Senate Special Committee on Aging

National Plan to Address Alzheimer's Disease

Are We On Track to 2025?

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Statement of

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Good afternoon, Chairman Nelson, Senator Collins and distinguished members of the Senate Special Committee on Aging. My name is Ronald C. Petersen, Ph.D., M.D., and I serve as the Chair of the Advisory Council on Research, Care and Services for the National Alzheimer's Project Act. I am also a Professor of Neurology and Director of the Mayo Alzheimer's Disease Research Center at the Mayo Clinic in Rochester, Minnesota.

The first United States National Plan to Address Alzheimer's Disease was released in May of 2012, and it represents a major step forward toward accomplishing the primary goal of the Plan to prevent and effectively treat Alzheimer's disease by 2025. My colleague, Dr. Donald Moulds, has nicely outlined the structure of the Plan and the accomplishments by the federal government to this point. I would like to expand upon the terminology issue that Dr. Moulds mentioned. While we are discussing primarily Alzheimer's disease, this discussion also pertains to other forms of dementia such as frontotemporal degeneration, dementia with Lewy bodies and vascular cognitive impairment. Dementia is an umbrella term referring to a change in thinking abilities that impacts daily function, and there are several causes or types of dementia of which Alzheimer's disease is the most common in older persons. In response to the National Plan, the National Institutes of Health will be holding an additional research summit on the related dementias in May of this year to complement the summit held last year on Alzheimer's disease. It is important to keep in mind that we are discussing a group of conditions that have similar effects but different pathologies. With this as a preamble, I would like to provide some additional comments from the Advisory Council.

Advisory Council Recommendations

The National Alzheimer's Project Act charged the Secretary of Health and Human Services with developing a National Plan for Alzheimer's disease. In addition, the law charged the Advisory Council with generating recommendations for the Secretary and to Congress. The Advisory Council is comprised of 26 members, half of whom represent the various agencies in the federal government dealing with Alzheimer's disease and half are non-federal members representing care providers, caregivers, state agencies, voluntary health associations and researchers. The recommendations of the non-federal members of the Council set forth an ambitious blueprint for achieving the goal outlined in the National Plan by 2025. The National Plan itself is somewhat constrained by the current resources available to the federal government, but the recommendations from the Advisory Council were not constrained in any fashion.

I would like to outline a few of the more salient recommendations for your consideration. The goal of the National Plan is to effectively treat Alzheimer's disease by 2025; to achieve that we must be able to identify the disease process in its nascent stages. This will enable effective treatments to be used early and achieve greater success at preventing the subsequent damage to the brain. However, we must ensure that the millions of people and families who are currently facing this disease have the resources and supports they need to carry on until a treatment is developed.

Research Funding for Alzheimer's Disease

The research community is poised to make key contributions, however, insufficient resources are impeding progress towards overcoming this disease. Therefore, the Advisory Council states that: *"There is as an urgent need for annual federal research funding to be increased to the level needed to fund a strategic research plan and to achieve the breakthroughs required to meet the 2025 goal. Initial* *estimates of that level are $2billion per year but may be more."* Other research endeavors funded by the National Institutes of Health (NIH) are of similar or greater magnitude. Currently, NIH spends approximately $6 billion on cancer research, $3billion on HIV/AIDS research and a little over $2 billion for cardiovascular disease research on an annual basis. At present, the federal budget for Alzheimer's disease research is less than $ 0.5 billion per year. Yet Alzheimer's disease may be the defining disease of our generation. In order to keep it from defining the next generation, it is incumbent upon us to make the appropriate investments now to enable the research community to carry out effective studies to halt this disease.

Have the investments in research on cancer, heart disease and HIV/AIDS been effective? The numbers of deaths that occur annually due to some cancers, heart disease, HIV/AIDS have been steadily *decreasing* in recent years. However, the deaths due to Alzheimer's disease are skyrocketing in the opposite direction in a very dramatic fashion. As such, we do not have the luxury to wait for a more convenient time to initiate funding increases for Alzheimer's disease. As Dr. Hurd will comment in a few moments, the amount to be saved by intervening early in the disease process will more than adequately recoup the investment in research. However, it takes the foresight on the part of Congress to make these bold steps now at a very difficult time.

Will augmentation to the budget for research in Alzheimer's disease be utilized immediately? As Dr. Moulds mentioned, the President directed a repurposing of funds from the FY 2012 budget to Alzheimer's research and under the direction of Dr. Francis Collins and Dr. Richard Hodes at the NIH, two new treatment trials for Alzheimer's disease were quickly launched. The research community has the innovative ideas and is poised to take the next crucial steps, but we need funding to do so.

Therapeutic Pipeline

Another recommendation from the Advisory Council pertains to the compression of the therapeutic pipeline, or shortening the extended period of time, often over 10 years, it takes from the discovery of a molecule to the production of a drug for treatment. This is a challenging disease and there are many therapeutic failures throughout the pipeline, but that does not mean that we will not get there. The time to development of a treatment is painfully long and this is a disincentive to those investing in these types of therapies. It is even more frustrating to patients and families. As such, the Advisory Council has recommended that the research community, in conjunction with the Food and Drug Administration, develop a plan to reduce the timeline needed to develop drugs and get them approved.

