

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
July 19, 2016

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Jennifer Shepherd, RPh

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

DERMATOLOGIC AND OPHTHALMIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Michael Bigby, MD

(Chairperson)

Associate Professor of Dermatology
Harvard Medical School and
Beth Israel Deaconess Medical Center
Boston, Massachusetts

Ken Katz, MD, MSc, MCSE

Dermatologist
Kaiser Permanente
San Francisco, California

DERMATOLOGIC AND OPHTHALMIC DRUGS ADVISORY COMMITTEE MEMBER (Non-Voting)

Marla B. Sultan, MD, MBA

(Industry Representative)

Global Clinical Lead, Clinical Development
Pfizer, Inc.
New York, New York

TEMPORARY MEMBERS (Voting)

Bonnie H. Arkus, RN

(Acting Consumer Representative)

President, Women's Heart Foundation
Hamilton Township, New Jersey

Warren B. Bilker, PhD

Professor of Biostatistics
Department of Biostatistics and Epidemiology
Perelman School of Medicine
University of Pennsylvania
Philadelphia, Pennsylvania

Michael J. Blaha, MD, MPH

Director of Clinical Research and Assistant Professor
Johns Hopkins Ciccarone Center for Prevention of
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Baltimore, Maryland

Erica Brittain, PhD

Mathematical Statistician and Deputy Branch Chief
Biostatistics Research Branch
National Institute of Allergy and Infectious Disease
(NIAID)
National Institutes of Health (NIH)
Bethesda, Maryland

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MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting) (cont.)

John J. DiGiovanna, MD

Senior Research Physician
DNA Repair Section
Dermatology Branch
Center for Cancer Research
National Cancer Institute, NIH
Bethesda, Maryland

Lynn A. Drake, MD

Lecturer
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Department of Dermatology
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Michael R. Irwin, MD

Cousins Distinguished Professor of Psychiatry and
Biobehavioral Sciences, David Geffen School of
Medicine at UCLA
Distinguished Professor of Psychology, UCLA
College of Letters and Sciences
Director, Cousins Center for
Psychoneuroimmunology, Semel Institute for
Neuroscience
Director, Mindful Awareness Research Center
Los Angeles, California

Francis E. Lotrich, MD, PhD

Associate Professor of Psychiatry
University of Pittsburgh Medical Center
Pittsburgh, Pennsylvania

Stephen R. Marder, MD

Professor and Director, Section on Psychosis
Semel Institute for Neuroscience at UCLA
Los Angeles, California

Elaine H. Morrato, DrPH, MPH

Associate Dean for Public Health Practice
Associate Professor Department of Health
Systems
Management and Policy
Colorado School of Public Health
University of Colorado Anschutz Medical Campus
Aurora, Colorado

Matthew V. Rudorfer, MD

Chief, Somatic Treatments and Psychopharmacology
Program
Division of Services and Intervention Research
National Institute of Mental Health (NIMH), NIH
Bethesda, Maryland

Elizabeth Smith

(Patient Representative)
Burke, Virginia

Ming T. Tan, PhD

Professor & Chair
Department of Biostatistics, Bioinformatics &
Biomathematics
Georgetown University
Washington, District of Columbia

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MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting) (cont.)

Consuelo Walss-Bass, PhD

Associate Professor
Department of Psychiatry and Behavioral Sciences
McGovern Medical School
University of Texas Health Science Center at
Houston
Houston, Texas

David D. Waters, MD

Professor Emeritus,
Division of Cardiology,
San Francisco General Hospital
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University of California, San Francisco
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Julie M. Zito, PhD

Professor of Pharmacy and Psychiatry
University of Maryland, Baltimore
Pharmaceutical Health Services Department
Baltimore, Maryland

FDA PARTICIPANTS (Non-Voting)

Amy Egan, MD

Deputy Director
Office of Drug Evaluation III (ODE-III)
Office of New Drugs (OND), CDER, FDA

Kendall A. Marcus, MD

Director
Division of Dermatology and Dental Products
(DDDP)
ODE-III, OND, CDER, FDA

Gary Chiang, MD, MPH

Medical Officer
DDDP, ODE-III, OND, CDER, FDA

Cynthia L. LaCivita, PharmD

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

Simone P. Pinheiro, ScD, MSc

Deputy Director (Acting)
Division of Epidemiology I, Office of
Pharmacovigilance and Epidemiology (OPE)
OSE, CDER, FDA