

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

Bone, Reproductive, and Urologic Drugs Advisory Committee Meeting
College Park Marriott Hotel and Conference Center, General Vessey Ballroom
3501 University Blvd. East, Hyattsville, Maryland
January 9, 2018

DRAFT MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Kalvani Bhatt, BS, MS

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

**BONE, REPRODUCTIVE, AND UROLOGIC DRUGS ADVISORY COMMITTEE MEMBERS
(Voting)**

Douglas C. Bauer, MD

Professor of Medicine and Epidemiology &
Biostatistics
University of California, San Francisco
San Francisco, California

Roger T. Dmochowski, MD

Professor of Urology
Director, Pelvic Medicine and Reconstruction
Fellowship
Department of Urology
Vanderbilt University Hospital
Nashville, Tennessee

Matthew T. Drake, MD, PhD

Associate Professor of Medicine
Chair, Metabolic Bone Disease Core Group
Division of Endocrinology
Mayo Clinic College of Medicine
Rochester, Minnesota

Beatrice J. Edwards, MD, MPH, FACP

Associate Professor
Department of General Internal Medicine
Division of Internal Medicine
University of Texas MD Anderson Cancer Center
Houston, Texas

Margaret Gass, MD

Executive Director Emerita
North American Menopause Society
Fred Hutchinson Cancer Research Center
Seattle, Washington

Vivian Lewis, MD

(Chairperson)
Vice Provost for Faculty Development & Diversity
Professor, Obstetrics and Gynecology
University of Rochester
Rochester, New York

Pamela Shaw, PhD

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

Sarah Sorscher, JD, MPH

(Consumer Representative)
Chief Regulatory Affairs Counsel
Center for Science in the Public Interest
Washington, District of Columbia

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DRAFT MEETING ROSTER (cont.)

**BONE, REPRODUCTIVE, AND UROLOGIC DRUGS ADVISORY COMMITTEE MEMBERS
MEMBERS (Non-Voting)**

Gerard G. Nahum, MD, FACOG

(Industry Representative)

Vice President of Global Development, General
Medicine
Women's Healthcare, Long-Acting Contraception,
Medical Devices, and Special Projects
Bayer HealthCare Pharmaceuticals, Inc.
Parsippany, New Jersey

TEMPORARY MEMBERS (Voting)

Robert A. Adler, MD

Chief, Endocrinology and Metabolism
McGuire Veterans Affairs Medical Center
Professor of Internal Medicine and of
Epidemiology
Virginia Commonwealth University School of
Medicine
Richmond, Virginia

George Bisphoric

(Patient Representative)
Fort Lauderdale, Florida

Robert Brannigan, MD

Chief of Male Reproductive Medicine and Men's
Health in the Department of Urology
Professor of Urology
Northwestern University School of Medicine
Chicago, Illinois

Glenn D. Braunstein, MD

The James R. Klinenberg, M.D. Professor of
Medicine
Vice President for Clinical Innovation
Cedars-Sinai Medical Center
Los Angeles, California

Tobias Gerhard, PhD, RPh

Associate Professor of Pharmacoepidemiology
Ernest Mario School of Pharmacy, and
Institute for Health, Health Care Policy and Aging
Research
Rutgers University
New Brunswick, New Jersey

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Professor of Urology
Department of Urology
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National Institute of Kidney
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A. Michael Lincoff, MD

Director, Cleveland Clinic Coordinating Center for
Clinical Research (C5Research)
Vice Chairman, Department of Cardiovascular
Medicine and Lerner Research Institute
Professor of Medicine
Cleveland, Ohio

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DRAFT MEETING ROSTER (cont.)

Donald E. Mager, PharmD, PhD

Associate Professor of Pharmaceutical Sciences
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Buffalo, New York

Robert Rej, PhD

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Biomedical Sciences
Wadsworth School of Laboratory Sciences
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Albany, New York

Peter W. F. Wilson, MD

Professor of Medicine, Division of Cardiology
Emory University School of Medicine
Atlanta, Georgia

FDA PARTICIPANTS (Non-Voting)

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Director
Division of Bone, Reproductive and Urologic
Products (DBRUP)
Office of Drug Evaluation III (ODE III)
Office of New Drugs (OND), CDER, FDA

A. Roger Wiederhorn, MD, DMSci

Medical Officer
DBRUP, ODE III, OND, CDER, FDA

Mark Hirsch, MD

Clinical Team Leader
DBRUP, ODE III, OND, CDER, FDA

Dhananjay D. Marathe, PhD

Pharmacometrics Reviewer
Division of Pharmacometrics (DPM)
Office of Clinical Pharmacology (OCP)
Office of Translational Sciences (OTS), CDER, FDA

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ODE I, OND, CDER, FDA

Chongwoo Yu, PhD

Clinical Pharmacology Reviewer
Division of Clinical Pharmacology-III (DCP-III)
OCP, OTS, CDER, FDA