

Congress of the United States

Washington, DC 20515

June 21, 2012

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

Dear Secretary Sebelius:

As co-Chairmen of the Congressional Taskforce on Alzheimer's Disease and House authors of P.L. 111-375, the National Alzheimer's Project Act (NAPA), we commend the Department of Health and Human Services (HHS) on its swift implementation of the Act. In particular, we applaud the creation of the first-ever, national strategy to combat Alzheimer's disease, as mandated by NAPA. The National Plan to Address Alzheimer's Disease is far-reaching and comprehensive. It takes into consideration the many complicated issues surrounding this disease and sets aggressive goals for the future, including the treatment or prevention of Alzheimer's disease by 2025.

Caring for our aging Baby-Boomers is one of the most pressing challenges facing our health care system today. While there are currently more than five million Americans afflicted with Alzheimer's disease, this number will nearly triple in less than one generation unless we find a way to prevent, slow, or cure this disease. The work already underway at HHS, along with the Department's strategy for future action, reflects the urgency needed to address this national priority.

We are heartened by the Department's new plan, and we have questions regarding its formation and implementation. Accordingly, we seek answers to the following questions:

- 1. How did HHS determine funding levels outlined in the plan?** Several advocacy organizations have estimated that more funds might be needed to achieve the bold research goals outlined in the plan. How did HHS arrive at the \$80 million request for additional research funding for Fiscal Year 2013? How does this investment compare to other disease-specific research initiatives at HHS?
- 2. How will research funding be allocated?** The national plan breaks down Goal 1, "Preventing and Effectively Treating Alzheimer's by 2025", into sub-strategies, including the expansion of basic science, increased enrollment of clinical trials, and translation of research findings into medical practice and drug development. What percentage of the funding allocated for Alzheimer's research will be designated for these various strategies?

3. **When can the public expect an updated version of Goal 1?** Action 1.A.3 states that the National Institute of Aging (NIA) will seek public input in order to update “the priorities, milestones, and timeline elements” laid out in Goal 1.
4. **What benchmarks will be utilized to track research progress and make sure HHS and the federal government at large is on track for the research goal of treating or preventing Alzheimer's by 2025?**
5. **What types of specific grants and program models will be utilized to coordinate research between public and private entities?** Strategy 1.D states the need for increased communication between all public and private researchers working on Alzheimer’s disease. Strategy 1.E states that “additional steps are needed to highlight the promising findings and facilitate dissemination and implementation of effective interventions to the general public, medical practitioners, and pharmaceutical industry.” Are there specific funding mechanisms, grant types, or program models to incent public-private partnerships and increased translational research?

We know that some labs working on identifying therapeutic targets for Alzheimer’s disease have benefited from cooperative agreements, specifically UO1 research grants, which connect researchers with chemists from the pharmaceutical industry with the intention of taking new compounds through a Phase 1 clinical trial. Will these types of grant programs, or others, be expanded or utilized to support the translation of identifying therapeutic targets related to Alzheimer’s disease into the development of effective, therapeutic drugs? What milestones and/or benchmarks are currently being explored for this translational research component of the plan?

6. **Which additional institutes within the NIH, and agencies within HHS, can support public-private partnerships and the advancement of translational research as it relates to the treatment of Alzheimer’s disease?** Appendix 4: Implementing Milestones lists NIH, NIA and the Administration of Aging as lead agencies for Action 1.E.2, “Leveraging Public and Private Collaborations”. However, we know that many scientists working on Alzheimer’s disease have benefited from grants administered through a wide range of institutes at the NIH including the National Institute of Child Health and Human Development, National Institute of Neurological Disorders and Stroke, and the NIH Blueprint for Neuroscience Research. How will HHS and NIH ensure that all relevant institutes are included in determining and achieving translational research milestones?

Also, as noted in Action 1.E., NIH will need to partner with other federal agencies, including the Food and Drug Administration (FDA), to achieve the goal of accelerating patient access to potential Alzheimer's treatments as outlined in the plan. In what ways is NIH partnering with FDA to foster public-private dialogues and compress the time between when a therapeutic target is identified and a treatment is released for patients?

7. **What matrices will be utilized for tracking progress of Goals 2-5 outlined in the plan?** For instance, Appendix 4 states that Action 2.A.4, “Strengthening the Direct-Care

Workforce”, will be accomplished this summer through the release of training materials for the nursing home and care workforce. How will HHS and, specifically, the Center for Medicare Services (CMS), conduct oversight and track the progress, reception and utilization of this training material? Will progress made under each strategy and action item be included in the annual reports to Congress and updated versions of the national plan, which are required by the law?

- 8. How will HHS ensure the success of dementia-specific education for physicians and health care providers?** According to Appendix 4, action number 2.C.1, “Educate Physicians and Other Health Care Providers about Accessing Long-Term Services and Supports”, will convene key players to identify information and available resources. How will HHS and other federal partners educate physicians and other health care providers in a way that is convenient and useful to them?

We hope that HHS will pose questions such as:

- Where are doctors already seeking information and training?
- What resources do doctors currently use for training?
- What gaps in dementia-specific knowledge do they identify?
- CMS has previously utilized Medscape for provider education.¹ Will this be considered again or are other models being considered?

We congratulate HHS on the innovative strategies and large-scale goals outlined in the National Plan to Address Alzheimer’s disease. Improving care for Alzheimer’s patients and expanding Alzheimer’s disease research are critical to addressing the growing number of people who struggle daily with this disease, including their caregivers. We commend the careful and timely work done by HHS and partnering federal agencies to implement NAPA and develop this historic National Alzheimer’s Plan.

Thank you for your attention in this important matter. We request that you provide your response to the questions outlined above by July 11, 2012. If you have any questions please have your staff contact Sara Schaumburg with Rep. Markey’s office at (202) 225-2836 or Tim Lynagh with Rep. Smith’s office at (202) 225-3765.

Sincerely,


Edward J. Markey


Christopher Smith

¹ <http://www.medscape.org/sites/advances/healthcare-updates>