

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

May 25, 2017

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)

Bernard F. Cole, PhD

Professor

Department of Mathematics and Statistics

University of Vermont

Burlington, Vermont

Heidi D. Klepin, MD, MS

Associate Professor of Internal Medicine

Section of Hematology and Oncology

Wake Forest University Health Sciences

Winston Salem, North Carolina

Grzegorz S. Nowakowski, MD

Associate Professor of Medicine and Oncology

Mayo Clinic Rochester

Rochester, Minnesota

Courtney J. Preusse, MA

(Consumer Representative)

Research Administrator and Patient Advocate

Clinical Research Division

Fred Hutchinson Cancer Research Center

Seattle, Washington

Gregory J. Riely, MD, PhD

Associate Attending Physician and Associate
Professor

Memorial Sloan-Kettering Cancer Center

New York, New York

Brian I. Rini, MD, FACP

(Acting Chairperson)

Professor of Medicine, Lerner College of Medicine

Leader, GU Program

Department of Hematology and Oncology

Cleveland Clinic Taussig Cancer Institute

Cleveland, Ohio

Thomas S. Uldrick, MD, MS

Clinical Director

HIV & AIDS Malignancy Branch

Center for Cancer Research

National Cancer Institute

Bethesda, Maryland

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MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting)

Karen E. Arscott, DO, MSc

(Patient Representative)

Associate Professor in Clinical Sciences
The Commonwealth Medical College
Scranton, Pennsylvania

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Associate Professor of Medicine
School of Medicine
University of California San Francisco
Staff Physician, San Francisco VA Medical Center
San Francisco, California

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

Steven M. Cramer, PhD

William Weightman Walker Professor
Department of Chemical and Biological Engineering
Rensselaer Polytechnic Institute
Troy, New York

William S. Hancock, PhD

Bradstreet Chair in Bioanalytical Chemistry
Barnett Institute and Department of Chemistry and
Chemical Biology
Northeastern University
Boston, Massachusetts

Julia B. Lewis, MD

Professor of Medicine
Division of Nephrology
Department of Medicine
Vanderbilt University School of Medicine
Nephrologist
Vanderbilt Medical Center
Nashville, Tennessee

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

Samuel M.V. Hamilton Professor of Medicine and
Chair, Departments of Pharmacology and
Experimental Therapeutics
Thomas Jefferson University
Philadelphia, Pennsylvania

ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

Gary Gordon, MD, PhD

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

FDA PARTICIPANTS (Non-Voting)

Ann Farrell, MD

Director
Division of Hematology Products (DHP)
OHOP, OND, CDER, FDA

R. Angelo de Claro, MD

Medical Officer Team Leader
DHP, OHOP, OND, CDER, FDA

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MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting) (Cont.)

Leah Christl, PhD

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

Emanuela Lacana, PhD

Associate Director for Biosimilars and Biologics
Policy
Office of Biotechnology Products (OBP)
Office of Pharmaceutical Quality (OPQ)
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Susan Kirshner, PhD

Review Chief
Division of Biotechnology Review and Research III
OBP, OPQ, CDER, FDA