

**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

**MEETING ROSTER**

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**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 *(via phone)***

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

**Margery 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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**MEETING ROSTER (cont.)**

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**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 Bishopric**

*(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**

Professor of Medicine  
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

**Stuart S. Howards, MD**

Professor of Urology  
Department of Urology  
University of Virginia  
Charlottesville, Virginia

**Ziva Kirkali, MD**

Senior Scientific Advisor  
National Institute of Kidney  
National Institute of Health  
Bethesda, Maryland

**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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**MEETING ROSTER (cont.)**

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**Donald E. Mager, PharmD, PhD**

Associate Professor of Pharmaceutical Sciences  
University of Buffalo, SUNY  
Department of Pharmaceutical Sciences  
School of Pharmacy and Pharmaceutical Sciences  
Buffalo, New York

**Robert Rej, PhD**

Associate Professor, School of Public Health,  
Biomedical Sciences  
Wadsworth School of Laboratory Sciences  
Albany Medical College  
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)**

**Hylton V. Joffe, MD, MMSc**

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

**Dhananjay D. Marathe, PhD**

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

**Preston Dunnmon, MD**

Medical Officer  
Division of Cardiovascular and Renal  
Products (DCRP)  
ODE I, OND, CDER, FDA

**Chongwoo Yu, PhD**

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