Center for Drug Evaluation and Research (CDER)

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting November 30, 2021

MEETING ROSTER

ACTING DESIGNATED FEDERAL OFFICER (Non-Voting)

Joyce Yu, 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

Sally A. Hunsberger, PhD

Mathematical Statistician

Biometrics Research Branch

National Institute of Allergy and Infectious

Diseases

National Institutes of Health

Rockville, Maryland

Richard A. Murphy, MD, MPH

Staff Physician, Infectious Diseases

VA White River Junction Medical Center

Medicine Service

White River Junction, Vermont

Timothy H. Burgess, MD, MPH, FACP

Captain, Medical Corps, U.S. Navy

Director, Infectious Disease Clinical Research

Program

Uniformed Services University of the Health Sciences

Bethesda, Maryland

W. David Hardy, MD

Scientific and Medical Consultant

Co-Investigator – CoVPN, CDU/UCLA CTRC

Charles Drew University School of Medicine and

Science

Los Angeles, California

Jennifer Le, PharmD, MAS, FIDSA, FCCP,

FCSHP, BCPS-ID

Professor of Clinical Pharmacy

University of California, San Diego

Skaggs School of Pharmacy and Pharmaceutical

Sciences

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

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MEETING ROSTER (cont.)

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

George K. Siberry, MD, MPH

Medical Officer, Adult Clinical Branch Office of HIV/AIDS Bureau of Global Health United States Agency for International Development

Washington, District of Columbia

Roblena E. Walker, PhD

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

Sankar Swaminathan, MD

Don Merrill Rees Presidential Endowed Chair Professor and Chief Division of Infectious Diseases Department of Internal Medicine University of Utah School of Medicine Salt Lake City, Utah

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

Colonel, Medical Corps, US Army Director, Office of Research Protections Defense Health Agency Defense Health Headquarters Falls Church, Virginia

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)

John M. Coffin, PhD

American Cancer Society Research Professor Molecular Biology and Microbiology Tufts University Boston, Massachusetts

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Medical Officer
Division of Birth Defects and Infant Disorders
National Center on Birth Defects and
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Centers for Disease Control and Prevention
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Kaiser Permanente Washington Health Research
Institute
General Internal Medicine Physician, Kaiser
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David A. Eastmond, PhD

Professor and Toxicologist, Emeritus Environmental Toxicology Graduate Program Department of Molecular, Cell and Systems Biology University of California, Riverside Riverside, California

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MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting) (cont.)

A. Oveta Fuller, PhD

Member, African Studies Center International Institute Associate Professor, Microbiology and Immunology, Medical School University of Michigan Ann Arbor, Michigan

James E.K. Hildreth Sr., MD, PhD

President and Chief Executive Officer Professor, Internal Medicine Meharry Medical College Nashville, Tennessee

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Scientist Emeritus Laboratory of Cancer Biology and Genetics Center for Cancer Research National Cancer Institute National Institutes of Health Bethesda, Maryland

Rita S. Schoeny, PhD

Senior Science Advisor
U.S. Environmental Protection Agency (retired)
Consultant in Risk Assessment and Science Policy
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FDA PARTICIPANTS (Non-Voting)

Peter Stein, MD

Director
Office of New Drugs (OND), CDER, FDA

Terry Gillespie

(Patient Representative) Westmont, Illinois

Daniel B. Horton, MD, MSCE

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Uma M. Reddy, MD, MPH

Professor

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John Farley, MD, MPH

Director

Office of Infectious Diseases (OID) OND, CDER, FDA

Center for Drug Evaluation and Research (CDER)

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MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting) (cont.)

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Patrick R. Harrington, PhD

Senior Clinical Virology Reviewer DAV, OID, OND, CDER, FDA

Mark Seaton, PhD, DABT

CAPT, U.S. Public Health Service Research Officer Division of Pharmacology/Toxicology-Infectious Diseases OID, OND, CDER, FDA

Robert H. Heflich, PhD

Director Division of Genetic and Molecular Toxicology National Center for Toxicological Research Office of the Chief Scientist Office of the Commissioner, FDA

Aimee Hodowanec, MD

Senior Medical Officer DAV, OID, OND, CDER, FDA