# FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

# Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503) 10903 New Hampshire Avenue, Silver Spring, Maryland October 24 – 25, 2018

#### **MEETING ROSTER**

# **DESIGNATED FEDERAL OFFICER (Non-Voting)**

#### LaToya Bonner, PharmD, NCPS

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

# ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

# Michael Blaha, MD, MPH

Associate Professor, Cardiology and Epidemiology Director of Clinical Research Johns Hopkins Ciccarone Center for the Prevention of Heart Disease Baltimore, Maryland

# Kenneth D. Burman, MD

Chief, Endocrine Section Medstar Washington Hospital Center Professor, Department of Medicine Georgetown University Washington, District of Columbia

# Susan S. Ellenberg, PhD

Professor of Biostatistics Professor of Medical Ethics and Health Policy (secondary) Department of Biostatistics, Epidemiology and Informatics

Perelman School of Medicine University of Pennsylvania Philadelphia, Pennsylvania

# **Anna McCollister-Slipp**

(Consumer Representative)
Founder, VitalCrowd
Washington, District of Columbia

#### Daniel Budnitz, MD, MPH

CAPT, US Public Health Service Director, Medication Safety Program Division of Healthcare Quality Promotion Centers for Disease Control and Prevention Atlanta, Georgia

#### James de Lemos, MD

Professor of Medicine Sweetheart Ball/Kern Wildenthal, MD, PhD Distinguished Chair in Cardiology UT Southwestern Medical Center Dallas, Texas

# Cecilia C. Low Wang, MD

Associate Professor of Medicine
Director, Glucose Management Team
University of Colorado Hospital
Department of Medicine, Division of Endocrinology,
Metabolism and Diabetes
University of Colorado Anschutz Medical Campus
School of Medicine
Lead Clinician-Scientist, CPC Clinical Research
Aurora, Colorado

# Peter W. F. Wilson, MD

(Chairperson)

Director, Epidemiology and Genomic Medicine Atlanta Veterans Administration Medical Center Professor of Medicine and Public Health Emory University Emory Clinical Cardiovascular Research Institute Atlanta, Georgia

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# **MEETING ROSTER (cont.)**

# ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting) (cont.)

# Susan Z. Yanovski, MD

Co-Director, Office of Obesity Research Senior Scientific Advisor for Clinical Obesity Research National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) National Institutes of Health (NIH) Bethesda, Maryland

# **TEMPORARY MEMBERS (Voting)**

# Brendan M. Everett, MD, MPH

Assistant Professor of Medicine Harvard Medical School Director, General Cardiology Inpatient Service Brigham and Women's Hospital Boston, Massachusetts

# George Grunberger, MD, FACP, FACE

Chairman, Grunberger Diabetes Institute
Bloomfield Hills, Michigan
Clinical Professor, Internal Medicine and
Molecular Medicine & Genetics
Wayne State University School of Medicine
Professor, Internal Medicine
Oakland University William Beaumont School of
Medicine
Visiting Professor, Internal Medicine
First Faculty of Medicine, Charles University

# **Richard Dan Lumley**

Prague, Czech Republic

(Patient Representative) Kansas, Missouri

# Judith Fradkin, MD

Director, Division of Diabetes, Endocrinology, and Metabolic Diseases NIDDK, NIH Bethesda, Maryland

# Fred Kushner, MD, FACC

Clinical Professor of Medicine Louisiana State University Medical Center Clinical Professor of Medicine at Tulane University Adjunct Professor of Medicine New York University Langone Health New York, New York

# Martha Nason, PhD

Mathematical Statistician Biostatistics Branch National Institute of Allergy and Infectious Diseases, NIH Bethesda, Maryland

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# **MEETING ROSTER (cont.)**

# TEMPORARY MEMBERS (Voting) (cont.)

# Connie B. Newman, MD, FACP, FAHA, FAMWA

Adjunct Professor, Department of Medicine Division of Endocrinology, Diabetes and Metabolism New York University School of Medicine New York, New York

# Yves Rosenberg, MD, MPH

Chief, Atherothrombosis and Coronary Artery Disease Branch Division of Cardiovascular Sciences National Heart, Lung and Blood Institute, NIH Bethesda, Maryland

# David C. Robbins, MD

Professor of Medicine Director, University of Kansas Diabetes Institute University of Kansas School of Medicine Kansas City, Kansas

# Thomas J. Wang, MD

Professor of Medicine
Gottlieb C. Friesinger II Chair in Cardiovascular
Medicine
Director, Division of Cardiovascular Medicine
Physician-in-Chief
Vanderbilt Heart & Vascular Institute
Vanderbilt University Medical Center
Nashville, Tennessee

# ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

# Scott Wasserman, MD, FACC

(Acting Industry Representative)
Vice President, Global Development
Head, Cardiovascular, Metabolic, and Neuroscience
Therapeutic Areas
Amgen, Inc.
Thousand Oaks, California

# FDA PARTICIPANTS (Non-Voting)

# Mary Thanh Hai, MD

Director (Acting)
Office of Drug Evaluation II (ODE-II)
Office of New Drugs (OND), CDER, FDA

#### Lisa Yanoff, MD

Deputy Director (Acting)
DMEP, ODE-II, OND, CDER, FDA

# Mahtab Niyyati, MD

Clinical Reviewer DMEP, ODE-II, OND, CDER, FDA

# William Chong, MD

Director (Acting)
Division of Metabolism and Endocrinology Products (DMEP)
ODE-II, OND, CDER, FDA

#### Patrick Archdeacon, MD

Clinical Team Lead DMEP, ODE-II, OND, CDER, FDA