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Room 424E, Humphrey Building
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February 8, 2012

Re: Alzheimer's Association comments on the Draft Framework for the National Plan to Address Alzheimer's Disease

Dear Dr. Lamont,

Thank you for the opportunity to comment on the U.S. Department of Health and Human Services "Draft Framework for the National Plan to Address Alzheimer's Disease." The Alzheimer's Association is the leading voluntary health organization in Alzheimer's care, support and research. Today, there are an estimated 5.4 million Americans with Alzheimer's disease and almost 15 million unpaid caregivers. Alzheimer's is the 6th leading cause of death and the only cause of death among the top ten in America without a way to prevent, cure, or even slow its progression. Caring for people with this heartbreaking disease cost Medicare and Medicaid an estimated $130 billion last year.

Barring the development of medical breakthroughs to prevent or treat the disease, the future will be even bleaker. By 2050, as many as 16 million Americans will have the disease, and the cost of care will surpass $1 trillion annually (in today's dollars). However, if through the National Plan the federal government makes a meaningful commitment to finding a treatment and cure, the long-term payoff will be substantial. For example, a treatment that delayed onset of the disease by five years, similar to the effect of anti-cholesterol drugs on preventing heart disease, would cut government spending on caring for those with Alzheimer's by nearly half in 2050. This is both the challenge and promise of the National Alzheimer's Project Act and the development of a National Plan to Address Alzheimer's Disease.

Alzheimer's cannot wait. Individuals living with this devastating disease and their families cannot wait. Strengthening the financial underpinnings of Medicare and Medicaid cannot wait. We are at a critical moment – a strategic plan is within our grasp. The Draft Framework sets that plan in motion. But while this framework is extensive in scope, there are a number of items that need to be addressed. Those items are raised in this letter.

Having reviewed this Draft Framework, however, the leading comment of the Alzheimer's Association is that the Draft Framework should be adjusted to facilitate the Department's incorporation of the recommendations of the three Advisory Council subcommittees, as presented at the January 17, 2012 Advisory Council meeting, into the National Alzheimer's Plan. These recommendations represent a bold, transformative, and comprehensive way to address the Alzheimer's crisis – exactly what is needed in a National Alzheimer's Plan.

General Comments

We believe the firm deadline of 2025 in this initial framework is bold and transformative. While intermediary milestones may be needed, the Department is to be commended for including, for the first time, a clear, accountable goal for the availability of urgently needed treatment advances.

Second, the draft includes often neglected, but important, issues such as public health surveillance and comprehensive data collection, which are crucial to understanding the burden of the disease and assessing ways to reduce its impact.

Third, there is a strong section on expanding and strengthening the health care workforce. Without an adequate number of health care providers who are properly trained, individuals living with Alzheimer's will not have access to coordinated, quality care in all health care settings, including acute care, long-term care, and home care settings.

These are three leading examples of the Draft Framework's many strengths. However, before a draft plan is released, several gaps must be addressed to fulfill the promise of a comprehensive and bold National Alzheimer's Plan. The largest omissions in the Draft Framework are a clear call for adequate and sustainable funding for Alzheimer's disease research, and for the resources required to implement the national plan. A strategy without funds to implement it or resources to drive research breakthroughs will not achieve the goals laid out in the Draft Framework by 2025.

Another shortcoming is that there is little mention of the Food and Drug Administration (FDA) beyond general references to increasing clinical trial participation and expediting the development and use of biomarkers, and there is no mention of ways to spur development of treatments or other regulatory science efforts. The draft plan must create opportunities for multi-sector partnerships to stimulate new ideas and innovations, and the FDA must play a pivotal role in the development and translation of these new treatments.

A final overarching weakness in the Draft Framework is the limited emphasis on educating affected individuals, their families, and their caregivers about Alzheimer's. The importance of understanding Alzheimer's disease, particularly in context of other health conditions, should be emphasized, as should educating individuals and their families about the support services available to them and the need for advance planning. Similarly, there is no mention of how to improve documentation of a diagnosis, which is crucial to enabling care coordination among health care providers. A formal and documented diagnosis allows individuals to participate in their own care planning, better manage other chronic conditions, participate in clinical trials, and ultimately alleviate the burden on themselves and their loved ones.

Specific Comments

Following are specific comments on the various proposed goals and strategies as outlined in the Draft Framework.

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

As previously stated, establishing a firm deadline of 2025 is bold and transformative. However, there is no mention of funding for Alzheimer's research or what will be required to implement the National Alzheimer's Plan. Without this commitment to adequate research funding, 2025 risks appearing more a hope than a goal.

Strategy 1.A: Identify Research Priorities and Milestones

The Alzheimer's Association believes that Alzheimer's research needs to be a goal of the entire National Institutes of Health (NIH), not just the National Institute on Aging (NIA). NIA is underfunded, so prioritizing funding within NIA does not hold the potential to sufficiently elevate Alzheimer's research. Making Alzheimer's research a priority of the entire NIH is also important to help ensure coordination among the 27 Institutes and Centers, 23 of which are currently funding Alzheimer's research.

