

**THE NATIONAL PLAN TO ADDRESS ALZHEIMER'S
DISEASE: ARE WE ON TRACK TO 2025?**

HEARING
BEFORE THE
SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE
ONE HUNDRED THIRTEENTH CONGRESS

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WEDNESDAY, APRIL 24, 2013

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The Committee met, pursuant to notice, at 2:11 p.m., in Room 106, Dirksen Senate Office Building, Hon. Bill Nelson, Chairman of the Committee, presiding.

Present: Senators Nelson, Whitehouse, Manchin, Blumenthal, Donnelly, Collins, and Ayotte.

OPENING STATEMENT OF SENATOR BILL NELSON, CHAIRMAN

The CHAIRMAN. Good afternoon. We are going to do things a little bit different here today. Ms. Campbell, if you would come on up, after the opening statements, in order to accommodate the Campbells' schedule, we will have them testify first and answer questions so that they can get on to the airport. I certainly hope you are not experiencing a lot of the delays at the airport like everybody else is.

I want to really thank everybody for being here and this show of support and the enthusiasm that has been generated and for all of the purple that is displayed today, we want you to know how much we appreciate it.

I want to turn to our Ranking Member, Senator Collins, for her to make the opening statement.

OPENING STATEMENT OF SENATOR SUSAN M. COLLINS

Senator COLLINS. Mr. Chairman, first of all, I cannot tell you how grateful I am that you have called this very important hearing to examine the enormous toll that Alzheimer's disease is taking on our nation and to assess the progress since the enactment of the National Alzheimer's Project Act in 2011. Along with former Senator Evan Bayh, I am proud to have been the sponsor of that law, known as NAPA.

Alzheimer's is a terrible disease that exacts a tremendous personal and economic toll on both the individual and the family. As someone whose family has experienced the pain of Alzheimer's time and time again, I know there is no more helpless feeling than to watch the progression of this devastating disease. It is an agonizing experience to look into the eyes of a loved one and receive only a confused look in return. It is equally painful to witness the emo-

tional and physical damage inflicted on many family caregivers, exhausted by an endless series of 36-hour days.

And my family is by no means alone. An estimated 5.2 million Americans have Alzheimer's, more than double the number in 1980. Based on the current trajectory, as many as 16 million Americans over the age of 65 will have Alzheimer's disease by the year 2050.

Moreover, in addition to the human suffering it causes, Alzheimer's costs the United States more than \$200 billion a year, including \$142 billion in costs to Medicare and Medicaid. This price tag will increase exponentially as the baby boom generation ages. If nothing is done to stop or slow this disease, Alzheimer's will cost the United States an astonishing \$20 trillion over the next 40 years, according to the Alzheimer's Association.

It is estimated that nearly one in two of the baby boomers reaching 85 will develop Alzheimer's. As a consequence, chances are that the members of the baby boom generation will either be spending their/our golden years with Alzheimer's or caring for someone dear to them who has it. In many ways, Alzheimer's has become the defining disease of my generation.

A strong and sustained research effort is our best tool to slow the progression and ultimately prevent the onset of this disease. If we fail to change the current trajectory of Alzheimer's disease, our country will face not only a mounting national health care crisis, but an economic one, as well.

Despite all the alarming statistics, until now, there has been no national strategy to defeat Alzheimer's and our efforts to combat the disease have lacked coordination and focus, and that is why the National Alzheimer's Project Act, or NAPA, creates a strategic National Plan for combating Alzheimer's. This National Plan, which will be updated annually, will help us focus our efforts and accelerate our progress toward better treatments, a means of prevention, and ultimately even a cure.

The annual review process required by the law is intended to help us answer an important straightforward question: Have we made satisfactory progress this year in the fight against Alzheimer's? And that is why we are here today and why I am so grateful to our Chairman.

The primary goal of this hearing is to assess the progress that we are making. The goal of the National Plan to Address Alzheimer's Disease, the plan which was released last May, was to, quote, "prevent and effectively treat Alzheimer's disease by the year 2025." It is my understanding that the next version of the National Plan will be released next month. So this is the perfect time for a progress check. I personally am convinced that we need to more than double the amount of money that we are investing in Alzheimer's research in order to achieve significant progress.

I want to thank all of our witnesses who are here today, but particularly Glen Campbell and his family. It was wonderful to hear him play many of my favorite songs. His guitar skills are second to none and he still has that wonderful voice. And it was wonderful to be honored to meet him, his wife, and daughter. And I am also grateful to the other experts who have joined us today. Issues re-

lated to Alzheimer's clearly are near and dear to my heart and I look forward to hearing from our witnesses.

Thank you, Mr. Chairman.

The CHAIRMAN. Well, and Senator Collins, thank you for all your hard work in this area.

It is shocking that, today, one in three seniors will die with Alzheimer's. And as the baby boomers age, this fact is going to confront us all the more. You take a State like mine, Florida, where we have a higher percentage of the population is elderly, it all the more will be accentuated.

And we have got places all over the country that are working on this disease. Senator Collins and I want to focus in on this today, and we want to give some additional heft and lift to what all of you out there are doing.

