### FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

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

#### **Draft 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

#### 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

### Nimish Patel, PharmD, PhD

Professor of Clinical Pharmacy

Skaggs School of Pharmacy and Pharmaceutical Sciences

Sciences

University of California San Diego, Division of

Clinical Pharmacy La Jolla, California

### 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

### 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

Biostatistician

Biometrics Research Branch

National Institute of Allergy and Infectious Diseases

(NIAID)

National Institutes of Health (NIH)

Rockville, Maryland

#### Federico Perez, MD, MS

Infectious Disease Physician

Louis Stokes Cleveland VA Medical Center

Associate Professor of Medicine

Case Western Reserve University

Cleveland, Ohio

#### Roblena E. Walker, PhD

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

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# **Draft MEETING ROSTER (cont.)**

### 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

**TBD** 

# Peter L. Havens, MD, MS

Professor Emeritus, Pediatrics (Infectious Diseases) Medical College of Wisconsin Children's Wisconsin Milwaukee, Wisconsin

# 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

### 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

## 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

#### Rohan Hazra, MD

Director, Division of Extramural Research Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), NIH Bethesda, Maryland

### 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

### Tamorah 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

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## **Draft MEETING ROSTER (cont.)**

Hospital

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

#### 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

#### **Jasmine Shackleford Thomas**

(Patient Representative)

Patient Advocate

Lupus and Allied Diseases Association, Inc.

Waldorf, Maryland

# Benjamin Wilfond, MD

Stacey Stokes, MD, MPH

George Washington University

Washington District of Columbia

Professor, Divisions of Bioethics and Palliative Care

Assistant Professor, Pediatric Hospital Medicine,

Medical Director of Informatics, Children's National

& 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

### Melisse Baylor, MD

Clinical Reviewer

DAV, OID, OND, CDER, FDA

#### Yodit Belew, MD

Associate Director for Therapeutic Review

Division of Antivirals (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

### Neha Gada, PharmD, BCPS

Cross Discipline Safety Advisor

Office of Pharmacovigilance and Epidemiology

Office of Surveillance and Epidemiology

CDER, FDA

### Yang Zhao, PhD

Clinical Pharmacology Reviewer Division of Infectious Disease Pharmacology

OCP, OTS, CDER, FDA

### Anna Kettermann, Dipl.-Math, MA

Statistics Reviewer

Division of Biostatistics IV

Office of Biostatistics

OTS, CDER, FDA