

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
October 29, 2019

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

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

Pamela Shaw, PhD

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

TEMPORARY MEMBERS (Voting)

Jonathan M. Davis, MD

Vice-Chair of Pediatrics
Chief of Newborn Medicine
The Floating Hospital for Children at Tufts
Medical Center
Professor of Pediatrics
Tufts University School of Medicine
Boston, Massachusetts

Ahizechukwu Eke, MD, MPH

Assistant Professor
Division of Maternal Fetal Medicine
Department of Gynecology & Obstetrics
Johns Hopkins University School of Medicine
Baltimore, Maryland

Annie Ellis

(Patient Representative)
White Plains, New York

Daniel Gillen, PhD

Professor and Chair, Statistics
University of California, Irvine
Irvine, California

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MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting) (cont.)

Kimberly Hickey, MD

Colonel, Medical Corps, US Army
Chief, Maternal Fetal Medicine
Walter Reed National Military Medical Center
Deputy Director, National Capital Consortium
Uniformed Services University of the Health
Sciences
Bethesda, Maryland

Michael K. Lindsay, MD, MPH

Luella Klein Associate Professor
Chief, Gynecology and Obstetrics Service Grady
Health Systems
Director, Division of Maternal Fetal Medicine
Emory University
Atlanta, Georgia

Uma M. Reddy, MD, MPH

Professor, Department of Obstetrics,
Gynecology and Reproductive Sciences
Division Chief, Maternal Fetal Medicine
Section Chief, Maternal Fetal Medicine of Yale
New Haven Hospital
Program Director, Maternal-Fetal Medicine
Fellowship
Department of Obstetrics, Gynecology and
Reproductive Sciences
Yale School of Medicine
New Haven, Connecticut

Kelly Wade, MD, PhD, MSCE

Attending Neonatologist
Children's Hospital of Philadelphia (CHOP)
Associate Professor of Clinical Pediatrics
University of Pennsylvania
CHOP Newborn Care
Philadelphia, Pennsylvania

Sally Hunsberger, PhD

Mathematical Statistician
Division of Clinical Research
National Institute of Allergy and Infectious Disease
National Institute of Health
Rockville, Maryland

Michele Orza, ScD

(Acting Consumer Representative)
Chief of Staff
Patient-Centered Outcomes Research Institute
(PCORI)
Washington, District of Columbia

Brian Smith MD, MPH, MHS

Samuel L. Katz Professor of Pediatrics
Division of Neonatal-Perinatal Medicine
Duke University Medical Center
Durham, North Carolina

Deborah A. Wing, MD, MBA

Senior Client Partner
Los Angeles, California
Formerly, Professor of Obstetrics-Gynecology
Division of Maternal Fetal Medicine
University of California, Irvine
Orange, California

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MEETING ROSTER (cont.)

ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

Venkateswar Jarugula, PhD

(Acting Industry Representative)

Executive Director

Translation Medicine

Novartis Institutes for Biomedical Research

East Hanover, New Jersey

FDA PARTICIPANTS (Non-Voting)

Christine Nguyen, MD

Deputy Director for Safety

Division of Bone, Reproductive and Urologic
Products (DBRUP)

Office of Drug Evaluation III (ODE III)

Office of New Drugs (OND), CDER, FDA

Barbara Wesley, MD, MPH

Medical Officer

DBRUP, ODEIII, OND, CDER, FDA

Christina Chang, MD, MPH

Clinical Team Leader

DBRUP, ODEIII, OND, CDER, FDA

Jia Guo, PhD

Statistical Reviewer

Division of Biometrics 3 (DB3)

Office of Biostatistics (OB)

Office of Translational Sciences (OTS), CDER, FDA