Alliance
FOR AGING RESEARCH

www.agingresearch.org

750 17th Street, NW | Suite 1100 | Washington, DC 20006
t 202.293.2856 | f 202.955.8394

March 30, 2012

Helen Lamont, Ph.D.
Office of the Assistant Secretary for Planning and Evaluation
United States Department of Health and Human Services
Hubert H. Humphrey Building, Room 424E
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Dr. Lamont:

On behalf of the Alliance for Aging Research, we thank you for the opportunity to comment on the draft National Plan to Address Alzheimer's Disease. The Alliance for Aging Research, www.agingresearch.org, is a leading nonprofit organization dedicated to accelerating the pace of medical discoveries to improve the universal experience of aging and health. Our work in Alzheimer's disease includes chairing the Accelerate Cure/Treatments for Alzheimer's Disease (ACT-AD) Coalition that brings together stakeholders to accelerate development of new treatments; and as an active member of the Leaders Engaged in Alzheimer's Disease (LEAD) coalition, serving as co-chair of its research and drug development workgroup.

Thank You and Introduction

We would like to first thank and praise the Administration and U.S. Department of Health and Human Services (HHS) for its swift implementation of the National Alzheimer's Project Act (NAPA). In only 14 months since President Obama signed the legislation into law, HHS has appointed the Advisory Council on Alzheimer's Research, Care, and Services, convened the council three times, and developed both a draft framework and draft national plan.

Perhaps most important, we would like to thank you for the Obama Administration's commitment of a $50 million boost in immediate funding for Alzheimer's disease research at the National Institutes of Health (NIH) in 2012 and for the $80 million increase in the President's fiscal 2013 budget. The announcement about the availability of these funds marks a historic moment for the country. No previous administration has proposed a research increase specific to this dreaded disease. In addition, the initiative also includes a much-needed increase of $26 million for FY 2013 to enhance support for people with Alzheimer's disease and their family caregivers as well as education for providers and the general public.

We praise HHS for recognizing the importance of the larger demographic shift in the U.S. aging population as a motivator for success of the National Plan, which states:

> NAPA offers a historic opportunity to address the many challenges facing people with Alzheimer's disease and their families. Given the great demographic shifts that will occur over the next 30 years, including the doubling of the population of older adults, the success of this effort is of great importance to people with AD and their family members, public policy makers, and health and social service providers.

The Alliance believes that increased investment in preventing, treating or curing chronic diseases of the aging, such as Alzheimer's disease, is perhaps the single most effective strategy in reducing national spending on healthcare. As you are aware, eighty percent of seniors have at least one major chronic condition and half have two or more. Chronic diseases associated with aging account for more than 75 percent of Medicare and other federal health expenditures. Unprecedented increases in age-related diseases as the population ages are one reason the Congressional Budget Office projects that total spending on healthcare will rise to 25 percent of the U.S. gross domestic product by 2025 from 17 percent today. Simply put, our nation does not have the luxury of time to address the health research needs of this population.

The Alliance recognizes that fiscal restraints are required in the current economic climate, and that the Administration has already extended itself to support Alzheimer's disease funding in the National Plan. However, one of our overall comments is that funding lines must be developed and additional resources provided to adequately meet the goals of an otherwise ambitious plan. The National Institute on Aging (NIA) specifically, and NIH in general, will need a funding commitment in the billion dollar range to meet the defined 2025 goal to "prevent and effectively treat Alzheimer's disease"; FDA will need an increase of hundreds of millions to accelerate the regulatory process and promote innovation in the development of Alzheimer's disease treatments; and other agencies from AoA to CMS and HRSA will need additional resources to meet Alzheimer's-specific objectives identified in the plan that are expected to occur in conjunction with implementation of Affordable Care Act programs. The Alliance suggests that HHS create a detailed chart of current (within the next fiscal year) expected federal/private investment in each area and costs associated with meeting each goal and strategy within the plan. Otherwise, a majority of these activities look to be unfunded mandates for federal programs with already limited resources.

Second, the Alliance is pleased that HHS has recognized the data gaps that exist for Alzheimer's disease and has additionally committed $1.3 million for FY 2013 to address them. HHS' use of NIA-generated, peer-reviewed, figures for Alzheimer's disease prevalence is monumental. While seemingly academic, the identification and development of reliable data is the necessary starting point for accurate needs assessment and programmatic response. Data development is a cornerstone of the plan that the Alliance believes should be integrated throughout each goal as well as remain its own goal.

