LEAD
Leaders Engaged on Alzheimer's Disease

March 12, 2013

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

VIA ELECTRONIC DELIVERY

Dear Secretary Sebelius:

Leaders Engaged on Alzheimer's Disease (LEAD) commends you and the Advisory Council on Alzheimer's Research, Care and Services for the first National Plan to Address Alzheimer's Disease ("the Plan") and all the public and private sector stakeholders collaborating effectively to implement strategies crucial to transformative change for people with Alzheimer's disease and their families. LEAD is pleased that a number of priority recommendations previously submitted by the coalition are included in the first Plan and is optimistic that the revised Plan will be even stronger.

LEAD is a diverse and growing coalition of 56 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. Working collaboratively with LEAD member organizations and other stakeholders across the Alzheimer's-serving continuum, we offer the recommendations below for the revised National Plan to Address Alzheimer's Disease. Equally important, we are prepared to work with the Administration, Congress, and all other interested parties to achieve the shared goals articulated in the Plan.

LEAD's recommendations seek to strengthen the goals, strategies, and actions within the Plan. As noted in earlier comments, LEAD believes that some actions can be pursued at no or only low cost but that the topline goals can be achieved only with a significant increase in investment from the public, private, and non-profit sectors. It is imperative that both Plan work and outcomes are

accomplished with the utmost public transparency and that there is an effective methodology for assessing the impact that strategies within the Plan have on progress toward the timely achievement of stated goals. To that end, LEAD recommends that immediate action be taken to develop a model in 2013 that will allow HHS to assess the impact of the action steps in the Plan and identify areas for course adjustments. We, as a nation, should pursue only implementation steps that clearly are moving toward our goals. In that regard we recommend that each goal and strategy set forth in the final Plan include a budget, clear milestones and quantifiable metrics to achieving the desired outcome.

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

Sincerely,

Abe's Garden

Academy of Radiology Research

Alliance for Aging Research

Alzheimer's & Dementia Alliance of Wisconsin

Alzheimer's Drug Discovery Foundation

Alzheimer's Foundation of America

Alzheimers North Carolina

Alzheimer's Tennessee

AMDA – Dedicated to Long Term Care Medicine ™

American Academy of Neurology

American Association for Geriatric Psychiatry

American Association for Long Term Care Nursing

American Geriatrics Society

Assisted Living Federation of America

Beating Alzheimer's by Embracing Science

BrightFocus Alzheimer's Disease Research

Caregiver Action Network

Cleveland Clinic Foundation

Coalition for Imaging and Bioengineering Research

Cognition Therapeutics

Cortica Neurosciences, Inc.

Critical Path Institute – Coalition Against Major Disease

Cure Alzheimer's Fund

FasterCures

Geoffrey Beene Foundation - Alzheimer's Initiative

Georgetown University Medical Center Memory Disorders Program

Gerontological Society of America

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.

Memory Enhancement Center of America, Inc.

National Alliance for Caregiving

National Association of States United for Aging and Disabilities

National Caucus and Center on Black Aged, Inc. (NCBA)

National Down Syndrome Society

Neurotechnology Industry Organization

New York Academy of Sciences

North Carolina Neurological Society

Pat Summitt Foundation

Prevent Alzheimer's Disease 2020

Project Lifesaver International

RemeGenix, Inc.

Research!America

RetireSafe

The Association for Frontotemporal Degeneration

USAgainstAlzheimer's

USF Health Byrd Alzheimer's Institute

Volunteers of America

Vradenburg Foundation

Wooten Laboratory for Alzheimer's and Neurodegenerative Diseases Research

In developing these comments LEAD relied upon three workgroups -- one each in the areas of research and drug development, clinical care, and long-term care support and services -- representative of the sentiment and unique needs of the entire Alzheimer's-serving 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.

