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

RE: Docket FDA-2013-D-0077-0042

COMMENTS ON EARLY ALZHEIMER'S DISEASE: DEVELOPING DRUGS FOR TREATMENT GUIDANCE FOR INDUSTRY

In April 2017, the Global Coalition on Aging (GCOA) and Alzheimer's Disease International (ADI) published the first-ever Dementia Innovation Readiness Index. The Index examined key barriers that slow the development of treatments for dementias and identified opportunities and innovations that would promote the removal of those barriers among the G7 countries. One of the major barriers to treatment identified in the Index is the lack of clear, finalized regulatory guidance that is the foundation to the development and distribution of new treatment options. GCOA believes that the FDA's new draft guidance effectively addresses this barrier (given the limits of current scientific understanding) and we commend the FDA for this work.

FDA's new draft guidance is a critical step forward to spur pharmaceutical innovation in Alzheimer's disease

Providing clarity on endpoints for Alzheimer's disease has potential to incentivize investment and innovation, improve the environment for drug development globally, and ultimately lead to breakthrough treatments that improve quality of life for those who so desperately need it. We encourage the FDA to make similar changes to guidance surrounding other forms of dementia, including vascular dementia, FTD and Dementia with Lewy bodies, as well as guidance for mixed dementia. Additionally, the FDA can give further clarity regarding evidence for the use of a biomarker as a surrogate endpoint for Alzheimer's disease.

We also urge the consideration of common diagnostic criteria that would be satisfactory for enrollment in clinical trials and recommendations of assessment tools that would measure the subtle cognitive changes referenced in the guidance.

Finally, we advise that the FDA support more aggressive and earlier detection and diagnosis of dementia to better support and include people with dementia in clinical trials. As new treatments are developed – particularly treatments that target people with early to moderate dementia – action for earlier detection and diagnosis is critical to ensure adequate participation in trials. More effective inclusion of people with dementia in clinical trials will help accelerate the review of innovative treatments by regulators by supporting the development of relevant data.

GCOA supports the FDA's draft guidance and calls for finalized federal guidance to bring clarity to the endpoints issue in Alzheimer's disease

The FDA has demonstrated global leadership and commitment to supporting the discovery of disease-modifying treatments for Alzheimer's disease with updated draft guidance. Regulators can facilitate a clearer path to success for researchers, promote stability in the field, and incentivize investment in innovative models of research and development to create new treatments for Alzheimer's disease. By promoting focus and investment, clarified guidance will help ensure ongoing pipeline opportunities and drive effective treatments into regulators' hands, and, ultimately, to the people who need them most. We hope the FDA will lead the global regulatory environment in reflecting the latest scientific understanding of the diseases that cause dementia.

About the Global Coalition on Aging

The Global Coalition on Aging aims to reshape how global leaders approach and prepare for the 21st century's profound shift in population aging. GCOA uniquely brings together leading global corporations across industry sectors with common strategic interests in aging populations, a comprehensive and systemic understanding of aging, and an optimistic view of its impact. Through research, public policy analysis, advocacy and communication, GCOA shapes the dialogue and advances solutions to ensure aging is a path for nations' economic growth and winning business strategies.