Last, the Alliance was disappointed that this draft plan did not include the inventory conducted by the federal interagency working group. It is challenging to comment on the goals and strategies of the draft plan when the rationale behind them is not included as a resource. We understand that this was the first inventory conducted and that certain federal regulations must be met before presenting it in a clear format for the public. However, we wanted to note the issue and strongly recommend that future draft plans include the inventory to allow for more informed public comment.

The comments below are organized by the goals and strategies identified in the plan in specific areas where we felt the Alliance had expertise and that were not already being addressed in comments submitted by the research and drug development workgroup that the Alliance co-chairs through LEAD.

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

The Alliance praises HHS for setting a goal of 2025 to "develop effective prevention and treatment modalities." We believe that setting this goal makes sense for a number of reasons, including the fact that the NAPA legislation expires in 2025. Goal setting is valuable for mobilizing policymakers and the advocacy community, motivating researchers and industry, and galvanizing public attention and awareness of the issue. The Alliance feels strongly that HHS and NIH should be clear with the public in particular about the state of Alzheimer's disease research to manage expectations. We hope that the upcoming May Alzheimer's Research Summit will include an explanation of this goal that will be captured by the press.

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

The Alliance is very supportive of this particular action to "examine ways to speed up the processes for bringing pharmacological treatments to market, including: identifying and validating therapeutic targets; developing new interventions: testing efficacy and safety; and regulatory approval." In fact, the Alliance spearheaded a coalition effort, Accelerate Cure/Treatments for Alzheimer's Disease (ACT-AD) Coalition, www.act-ad.org, in 2006 to accomplish similar goals. HHS should consult with ACT-AD as it moves ahead with this action.

ACT-AD is a coalition of nearly 50 national non-profit health professional, patient, health provider and consumer organizations seeking to accelerate development of potential cures and treatments for Alzheimer's disease. ACT-AD's mission is to support accelerating research for transformational therapies to potentially slow, halt or reverse the progression of Alzheimer's disease.

Until the formation of the ACT-AD Coalition, there was no point of advocacy combining the perspectives and commitment of respected advocates for women's health, consumer interests, caregiver support groups and aging interested organizations. ACT-AD is strengthened by the diversity and credibility of those voices and is bringing that strength to bear on critical issues concerning the development, review and approval of a new generation of disease-modifying therapies for Alzheimer's disease.

Under the current regulatory environment, research being performed today cannot reach patients in time to avert this disaster. CNS drugs take, on average, 13 years from initial animal studies of a drug candidate to approval. A delay of one year negatively impacts the lives of nearly 333,000 patients and their families. While these figures underscore the urgency of seeking more effective therapeutic interventions for patients with Alzheimer's disease, there are promising treatments being tested that may slow, halt or reverse Alzheimer's disease.

The ACT-AD Coalition works with urgency to accelerate development of potential cures and treatments for Alzheimer's disease. The methods the Coalition uses to conduct its important work include:

- Educating healthcare professionals, providers and other key constituencies about ways to focus the attention of Food and Drug Administration (FDA) officials and other decision makers about the need to expedite Alzheimer's disease treatments in the crowded landscape of those vying for consideration and action.

- Advancing ACT-AD's profile with the Food and Drug Administration officials and other key influencers and audiences as an organization that has critical mass and strategic focus to sustain a long-term commitment to improving the regulatory review of Alzheimer's disease drugs.
- Initiating efforts to build support for FDA reform among key Congressional leaders who influence appropriations necessary for Agency reform.
- Developing needed research and link Alzheimer's disease expertise to the Food and Drug Administration in order to support their efforts to prioritize drug review with a comprehensive, multidisciplinary base of facts.
- Mobilizing support and pressure upon the Food and Drug Administration from outside the agency, especially through ACT-AD member organizations and collaborations with other third-party organizations.
- Engaging the caregiver population that continues to be overburdened and unfocused on the need for political and regulatory reform.

The ACT-AD Coalition holds periodic meetings with its members and representatives of the Food and Drug Administration. Scientific workshop topics have included clinical meaningfulness and Phase II trial issues—and the focus is always on areas relating to an open dialogue between the Food and Drug Administration and Alzheimer's disease community to advance efforts to combat the illness.

