

## **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  
December 14, 2015

### **MEETING ROSTER**

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

##### **Stephanie L. Begansky, PharmD**

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**

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

##### **Diana Hallare, MPH**

*(Consumer Representative)*  
Visalia, California

##### **William R. Hiatt, MD, FACP, FAHA**

*(via telephone)*  
Professor of Medicine/Cardiology  
University of Colorado School of Medicine  
President, CPC  
Aurora, Colorado

##### **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

##### **Brendan M. Everett, MD, MPH**

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

##### **Susan R. Heckbert, MD, PhD**

Professor  
Department of Epidemiology  
University of Washington  
Cardiovascular Health Research Unit  
Seattle, Washington

##### **Robert J. Smith, MD**

*(Chairperson)*  
Professor of Medicine (Endocrinology)  
Alpert Medical School of Brown University  
Professor of Health Services, Policy and Practice  
Brown School of Public Health  
Research Staff, Ocean State Research Institute  
Providence Veterans Administration (VA) Medical  
Center  
Providence, Rhode Island

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**MEETING ROSTER (cont.)**

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**TEMPORARY MEMBERS (Voting)**

**Michael J. Blaha, MD, MPH**

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

**Sanjay Kaul, MD**

Professor  
UCLA School of Medicine  
Attending Cardiologist  
Cedars-Sinai Medical Center  
Los Angeles, California

**Milton Packer, MD**

Distinguished Scholar in Cardiovascular Science  
Baylor University Medical Center  
Dallas, Texas

**Robert D. Shamburek, MD**

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

**Thomas R. Fleming, PhD**

Professor, Department of Biostatistics  
University of Washington  
Seattle, Washington

**Debra McCall, MBA**

*(Patient Representative)*  
Murrieta, California

**Michael Proschan, PhD**

Mathematical Statistician  
Biostatistics Research Branch  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health (NIH)  
Bethesda, Maryland

**John R. Teerlink, MD**

Director, Heart Failure  
Director, Echocardiography  
San Francisco Veterans Affairs Medical Center  
Professor of Medicine  
School of Medicine  
University of California San Francisco  
San Francisco, California

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

**Reshma Kewalramani, MD**

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

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**MEETING ROSTER (cont.)**

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**FDA PARTICIPANTS (Non-Voting)**

**Curtis J. Rosebraugh, MD, MPH**

Director

Office of Drug Evaluation II (ODE II)

Office of New Drugs (OND), CDER, FDA

**Jean-Marc Guettier, MD**

Director

Division of Metabolism and Endocrinology Products  
(DMEP)

ODE II, OND, CDER, FDA

**James P. Smith, MD, MS**

Deputy Director

DMEP, ODE II, OND, CDER, FDA

**Iffat Nasrin Chowdhury, MD**

Medical Officer

DMEP, ODE II, OND, CDER, FDA

**Jennifer Clark, PhD**

Mathematical Statistician

Division of Biometrics (DB) II

Office of Biostatistics (OB)

Office of Translational Sciences (OTS)

CDER, FDA