Summary of Recommendations

Over-arching Plan Recommendations

- New Recommendation 1: *Adopt all 2013 recommendations from the Advisory Council*

- New Recommendation 2: *Until such time as the statute may expand the number of seats on the Advisory Council, invite a person with Alzheimer's disease or a related disorder to participate on each Advisory Council subcommittee as on outside expert*

- New Recommendation 3: *Create a formal mechanism for additional federal government agencies to participate in the Advisory Council process*

- New Recommendation 4: *Encourage participation in the Plan process by experts on non-dementing disorders that have a high rate of co-morbidity with Alzheimer's disease or a related disorder*

- New Recommendation 5: *Identify and define a role for individuals and family members/family caregivers in each major section of the Plan*

- New Recommendation 6: *Incorporate throughout the Plan clear and transformative time-based metrics with projected necessary funding levels*

- New Recommendation 7: *Commission an independent analysis of the investment value of Alzheimer's disease spending by the federal government*

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

- Action 1.A.1: Convene an Alzheimer's disease research summit with national and international scientists to identify priorities, milestones, and a timeline

  - *LEAD recommends that each summit provide explicit strategies and milestones to be met within defined timeframes.*

  - *LEAD recommends that each summit have a specific session to report milestones and the progress of strategies set at previous summits.*

- Action 1.B.3: Increase enrollment in clinical trials and other clinical research through community, national, and international outreach

    - *LEAD recommends that by the end of 2013 HHS begin implementing the action plan produced by its intended convening of representatives from across the federal government, state and local governments, academic medical research institutions, and the private sector to create an action plan for increasing enrollment in clinical trials, including through the building of registries.*

- Action 1.B.5: Conduct clinical trials on the most promising pharmacologic interventions

    - *LEAD recommends that strategies should build on existing industry infrastructure including combination therapies.*

    - *LEAD recommends that this Action should be expanded to include non-pharmacological interventions.*

    - *LEAD recommends that each strategy state needed resources and projected reductions in cost and time for the clinical trial process.*

- Action 1.C.1: Identify imaging and biomarkers to monitor disease progression

    - *LEAD recommends development of a large-scale, open-source patient registry of subjects that can be approached for recruitment in prevention trials, including specifically under-represented ethnic and other sub- populations.*

    Action 1.C.2: Maximize collaboration among federal agencies and with the private sector

    - *LEAD recommends that HHS and the White House Office of Science and Technology Policy (OSTP) collaboratively coordinate alignment of government, industry and academic sponsored studies to achieve consensus on defined recommendations for advancing new drug candidates.*

- Action 1.E.1: Pursue ways to compress the time between target identification and release of pharmacological treatments

    - *LEAD recommends that this Action include expanded public and*

private support for a uniform patient consent and the National Institutional Review Board for Neurodegenerative Diseases (NIRB-ND) being developed by the National Biomedical Research Ethics Council (NBREC).

- Action 1.E.2: Leverage public and private collaborations to facilitate dissemination, translation, and implementation of research findings

    - *LEAD recommends that ASPE lead an effort to coordinating the exponential growth in public-private partnerships (PPPs) to avoid duplication of effort.*

- New Recommendation 1: *Address the unique circumstances of individuals with Alzheimer's disease and their ability to provide informed consent for clinical trial participation*

- New Recommendation 2: *Implement Alzheimer's disease specific data standards to ensure a uniform approach for collection, transfer, analysis, reporting and archiving of data*

Goal 2: Enhance Care Quality and Efficiency

- Action 2.A.2: Encourage providers to pursue careers in geriatric specialties

    - *LEAD recommends that the Health Resources and Services Administration (HRSA) support training projects that provide fellowships for individuals studying to be geriatric social workers.*

- Action 2.A.6: Support state and local Alzheimer's strategies

    - LEAD recommends that HHS and the Department of Labor collaboratively develop best practices for direct-care workforce development, recruitment, and retention tailored to each provider setting in the care continuum including: home health, adult day, assisted living, skilled nursing, and hospice.

- New Recommendation 1: *Address inconsistencies across geographic areas and subspecialties, and from provider to provider*

- New Recommendation 2: *Update reimbursement formulas to encourage brain health risk management, early diagnosis of memory disorders,*

persistent and multi-disciplinary treatment, and uniform levels of treatment across care settings

- New Recommendation 3: *Address inadequate emergency and acute hospital care for people with memory disorders, especially those with dementia*

- New Recommendation 4: *Establish a network of geographically dispersed and accessible memory disorders centers, linked to sites providing integrated research and patient care, to facilitate translational medicine, and to continuously develop and improve the standard of care*

Goal 3: Expand Supports for People with Alzheimer's Disease and Their Families

- Action 3.A: Ensure Receipt of Culturally Sensitive Education, Training, and Support Materials

    o *LEAD recommends that stigma be identified as a specific criteria when implementing Actions 3.A.1, 3.A.2, and 2.A.3.*

