

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

Gastrointestinal Drugs Advisory Committee (GIDAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
April 7, 2016

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Cindy Hong, PharmD

Division of Advisory Committee and Consultant Management
Office of Executive Programs
CDER, FDA

GASTROINTESTINAL DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Elizabeth Bell-Perkins, MPH

(Consumer Representative)
EBP Health Communications
Williamsburg, Massachusetts

Lin Chang, MD

Professor of Medicine
Program Director, University of California, Los Angeles (UCLA) GI Fellowship Program
Co-Director, Oppenheimer Family Center for Neurobiology of Stress
David Geffen School of Medicine at UCLA
Los Angeles, California

Linda Feagins, MD

Associate Professor of Medicine
Division of Digestive and Liver Diseases
University of Texas Southwestern Medical Center
Staff Physician and Director of the Inflammatory Bowel Diseases Clinic
VA North Texas Health Care System
Dallas, Texas

Sandeep Khurana, MBBS

Associate Professor of Medicine
Director of Hepatology
Division of Gastroenterology and Hepatology
Georgia Regent University
Augusta, Georgia

Timothy O. Lipman, MD

Emeritus Chief, GI-Hepatology-Nutrition Section
Department of Veterans Affairs Medical Center
50 Irving St NW
Washington, District of Columbia

Jean-Pierre Raufman, MD

(Chairperson)
Moses and Helen Golden Paulson Professor of Medicine
Head, Division of Gastroenterology & Hepatology
University of Maryland School of Medicine
Baltimore, Maryland

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MEETING ROSTER (cont.)

GASTROINTESTINAL DRUGS ADVISORY COMMITTEE MEMBERS (Voting) cont.

Miriam Vos, MD, MSPH

Associate Professor of Pediatrics
Division of Gastroenterology, Hepatology and
Nutrition
Department of Pediatrics
Emory University School of Medicine
Atlanta, Georgia

TEMPORARY MEMBERS (Voting)

David Assis, MD

Assistant Professor
Department of Internal Medicine
Section of Digestive Diseases
Yale University School of Medicine
New Haven, Connecticut

Hari Conjeevaram, MD

Professor of Medicine
Program Director, GI Fellowship Program
Division of Gastroenterology
University of Michigan
Ann Arbor, Michigan

Donna Crver, JD

(Patient Representative)
Washington, District of Columbia

Srinivasan Dasarathy, MD

Staff
Cleveland Clinic Foundation
Cleveland, Ohio

Susan Ellenberg, PhD

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

Atul Kumar, MD

Staff Gastroenterologist
Northport Veterans Affairs (VA) Medical Center
Assistant Professor
Gastroenterology & Hepatology
Stony Brook University
Northport, New York

Patricia Lupole

(Patient Representative)
Norfolk, Virginia

Michael Proschan, PhD

Mathematical Statistician
Biostatistics Research Branch
National Institute of Allergy and
Infectious Diseases
Bethesda, Maryland

Marina Silveira, MD

Physician
Division of Gastroenterology
Louis Stokes Cleveland VA Medical Center
Cleveland, Ohio

Maria Sjogren, MD, MPH

Hepatologist
Walter Reed National Military Medical Center
Bethesda, Maryland

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MEETING ROSTER (cont.)

ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

Douglas Levine, MD, FACP

Head of Medical Affairs
Gastroenterology/Internal Medicine
Shire
Lexington, Massachusetts

FDA PARTICIPANTS (Non-Voting)

Amy G. Egan, MD, MPH

Deputy Director
Office of Drug Evaluation III (ODE III)
Office of New Drugs (OND), CDER, FDA

Dragos Roman, MD

Associate Director
Division of Gastroenterology and Inborn Errors
Products (DGIEP)
ODE III, OND, CDER, FDA

Lara Dimick-Santos, MD

Cross Discipline Team Leader
DGIEP, ODE III, OND, CDER, FDA

Ruby Mehta, MD

Medical Reviewer
DGIEP, ODE III, OND, CDER, FDA

Yeh-Fong Chen, PhD

Mathematical Statistician (Team Lead)
Division of Biometrics III
Office of Biostatistics
Office of Translational Sciences (OTS)
CDER, FDA

Dhananjay Marathe, PhD

Senior Pharmacometrics Reviewer
Division of Pharmacometrics
Office of Clinical Pharmacology
OTS, CDER, FDA