Now, today, there are over 900 of you fanning out across Capitol Hill and we are very grateful for your tireless efforts on behalf of this issue. And for the Alzheimer's Association, including former Congressman Dennis Moore, we are grateful for all of you being here today.

Now, I said we are going to do this differently to accommodate the Campbell family so they can get to the airport. So, first, we are going to hear from Ms. Ashley Campbell, the daughter of Glen and Kim. She is a recent graduate of Pepperdine. Her father is a five-time Grammy winning country singer. During his 50 years of show business, he has recorded some of the most beloved songs of his generation: "Gentle on My Mind," "Rhinstone Cowboy," more than 70 albums. And he has won numerous accolades for his music: The Academy of Country Music's Entertainer of the Year Award, three Grammy Hall of Fame Awards, and a Grammy Lifetime Achievement Award. He was also inducted into the Country Music Hall of Fame in 2005.

A couple of years ago, Mr. Campbell was diagnosed with Alzheimer's. Mr. Campbell, with his wife, Kim, who is with us, and his children, Ashley, Cal, and Shannon, have decided to face his illness head on. And so we want to hear from Ms. Ashley Campbell first.

STATEMENT OF ASHLEY CAMPBELL, ON BEHALF OF GLEN CAMPBELL AND FAMILY

Ms. CAMPBELL. Thank you, Chairman Nelson and Senator Collins and members of the committee for the opportunity to testify today, and thank you for holding this hearing on Alzheimer's disease and the National Plan.

Before my dad was diagnosed, I did not realize what a serious disease Alzheimer's is or how many people were affected by it. Over the past few years, here is some of what I have learned.

Over five million Americans are living with Alzheimer's today. As many as 16 million will have Alzheimer's disease by 2050. This year, our country will spend \$203 billion in direct costs for those with Alzheimer's, including \$142 billion in government costs to Medicare and Medicaid. Those costs are expected to exceed \$1.2 trillion by 2050. In fact, a recent study in the New England Journal of Medicine confirmed that Alzheimer's is the most expensive disease in America.

Because the costs are set to skyrocket and so much of this is paid by government, overcoming Alzheimer's is the key to fixing the country's growing fiscal challenges. For example, if a new medicine was developed to delay the onset of the disease by just five years, we could cut government Alzheimer's costs nearly in half by 2050, if only we fund the research needed to get there.

What all of these numbers cannot tell you is the cost of the disease to the families. Since we announced that my dad has Alzheimer's, perfect strangers have been coming up to me and crying to tell me about Alzheimer's in their family. In fact, there are a thousand advocates on Capitol Hill today, hundreds in this hearing room now, who have been touched by Alzheimer's, and I have been honored to hear many of their stories, and today, I am honored to share my family's story with you.

In June of 2011, my dad announced that he had been diagnosed with Alzheimer's disease. I was 24 years old at the time. I met a young man last night who was in sixth grade when he heard his father was diagnosed, and a little girl who could not have been more than 12 years old whose father just passed away from Alzheimer's. Dad thought it was important for people to know that you can keep doing what you love and that life does not end right away when you get Alzheimer's. It was also so important for my dad to take action and help spread the word about the need to find a cure for Alzheimer's.

Shortly after my dad's announcement, my brothers and I joined my dad for the Glen Campbell Goodbye Tour. My mom was by my dad's side, of course, and we were also joined by the filmmakers who are doing a documentary about my dad. For dad, music has been therapeutic, and being public about his diagnosis was really helpful, because he did not want people to get the wrong idea at concerts if something appeared to go wrong.

While there were a few challenges on stage during some of the shows, we always smoothed things out quickly. It helped to have my brothers and me on stage with him, and it helped to have such amazing support from my dad's fans. And it helped that my dad has been playing and touring for so long that the stage for him feels like home. That is where he is most comfortable, I think.

One highlight of the Glen Campbell Goodbye Tour was playing at the Grammys last year and getting to meet Paul McCartney there. And another highlight was our visit to Capitol Hill last year. My family and I came to Washington, D.C., last May when the first National Alzheimer's Plan had just been released. We spent a few days meeting with members of Congress to ask for funding for the plan. We also played a special performance for members of Congress during a briefing put on by the Alzheimer's Association. I was so grateful to see Senators and Representatives singing along with dad and to know that they were fighting to end this terrible disease.

Dad has been really committed to this fight, and we all have, and we are committed to doing more about it, which is why we are here today.

Senators, there is something that my family and this whole community needs you to do. Congress passed a bill two years ago which resulted in the first ever National Alzheimer's Plan. The plan is

strong and so is its goal to prevent and effectively treat Alzheimer's by 2025. As our nation's leaders, I respectfully ask that you support the implementation of the National Alzheimer's Plan and that you fund the President's budget request of an additional \$100 million for Alzheimer's this year.

In my family, music was always a part of our home and we are still playing. We knew at the beginning that Alzheimer's does not rob you of the things you love right away, but the disease will keep getting worse and there are not any medications today that can stop it.

Alzheimer's is a disease that robs people of their lives while they are still living it, and it robs families of the people they love while they are still standing right in front of their eyes. I think a person's life is comprised of memories, and that is exactly what this disease takes away from you, like a memory of my dad taking me fishing in Flagstaff when I was a little girl, or playing banjo with my dad while he plays guitar. Now, when I play banjo with my dad, it is getting harder for him to follow along and it is getting harder for him to recall my name. It is hard to come to the realization that, someday, my dad might look at me and I will be absolutely nothing to him.

