# Joint Meeting of the Pediatric Advisory Committee (PAC) and Drug Safety and Risk Management Advisory Committee (DSaRM) FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503) 10903 New Hampshire Avenue, Silver Spring, MD September 26, 2019

# FINAL MEETING ROSTER

## **DESIGANTED FEDERAL OFFICER (Non-Voting)**

### Marieann Brill, MBA, RAC, MT(ASCP)

Office of Pediatric Therapeutics (OPT) Office of Clinical Policy and Programs (OCPP) OC, FDA

## PEDIATRIC ADVISORY COMMITTEE MEMBERS (Voting)

### Kelly Wade, MD, PhD

*(Chairperson)* Attending Neonatologist Department of Pediatrics Children's Hospital of Philadelphia Philadelphia, PA 19107

### David Callahan, M.D.

Associate Professor, Clinical Neurology Washington University, School of Medicine Child Neurology Washington University Clinical Associates, LLC Chesterfield, MO 63017

### Peter Havens, MD, MS

Director, Pediatric HIV Care Program Children's Hospital of Wisconsin Professor, Pediatric and Population Health Medical College of Wisconsin Milwaukee, WI 53201

#### Randi Oster, MBA

*(Consumer Representative)* Co-Founder and CEO, Help Me Health Fairfield, Connecticut 06824

### Premchand Anne, MD, MBA, MPH, FACC

Director, Division of Pediatric Cardiology St. John Providence Children's Hospital Detroit, MI 48236

### Randall Flick, MD, MPH

Medical Director Mayo Clinic Children's Center Rochester, MN 55905

## Sarah Hoehn, MD, MBe, FAAP

Associate Professor of Pediatrics Director, Pediatric Palliative Care Team University of Chicago Chicago, IL 60637

### Wael Sayej, MD

Expertise: Pediatric Gastroenterology Attending Physician Connecticut Children's Medical Center Associate Professor of Pediatrics University of Connecticut School of Medicine Hartford, Connecticut, 06106

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## FINAL MEETING ROSTER (cont.)

#### Christy Turer, MD, MHS, FAAP, FTOS

Assistant Professor, Pediatrics, Clinical Sciences and Medicine Director, General Academic Pediatrics Fellowship Professor, Division of Pulmonary and Sleep UT Southwestern and Children's Medical Center Dallas, Texas 75390

#### **Benjamin Wilfond, MD**

Professor and Chief, Division of Bioethics and Palliative Care Medicine Department of Pediatrics, School of Medicine University of Washington Seattle, Washington 98195

#### PEDIATRIC ADVISORY COMMITTEE MEMBER (Non-Voting)

#### **Ronald Portman, MD, FAAP**

(Industry Representative) Executive Director, Pediatric Development, Science and Innovation Novartis Pharmaceutical Company East Hanover, New Jersey 07936

### DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE MEMBERS (Voting)

### Sonia Hernandez-Diaz, MD, MPH, DrPH

Professor of Epidemiology Department of Epidemiology Harvard T.H. Chan School of Public Health Boston, Massachusetts 02115

#### Laurel A. Habel, MPH, PhD

Associate Director, Cancer Research **Division of Research** Kaiser Permanente Northern California Oakland, California 94612

#### Marie R. Griffin, MD, MPH

Professor, Health Policy and Medicine Director, Vanderbilt MPH Program Department of Health Policy Vanderbilt University Medical Center Nashville, Tennessee 37212

### Martin Kulldorff, PhD

Professor of Medicine and Biostatistician Division of Pharmacoepidemiology and Pharmacoeconomics Department of Medicine Harvard Medical School and Brigham & Women's Hospital Boston, Massachusetts 02120

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## FINAL MEETING ROSTER (cont.)