- Action 3.B.3: Review the state of the art of evidence-based interventions that can be delivered by community-based organizations

    o *LEAD recommends that the Plan action for HHS to "partner with private organizations to convene a meeting of leading scientists and practitioners to review the state of the art of research and translational activities related to evidence-based interventions that can be delivered by community-based organizations" be annualized.*

- Action 3.D.1: Educate legal professionals about working with people with Alzheimer's disease

    o *LEAD recommends that this Action be expanded to include education for court personnel, financial planners, and first responders.*

- New Recommendation 1: *Require training for health and social service professionals caring for people with Alzheimer's disease and related disorders*

- Recommendation 2: *Develop best practices to help family caregivers remain productive in the workplace*

- Recommendation 3: *Assess the impact on and develop best practices for supporting children who are family caregivers*

Over-arching Plan Recommendations

New Recommendation 1: *Adopt all 2013 recommendations from the Advisory Council*

LEAD recommends that the Plan incorporate all the recommendations adopted by the Advisory Council at its January 2013 meeting.

New Recommendation 2: *Until such time as the statute may expand the number of seats on the Advisory Council, invite a person with Alzheimer's disease or a related disorder to participate on each Advisory Council subcommittee as on outside expert*

LEAD recommends that a mechanism be developed to have at least one person diagnosed with Alzheimer's disease and one person diagnosed with a non-Alzheimer's dementing disorder begin actively participating in Advisory Council work no later than the summer of 2013. The public comment process is not an adequate substitute for comprehensive participation. The Advisory Council members and all federal officials involved in developing and implementing the Plan have stated unambiguously and with great integrity that the Plan addresses not only Alzheimer's disease but all dementing disorders; among the most important ways to give life to that commitment is to invite voices from a diverse range of dementing disorders.

New Recommendation 3: *Create a formal mechanism for additional federal government agencies to participate in the Advisory Council process*

Rightly, HHS is leading the federal effort to develop and implement the Plan; HHS has encouraged and welcomed participation by other federal agencies. LEAD recommends that such participation be more formal, consistent, and robust. While expansion of statutory membership on the Advisory Council is one option worth consideration, LEAD believes that amending the statute is not a necessary prerequisite to convincing other federal agencies to participate voluntarily. At a minimum, the Departments of Homeland Security, Justice, Commerce, Labor, Housing and Urban Development, Transportation, and Education, along with the Office of Personnel Management (OPM) and the Office of Management and Budget (OMB) should participate in developing and implementing the Plan alongside colleagues from HHS and the Department of Veterans Affairs who already are engaged. Consider some representative examples: Labor and Education are critical to addressing health care workforce challenges; Hurricane Katrina and super storm Sandy painfully demonstrated the need for the Federal Emergency Management Agency (FEMA) to develop preparedness strategies for when natural disasters separate people with dementia from their care providers and settings; Alzheimer's disease science rapidly has become a critical issue in global economic competitiveness requiring attention by Commerce; both the Commerce Department and the State

Department likely could contribute to HHS efforts to expand collaboration with foreign governments in coordinating existing national plans and potentially developing a global Plan; OPM and OMB need to be at the table to assess the impact on both the federal workforce and the federal budget.

New Recommendation 4: *Encourage participation in the Plan process by experts on non-dementing disorders that have a high rate of co-morbidity with Alzheimer's disease or a related disorder*

The Plan already encourages public-private partnerships (PPPs) and breaking down any tendencies to work in silos. LEAD recommends that the Advisory Council and HHS strongly encourage both formal and informal participation in the process of developing and implementing the Plan by public and private sector stakeholders with expertise in other disorders which have a high rate of co-morbidity with Alzheimer's disease or related disorders. For example, many people have both Alzheimer's disease and diabetes; while it is not yet clear with there is only a high correlation or a causal relationship, it is clear that it is much more financially costly and physically injurious to have both conditions together than either condition alone. The National Institute on Aging certainly could establish dialogue with other relevant NIH institutes focused on co-morbid conditions while Alzheimer's disease patient advocacy organizations on the Advisory Council could establish similar dialogue with patient advocacy organizations focused on co-morbid conditions to advance implementation of the Plan and develop recommendations for future revisions. Working collaboratively in the public and private sectors should make more effective efforts to reduce or better manage co-morbid conditions and, potentially, accelerate pursuit of scientific interventions to reduce the incidence of such conditions.