We need to find a cure for this because we are not the only family affected. So much pain should not exist in the world. Let us work together to end Alzheimer's. Thank you.

[The prepared statement of Ms. Campbell follows:]

Testimony of Ashley Campbell
Hearing on The National Plan to Address Alzheimer's Disease:
Are We On Track to 2025?

Special Committee on Aging
United States Senate

April 24, 2013

Mr. Chairman, Ranking Member Collins and members of the Committee, thank you for this opportunity to share with you how my family has been affected by Alzheimer's and the importance of the National Alzheimer's Plan. I would also like to thank the Special Committee on Aging for focusing on Alzheimer's, an escalating national epidemic. In my testimony today, I ask you to understand the human toll of this disease -- on my family and millions of others -- and I respectfully request that you support implementation of the National Alzheimer's Plan, including funding the President's FY 2014 budget request of an additional \$100 million for Alzheimer's.

My family's story

Two years ago my father, Glen Campbell, announced that he had been diagnosed with Alzheimer's disease. This diagnosis came after years of short-term memory loss.

For my dad and my family, talking about his diagnosis publicly was important. It is important for people to know that individuals with Alzheimer's can keep doing what they love -- that life doesn't end right away when you are diagnosed with Alzheimer's. It was also important for my dad to help spread the word about the need for more research to find a cure for Alzheimer's.

For my dad, music has been therapeutic. If he can put that guitar in his hands and use his fingers to pick music, he's much better. And, he's comfortable on stage -- sometimes more than if he's sitting at home or playing golf.

Shortly after my dad announced that he had Alzheimer's, my brothers and I joined my dad for the Glen Campbell Goodbye Tour. My mom was by Dad's side, of course, and we were also joined on tour by filmmakers who are doing a documentary about my dad.

For Dad, being public about his diagnosis was also helpful because he did not want people to get the wrong idea at concerts if something appeared to go awry. While there were a few challenges on stage during some of the shows, those were corrected and smoothed out quickly. His love to perform and play his music was always vibrant, even if at times the lyrics were tough to find or other elements on stage might momentarily frustrate him. It helped to have my brothers and me with him on stage, and it helped that my dad had been playing and touring for so long that the stage, for him, feels a lot like home.

As much as raising awareness of Alzheimer's was a driving force for my family, the response to the tour was phenomenal and heartwarming for all of us. People came out in droves and they totally supported my dad. My dad loved the crowds at the concerts -- and they kept on loving him right back. From the first night of the tour until the last, I couldn't get over how supportive people were of him.

One highlight of the Glen Campbell Goodbye Tour was the Grammy's and another was our visit to Capitol Hill last year. My family and I came to Washington, DC along with the documentary filmmakers and the Alzheimer's Association to meet with many Senators and Representatives. This was last May when the first-ever National Alzheimer's Plan had just been released, and we were meeting with members of Congress to ask that they please make sure there was funding for the Plan. While we were here, we also played a special performance for members of Congress at the Library of Congress during a briefing put on by the Alzheimer's Association. It was amazing to see Senators and Representatives sing along with Dad and to know that they were fighting along side my family to end this terrible disease.

State of the Disease

Before my family was affected, I didn't realize what a serious disease Alzheimer's is or how many people were affected by it. Frankly, it's still hard to imagine how huge this problem is in America and all over the world.

Since my Dad's diagnosis, I have spent time with community members, policy makers, researchers, and physicians. While I am an actor and musician, I am also a dedicated Alzheimer's advocate and I would like to share with you some of what I have learned.

Alzheimer's is a progressive and fatal brain disorder. Over five million Americans are living with Alzheimer's today, with 200,000 under the age of 65.

According to the Alzheimer's Association, our nation is estimated to spend \$203 billion in direct costs for those with Alzheimer's this year, including \$142 billion in costs to Medicare and Medicaid. Average per person Medicare costs for those with Alzheimer's and other dementias are three times higher than those without these conditions. Average per senior Medicaid spending is 19 times higher. A primary reason for these costs is that Alzheimer's makes treating other diseases more expensive, as most individuals with Alzheimer's have one or more co-morbidity that complicate the management of the condition(s) and increase costs. For example, a senior with diabetes and Alzheimer's costs Medicare 81 percent more than a senior who only has diabetes.¹

If nothing is done, as many as 16 million Americans will have Alzheimer's disease by 2050 and costs will exceed \$1.2 trillion dollars (not adjusted for inflation) - creating an enormous strain on the healthcare system, families and the federal budget. In fact, an NIH-funded study in the *New England Journal of Medicine* confirmed that Alzheimer's is the most costly disease in America, with costs set to skyrocket at unprecedented rates.²

Currently, Alzheimer's is the sixth leading cause of death in the United States and the only one of the top ten without a means to prevent, cure or slow its progression. That there are not any treatments to really change the course of the disease is still shocking to many families, including mine.

