

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

*Joint Meeting of the Advisory Committee for Reproductive Health Drugs and the
Drug Safety and Risk Management Advisory Committee*

Marriott Inn and Conference Center

University of Maryland University College (UMUC)

3501 University Blvd. East

Adelphi, Maryland

December 8, 2011

MEETING ROSTER

DESIGNATED FEDERAL OFFICER

(Non-Voting)

Kalyani Bhatt, M.S.

Division of Advisory Committee and Consultant Management
Office of Executive Programs
Center for Drug Evaluation and Research

**ADVISORY COMMITTEE FOR REPRODUCTIVE HEALTH DRUGS MEMBERS
(VOTING)**

Richard Bockman, M.D., Ph.D.

Head, Endocrine Service
The Hospital for Special Surgery
New York, New York

John Kittelson, Ph.D.

Department of Biostatistics and Informatics
University of Colorado Denver
Aurora, Colorado

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Associate Professor of Medicine
Mayo Clinic College of Medicine
Department of Medicine, Endocrinology,
Diabetes, Metabolism and Nutrition
Rochester, Minnesota

Michele Orza, Sc.D.

(Consumer Representative)
Public Health
Principal Policy Analyst
National Health Policy Forum
George Washington University
Washington, District of Columbia

Melissa Gilliam, M.D., M.P.H.

Department of Obstetrics and Gynecology
University of Chicago
Chicago, Illinois

Valerie Montgomery Rice, M.D.

Dean and Executive Vice President
Office of the Dean
Morehouse School of Medicine
Atlanta, Georgia

Kathleen Hoeger, M.D., M.P.H.

Associate Professor of OB/GYN
Director, Division of Reproductive and
Obstetrics
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Rochester, New York

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MEETING ROSTER (cont.)

**ACTING INDUSTRY REPRESENTATIVE TO THE ADVISORY COMMITTEE FOR
REPRODUCTIVE HEALTH DRUGS**

(Non-Voting)

Robert Gut, M.D., Ph.D.

(Acting Industry Representative)

Vice President, Clinical Development & Medical Affairs

Biopharmaceuticals

Novo Nordisk Inc.

Medical Department

Princeton, New Jersey

**DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE MEMBERS
(VOTING)**

Sonia Hernandez-Diaz, M.D., Dr.PH.

Associate Professor

Department of Epidemiology

Harvard School of Public Health

Boston, Massachusetts

Elaine Morrato, Dr.PH.

Assistant Professor

Department of Pediatrics

University of Colorado Denver

Aurora, Colorado

Peter Kaboli, M.D.

Associate Professor, Department of Internal
Medicine

University of Iowa Carver College of Medicine,

Iowa City Veterans Administration Medical

Center

Iowa City, Iowa

Maria Suarez-Almazor, M.D., Ph.D.

Barns Family Distinguished Professor

University of Texas MD Anderson Cancer

Center

Houston, Texas

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MEETING ROSTER (cont.)

**DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE MEMBERS
(VOTING) cont.**

Almut Winterstein, Ph.D.

Associate Professor

Department of Pharmaceutical Outcomes and
Policy

College of Pharmacy

Department of Epidemiology

Colleges of Medicine and Public Health

Director, FDA/CDER Graduate Program in

Pharmaceutical Outcomes Research

University of Florida

Gainesville, Florida

T. Mark Woods, Pharm.D.

Clinical Coordinator and Residency Program Director

Pharmacy Department

Saint Luke's Hospital

Kansas City, Missouri

New York University School of Medicine

New York, New York

**DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE MEMBER (NON-
VOTING)**

Sidney Wolfe, M.D.

(Consumer Representative)

Director

Health Research Group of Public Citizen

Washington, District of Columbia

TEMPORARY MEMBERS (VOTING)

Diane Aronson

(Patient Representative)

Cambridge, Massachusetts

Anne E Burke, M.D., M.P.H

Assistant Professor

Department of Gynecology and Obstetrics

Johns Hopkins Bayview

Baltimore, Maryland

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MEETING ROSTER (cont.)

Eve Espey, M.D., M.P.H.

Associate Professor
Department of OB-GYN
Albuquerque, New Mexico

Jacqueline S. Gardner, Ph.D.

Professor, University of Washington
Seattle, Washington

Sean Hennessey, Ph.D.

Associate Professor of Epidemiology &
Pharmacology
University of Pennsylvania School of Medicine
Philadelphia, Pennsylvania

Geri D. Hewitt, M.D.

Ohio State University
Department of Obstetrics and Gynecology
Columbus, Ohio

Paula Hillard, M.D.

Professor and Chief
Division of Gynecologic Specialties
Department of Obstetrics and Gynecology
Stanford University School of Medicine
Stanford, California

Julia Johnson, M.D.

(Acting Chairperson)

Professor and Chair
Department of Obstetrics and Gynecology
University of Massachusetts Medical School
UMass Memorial Campus
Worcester, Massachusetts

Elizabeth Raymond, M.D., M.P.H.

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Gynuity Health Projects
New York, New York

Enrique Schisterman, Ph.D.

National Institute of Health
Branch Chief and Senior Investigator
Bethesda, Maryland

Dale Stovall, M.D.

Professor and Director
The University of Virginia Health System
Charlottesville, Virginia

Naomi K. Tepper, M.D., MPH

Medical Officer
Division of Reproductive Health
Centers for Disease Control and Prevention
Assistant Clinical Professor of Gynecology &
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Emory University School of Medicine
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Robert Wild, M.D.

Professor,
Oklahoma University Health Sciences Center
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GUEST SPEAKER (Non-Voting, Presenting Only)

Stephen Sidney, M.D., M.P.H

Associate Director for Clinical Research
Division of Research, Kaiser Permanente
Oakland, California

FDA PARTICIPANTS (Non-Voting)

Julie Beitz, M.D.

Director, Office of Drug Evaluation III
Office of New Drugs,
Center for Drug Evaluation and Research
(CDER)
Food and Drug Administration (FDA)

Gerald Dal Pan, M.D.

Acting Director
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research
(CDER), FDA

Scott Monroe, M.D.

Director, Division of Reproductive and Urologic
Products (CDER), FDA

Rita Ouellet-Hellstrom, Ph.D., M.P.H.

Associate Director for Epidemiology
Division of Epidemiology II
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Center for Drug Evaluation and Research
(CDER), FDA

Judy A. Staffa, Ph.D., R.Ph.

Director, Division of Epidemiology II
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Lisa Soule, M.D.

Medical Officer Team Leader, Division of
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(CDER), FDA