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

The phrase "…will continue to aggressively conduct clinical trials…" should be characterized relative to the scale of the crisis and, by that measure, we strongly disagree that current levels warrant a description of "aggressive" – aggressive is what we *need*, not what we *have*.

When examining how to manage and treat symptoms of Alzheimer's, research should be more closely linked to quality measures. Moreover, novel ways to conduct and encourage prevention trials and trials on agents that are not patentable should be included. This strategy must also address information protection, patents, and technology transfer in academic institutions.

Other than increasing clinical trial participation or expediting the development and use of biomarkers, the Draft Framework does not mention the FDA. FDA is a critical piece to the puzzle and is a necessary player in addressing ways to provide incentives that spur development of treatments or other regulatory science efforts, including biomarkers and critical scientific methods and tools.

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

With regard to advances in imaging and other technologies that may enable an earlier diagnosis of Alzheimer's disease in clinical settings, the coverage determinations and reimbursement hurdles associated with accessing these new technologies are not addressed in the Draft Framework. In addition, longitudinal trials, which were explicitly endorsed during the 2010 NIH State of the Science Conference, are not addressed but should be in the Draft Framework.

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

The Secretary of Health and Human Services, the Secretary of Veterans Affairs, and the Secretary of Defense should work together to reduce barriers to working with private entities on agreed upon national strategic goals in Alzheimer's research. The federal government must increase its engagement with the private sector to move science forward as quickly as possible. Public-private partnerships present a key opportunity to leverage both public and private resources in this scarce fiscal environment. Government funders of Alzheimer's science should make available contracts, grants, or cooperative agreements to facilitate new and innovative partnerships between public and private entities, which may include private or public research institutions, institutions of higher education, medical centers, biotechnology companies, pharmaceutical companies, disease advocacy organizations, patient advocacy organizations, or academic research institutions.

We believe that effectively achieving this strategy requires a single, dedicated individual or office to oversee and manage this coordination, particularly internationally. This office could also be charged with coordinating all Alzheimer's-related efforts across the federal government, including care and support, thereby fulfilling the charge of the National Alzheimer's Project Act to ensure "coordination of Alzheimer's research and services across all Federal agencies."

Goal 2: Enhance Care Quality and Efficiency

Strategy 2.A: Build a Workforce with the Skills to Provide High-Quality Care

We strongly support a robust and well-educated workforce as an essential component to providing high-quality care to those with Alzheimer's disease. An adequate number of health care providers who are properly trained will help ensure that people with Alzheimer's disease have access to coordinated, quality care and will ultimately drive us toward a dementia-capable health care system. Funding and incentives for individuals interested in pursuing careers in geriatric specialties should be expanded.

Strategy 2.B: Ensure Timely and Accurate Diagnosis
To diagnose an individual with Alzheimer's disease, cognitive impairment must first be detected in a clinical setting. The Medicare Annual Wellness Visit will help on this front, but we recommend including a strategy on enhancing detection separate from the strategy for diagnosis. While the Draft Framework refers to some of the issues involved in detecting cognitive impairment – namely, assessment tools – we believe it is a mistake to conflate the issues of detection and diagnosis in a single strategy. And, in fact, this strategy could be read as confusing the distinct processes of detection and diagnostic evaluation for Alzheimer's disease.

Furthermore, the strategy is silent on educating health care professionals, particularly physicians, on the value of an early diagnosis. Too often, many physicians do not see or understand the value of an early diagnosis and therefore fail to diagnose and/or document Alzheimer's disease. Even among willing physicians, their lack of training in the use of assessment tools and methods to encourage follow-up often delay detection of cognitive impairment and further diagnostic evaluations.

Strategy 2.C: Educate and Support Patients and Families Upon Diagnosis
The education component within this strategy appears limited. CMS should issue guidance to providers outlining information that should be discussed after a diagnosis, including referrals to existing community supports and services. It is also important that patient education emphasize the importance of understanding Alzheimer's disease in the context of other health conditions. Moreover, family consultation with appropriately-trained health care professionals should be provided and reimbursed under Medicare, even when the patient is not present, so families do not feel abandoned after a diagnosis.

Strategy 2.D: Identify and Implement High-Quality Dementia Care Guidelines and Measures Across Care Settings
We believe this strategy is vitally important, particularly with regard to the measurement of quality indicators. Once appropriate quality indicators are identified and validated, efforts should be undertaken to integrate them into the health care system.

