

Joint Meeting of the Gastrointestinal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee July 31, 2007

Holiday Inn Gaithersburg, Two Montgomery Village Avenue, Gaithersburg, Maryland

Participant Roster

GASTROINTESTINAL DRUGS ADVISORY COMMITTEE MEMBERS PRESENT (Voting)

David B. Sachar, M.D. (Chair)

Director Emeritus Division of Gastroenterology Mount Sinai School of Medicine One Gustave L. Levy Place Annenberg Building, Room 5-207 New York, NY

Lin Chang, M.D.

Co-Director, Center for Neurovisceral Sciences and Women's Health CURE: Digestive Diseases Research Center VA Greater Los Angeles Healthcare System Building 115, Room 223 11301 Wilshire Boulevard Los Angeles, CA

Pankaj Jay Pasricha, M.D.

Chief, Division of Gastroenterology and Hepatology University of Texas Medical Branch 4.106 McCullough Building 301 University Boulevard Galveston, TX

INDUSTRY REPRESENTATIVE

(Non-voting)
Jose M. Vega, M.D.
Senior Medical Director, Early Development
One Amgen Center Drive
Mail Stop 38-3-A
Thousand Oaks, CA

DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE MEMBERS PRESENT (Voting)

Richard Platt, M.D., M.Sc. (Chair)

Professor, Harvard Medical School 133 Brookline Avenue, 6th Floor Boston, MA

Terry C. Davis, Ph.D.

Professor, Department of Medicine & Pediatrics Louisiana State University Health Sciences Center 1501 Kings Highway, Room 6-212 Shreveport, LA

Sean Hennessy, Pharm.D., Ph.D.

Assistant Professor of Epidemiology University of Pennsylvania School of Medicine 423 Guardian Drive 803 Blockley Hall Philadelphia, PA

Judith M. Kramer, M.D., M.S.

Associate Professor Division of General Internal Medicine Duke University Medical Center Duke Clinical Research Institute P.O. Box 17968 Durham, NC

Timothy S. Lesar, Pharm.D.

Director of Pharmacy Albany Medical Center 43 New Scotland Avenue Albany, NY

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Participant Roster (continued)

TEMPORARY VOTING MEMBERS

James R. Couch, Jr., M.D., Ph.D.

Chair, Department of Neurology University of Oklahoma Health Sciences Center 711 S.L. Young Boulevard, Room 209 Oklahoma City, OK

Ruth S. Day, Ph.D.

Director, Medical Cognition Laboratory Duke University Box 90085 Durham, NC

Marilyn S. Eichner

Patient Representative Rockville, MD

Jacqueline S. Gardner, Ph.D., M.P.H.

Professor, Department of Pharmacy University of Washington Seattle, WA

Carol Lee Koski, M.D.

Professor of Neurology (retired) Guillain Barre Syndrome/CIDP Foundation International Narbeth, PA

Alexander H. Krist, M.D.

Fairfax Family Practice Center Virginia Commonwealth University 3650 Joseph Siewick Drive, Suite 400 Fairfax, VA

Arthur Levin, M.P.H.

Director, Center for Medical Consumers 239 Thompson Street New York, NY

Robert A. Levine, M.D.

Professor, Division of Gastroenterology State University Hospital 750 East Adams Street Syracuse, NY

James Neaton, Ph.D.

Professor of Biostatistics School of Public Health University of Minnesota 2221 University Ave, S.E.,Suite 200 Minneapolis, MN

Lewis S. Nelson, M.D.

Director, Fellowship in Medical Toxicology New York City Poison Control Center New York University School of Medicine 455 First Avenue; Room 123 New York, NY

Margo Smith, M.D.

Associate Program Director Department of Medicine Washington Hospital Center 110 Irving Street, N.W., #2A-56 Washington, D.C.

FDA PARTICIPANTS (Non-Voting)

Mark Avigan, M.D., C.M.

Director, Division of Drug Risk Evaluation Office of Surveillance and Epidemiology (OSE)

Julie Beitz, M.D.

Director, Office of Drug Evaluation III (ODE III)/ Office of New Drugs (OND)

Gerald Dal Pan, M.D., M.H.S.

Director

Office of Surveillance and Epidemiology (OSE)

John Hyde, Ph.D., M.D.

Medical Team Leader Division of Gastrointestinal Drug Products (DGDP)/ODE III/OND

Claudia Karwoski, Pharm.D.

Risk Management Team Leader, OSE

Joyce Korvick, M.D., M.P.H.

Deputy Director Division of Gastrointestinal Drug Products (DGDP) /ODE III/OND

Sandra Kweder, M.D.

Deputy Director/OND

Anil Rajpal, M.D.

Medical Officer, DGDP ODE III/OND