With Alzheimer's, it is not just those with the disease who suffer -- it is also their caregivers and families -- and the data here is just as startling. In 2012, 15.4 million family members and friends provided unpaid care

¹ Alzheimer's Association. 2013 Alzheimer's Disease Facts and Figures, *Alzheimer's & Dementia*, Volume 9, Issue 2

² Monetary Costs of Dementia in the United States, *New England Journal of Medicine* 2013; 368:1326-1334

valued at over \$216 billion. More than 60 percent of Alzheimer's and dementia caregivers rate the emotional stress of caregiving as high or very high, with one-third reporting symptoms of depression. Caregiving also has a negative impact on health, employment, income and finances for countless American families. Due to the physical and emotional toll of caregiving on their own health, Alzheimer's and dementia caregivers had \$9.1 billion in additional health costs in 2011.

Changing the Trajectory

Until recently, there was no federal government strategy to address this looming crisis. In 2010, thanks to bipartisan support in Congress, the National Alzheimer's Project Act (NAPA) (P.L. 111-375) passed unanimously. NAPA mandated the creation of a strategic national plan to address Alzheimer's disease.

On May 15, 2012, the U.S. Department of Health and Human Services (HHS) released the first-ever *National Plan to Address Alzheimer's Disease*. The Plan established goals and action steps in the areas of research, care, support and public awareness in order to prevent and effectively treat Alzheimer's disease by 2025.

The Plan has made some progress in the fight against Alzheimer's including:

- Created a blueprint for Alzheimer's research at the National Institutes of Health (NIH), a much needed first step in setting priorities for Alzheimer's research.
- Expedited Food and Drug Administration (FDA) approval of drugs for early-stage Alzheimer's.
- Developed quality measures for dementia care in nursing homes.
- Enhanced dementia training for healthcare professionals.
- Promoted resources for caregivers through the creation of www.alzheimers.gov.

What's Needed Next?

The first year of the *National Plan to Address Alzheimer's Disease (The Plan)* has seen some great steps towards changing the trajectory of Alzheimer's disease, but there is still much work to be done. For two years, the Advisory Council on Alzheimer's Research, Care and Support has recommended a rapid ramp up in Alzheimer's research to at least \$2 billion a year to take advantage of current scientific opportunities that will allow us to develop better treatments and prevention for Alzheimer's disease. In Fiscal Year 2014, NIH is expected to spend only \$484 million on Alzheimer's research. This level of funding is no where near the \$2 billion called for by the Council and it is fractions less than what our government is spending on Alzheimer's care. This means that for every \$29,000 Medicare and Medicaid spends caring for individuals with Alzheimer's, the NIH spends only \$100 on research to find treatments for Alzheimer's.

Understanding this, the President's FY 2014 budget request included \$80 million for Alzheimer's research and \$20 million for education, outreach and support. These funds are a critically needed down payment for needed research and services for Alzheimer's patients and their families.

With these funds, states will be able to improve dementia care services and supports, create greater public awareness campaigns to connect caregivers to community resources and provide better provider education and training. These steps will better prepare individuals with the disease and their caregivers while lengthening the ability to provide care in the home and community setting.

Ultimately, strategic research funding is the key to preventing human suffering and reducing the enormous costs related to Alzheimer's. Research is the only way to get to earlier diagnosis, preventive treatments or even a life-saving cure. We have seen the smart investments in research yield treatments that have saved individuals and the healthcare system millions while creating research and clinical jobs. If a treatment were developed that delayed the onset of Alzheimer's by just five years, it would cut government spending on care for people with Alzheimer's nearly in half. But to do so, we must give the scientists funds to do the job.

That is why I believe it is imperative for Congress to provide the resources necessary to implement the Plan, and why I ask you to support the President's FY 2014 budget request for \$100 million for the Plan's implementation.

Conclusion

Music was always part of our home, and we're all still playing even if we are not on stage in the same way. We knew at the beginning that Alzheimer's doesn't rob you of the things you love right away. But, the disease keeps getting worse and there aren't any medications to stop it. For my dad that's been true as well. To truly fight this disease, we need your help.

I would like to thank the Committee again for the opportunity to share my story and support for the work being done to address Alzheimer's disease. I strongly believe in the Plan and the goal of preventing and effectively treating Alzheimer's disease by 2025. I am hopeful that the Congress will support the President's budget request of \$100 million to ensure implementation of the Plan.

The CHAIRMAN. Thank you very much.
[Applause.]

Do any of the members, before we excuse the Campbell family, have any questions? Any additional comments?

Senator COLLINS. I just want to thank Ashley for her very moving and compelling testimony. It is so important that we put a human face on this, and I admire the decision of your entire family to step forward out of the shadows and shine a spotlight on this devastating disease, so thank you so much for being here today.

Ms. CAMPBELL. Thank you.

Senator WHITEHOUSE. I just want to join my colleagues in thanking the Campbell family, thanking Ashley for her wonderful testimony, and thanking Mr. Campbell for the many years of pleasure that I got listening to him as I was growing up.

The CHAIRMAN. Courage is an American characteristic that is embraced by the American people. You clearly have shown that courage, as have your mom and dad, and we want to thank you for sharing your story. This wretched disease has touched almost every one of us in this room one way or another, and you have stood tall to bring the focus all the more on this issue of monumental consequence. So we are deeply grateful.

