

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Peripheral and Central Nervous System Drugs Advisory Committee (PCNS) Meeting
College Park Marriott Hotel and Conference Center, Chesapeake Ballroom
3501 University Blvd. East, Hyattsville, Maryland
April 25, 2016

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Moon Hee V. Choi, PharmD

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

PERIPHERAL AND CENTRAL NERVOUS SYSTEM DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

G. Caleb Alexander, MD, MS

(Chairperson)

Associate Professor of Epidemiology & Medicine
Johns Hopkins School of Public Health
Center for Drug Safety and Effectiveness
Baltimore, Maryland

Nicole R. Gonzales, MD

Associate Professor

University of Texas-Houston Medical School
Department of Neurology – Stroke Program
Houston, Texas

Mark W. Green, MD, FAAN

Professor of Neurology, Anesthesiology, and
Rehabilitation Medicine
Director of Headache and Pain Medicine
Icahn School of Medicine at Mt Sinai
New York, New York

Richard P. Hoffmann, PharmD

(Consumer Representative)

Drug Information Consultant/Medical Writer
Hernando, Florida

Richard J. Kryscio, PhD

Professor, Statistics
Chair, Biostatistics
University of Kentucky
Lexington, Kentucky

Chiadi U. Onyike, MD

Associate Professor of Psychiatry and Behavioral
Sciences
Division of Geriatric Psychiatry and
Neuropsychiatry
Department of Psychiatry and Behavioral Sciences
The Johns Hopkins University School of Medicine
Baltimore, Maryland

Bruce I. Ovbiagele, MD, MSc, MAS

Professor and Chairman of Neurology
Medical University of South Carolina
Charleston, South Carolina

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MEETING ROSTER (cont.)

**PERIPHERAL AND CENTRAL NERVOUS SYSTEM DRUGS ADVISORY COMMITTEE
MEMBER (Non-Voting)**

Mark Gordon, MD

(Industry Representative)

Director, Clinical Development and Medical Affairs, General Medicine/Central Nervous Systems
Boehringer Ingelheim Pharmaceuticals, Inc.
Ridgefield, Connecticut

TEMPORARY MEMBERS (Voting)

Benjamin Dupree

(Patient Representative)

Dallas, Texas

A. Reghan Foley, MD

Staff Clinician

Neuromuscular and Neurogenetic Disorders of
Childhood Section, Neurogenetics Branch
Division of Intramural Research
National Institute of Neurological Disorders of
Stroke (NINDS)
National Institutes of Health (NIH)
Bethesda, Maryland

Cheri Gunvalson, RN, MS

(Patient Representative)

Clinical Assistant Professor
University of North Dakota, College of Nursing
Grand Forks, North Dakota

Aaron S. Kesselheim, MD, JD, MPH

Associate Professor of Medicine

Harvard Medical School
Director, Program on Regulation, Therapeutics, and
Law (PORTAL)
Division of Pharmacoepidemiology and
Pharmacoeconomics
Brigham & Women's Hospital
Boston, Massachusetts

Glen Nuckolls, PhD

Program Director and Executive Secretary
Interagency Muscular Dystrophy Coordinating
Committee, Neurogenetics Cluster
Division of Extramural Research, NINDS, NIH
Bethesda, Maryland

Paul Romitti, PhD

Professor

Department of Epidemiology and Interdisciplinary
Program in Toxicology
University of Iowa
Iowa City, Iowa

FDA PARTICIPANTS (Non-Voting)

Janet Woodcock, MD

Director
CDER, FDA

John Jenkins, MD

Director
Office of New Drugs (OND), CDER, FDA

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MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting) (cont.)

Ellis Unger, MD

Director
Office of Drug Evaluation I (ODE-I)
OND, CDER, FDA

Robert Temple, MD

Deputy Director
ODE-I, OND, CDER, FDA

Billy Dunn, MD

Director
Division of Neurology Products (DNP)
ODE-I, OND, CDER, FDA

Eric Bastings, MD

Deputy Director
DNP, ODE-I, OND, CDER, FDA

Ronald Farkas, MD, PhD

Clinical Team Leader
DNP, ODE-I, OND, CDER, FDA