FOOD AND DRUG ADMINISTRATION Office of the Commissioner (OC) Office of Pediatric Therapeutics (OPT)

Pediatric Advisory Committee (PAC) Meeting

U.S. Food and Drug Administration 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002

Pediatric Advisory Committee April 8, 2019 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)

Robert Dracker, MD, MHA, MBA, CPI - Chair Expertise: Pediatrics Director, Summerwood Pediatrics Infusacare Medical Services Liverpool, New York 13088	Randall Flick, MD, MPH Expertise: Pediatrics & Anesthesiology Medical Director Mayo Clinic Children's Center Rochester, MN 55905
Premchand Anne, MD, MBA, MPH, FACC Expertise: Pediatric Cardiology Director, Division of Pediatric Cardiology St. John Providence Children's Hospital Detroit, MI 48236	Peter Havens, MD, MS 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
David Callahan, MD Expertise: Child Neurology Associate Professor, Clinical Neurology Washington University, School of Medicine Child Neurology Washington University Clinical Associates, LLC Chesterfield, MO 63017	Sarah Hoehn, MD, MBe, FAAP Expertise: Pediatric Critical Care Associate Professor of Pediatrics Director, Pediatric Palliative Care Team University of Chicago Chicago, IL 60637
Mary Cataletto, MD, FAAP Expertise: Pediatric Pulmonary Attending Physician Winthrop University Hospital Mineola, New York 11501 Professor of Clinical Pediatrics SUNY Stony Brook Stony Brook, New York 11794	Randi Oster, MBA Expertise: Consumer Representative Co-Founder and CEO, Help Me Health Fairfield, CT 06824

Wael Sayej, MD	Kelly Wade, MD, PhD
Expertise: Pediatric Gastroenterology	Expertise: Neonatology
Attending Physician	Attending Neonatologist
Connecticut Children's Medical Center	Department of Pediatrics
Assistant Professor of Pediatrics	Children's Hospital of Philadelphia
University of Connecticut School of Medicine	Philadelphia, PA 19107
Hartford, Connecticut, 06106	
Christy Turer, MD, MHS, FAAP, FTOS	
Expertise: Internal & Obesity Medicine	
Assistant Professor, Pediatrics,	
Clinical Sciences and Medicine	
Director, General Academic Pediatrics Fellowship	
UT Southwestern and Children's Medical Center	
Dallas, TX 75390	

PEDIATRIC ADVISORY COMMITTEE MEMBERS (Non-Voting)

Bridgette Jones, MD, MS	Ronald Portman, MD, FAAP
Expertise: Pediatric Health Organization	Expertise: Industry Representative & Pediatric
Representative, Allergy/Immunology, & Pediatric	Nephrology
Clinical Pharmacology	Executive Director
Associate Professor of Pediatrics	Pediatric Development, Science and Innovation
Children's Mercy Hospital	Novartis Pharmaceutical Company
Kansas City, MO 64108	East Hanover, NJ 07936

TEMPORARY MEMBERS (Voting)

David Cooke, MD Expertise: Pediatric Endocrinology Clinical Director, Pediatric Endocrinology Johns Hopkins University School of Medicine Baltimore, MD 21287	Richard Holubkov, PhD Expertise: Biostatistics Professor, Division of Critical Care Department of Pediatrics, School of Medicine University of Utah
Angela Delaney, MD Expertise: Pediatric Endocrinology Assistant Research Physician NICHD, National Institutes of Health Bethesda, MD 20892	Salt Lake City, Utah, 84112 James McGough, MD Expertise: Child and Adolescent Psychiatry Attending Physician, Division of Child & Adolescent Psychiatry Director, Child & Adolescent Psychopharmacology Clinic Semel Institute for Neuroscience & Human Behavior at UCLA Los Angeles, CA 90024
Peggy DiCapua Expertise: Patient-Family Representative Dyer, IN	

FDA PARTICIPANTS (Non-Voting)

John Alexander, MD, MPH Deputy Director Division of Pediatric and Maternal Health, Office of Drug Evaluation IV Office of New Drugs, Center for Drug Evaluation and Research	Susan McCune, MD Director Office of Pediatric Therapeutics Office of the Commissioner
Ovidiu Galescu, MD, MS Medical Officer Division of Metabolism and Endocrinology Products, Office of Drug Evaluation II, Office of New Drugs, Center for Drug Evaluation and Research	Christine P. Nguyen, MD Deputy Director for Safety Division of Bone, Reproductive, and Urologic Products, Office of Drug Evaluation III Office of New Drugs, Center for Drug Evaluation and Research
Ethan Hausman, MD Medical Officer Division of Pediatric and Maternal Health Office of Drug Evaluation IV Office of New Drugs, Center for Drug Evaluation and Research	John Sharretts, MD Medical Officer Division of Metabolism and Endocrinology Products, Office of Drug Evaluation II, Office of New Drugs, Center for Drug Evaluation and Research