

Agenda: Tuesday, March 13, 2001

Peripheral and Central Nervous System Drugs Advisory Committee

**Food and Drug Administration
Holiday Inn, Gaithersburg, Maryland**

8:00 Call to Order, Introductions
Claudia Kawas, M.D., Chair, PCNS

Conflict of Interest Statement
Sandra Titus, Ph.D., Executive Secretary, PCNS

Presentations & Discussion on Mild Cognitive Impairment (MCI) and Drug Development Issues:

1. Can MCI be clearly defined in a clinical setting?
2. Are there valid criteria for the diagnosis of MCI?
3. Can MCI be distinguished from Alzheimer's Disease and other causes of dementia?
4. What outcome measures are appropriate to use in clinical drug trails conducted in MCI?
5. Should clinical drug trials in MCI incorporate any special features in their design?

8:15 Welcome and FDA Overview of Issues
Russel Katz, M.D., Director, Neuropharmacological Drug Products

8:30 Steven Dekosky, M.D., Director, Alzheimer's Disease Research Center, University of Pittsburgh

8:50 Ranjan Duara, M.D., Wien Center for Alzheimer's Disease, Mount Sinai Medical Center, Miami Beach Florida
Factors that modify conversion rates of MCI to Dementia in a clinic-based and a community-based study.

9:10 Steven Ferris, Ph.D., Silberstein Aging and Dementia Research Ctr., NYU
Mild Cognitive Impairment as a Target for Drug Development

9:30 Ronald Petersen, M.D., Department of Neurology, Mayo
Thorny Issues in the MCI Field

10:00 Break

10:30 Mary Ganguli, M.D., Professor of Psychiatry and Epidemiology, University of Pittsburgh
Mild Cognitive Impairment: a View from the Trenches."

10:50 Michael Grundman, M.D., Alzheimer's Disease Cooperative Study, University of California, San Diego
Clinical Trial Designs for MCI

Public Speakers:

11:10 Ruth O'Hara, Ph.D., Assistant Professor, Department of Psychiatry, Stanford University
Model for Estimating MCI Prevalence & Assessment of Cognitive Decline in Older Adults

11:30 Tony Waegeman, M.D., UCB Pharma
MCI is a clinical entity: Overview of Design Issues

11:50 Barry Reisberg, M.D., Representing International Psychogeriatric Association (IPA),

12:15 Lunch

1:30 Continued Committee Discussion and Deliberation