Goal 2: Enhance Care Quality and Efficiency

Our nation faces an impending healthcare crisis as the number of older individuals with Alzheimer's disease and other complex health needs increasingly outpaces the number of healthcare providers with the knowledge and skills to adequately care for them. If current workforce trends do not change, we will continue to fail to ensure that every older American is able to receive high-quality care. The Institute of Medicine's (IOM) April 2008 report, "Retooling for an Aging America: Building the Health Care Workforce," calls for immediate investments in enhancing the geriatric competencies of the entire workforce, increasing the recruitment and retention of geriatric specialists and caregivers, and improving the way that care for older adults is delivered.[1]

Strategy 2.A: Build a workforce with the skills to provide high-quality care

First, direct-care workers provide critical support to older adults in need of long-term care, providing eight out of every ten hours of paid service delivered.[2] This field, which is increasing at three times the rate of other jobs within the United States economy, provides the best opportunity for caring individuals to obtain vital employment positions.[3] There is also a significant shortage of health professionals and direct-care workers with specialized training in geriatrics and an even greater shortage of the geriatrics faculty needed to train the entire workforce. Title VII Geriatrics Health Professions programs are the only federal programs that increase the number of faculty with geriatrics expertise in a variety of disciplines and offer critically important geriatrics training to the entire healthcare workforce. Title VIII Geriatrics Nursing Workforce Development Programs are the primary

[1] http://www.iom.edu/Reports/2008/Retooling-for-an-Aging-America-Building-the-Health-Care-Workforce.aspx
[2] C.A. McDonald, "Recruitment, Retention and Recognition of Frontline Workers in Long-Term Care," Generations: Journal of the American Society on Aging (Fall1994), Vol. XVIII. No 3.
[3] Paraprofessional Healthcare Institute, Direct-care Health Workers: The Unnecessary Crisis in Long-Term. The Aspen Institute, January 2001.

source of federal funding for advanced education nursing, workforce diversity, nursing faculty loan programs, nurse education, practice and retention, comprehensive geriatric education, loan repayment, and scholarship.

The $6 million investment by the Administration for "provider education and outreach" will barely scratch the surface in addressing shortages in geriatric workforce and training outlined in actions under Strategy 2.A. Much more substantial investment is needed to fund the recommendations by IOM and we suggest that HHS revisit that report and the three others that came before it.

Even if more students enter geriatrics training, incentivizing them to stay will require loan forgiveness options. Senator Barbara Boxer (D-CA) introduced S. 1095, the "Caring for an Aging America Act" that would amend the National Health Service Corps (NHSC) requirements to add geriatrics and gerontology to the permanent eligibility. This small change in the language governing eligibility for NHSC loans would mean that geriatrics and gerontology specialists would always be eligible for NHSC loans as opposed to the current situation which is that these geriatrics and gerontology specialists can only participate in the program if the HHS Secretary so designates it. An additional advantage is that the loan forgiveness would be fully funded through the NHSC.

By 2030, our nation will require 3.5 million additional healthcare professionals and direct-care workers to fulfill the growing demand for care. The National Health Care Workforce Commission, established by the Affordable Care Act, will play a central role in formulating a national strategy for bolstering the healthcare workforce in order to meet the needs of the escalating number of older Americans. There is no mention of the commission in Strategy 2A.

Action 2.B.1: Link the public to diagnostic and treatment services

We are concerned that the use of warning signs to promote early detection by providers and patients may create confusion in the public. Warning signs for Alzheimer's disease have not been validated and are not promoted as screening instruments; however, concern has been raised that individuals experiencing cognitive deficits and their families may treat warning sign lists as a screening tool.[4] Although warning signs are publicized by several national organizations for educational purposes, they are not a substitute for a structured screening or consultation with a primary care provider. Further, the utility of these warning signs is questionable since the individuals in whom these problems are first noticed are frequently well into a dementia course. In addition:

- Most of the warning signs may be indicative of a number of other health issues, including everything from depression (changes in mood/personality) to transient ischemic attack (problems with language/disorientation). There is often no mention that these warning signs may indicate other conditions.
- By the time any one or more of the warning signs presents the individual may be in the early moderate/moderate stage at best so "early detection" is a misnomer.
- Warning signs may be useful in raising public awareness about Alzheimer's disease. However, elevating warning signs to an early detection tool and then placing the onus of recognition on those with the illness and their loved ones is not sound policy—especially given that anosognosia (unawareness of a problem of cognition in oneself, usually to the point of vigorously denying the problem) is a common symptom for individuals with the disease.

