

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 (Rm. 1503)

White Oak Conference Center, Silver Spring, Maryland

December 7, 2011

MEETING ROSTER

ACTING DESIGNATED FEDERAL OFFICER (Non-Voting)

Yvette Waples, Pharm.D.

Division of Advisory Committee and Consultant Management

Office of Executive Programs, CDER, FDA

ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Deborah K. Armstrong, M.D.

Associate Professor of Oncology
The Sidney Kimmel Comprehensive Cancer
Center at Johns Hopkins
The Johns Hopkins University School of
Medicine
Baltimore, Maryland

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M.D. Anderson Cancer Center
Houston, Texas

Wm Kevin Kelly, D.O.

Professor, Medical Oncology and Urology
Director, Division of Solid Tumor Oncology
Associate Director, Translational Research
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Philadelphia, Pennsylvania

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Division of Biostatistics
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Department of Hematologic Oncology and
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Julie M. Vose, M.D., M.B.A.

Neumann M. and Mildred E. Harris Professor
Chief, Division of Hematology/Oncology
Professor of Medicine
Nebraska Medical Center
Omaha, Nebraska

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

Chief, Lymphoma Therapeutics Section
Metabolism Branch
Center for Cancer Research
National Cancer Institute (NCI)
National Institutes of Health (NIH)
Rockville, Maryland

Antoinette Wozniak, M.D., FACP

(Afternoon Session Only)
Professor, Department of Oncology
Wayne State University School of Medicine and
Barbara Ann Karmanos Cancer Institute
Detroit, Michigan

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MEETING ROSTER (*cont.*)

TEMPORARY MEMBERS (Voting)

Susan B. Broyles, R.N.

(Afternoon Session Only)

(Patient Representative)

Fort Worth, Texas

Aman U. Buzdar, M.D.

Vice President Clinical Research and Interim

Professor of Medicine

University of Texas MD Anderson Cancer Center

Dept. of Breast Medical Oncology

Houston, Texas

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Professor of Medicine

Duke University Medical Center

Durham, North Carolina

Michael F. Flessner, M.D., Ph.D

(Afternoon Session Only)

Director of Inflammatory Renal Diseases

Kidney, Urology, Hematology Division

National Institute of Diabetes and Digestive and

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Tito Fojo, M.D., Ph.D.

Senior Investigator and

Director, Medical Oncology Fellowship

Program, NCI, NIH

Bethesda, Maryland

Marc Garnick, M.D. *(Morning Session Only)*

Beth Israel Deaconess Medical Center

Clinical Professor of Medicine

Harvard Medical School

Boston, Massachusetts

Julia B. Lewis, M.D.

(Afternoon Session Only)

Professor of Medicine

Department of Nephrology

Vanderbilt University School of Medicine

Nashville, Tennessee

Mary Meyer *(Morning Session Only)*

(Patient Representative)

South Salem, New York

Steven E. Nissen, M.D., MACC

(Afternoon Session Only)

Chairman, Department of Cardiovascular

Medicine, Cleveland Clinic Foundation

Professor of Medicine

Cleveland Clinic Lerner School of Medicine

at Case Western Reserve University

Cleveland, Ohio

Udho Thadani, M.D., M.R.C.P.

(Afternoon Session Only)

Professor Emeritus of Medicine

Oklahoma University Health Sciences Center

Staff Cardiologist

Division of Medicine/Cardiology

Oklahoma City Veterans Affairs Medical Center

Oklahoma City, Oklahoma

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TEMPORARY MEMBERS (Voting)

Jane Zones, Ph.D.

(Acting Consumer Representative)

Medical Sociologist (retired)

Breast Cancer Action

National Women's Health Network

San Francisco, California

ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

Gregory Curt, M.D.

(Acting Industry Representative)

U.S. Medical Science Lead, Emerging Products

AstraZeneca Oncology

Wilmington, Delaware

FDA PARTICIPANTS (Non-Voting)

Richard Pazdur, M.D.

Director,

Office of Hematology & Oncology Products
(OHOP)

Office of New Drugs (OND), CDER, FDA

Amna Ibrahim, M.D. (*Morning Session Only*)

Deputy Director

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

John Johnson, M.D. (*Morning Session Only*)

Medical Team Leader

DOP1, OHOP, OND, CDER, FDA

Amy McKee, M.D. (*Morning Session Only*)

Medical Officer

DOP1, OHOP, OND, CDER, FDA

Somesh Chattopadhyay, Ph.D.

(Morning Session Only)

Statistical Reviewer

Division of Biostatistics V (DBV)

Office of Biostatistics (OB)

Office of Translational Science (OTS)

CDER, FDA

Ann Farrell, M.D. (*Afternoon Session Only*)

Acting Director

Division of Hematology Products (DHP)

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MEETING ROSTER (*cont.*)

FDA PARTICIPANTS (Non-Voting)

Robert Kane, M.D.

(Afternoon Session Only)

Deputy Director for Safety

DHP, OHOP, OND, CDER, FDA

Andrew Dmytrijuk, M.D.

(Afternoon Session Only)

Medical Officer

DHP, OHOP, OND, CDER, FDA

Qing Xu, Ph.D. *(Afternoon Session Only)*

Statistical Reviewer

DBV, OB, OTS, CDER, FDA