April 9, 2013

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

[Docket No. FDA–2013–D–0077]
Draft Guidance for Industry on Alzheimer's Disease: Developing Drugs for the Treatment of Early Stage Disease; Availability

VIA ELECTRONIC SUBMISSION

Leaders Engaged on Alzheimer's Disease (LEAD) is a diverse and growing coalition of 57 member organizations including patient advocacy and voluntary health non-profits, philanthropies and foundations, trade and professional associations, academic research and clinical institutions, and biotechnology and pharmaceutical companies. LEAD works collaboratively to focus the nation's strategic attention on Alzheimer's disease and related disorders and to accelerate transformational progress in care and support, detection and diagnosis, and research leading to prevention, effective treatment and eventual cure.

LEAD supports adoption of FDA's "Draft Guidance for Industry on Alzheimer's Disease: Developing Drugs for the Treatment of Early Stage Disease."

LEAD joins the Food and Drug Administration (FDA) in recognizing the urgency of moving diagnosis and intervention earlier in the Alzheimer's disease process. This is necessary in terms of efficacy for better symptomatic treatments, disease-modifying interventions and social interventions aimed at reducing stigma, facilitating planning (care, financial, and legal), and enabling people with the disease to become self-advocates prior to, or at the earliest possible stages of, symptomatic onset.

LEAD applauds FDA for accepting very sensitive cognitive measures as primary

endpoints for certain subsets of people with early signs of Alzheimer's disease without requiring demonstration of functional measures prior to overt dementia symptoms. As FDA is aware, researchers supported by the National Institutes of Health (NIH) and industry are moving forward aggressively to expand the study of people at the earliest stages of the disease; as the science moves in this direction, so must the regulatory framework.

It is no secret that the current drug development process is too long, too slow and too uncertain. FDA's proposed guidance begins to correct these burdens while scrupulously maintaining strict safety requirements for patients and rigorous efficacy standards for treatments.

LEAD concurs with the comment being submitted by the Alzheimer's Disease Neuroimaging Initiative (ADNI) citing the consensus view that measurements of brain amyloid and measurement of cerebrospinal fluid (CSF) tau/phospho-tau are biomarkers that reflect the neurobiology of Alzheimer's disease and whose changes indicate disease modification in treatment trials. LEAD recommends that FDA provide additional clarity about the evidence it would require to accept the use of a biomarker as a surrogate endpoint for Alzheimer's disease.

Thank you for the opportunity to offer comment and for FDA's thoughtful approach to these guidelines. We share your hope that focusing drug development at the earliest stages of Alzheimer's disease will accelerate meaningful progress toward effective treatments.

Should you have questions or require additional information, please contact Ian Kremer, LEAD's executive director, at ikremer@leadcoalition.org or (571) 383-9916. We look forward to working with you on this important effort.

Sincerely,

Abe's Garden

Academy of Radiology Research

Aging and Memory Disorder Programs, Howard University

Alliance for Aging Research

Alzheimers North Carolina

Alzheimer's & Dementia Alliance of Wisconsin

Alzheimer's Drug Discovery Foundation

Alzheimer's Tennessee

American Association for Geriatric Psychiatry

American Association for Long Term Care Nursing

Assisted Living Federation of America

Beating Alzheimer's by Embracing Science

Biotechnology Industry Organization (BIO)

BrightFocus Alzheimer's Disease Research

Caregiver Action Network

Center for Alzheimer Research and Treatment, Harvard Medical School

Cleveland Clinic Foundation

Coalition for Imaging and Bioengineering Research

Cognition Therapeutics

Cortica Neurosciences, Inc.

Cure Alzheimer's Fund

Rachelle S. Doody, MD, PhD (Baylor College of Medicine*)

Eli Lilly & Company

Georgetown University Medical Center Memory Disorders Program

Global Coalition on Aging

Inspire

Iona Senior Services

Janssen Alzheimer's Immunotherapy

Keep Memory Alive

Latino Alzheimer's and Memory Disorders Alliance

Linked Senior, Inc.

Kostas Lyketsos, MD (Johns Hopkins Medicine*)

Merck

Memory Enhancement Center of America, Inc.

National Alliance for Caregiving

National Association of States United for Aging and Disabilities

National Down Syndrome Society

Neurotechnology Industry Organization

New York Academy of Sciences

Prevent Alzheimer's Disease 2020

RemeGenix, Inc.

Smith & Harroff, Inc.

USAgainstAlzheimer's

USF Health Byrd Alzheimer's Institute

Volunteers of America

Vradenburg Foundation

Michael W. Weiner, MD (University of California San Francisco*)

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