Center for Drug Evaluation and Research (CDER)

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting

Tommy Douglas Conference Center 10000 New Hampshire Avenue, Silver Spring, Maryland April 13, 2017

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Lauren Tesh, PharmD, BCPS

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

ANTIMICROBRIAL DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Ellen 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

Nina M. Clark, MD

Associate Professor Director, Transplant Infectious Disease Program Division of Infectious Diseases Loyola Medical Center Maywood, Illinois

Amanda H. Corbett, PharmD, BCPS, FCCP

Clinical Associate Professor, Division of Pharmacotherapy and Experimental Therapeutics Associate Director of Global Engagement Office of Global Engagement Eshelman School of Pharmacy Global Pharmacology Coordinator Institute of Global Health and Infectious Diseases School of Medicine The University of North Carolina Chapel Hill, North Carolina

Demetre C. Daskalakis, MD, MPH

Acting Deputy Commissioner Division of Disease Control New York City Department of Health and Mental Hygiene Long Island City, New York

Dean A. Follmann, PhD

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

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MEETING ROSTER (cont.)

ANTIMICROBRIAL DRUGS ADVISORY COMMITTEE MEMBER (Voting) (cont.)

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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Jonathan 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
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Ighovwerha Ofotokun, MD, MSc

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

Peter Weina, MD, PhD, FACP, FIDSA

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

TEMPORARY MEMBERS (Voting)

John E. Bennett, MD

Chief, Clinical Mycology Section Laboratory of Clinical Infectious Diseases NIAID, NIH Bethesda, Maryland

Barbara M. Gripshover, MD

Associate Professor of Medicine University Hospitals Cleveland Medical Center Case Western Reserve University Division of Infectious Diseases and HIV Medicine Cleveland, Ohio

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Matthew Bidwell Goetz, MD

Chief, Infectious Diseases, VA Greater Los Angeles Healthcare System Professor of Clinical Medicine David Geffen School of Medicine at UCLA Los Angeles, California

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MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting) (cont.)

Joan F. Hilton, DSc, MPH

Professor Department

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Thomas A. Moore, MD

Infectious Disease Consultants Wichita, Kansas

Debra G. McCall, MBA

(Patient Representative) Murrieta, California

Yu Shyr, PhD

Harold L. Moses Chair in Cancer Research
Director, Vanderbilt Center for Quantitative Sciences
Director, Vanderbilt Technologies for Advanced
Genomics Analysis and Research Design
Associate Director for Quantitative Sciences Integration,
VICC

Professor of Biostatistics, Biomedical Informatics, and Cancer Biology Vanderbilt University Medical Center Nashville, Tennessee

Melvin P. Weinstein, MD

Professor of Medicine and Pathology & Laboratory Medicine Chief, Division of Infectious Diseases, Allergy & Immunology Vice Chair for Clinical Affairs, Department of Medicine Rutgers Robert Wood Johnson Medical School New Brunswick, New Jersey

ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

Lynn Marks, MD

Senior Vice President Projects, Clinical, and Sciences Team Glaxo Smith Kline Collegeville, Pennsylvania

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MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting)

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Director

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

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Medical Team Leader DAIP, OAP, OND, CDER, FDA

Dionne L. Price, PhD

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Division of Biometrics IV
Office of Biostatistics (OB)
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Sumathi Nambiar, MD, MPH

Director

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

Peter Kim, MD

Clinical Reviewer DAIP, OAP, OND, CDER, FDA

Daniel B. Rubin, PhD

Biometrics Reviewer OB, OTS, CDER, FDA