## FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

# Endocrinologic and Metabolic Drug Advisory Committee (EMDAC) Meeting

FDA White Oak Campus, 10903 New Hampshire Avenue Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, Maryland April 14, 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

(Afternoon Session Only)

Associate Professor of Pediatrics

Clinical Director, Division of Pediatric

Endocrinology

Director, Pediatric Endocrine Fellowship Training

Program,

Johns Hopkins University School of Medicine

Baltimore, Maryland

## Susan R. Heckbert, MD, PhD

Professor

Department of Epidemiology University of Washington Seattle, Washington

# William R. Hiatt, MD, FAHA

Professor of Medicine Division of Cardiology

University of Colorado School of Medicine President, Colorado Prevention Center

Clinical Research Aurora, Colorado

## James D. Neaton, PhD

Professor of Biostatistics Division of Biostatistics Coordinating Centers for Biometric Research School of Public Health University of Minnesota Minneapolis, Minnesota

#### Robert J. Smith, MD

(Chairperson)

Professor of Medicine

Alpert Medical School of Brown University

Ocean State Research Institute

Providence Veterans Administration (VA) Medical

Center

Providence, Rhode Island

## Charles A. Stanley, MD

(Afternoon Session Only)

**Professor of Pediatrics** 

Perelman School of Medicine University of

Pennsylvania

Division of Endocrinology & Diabetes Children's Hospital of Philadelphia

Philadelphia, Pennsylvania

# Peter W. F. Wilson, MD

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 MEMBER (Non-Voting)

# Mads F. Rasmussen, MD, PhD

(Industry Representative)
Project Vice President
GLP-1 and Obesity
Global Development
Novo Nordisk A/S
Denmark

# **TEMPORARY MEMBERS (Voting)**

#### Bonnie H. Arkus, RN

(Acting Consumer Representative)
President, Women's Heart Foundation
Hamilton Township, New Jersey

## 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

# Erica H. Brittain, PhD

Deputy Branch Chief Biostatistical Research Branch National Institute of Allergy and Infectious Diseases, NIH Bethesda, Maryland

#### Nakela L. Cook, MD, MPH, FACC

(Morning Session Only)
Chief of Staff
National Heart, Lunch and Blood Institute (NHLBI)
National Institutes of Health (NIH)

#### **Gregory McIntyre**

Bethesda, Maryland

(Patient Representative)
Mitchellville, Maryland

# Yves Rosenberg, MD, MPH

Branch Chief Atherothrombosis and Coronary Artery Disease Branch, Adult and Pediatric Cardiac Research Program, Division of Cardiovascular Services NHLBI, NIH Bethesda, Maryland

# Morris Schambelan, MD

Professor Emeritus of Medicine University of California, San Francisco Division of Endocrinology San Francisco General Hospital San Francisco, California

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# Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting April 14, 2015

# **MEETING ROSTER (cont.)**

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

## Thomas J. Wang, MD

Gottlieb C. Friesinger II, MD Chair in Cardiovascular Medicine Vanderbilt University School of Medicine Director, Division of Cardiovascular Medicine Vanderbilt University Medical Center Nashville, Tennessee

### FDA PARTICIPANTS (Non-Voting)

# Curtis Rosebraugh, MD

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

## Lisa Yanoff, MD

(Morning Session Only)
Clinical Team Leader (Acting)
DMEP, ODE II, OND, CDER, FDA

#### Frank Pucino, PharmD, MPH

(Morning Session Only) Clinical Reviewer DMEP, ODE II, OND, CDER, FDA

#### Shanti Gomatam, PhD

(Morning Session Only)
Statistician, Division of Biometrics (DB) VII
Office of Biometrics (OB)
Office of Translational Sciences (OTS)
CDER, FDA

# Lamont G. Weide, MD, PhD, FACE

Chief, Endocrinology/Metabolism Truman Medical Center Professor, University of Missouri – Kansas City School of Medicine Kansas City, Missouri

## Jean-Marc Guettier, MD

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

## William Chong, MD

(Afternoon Session Only)
Clinical Team Leader (Acting)
DMEP, ODE II, OND, CDER, FDA

## Valerie S.W. Pratt, MD

(Afternoon Session Only)
Medical Officer
DMEP, ODE II, OND, CDER, FDA

#### Eugenio Andraca-Carrera, PhD

(Afternoon Session Only)
Statistician
DB VII, OB, OTS, CDER, FDA