New Recommendation 5: *Identify and define a role for individuals and family members/family caregivers in each major section of the Plan*

Individuals and family members/family caregivers are capable of contributing to memory loss detection, increasing participation in clinical trials, improving clinical care, reducing stigma, and raising public awareness. LEAD recommends that the Plan clearly identify and define ways in which individuals and family members (or their identified family caregivers) can support effective implementation of each major action or strategy within the Plan.

New Recommendation 6: *Incorporate throughout the Plan clear and transformative time-based metrics with projected necessary funding levels*

It is abundantly clear to LEAD and others across the Alzheimer's-serving community how remarkable the work is that the Advisory Council and federal officials have done in a very compressed time frame. The depth and variety of recommendations and actions developed thus far have been impressive. Policy experts likely are able to unpack how these elements translate to changing real

people's real problems. The Plan as a whole needs language that can be much more readily identified by the general public, language that will make clear how the Plan will change their lives. This is particularly needed in the Plan's clinical care and long terms supports goals. In the research goal, the Plan has that language in the form of the 2025 goal. But the complexity of the language and the sort of inside Washington nature of what is proposed in the Advisory Council recommendations and what is already embedded in the Plan's clinical care and long term supports sections, is impenetrable for average citizens who need the Plan to work but who also need to be inspired by the Plan and have their hope sustained or restored by the Plan. There should be aspirational goals across the Plan that are tangible, transformative, and clear. Take the model of the 2025 goal and frame parallel goals in the clinical care and long term supports portions of the Plan. Much of what already exists in those sections of the Plan already point in the direction of what would be aspirational goals but those aspirational goals have not been articulated. The Plan proposes to fix the systems but does not articulate why the systems need to be fixed or what would be achieved as a result of fixing the systems.

LEAD recommends that the Plan adopt time-based goals -- that the Centers for Disease Control (CDC) and other public and private sector agencies could collaborate to implement -- for:

- increasing the percentage of people with Alzheimer's disease or a related disorder who are diagnosed and the diagnosis properly charted in the medical record, informed of the diagnosis, and referred by the diagnosing medical practice to community resources;

- decreasing the incidence of wandering and the rate of injury or death;

- decreasing the incidence of family caregiver depression;

- decreasing the incidence of falls by people with Alzheimer's disease or a related disorder in home and community based settings as well as in residential care facilities; and

- increasing the utilization of hospice and other palliative care services.

LEAD recognizes that most or all of the goals, strategies and action items within the Plan entail significant federal investments designed to reduce over time costs to the public and private health care systems, the economy, and the toll of human suffering. LEAD recommends that the Plan articulate the federal investments needed to achieve the established goals and value of the budgetary, economic and social benefits that are to be accomplished.

New Recommendation 7: *Commission an independent analysis of the investment value of Alzheimer's disease spending by the federal government*

Members of Congress, the Administration and tens of millions of Americans recognize the strategic irrationality and inhumanity of the enormous federal expenditures on care for people with Alzheimer's compared to the relatively miniscule federal investment on research to prevent, treat or cure this devastating disease. But that imbalance persists and worsens year after year in part because the federal government scores federal research spending as a cost rather than an investment. The scoring system therefore ignores not only the future cost-savings to social safety net programs but also the future revenue gains that would accrue from development of new products with a vast global market, increases in workplace productivity, and an expanded workforce. LEAD recommends that the Plan call for an independent body to assess the investment value of the federal government's Alzheimer's disease research funding and provide policy options to correct the current imbalance between federal funding for research and care.

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

LEAD supports this bold goal, with the hope that it will be achieved more rapidly with the right plan and resource commitment. LEAD is pleased that the Advisory Council has included a number of recommendations submitted by the coalition under Goal 1, including the recommendation for a strategic approach to focus efforts and resources on "the most promising pharmacological interventions" as well as accelerating efforts to "identify early and presymptomatic stages of Alzheimer's disease." LEAD applauds the increasing emphasis on international coordination and collaboration with commercial and nonprofit partners. However, it is imperative that any goal to prevent and effectively treat Alzheimer's disease must include research investments in non-pharmacological treatments. Non-pharmacological approaches can improve relevant outcomes including improved behavior and delay of institutionalization.

