

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

***Oncologic Drugs Advisory Committee (ODAC) Meeting***  
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)  
10903 New Hampshire Avenue, Silver Spring, Maryland  
July 12, 2017

**MEETING ROSTER**

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

**Jennifer Shepherd, RPh**

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

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

**Grzegorz S. Nowakowski, MD**

Associate Professor of Medicine and Oncology  
Mayo Clinic Rochester  
Rochester, Minnesota

**Brian I. Rini, MD, FACP**

Professor of Medicine, Lerner College of Medicine  
Leader, GU Program  
Department of Hematology and Oncology  
Cleveland Clinic Taussig Cancer Institute  
Cleveland, Ohio

**Bruce J. Roth, MD**

*(Chairperson)*

Professor of Medicine  
Division of Oncology  
Washington University School of Medicine  
St. Louis, Missouri

**ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)**

**Gary Gordon, MD, PhD**

Vice President, Oncology Development  
AbbVie, Inc.  
North Chicago, Illinois

**TEMPORARY MEMBERS (Voting)**

**Catherine M. Bollard, MBChB, MD**

Professor of Pediatrics and Microbiology,  
Immunology  
Chief, Division of Allergy and Immunology  
Director, Program for Cell Enhancement  
and Technologies for Immunotherapy  
Children's National Medical Center  
The George Washington University  
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**Bernard F. Cole, PhD**

Professor  
Department of Mathematics and Statistics  
University of Vermont  
Burlington, Vermont

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**MEETING ROSTER (cont.)**

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

**Timothy P. Cripe, MD, PhD, FAAP, CPI**

Professor and Chief  
Division of Hematology/Oncology/BMT  
Nationwide Children's Hospital  
The Ohio State University  
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**James L. Gulley, MD, PhD, FACP**

Chief  
Genitourinary Malignancies Branch  
Center for Cancer Research  
National Cancer Institute (NCI)  
National Institutes of Health (NIH)  
Bethesda, Maryland

**Larry W. Kwak, MD, PhD**

Vice President and Cancer Center Associate  
Director, Translational Research &  
Developmental Therapeutics  
Director, Toni Stephenson Lymphoma Center  
Dr. Michael Friedman Professor  
Department of Hematology and Hematopoietic  
Stem Cell Transplantation  
City of Hope National Medical Center  
Duarte, California

**Gianna McMillan, MA**

*(Patient Representative)*  
Los Angeles, California

**Alan Rein, PhD**

Head  
Retroviral Assembly Section  
HIV Dynamics and Replication Program  
National Cancer Institute at Frederick, NIH  
Frederick, Maryland

**Malcolm A. Smith, MD, PhD**

Associate Branch Chief for Pediatric Oncology  
Cancer Therapy Evaluation Program  
Division of Cancer Treatment and Diagnosis  
NCI, NIH  
Bethesda, Maryland

**FDA PARTICIPANTS (Non-Voting)**

**Richard Pazdur, MD**

Director, Oncology Center of Excellence (OCE),  
FDA  
Acting Director, Office of Hematology & Oncology  
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Office of New Drugs (OND), CDER, FDA

**Wilson W. Bryan, MD**

Director, Office of Tissues and Advanced Therapies  
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Center for Biologics Evaluation and Research  
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**Maura O'Leary, MD**

Medical Officer, Team Leader  
Clinical Hematology Branch (CHB)  
Division of Clinical Evaluation &  
Pharmacology/Toxicology (DCEPT)  
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**Xiaobin Victor Lu, PhD**

*(Morning Session Only)*  
CMC Reviewer  
Gene Therapies Branch (GTB)  
Division of Cellular & Gene Therapies (DCGT)  
OTAT, CBER, FDA

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**MEETING ROSTER (cont.)**

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**FDA PARTICIPANTS (Non-Voting) (cont.)**

**Denise Gavin, PhD**

*(Morning Session Only)*

Branch Chief

GTB, DCGT, OTAT, CBER, FDA

**Marc Theoret, MD**

*(Afternoon Session Only)*

Acting Associate Director of Immuno-Oncology

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OCE, FDA

**Bindu George, MD**

*(Afternoon Session Only)*

Branch Chief

Clinical Hematology Branch (CHB)

DCEPT, OTAT, CBER, FDA

**Donna Przepioraka, MD, PhD**

*(Afternoon Session Only)*

Team Leader

Division of Hematology Products

OHOP, OND, CDER, FDA