[4] Solomon PR, Murphy CA. Should we screen for Alzheimer's disease? A review of the evidence for and against screening for Alzheimer's disease in primary care practice. Geriatrics. 2005, 60(Nov): 26-31.

- Moreover, promoting the use of warning signs among individuals and family caregivers may serve as a disincentive to providers to learn more about proper, proactive detection methods.

Action 3.D.2: Monitor, report and reduce inappropriate use of anti-psychotics in nursing homes

Behavioral issues are a main reason that psychoactive medications are administered in long-term care settings, which may result in increased falls, increased mortality and increased confusion. There has been increased focus on the use of "atypical" antipsychotic medications in particular, after FDA introduced its black box warning in 2005 and for "conventional" antipsychotics in 2008 for patients with dementia.[5]

In May 2011 the HHS Office of the Inspector General released a report Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents," which found that over a six month period from January-June 2007, 51 percent of Medicare claims for atypical antipsychotic drugs were erroneous, amounting to $116 million.[6] The report found that over 726,000 of the 1.4 million atypical antipsychotic drug claims for elderly nursing home residents did not comply with Medicare reimbursement criteria. The claimed drugs were either not used for medically accepted indications as supported by the compendia or not documented as having been administered to the elderly nursing home residents. The OIG report concludes "We suggest that CMS either use its existing authority or seek new statutory authority to *prevent payment* [emphasis added] and hold nursing homes responsible for submitting claims for drugs that are not administered according to CMS's standards regarding unnecessary drug use in nursing homes."

The two main reasons for overuse of antipsychotics in nursing home residents with dementia are 1) understaffing and 2) lack of training. Required staff ratios have been suggested for years by nursing home advocates but Congress is reluctant to touch the issue. Training was somewhat addressed in the Affordable Care Act as part of the Nursing Home Transparency provisions, but the training section only applies to nursing assistants—not supervisors. Dementia training for nursing home staff should apply to nursing supervisors as well as assistants.

What makes the issue even more complicated is that there is valid use for antipsychotics in the treatment of dementia-related psychosis. A September 2011 report, a comparative effectiveness review prepared for AHRQ's Effective Health Care Program by the Southern California Evidence-based Practice Center, based at the RAND Corporation, found statistically significant evidence for risperidone, olanzapine, and quetiapine, for the off-label indications of dementia.[7]

There are provisions in the Nursing Home Reform Law, enacted in 1987, that clearly define appropriate use of psychoactive drugs, circumstances when antipsychotic drugs should be limited and provides for review of a patients drug regimen. CMS guidance to surveyors in the State Operations Manual[8]also encourages facilities to use non-pharmacological alternatives, identifies situations where antipsychotic medications are not indicated,[9] and provides an investigative protocol for unnecessary

[5] http://www.webmd.com/alzheimers/news/20080616/antipsychotics-for-dementia-up-death-risk
[6] http://oig.hhs.gov/oei/reports/oei-07-08-00150.asp.
[7] http://www.effectivehealthcare.ahrq.gov/ehc/products/150/786/CER43_Off-LabelAntipsychotics_execsumm_20110928.pdf.
[8] State Operations Manual, Appendix PP,https://cms.gov/manuals/Downloads/som107ap_pp_guidelines_ltcf.pdf (scroll down to page 344 for the beginning of guidance for §483.25(l).
[9] *Id.* 386 ("1) wandering; 2) poor self-care; 3)restlessness; 4) impaired memory; 5) mild anxiety; 6) insomnia; 7) unsociability; 8) inattention or indifference to surroundings; 9) fidgeting; 10) nervousness; 11) uncooperativeness; or 12)

drugs, including antipsychotic drugs. Despite these strong provisions antipsychotic drug use remains a serious concern, in part because the law, regulations, and surveyor guidance are inadequately and ineffectively enforced. Stronger enforcement of these standards would make an enormous difference.

Conclusion

As HHS considers ways to strengthen its National Plan to Address Alzheimer's Disease, the Alliance looks forward to working with you. Thank you for considering our views, and please do not hesitate to contact Alliance for Aging Research Director of Public Policy Cynthia Bens at cbens@agingresearch.org or (202) 293-2856 if you have any questions or would like additional information.

Sincerely,

Susan Peschin, MHS
Chief Operating Officer

Cynthia Bens
Director of Public Policy

verbal expressions or behavior that are not due to the conditions listed under 'indications' and do not represent a danger to the resident or others").