And I know you have to get to the airport, so at your pleasure, you all just excuse yourselves whenever you would like.

Ms. CAMPBELL. Thank you.

The CHAIRMAN. Next, we are going to hear from Dr. Don Moulds. He is the Acting Assistant Secretary of Planning and Evaluation at the Department of Health and Human Services, and in this capacity, Dr. Moulds is overseeing the development of the national strategy to end Alzheimer's disease. He is also a member of the Federal Advisory Council on Alzheimer's Research, Care, and Services.

We also have Dr. Ronald Petersen. Dr. Petersen is the Director of the world-renowned Mayo Clinic's Alzheimer's Disease Research Center and the Mayo Clinic Study of Aging. He has authored over 400 peer-reviewed articles on memory disorders, aging, and Alzheimer's disease. Dr. Petersen's most recent research focuses on the study of normal aging, mild cognitive impairment, dementia, and Alzheimer's.

And then we will hear from Dr. Michael Hurd. Dr. Hurd is the senior principal researcher at the RAND Corporation, where he directs the RAND Center for the Study of Aging. His research focuses on the economics of retirement as well as other topics related to aging and the elderly. Dr. Hurd recently wrote a New England Journal of Medicine Study on the economic cost of Alzheimer's entitled, "Monetary Cost of Dementia in the United States."

Gentlemen, welcome. We will take you in the order in which I introduced you and then we will get into the questions after all three of you have testified. Your formal statement is entered into the record, and so we would ask you to summarize your comments.

Dr. Moulds.

STATEMENT OF DONALD B. MOULDS, PH.D., ACTING ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. MOULDS. Mr. Chairman and members of the committee, my name is Don Moulds and I am the Acting Assistant Secretary for Planning and Evaluation in the Office of the Secretary of the Department of Health and Human Services. I am honored to come before you today to talk about the implementation of the National Alzheimer's Project Act, or NAPA, and the National Plan to Address Alzheimer's Disease.

We have an historic opportunity to influence the way we address Alzheimer's disease, its impact on those who have it and their families, and perhaps reduce the incidence and the devastation it causes in the future. President Obama and Secretary Sebelius have made it abundantly clear that we cannot wait to act on this urgent national priority.

In my testimony, I refer to Alzheimer's disease under this term. I include related dementias, consistent with the approach Congress used in the crafting of the law.

As many as five million people in the United States have Alzheimer's disease. The effects of Alzheimer's can be devastating for both individuals with the disease and their families. As Dr. Hurd will testify, the annual cost of care for people with AD is estimated to be between \$160 and \$215 billion annually. There is no treatment for AD and eventually it is fatal. It is the fifth leading cause of death among people aged 65 and older. As we have made progress fighting other diseases and the population has aged, mortality from Alzheimer's has risen.

The National Alzheimer's Project Act establishes an Advisory Council on Alzheimer's Research, Care, and Services, which brings together some of the nation's foremost experts on Alzheimer's disease. Ron Petersen, the Chair of the Advisory Council, will speak about their work in just a few moments.

Our work on the National Plan began in 2011 with the establishment of an Interagency Group on Alzheimer's Disease and Related Dementias. The group included the Departments of Veterans Affairs and Defense, the National Science Foundation, and over a dozen HHS agencies. The Interagency Group inventoried Federal programs, including research, clinical care, and services and supports. It then identified areas of overlap, opportunities for collaboration, and gaps, forming the basis of the initial work for the National Plan.

In early 2012, we shared a framework and drafted the National Plan to Address Alzheimer's Disease with the Advisory Council and with the public. We incorporated the input received from the Advisory Council and thousands of stakeholders. We built off the President's historic "We Can't Wait" investments in Alzheimer's and identified concrete steps to address the disease. The National Plan was released on May 15, 2012. As Secretary Sebelius said, it provides the cornerstone of an historic effort to fight Alzheimer's.

The National Plan addresses five ambitious goals. First, to prevent and effectively treat Alzheimer's disease by 2025. Second, to optimize care quality and efficiency. Third, to expand supports for people with Alzheimer's disease and their families. Fourth, to en-

hance public awareness and engagement. And finally, to track progress and drive improvement.

In the 11 short months since the National Plan was released, we have already made significant progress. In May of 2012, the National Institutes of Health convened an Alzheimer's Disease Research Summit, which brought together national and international researchers to develop recommendations on how to best advance Alzheimer's research. The summit recommendations, which are designed to capitalize on current scientific opportunities, will inform Alzheimer's research for years to come.

The administration's Alzheimer's commitment of \$50 million in 2012 supported some exciting research projects, including a clinical trial of an insulin nasal spray that could prevent memory impairment and improve cognition during the initial period of the disease. This funding supported the first clinical trial of a treatment to prevent the disease by targeting amyloid, a brain hallmark of AD, among a unique family in Colombia whose otherwise healthy members share a genetic mutation that causes early onset of Alzheimer's disease.

We have also taken steps to improve the care received by people with AD. The Network of Geriatric Education Centers funded by HRSA have provided training to over 10,000 doctors, nurses, and direct care workers to better recognize the symptoms of AD and provide screening and help consumers and families who are living with the disease.

