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University of Pittsburgh
Medical Center

Western Psychiatric Institute and Clinic

3811 O'Hara Street
Pittsburgh, PA 15213-2593

February 16, 2000

Sandra Titus, Ph.D.
Food and Drug Administration,
Center for Drug Evaluation and Research (HFD-21)
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Titus:

RE: Docket Number 00N-0088

This letter is in response to the Food and Drug Administration (FDA) Position Paper for the March 9, 2000 Meeting "Treating Psychiatric Disturbances Associated with Dementias". I would like to take this opportunity to request a 10-minute oral presentation to the Committee during which time I will address the cognitive aspects of dementing disorders with specific reference to the more advanced or severe stages of dementia.

As the FDA indicates in their Position Paper the term dementia is a broad term which refers to multiple clinical entities. However, because of the progressive nature of most dementing disorders the term not only refers to multiple clinical disorders but also to multiple levels or stages of dementia through which the cognitive, behavioral and psychiatric symptoms of dementia evolve over months and years presenting a constantly changing clinical picture. While the behavioral and psychological symptoms of dementia may vary with the stage of disease and may be targets for pharmacological treatment, it is the progressive memory and cognitive decline that is the hallmark of dementia. This too has been identified as a target for pharmacotherapy. However, researchers investigating the cognitive changes in dementia have typically focused on the early to middle stages adopting the view that more severely impaired patients are too impaired to cooperate with testing. Nevertheless, it has become clear that more severely demented patients can, and do, show a range of functioning in fundamental cognitive abilities and, indeed, can be tested using appropriate measures (Saxton et al., 1990; Panisset et al., 1994; Schmitt et al., 1996; Schmitt et al., 1997).

As pharmacological treatments become available, particularly those which "slow-the-progression" of the dementia greater numbers of patients will spend longer periods of time within that stage generally referred to as moderate-to-severe dementia. Furthermore, clinicians will use these medications in more advanced cases of dementia making these individuals potential candidates for treatment.

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It is imperative that when developing standardized criteria the FDA not only identify the specific clinical entities, such as disease state, but also level or stage of dementia. By doing this the FDA will encourage researchers to include individuals with advanced dementia in their research and consider potential differences in the effects of treatment depending on level of dementia. As discussed above the advent of pharmacological treatments could result in a significant increase in the number of individuals within this group, which has to a large extent been ignored by the research community. Developing specific criteria will enable researchers to address important clinical questions regarding the efficacy of treatments in more demented patients and, thus the cost effectiveness of providing such treatments.

My name, address and phone number are listed below I will be the only participant.

Sincerely,

Judith Saxton, Ph.D.
Associate Professor of Psychiatry

Judith Saxton, Ph.D.
Western Psychiatric Institute & Clinic
3811 O'Hara Street, Room 1098
Pittsburgh, PA 15213
(412) 624-3616
email: saxtonja@msx.upmc.edu

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