February 8, 2012

Advisory Council on Research, Care and Services
C/O Helen Lamont, Ph.D.
Department of Health and Human Services
Office of the Assistant Secretary for Planning and Evaluation
Room 424E, Humphrey Building
200 Independence Avenue, SW
Washington DC, 20201

Dear Members of the Advisory Council on Research, Care and Services:

Leaders Engaged on Alzheimer's Disease (LEAD) commends the Advisory Council for developing goals and strategies that address the most pressing issues facing people with Alzheimer's disease and their families within the Draft Framework for the National Plan to Address Alzheimer's Disease. Also significant is the Advisory Council's action to set a timely objective for the development of effective prevention and treatment modalities in the Framework. Enclosed please find comments on the Framework developed by LEAD around research, clinical care, long-term care support and services, and drug discovery and development. We hope that the Advisory Council will consider these comments and recommendations as it advises on a national strategic plan for Alzheimer's disease.

The comments and recommendations provided in this document seek to strengthen the goals and supporting strategies within the Framework. However, it is important to note that these goals can be achieved only with a significant increase in investment from the public, private and non-profit sectors and by establishing quantified metrics to track progress. LEAD strongly urges that the Advisory Council advocate for adequate resources to be allocated to each of the outlined goals and strategies included in the final national plan. Furthermore, each goal and strategy outlined in the final national plan should include a targeted budget with assigned milestones and metrics to achieving the desired outcome.

Should you have questions or require additional information about this document, please contact Sally Sachar, Chief Operating Officer of USAgainstAlzheimer's at (202) 360-2043, ssachar@usagainstalzheimers.org, or Eric Sokol, Vice President of Public Policy at the Alzheimer's Foundation of America, at (202) 466-0590, esokol@alzfdn.org. We look forward to working with you on this important effort.

Respectfully,

George Vradenburg
Chair & Co-Founder
USAgainstAlzheimer's

Eric J. Hall
Founding President & Chief Executive Officer
Alzheimer's Foundation of America

LEAD Participating Organizations

AHAF Alzheimer's Disease Research
Alliance for Aging Research
Alzheimer's Drug Discovery Foundation
Alzheimer's Foundation of America
Alzheimer's Research and Prevention Foundation
American Academy of Neurology
American Association for Geriatric Psychiatry
American Geriatrics Society
American Life Science Pharmaceuticals, Inc.
Banner Alzheimer's Institute
Baylor College of Medicine
Critical Path Institute
Cure Alzheimer's Fund
Direct Care Alliance
Eisai Co., Ltd.
Elan
Eli Lilly & Company
Geoffrey Beene Foundation
Inspire
Janssen Alzheimer Immunotherapy Research & Development, LLC
Johnson & Johnson
Mayo Clinic
Memory Enhancement Centers of America, Inc.
National Alliance for Caregiving
National Association of States United for Aging and Disabilities
National Association of Area Agencies on Aging
National Association of States United for Aging and Disabilities
National Council on Aging
National Family Caregivers Association
Parkinson's Action Network
Pfizer Inc.
Project Lifesaver
The Gerontological Society of America
University of Washington
USAgainstAlzheimer's
Visiting Nurse Associations of America
Volunteers of America

In developing these comments LEAD established four workgroups -- one each in the areas of research, clinical care, long-term care support and services, and drug discovery and development -- representative of the sentiment and unique needs of the Alzheimer's community. Participation in LEAD or in the development of these comments does not constitute an endorsement of each of the recommendations within this document by any particular organization.

Goal 1: Prevent and Effectively Treat Alzheimer's Disease by 2025

LEAD is pleased that the Advisory Council has set an aggressive goal to develop effective prevention and treatment modalities for Alzheimer's disease by 2025. The lack of tools such as biomarkers and an understanding of the biological basis of Alzheimer's disease currently impede the ability to appropriately address the needs of people with Alzheimer's disease and their families. The strategies outlined in the Framework have the potential for accelerating the therapeutic pipeline and rapidly translating basic science into new therapies for people with Alzheimer's disease. Below please find LEAD's recommendations for Goal 1:

