

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

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

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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

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Duke University School of Medicine
Durham, North Carolina

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Professor
Department of Mathematics and Statistics
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Craig W. Hendrix, MD

Wellcome Professor and Director
Division of Clinical Pharmacology
Departments of Medicine and Pharmacology and
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School of Pharmacy
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School of Pharmacy and Pharmaceutical Sciences
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Antonio R. Moreira, PhD

Vice Provost for Academic Affairs
Professor of Chemical, Biochemical and
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Diane Reidy-Lagunes, MD

(morning session only)
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John E. Schiel, PhD

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

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July 13, 2017

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
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Memorial Sloan Kettering Cancer Center
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New York, New York

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

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

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MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting)

Richard Pazdur, MD

(afternoon session only)

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

Leah Christl, PhD

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

Patricia Keegan, MD

(morning session only)

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

Julia Beaver, MD

(afternoon session only)

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

Steven Kozlowski, MD

Director

Office of Biotechnology Products (OBP)
Office of Pharmaceutical Quality (OPQ)
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Steven Lemery, MD

(morning session only)

Acting Associate Deputy Director
DOP2, OHOP, OND, CDER, FDA

Laleh Amiri-Kordestani, MD

(afternoon session only)

Clinical Team Leader
Breast Cancer Team
DOP1, OHOP, OND, CDER, FDA