FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Meeting of the Anti-Infective Drugs Advisory Committee

Hilton Washington DC/Silver Spring
8727 Colesville Avenue, Silver Spring, Maryland
November 3, 2011

DRAFT MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Minh Doan, Pharm.D.
Division of Advisory Committee and Consultant Management
Office of Executive Programs
Center for Drug Evaluation and Research

ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Diane Cappelletty, Pharm.D.
Associate Professor Pharmacy Practice
University of Toledo College of Pharmacy
Toledo, Ohio

Dean Follmann, Ph.D.
Assistant Director for Biostatistics
Chief, Biostatistics Research Branch
National Institute of Allergy and Infectious Diseases/National Institutes of Health
Bethesda, Maryland

Matthew Goetz, M.D.
Professor of Clinical Medicine
David Geffen School of Medicine at UCLA
Chief, Infectious Diseases Section
VA Greater Los Angeles Healthcare System
Los Angeles, California

Thomas Moore, M.D.
(Chairperson)
Chairman
Department of Infectious Diseases
Ochsner Health System
New Orleans, Louisiana

Michael Neely, M.D.
Assistant Professor of Clinical Pediatrics
Division of Pediatric Infectious Disease
University of Southern California Keck School of Medicine
Los Angeles, California

Kent Sepkowitz, M.D.
Vice Chairman
Clinical Affairs Director, Hospital Infection Control
Memorial Sloan-Kettering Cancer Center
New York, New York

Melvin Weinstein, M.D.
Professor of Medicine and Pathology
Chief, Division of Infectious Diseases, Allergy & Immunology
UMDNJ-Robert Wood Johnson Medical School
Director, Microbiology Laboratory
Robert Wood Johnson University Hospital
New Brunswick, New Jersey

Kathleen Young
(Consumer Representative)
Executive Director
Alliance for Prudent Use of Antibiotics
Boston, Massachusetts

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DRAFT MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting)

John Bennett, M.D.
Head, Clinical Mycology Section
National Institute of Allergy and Infectious Diseases/National Institutes of Health
Bethesda, Maryland

William Calhoun, M.D.
Renfert Professor in Internal Medicine
Vice Chair for Research
Department of Internal Medicine
University of Texas Medical Branch
Galveston, Texas

Ralph D'Agostino, Ph.D.
Professor of Mathematics, Biostatistics, and Epidemiology
Boston University
Boston, Massachusetts

Thomas Fleming, Ph.D.
Professor of Biostatistics
University of Washington
Seattle, Washington

James Fratzke
(Patient Representative)
Portland, Oregon

Henry Masur, M.D.
Chief
Critical Care Medicine Department
National Institutes of Health Clinical Center
Bethesda, Maryland

L. Barth Reller M.D., D.T.M.&H.
Professor of Medicine and Pathology
Director of Clinical Microbiology
Duke University Medical Center
Durham, North Carolina

Allen Roberts, II, M.D., F.A.C.P.
Associate Professor of Medicine
Attending Physician, Pulmonary, Critical Care, and Sleep Medicine
Georgetown University Hospital
Washington, District of Columbia

Yu Shyr, Ph.D.
Professor and Chief
Division of Cancer Biostatistics
Vanderbilt University School of Medicine
Nashville, Tennessee

Bernhard Wiedermann, M.D.
Professor of Pediatrics
George Washington University School of Medicine and Health Sciences
Attending, Infectious Diseases
Children's National Medical Center
Washington, District of Columbia

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ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

John Rex, M.D.
(Acting Industry Representative)
Vice President, Clinical Infection
AstraZeneca, Alderley House
United Kingdom

GUEST SPEAKERS (Non-Voting, Presenting Only)

Barry Eisenstein, M.D., F.A.C.P., FIDSA
Senior Vice President
Scientific Affairs
Cubist Pharmaceuticals
Washington, District of Columbia

Thomas M. File, Jr., M.D., M.Sc.
Chair, Division of Infectious Disease
Summa Health System
Professor, Internal Medicine; Master Teacher;
Chair, Infectious Disease Section
Northeast Ohio Medical University
Rootstown, Ohio

Jeff Dubin. M.D., M.B.A.
Vice Chair
Department of Emergency Medicine
Washington Hospital Center
Washington, District of Columbia

James Floyd, M.D., M.S.
Representing Public Citizen
Department of Epidemiology
University of Washington
Seattle, Washington

Diana Zuckerman, Ph.D.
President
National Research Center for Women & Families
Washington, District of Columbia

John Bartlett, M.D.
Professor of Medicine
Johns Hopkins University School of Medicine
Baltimore, Maryland

FDA PARTICIPANTS (Non-Voting)

Edward Cox, M.D., M.P.H.
Director
Office of Antimicrobial Products (OAP)

John Farley, M.D., M.P.H.
Deputy Director
OAP, OND
Acting Director
Division of Anti-Infective Products (DAIP), OAP, OND

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DRAFT MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting) cont.

Katie Laessig, M.D.
Deputy Director
DAIP, OAP, OND

Sumati Nambiar, M.D., M.P.H.
Deputy Director for Safety
DAIP, OAP, OND

Thamban Valappil, Ph.D.
Statistical Team Leader
Division of Biometrics IV
Office of Biostatistics, Office of Translational Sciences

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