

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 (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
October 16, 2019

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Lauren Tesh Hotaki, PharmD, BCPS, BCIDP

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

ANTIMICROBIAL DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

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

Nina M. Clark, MD

Professor of Medicine
Interim Co-Director, Infectious Disease &
Immunology Research Institute
Stritch School of Medicine
Division Director, Infectious Diseases
Director, Transplant Infectious Diseases Program
Loyola University Medical Center
Maywood, Illinois

Dean A. Follmann, PhD

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

Michael 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
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Barbara M. Gripshover, MD

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Center
Case Western Reserve University
Division of Infectious Diseases and HIV
Medicine
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Jennifer Le, PharmD, MAS

Professor of Clinical Pharmacy
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La Jolla, California

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MEETING ROSTER (cont.)

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

Ighovwerha Ofotokun, MD, MSc

Professor of Medicine
Division of Infectious Diseases
Department of Medicine
Emory University School of Medicine
Atlanta, Georgia

George K. Siberry, MD, MPH

Medical Officer
Division of Prevention, Care & Treatment
Office of HIV/AIDS (U.S. President's Emergency
Plan for AIDS Relief)
U.S. Agency for International Development
Arlington, Virginia

Roblena E. Walker, PhD

(Consumer Representative)
Chief Executive Officer
EMAGAHA, INC.
Mableton, Georgia

Peter Joseph Weina, PhD, MD

Colonel, Medical Corps, US Army
Branch Chief
Research Regulatory Oversight Office
Office of the Under Secretary of Defense
(Personnel and Readiness)
Defense Health Headquarters
Falls Church, Virginia

ANTIMICROBIAL DRUGS ADVISORY COMMITTEE MEMBER (Non-Voting)

Nicholas A. Kartsonis, MD

(Industry Representative)
Senior Vice President
Infectious Disease & Vaccines, Clinical
Research
Merck Research Laboratories
North Wales, Pennsylvania

TEMPORARY MEMBERS (Voting)

Frank R. DeLeo, PhD

Chief, Laboratory of Bacteriology
NIAID/NIH
Hamilton, Montana

**Arthur G. Lyons, PhD, MD, COL, USA, MC,
FS, FACP, FIDSA**

Medical Director, Executive Medicine
Washington, District of Columbia

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MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting) (cont.)

Susanne May, PhD

Professor, Department of Biostatistics
University of Washington
Seattle, Washington

Thomas A. Moore, MD

Clinical Professor of Medicine
University of Kansas School of Medicine-
Wichita Campus
Department of Medicine Wichita
Wichita, Kansas

David “Davey” Smith, MD, MAS

(via phone)
Professor and Chief
Division of Infectious Diseases and Global
Public Health
Department of Medicine
University of California San Diego
San Diego, California

Jill M. Thomas

(Patient Representative)
Westminster, Maryland

FDA PARTICIPANTS (Non-Voting)

John Farley, MD, MPH

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

Sumati Nambiar, MD, MPH

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OAP, OND, CDER, FDA

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DAIP, OAP, OND, CDER, FDA

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Kalavati Suvarna, PhD

Clinical Microbiology Reviewer
DAIP, OAP, OND, CDER, FDA