

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting
June 8, 2023

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

She-Chia Jankowski, PharmD

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
Professor of Medicine, Harvard Medical School
Boston, Massachusetts

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

W. David Hardy, MD, AAHIVS

Attending, Rand Schrader (HIV) Clinic
Adjunct Clinical Professor of Medicine
Division of Infectious Diseases
Keck School of Medicine of
University of Southern California
Los Angeles, California

Sally A. Hunsberger, PhD

Biostatistician
Biometrics Research Branch
National Institute of Allergy and Infectious Diseases
(NIAID)
National Institutes of Health (NIH)
Rockville, Maryland

Ighovwerha Ofotokun, MD, MSc

Professor of Medicine
Division of Infectious Diseases
Emory University School of Medicine
Infectious Disease Specialist
Grady Memorial Health System
Atlanta, Georgia

Nimish Patel, PharmD, PhD

Professor of Clinical Pharmacy
Skaggs School of Pharmacy and Pharmaceutical
Sciences
University of California San Diego, Division of
Clinical Pharmacy
La Jolla, California

Federico Perez, MD, MS

Infectious Disease Physician
Louis Stokes Cleveland VA Medical Center
Associate Professor of Medicine
Case Western Reserve University
Cleveland, Ohio

George K. Siberry, MD, MPH

Senior Clinical Advisor to the Director
Office of HIV/AIDS
Bureau of Global Health
United States Agency for International Development
Washington, District of Columbia

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MEETING ROSTER (cont.)

ANTIMICROBIAL DRUGS ADVISORY COMMITTEE MEMBER (Voting, cont.)

Roblena E. Walker, PhD

(Consumer Representative)

Chief Executive Officer

EMAGAHA, INC.

Mableton, Georgia

ANTIMICROBIAL DRUGS ADVISORY COMMITTEE MEMBER (Non-Voting)

Richa S. Chandra, MD, MBA

(Industry Representative)

Clinical Development Head

Communicable Diseases

Global Health Development Unit

Novartis Pharmaceuticals

East Hanover, New Jersey

TEMPORARY MEMBERS (Voting)

Mary Cataletto, MD, MMM

(Retired February 2023)

Clinical Professor of Pediatrics

NYU Langone School of Medicine

Pediatric Pulmonologist

NYU Health

Mineola, New York

Douglas S. Diekema, MD, MPH

Professor of Pediatrics and Bioethics & Humanities

University of Washington School of Medicine

Director of Education, Treuman Katz Center for

Pediatric Bioethics

Seattle Children's Research Institute

Seattle, Washington

Peter L. Havens, MD, MS

Professor Emeritus, Pediatrics (Infectious Diseases)

Medical College of Wisconsin

Children's Wisconsin

Milwaukee, Wisconsin

Rohan Hazra, MD

Director, Division of Extramural Research

Eunice Kennedy Shriver National Institute of Child

Health and Human Development (NICHD), NIH

Bethesda, Maryland

Mary Anne Jackson, MD, FAAP, FIDSA, FPIDS

Dean and Professor of Pediatrics

Children's Mercy, Kansas City

University of Missouri-Kansas City

School of Medicine

Kansas City, Missouri

Karen L. Kotloff, MD

John A. Scholl, MD and Mary Louise Scholl, MD

Distinguished Professor

Head, Infectious Disease and Tropical Pediatrics, and

Associate Director, Clinical Research

Center for Vaccine Development and Global Health

University of Maryland School of Medicine

Baltimore, Maryland

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MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting, cont.)

Steven Krug, MD

Professor of Pediatrics
Northwestern University Feinberg
School of Medicine
Prior Head, Division of Emergency Medicine
Ann & Robert H. Lurie Children's Hospital of
Chicago
Chicago, Illinois

Tamurah Lewis, MD, PhD

Division Head, Clinical Pharmacology & Toxicology
Staff Neonatologist
The Hospital for Sick Children
Associate Professor, Department of Paediatrics
University of Toronto Temerty Faculty of Medicine
Toronto, Ontario

Meredith McMorrow, MD, MPH

CAPT, US Public Health Service
Acting Branch Chief
Surveillance and Prevention Branch
Coronavirus and Other Respiratory Viruses Division
National Center for Immunization and Respiratory
Diseases
U.S. Centers for Disease Control and Prevention
Atlanta, Georgia

Stacey Stokes, MD, MPH

Assistant Professor, Pediatric Hospital Medicine,
George Washington University
Medical Director of Informatics, Children's National
Hospital
Washington District of Columbia

Jasmine Shackelford Thomas

(Patient Representative)
Patient Advocate
Lupus and Allied Diseases Association, Inc.
Waldorf, Maryland

Benjamin Wilfond, MD

Professor, Divisions of Bioethics and Palliative Care
& Pulmonary and Sleep Medicine,
Department of Pediatrics, University of Washington
School of Medicine
Seattle, Washington

FDA PARTICIPANTS (Non-Voting)

John Farley, MD, MPH

Director
Office of Infectious Diseases (OID)
Office of New Drugs (OND), CDER, FDA

Yodit Belew, MD

Associate Director for Therapeutic Review
Division of Antivirals (DAV)
OID, OND, CDER, FDA

Melisse Baylor, MD

Clinical Reviewer
DAV, OID, OND, CDER, FDA

Justin Earp, PhD

Pharmacometrics Reviewer
Division of Pharmacometrics
Office of Clinical Pharmacology (OCP)
Office of Translational Science (OTS)
CDER, FDA

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MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting, cont.)

Neha Gada, PharmD, BCPS

Cross Discipline Safety Advisor
Office of Pharmacovigilance and Epidemiology
Office of Surveillance and Epidemiology
CDER, FDA

Anna Kettermann, Dipl.-Math, MA

Statistics Reviewer
Division of Biostatistics IV
Office of Biostatistics
OTS, CDER, FDA

Yang Zhao, PhD

Clinical Pharmacology Reviewer
Division of Infectious Disease Pharmacology
OCP, OTS, CDER, FDA