Below please find LEAD's recommendations for Goal 1 of the Plan:

Action 1.A.1: Convene an Alzheimer's disease research summit with national and international scientists to identify priorities, milestones, and a timeline

LEAD applauds NIH/NIA for convening the first Research Summit in May of 2012 and for its plans to reconvene every other year around specific research topics of high priority to the field. LEAD recommends that each summit provide explicit strategies and milestones to be met within defined timeframes. Furthermore, LEAD recommends that each summit have a specific session to report milestones and the progress of strategies set at previous summits.

Action 1.B.3: Increase enrollment in clinical trials and other clinical research through community, national, and international outreach

LEAD recommends that HHS carryout and begin implementing by the end of 2013 the action plan produced by its intended convening of representatives from across the federal government, state and local governments, academic medical research institutions, and the private sector to create an action plan for increasing enrollment in clinical trials, including through the building of registries.

Action 1.B.5: Conduct clinical trials on the most promising pharmacologic interventions

Strategies to expand research aimed at preventing and treating Alzheimer's disease should reference industry's contribution in conducting clinical trials. Strategies should build on the infrastructure that exists in industry for discovering promising new therapeutic targets and therapies—including combination therapies—for trials and their existing working relationships with regulators to ensure that safe and effective treatments get approved. The NIH/NIA 2012 Alzheimer's disease Summit included debate on examining the current

conceptual models in studying the disease as well as providing a portion of federal funding for cutting-edge proposals. Non-pharmacologic interventions should also be explored, including community-based interventions and technologies that allow people with dementia to function independently for as long as possible. Strategies should include a statement of what each federal and industry partner can contribute and where the cost and time of the clinical trial process can be reduced consistent with standards of safety and efficacy.

Action 1.C.1: Identify imaging and biomarkers to monitor disease progression

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 large-scale, open-source patient registry of subjects that can be approached for recruitment in prevention trials, including specifically under-represented ethnic and other sub-populations. Consider a broader healthy aging registry, similar to the Framingham study for cardiovascular disease, to follow asymptomatic individuals and those with correlated diseases such as diabetes (the new European Medical Information Framework – Innovative Medicines Initiative consortium has a similar aim). Trials focused on identifying early stages of Alzheimer's disease should be based on development of quantitative clinical trial models designed for studies in early Alzheimer's disease.

Action 1.C.2: Maximize collaboration among federal agencies and with the private sector

With the levels of funding now dedicated by government, academia, and industry to Alzheimer's disease research, it is important to make the most efficient use possible of all partners and resources – and make the best use of the limited number of patients available for clinical trials. There is a need to align government, industry and academic sponsored studies to achieve consensus on defined recommendations for advancing new drug candidates for the treatment of Alzheimer's disease. A precedent exists in other disease areas (e.g. STAIR recommendations for stroke). Current public-private partnerships in the Alzheimer's disease arena have not yet owned this opportunity to date. Funding would catalyze such progress. Research should be a community-wide effort for public private collaboration and HHS should consider asking the White House Office of Science and Technology Policy (OSTP) to help coordinate this effort with them.

Action 1.E.1: Pursue ways to compress the time between target identification and release of pharmacological treatments

There are many important – albeit underfunded – strategies being pursued to speed treatments to patients such as disease modeling, drug repurposing, better target identification, and strategies for combination therapy. However, a major

issues remains with respect to the lack of a centralized Institutional Review Board (IRB). LEAD recommends that this Action include expanded public and private support for a uniform patient consent and centralized IRB to review all multi-center Alzheimer's disease trials to decrease the time for trial start-up and protocol amendments.

The National Biomedical Research Ethics Council (NBREC) has been incorporated as a "neutral" home to develop a National IRB for Neurodegenerative Diseases (NIRB-ND). The NIRB-ND will closely follow the Central IRB model pioneered successfully by the National Cancer Institute, and it will be managed by a Steering Committee composed of representatives from the sponsoring organizations/foundations.

Given the proposed changes to the "Common Rule" on the topic of centralized IRBs (cIRBs) and the National Institutes of Health's growing interest in cIRBs, this effort will provide an innovative solution to a problem shared by many constituencies interested in therapy development. The NBREC approach features the establishment of a successful public-private partnership business model. The NIRB-ND will guarantee the protection of study volunteers, reduce needless delays in large clinical trials, decrease costs and reduce risks associated with studies. The project is exploring options for expanding reviews to include Canada and eventually countries within the European Union.

