Center for Drug Evaluation and Research (CDER)

# Antiviral Drugs Advisory Committee (AVDAC) Meeting

FDA White Oak Campus, Building 31, The Great Room (Rm. 1503) White Oak Conference Center, Silver Spring, Maryland May 10, 2012

## **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

## ANTIVIRAL DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

## Amanda H. Corbett, Pharm.D.

Clinical Assistant Professor
University of North Carolina
Eshelman School of Pharmacy
Division of Pharmacotherapy and Experimental
Therapeutics
Chapel Hill, North Carolina

## Demetre C. Daskalakis, M.D., M.P.H.

Assistant Professor New York University School of Medicine Infectious Diseases and Immunology Division New York, New York

#### Susan S. Ellenberg, Ph.D.

Professor of Biostatistics Associate Dean for Clinical Research University of Pennsylvania School of Medicine Center for Clinical Epidemiology and Biostatistics Philadelphia, Pennsylvania

## Thomas P. Giordano, M.D., M.P.H.

Associate Professor of Medicine
Baylor College of Medicine
Medical Director of HIV Services
Harris County Hospital District
HSR&D Center of Excellence
Michael E. DeBakey VA Medical Center
Houston, Texas

# Jeffrey S. Glenn, M.D., Ph.D.

Associate Professor of Medicine Division of Gastroenterology and Hepatology Director, Center for Hepatitis and Liver Tissue Engineering Stanford University School of Medicine Stanford, California

## Yoshihiko Murata, M.D., Ph.D.

Associate Professor
Division of Infectious Diseases
Department of Medicine
University of Rochester School of Medicine and
Dentistry
Rochester, New York

#### **Daniel Raymond**

(Consumer Representative)
Policy Director
Harm Reduction Coalition
New York, New York

## Doris B. Strader, M.D.

Associate Professor of Medicine Fletcher Allen Health Care The University of Vermont College of Medicine Division of Gastroenterology Burlington, Vermont

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## **MEETING ROSTER (cont.)**

## ANTIVIRAL DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

## Russell B. Van Dyke, M.D.

Professor of Clinical Pediatrics Head, Section of Pediatric Infectious Diseases Tulane University School of Medicine New Orleans, Louisiana

## **TEMPORARY MEMBERS (Voting)**

## Sally Blower, Ph.D.

Director of Center for Biomedical Modeling Semel Institute for Neuroscience & Human Behavior UCLA David Geffen School of Medicine Los Angeles, California

## Laura W. Cheever, M.D., ScM

Deputy Associate Administrator and Chief Medical Officer, HIV/AIDS Bureau Health Resources and Services Administration Department of Health and Human Services Rockville, Maryland

## Michelle M. Estrella, M.D., M.H.S

Assistant Professor and Associate Fellowship Program Director, Nephrology Division Johns Hopkins University School of Medicine Baltimore, Maryland

# Judith Feinberg, M.D., FACP, FIDSA

(Acting Chairperson)

Associate Chair of Medicine for Faculty Development University of Cincinnati College of Medicine Division of Infectious Diseases Holmes Hospital Cincinnati, Ohio

# Lawrence G. Hunsicker, M.D.

Professor of Medicine Emeritus Medical Director of Organ Transplantation, Nephrology Division University of Iowa College of Medicine Iowa City, Iowa

## David T. Kuhar, M.D.

Medical Officer, Prevention and Response Branch Division of Healthcare Quality Promotion Centers for Disease Control and Prevention (CDC) Atlanta, Georgia

## Elaine H. Morrato, Dr.PH., M.P.H., C.P.H.

Assistant Professor
Departments of Health Systems, Management &
Policy Clinical Pharmacy and Pediatrics
Assistant Director
Children's Outcomes Research Program
Anschutz Medical Campus
University of Colorado-Denver
Aurora, Colorado

## Susan Newcomer, Ph.D.

Statistician/Demographer
Demographic and Behavioral Sciences Branch
Eunice Kennedy Shriver National Institute of Child
Health and Human Development National
Institutes of Health (NIH)
Bethesda, Maryland

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## **MEETING ROSTER (cont.)**

#### **TEMPORARY MEMBERS (Voting)**

## Nancy S. Padian, Ph.D., M.P.H.

Adjunct Professor of Epidemiology University of California, Berkeley School of Public Health Berkeley, California

## Monica S. Ruiz, Ph.D., M.P.H.

Visiting Assistant Professor George Washington University School of Public Health and Health Services Department of Prevention and Community Health Washington, District of Columbia

# Marlena Vega, MSW, Ph.D.

(Patient Representative) New York, New York

## Lauren V. Wood, M.D.

(Health Disparities Specialist)
Captain, United States Public Health Service
Senior Clinical Investigator, Vaccine Branch
National Cancer Institute (NCI), NIH
Bethesda, Maryland

#### Matthew V. Sharp

(Patient Representative)
San Francisco, California

## ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

## Patrick A. Robinson, M.D.

(Acting Industry Representative)
Executive Director and Deputy
International Therapeutic Area Head- Virology
Boehringer Ingelheim Pharmaceuticals, Inc.
Ridgefield, Connecticut

#### **GUEST SPEAKER (Non-Voting)**

## Susan Buchbinder, M.D.

Director, HIV Research Section San Francisco Department of Public Health San Francisco, California

#### CDC SPEAKER (Non-Voting)

## Lynn A. Paxton, M.D., M.P.H.

Captain, United States Public Health Service Medical Epidemiologist, Epidemiology Branch Division of HIV/AIDS Prevention, CDC Atlanta, Georgia

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## **MEETING ROSTER (cont.)**

# **NIH SPEAKER (Non-Voting)**

## Jeanna M. Piper, M.D.

Senior Medical Officer, Division of AIDS National Institute of Allergy and Infectious Diseases, NIH Bethesda, Maryland

# FDA PARTICIPANTS (Non-Voting)

## Edward Cox, M.D., M.P.H.

Director Office of Antimicrobial Products (OAP) OND, CDER, FDA

## Jeffrey Murray, M.D., M.P.H.

Deputy Director DAVP, OAP, OND, CDER, FDA

## Peter Miele, M.D.

Medical Officer DAVP, OAP, OND, CDER, FDA

## Debra B. Birnkrant, M.D.

Director Division of Antiviral Products (DAVP) OAP, OND, CDER, FDA

## Kendall A. Marcus, M.D.

Deputy Director for Safety DAVP, OAP, OND, CDER, FDA