Congress of the United States

Washington, DC 20515

November 29, 2011

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, D.C. 20201

Dear Madame Secretary,

As the Co-founders and Co-chairs of the Bipartisan Congressional Taskforce on Alzheimer's Disease and House authors of the National Alzheimer's Project Act (NAPA), we are writing to urge the Department of Health and Human Services (HHS) to continue its swift and efficient implementation of the Act. NAPA is intended to be transformative, creating a groundbreaking, far-reaching, and thoughtful National Alzheimer's Plan to improve care for Alzheimer's patients across the country and ultimately cure this disease.

We applaud the ongoing work of the Nation Alzheimer's Project Act's Advisory Council and federal agency working groups. We are pleased to hear that a draft National Alzheimer's Plan required by the law will be ready by early next year. As you know, several of the largest Alzheimer's advocacy, care, and research organizations have submitted ideas and priorities for the National Alzheimer's Plan.[1] We hope that the agencies working to develop the draft plan will strongly consider these various proposals.

We provide below our recommendations for your consideration as you prepare the National Alzheimer's Plan:

1. **Increase medical research funding and coordination**

As millions of baby-boomers age and retire, Alzheimer's is becoming a national pandemic, threatening to undermine our Medicare and Medicaid systems. Today the federal government spends $93 billion out of Medicare to care for Alzheimer's patients -- almost one out of every five Medicare dollars (18%) each year. This money pays for hospitalizations, doctor visits, and drugs associated with the disease. An additional $37 billion comes out of the Medicaid budget every year -- more than one out every 10 Medicaid dollars (11%). Taken

[1] See: Leaders Engaged in Alzheimer's Disease (LEAD), *A Path Forward* http://c3320830.r30.cf0.rackcdn.com/LEAD-ThePathAhead-2011-11-01.pdf; Alzheimer's Association, *Alzheimer's from the Frontlines* http://www.alz.org/documents_custom/napareport.pdf; Alzheimer's Foundation of America, *No Time to Waste* http://www.alzfdn.org/documents/No%20Time%20to%20Waste%20Report-10-11.pdf.

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together, that's $130 billion every year from Medicare and Medicaid that is spent on this one disease alone.

In addition, nearly 15 million caregivers provide approximately 17 billion hours of unpaid care to family members and friends with Alzheimer's, which represents a large drain on the time and the resources of families and employers. Now more than ever, we need to accelerate research breakthroughs in the causes, treatments and prevention of this disease and reduce the emotional and financial burden of Alzheimer's on families and federally-funded programs.

Basic research is our best hope for understanding the fundamentals of this disease and finding a cure. Currently, Alzheimer's research is underfunded across the federal government, academia and the private sector. According to data from HHS, Alzheimer's disease receives a fraction of the research funding at the National Institutes of Health (NIH) compared to other diseases. Today, the NIH spends about $6 billion a year on cancer research and $3 billion a year on AIDS research. Alzheimer's has five times as many victims as AIDS, yet receives only $469 million in research funding a year – less than 1/6 the amount spent on AIDS research.

Deaths from AIDS, cancer, and heart disease have fallen in the last decade. As a nation, we should learn from our past successes. Prioritizing and funding medical research has lead to breakthroughs and treatments and ultimately saved lives. In the same way, we must expand funding for basic medical research for Alzheimer's disease, which continues to have a dramatically increasing number of patients every year across the country.[2]

It is also our hope that in drafting the National Alzheimer's Plan, HHS will also explore ways to better coordinate research and grants dollars within the centers and institutes of the NIH. Currently, over a dozen institutes at the NIH support or conduct Alzheimer's related research. Perhaps there is a need for an institute focused solely on the disease or a way to enhance data sharing amongst researchers. Whatever the solutions, the National Alzheimer's Plan should include concrete ideas to guarantee that all money, given through grants or used internally, is spent effectively and in coordination with other research projects in support of a larger research agenda.

In addition, we urge HHS to consider innovative projects to facilitate research and therapy development across public and private sectors. For instance, HHS should consider the feasibility of increasing accessibility to lumbar punctures for patients in order to develop national databases and registries for at risk patients. Cerebral spinal fluid tests are proven to identify those at high risk of Alzheimer's disease.[3] Increasing access to this screening technique would help facilitate entries into clinical trials, and, once therapies have been developed, identify those who should receive such therapies.

2. Incent private sector research and development

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[2] See: http://report.nih.gov/rcdc/categories/ and LEAD, *A Path Forward:* 10.

[3] Richard J. Perrin, Anne M. Fagan, and David M. Holtzman, "Multimodal techniques for diagnosis and prognosis of Alzheimer's disease," *Nature* 461:15 (Oct. 2009).

Biopharmaceutical companies have approximately 21,000 ongoing clinical drug trials in the U.S., yet only 100 of them are focused on Alzheimer's disease. It is our hope that new incentives for pharmaceutical companies to invest in research and therapy development, including the development of new drugs, devices, biological products, biomarkers, or diagnostic tools, are included in the National Alzheimer's Plan.

Federal agencies have adopted methods in the past for encouraging research and therapy development under adverse conditions, including: extended market exclusivity for demonstrably effective treatments, priority review or fast-tracking by the Food and Drug Administration for treatments in the pipeline, review of guidelines regarding clinical trials, and patent life reform. It is our hope that the benefits and consequences of all methods are thoughtfully examined and considered in this case.

In addition, we urge HHS to consider ways to increase public-private partnerships for research and therapy development including possible strategic investments in start-up or growth companies engaged in advanced research and novel therapeutics, especially those companies willing to match funds from HHS.

