

Food and Drug Administration
Center for Drug Evaluation and Research
Oncologic Drugs Advisory Committee (ODAC) Meeting
FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center
(Rm. 1503), Silver Spring, MD

September 14, 2011

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Caleb Briggs, Pharm.D.

Division of Advisory Committee and Consultant Management
Office of Executive Programs
Center for Drug Evaluation and Research

ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Deborah Armstrong, M.D.

Associate Professor of Oncology
Johns Hopkins Kimmel Cancer Center
Johns Hopkins University School of Medicine
Baltimore, Maryland

Ralph Freedman, M.D., Ph.D.

Clinical Professor
Department of Gynecologic Oncology
The University of Texas
M.D. Anderson Cancer Center
Houston, Texas

William Kelly, D.O.

Professor of Medical Oncology and Urology
Thomas Jefferson University
Philadelphia, Pennsylvania

Patrick Loehrer, Sr., M.D. (Afternoon Session Only)

Director, Indiana University
Melvin and Bren Simon Cancer Center
Indiana University
Indianapolis, Indiana

Brent Logan, Ph.D.

Associate Professor of Biostatistics
Division of Biostatistics
Medical College of Wisconsin
Milwaukee, Wisconsin

Mikael Sekeres, M.D., M.S.

Associate Professor of Medicine
Staff
Cleveland Clinic Taussig Cancer Institute
Department of Hematologic Oncology and
Blood Disorders
Cleveland, Ohio

Wyndham Wilson, M.D., Ph.D.
(Chairperson)

Chief, Lymphoma Therapeutics Section
Metabolism Branch
Center for Cancer Research
National Cancer Institute
Rockville, Maryland

Antoinette Wozniak, M.D., F.A.C.P.

Professor, Department of Oncology
Wayne State University School of Medicine and
Karmanos Cancer Institute
Detroit, Michigan

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MEETING ROSTER (cont.)

**ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBER
(Non-Voting)**

Gregory Curt, M.D.

(Industry Representative)

U.S. Medical Science Lead, Emerging Products
AstraZeneca Oncology
Garrett Park, Maryland

TEMPORARY MEMBERS (Voting) (Morning Session)

Dawn Aldrich

(Patient Representative)

New Rochelle, New York

Gregory Kato, M.D.

Tenure Track Investigator
Head, Sickle Cell Vascular Disease Section
Cardiovascular and Pulmonary Medicine Branch
National Heart, Lung and Blood Institute
National Institutes of Health
Bethesda, Maryland

Susan Shurin, M.D.

Acting Director, National Heart, Lung and
Blood Institute
National Institutes of Health
Bethesda, Maryland

Ann Zimrin, M.D.

Associate Professor of Medicine
Marlene and Stewart Greenebaum Cancer
Center
University of Maryland School of Medicine
Baltimore, Maryland

Jane Zones, Ph.D.

(Acting Consumer Representative)

Medical Sociologist (retired)
Breast Cancer Action
National Women's Health Network
San Francisco, California

TEMPORARY MEMBERS (Voting) (Afternoon Session)

James Anderson

(Patient Representative)

La Plata, Maryland

Timothy Donahue, M.D.

Urology Service Chief, National Naval Medical
Center Campus
Integrated Urology Service
Walter Reed National Military Medical Center
Bethesda, Maryland

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MEETING ROSTER (cont.)

Mario Eisenberger, M.D.

R. Dale Hughes Professor of Oncology
Professor of Urology
The Johns Hopkins University School of
Medicine
Baltimore, Maryland

Marc Garnick, M.D.

Clinical Professor of Medicine
Harvard Medical School
Boston, Massachusetts

Bhupinder Mann, M.D.

Senior Clinical Investigator
Adult Brain and GU Cancer Therapeutics
Clinical Investigations Branch
Cancer Therapy Evaluation Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute
Bethesda, Maryland

David Penson, M.D.

Director, Center for Surgical Quality and
Outcomes Research
Vanderbilt University Medical Center
Professor of Urologic Surgery
Vanderbilt University
Nashville, Tennessee

Derek Raghavan, M.D., Ph.D.

President, Levine Cancer Institute
Carolinas HealthCare System
Charlotte, North Carolina

Jane Zones, Ph.D.

(Acting Consumer Representative)
Medical Sociologist (retired)
Breast Cancer Action
National Women's Health Network
San Francisco, California

GUEST SPEAKERS (Non-Voting, Presenting Only) (Afternoon Session)

Joel B. Nelson, M.D.

Frederic N. Schwentker Professor and Chairman
Department of Urology
University of Pittsburgh School of Medicine
Chairman, Department of Surgery
UPMC Shadyside Hospital
Pittsburgh, Pennsylvania

Howard Scher, M.D.

D. Wayne Calloway Chair in Urologic Oncology
Chief, Genitourinary Oncology Service
Attending Physician, Department of Medicine
Memorial Sloan-Kettering Cancer Center
New York, New York

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MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting)

Morning Session

Richard Pazdur, M.D.

Director, Office of Hematology Oncology
Products (OHOP)
Office of New Drugs (OND)
CDER, FDA

George Shashaty, M.D.

Medical Officer
DHP, OHOP, OND, CDER, FDA

Ann Farrell, M.D.

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

Tejashri Purohit-Sheth, M.D.

Acting Division Director
Division of Good Clinical Practice Compliance
Office of Scientific Investigations
Office of Compliance, CDER, FDA

Kathy Robie-Suh, M.D., Ph.D.

Clinical Team Leader
DHP, OHOP, OND, CDER, FDA

Afternoon Session

Richard Pazdur, M.D.

Director
OHOP, OND, CDER, FDA

Paul G. Kluetz, M.D.

Medical Officer
DOP1, OHOP, OND, CDER, FDA

Robert Justice, M.D.

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

Yang-Min (Max) Ning, M.D., Ph.D.

Medical Officer
DOP1, OHOP, OND, CDER, FDA

John Johnson, M.D.

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