Strategy 2.E: Ensure that People with Alzheimer's Disease Experience Safe and Effective Transitions Between Care Settings and Systems
There is no mention of the use of electronic medical records or the importance of making sure a diagnosis is actually included in a medical record. This is especially important for safe and effective care transitions. Prior to any care transition, an individual should have a documented diagnosis in his or her medical record, as well as a list of relevant medications. In addition, acute care settings should implement Alzheimer's disease training for all health care practitioners.

Strategy 2.F: Advance Coordinated and Integrated Health and Long-Term Care Services and Supports for Individuals Living with Alzheimer's Disease
Alzheimer's disease is progressive and terminal and therefore general research on care coordination may not address the unique needs of individuals with Alzheimer's disease or their caregivers. Additional research should be conducted specifically on care coordination for this population.

Strategy 2.G: Improve Care for Populations Disproportionally Affected by Alzheimer's Disease
A National Plan must identify the specific action steps to be undertaken to improve the care of those disproportionately affected by Alzheimer's disease. We appreciate the acknowledgement that people with younger-onset Alzheimer's disease, racial and ethnic minorities, and people with intellectual disabilities are disproportionally burdened by Alzheimer's and related dementias. However, we are looking forward to reviewing specific plans that will meaningfully address the challenges faced by these populations.

Goal 3: Expand Patient and Family Support

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

During the course of the Alzheimer's Association's public input sessions last summer, this was a consistent theme, and we commend its inclusion in the Draft Framework. A National Alzheimer's Plan provides a unique and important opportunity to widely deploy effective, evidenced-based strategies to help family caregivers.

Strategy 3.C: Assist Families in Planning for Future Long-Term Care Needs

The intent of this strategy is unclear. If the goal is to encourage the purchase of long-term care insurance – or at least educate families about the option of long-term care insurance – it is important to realize that the private long-term care insurance market presents particular challenges to those with Alzheimer's disease. It may not be a viable option, and families should be made aware of the potential issues.

In addition, while planning for long-term care is important, there are other future needs for which a diagnosed individual needs to plan – planning regarding finances, driving and safety, advance directives, and end-of-life care. The Draft Framework should refer to the importance of advance planning education once someone receives an Alzheimer's diagnosis.

Strategy 3.D: Maintain the Dignity, Safety, and Rights of People with Alzheimer's Disease

As indicated in Strategy 2A, all health care practitioners should have proper dementia training, which should help mitigate abuse. In addition to health care practitioners, training efforts should include first responders.

The National Plan must acknowledge the large number of individuals with Alzheimer's who live alone – many of whom do not even have an identifiable caregiver. In maintaining the dignity, safety, and rights of those with the disease, special attention must be given to this population. This includes the issue of self-neglect, which is not addressed in the Draft Framework.

State Adult Protective Services (APS) agencies are over-burdened and understaffed, resulting in a limited ability to provide any support except in the most dire circumstances. The Draft Framework does not address the need for additional resources for APS agencies so that they can adequately protect the safety and rights of individuals with Alzheimer's.

Goal 4: Enhance Public Awareness and Engagement

Strategy 4.A: Educate the Public about Alzheimer's Disease

As indicated in Strategy 2G, education campaigns must be language-specific and culturally appropriate.

Goal 5: Improve Data to Track Progress

Strategy 5.A: Enhance HHS' Ability to Track Progress

Obtaining a more definitive picture of Alzheimer's, cognitive impairment, and related caregiving burdens is essential to any successful strategy to combat the disease. Public health surveillance and comprehensive data collection will not only assist the federal government in addressing policy questions and planning new initiatives, they will provide the research, caregiving, and public health communities a better understanding of people with cognitive impairment and Alzheimer's, and identify opportunities for reducing the impact of the disease at all levels of government.

At a minimum, this should include state-by-state public health surveillance both on cognitive impairment and caregiver burden, preferably through the Behavioral Risk Factor Surveillance System, coordinated by the Centers for Disease Control and Prevention (CDC). Moreover, this strategy should also include improving existing federal surveys such as the Medical Expenditure Panel Survey and the National Health Interview Survey so that they more adequately capture information about those with Alzheimer's and other dementias.

Strategy 5.B: Monitor Progress on the National Plan

Although sometimes overlooked, improving data to track progress is critical, and we commend its inclusion in the Draft Framework. This critical information should be publically available, or at least available to the Advisory Council. In monitoring progress, it would be useful to have de-identified data that corresponds to the disease stage (early stage through end-of-life) to identify areas for improvement in care and services.

Conclusion

The Draft Framework provides a good foundation for a National Alzheimer's Plan. But much work needs to be done to fulfill the promise of a detailed National Alzheimer's Plan that is urgent, transformational, achievable and accountable. The recommendations listed above, combined with the recommendations of the Advisory Council subcommittees, would result in just such a National Alzheimer's Plan.

We appreciate the opportunity to comment on the Draft Framework for the National Plan to Address Alzheimer's Disease. Please contact us if you wish to discuss any of these issues further.

Sincerely,

Robert Egge
Vice President, Public Policy