1.A: Identify Research Priorities and Milestones

With limited resources, private and public funders of Alzheimer's research must develop methods to coordinate research funding to assure that resources are spent strategically on the most promising areas and that investments are outcome-oriented and accountable. LEAD is pleased that the Advisory Council will consider input from the upcoming May 2012 National Institute on Aging Conference, which will seek to identify strategies and milestones to slow progression, delay onset and prevent Alzheimer's disease. Specifically, LEAD recommends the following:

- Development of methods to more efficiently and expeditiously determine diagnosis, prognosis and response to therapies using appropriate biomarkers and genetic markers.
- Development of methodologies and tools needed to quantify the outcomes of interventional approaches that are more sensitive—but relevant—indicators of therapeutic effectiveness. While such research should include biomarkers and genetic markers, the primary focus should be related to the identification of more relevant clinical endpoints that may ultimately be used to demonstrate the effectiveness of novel therapeutic approaches. It is essential that such research be closely aligned with the Food and Drug Administration (FDA) so that any progress in the field can be rapidly adopted by regulators, thereby expediting regulatory review and patient access to successful therapeutics.
- Development of better methods to study individuals who are non-symptomatic or have mild cognitive impairments to effect better prediction of risk factors, primary and secondary prevention, and effective delay in progression.

1.B: Enhance Scientific Research Aimed at Preventing and Treating Alzheimer's Disease

To enhance research and drug development aimed at preventing and treating Alzheimer's disease, the Advisory Council should advocate for the use of large-scale patient registries to facilitate faster and less expensive clinical trial recruitment. To assist this effort, public and private sectors should work together to address the unique circumstances of individuals with Alzheimer's disease and their ability to provide informed consent for clinical trial participation. Currently, patients sign an informed consent form for a specific study and narrow purpose, rendering the data useless as other ideas become promising. As a result, data is essentially lost and new studies have to be conducted resulting in additional expense, delays and more patients subjected to experimental trials. LEAD recommends a mechanism be developed to let patients opt into having their de-identified data used for broader research purposes that advance understanding, treatment and prevention of Alzheimer's disease.

The National Plan should also encourage all new and ongoing federally-funded and industry-sponsored Alzheimer's disease clinical trials to use the same Alzheimer's disease data standards developed by the Clinical Data Interchange Standards Consortium (CDISC) which will facilitate data sharing and review by the FDA. In addition, Alzheimer's disease clinical trials data rich in biomarker information should be remapped to the same common Alzheimer's Disease CDISC data standards and any federally-funded and industry-sponsored Alzheimer's disease clinical trials data recorded should be shared in a common Alzheimer's disease database for qualified research use.

While Alzheimer's disease researchers have identified promising candidate biomarkers, providing the level of evidence needed for qualification by the FDA requires additional data and rigorous analysis. Such efforts are beyond the scope and resources of companies or academic researchers and are best carried out through existing public-private partnerships such as the Coalition Against Major Diseases (CAMD) and the Alzheimer's Disease Neuroimaging Initiative (ADNI). Also, the lack of standardization for imaging modalities and assays of CSF analytes can delay the FDA from qualifying a biomarker

for use in Alzheimer's disease clinical trials. Standardization of analytic methods together with establishing a resource of appropriate reference samples and reference standards, therefore, should be part of any national Alzheimer's research strategy.

Finally, quantitative clinical disease progression models should be developed to inform the design of Alzheimer's disease clinical trials in the evaluation of new medicines. These models would offer a tool to differentiate between symptomatic and disease-modifying drug effects, as well as help determine the optimal sample sizes and sampling times. A disease model will also help to identify subpopulations with unique characteristics for trials, and assess the impact of baseline disease severity on drug response.

1.C: Accelerate Efforts to Identify Early and Presymptomatic Stages of Alzheimer's Disease

The Advisory Council should consider the term "presymptomatic Alzheimer's disease treatment" to refer to those interventions that are initiated before apparent cognitive decline and are intended to reduce the chance of developing Alzheimer's disease-related symptoms. This will accelerate efforts to identify early and presymptomatic stages of Alzheimer's disease, address uncertainties surrounding the term "prevention" and be more acceptable to regulatory agencies conducting reviews of clinical trials. In addition, a cognitive assessment tool should be developed that can be used to assess therapies at earlier stages of Alzheimer's disease.

