

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

Meeting of the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (pedsODAC)
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
June 28-29, 2016

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Lauren D. Tesh, PharmD, BCPS

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

ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Deborah K. Armstrong, MD

Professor of Oncology
The Sidney Kimmel Comprehensive Cancer Center
at Johns Hopkins
The Johns Hopkins University School of Medicine
Baltimore, Maryland

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

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
Thousand Oaks, California

TEMPORARY MEMBERS (Voting)

Peter C. Adamson, MD

(Day 1 Only)
Chair, Children's Oncology Group
Alan R. Cohen Endowed Chair in Pediatrics
The Children's Hospital of Philadelphia
Philadelphia, Pennsylvania

Patrick Brown, MD

Director, Pediatric Leukemia Program
Associate Professor of Oncology and Pediatrics
Sidney Kimmel Comprehensive Cancer Center
Johns Hopkins University School of Medicine
Baltimore, Maryland

Steven G. DuBois, MD, MS

(Day 1, Day 2 Topics 2 and 3 Only)
Director, Experimental Therapeutics
Dana-Farber/Boston Children's Hospital
Faculty of Pediatrics, Harvard Medical School
Boston, Massachusetts

Ira J. Dunkel, MD

Member
Memorial Sloan-Kettering Cancer Center
Professor of Pediatrics
Weill Cornell Medical College Department of
Pediatrics
New York, New York

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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

Pamela Haylock

(Acting Consumer Representative)
Medina, Texas

Tobey J. MacDonald, MD

Aflac Chair for Pediatric Neuro-Oncology
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

Gigi McMillan

(Patient Representative)
Manhattan Beach, California

Kathleen A. Neville, MD, MS

Director, Experimental Therapeutics Program
Professor of Pediatrics, University of Arkansas for
Medical Sciences
Section of Clinical Pharmacology and Toxicology
Arkansas Children's Hospital
Little Rock, Arkansas

Elizabeth A. Raetz, MD

Professor of Pediatrics
Pediatric Hematology/Oncology
University of Utah
Huntsman Cancer Institute
Primary Children's Hospital
Salt Lake City, Utah

Nita L. Seibel, MD

Head, Pediatric Solid Tumor Therapeutics
Clinical Investigations Branch, CTEP/Division of
Cancer Treatment and Diagnosis
National Cancer Institute, NIH
Adjunct Professor of Pediatrics
George Washington University School of Medicine
and Health Sciences
Bethesda, Maryland

Katherine E. Warren, MD

Head, Pediatric Neuro-Oncology
Pediatric Oncology Branch
National Cancer Institute, NIH
Bethesda, Maryland

Brenda Weigel, MD, MSc

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

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MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting)

Richard Pazdur, MD

(Afternoon Session, Day 2 Only)
Director
Office of Hematology Oncology Products (OHOP)
Office of New Drugs (OND), CDER, FDA

Edvardas Kaminskas, MD

(Morning Session, Day 2 Only)
Deputy Director
Division of Hematology Products (DHP)
OHOP, OND, CDER, FDA

Amy Barone, MD

(Morning Session, Day 1)
(Afternoon Session, Day 2)
Medical Officer
DOP II, OHOP, OND, CDER, FDA

Rachel Ershler, MD

(Morning Session, Day 2 Only)
Medical Officer
DHP, OHOP, OND, CDER, FDA

Christy Osgood, MD

(Morning Session, Day 2 Only)
Medical Officer
DOP II, OHOP, OND, CDER, FDA

Joohee Sul, MD

(Afternoon Session, Day 2 Only)
Medical Officer
DOP II, OHOP, OND, CDER, FDA

Gregory Reaman, MD

Associate Director for Oncology Sciences
OHOP, OND, CDER, FDA

Martha Donoghue, MD

(Afternoon Session, Day 1 Only)
Acting Associate Director
Division of Oncology Products (DOP) II
OHOP, OND, CDER, FDA

Lori Ehrlich, MD, PhD

(Morning Session, Day 1 Only)
Medical Officer
DHP, OHOP, OND, CDER, FDA

Robert (Skip) Nelson, MD

(Afternoon Session, Day 2 Only)
Deputy Director and Senior Pediatric Ethicist
Office of Pediatric Therapeutics
Office of the Commissioner, FDA

Jeffrey D. Seidman, MD

(Afternoon Session, Day 2 Only)
Medical Officer/Pathologist
Molecular Pathology and Cytology Branch
Division of Molecular Genetics and Pathology
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health, FDA