

FOOD AND DRUG ADMINISTRATION

Joint Meeting of the Pediatric Advisory Committee (PAC) and the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC)

Tommy Douglas Conference Center
10000 New Hampshire Avenue
Silver Spring, Maryland 20903
May 11, 2018

FINAL MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Marieann Brill, MBA, RAC, MT(ASCP)

Office of the Commissioner
Office of Pediatric Therapeutics (OPT)
Food and Drug Administration (FDA)

PEDIATRIC ADVISORY COMMITTEE MEMBERS (Voting)

<p><u>Mark Hudak, MD - Chair</u> Expertise: Neonatology Professor and Chairman of Pediatrics University of Florida, College of Medicine Jacksonville, Florida 32209</p>	<p><u>Danielle Boyce, M.P.H.</u> Expertise: Patient-Family Representative Senior Research Data Analyst Johns Hopkins University Baltimore, MD 21218</p>
<p><u>Mary Cataletto, MD, FAAP</u> Expertise: Pediatric Pulmonary Attending Physician Winthrop University Hospital Mineola, New York 11501 Professor of Clinical Pediatrics SUNY Stony Brook Stony Brook, New York 11794</p>	<p><u>Melody Cunningham, M.D.</u> Expertise: Hematology/Oncology/Palliative Medicine Medical Director Palliative Medicine Service Le Bonheur Children's Hospital Associate Professor of Pediatrics University of Tennessee, Medical School Memphis, TN 38103</p>
<p><u>Robert Dracker, MD, MHA, MBA, CPI</u> Expertise: Pediatrics Director, Summerwood Pediatrics Infusacare Medical Services Liverpool, New York 13088</p>	<p><u>Peter Havens, MD, MS</u> Expertise: Pediatric Infectious Diseases Director, Pediatric HIV Care Program Children's Hospital of Wisconsin Professor, Pediatric and Population Health Medical College of Wisconsin Milwaukee, WI 53201</p>
<p><u>Michael White, MD, PhD, FACC, FAAP</u> Expertise: Pediatric Cardiology Pediatric Cardiologist Ochsner Health System New Orleans, Louisiana, 70121</p>	

PEDIATRIC ADVISORY COMMITTEE MEMBERS (Non-Voting)

<p><u>Ronald Portman, M.D., F.A.A.P.</u> Expertise: Industry Representative & Pediatric Nephrology Executive Director Pediatric Development, Science and Innovation Novartis Pharmaceutical Company East Hanover, NJ 07936</p>	
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Endocrinologic and Metabolic Drugs Advisory Committee Members (Voting)

<p><u>Michael Blaha, MD, MPH</u> Expertise: Cardiology, Lipidology, Epidemiology Term: 07/01/2016 – 06/30/2020 Assistant Professor, Cardiology and Epidemiology Director of Clinical Research Johns Hopkins Ciccarone Center for the Prevention of Heart Disease Baltimore, Maryland 21287</p>	<p><u>Daniel Budnitz, MD, MPH</u> Expertise: Epidemiology Term: 07/01/2015 – 06/30/2019 CAPT, US Public Health Service Director, Medication Safety Program Division of Healthcare Quality Promotion Centers for Disease Control and Prevention Atlanta, Georgia 30333</p>
<p><u>Kenneth D. Burman, MD</u> Expertise: Endocrinology, Diabetology Term: 07/01/2016 – 06/30/2020 Chief, Endocrine Section MedStar Washington Hospital Center Professor, Department of Medicine Georgetown University Washington, District of Columbia 20010</p>	<p><u>Brendan M. Everett, MD, MPH</u> Expertise: Cardiology Term: 10/30/2014 – 06/30/2018 Assistant Professor of Medicine Harvard Medical School Director, General Cardiology Inpatient Service Brigham and Women’s Hospital Boston, Massachusetts 02215</p>
<p><u>Cecilia C. Low Wang, MD, FACP</u> Expertise: Endocrinology, Diabetes, and Metabolism Term: 07/01/2016 – 06/30/2020 Associate Professor of Medicine Director, Glucose Management Team University of Colorado Hospital Associate Director, Fellowship/Education Division of Endocrinology, Metabolism and Diabetes University of Colorado Anschutz Medical Campus School of Medicine Medical Safety Officer and Safety Lead CPC Clinical Research Aurora, Colorado 80045</p>	<p><u>James D. Neaton, PhD</u> Expertise: Biostatistics Term: 10/30/2014 – 06/30/2018 Professor of Biostatistics Division of Biostatistics Coordinating Centers for Biometric Research School of Public Health University of Minnesota Minneapolis, Minnesota 55414</p>

<p><u>Thomas J. Weber, MD</u> Expertise: Endocrinology, Metabolic Bone Disease Term: 07/01/2016 – 06/30/2020 Associate Professor, Endocrinology, Metabolism and Nutrition Duke University Medical Center Durham, North Carolina 27710</p>	<p><u>Peter W. F. Wilson, MD</u> Expertise: Cardiology, Endocrinology, Public Health Term: 07/01/2014 – 06/30/2018 Director, Epidemiology and Genomic Medicine Atlanta Veterans Administration Medical Center Professor of Medicine and Public Health Emory University Emory Clinical Cardiovascular Research Institute Atlanta, Georgia 30322</p>
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TEMPORARY MEMBERS (Voting)

<p><u>Jatinder Bhatia, MD, FAAP</u> Expertise: Neonatology Chief, Division of Neonatology Department of Pediatrics School of Medicine Director, Fellowship Program in Neonatal-Perinatal Medicine Vice Chair, Clinical Research Department of Pediatrics Augusta University Augusta, Georgia 30912</p>	<p><u>David Cooke, MD</u> Expertise: Pediatric Endocrinology Clinical & Interim Director Pediatric Endocrinology Johns Hopkins University School of Medicine Baltimore, MD 21205</p>
<p><u>Kathleen Neville, MD, MS, FAAP, FCCP</u> Expertise: Clinical Pharmacology Section Chief, Division of Clinical Pharmacology & Medical Toxicology Arkansas Children’s Hospital Professor of Pediatrics University of Arkansas for Medical Sciences Little Rock, AR 72202</p>	<p><u>Joshua Pahys, MD</u> Expertise: Orthopedic Surgery Attending Spine Surgeon Shriners Hospitals for Children Philadelphia, PA 19140</p>
<p><u>Han Phan, MD</u> Expertise: Child Neurology & Sleep Medicine Guest Researcher and Consultant, Newborn Screening Branch Centers for Disease Control and Prevention Atlanta, GA 30329</p>	

FDA PARTICIPANTS (Non-Voting)

<u>Smita Abraham, MD</u> Clinical Reviewer Division of Metabolism and Endocrinology Products Center for Drug Evaluation and Research (CDER), FDA	<u>Mary Thanh Hai, MD</u> Acting Director Office of New Drugs, Office of Drug Evaluation II CDER, FDA
<u>Donna Snyder, MD, FAAP</u> Pediatric Ethicist/Team Lead Office of Pediatric Therapeutics, Office of the Commissioner, FDA	<u>Marina Zemskova, M.D.</u> Clinical Team Leader Division of Metabolism and Endocrinology Products CDER, FDA