The Administration on Community Living has partnered with the National Family Caregiver Alliance to create a resource with assessment measures that providers can also use to help identify caregiver needs and create a care plan to address them.

HHS launched Alzheimers.gov, a one-stop resource for families and caregivers. There were over 200,000 visits to Alzheimers.gov in the first ten months.

Despite all of the progress, we still have a long way to go in our fight against Alzheimer's disease. We are finalizing the 2013 update of the National Plan, which will add additional steps we take to beat this disease. The President's fiscal year 2014 budget includes a \$100 million initiative to fight the disorder through expanded research, improve supports for caregivers, and enhance provider education and public awareness.

In addition, the President's Brain Initiative will complement our research by giving us insight into healthy brain functioning and the impact of Alzheimer's disease. It may also help pinpoint interventions to treat the disease.

With many partners, the administration has taken significant steps to fight Alzheimer's over the past two years, but much work remains. I look forward to working with you to improve the care received by millions of people with the disease, better support their families and caregivers, and prevent and effectively treat AD by 2025.

[The prepared statement of Mr. Moulds follows:]



**Testimony
Before the Senate Aging Committee
United States Senate**

Statement of

Donald Moulds, Ph.D.

*Acting Assistant Secretary for Planning and
Evaluation*

U.S. Department of Health and Human Services

Wednesday, April 24, 2013

Mr. Chairman and Members of the Committee, I am Donald B. Moulds, Ph.D., Acting Assistant Secretary for Planning and Evaluation (ASPE) in the Office of the Secretary of the Department of Health and Human Services (HHS). I am honored to come before you today to talk about the implementation of the National Alzheimer's Project Act (NAPA) and the National Plan to Address Alzheimer's Disease. We have an historic opportunity to engage in an open collaborative discussion focused on reducing the burden of this disease with the active engagement of government and the private sector. I will provide a brief overview of Alzheimer's disease and related dementias in the United States, offer a brief history of the development of the National Alzheimer's Plan and its implementation, discuss our work on each goal of the plan, and preview upcoming work on Alzheimer's disease.

The Administration and the Congress are partnering in this unprecedented opportunity to influence the way we address Alzheimer's disease, its impact on those who have it and their families, and, perhaps, reduce the incidence – and devastation it causes – in the future. In January 2011, President Obama signed the NAPA, calling for an aggressive and coordinated national Alzheimer's disease plan to be updated annually. In 2012, President Obama directed that HHS make available \$56 million for initiatives in cutting edge research, increased public awareness, and provider education on the disease. Increasing the momentum, the Administration is seeking to direct \$100 million to such initiatives in 2014. President Obama and Secretary Sebelius have made it abundantly clear: we cannot wait to act on this urgent national priority.

In my testimony, I refer to Alzheimer's disease; under this term I include related dementias consistent with the approach the Congress used in the law. It can be difficult to distinguish between

Alzheimer's disease and other dementias in clinical presentation and diagnosis. People with dementia and their families face similar challenges finding appropriate and necessary medical and supportive care.

Burden of Alzheimer's Disease

As many as five million people in the United States have Alzheimer's disease¹. While estimates of the number of people vary, few dispute the urgent need to find ways to prevent, delay, and treat this disease—especially in light of America's aging population. The effects of Alzheimer's can be devastating, both for individuals with the disease and their families. People with Alzheimer's may require significant health care and intensive long-term services and supports including, but not limited to, management of chronic conditions, help taking medications, round-the-clock supervision and care, or assistance with personal care activities, such as eating, bathing, and dressing. As Dr. Hurd will testify, the cost of care for people with AD was estimated to be in the range of \$159 billion to \$215 billion in 2010². There is no treatment for AD and eventually it is fatal. It is the fifth leading cause of death among people age 65 and older. As we have made progress fighting other diseases and the population has aged, mortality from Alzheimer's has risen.³

National Alzheimer's Project Act Implementation

The Act establishes an Advisory Council on Alzheimer's Research, Care, and Services, which brings together some of the Nation's foremost experts on Alzheimer's disease. Ron Petersen, the chair of the Advisory Council, will speak about their work in a few moments.

¹ Hebert LE, Weuve J, Scherr PA, Evans DA (2013). Alzheimer's disease in the United States (2010-2050) estimated using the 2010 census. *Neurology*, March 2013.

² Hurd MD, et al. (2013). Monetary costs of dementia in the United States. *N Engl J Med*; 368: 1326-34.

³ Tejada-Vera B (2013). Mortality from Alzheimer's disease in the United States: Data for 2000 and 2010. *NCHS Data Brief* No. 116.

Soon after enactment, we began work on the National Plan. In April 2011, HHS established an Interagency Group on Alzheimer's Disease and Related Dementias to begin carrying out the National Alzheimer's Project Act. This Interagency Group includes the Departments of Veterans Affairs and Defense, the National Science Foundation, and over a dozen HHS agencies. The Interagency Group inventoried all Federal programs including research, clinical care, and services and supports. It then identified areas of overlap, opportunities for collaboration, and gaps. The inventory and gap analysis formed the basis for initial work on the National Plan.