To further support a strategy to identify early and presymptomatic stages of Alzheimer's disease, government, industry and patient advocacy organizations should work together to develop a patient registry of subjects that can be used for prevention trials. Trials focused on identifying early stages of Alzheimer's disease should be based on accepted quantitative clinical trial models designed for studies in early Alzheimer's disease. Finally, biomarkers should be identified for tracking earlier cognitive decline by developing consensus on the scientific evidence.

1.D: Coordinate Research with International Public and Private Entities

LEAD recommends the establishment of a central Alzheimer's disease research coordinating entity within the National Institutes of Health (NIH). This entity should maintain the authority and ability to convene inter-agency and non-government constituencies, domestically and internationally. We propose that the entity gather and distribute data, and make recommendations to the HHS Secretary for federal policy regarding funding strategies for stopping Alzheimer's disease.

In addition, an international action plan against Alzheimer's disease should be developed by nations with national Alzheimer's disease plans in place or in progress. Developing a plan is an important first step to coordinate efforts against this global challenge. The global plan should include efforts to standardize biomarkers and surrogate end-points, coordinate surveillance and enhance regulatory cooperation. Any global effort should also include funds for research, strategies for cost containment efforts and goals to improve the delivery of clinical care and long term services.

Goal 2: Enhance Care Quality and Efficiency

LEAD is pleased that the draft Framework includes the goal to enhance care quality and efficiency. A national plan for Alzheimer's disease should focus on developing and continuously improving the care of our citizens in home or community settings by offering the best risk management, prevention strategies, early detection, precise diagnosis and long-term management available. The strategies outlined for Goal 2 in the Framework will provide a platform for ensuring that all Americans that require care for Alzheimer's disease are able to access quality care across various care settings. Below are additional strategies that could, if implemented, improve care quality and efficiency for people with Alzheimer's disease:

2.D: Identify and Implement High-Quality Dementia Care Guidelines and Measures Across Care Settings

To achieve quality care and a safe transition for people with Alzheimer's disease between care settings, it is imperative that healthcare professionals are more adequately reimbursed for services such as comprehensive, longitudinal evaluation and management services, acute and chronic psychiatric management, evaluation of cognitive function (including psychometrics) and caregiver education and counseling.

2.E: Ensure that People with Alzheimer's Disease Experience Safe and Effective Transitions Between Care Settings and Systems

Improved emergency department and inpatient hospital care can be achieved by enhanced recognition of Alzheimer's disease in acute care settings. A key element to achieving this objective is providing information and training for physicians, nurses, nursing aides and other staff to help manage patient care. This should include psychiatric care for patients with escalating levels of depression, agitation or psychosis, and hospital care for acute agitation or psychosis in both public and private hospital settings. In addition, psychosocial support services must be available to families that allow for the continued home-care of loved ones when illness or other emergency strikes the primary caregiver.

To improve coordination of care and to share information on Alzheimer's disease care and best practices, the Advisory Council should advocate for the creation of regional Memory Evaluation and Treatment Centers that leverage existing infrastructure and resources. Memory Evaluation and Treatment Centers should focus on developing, improving and disseminating best practices in clinical care for people with Alzheimer's disease and family caregivers. The Centers are necessary to ensure the translation of clinical research into practice. There should be particular focus on advances related to identification of persons with genetic mutations and persons with genetic, biological and environmental risk factors, and to the implementation of biomarker-based risk assessments. Such Centers will also serve to mobilize assessed populations for clinical trials of new prevention and disease modifying treatments.

2.F: Advance Coordinated and Integrated Health and Long-Term Care Services and Supports for Individuals Living with Alzheimer's Disease

Often, even though a physician has identified cognitive impairment, the diagnosed individual and his or her family are not told of the diagnosis. Further, once a diagnosis is made and disclosed, as few as half of diagnosed individuals and families receive counseling, support or information about next steps, which would include available home care support, long-term care, and palliative care options and qualifications. This information is important, especially for individuals in the early- stage of the disease who experience positive outcomes when physicians are involved in planning and advance care counseling.

