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 (DSaRM) FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503) 10903 New Hampshire Avenue, Silver Spring, Maryland October 31, 2017

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

<u>Kalyani Bhatt, MS</u> Division of Advisory Committee and Consultant Management Office of Executive Programs, CDER, FDA

PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Satish Iyengar, PhD

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

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

David Pickar, MD

Adjunct Professor of Psychiatry Johns Hopkins Medical School Uniformed Services University of Health Sciences Gabriel Sciences, LLC Chevy Chase, Maryland

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. Witczak

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

PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (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

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MEETING ROSTER (cont.)

DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE MEMBERS (Voting)

Denise M. Boudreau, PhD, RPh

Professor (Affiliate) Departments of Pharmacy and Epidemiology University of Washington Senior Scientific Investigator Group Health Research Institute Seattle, Washington

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 Banner University Medical Center Clinical Associate Professor of Emergency Medicine University of Arizona College of Medicine Phoenix, Arizona

TEMPORARY MEMBERS (Voting)

G. Caleb Alexander, MD

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

Chester Buckenmaier, II, MD

Associate Professor & Director Defense & Veterans Center for Integrative Pain Management Uniformed Services University Bethesda, Maryland

Laurel A. Habel, MPH, PhD

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

Suzanne B. Robotti

(Consumer Representative) Executive Director DES Action USA Founder and President MedShadow Foundation New York, New York

Almut Winterstein, RPh, PhD, FISPE

Professor and Crisafi Chair Pharmaceutical Outcomes & Policy College of Pharmacy University of Florida Gainesville, Florida

Kathleen T. Brady, MD, PhD

Distinguished University Professor of Psychiatry Director, South Carolina Clinical and Translational Research Institute Medical University South Carolina Charleston, South Carolina

Kathleen M. Carroll, PhD

Albert E, Kent Professor of Psychiatry Director of Psychosocial Research Division of Addictions Principal Investigator, Psychotherapy Development Center for Drug Abuse Yale University School of Medicine West Haven, Connecticut

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MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting) (cont.)

Daniel Ciccarone, MD, MPH

Professor of Family and Community Medicine University of California, San Francisco San Francisco, California

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

Elbert F. and Marie Christensen Endowed Research Professor Medicine and Psychiatry University of Utah School of Medicine Chief of Addiction Medicine Salt Lake City Veterans Administration Medical Center Salt Lake City, Utah

Daniel L. Krinsky, MS, RPh

Associate Professor Department of Pharmacy Practice Northeast Ohio Medical University Rootstown, Ohio

FDA PARTICIPANTS (Non-Voting)

<u>Sharon Hertz, MD</u>

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

Celia Winchell, MD

Clinical Team Leader DAAAP, ODE II, OND, CDER, FDA

Cynthia LaCivita, PharmD

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

Sabrina Numann

(Patient Representative) Founder and Director Leaders Against Pain Action Network New Albany, Indiana

Rigoberto Roca, MD

Deputy Director DAAAP, ODE II, OND, CDER, FDA

Judy Staffa, PhD, RPh

Associate Director for Public Health Initiatives Office of Surveillance and Epidemiology (OSE) CDER, FDA

Dominic Chiapperino, PhD

Acting Director Controlled Substance Staff Office of Center Director, CDER, FDA