

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

***Joint Meeting of the Psychopharmacologic Drugs Advisory Committee (PDAC) and the
Drug Safety and Risk Management Advisory Committee Meeting (DSaRM)***

FDA White Oak Campus, 10903 New Hampshire Avenue, Building 31 Conference Center
The Great Room (Rm. 1503), Silver Spring, Maryland

November 2, 2018

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Kalyani Bhatt, BS, MS

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

PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Walter S. Dunn, MD, PhD

Staff Psychiatrist and Assistant Clinical Professor
West Los Angeles Veterans Administration
Medical Center
University of California Los Angeles
Department of Psychiatry
Los Angeles, California

Jess G. Fiedorowicz, MD, PhD

Associate Professor
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Medicine
University of Iowa Carver College of Medicine
Iowa City, Iowa

Satish Iyengar, PhD

Chair and Professor of Statistics
Department of Statistics
University of Pittsburgh
Pittsburgh, Pennsylvania

Felipe A. Jain, MD

Assistant Professor of Psychiatry
Department of Psychiatry
Harvard Medical School
Massachusetts General Hospital
Boston, Massachusetts

Rajesh Narendran, MD

(Chairperson)
Attending Psychiatrist
Re:solve Crisis Network
Western Psychiatric Institute and Clinics
Associate Professor in Radiology and Psychiatry
Psychiatric Molecular Imaging Program
University of Pittsburgh
Pittsburgh, Pennsylvania

Erick H. Turner, MD

Associate Professor
Department of Psychiatry
Oregon Health and Science University
Staff Psychiatrist, VA Portland Health Care System
Portland, Oregon

Kim O. Witzak

(Consumer Representative)
Co-Founder, Executive Director
Woodymatters
Minneapolis, Minnesota

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MEETING ROSTER (cont.)

PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE MEMBER (Non-Voting)

Robert R. Conley, MD

(Industry Representative)

Global Development Leader
Pain and Core Therapeutic
Team and Distinguished Scholar
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana

DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE MEMBERS (Voting)

Kelly Besco, PharmD, FISMP, CPPS

Health-System Medication Safety Officer
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Dublin, Ohio

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Director, Vanderbilt MPH Program
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Vanderbilt University Medical Center
Nashville, Tennessee

Laurel A. Habel, MPH, PhD

Associate Director, Cancer Research
Division of Research
Kaiser Permanente Northern California
Oakland, California

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Division of Pharmacoepidemiology and
Pharmacoeconomics
Department of Medicine
Harvard Medical School and Brigham & Women's
Hospital
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Steven B. Meisel, PharmD

System Director of Patient Safety
Fairview Health Services
Minneapolis, Minnesota

Anne-Michelle Ruha, MD, FACMT

Director, Medical Toxicology Fellowship Program
Department of Medical Toxicology
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Clinical Associate Professor of Emergency
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University of Arizona College of Medicine
Phoenix, Arizona

Terri L. Warholak, PhD, RPh, CPHQ, FAPhA

Professor and Assistant Dean
Academic Affairs and Assessment
College of Pharmacy
University of Arizona
Tucson, Arizona

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MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting)

**Gregory Burger, PharmD, CPPS, FASHP,
NREMT**

Medication Safety Coordinator
Risk Management Department
Lecompton, Kansas

Sabrina Numann

(Patient Representative)
New Albany, Indiana

Tina Valbh, PharmD

Clinical Program Development
Pharmacy Services Division
Pharmaka Consulting
Mount Dora, Florida

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

Ellis Unger, MD

Director
ODE I, OND, CDER, FDA

Mitchell Mathis, MD

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

Cynthia LaCivita, PharmD

Director
Division of Risk Management
Office of Medication Error Prevention and
Risk Management
Office of Surveillance and Epidemiology
CDER, FDA

Tiffany Farchione, MD

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

Bernard Fischer, MD

Clinical Team Leader
DPP, ODE I, OND, CDER, FDA