It is especially important that people with Alzheimer's disease and their families are educated early in the disease process about palliative and hospice care. Palliative care is specialized medical care provided by a team of doctors, nurses, social workers and other specialists who work collaboratively to provide the best possible quality of life for people facing the pain, symptoms and stresses of serious illness, including Alzheimer's disease. Palliative care relieves suffering while affirming life, regards dying as a normal process, and intends neither to hasten nor postpone death. The integration of the psychological aspects of patient care offers a support system to the patient and, when in need, to help the family cope during the bereavement process.

New Strategy: Ensure People with Alzheimer's Disease and their Families Have Access to New Alzheimer's Therapies

As new biologic therapies are approved for Alzheimer's disease over the coming years, the Centers for Medicare and Medicaid Services (CMS) should consider policy safeguards ensuring Medicare beneficiaries have access to these therapies as health care reform provisions are implemented through regulation. This will be particularly important as CMS continues to improve the Accountable Care Organization (ACO) program within Medicare. Under current regulations, ACOs will be allowed to share savings with the government to the extent they can achieve savings from an historic baseline trended forward for ACO patients within Parts A and B of the Medicare program. Due to the absence of spending on biologic therapies for Alzheimer's disease in an ACO's benchmark baseline, it could cause an ACO to be "penalized" for providing the new treatment to its patients. To address this problem, LEAD recommends that CMS create a process under which stakeholders would be able to identify certain high cost or high volume, break-through treatments and request that CMS make a special adjustment to ACO baselines that would remove incentives to underuse the new treatments.

Goal 3: Expand Patient and Family Support

LEAD is pleased that the draft Framework includes goals and strategies seeking to improve quality care and expand support for people with Alzheimer's disease and their families. Specifically, we are pleased that strategies are included that would help individuals with Alzheimer's disease remain in the community by establishing infrastructure to provide resources for family caregivers and support planning for long-term care needs. It is important that the Advisory Council advocate for adequate resources to be available to support the implementation of these strategies. Below are LEAD comments on Goal 3 of the Draft Framework:

3.A: Ensure Receipt of Culturally-Sensitive Education, Training and Support Materials by all Health and Social Service Providers who Interact with People with Alzheimer's Disease and Their Families

LEAD recommends that both government and private agencies that regulate, accredit, license and certify residential care and community care providers require training for health and social service professionals caring for people with Alzheimer's disease and other dementias. Such providers should include directors of nursing, nurse supervisors, nursing assistants and respite caregivers. The settings requiring certification should include assisted living, adult day care, nursing home and home care. The training should be based on evidence-based guidelines that have been developed through a consensus processes that includes providers, family caregivers, other advocates and people with dementia.

3.B: Enable Family Caregivers to Continue to Provide Care While Maintaining Their Own Health and Well-Being

In order to meet the unique care requirements of this population, the Advisory Council must advance proven federal, state and local programs supporting both the diagnosed individual and family. While Federal programs are in place that provide many of the services required by people with Alzheimer's disease and their families at the community level, additional funds should be appropriated to implement evidence-based, non-pharmacologic interventions for people with dementia and their family members.

LEAD members are concerned with the current and proposed cuts to the Administration on Aging's Alzheimer's Disease Supportive Services Program (ADSSP). ADSSP's focus is to expand the availability of diagnostic and support services for persons with Alzheimer's disease, their families, and their caregivers, as well as to improve the responsiveness of the home and community-based care system to persons with dementia. The program focuses on serving hard-to-reach and underserved persons using proven and innovative models. In order to achieve goal 3 in the Framework funding for ADSSP should be increased rather than reduced so that evidence-based programs can continue to support the growing number of people with Alzheimer's disease and their families at the community level.

Below is a list of successful federal programs that the Advisory Council should include and expand upon under strategy 3B in the final plan:

- Older Americans Act - Reauthorization of this legislation would ensure grants to states for community planning and social services, research and development projects, and personnel training in the field of aging.
- Lifespan Respite Care Act – Reauthorization of this legislation would authorize grants to statewide respite care service providers. Grants can be used for various purposes, including training and recruiting workers and volunteers, training family caregivers and providing information about available services.
- National Family Caregivers Support Program - At a minimum, funding levels should meet the recommended levels of the President's FY12 budget ($192 million). This program provides grants to states and territories to pay for a range of programs assisting family and informal caregivers to care for loved ones at home and for as long as possible. In addition, this program should add the family caregiver assessment to the list of services for which states can use program funds.