



STATEMENT OF THE  
MEDICAL AND SCIENTIFIC ADVISORY COUNCIL  
of the  
ALZHEIMER'S ASSOCIATION  
submitted to the  
PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE,  
FOOD AND DRUG ADMINISTRATION  
March 9, 2000

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The Alzheimer's Association is the national voluntary health organization dedicated to research to discover the causes, treatments, and methods of prevention of Alzheimer's disease and related dementias; to support for people who have the disease, their families and caregivers; and to advocacy for affordable quality health and long term care. The Medical and Scientific Advisory Council (MSAC), the scientific arm of the Association, submits this comment on behalf of the entire Alzheimer's Association.

The Association commends the Food and Drug Administration for addressing the issue of the appropriate use of psychopharmacologic drugs for the treatment of psychiatric and behavioral disturbances that are frequently associated with Alzheimer's disease and other dementias. We applaud the efforts of the FDA to establish an evidenced-based approach to the approval and labeling of drugs to treat these disturbances.

The behavioral symptoms of Alzheimer's disease -- such as psychosis, agitation and depression -- are commonly seen during the course of the disease. And they are often the most challenging part of caring for a person with the disease. This is true for family

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caregivers; it is equally so for formal care providers in community and residential care settings. Management of these disturbances, through behavioral interventions and when necessary with the appropriate use of pharmaceuticals, directly impacts the health and well being of the person with the disease and the caregiver.

Thus, the work that the Advisory Committee is undertaking is critical, not just to assure appropriate testing and labeling of pharmaceuticals that a clinician may use or a family may seek for treatment, but to underscore for clinicians and payers alike that treatment of these psychiatric and behavioral disturbances is an essential part of the management, treatment and care of people with Alzheimer's disease and related dementias.

The Medical and Scientific Advisory Council calls the Committee's attention to the fine work done by Drs. Whitehouse, Cummings and Homa in their statement from the International Working Group on the Harmonization of International Drug Trials. We are essentially in agreement with that statement and encourage the Advisory Committee to include this perspective in developing its recommendations to the FDA.

The Alzheimer's Association is available to provide any appropriate assistance to the Committee as it carries out its very important mission. The contact person for the MSAC is Dr. William Thies, Vice President for Medical and Scientific Affairs, at 312/335-5795; e-mail: [Bill.Thies@alz.org](mailto:Bill.Thies@alz.org).

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