

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 13, 2017

DRAFT MEETING ROSTER

ACTING DESIGNATED FEDERAL OFFICER (Non-Voting)

Jay R. Fajiculay, PharmD

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

Courtney J. Preusse, MA

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

Gregory J. Riely, MD, PhD

(morning session only)
Associate Attending Physician
Memorial Sloan-Kettering Cancer Center
Associate Professor
Weill Cornell Medical College
New York, New York

Brian I. Rini, MD, FACP

(afternoon session only)
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

Thomas S. Uldrick, MD, MS

Clinical Director
HIV & AIDS Malignancy Branch
Center for Cancer Research
National Cancer Institute
Bethesda, Maryland

ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

Gary Gordon, MD, PhD

Vice President, Oncology Development
Abbvie
North Chicago, Illinois

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
July 13, 2017

DRAFT MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting)

Deborah K. Armstrong, MD

Professor of Oncology
Johns Hopkins Kimmel Cancer Center
Johns Hopkins University School of Medicine
Professor of Gynecology and Obstetrics
Johns Hopkins School of Medicine
Baltimore, Maryland

Cynthia Chauhan

(Patient Representative)
Wichita, Kansas

Shein-Chung Chow, PhD

Professor, Biostatistics and Bioinformatics
Duke University School of Medicine
Durham, North Carolina

Bernard F. Cole, PhD

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

Craig W. Hendrix, MD

Wellcome Professor and Director
Division of Clinical Pharmacology
Departments of Medicine and Pharmacology and
Molecular Sciences
Johns Hopkins University School of Medicine
Baltimore, Maryland

Adel H. Karara, PhD, FCP

Professor of Pharmaceutical Sciences
School of Pharmacy
University of Maryland Eastern Shore
Princess Anne, Maryland

Donald E. Mager, PharmD, PhD

Professor of Pharmaceutical Sciences
Department of Pharmaceutical Sciences
School of Pharmacy and Pharmaceutical Sciences
University of Buffalo, State University of
New York
Buffalo, New York

Antonio R. Moreira, PhD

Vice Provost for Academic Affairs
Professor of Chemical, Biochemical and
Environmental Engineering
University of Maryland, Baltimore County
Baltimore, Maryland

Diane Reidy-Lagunes, MD

(morning session only)
Associate Deputy Physician in Chief of Clinical
Operations
Memorial Sloan-Kettering Cancer Center
Weill Cornell Medical College
New York, New York

John E. Schiel, PhD

Research Chemist
Institute for Bioscience and Biotechnology Research
National Institute of Standards and Technology
Rockville, Maryland

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
July 13, 2017

DRAFT MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting) (cont.)

Deborah Schrag, MD, MPH

(morning session only)

Chief, Population Sciences
Dana Farber Cancer Institute
Professor of Medicine
Harvard Medical School
Boston, Massachusetts

Andrew D. Seidman, MD

(afternoon session only)

Attending Physician
Breast Medicine Service
Associate Chair, Academic Administration
Department of Medicine
Memorial Sloan Kettering Cancer Center
Professor of Medicine
Weill Cornell Medical College
New York, New York

Scott A. Waldman, MD, PhD, FCP, FAHA

Director, Gastrointestinal Cancer Program of the
Sidney Kimmel Cancer Center
Samuel M.V. Hamilton Professor of Medicine
Chair, Department of Pharmacology and
Experimental Therapeutics
Thomas Jefferson University
Philadelphia, Pennsylvania

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
July 13, 2017

DRAFT MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting)

Richard Pazdur, MD

Director, Oncology Center of Excellence, FDA
Acting Director, Office of Hematology &
Oncology
Products (OHOP), OND, CDER, FDA

Patricia Keegan, MD

(morning session only)
Director
Division of Oncology Products 2 (DOP2)
OHOP, OND, CDER, FDA

Steven Kozlowski, MD

Director
Office of Biotechnology Products (OBP)
Office of Pharmaceutical Quality (OPQ)
CDER, FDA

Laleh Amiri-Kordestani, MD

(afternoon session only)
Clinical Team Leader
Breast Cancer Team
DOP1, OHOP, OND, CDER, FDA

Leah Christl, PhD

Associate Director for Therapeutic Biologics
OND Therapeutic Biologics and Biosimilars
Staff (TBBS)
OND, CDER, FDA

Julia Beaver, MD

(afternoon session only)
Acting Director
Division of Oncology Products 1 (DOP1)
OHOP, OND, CDER, FDA

Steven Lemery, MD

(morning session only)
Acting Associate Deputy Director
DOP2, OHOP, OND, CDER, FDA