

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

January 12, 2016

MEETING ROSTER

ACTING DESIGNATED FEDERAL OFFICER (Non-Voting)

Jennifer Shepherd, RPh

Division of Advisory Committee and Consultant Management

Office of Executive Programs, CDER, FDA

PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Thomas A. Grieger, MD

Staff Psychiatrist

Maryland Department of Health and Mental Hygiene

Thomas B. Finan Center

Cumberland, Maryland

David Pickar, MD

Adjunct Professor of Psychiatry

Johns Hopkins Medical School

Uniformed Services University of Health Sciences

Gabriel Sciences, LLC

Chevy Chase, Maryland

TEMPORARY MEMBERS (Voting)

Warren K. Bickel, PhD

Director, Addiction Recovery Research Center

Professor, Department of Psychology

Virginia Tech University

Professor, Department of Psychiatry, Virginia Tech

Carilion School of Medicine

Roanoke, Virginia

Kathleen T. Brady, MD, PhD

Distinguished University Professor

Medical University of South Carolina

Staff Psychiatrist

Mental Health Service Line

Ralph H. Johnson VA Medical Center

Charleston, South Carolina

Melinda Campopiano, MD

Medical Officer and Branch Chief for Regulatory

Programs

Division of Pharmacologic Therapies

Center for Substance Abuse Treatment

Substance Abuse and Mental Health Services

Administration

Rockville, Maryland

Kathleen M. Carroll, PhD (via phone)

Albert E. Kent Professor of Psychiatry

Yale University School of Medicine

West Haven, Connecticut

Lori E. Dodd, PhD

Mathematical Statistician

Biostatistics Research Branch, Division of Clinical

Research, National Institute of Allergy and Infectious

Diseases, National Institutes of Health (NIH)

Bethesda, Maryland

Adam J. Gordon, MD, MPH, FACP, FASAM

Professor, Medicine and Clinical and

Translational Sciences

University of Pittsburgh and VA Pittsburgh

Healthcare System

Pittsburgh, Pennsylvania

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MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting) (cont.)

Jennifer Higgins, PhD

(Acting Consumer Representative)
Director, Strategic Planning and Business
Development
Center for Human Development
Springfield, Massachusetts

Dawn F. Ionescu, MD

Depression Clinical and Research Program
Massachusetts General Hospital
Harvard Medical School
Boston, Massachusetts

Margaret Kotz, DO

Professor of Psychiatry and Anesthesiology
Case Western Reserve University School of
Medicine
Director, Addiction Recovery Services
University Hospitals
Cleveland, Ohio

Judith M. Kramer, MD, MS

(Acting Chairperson)
Professor Emerita of Medicine
Duke University School of Medicine
Durham, North Carolina

Laura F. McNicholas, MD, PhD

Clinical Associate Professor
Department of Psychiatry
Perelman School of Medicine
University of Pennsylvania
Philadelphia, Pennsylvania

Rajesh Narendran, MD

Associate Professor in Radiology and Psychiatry
University of Pittsburgh School of Medicine
Pittsburgh, Pennsylvania

Kenzie L. Preston, PhD

Chief/Senior Investigator
Clinical Pharmacology and Therapeutics Research
Branch
Intramural Research Program
National Institute on Drug Abuse
National Institutes of Health
Baltimore, Maryland

James Troendle, PhD

Mathematical Statistician
Office of Biostatistics
National Heart, Lung, and Blood Institute
National Institutes of Health
Bethesda, Maryland

Michael Yesenko, MDiv

(Patient Representative)
Laytonsville, Maryland

ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

Robert Russell Conley, MD

Global Development Leader, Pain and Core
Therapeutics and Distinguished Scholar
Eli Lilly and Company
Indianapolis, Indiana

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MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting)

Sharon Hertz, MD

Director
Division of Anesthesia, Analgesia, and Addiction
Products (DAAAP)
Office of Drug Evaluation II (ODEII)
Office of New Drugs (OND), CDER, FDA

Rigoberto Roca, MD

Deputy Director
DAAAP, ODEII, OND, CDER, FDA

Celia Winchell, MD

Clinical Team Leader
DAAAP, ODEII, OND, CDER, FDA

David Petullo, MS

Statistical Team Leader
Division of Biostatistics II (DB-II)
Office of Biostatistics (OB)
Office of Translational Sciences (OTS), CDER, FDA

Kimberly Lehrfeld, PharmD

Team Leader
Division of Risk Management (DRISK)
Office of Medication Error Prevention and Risk
Management (OPEPRM)
Office of Surveillance and Epidemiology (OSE)
CDER, FDA