Action 1.E.2: Leverage public and private collaborations to facilitate dissemination, translation, and implementation of research findings

There is an exponential growth in the number of public and private partnerships (PPPs) in the Alzheimer's disease arena, which is simultaneous with a concern of consortia fatigue. The sense of urgency exists to address improved understanding of the scope of activities (in scope and out of scope) for the numerous PPPs, and specifically how alignment is taking place to avoid duplication of effort. Positive examples exist of synergistic alliances between ACT-AD, C-Path and CAMD, ADNIPPSB/Alzheimer's Association, and the Global CEO Initiative on Alzheimer's Disease. Defining specified resources aimed at facilitating coordinating PPPs is an unmet and urgent need. Leadership from ASPE is crucial and should be made a priority.

New Recommendation 1: *Address the unique circumstances of individuals with Alzheimer's disease and their ability to provide informed consent for clinical trial participation*

LEAD recommends that the Plan include a process for developing standardized informed consent to allow participants in clinical trials to authorize their de-identified data be used for research purposes broader than a single study in order to advance understanding, treatment and prevention of Alzheimer's disease. LEAD recommends pooling of individual de-identified data into larger Alzheimer's disease databases – globally available to qualified researchers – to

allow data mining and to increase statistical significance, provide information on the natural history of Alzheimer's disease, identify promising biomarkers and response or non-response to treatment. This database would need to address privacy, HIPPA, informed consent and liability issues and need a mechanism to protect proprietary and confidential data. Research activities involving human participants will continue to be conducted in a way that promotes their rights and welfare but include a feature for allowing Alzheimer's patients to opt in and contribute their de-identified data for research as in public databases or opt out for those who do not want to allow their data to be used for research purposes.

New Recommendation 2: *Implement Alzheimer's disease specific data standards to ensure a uniform approach for collection, transfer, analysis, reporting and archiving of data*

The Plan should encourage all new and ongoing federally funded and industry-sponsored Alzheimer's disease clinical trials to use the same Alzheimer's disease specific data standards developed by the Clinical Data Interchange Standards Consortium (CDISC). Data standards provide a uniform approach for collection, transfer, analysis, reporting and archiving of data. The benefits of using common data standards include improved learning and knowledge generation and a reduction in time, resources and costs. Using these standards will facilitate data sharing and review by the FDA and EMA. Alzheimer's disease clinical trials data, including data in failed trials, data with respect to dormant drugs, and 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. Given the FDA's preference and future requirement for submission of clinical data in CDISC unified clinical data standards, it is recommended that data be collected for current and future clinical trials in CDISC format using the AD CDISC therapeutic area specific standards. Lack of action on this recommendation will slow the time for regulatory drug review of any new therapeutic candidate.

Goal 2: Enhance Care Quality and Efficiency

LEAD is pleased that the Plan includes the goal to enhance care quality and efficiency. The 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 provide a platform for ensuring that all Americans requiring care for Alzheimer's disease are able to access quality care across various care settings.

As the Plan has evolved from the Alzheimer's Disease Study Group (ASG), to the Advisory Council and the first Plan, we have not adequately motivated the Plan with a clear vision of what clinical care should look like in the United States. The comprehensive effort to date has been laudable and has advanced the country's goals with respect to research. But research advances will not have the impact that they should unless we begin with an equally broad and forward-looking conceptualization of clinical care.

ASG recommendations related to clinical care in 2009 were limited to a focus on measurements of quality, making paid caregiving available, and educating the public about the disease. There was an implicit assumption that medical care is already uniform, executed consistently and well in diverse settings, and that it encompasses the public need. In 2011, LEAD recommended that the Plan include development of a workforce to diagnose and care for people with memory disorders; improve models for reimbursement that incentivize practitioners to diagnose early and treat persistently; support pilot and demonstration projects to improve the care that is available; develop innovative new models for care; improvement of emergency care for people with dementia; and establishment of a network of geographically accessible memory disorders centers to serve as translational sites to advance the medicine around prevention, diagnosis, and treatment of AD and related conditions. The first Plan was very strong on collaborations among agencies, advancement of neuroimaging and biological markers to aid in early diagnosis and drug development, educating the workforce and disseminating existing guidelines (albeit limited and out of date), as well as educating the public. It also mentioned the need to strengthen direct care, without describing the deficiencies; the need to survey unmet needs; to develop cost-effective models of care; to improve minority care; to protect the vulnerable; and to assess the housing needs of people with dementia. These listings may be perceived as somewhat piecemeal and secondary by people at risk for and living with memory disorders, their families, and healthcare workers.

