS) and the Office of Pediatric Therapeutics (OPT). Dr. Mulugeta serves as the Office representative on the FDA Pediatric Review Committee (PeRC).

DIANNE MURPHY, M.D., F.A.A.P., Office of the Commissioner, FDA

Dianne Murphy, M.D., is the Director of the Office of Pediatric Therapeutics (OPT) in the Office of the Commissioner at FDA. OPT has legislatively mandated responsibilities for all of FDA's pediatric activities with a particular focus on safety and ethics. Previously, at the Center for Drugs at FDA, Dr. Murphy was Director of the Office of Counter-terrorism and Pediatric Drug Development (2001–2004), the Associate Director for Pediatrics (1998–2001), and Director of the Office of Drug Evaluation IV with oversight for all of the divisions involved with antimicrobial therapeutics (1998–2001). Dr. Murphy received her medical degree from the Medical College of Virginia. After completing a pediatric residency at the University of Virginia, she spent 3 years at the National Naval Medical Center as a Navy pediatrician before completing a fellowship in pediatric infectious diseases at the University of Colorado. Dr. Murphy was an assistant professor for pediatrics at the University of Texas Health Science Center at San Antonio, an associate professor of pediatrics and a medical consultant to the Diagnostic Virology Laboratory at the University of Tennessee Medical Center at Knoxville, and Professor of Pediatrics and Chief of General Pediatrics at the University of Florida Health Science Center at Jacksonville. Dr. Murphy has authored numerous articles in refereed publications on pediatric infectious diseases, pediatric drug development, residency teaching, and laboratory diagnosis, and is the editor of books on office laboratory procedures and Pediatric Drug Development. Dr. Murphy received the Academy's Excellence in Public Service Award from the American Academy of Pediatrics in May, 2013 and the Dr. Francis Kelsey Award from the FDA in June 2014.

ROBERT "SKIP" NELSON, M.D., Ph.D., Office of the Commissioner, FDA

Robert "Skip" Nelson, is currently the Deputy Director and Senior Pediatric Ethicist in the Office of Pediatric Therapeutics, Office of the Commissioner. Immediately prior to joining FDA full-time in 2009, he was Professor of Anesthesiology, Critical Care and Pediatrics at The Children's Hospital of Philadelphia and University of Pennsylvania School of Medicine. After receiving his M.D. degree from Yale University, Dr. Nelson trained in pediatrics (Massachusetts

General Hospital), neonatology and pediatric critical care (University of California, San Francisco). He has a Master of Divinity degree from Yale Divinity School and a Ph.D. in The Study of Religion from Harvard University.

Dr. Nelson was a member (2004-2006) and former Chair (2005-2006) of the FDA Pediatric Advisory Committee and the Pediatric Ethics Subcommittee. He was a member of the Subcommittee on Research Involving Children of the Secretary's Advisory Committee on Human Research Protections (2003-2006), and the Human Studies Review Board of the Environmental Protection Agency (2006). Dr. Nelson was a member of the Committee on Clinical Research Involving Children of the Institute of Medicine (2002-2004), and a member and former Chair of the Committee on Bioethics of the American Academy of Pediatrics (1994-2001). Dr. Nelson is the Editor-in-Chief of the AJOB – Empirical Bioethics, which publishes empirical research in bioethics. Dr. Nelson's academic research explored various aspects of child assent and parental permission, including risk perception and voluntary choice, and was funded by the Greenwall Foundation, the National Institutes of Health, and the National Science Foundation.

ANNE PARISER, M.D., Center for Drug Evaluation and Research, FDA

Anne Pariser is the Associate Director for Rare Diseases in the Office of New Drugs in CDER. She established the Rare Diseases Program in OND in 2010, where she is currently working to support, facilitate and accelerate the development of therapeutics for rare diseases. The Rare Diseases Program concentrates on the development of biomedical and regulatory science, rare disease-specific training and education, and policy and guidance generation for rare disease product review and regulation. Dr. Pariser is also actively involved in numerous collaborations within FDA and with drug developers, other governmental agencies, advocacy groups and other stakeholders to further the development of treatments for rare diseases. Dr. Pariser has worked at FDA since 2000. Prior to founding the Rare Diseases Program, she was a Medical Officer and Team Leader in OND where she worked almost exclusively on the review and regulation of products for rare genetic disorders. Her research interests include the development of regulatory, translational and biomedical science for rare diseases and Orphan products.

JULIA PINTO, Ph.D., Center for Drug Evaluation and Research, FDA

Julia Pinto is a chemistry reviewer in the Office of New Drug Quality Assessment in CDER. Dr. Pinto received her Bachelor's degree in Chemistry and her Ph.D. in Organic/ Medicinal Chemistry from Rutgers University in NJ, in 1991. She did her postdoctoral training in Medicinal Chemistry at the University of Louis Pasteur in Strasbourg, France and in the Laboratory of Medicinal Chemistry at the NIH, NIDDK. Prior to joining the FDA in 2005, she worked in the Pharmaceutical Industry for 10 years, as Associate Director of Chemistry and Principle Scientist, responsible for the lead optimization and drug development for the opiate, cannabinoid, ion channel and anti-infective programs. Dr. Pinto joined the Agency in January 2005, as a Chemistry Reviewer in the CDER's Office of New Drug Quality Assessment.

