Peripheral and Central Nervous System Drugs Advisory Committee Meeting

January 7- 8, 2009 Hilton Washington DC/Rockville Rockville, Maryland

Meeting Roster

PERIPHERAL AND CENTRAL NERVOUS SYSTEM (PCNS) DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Larry B. Goldstein, M.D. (Acting Chair)

Professor of Medicine Duke University Medical Center Bryan Research Building Durham, NC

Lily K.F. Jung, M.D., M.M.M.

(Consumer Representative)

Medical Director, Neurology Clinic Swedish Neuroscience Institute Medical Center, Neurology Clinic Seattle, WA

Ying Lu, Ph.D.

Professor in Residence Department of Radiology University of California, San Francisco San Francisco, CA

Matthew Rizzo, M.D.

Director, Division of Neuroergonomics Department of Neurology University of Iowa Iowa City, IA

TEMPORARY MEMBERS (Voting)

Marshall S. Balish, M.D.

Asst. Chief Neurology, Department of Neurology Washington VA Medical Center Assistant Professor of Neurology Georgetown University Washington, DC

Richard L. Gorman, M.D.

Clinical Associate Professor of Pediatrics University of Maryland School of Medicine Baltimore, MD

Harry T. Chugani, M.D.

Professor, Departments of Pediatrics, Neurology and Radiology Director, Positron Emission Tomography Center Director, Pediatric Epilepsy Surgery Program Chief, Division of Pediatric Neurology Children's Hospital of Michigan Wayne State University Detroit, MI

Richard R. Heckert, M.D.

Pediatric Ophthalmologist Green Bay Eye Clinic, Ltd. Green Bay, WI

Stephanie Y. Crawford, Ph.D., M.P.H.

Associate Professor and Associate Head Department of Pharmacy Administration College of Pharmacy, University of Illinois Chicago, IL

Deborah G. Hirtz, M.D.

Pediatric Neurologist Program Director, National Institute of Neurological Disorders and Stroke National Institutes of Health Bethesda, MD

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Jacqueline S. Gardner, Ph.D.

Professor University of Washington Seattle, WA

Frances E. Jensen, M.D.

Professor of Neurology, Harvard Medical School Director of Epilepsy Research Department of Neurology, Children's Hospital Boston, MA

Karl D. Kieburtz, M.D. (January 8 Only)

Professor of Neurology and Community and Preventive Medicine Department of Neurology University of Rochester Rochester, NY

Eli Mizrahi, M.D.

Chairman, Department of Neurology Professor of Neurology and Pediatrics Baylor College of Medicine Houston, TX

Lewis S. Nelson, M.D.

Associate Professor Department of Emergency Medicine Director, Medical Toxicology Fellowship Training Program, New York University New York, NY

Michael X. Repka, M.D. (January 8 Only)

Professor of Ophthalmology and Pediatrics The Wilmer Eye Institute The Johns Hopkins Hospital Baltimore, MD

Michael A. Rogawski, M.D., Ph.D.

(January 7 Only)
Professor (tenured) and Chair,
Department of Neurology
University of California, Davis
Sacramento, CA

Wayne R. Snodgrass, M.D., Ph.D.

Professor, Pediatrics and Pharmacology-Toxicology Head, Clinical Pharmacology-Toxicology Unit Medical Director, Texas Poison Center University of Texas Medical Branch Galveston, TX

Gerald van Belle, Ph.D.

Professor, Department of Biostatistics
Professor, Department of Environmental and
Occupational Health Sciences
School of Public Health and Community
Medicine, University of Washington
Seattle, WA

Marielos L. Vega, B.S.N., R.N.

Research Nurse Department of Family Medicine, University of Medicine and Dentistry of New Jersey New Jersey Medical School Newark, NJ

Steven L. Weinstein, M.D.

Director, Pediatric Epilepsy Program New York Presbyterian Hospital Weill Cornell Medical Center New York, NY

Constance E. West, M.D.

Director, Division of Pediatric Ophthalmology and the Abrahamson Pediatric Eye Institute Cincinnati Children's Hospital Medical Center Cincinnati, OH

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PERIPHERAL AND CENTRAL NERVOUS SYSTEM (PCNS) DRUGS ADVISORY COMMITTEE MEMBER (Non-Voting)

Roy E. Twyman, M.D. (Industry Representative)

Vice President, CNS Franchise Development Johnson & Johnson Pharmaceutical Research And Development, LLC Titusville, NJ

PERIPHERAL AND CENTRAL NERVOUS SYSTEM (PCNS) DRUGS ADVISORY COMMITTEE TEMPORARY MEMBER (Non-Voting)

Michael C. Bartenhagen (Patient Representative)

Gretna, NE

DRUG SAFETY AND RISK MANAGEMENT (DSaRM) ADVISORY COMMITTEE MEMBER (Voting)

Judith M. Kramer, M.D., M.S. Timothy S. Lesar, Pharm.D.

Associate Professor of Medicine

Director of Pharmacy

Division of General Internal Medicine and Clinical

Pharmacology, Duke University Medical Center

Director of Pharmacy

Albany Medical Center

Albany, NY

Durham, NC

PEDIATRIC ADVISORY COMMITTEE MEMBER (Voting)

Leon Dure, M.D.

Director and Professor of Pediatric Neurology University of Alabama School of Medicine Birmingham, AL

RISK COMMUNICATION ADVISORY COMMITTEE (RCAC) MEMBER (Voting)

Betsy L. Sleath, Ph.D.

Professor of Pharmaceutical Outcomes and Policy University of North Carolina School of Pharmacy Chapel Hill, NC

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FDA PARTICIPANTS (Non-Voting)

Robert Temple, M.D.

Director, Office of Drug Evaluation I (ODE-1) Office of New Drugs (OND), CDER, FDA

Russell G. Katz, M.D.

Division Director Division of Neurology Products ODE-1, OND, CDER, FDA

Wiley Chambers, M.D.

Acting Director, Division of Anti-Infective and Ophthalmology Products, Office of Antimicrobial Products, OND, CDER, FDA

Norman Hershkowitz, M.D. (*January 7 Only*) Acting Team Leader, ODE-1, OND, CDER,

FDA

Philip Sheridan, M.D. (January 8 Only)

Clinical Reviewer, ODE-1, OND, CDER, FDA

Ronald Farkas, M.D., Ph.D.

Clinical Reviewer, ODE-1, OND, CDER, FDA