### Steven B. Meisel, PharmD, CPPS

Expertise: Medication Safety System Director of Medication Safety Fairview Health Services Minneapolis, Minnesota 55414

### **TEMPORARY MEMBERS (Voting)**

#### Amy Celento, BS

(Patient-Family Representative) National Vice President Cooley's Anemia Foundation New York, New York 10001

#### **Richard Holubkov, PhD**

Professor, Division of Critical Care Department of Pediatrics University of Utah Salt Lake City, Utah 84108

#### James McGough, MD

Attending Physician Division of Child and Adolescent Psychiatry Resnick Neuropsychiatric Hospital at UCLA University of California, Los Angeles Los Angeles, California 90095

#### Stephen Patrick, MD, MPH, MS

Assistant Professor of Pediatrics & Healthy Policy Division of Neonatology Vanderbilt Center for Health Services Research Vanderbilt Center for Addiction Research Director, Vanderbilt Center for Child Health Policy Vanderbilt University School of Medicine Nashville, Tennessee 37203

#### <u>Suzanne B. Robotti</u>

*(Consumer Representative)* Executive Director DES Action USA Founder and President MedShadow Foundation New York, New York 10023

#### Angela Czaja, MD, MSc

Associate Professor Division of Critical Care, Department of Pediatrics School of Medicine University of Colorado Aurora, Colorado 80045

#### Timothy Lesar, PharmD

Patient Care Service Director for Pharmaceutical Care Services Director of Clinical Pharmacy Services Albany Medical Center Albany, New York 12208

#### Roberto Ortiz-Aguayo, MD, MMM

Associate Chair & Attending Physician Department of Child & Adolescent Psychiatry & Behavioral Sciences Children's Hospital of Philadelphia Philadelphia, Pennsylvania 19104

#### Jeanmarie Perrone, MD

Attending Physician, Emergency Department Hospital of the University of Pennsylvania Director, Division of Medical Toxicology, Department of Emergency Medicine University of Pennsylvania Philadelphia, PA 19104

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### FINAL MEETING ROSTER (cont.)

#### Lynn Sleeper, ScD

Associate Professor, Pediatrics Harvard Medical School Scientific Research Associate, Cardiology Boston Children's Hospital Boston, Massachusetts 02115

#### **TEMPORARY MEMBER (Non-Voting)**

#### **Bridgette Jones, MD, MS**

(Pediatric Health Organization Representative) Associate Professor of Pediatrics Divisions of Allergy/Asthma/Immunology and Pediatric Clinical Pharmacology, Toxicology, and Therapeutic Innovation Children's Mercy Hospitals and Clinics Kansas City, Missouri 64108

#### FDA PARTICIPANTS (Non-Voting)

#### Susan McCune, MD

Director OPT, OCPP, OC, FDA

#### Judy Staffa, PhD, RPh

Associate Director for Public Health Initiatives Office of Surveillance and Epidemiology (OSE) CDER, FDA

### Jana McAninch, MD, MPH, MS Senior Medical Epidemiologist Prescription Drug Abuse Teams DEPI-II, OPE, OSE, CDER, FDA

#### <u>Terri Voepel-Lewis, RN, PhD</u>

Associate Professor with Tenure School of Nursing Associate Research Scientist University of Michigan Ann Arbor, Michigan 48109

#### Ethan Hausman, MD

Medical Officer Division of Pediatric and Maternal Health Office of Drug Evaluation IV Office of New Drugs (OND) Center for Drug Evaluation and Research (CDER) FDA

#### Rajdeep Gill, PharmD

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### Chaitali Patel, PharmD, BCPS

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## FINAL MEETING ROSTER (cont.)

### Ellen Fields, MD, MPH

Associate Director Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE-II) OND, CDER, FDA

# <u>Joshua Lloyd, MD</u>

Clinical Team Leader DAAAP, ODE-II OND, CDER, FDA

### Ibrahim T. Ibrahim, PharmD, MPH, BCPS

Drug Utilization Data Analyst DEPI-II, OSE, CDER, FDA

### Daniel Bak, PharmD

Drug Utilization Data Analyst DEPI-II, OSE, CDER, FDA

### Christina R. Greene PhD

Epidemiologist, Drug Abuse Team II DEPI-II, OSE, CDER, FDA