Clinical care should encompass detection of risk factors, management of risk factors, early diagnosis and lifelong management, regardless of social differences, medical co-morbidities, and physical location. Citizens should be able to count on comparable approaches regardless of where they live or how they fund their healthcare. New advances in research related to risk, diagnosis,

and treatment should translate easily into clinical settings, so that willing patients can help to prove or disprove their utility. And clinicians who choose to promote brain health and provide care to people with memory disorders across the stages of their lives should be able to do so without bankrupting their practices. Without some effort to develop a national, clinical focus on specialized prevention and care approaches, there will be no true expertise—and the greatest advances to date are at risk of being irrelevant because there is no coherent approach to ensuring that they shape practices in a timely manner.

Below please find LEAD's recommendations for Goal 2 of the Plan:

Action 2.A.2: Encourage providers to pursue careers in geriatric specialties

The Plan recognizes both the worsening shortage in the geriatric specialty workforce and the dire consequences that the shortage causes for the growing population of people with Alzheimer's disease and related disorders. LEAD recommends that the Health Resources and Services Administration (HRSA) support training projects that provide fellowships for individuals studying to be geriatric social workers.

Action 2.A.6: Support state and local Alzheimer's strategies

The Plan recognizes that many states and local communities have developed dementia strategies and action plans. The Advisory Council repeatedly has discussed opportunities for the national Plan and these state or local plans to share and reinforce best practices. LEAD recommends that HHS and the Department of Labor collaboratively develop best practices for direct-care workforce development, recruitment, and retention tailored to each provider setting in the Alzheimer's disease care continuum including: home health, adult day, assisted living, skilled nursing, and hospice.

New Recommendation 1: *Address inconsistencies across geographic areas and subspecialties, and from provider to provider*

Clinical approaches to risk management, diagnosis, and treatment are inconsistent across geographical areas and subspecialties, and also vary from care provider to care provider. Existing education of physicians regarding dementia and related disorders is also quite limited, despite the fact that the Medicare Trust Fund spends over $9 billion annually to subsidize Graduate Medical Education. LEAD recommends that the Plan call for conducting a nationwide assessment of available expertise by region of the country including expert clinicians in all relevant specialties (family practice, general internal medicine, geriatrics, neurology, psychology, psychiatry, and social work), paid caregivers, day centers, overnight respite care, and long term care options. This should include examination of current practices for risk factor management, diagnosis, longitudinal outpatient management, emergency management, and

long term residential care in each area. Additionally, all residency programs should be assessed for the amount of education and training focused on dementia and related disorders.

New Recommendation 2: *Update reimbursement formulas to encourage brain health risk management, early diagnosis of memory disorders, persistent and multi-disciplinary treatment, and uniform levels of treatment across care settings*

The current reimbursement system discourages brain health related risk management, early diagnosis of memory disorders, persistent treatment, multi-disciplinary treatment, and uniform levels of treatment regardless of care setting. LEAD recommends that the Plan call for an analysis (to be completed by the end of 2013) of the actual costs and reimbursements for laboratory services and patient visits for risk factor management, diagnosis, and longitudinal outpatient management, and for diagnosis and management within long term care settings. The analysis should benchmark successful programs and practices. LEAD also recommends that the Plan call for HHS to propose (by the summer of 2014) options to correct the reimbursement formulas as needed to optimize these efforts; funding for demonstration projects for models of care across the spectrum of disease; and funding for demonstration projects to assess the impact of dementia specific medical homes. For example, reimbursement levels might be tied to whether nationally certified dementia specific services were provided.