Currently, she is the Acting Branch Chief in Division III, of Office of New Drug Quality Assessment, supporting both the Divisions of Anesthesia, Analgesia and Pain and the Division of Pulmonary and Rheumatology Products. In addition to her review related functions, Dr. Pinto continues to serve as a member of the Pediatric Research Equity Act (PREA) Committee.

HARI SACHS, M.D., Center for Drug Evaluation and Research, FDA

Hari Sachs is a team leader with the Pediatric and Maternal Health Staff in CDER. Dr. Sachs joined the pediatric group at FDA in Sept 2002 as a medical officer and is now the pediatric team leader on PMHS. She also is a member of the Pediatric Review Committee and serves as one of the FDA liaisons to the AAP Committee on Drugs. Dr. Sachs graduated from the University of Maryland at College Park with a BS in Zoology, received her MD from the University of Maryland at Baltimore and completed her residency training at Children's Hospital National Medical Center. Dr. Sachs has been treating patients for over 25 years and continues to see patients on a weekly basis.

BRIAN SMITH, M.D., M.P.H., M.H.S., Duke University Medical Center

Brian Smith is a neonatologist and chief of the Division of Quantitative Sciences in the Department of Pediatrics at Duke University. He completed his residency in pediatrics and a fellowship in neonatal medicine at Duke University Medical Center in 2004 and 2007, respectively. He is the author of more than 150 peer-reviewed publications, most in the areas of pediatric drug safety, neonatal pharmacology, and the epidemiology of neonatal infections. He has leadership roles in several large ongoing, multicenter studies evaluating the safety, dosing, and efficacy of drugs in children. He is a steering committee member of the NICHD-funded Pediatric Trials Network (PTN) which is tasked with evaluating the safety and dosing of off-patent drugs and devices in children under the BPCA.

MELISSA S. TASSINARI, Ph.D., DABT, Center for Drug Evaluation and Research, FDA

Melissa Tassinari is a Senior Clinical Advisor with the Pediatric and Maternal Health Staff (PMHS), in the Office of New Drugs at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA). She joined the FDA after retiring from Pfizer, Inc. where she held several leadership positions in the toxicology laboratories and in regulatory affairs. Prior to joining Pfizer, she was Assistant Professor in Cell Biology at the University of Massachusetts Medical Center and taught at both Simmons and Wellesley College. She is a past-president of the Teratology Society and has broad experience in both developmental toxicology and pediatric drug development. She received her BA in Biology from Mount Holyoke College, her PhD in Anatomy from the Medical College of Wisconsin and did her post doctoral training in the Harvard School of Dental Medicine and the Department of Orthopedics at Boston Children's Hospital.

LYNNE YAO, M.D., Center for Drug Evaluation and Research, FDA

Lynne Yao is the Associate Director, Office of New Drugs, Pediatric and Maternal Health Staff, a position she has held since 2012. The Pediatric and Maternal Health Staff oversees quality initiatives which promote and necessitate the study of drug and biological products in the pediatric population; and improve pregnancy and lactation-related information in product labeling. Dr. Yao started at FDA as a Medical Officer and primary reviewer on the Inborn Errors of Metabolism team in the Division of Gastroenterology and Inborn Errors Products (DGIEP) in 2008, and was a team leader in DGIEP from 2009-2012. Dr. Yao graduated from the George Washington University School of Medicine, completed residency in Pediatrics at Walter Reed Army Medical Center, and fellowship in Pediatric Nephrology at the Georgetown University Children's Medical Center. Dr. Yao is board certified in both Pediatrics and Pediatric Nephrology.

ANNE ZAJICEK, M.D., Pharm.D., The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, NIH

Anne Zajicek is a board-certified pediatrician and pediatric clinical pharmacologist who currently serves as Chief of the Obstetric and Pediatric Pharmacology and Therapeutics Branch at the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD). She received a Bachelor's degree in Pharmacy from Duquesne University and a PharmD from the State University of New York at Buffalo; completed a postdoctoral fellowship in the Department of Pharmaceutics of St. Jude Children's Research Hospital; and served as an assistant professor at the University of Colorado School of Pharmacy and a Clinical Pharmacist at National Jewish Hospital and Research Center. In 1991, Dr. Zajicek entered medical school at the University of Pittsburgh, and, in 1998, completed a residency in pediatrics at the Children's Hospital of Pittsburgh. She practiced primary care pediatrics for 2 years and then continued her training as a pediatric clinical pharmacology fellow at Stanford University. She subsequently joined the U.S. Food and Drug Administration (FDA) in the Office of Clinical Pharmacology and Biopharmaceutics. She joined NICHD as a Pediatric Medical Officer in August 2003, and was appointed Chief of the Obstetric and Pediatric Pharmacology and Therapeutics Branch in 2010. The Branch is responsible for the NIH implementation of the Best Pharmaceuticals for Children Act, and manages a portfolio of basic, translational and clinical research and training grants in obstetric and pediatric pharmacology.