# FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting DoubleTree by Hilton Hotel Bethesda – Washington DC, Grand Ballroom 8120 Wisconsin Avenue Bethesda, Maryland May 2, 2018

# **MEETING ROSTER**

## **ACTING DESIGNATED FEDERAL OFFICER (Non-Voting)**

<u>Cindy Chee, PharmD</u>

Division of Advisory Committee and Consultant Management Office of Executive Programs, CDER, FDA

# ANTIMICROBIAL DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

#### Nina M. Clark, MD

Associate Professor Director, Transplant Infectious Disease Program Division of Infectious Diseases Loyola Medical Center Maywood, Illinois

#### Dean A. Follmann, PhD

Assistant Director of Biostatistics Chief Biostatistics Research Branch National Institute of Allergy and Infectious Diseases National Institutes of Health (NIH) Bethesda, Maryland

### Barbara M. Gripshover, MD

Associate Professor of Medicine University Hospitals Cleveland Medical Center Case Western Reserve University Division of Infectious Diseases and HIV Medicine Cleveland, Ohio

#### Vincent Lo Re, MD, MSCE

Assistant Professor of Medicine and Epidemiology Division of Infectious Diseases Department of Medicine Center for Clinical Epidemiology and Biostatistics Perelman School of Medicine University of Pennsylvania Philadelphia, Pennsylvania

#### Demetre C. Daskalakis, MD, MPH

Acting Deputy Commissioner Division of Disease Control New York City Department of Health and Mental Hygiene Long Island City, New York

#### Michael D. Green, MD, MPH

Professor of Pediatrics, Surgery and Clinical & Translational Science University of Pittsburgh School of Medicine Division of Infectious Diseases Director, Antimicrobial Stewardship & Infection Prevention Co-Director, Transplant Infectious Diseases Children's Hospital of Pittsburgh Pittsburgh, Pennsylvania

# Jonathan R. Honegger, MD

Assistant Professor of Pediatrics The Ohio State University College of Medicine Division of Infectious Diseases and Center for Vaccines and Immunity Nationwide Children's Hospital Columbus, Ohio

### Joanna M. Schaenman, MD, PhD

Assistant Professor of Medicine Division of Infectious Diseases David Geffen School of Medicine at UCLA Los Angeles, California

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# **MEETING ROSTER (cont.)**

## ANTIMICROBIAL DRUGS ADVISORY COMMITTEE MEMBERS (Voting) (cont.)

### Peter Weina, MD, PhD, FACP, FIDSA

Colonel, Medical Corps, USA Chief, Department of Research Programs Walter Reed National Military Medical Center Division of Education, Training and Research Bethesda, Maryland

## ANTIMICROBIAL DRUGS ADVISORY COMMITTEE MEMBERS (Non-Voting)

### Nicholas A. Kartsonis, MD

(Industry Representative) Acting Section Head, Antibacterials/CMV Vice President and Therapeutic Area Head, Infectious Diseases, Clinical Research Merck Research Laboratories North Wales, Pennsylvania

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

## Lindsey R. Baden, MD

(Acting Chairperson) Director of Clinical Research Division of Infectious Diseases Brigham and Women's Hospital Director, Infectious Disease Service Dana-Farber Cancer Institute Associate Professor, Harvard Medical School Boston, Massachusetts

## Randy Hawkins, MD

(Acting Consumer Representative) Private Practice Inglewood, California

#### Debra Dunn

(Patient Representative) Libertyville, Illinois

## Jennifer Le, PharmD, MAS

Professor of Clinical Pharmacy University of California San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences Faculty-in-Residence Miller Children's and Women's Hospital of Long Beach Long Beach Memorial Hospital La Jolla, California

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# **MEETING ROSTER (cont.)**

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

## Paul M. Palevsky, MD

Chief, Renal Section VA Pittsburgh Healthcare System Professor of Medicine Renal-Electrolyte Division University of Pittsburgh Pittsburgh, Pennsylvania

## Robert Rej, PhD

Director, Clinical Chemistry and Hematology Laboratory of Molecular Diagnostics Associate Professor School of Public Health State University of New York at Albany Research Scientist, Wadsworth Center New York State Department of Health Albany, New York

## Jurgen Venitz, MD, PhD

Professor and Vice Chairman Virginia Commonwealth University School of Pharmacy Department of Pharmaceutics Richmond, Virginia

# FDA PARTICIPANTS (Non-Voting)

# Edward Cox, MD, MPH

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

# Shrimant Mishra, MD, MPH

Medical Officer DAIP, OAP, OND, CDER, FDA

## Sumathi Nambiar, MD, MPH

Director Division of Anti-Infective Products (DAIP) OAP, OND, CDER, FDA

# Daniel Rubin, PhD

Statistical Reviewer Division of Biometrics IV (DBIV) Office of Biostatistics (OB) Office of Translational Sciences (OTS), CDER, FDA