New Recommendation 3: *Address inadequate emergency and acute hospital care for people with memory disorders, especially those with dementia*

Inadequate emergency and acute hospital care imposes staggering costs on the physical and emotional well being of patients, families, and medical personnel. The economic costs to patients, providers, public and private insurers are unsustainable. The horror stories are well known, more typical than anecdotal, and all too true. LEAD recommends that the Plan call for HHS to complete (by the end of 2013) a nationwide assessment of the available inpatient and outpatient emergency care for dementia patients with acute agitation or psychosis and the quality of inpatient care for people with memory disorders hospitalized for non-dementia related conditions. LEAD further recommends that the Plan call for HHS to propose (by the summer of 2014) methods to incentivize hospitals and psychiatrists to handle dementia related emergencies and standards for emergency care for people with dementia. For example, HHS could consider proposing standards for geriatric psychiatry units, which currently are not required to have a psychiatrist or even a geriatrician.

New Recommendation 4: *Establish a network of geographically dispersed and accessible memory disorders centers, linked to sites providing*

integrated research and patient care, to facilitate translational medicine, and to continuously develop and improve the standard of care

Access to quality care – and the application of medical practice to transformative research -- all too frequently is compromised by geographical happenstance. LEAD recommends that the Plan call for provision of supplemental funding to the centers for infrastructure and reporting, and ensure adequate reimbursement within the centers to support clinical infrastructure. Additionally, LEAD recommends that the Plan establish a target date of 2017 for HHS to develop a comprehensive national public health strategy for Alzheimer's disease and related disorders which includes for all Americans regardless of age or care setting early assessment of risk factors, advice about risk mitigation, access to diagnosis and disease management.

Goal 3: Expand Supports for People with Alzheimer's Disease and Their Families

LEAD applauds the Plan for including goals and strategies that will improve quality care and expand support for people with Alzheimer's disease and other dementias and their families. Specifically, we are pleased that the Plan includes recommendations from LEAD to expand proven programs that are in place at the federal, state and local levels that provide adequate care and support for people with Alzheimer's and other dementias and their families. Moving forward it is important that the Plan provide adequate resources to be available to support the implementation of these strategies.

Below please find LEAD's recommendations for Goal 3 of the Plan:

Action 3.A: Ensure Receipt of Culturally Sensitive Education, Training, and Support Materials

Stigma has diverse cultural bases and forms of expression. Reducing stigma and its consequences requires culturally appropriate interventions. LEAD recommends that stigma be identified as a specific criteria when implementing Actions 3.A.1, 3.A.2, and 2.A.3.

Action 3.B.3: Review the state of the art of evidence-based interventions that can be delivered by community-based organizations

The Plan calls for HHS to "partner with private organizations to convene a meeting of leading scientists and practitioners to review the state of the art of research and translational activities related to evidence-based interventions that can be delivered by community-based organizations." LEAD recommends that the Plan now call for such a meeting to be an annual occurrence.

Action 3.D.1: Educate legal professionals about working with people with Alzheimer's disease

LEAD supports this Plan action and recommends that it be expanded to include education for court personnel, financial planners, and first responders.   A number of states and local communities have extensive and evidence-based experience partnering with private organizations such as the Alzheimer's Association in educating first responders and court personnel (some have worked with financial planners) to better meet the needs of people with Alzheimer's disease and related disorders and of family caregivers. At a minimum, HHS and the Department of Justice could serve as a clearinghouse for best practices in educating legal, financial, and emergency services professionals.

New Recommendation 1: *Require training for health and social service professionals caring for people with Alzheimer's disease and related disorders*

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

Recommendation 2: *Develop best practices to help family caregivers remain productive in the workplace*

Many family caregivers want or need to remain in the workforce but face substantial challenges that could be addressed successfully with workplace policies designed for elder care and based on the accommodations begun more than a generation ago for working parents. LEAD recommends that the Plan call for development of best practices to help family caregivers remain productive in the workplace. Best practices may include flextime; work-at-home options; job-sharing; counseling; dependent care accounts; information and referral to community services; and employer-paid services of a care manager.

Recommendation 3: *Assess the impact on and develop best practices for supporting children who are family caregivers*

At the local, state, and federal levels, enormous investments are committed to advancing the academic and personal success of children. Increasingly, there is widespread – perhaps universal – realization that the efficacy of such investments can be enhanced or diminished by students' home environment. LEAD recommends that the Plan call for HHS and the Department of Education to collaboratively examine the consequences of Alzheimer's disease family caregiving on the academic achievement, and social-emotional well being of children and develop best practices for schools to support the needs of these students.