

**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 24, 2017

**MEETING ROSTER**

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**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)**

**Harold J. Burstein, MD, PhD**

Institute Physician

Dana-Farber Cancer Institute

Associate Professor of Medicine

Harvard Medical School

Boston, Massachusetts

**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

**Vassiliki A. Papadimitrakopoulou, MD**

Professor of Medicine

The University of Texas MD Anderson Cancer  
Center

Department of Thoracic Head & Neck Medical  
Oncology

Division of Cancer Medicine

Houston, Texas

**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

Memorial Sloan Kettering Cancer Center

Associate Professor, Weill Cornell Medical

College

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

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**ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting) (cont.)**

**Thomas S. Uldrick, MD, MS**

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

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

**Phuong Khanh (P.K.) Morrow, MD, FACP**

Executive Medical Director, Amgen Oncology  
Therapeutic Area Head, US Medical Organization  
Thousand Oaks, California

**TEMPORARY MEMBERS (Voting)**

**Ralph B. D'Agostino, Sr., PhD**

Professor of Mathematics/Statistics, Epidemiology  
and Biostatistics  
Mathematics and Statistics Department  
Boston University  
Boston, Massachusetts

**Courtney Fitzhugh, MD**

*(Participation in afternoon session)*  
Investigator  
Laboratory of Early Sickle Mortality Prevention  
Sickle Cell Branch, Division of Intramural Research  
National Heart, Lung, and Blood Institute  
National Institutes of Health (NIH)  
Bethesda, Maryland

**Stanley Lipkowitz, MD, PhD**

*(Participation in morning session)*  
Chief  
Women's Malignancy Branch  
Center for Cancer Research  
National Cancer Institute, NIH  
Bethesda, Maryland

**Michael E. Menefee, MD**

*(Participation in afternoon session)*  
Assistant Professor of Oncology  
Division of Hematology and Oncology  
Mayo Clinic  
Jacksonville, Florida

**Shirley H. Miller, MA**

*(Participation in afternoon session)*  
*(Patient Representative)*  
Manager, Community Programs  
Sickle Cell Disease Program  
Carolinas Healthcare System  
Charlotte, North Carolina

**Lori M. Minasian, MD, FACP**

*(Participation in morning session)*  
Deputy Director  
Division of Cancer Prevention  
Investigator, Women's Malignancy Branch  
National Cancer Institute, NIH  
Bethesda, Maryland

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**TEMPORARY MEMBERS (Voting) (cont.)**

**Stacy Nerenstone, MD**

*(Participation in morning session)*  
Assistant Clinical Professor of Medicine  
University of Connecticut  
Senior Physician  
Department of Medicine  
Medical Staff President  
Hartford Hospital  
Hartford, Connecticut

**Andrew D. Seidman, MD**

*(Participation in morning session)*  
Attending Physician  
Breast Cancer 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

**Patricia A. Spears, BS**

*(Participation in morning session)*  
*(Patient Representative)*  
Raleigh, North Carolina

**Melanie E. Royce, MD, PhD**

*(Participation in morning session)*  
Consultant, Breast Cancer Specialist  
Immediate Past Director of the Breast Clinic and  
former Professor  
University of New Mexico Comprehensive Cancer  
Center  
Albuquerque, New Mexico

**FDA PARTICIPANTS (Non-Voting)**

**Richard Pazdur, MD**

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

**Julia Beaver, MD**

*(Participation in morning session)*  
Acting Director  
Division of Oncology Products 1 (DOP1)  
OHOP, OND, CDER, FDA

**Laleh Amiri-Kordestani, MD**

*(Participation in morning session)*  
Medical Team Leader  
Breast Cancer Group  
DOP1, OHOP, OND, CDER, FDA

**Harpreet Singh, MD**

*(Participation in morning session)*  
Medical Officer  
DOP1, OHOP, OND, CDER, FDA

**Amanda Walker, MD**

*(Participation in morning session)*  
Medical Officer  
DOP1, OHOP, OND, CDER, FDA

**Joyce Cheng, PhD**

*(Participation in morning session)*  
Statistical Reviewer  
Division of Biometrics V (DBV)  
Office of Biometrics (OB)  
Office of Translational Science (OTS)  
CDER, FDA

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**FDA PARTICIPANTS (Non-Voting) (cont.)**

**Ann Farrell, MD**

*(Participation in afternoon session)*

Director

Division of Hematology Products (DHP)

OHOP, OND, CDER, FDA

**Kathy Robie-Suh, MD, PhD**

*(Participation in afternoon session)*

Medical Team Leader

DHP, OHOP, OND, CDER, FDA

**Rosanna Setse, MD, MPH, PhD**

*(Participation in afternoon session)*

Medical Officer

DHP, OHOP, OND, CDER, FDA

**Che Smith, PhD**

*(Participation in afternoon session)*

Statistical Reviewer

DBV, OB, OTS, CDER, FDA