In early 2012, we shared a framework and draft of the National Plan to Address Alzheimer's Disease with the Advisory Council and the public and solicited feedback. We incorporated the input received from the Advisory Council and thousands of stakeholders – program providers, health professionals, policy makers, researchers and others – and most important, the experts who see the issues up close every day and every night - people who experience the disease personally and their caregivers. We built off the President's historic investments and identified concrete steps to address the disease. The final first National Plan was released on May 15, 2012. As Secretary Sebelius said, it provides "the cornerstones of an historic effort to fight Alzheimer's."

National Plan to Address Alzheimer's Disease

The National Plan addresses five ambitious goals:

1. *Prevent and Effectively Treat Alzheimer's Disease by 2025* – We will accelerate the pace of scientific research and ensure that evidence-based interventions are identified and quickly translated into clinical practice. In May 2012, the National Institute on Aging convened an international summit of scientists to assess research goals and suggest priorities. As you

know, we do not have effective ways to prevent AD today. However, under this goal we are funding studies of risk and protective factors to fill that gap. Clinical studies based on these findings will be directed at the earliest diagnosis and treatment of Alzheimer's, with a special emphasis on rapidly reporting research results to practitioners and the public who can use them.

2. ***Optimize Care Quality and Efficiency*** – This goal will provide people with Alzheimer's disease the highest quality of care, in all settings, from the earliest stages of the disease. Early diagnosis is essential. We have made progress in linking the latest research findings, such as new assessment technologies coming out of NIH, with the Administration on Community Living's information and referral sources in local communities and with the Medicare Annual Wellness Visit created by the Affordable Care Act. The Health Resources and Service Administration (HRSA) invested \$2 million in 2012 to educate health providers to help them detect Alzheimer's disease and care for people who have it. Further, because people with AD use a lot of services from multiple providers, the plan focuses on care coordination, information sharing among providers, and easing individuals' transitions between providers and settings. We are paying particular attention to the unique needs of different age and racial and ethnic groups affected by dementia.
3. ***Expand Supports for People with Alzheimer's Disease and Their Families*** – We are supporting care, which in the case of Alzheimer's disease is a 24/7 family endeavor, well beyond interactions with doctors, hospitals, or nursing homes. Families and caregivers frequently provide care to loved ones at home over many years, sometimes decades. The work is demanding physically, financially and emotionally. In the course of this work, I have had the opportunity to hear from many dedicated caregivers who cope with behavioral

changes, sleep disturbances, wandering, and a myriad of other challenges related to cognitive impairment as well as the physical demands of hands-on care. We are working to provide culturally sensitive resources, to help family caregivers with their own health and well-being, and to assist families in preparing for future long-term care needs. I have heard their testimony to the Advisory Council and in national listening sessions, and read comments they submitted to the NAPA website. People like Judy Roth – both of her parents were diagnosed with Alzheimer’s disease in 2009. She told the Advisory Council: “It breaks my heart to see them slowly slip away. And there is no respite from this horrible disease. So many around me are suffering from it or caring for those who have it. As Olga Molinari told us, “it takes a village to handle an aggressive, geriatric Alzheimer’s family member.”

4. ***Enhance Public Awareness and Engagement*** – We are educating and engaging the public in the fight against Alzheimer’s disease. Greater public awareness encourages families to seek assessments, reduces their sense of isolation, and provides them with accurate information, resources and services. As the Advisory Council heard last year, “Alzheimer’s is a quiet disease. People who have it don’t want to talk about it.” Engaging in a public dialogue can help remove the shame associated with the disease and ensure people with concerns about their memory or a diagnosis get the care and supports they need.
5. ***Track Progress and Drive Improvement*** – We need more and better information on people with Alzheimer’s, their caregivers and the care and support they receive, to improve programs, support policy initiatives, and evaluate the impact of the National Plan. We are investing in data collection on Alzheimer’s disease, to improve our understanding of who has Alzheimer’s disease and what caregivers do to help them. I am proud of the cutting edge

web-based planning tool developed by my office that enables policy makers, Advisory Council members, and the public to follow plan implementation and actions in real time.

Progress Since The Plan's Release

In the 11 short months since the National Plan was released, we have already made great progress. In May 2012, the National Institutes of Health (NIH) and HHS convened the Alzheimer's Disease Research Summit 2012: Path to Treatment and Prevention which brought together national and international researchers and advocacy groups to develop recommendations on how to best advance Alzheimer's research. The Summit recommendations, which are designed to capitalize on current scientific opportunities, will inform Alzheimer's research for years to come.

Through the International Alzheimer's Disease Research Portfolio, NIA has created a mechanism that enables funders of Alzheimer's disease research to coordinate efforts. The Administration's Alzheimer's commitment of \$50 million in 2012 supported some exciting research projects that enable us to "roll up our sleeves to see where we can go," as Francis Collins says. Among them:

- Whole-genome sequencing to identify new genetic variants that increase or reduce risk for AD.
- A clinical trial of an insulin nasal spray that could prevent memory impairment and improve cognition during the initial period of the disease.
- Testing the potential of a new treatment that targets amyloid, a brain hallmark of AD, with a unique and large family in Colombia whose members are otherwise healthy but share a genetic mutation that causes early onset Alzheimer's disease. This is the first clinical trial of a drug aimed at preventing the disease.
- Use of new stem cell methods to obtain insights into the cellular processes of Alzheimer's.

