

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Psychopharmacologic Drugs Advisory Committee (PDAC) Meeting

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)

10903 New Hampshire Avenue, Silver Spring, Maryland

March 29, 2016

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Kalvani Bhatt, BS, MS

Division of Advisory Committee and Consultant Management

Office of Executive Programs, CDER, FDA

PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

David A. Brent, MD

(Chairperson)

Academic Chief

Division of Child Adolescent Psychiatry

University of Pittsburgh School of Medicine

Western Psychiatric Institute and Clinic

Pittsburgh, Pennsylvania

Thomas A. Grieger, MD

Staff Psychiatrist

Maryland Department of Health and Mental Hygiene

Thomas B. Finan Center

Cumberland, Maryland

Dawn F. Ionescu, MD

Depression Clinical and Research Program

Massachusetts General Hospital

Harvard Medical School

Boston, Massachusetts

Rajesh Narendran, MD

Associate Professor in Radiology and Psychiatry

University of Pittsburgh School of Medicine

Pittsburgh, Pennsylvania

David Pickar, MD

Adjunct Professor of Psychiatry

Johns Hopkins Medical School

Uniformed Services University of Health Sciences

Gabriel Sciences, LLC

Chevy Chase, Maryland

Kim O. Witczak

(Consumer Representative)

Co-Founder, Executive Director

Woodymatters

Minneapolis, Minnesota

TEMPORARY MEMBERS (Voting)

John E. Duda, MD

Director, Parkinson's Disease Research

Education & Clinical Center

Philadelphia Veteran's Affairs Medical Center

Associate Professor of Neurology

Perelman School of Medicine

University of Pennsylvania

Philadelphia, Pennsylvania

Susan Elmore, DVM, MS, DAVCP, DABT

Pathologist and Staff Scientist

National Toxicology Program Pathology Group

Cellular and Molecular Pathology Branch

National Institute of Environmental Health Sciences

National Institutes of Health

Research Triangle Park, North Carolina

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MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting) (cont.)

Stanley Fahn, MD

H. Houston Merritt Professor of
Neurology/Columbia University
Director Emeritus, Movement Disorder Division
Neurological Institute
New York, New York

Tobias Gerhard, PhD, RPh

Associate Professor
Rutgers University
Department of Pharmacy Practice and
Administration
Ernest Mario School of Pharmacy
New Brunswick, New Jersey

Linda Morgan, MBA, RPh

(Patient Representative)
Asheville, North Carolina

Urmimala Sarkar, MD

Associate Professor in Residence
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University of California, San Francisco
San Francisco, California

Christopher H. Schmid, PhD

Professor of Biostatistics
Center for Evidence Based Medicine
Department of Biostatistics
Brown University School of Public Health
Providence, Rhode Island

Almut Winterstein, RPh, PhD, FISPE

Professor and Interim Chair
Pharmaceutical Outcomes & Policy
College of Pharmacy
Epidemiology, College of Public Health and Health
Professions and College of Medicine
University of Florida
Gainesville, Florida

ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

Mark Forrest Gordon, MD

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

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MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting)

Robert Temple, MD

Deputy Director for Clinical Science
CDER, FDA
Deputy Director (Acting)
Office of Drug Evaluation-I (ODE-I)
Office of New Drugs (OND), CDER, FDA

Mitchell Mathis, MD

Director
Division of Psychiatry Products (DPP)
ODE-I, OND, CDER, FDA

Tiffany R. Farchione, MD

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

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DPP, ODE-I, OND, CDER, FDA

Paul Andreason, MD

Medical Officer
DPP, ODE-I, OND, CDER, FDA