National Plan

Along that same theme, the Advisory Council realizes that this is a National Plan and not a federal plan. As such, we need to invoke the assistance of many private partners to come together to develop a therapeutic approach for this disease. We need the cooperation of the for-profit and not-for-profit private sector entities to align with the federal government and academia to accomplish these goals. Several conferences to promote this type of collaboration have been conducted and are being planned to address this issue.

Global Disease

We also realize that Alzheimer's disease is not unique to the United States. It is a global disease and we have a great deal both to learn from and to share with the other countries that have developed national plans prior to ours. The Advisory Council has recommended that global partnerships be established. HHS, in partnership with the Alzheimer's Association, will be convening international meetings to promote best practices with respect to investigating therapies and developing care plans for patients and families with Alzheimer's disease.

Need for Geriatricians

With the aging of America, we realize that the frontline of evaluation for individuals with early-stage Alzheimer's disease will likely be primary care practitioners. As such, the Advisory Council has recommended the development of a unified curriculum for primary care practitioners to become more knowledgeable about Alzheimer's disease and other dementias to enhance the skills necessary to deliver dementia-capable care. Training programs need to be incentivized to enhance the likelihood that individuals will pursue careers in geriatric specialties. In addition, curricula designed for caring for individuals with Alzheimer's disease need to be developed at all levels of care, including physician's assistants, nurses, allied health workers in skilled nursing facilities, and emergency department personnel, to ensure uniform practices are undertaken for those afflicted with the disease.

State Involvement

The Advisory Council has made several recommendations pertaining to the involvement of states in the delivery of care for individuals with Alzheimer's disease. The Council recommended that HHS provide federal funds to support a state-lead entity in every state and territory. This entity would facilitate development of the states' dementia-capable systems and coordinate available public and private services for the care of individuals with Alzheimer's disease. Ultimately, many functions including the coordination of public and private programs and the elimination of duplication of services must be delivered at the state level to achieve a meaningful impact on individuals with the disease.

Implications for Medicare

Physicians and other healthcare providers' reimbursement will need to be considered during deliberations about the redesign of the Medicare coverage system. Appropriate compensation is necessary to encourage appropriate diagnosis of Alzheimer's disease and provide care planning to those diagnosed and their caregivers. At present, the task of designing a care plan for individuals with Alzheimer's disease is tedious and time consuming, but absolutely necessary. However, while they are paid for seeing the patient, providers are not adequately compensated for the time it takes to work with the patient, family, and other providers to create an effective plan. There needs to be an appropriate emphasis and consideration for the primary care individuals who will be responsible for diagnosing and treating these individuals.

Caregiver Programs

The Advisory Council also recommended full funding of caregiver support under the Administration on Aging (AoA) in the Administration for Community living. Currently, AoA's National Family Caregiver Support Program is dramatically underfunded and therefore unable to meet the needs of the growing population of caregivers. Increased funding for this program will mitigate other costs in the system and is another example of a prudent investment now that will more than pay for itself in the near future.

Challenging but Tractable Problem

We believe that it will be possible to treat and ultimately prevent Alzheimer's disease and that the 2025 goal set forth in the Plan is ambitious but realistic. However, the current pace of research and recommendations for improvement in care in Alzheimer's disease need to be accelerated. For example, at the Mayo Clinic we have a translational research program designed to understand the disease at the basic biological level and translate this into patient care. Our research includes work to identify the disease process at its earliest point. In the Mayo Clinic Study of Aging, we are evaluating a random sample of people ages 50 to 89 years without dementia living in our community to construct a risk profile for the development of the disease. This formula will include factors such as age, sex, family history, genetic attributes and biomarkers for the disease. Why would you want to do this? We believe that when, not if, an effective therapy is developed, the sooner we intervene the more likely cognition and functional activities will be preserved. Ideally, we would like to intervene in people when they are normal but harbor the biological predisposition to developing the disease. This profile will help us identify those most at risk so we can effectively target treatments when they are developed. Analogous work has been accomplished in cardiovascular disease, and it has led to a reduction in annual mortality, and a similar effort for Alzheimer's disease would have enormous public health implications for the country.

I would like to close by thanking the Congress and the President for initial steps at increasing funding for Alzheimer's disease research. As Dr. Moulds mentioned, the initial redirection of funds in the fiscal 2012 budget have resulted in two large clinical trials being launched for the treatment and, ultimately, the prevention of the disease. These are the types of steps that can be translated very rapidly into reality with the infusion of additional resources.

While we all recognize that these are very difficult times for the federal budget, this is an issue that cannot wait. We do not have the luxury of waiting until it is more convenient to augment funding for Alzheimer's disease research. Our patients and families cannot wait. All of the economic models agree that this is perhaps the most costly disease from both a personal and economic perspective, and making the difficult decisions now will reward us all enormously in the future. With the aging of the baby boomers, who are turning 65 at approximately 10,000 persons per day, it is easy to see why this will be the defining disease of our generation. It will swamp all other diseases and be the single most salient condition of aging. It is likely that everyone in this room has been, or will be, impacted by this disease in one form or another, and it is our obligation to do everything we can to be certain our children will not have to face the same situation. It will take a few courageous people, likely on this committee, to make the bold statements necessary to make it possible to for us to achieve the goal of the National Plan to Address Alzheimer's Disease: to prevent and effectively treat Alzheimer's disease by 2025. Thank you for the opportunity to represent the Advisory Council.