

# Peripheral and Central Nervous System Drugs Advisory Committee

**March 13, 2001**  
**Mild Cognitive Impairment**

The meeting was held at the Holiday Inn, in Gaithersburg, Maryland. Prior to the meeting, the members, consultants and guests had reviewed background material from the FDA. In order for the public to be informed, the background material was also available on the Dockets page before the meeting. There were approximately 250 persons in attendance. The meeting started at 8 a.m. and ended at 5:00 p.m.

## **Attendance:**

**PCNS and Consultants Present:** Claudia Kawas, M.D., Acting Chair ,  
Gerald Van Belle, Ph.D., LeRoy Penix , M.D., Howard Weiner, M.D., Michael Grundman, M.D.,  
Jerry Wolinsky, M.D.

**PCNS Members Absent:** Richard Penn, M.D., Ella Lacey, Ph.D.,

**PCNS Guest Experts:** Steven DeKosky, M.D., Steven Ferris, M.D., Ronald Petersen, M.D.,  
Mary Ganguli, M.D., Philip Gorelick, M.D., Ranjan Duara, M.D.

**FDA Participants:** Robert Temple, M.D., Russell Katz, M.D, Ranjit Mani, M.D.

## **Overview of FDA's Presentation:**

Russell Katz, M.D., gave an overview of the FDA questions for the meeting.

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 trials conducted in vascular dementia?
5. Should clinical drug trials in MCI incorporate any special features in their design?

## **The Following speakers presented their viewpoints:**

**Ronald Petersen, M.D., Department of Neurology, Mayo**  
Mild Cognitive Impairment: Unresolved Issues

**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.

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

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

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

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

**Public Speakers:**

**Barry Reisberg, M.D., Representing International Psychogeriatric Association (IPA)**

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

**Yogesh Shah, M.D., Mayo**

**The committee did not vote on the questions. The committee and guests discussed the issues and their views are recorded in the transcript. A verbatim transcript of this meeting will be available on the FDA's Dockets Management Branch Website approximately 30 days after the meeting. The address is [HTTP://www.fda.gov/ohrms/dockets/ac/acmenu.htm](http://www.fda.gov/ohrms/dockets/ac/acmenu.htm).**

I certify that I attended the March 13, 2001 meeting of the Peripheral and Central Nervous System Drugs Advisory Committee and that these minutes accurately reflect what transpired.

  
Sandra Titus, Ph.D.      Date  
Executive Secretary, PCNS

  
Claudia Kawas, M.D.      Date  
Acting Chair, PCNS

Prepared on March 13, 2001  
Sandra Titus