#### FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

# Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting

Hilton Washington DC North/Gaithersburg, The Grand Ballroom 620 Perry Parkway, Gaithersburg, MD 20877 June 10, 2015

#### MEETING ROSTER

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

#### Philip A. Bautista, PharmD

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

# ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

#### David W. Cooke, MD

Associate Professor of Pediatrics Clinical Director, Division of Pediatric Endocrinology Director, Pediatric Endocrine Fellowship Training Program

Johns Hopkins University School of Medicine

Baltimore, Maryland

William R. Hiatt, MD, FACP, FAHA
Professor of Medicine
Division of Cardiology
University of Colorado School of Medicine
President, Colorado Prevention Center
Clinical Research
Aurora, Colorado

# Peter W. F. Wilson, MD

Philadelphia, Pennsylvania

Charles A. Stanley, MD

Professor of Pediatrics

Pennsylvania

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

Perelman School of Medicine University of

Division of Endocrinology & Diabetes

Children's Hospital of Philadelphia

#### Robert J. Smith, MD

(Chairperson)

Professor of Medicine (Endocrinology)
Alpert Medical School of Brown University
Ocean State Research Institute
Providence Veterans Administration Medical Center
Providence, Rhode Island

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

#### **TEMPORARY MEMBERS (Voting)**

#### Michael J. Blaha, MD, MPH

Director of Clinical Research Ciccarone Center for Prevention of Heart Disease Assistant Professor Johns Hopkins University School of Medicine Baltimore, Maryland

#### 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

#### Kenneth D. Burman, MD

Professor of Medicine Georgetown University and Uniformed Services University of the Health Sciences Director, Section of Endocrinology MedStar Washington Hospital Center Washington, District of Columbia

### Debra G. McCall, MBA

(Patient Representative) Murrieta, California

#### Martha Nason, PhD

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

#### Michele Orza, ScD

(Acting Consumer Representative)
Senior Advisor to the Executive Director
Patient-Centered Outcomes Research Institute
Washington, District of Columbia

#### Yves Rosenberg, MD, MPH

Branch Chief, Atherothrombosis and Coronary Artery Disease Branch Adult and Pediatric Cardiac Research Program Division of Cardiovascular Services National Heart, Lung, and Blood Institute (NHLBI) National Institutes of Health (NIH) Bethesda, Maryland

#### Philip Sager, MD, FACC, FAHA

Consulting Professor of Medicine Stanford University School of Medicine Chair, Scientific Programs Committee Cardiac Safety Research Consortium San Francisco, California

### Robert D. Shamburek, MD

Clinician/Scientist Lipoprotein Metabolism Section Cardiovascular and Pulmonary Branch NHLBI, NIH Bethesda, Maryland

#### Abraham Thomas, MD, MPH

Senior Vice President and Chair Department of Medicine New York University Lutheran Brooklyn, New York

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# **MEETING ROSTER (cont.)**

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

# Helmut H. Albrecht, MD, MS, FFPM

(Acting Industry Representative) Principal, H2A Associates, LLC Miami, Florida

## FDA PARTICIPANTS (Non-Voting)

## Curtis J. Rosebraugh, MD

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

## James P. Smith, MD, MS

Deputy Director DMEP, ODE II, OND, CDER, FDA

# Jean-Marc Guettier, MD

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

# Eileen Craig, MD

Medical Officer DMEP, ODE II, OND, CDER, FDA