

**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

September 9, 2011

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**FINAL MEETING ROSTER**

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**ACTING DESIGNATED FEDERAL OFFICER**

**(Non-Voting)**

**Yvette Waples, Pharm.D.**

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)**

**Bart Clarke, M.D.**

Associate Professor of Medicine

Mayo Clinic College of Medicine

Department of Medicine, Endocrinology,

Diabetes, Metabolism and Nutrition

Rochester, Minnesota

**John Kittelson, Ph.D.**

Department of Biostatistics and Informatics

University of Colorado Denver

Aurora, Colorado

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

Associate Professor of OB/GYN

Director, Division of Reproductive

Endocrinology

University of Rochester Medical Center.

Rochester, New York

**Michele Orza, Sc.D.**

*(Consumer Representative)*

Public Health

Principal Policy Analyst

National Health Policy Forum

George Washington University

Washington, District of Columbia

**ADVISORY COMMITTEE FOR REPRODUCTIVE HEALTH DRUGS MEMBER**

**(Non-Voting)**

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

*(Industry Representative)*

Vice President, Clinical Development & Medical Affairs

Biopharmaceuticals

Novo Nordisk Inc.

Medical Department

Princeton, New Jersey

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## FINAL MEETING ROSTER (cont.)

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

**William Cooper, M.D., M.P.H.**

Professor of Pediatrics and Preventive Medicine  
Departments of Pediatrics and Preventive  
Medicine  
Vanderbilt University School of Medicine  
Nashville, Tennessee

**Brian Erstad, Pharm.D.**

Professor  
University of Arizona College of Pharmacy  
Department of Pharmacy Practice & Science  
Tucson, Arizona

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

Associate Professor  
Department of Epidemiology  
Harvard School of Public Health  
Boston, Massachusetts

**David Madigan, Ph.D.**

Professor, Chair, Department of Statistics  
Columbia University  
New York, New York

**Elaine Morrato, Dr.PH.**

Assistant Professor  
Department of Pediatrics  
University of Colorado Denver  
Aurora, Colorado

**Lewis Nelson, M.D.**

Director, Fellowship in Medical Toxicology  
New York University School of Medicine  
New York, New York

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

Barnts Family Distinguished Professor  
University of Texas MD Anderson Cancer  
Center  
Houston, Texas

**Allen Vaida, Pharm.D., FASHP**

Executive Vice President  
Institute for Safe Medication Practices  
Horsham, Pennsylvania

**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

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**FINAL MEETING ROSTER (cont.)**

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**TEMPORARY MEMBERS (VOTING)**

**Kenneth Burman, M.D.**

Chief, Endocrine Section  
Washington Hospital Center  
Professor, Department of Medicine  
Georgetown University  
Washington, District of Columbia

**Sandra Ann Carson, M.D. (Acting Chair)**

Professor of Obstetrics and Gynecology  
Alpert Medical School of Brown University  
Director, Division of Reproductive  
Endocrinology and Infertility  
Women and Infants Hospital of Rhode Island  
Providence, Rhode Island

**Michael Collins, M.D.**

Chief, Skeletal Clinical Studies Unit  
Craniofacial and Skeletal Diseases Branch  
National Institute of Dental and Craniofacial  
Research  
National Institutes of Health  
Bethesda, Maryland

**William Duncan, M.D, Ph.D.**

Associate Deputy Under Secretary for Health for  
Quality and Safety  
Department of Veterans Affairs  
Washington, District of Columbia

**Julia Johnson, M.D.**

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

**Karla Miller, M.D.**

Assistant Professor  
University of Utah  
Division of Rheumatology  
School of Medicine  
Salt Lake City, Utah

**Clifford Rosen, M.D.**

Director of Center for Clinical and Translational  
Research  
Maine Medical Center Research Institute  
Scarborough, Maine

**Mary Ruppe, M.D.**

Assistant Professor  
The University of Texas Health Science Center  
at Houston  
Houston, Texas

**Elizabeth Tucker**

*(Patient Representative)*  
Lakeville, Minnesota

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**FINAL MEETING ROSTER (cont.)**

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**GUEST SPEAKER (Non-Voting, Presenting Only)**

**Douglas C. Bauer, M.D.**

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

**SPEAKER (Non-Voting, Presenting Only)**

**Robert A. Adler, M.D.**

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

**FDA PARTICIPANTS (Non-Voting)**

**Julie Beitz, M.D.**

Director, Office of Drug Evaluation III  
Office of New Drugs,  
Center for Drug Evaluation and Research

**George Benson, M.D.**

Deputy Director, Division of Reproductive and  
Urologic Products

**Theresa Kehoe, M.D.**

Medical Officer Team Leader, Division of  
Reproductive and Urologic Products

**Marcea Whitaker, M.D.**

Medical Officer, Division of Reproductive and  
Urologic Products

**Judy Staffa, Ph.D., R.Ph.**

Director, Division of Epidemiology II  
Office of Pharmacovigilance and Epidemiology  
Office of Surveillance and Epidemiology  
Center for Drug Evaluation and Research

**Fatmatta Kuyateh, M.D., M.S.**

Medical Officer, Division of Epidemiology II