# 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)

<table>
<thead>
<tr>
<th>Name &amp; Title</th>
<th>Expertise</th>
<th>Details</th>
</tr>
</thead>
</table>
| **Mark Hudak, MD** - Chair | Neonatology | Professor and Chairman of Pediatrics  
University of Florida, College of Medicine  
Jacksonville, Florida 32209 |
| **Danielle Boyce, M.P.H.** | Patient-Family Representative | Senior Research Data Analyst  
Johns Hopkins University  
Baltimore, MD 21218 |
| **Mary Cataletto, MD, FAAP** | Pediatric Pulmonary | Attending Physician  
Winthrop University Hospital  
Mineola, New York 11501  
Professor of Clinical Pediatrics  
SUNY Stony Brook  
Stony Brook, New York 11794|
| **Melody Cunningham, M.D.** | 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 |
| **Robert Dracker, MD, MHA, MBA, CPI** | Pediatrics | Director, Summerwood Pediatrics  
Infusacare Medical Services  
Liverpool, New York 13088 |
| **Peter Havens, MD, MS** | 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 |
| **Michael White, MD, PhD, FACC, FAAP** | Pediatric Cardiology | Pediatric Cardiologist  
Ochsner Health System  
New Orleans, Louisiana, 70121 |
## PEDIATRIC ADVISORY COMMITTEE MEMBERS (Non-Voting)

<table>
<thead>
<tr>
<th>Name</th>
<th>Expertise</th>
<th>Position</th>
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</table>
| Ronald Portman, M.D., F.A.A.P. | Expertise: Industry Representative & Pediatric Nephrology  
Executive Director  
Pediatric Development, Science and Innovation  
Novartis Pharmaceutical Company  
East Hanover, NJ 07936 | **Executive Director**  
**Pediatric Development, Science and Innovation**  
**Novartis Pharmaceutical Company**  
**East Hanover, NJ 07936** |

## Endocrinologic and Metabolic Drugs Advisory Committee Members (Voting)

<table>
<thead>
<tr>
<th>Name</th>
<th>Expertise</th>
<th>Position</th>
</tr>
</thead>
</table>
| Michael Blaha, MD, MPH      | 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 | **Assistant Professor, Cardiology and Epidemiology Director of Clinical Research**  
**Johns Hopkins Ciccarone Center for the Prevention of Heart Disease**  
**Baltimore, Maryland 21287** |
| Kenneth D. Burman, MD       | 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 | **Chief, Endocrine Section**  
**MedStar Washington Hospital Center**  
**Professor, Department of Medicine**  
**Georgetown University**  
**Washington, District of Columbia 20010** |
| Cecilia C. Low Wang, MD, FACP | 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 | **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** |
| Daniel Budnitz, MD, MPH     | 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 | **CAPT, US Public Health Service Director, Medication Safety Program Division of Healthcare Quality Promotion**  
**Centers for Disease Control and Prevention**  
**Atlanta, Georgia 30333** |
| Brendan M. Everett, MD, MPH | 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 | **Assistant Professor of Medicine**  
**Harvard Medical School**  
**Director, General Cardiology Inpatient Service**  
**Brigham and Women’s Hospital**  
**Boston, Massachusetts 02215** |
| James D. Neaton, PhD        | 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 | **Professor of Biostatistics**  
**Division of Biostatistics**  
**Coordinating Centers for Biometric Research School of Public Health**  
**University of Minnesota**  
**Minneapolis, Minnesota 55414** |
<table>
<thead>
<tr>
<th>Thomas J. Weber, MD</th>
<th>Peter W. F. Wilson, MD</th>
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<tbody>
<tr>
<td>Expertise: Endocrinology, Metabolic Bone Disease Term: 07/01/2016 – 06/30/2020</td>
<td>Expertise: Cardiology, Endocrinology, Public Health Term: 07/01/2014 – 06/30/2018</td>
</tr>
<tr>
<td>Associate Professor, Endocrinology, Metabolism and Nutrition</td>
<td>Director, Epidemiology and Genomic Medicine Atlanta Veterans Administration Medical Center Professor of Medicine and Public Health</td>
</tr>
<tr>
<td>Duke University Medical Center</td>
<td>Emory University</td>
</tr>
<tr>
<td>Durham, North Carolina 27710</td>
<td>Emory Clinical Cardiovascular Research Institute</td>
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<tr>
<td></td>
<td>Atlanta, Georgia 30322</td>
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**TEMPORARY MEMBERS (Voting)**

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

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