FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM) and Psychopharmacologic Drugs Advisory Committee (PDAC) November 19, 2024

MEETING ROSTER

ACTING DESIGNATED FEDERAL OFFICER (Non-Voting)

Jessica Seo, PharmD, MPH

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

DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE MEMBERS (Voting)

<u>Maryann Amirshahi PharmD, MD, MPH, PhD,</u> <u>BCPS, FACMT, FACEP, FASAM, FCP</u>

Professor of Emergency Medicine, Georgetown University School of Medicine Department of Emergency Medicine, MedStar Washington Hospital Center Washington, District of Columbia

Sascha Dublin, MD, PhD

Senior Scientific Investigator Kaiser Permanente Washington Health Research Institute Seattle, Washington

John B. Hertig, PharmD, MS, CPPS, FASHP

(via video conferencing platform) Associate Professor Department of Pharmacy Practice Butler University College of Pharmacy and Health Sciences Indianapolis, Indiana

Michael C. Dejos, PharmD, MBA, BCPS, CHOP, CPPS

System Medication Safety Officer Methodist Le Bonheur Healthcare Assistant Professor University of Tennessee Health Science Center Memphis, Tennessee

James Floyd, MD, MS

(Acting Chairperson) Co-Director, Cardiovascular Health Research Unit Professor of Medicine Adjunct Professor of Epidemiology University of Washington Seattle, Washington

Elizabeth Rebo, PharmD, MBA, CPPS

Executive Director, Pharmacy Quality and Medication Safety National Pharmacy Services Kaiser Permanente Downey, California

DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE MEMBERS (Non-Voting)

Jens-Ulrich Stegmann, RN, MD

(Alternate Industry Representative) Senior Vice President Global Head Clinical Safety and Pharmacovigilance, EU QPPV GlaxoSmithKline (GSK) Wavre, Belgium

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM) and Psychopharmacologic Drugs Advisory Committee (PDAC) November 19, 2024

MEETING ROSTER (cont.)

PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Walter S. Dunn, MD, PhD

Assistant Clinical Professor University of California Los Angeles Department of Psychiatry Director, Mood Disorders Section Director, Interventional Psychiatry Service West Los Angeles Veterans Affairs Medical Center Los Angeles, California

Rajesh Narendran, MD

Attending Psychiatrist Resolve Crisis Services UPMC Western Psychiatric Hospital Professor in Radiology and Psychiatry University of Pittsburgh School of Medicine Psychiatric Molecular Imaging Program University of Pittsburgh Pittsburgh, Pennsylvania

Jess G. Fiedorowicz, MD, PhD

(via video conferencing platform) Head and Chief, Department of Mental Health The Ottawa Hospital Professor and Senior Research Chair in Adult Psychiatry, Department of Psychiatry University of Ottawa Ottawa, Ontario

PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Non-Voting)

Carla M. Canuso, MD

(Industry Representative) Vice President, Head of Neuropsychiatry Clinical Development Janssen Research and Development, LLC Titusville, New Jersey

TEMPORARY MEMBERS (Voting)

Jacob S. Ballon, MD, MPH.

Associate Professor Co-Division Chief - Division of General Adult Psychiatry and Psychology Co-Director, INSPIRE Clinic Department of Psychiatry Stanford University Stanford, California

Michael Brisbin

(*Patient Representative*) Odessa, Missouri

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM) and Psychopharmacologic Drugs Advisory Committee (PDAC) November 19, 2024

MEETING ROSTER (cont.)

Megan J. Ehret, PharmD, MS, BCPP

Professor, Co-Director Mental Health Program University of Maryland, School of Pharmacy Baltimore, Maryland

Jeremy G. Perkins, MD, FACP, COL, US Army (ret)

Deputy Director, Hematopoietic Stem Cell Program Murtha Cancer Center, Walter Reed National Military Medical Center Hematology-Medical Oncology Service, Department of Medicine Associate Professor of Medicine, Uniformed Services University of the Health Sciences (USUHS) Bethesda, Maryland

Brian W. Salvas, PharmD, RPh

Vice President Pharmacy Innovation and Engineering CVS Health Woonsocket, Rhode Island

FDA PARTICIPANTS (Non-Voting)

Gerald Dal Pan, MD, MHS

Director Office of Surveillance and Epidemiology (OSE) CDER, FDA

<u>Teresa Buracchio, MD</u> Director Office of Neuroscience (ON) Office of New Drugs (OND) CDER, FDA

<u>Tiffany R. Farchione, MD</u> Director Division of Psychiatry (DP) ON, OND, CDER, FDA

<u>Marc Stone, MD</u> Deputy Director for Safety DP, ON, OND, CDER, FDA

Gopal Vyas, DO

Clinical Assistant Professor Department of Psychiatry University of Maryland School of Medicine Maryland Psychiatric Research Center Baltimore, Maryland

Irene Z. Chan, PharmD

Director Office of Medication Error Prevention and Risk Management (OMEPRM) OSE, CDER, FDA

Cynthia LaCivita, PharmD

Director Division of Risk Management (DRM) OMEPRM, OSE, CDER, FDA

Bernard Fischer, MD

Deputy Director DP, ON, OND, CDER, FDA

<u>Carolyn Tieu, PharmD, MPH</u>

Team Leader DRM, OMEPRM, OSE, CDER, FDA