## 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 May 24, 2016

#### 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)

### Daniel Budnitz, MD, MPH

Medical Officer, Division of Healthcare Quality Promotion Director, Medication Safety Program Centers for Disease Control and Prevention Atlanta, Georgia

## Brendan M. Everett, MD, MPH

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

### James D. Neaton, PhD

Professor of Biostatistics Division of Biostatistics School of Public Health University of Minnesota Minneapolis, Minnesota

#### Charles A. Stanley, MD

Professor of Pediatrics University of Pennsylvania Perelman School of Medicine Division of Endocrinology Children's Hospital of Philadelphia Philadelphia, Pennsylvania

#### David W. Cooke, MD

Associate Professor of Pediatrics Interim Director, Pediatric Endocrinology Johns Hopkins University School of Medicine Baltimore, Maryland

## Diana Hallare, MPH

(Consumer Representative) Visalia, California

## Robert J. Smith, MD

(Chairperson)
Professor of Medicine (Endocrinology)
The Warren Alpert School of Medicine
Professor of Health Services, Policy and Practice
Brown University
Providence, Rhode Island

## 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 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 National Institutes of Health (NIH) Bethesda, Maryland

# ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE MEMBER (Non-Voting)

## Reshma Kewalramani, MD

(Industry Representative)
Vice President, US Medical Organization
Amgen
Thousand Oaks, California

## **TEMPORARY MEMBERS (Voting)**

#### **Barbara Berney**

(Patient Representative)
Rockford, Illinois

#### Marie C. Gelato, MD, PhD

Professor of Medicine Director, Master's Program in Clinical Research Stony Medicine Stony Brook University Stony Brook, New York

## Steven B. Meisel, PharmD

System Director of Patient Safety Fairview Health Services Minneapolis, Minnesota

## Kenneth Burman, MD

Director, Section of Endocrinology MedStar Washington Hospital Center Director, Integrated Endocrine Training Program MedStar Georgetown University Hospital Washington, District of Columbia

#### Timothy S. Lesar, PharmD

Patient Care Service Director Director of Clinical Pharmacy Services Albany Medical Center Albany, New York

## Martha C. Nason, PhD

Mathematical Statistician
Division of Clinical Research
National Institute of Allergy and Infectious
Diseases, National Institutes of Health
Bethesda, Maryland

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

## TEMPORARY MEMBERS (Voting) (cont.)

### Michael D. Reed, PharmD, FCCP, FCP

Director Rainbow Clinical Research Center Rainbow Babies and Children's Hospital University Hospitals Case Medical Center Cleveland, Ohio

## FDA PARTICIPANTS (Non-Voting)

## Mary Parks, MD

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

## Lisa Yanoff, MD

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

# Anna Kettermann, Dipl. Math, MA

Biostatistician Division of Biostatistics (DB) II Office of Biostatistics (OB) Office of Translational Sciences (OTS) CDER, FDA

## Jean-Marc Guettier, MDCM

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

## Tania Condarco, MD

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