

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)

10903 New Hampshire Avenue, Silver Spring, Maryland

November 4, 2016

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Lauren Tesh, PharmD, BCPS

Division of Advisory Committee and Consultant Management

Office of Executive Programs, CDER, FDA

ANTIMICROBIAL DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Ellen M. Andrews, PhD

(Consumer Representative)

Executive Director

CT Health Policy Project

New Haven, Connecticut

Lindsey R. Baden, MD

(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

Demetre C. Daskalakis, MD, MPH

Assistant Commissioner

Bureau of HIV Prevention and Control

New York Department of Health and Mental

Hygiene

Queens, New York

Michael D. Green, MD, MPH

Professor of Pediatrics and Surgery

Pediatrics and Surgery Division of Infectious Diseases

University of Pittsburgh School of Medicine

Children's Hospital of Pittsburgh of University of

Pittsburgh Medical Center

Pittsburgh, Pennsylvania

Barbara M. Gripshover, MD

Associate Professor of Medicine

University Hospitals Case Medical Center

Case Western Reserve University

Division of Infectious Diseases and HIV Medicine

Cleveland, Ohio

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

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

Marc H. Scheetz, PharmD, MSc

Associate Professor of Pharmacy Practice

Midwestern University Chicago College of Pharmacy

Downers Grove, Illinois

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MEETING ROSTER (cont.)

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

Peter J. Weina, MD, PhD, FACP, FIDSA

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

TEMPORARY MEMBERS (Voting)

Thomas D. Boyer, MD

Professor of Medicine, Professor of Cell Biology
and Anatomy, Director, Liver Research Institute
University of Arizona, University of Arizona
Health Sciences Center
Tucson, Arizona

William M. Lee, MD, FACP, FAASLD

Professor of Internal Medicine
Holder of the Meredith Mosle Chair in Liver Diseases
The University of Texas Southwestern Medical Center at
Dallas
Dallas, Texas

J. Stephen Mikita, JD

(Patient Representative)
Salt Lake City, Utah

Michael Proschan, PhD

Biostatistics Research Branch
National Institute of Allergy and Infectious Diseases
Bethesda, Maryland

ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

Douglas S. Levine, MD

Head, Internal Medicine
Vice President, Global Medical Affairs
Shire
Lexington, Massachusetts

FDA PARTICIPANTS (Non-Voting)

Edward M. Cox, MD, MPH

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

Sumathi Nambiar, MD, MPH

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

Yuliya I. Yasinskaya, MD

Cross-Discipline Team Leader
DAIP, OAP, OND, CDER, FDA

Ramya Gopinath, MD

Clinical Reviewer
DAIP, OAP, OND, CDER, FDA

Mark I. Avigan, MD, CM

Consultative Reviewer for Hepatology
Office of Surveillance and Epidemiology

Daniel B. Rubin, PhD

Biometrics Reviewer, Office of Biostatistics
Office of Translational Sciences, CDER, FDA