

**FOOD AND DRUG ADMINISTRATION (FDA)**  
Center for Drug Evaluation and Research (CDER)

***Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (pedsODAC) Meeting***  
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)  
10903 New Hampshire Avenue, Silver Spring, Maryland  
June 20, 2018

**MEETING ROSTER**

---

**DESIGNATED FEDERAL OFFICER (Non-Voting)**

**Lauren Tesh, PharmD, BCPS**

Division of Advisory Committee and Consultant Management  
Office of Executive Programs, CDER, FDA

**ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)**

**Alberto S. Pappo, MD**

*(Chairperson, pedsODAC)*  
Member and Head, Division of Solid Malignancies  
St Jude Children's Research Hospital  
Professor of Pediatrics  
University of Tennessee Health Science Center  
Memphis, Tennessee

**Courtney J. Preusse, MA**

*(Consumer Representative)*  
Senior Research Administrator and CLIA Operations  
Director  
Clinical Research Division  
Fred Hutchinson Cancer Research Center  
Seattle, Washington

**ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Non-Voting)**

**Phuong Khanh (P.K.) Morrow, MD, FACP**

*(Industry Representative)*  
Executive Medical Director, Amgen Oncology  
Therapeutic Area Head, US Medical Organization  
One Amgen Center Drive  
Thousand Oaks, California

**TEMPORARY MEMBERS (Voting)**

**Steven G. DuBois, MD**

Director, Experimental Therapeutics  
Dana-Farber/Boston Children's Hospital  
Associate Professor of Pediatrics  
Harvard Medical School  
Boston, Massachusetts

**Ira Dunkel, MD**

Attending, Pediatric Neuro-oncology  
Memorial Sloan Kettering Cancer Center  
New York, New York

**FOOD AND DRUG ADMINISTRATION (FDA)**  
Center for Drug Evaluation and Research (CDER)

*Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (pedsODAC) Meeting*  
June 20, 2018

**MEETING ROSTER (cont.)**

---

---

**TEMPORARY MEMBERS (Voting) (cont.)**

**Julia Glade Bender, MD**

Associate Professor of Pediatrics at Columbia  
University Medical Center  
Associate Director, Division of Pediatric  
Hematology, Oncology and Stem Cell  
Transplantation  
Medical Director, Developmental Therapeutics  
and Precision Medicine Programs  
New York, New York

**E. Anders Kolb, MD**

Director, Nemours Center for Cancer and Blood  
Disorders  
Alfred I duPont Hospital for Children  
Wilmington, Delaware

**Donna M. Ludwinski**

*(Patient Representative)*  
Research Program Advisor  
Solving Kids' Cancer  
New York, New York

**Rajen Mody, MD, MS**

Ruth Heyn Professor of Pediatric Oncology and  
Communicable Diseases  
Interim Division Director, Pediatric  
Hematology/Oncology/BMT  
Director, Pediatric Phase-I and Experimental  
Therapeutics Program  
Ann Arbor, Michigan

**Elizabeth A. Raetz, MD**

Professor of Pediatrics, NYU School of Medicine  
Director, Division of Pediatric  
Hematology/Oncology  
Stephen D. Hassenfeld Children's Center for  
Cancer and Blood Disorders  
New York, New York

**Katherine A. Janeway, MD, MMSc**

Associate Professor of Pediatrics  
Harvard Medical School  
Senior Physician and Director Solid Tumor  
Service, Pediatric Oncology  
Dana-Farber Cancer Institute / Boston Children's  
Hospital  
Boston, Massachusetts

**Theodore W. Laetsch, MD**

Director, Experimental Therapeutics Program  
Children's Health  
Assistant Professor of Pediatrics, Division of  
Hematology-Oncology  
University of Texas Southwestern Medical Center  
Dallas, Texas

**Tobey J. MacDonald, MD**

Professor of Pediatrics  
Emory University School of Medicine  
Director, Pediatric Neuro-Oncology Program  
Aflac Cancer & Blood Disorders Center  
Children's Healthcare of Atlanta  
Atlanta, Georgia

**Kathleen A. Neville, MD, MS, MBA, FAAP,  
FCCP**

Professor of Pediatrics  
University of Arkansas for Medical Sciences  
Chief, Section of Clinical Pharmacology and  
Toxicology  
Director, Experimental Therapeutics Program  
Co-Director, Pediatric Precision Medicine Program  
Little Rock, Arkansas

**Nita Seibel, MD**

Head, Pediatric Solid Tumor Therapeutics  
Clinical Investigations Branch, Cancer Therapy  
Evaluation Program/Division of Cancer Treatment  
and Diagnosis, National Cancer Institute (NCI)  
National Institutes of Health (NIH)  
Bethesda, Maryland

**FOOD AND DRUG ADMINISTRATION (FDA)**  
Center for Drug Evaluation and Research (CDER)

*Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (pedsODAC) Meeting*  
June 20, 2018

**MEETING ROSTER (cont.)**

---

---

**TEMPORARY MEMBERS (Voting) (cont.)**

**Malcom A. Smith IV, MD, PhD**

Associate Branch Chief for Pediatrics, Clinical  
Investigations Branch, Cancer Therapy Evaluation  
Program/Division of Cancer Treatment and  
Diagnosis, NCI, NIH  
Bethesda, Maryland

**Brenda J. Weigel, MD, MSc**

Professor  
Division Director, Pediatric Hematology/Oncology  
University of Minnesota  
Developmental Therapeutics Chair  
Children's Oncology Group  
Minneapolis, Minnesota

**SPEAKER (Non-Voting)**

**Lia Gore, MD**

*(Participation in Topic 2)*

Professor of Pediatrics, Medical Oncology, and  
Hematology  
Chief, Pediatric Hematology/Oncology/Bone Marrow  
Transplant  
The Robert J. and Kathleen A. Clark Endowed Chair  
in Pediatric Cancer Therapeutics and the Ergen Chair  
in Pediatric Oncology  
Children's Hospital Colorado  
Center for Cancer and Blood Disorders  
Aurora, Colorado

**FDA PARTICIPANTS (Non-Voting)**

**Gregory Reaman, MD**

Associate Director Oncology Sciences  
Office of Hematology and Oncology  
Products (OHOP)  
Office of New Drugs (OND), CDER, FDA  
Associate Director for Pediatric Oncology  
Oncology Center of Excellence, FDA

**Amy Barone, MD**

Medical Officer  
Division of Oncology Products 2 (DOP2)  
OHOP, OND, CDER, FDA

**Diana Bradford, MD**

Medical Officer  
DOP2, OHOP, OND, CDER, FDA

**Sandra J. Casak, MD**

Senior Staff Fellow  
DOP2, OHOP, OND, CDER, FDA