3. Expand public awareness efforts

The National Alzheimer's Plan should call on relevant government agencies to work with local and state governments to develop public awareness campaigns around Alzheimer's disease, in the way HHS and the Centers of Disease Control have spearheaded public awareness campaigns in the past. It is our hope that the campaigns would focus on: the symptoms of Alzheimer's disease, the importance of diagnosis, how to access clinical trials, and the availability of resources and services for patients, families and caregivers.

4. Provide reimbursement for comprehensive diagnosis

Reports estimate that as few as 19 percent of people with Alzheimer's disease have a documented diagnosis of their condition in their primary care medical record.[4] African-American and Hispanic populations are even less likely to be diagnosed than whites despite being at higher risks for Alzheimer's disease.

Medicare currently covers diagnostic evaluations and some imaging tests. However, if the signs of dementia have not been detected in the first place, a diagnostic evaluation is not conducted. Furthermore, after a diagnosis has been made, time constraints and lack of reimbursement often preclude a necessary discussion with the newly diagnosed patients and their caregivers regarding the diagnosis, treatment options, and support services available. As a result, many people with dementia and their families are not effectively connected to resources to help them manage the condition and avoid crises.

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[4] "Implementing a screening and diagnosis program for dementia in primary care," *General Internal Medicine* (2005) http://www.ncbi.nlm.nih.gov/pubmed/16050849.

With an early diagnosis, patients and families can prepare for the oncoming symptoms of the disease. Facilitating conversations between doctors and caregivers and providing resources for patients' families can help mitigate the number of hospitalizations and complications for patients and ultimately bring down Medicare costs.

H.R. 1386, the Health Outcomes Planning and Evaluation Act (HOPE) for Alzheimer's, which we co-authored, proposes that the Centers for Medicare And Medicaid Services develop a new Medicare reimbursement code for a comprehensive diagnosis of Alzheimer's disease to help drive best practices among doctors. This includes reimbursement of the following: screening of dementia, diagnostic evaluation, discussion with doctor and caregiver, and medical record documentation.

5. Expand outcome-oriented care programs and dementia training for healthcare professionals

Models such as Independence at Home (IAH) and Resources for Enhancing Caregiver Health (REACH) have proven to improve the quality of care for patients and reduce health care costs by keeping patients in the comfort of their own homes longer and coordinating care services. IAH, currently a demonstration project slated to begin January 2012, creates a team of doctors, nurses, social workers, pharmacists, physical therapists and others to provide proactive care in the home for seniors with multiple chronic conditions like Alzheimer's, Parkinson's, and congestive heart failure. As you know, there are more than 57 million Americans living with multiple chronic illnesses in our country. These patients typically have numerous prescriptions written by an array of doctors, and struggle to visit their physicians when they need care. IAH aims to end the current disjointed approach of caring for these patients. Such successful programs that reduce costs and improve health care outcomes should be considered in the National Alzheimer's Plan and enacted across the country to support caregivers and increase access to quality care for all patients.[5]

In addition, it is our hope that the National Alzheimer's Plan will call on federal agencies to work with state and local governments to increase Alzheimer's and dementia training for health care professionals, social workers, employees of long-term care facilities and law enforcement. Increased training and education could dramatically improve the treatment of Alzheimer's patients and help avoid unnecessary costs and harm as the result of wrongful diagnosis and mistreatment.

6. Encourage State Plans

30 states currently have or are in the process of developing plans for supporting Alzheimer's patients.[6] The Massachusetts Executive Office of Elder Affairs, for example, established a committee of experts to evaluate services and resources available to Alzheimer's patients and their caregivers and develop a strategy for improving care. Their initial reports focused on the need to diagnose patients early, connect patients and their families to available resources, and facilitate at-home care.

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[5] R. Meyer, "Consider Medical Care at Home," *Geriatrics* (June 2009); S. Okie, "Home Delivery: Bringing Primary Care into the Household," *New England Journal of Medicine* (Dec. 2008).

[6] See: http://www.alz.org/join_the_cause_state_plans.asp.

The challenges associated with Alzheimer's disease are too varied and far-reaching for the federal government to tackle alone. From improving transportation services for patients in rural neighborhoods to assisting in the creation of new adult daycare centers, state and local governments are well positioned to improve the day-to-day care of Alzheimer's patients. In order to fully support the millions of Americans with Alzheimer's disease and their families struggling to care for them, we need local and state governments involved in developing appropriate service models.

For these reasons, we hope the National Alzheimer's Plan will encourage states to assess the services they currently provide and develop plans for caring for the growing number of patients in the future. In addition, the National Alzheimer's Plan should look for ways the federal government can support or reward state efforts to improve and coordinate care, especially if states develop innovative solutions with measurable cost-savings or improvements in care.

Caring for the aging baby-boomers will be one of the greatest tests of our society. Today, over 5 millions Americans and their families are struggling with Alzheimer's disease. Unless we find a way to prevent, slow, or cure this disease, in less than one generation those struggles will nearly triple, as millions more Americans face the prospect of an Alzheimer's diagnosis. We must change our current trajectory. NAPA was intended to outline innovative and large-scale strategies for improving care for our senior citizens, to which we owe so much, and ultimately find a cure for this devastating disease. We encourage HHS and its partnering federal agencies to continue their diligent, timely, and thoughtful work to implement NAPA and draft this historic National Alzheimer's Plan.

Sincerely,

Edward J. Markey
U.S. Representative

Chris Smith
U.S. Representative