

Minutes: March 9, 2000

Psychopharmacological Drugs Advisory Committee

Issue: Development of Drugs for Psychiatric Disturbances Associated with Alzheimer's Disease and other Dementias

The meeting was held at the Holiday Inn in Gaithersburg Maryland. Prior to the meeting, the members and consultants had reviewed background material from the FDA which included a position paper written by the FDA and the first 10 responses posted on the Dockets (00N-008). There were approximately 200 persons in attendance.

Attendance:

PDAC Members Present: Carol Tamminga, M.D., Roberto Dominguez, M.D., Andrew Winokur, M.D., Ph.D., Robert Hamer, Ph.D., Gaurdia Banister, Ph.D

PDAC Members Absent: Abby Fyer, M.D., Barbara Geller, M.D, Edwin Cook, M.D.,

PDAC Consultants: Peter Whitehouse, M.D., Ph.D., Barry Lebowitz, M.D., Dilip Jeste, M.D., Pierre Tariout, M.D., Barry Reisburg, M.D., Lon Schneider, M.D., Jeff Cummings, M.D., Jiska Cohen-Mansfield, Ph.D., Eric Caine, M.D., Michael Grundman, M.D.,

FDA Participants: Russell Katz, M.D, Thomas Laughren, M.D.,

Overview of FDA's Presentation:

Thomas Laughren, gave an overview of the FDA issues.

Overview of Invited Speakers:

Dilip Jeste gave a presentation on "Psychosis of Alzheimer Disease: A Distinct Syndrome."

Pierre Tariot discussed "The Concept of Secondary Mania in Dementia."

Jiska Cohen-Mansfield presented "The Conceptualization of behavioral and psychological symptoms associated with dementia: Issues related to the development of pharmacological interventions."

Eric Caine discussed the current issues in DSM labeling in a talk on "Classifying the Manifestations of Alzheimer's Disease in DSM-IV-TR."

Jeffrey Cummings explored the "Criteria of Psychiatric Symptoms in Alzheimer's Disease in Clinical Trials."

Barry Reisberg described "Depression Associated with Alzheimer's Disease and Psychosis."

Extended Public Hearing Presentations:

There were eight presentations made during the open public hearing. Two sponsors, Janssen and Lilly discussed data from their data bases. Many organizations had a representative give a presentation: American Psychiatric Association, American Association

of Geriatric Psychiatry and the International Psychogeriatric Association. And several universities had a presenter: Johns Hopkins Medical Institutions, University of Pittsburgh and Columbia.

Committee Discussion:


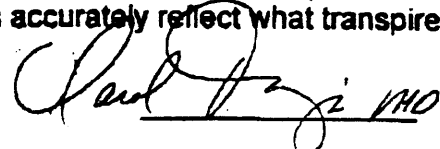

The transcript will provide the reader with a rich perspective. The following should only be viewed as a very truncated view of what was discussed.

There was consensus among committee members that

1. Alzheimer's patients do have psychosis and over the course of the illness virtually all patients develop some behavioral manifestations.
2. Psychosis observed in Alzheimer's is different than psychosis observed in schizophrenia. Further some members pointed out that it might indeed be the wrong approach to assume that a drug that works in schizophrenia will work in this population.
3. Drug development in this area should be held to a higher standard than in other areas. Specifically outcome measures should reflect not only the reduction of behavioral problems but also functional outcomes (for example ADLs).
4. Agitation in addition to psychosis needs to be studied but there was less consensus on how to do this. Participants did emphasize that we were using drugs now for agitation but that we had very little understanding regarding agitation. They urged that research on agitation needed to be studied.
5. Safety issues are difficult to resolve because the age of the population means some mortality would be expected. There was less consensus on how to study safety but many suggestions were made.

A verbatim transcript of this meeting will be available on the FDA's Dockets Management Branch Website approximately 2 weeks 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 9, 2000 meeting of the Psychopharmacologic Drugs Advisory Committee and that these minutes accurately reflect what transpired.

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

Carol Tamminga, M.D. Date
Chair, PDAC

Prepared on March 13, 2000
Sandra Titus, Ph.D.