

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Bone, Reproductive, and Urologic Drugs Advisory Committee (BRUDAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
December 7, 2017

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 *(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

Vivian Lewis, MD

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

Christian P. Pavlovich, MD

Director of Urologic Oncology and Associate
Professor
Brady Urological Institute
John Hopkins Bayview Medical Center
Baltimore, Maryland

Pamela A. Shaw, PhD

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

Sarah Sorscher, JD, MPH

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

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

Bone, Reproductive, and Urologic Drugs Advisory Committee (BRUDAC) Meeting
December 7, 2017

MEETING ROSTER (cont.)

BONE, REPRODUCTIVE, AND UROLOGIC DRUGS ADVISORY COMMITTEE 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)

Tamara G. Bavendam, MD, MS

Program Director of Women's Urology
Division of Kidney, Urologic and Hematologic
Diseases
National Institute of Diabetes and Digestive and
Kidney Diseases, National Institutes of Health
Bethesda, MD

David Cella, PhD

Professor and Chair
Department of Medical Social Sciences
Northwestern University
Chicago, Illinois

Thomas Chelimsky, MD

Professor of Neurology and Psychiatry
Medical College of Wisconsin
Milwaukee, Wisconsin

Stuart S. Howards, MD

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

Barbara Berney

(Patient Representative)
Rockford, Illinois

Toby Chai, MD

Vice Chair of Research
Co-Director of Female Pelvic Medicine and
Reconstructive Surgery Program
Department of Urology
Yale School of Medicine
New Haven, Connecticut

Monica M. Christmas, MD, FACOG, NCMP

Department of Obstetrics and Gynecology
The University of Chicago
Chicago, Illinois

Timothy Ness, MD, PhD

Professor of Anesthesia
Vice Chair for Clinical Research
University of Alabama
Birmingham, Alabama

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Bone, Reproductive, and Urologic Drugs Advisory Committee (BRUDAC) Meeting

December 7, 2017

MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting)

Audrey Gassman, MD

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

Suresh Kaul, MD, MPH

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

Debuene Chang, MD

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

Selena Daniels, PharmD, MS

Clinical Outcome Assessment Team Leader
Clinical Outcome Assessments Staff
OND, CDER, FDA