- Support to the Atherosclerosis Risk in Communities (ARIC) Neurocognitive study (ARIC-NCS) focused on mid-life vascular risk factors and markers that might predict cognitive impairment later.

While this important scientific work is underway, we have taken steps to improve the care received by people with AD. The network of Geriatric Education Centers funded by HRSA have provided training to over 10,000 doctors, nurses and direct care workers better recognize the symptoms of AD and provide screening and help for consumers and families who are living with the disease

The Centers for Medicare & Medicaid Services (CMS) and NIH identified tools that physicians can use to assess for cognitive impairment during the Medicare Annual Wellness Visit. These recently validated and free tools take 5 minutes or less to administer. They will help providers determine when someone needs further testing for dementia and speed up diagnoses.

CMS's Center for Medicare & Medicaid Innovation (CMMI) awarded grants to test four models of improved care for people with dementia. The grants test various models to assess individuals, develop and implement individualized treatment plans and support people in care transitions.

While there is still much we do not understand, there are concerns that using certain medications, including atypical antipsychotics, to treat the behavioral symptoms of Alzheimer's or other dementias may not be appropriate. CMS has taken important steps to address inappropriate use of these drugs to manage behavior in nursing homes. CMS and public and private partners have made major presentations, educated providers, and completed 200 nursing home case studies on how decisions are

made to use antipsychotic medication. Nursing home surveyors are specifically trained on how to look for inappropriate antipsychotic use. HHS has set a goal of reducing antipsychotic drug usage by 15 percent.

Family members and other informal, unpaid caregivers play an essential role in helping people with AD live with the disease. Karen Lowe told the Advisory Council about her 89 year old mother who once spoke four languages: “She thinks I’m an overly friendly nursing home staffer who kisses her and tells her how much I still love her. She has disappeared so slowly, I’m not even sure when I said goodbye to the mother I once knew. I am saddened and scared. I am scared now that I, too, will suffer this fate. And that my children will one day wonder where I went and who is this apparition is who looks like me but seems lost at sea.”

The Administration on Community Living has partnered with the National Family Caregiver Alliance to publish *Selected Caregiver Assessment Measures (2nd Edition): A Resource Inventory for Practitioners*. This resource provides assessment measures that providers can use to help identify the caregiver’s needs and build upon their strengths to create a care plan that addresses the individualized needs of the care recipient and the caregiver.

HHS launched www.alzheimers.gov as a one-stop resource for families and caregivers. It also fielded an awareness campaign to enhance public awareness of Alzheimer’s disease and link caregivers and people with a diagnosis to the resources they need. The campaign included an award winning commercial and print and web advertisements. There were over 200,000 visits to Alzheimers.gov in the first 10 months.

Upcoming Work

Despite all of the progress, we still have a long way to go in our fight against Alzheimer's disease. We are finalizing the 2013 Update to National Plan, which will add additional steps we will take to beat this disease. The President's FY 2014 budget includes a \$100 million initiative to fight this disorder through expanded research, improved supports for caregivers, and enhanced provider education and public awareness. In addition, the President recently announced his BRAIN initiative, which will create a dynamic picture of the interactions between cells and neural circuits. This effort will complement our research by giving us insight into healthy brain functioning and the impact of Alzheimer's disease, to help pinpoint interventions to treat this disease.

With many partners, the Administration has done a lot of work on Alzheimer's over the past year, but much work remains. I look forward to working with you to improve the care received by the millions of people with the disease, better support their families and caregivers, and prevent and effectively treat AD by 2025. Secretary Sebelius said it best: "We can't wait to act. Reducing the burden of Alzheimer's disease on patients and their families is an urgent national priority."

The CHAIRMAN. Dr. Petersen.

STATEMENT OF RONALD C. PETERSEN, M.D., PH.D., DIRECTOR, MAYO ALZHEIMER'S DISEASE RESEARCH CENTER, MAYO CLINIC, ROCHESTER, MN, AND CHAIR, ADVISORY COUNCIL ON RESEARCH, CARE, AND SERVICES, NATIONAL ALZHEIMER'S PROJECT ACT

Dr. PETERSEN. Good afternoon, Chairman Nelson, Senator Collins, and distinguished members of the Senate Special Committee on Aging. My name is Ron Petersen. 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 at Rochester, Minnesota.

The first United States Plan to Address Alzheimer's Disease was released in May of 2012 and 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. Don Moulds, has nicely outlined the structure of the plan and the accomplishments of the Federal Government.

The National Alzheimer's Project Act charged the Secretary of Health and Human Services with developing the National Plan, but in addition, the law charged the Advisory Council with generating recommendations to the Secretary and directly to Congress. I would like to take a couple moments to highlight some of the more salient recommendations.

The research community is poised to make key contributions. However, insufficient resources are impeding progress towards overcoming the disease. Therefore, the Advisory Council states that there is 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 \$2 billion per year or more.

Other research endeavors funded by the National Institutes of Health are of similar or greater magnitude. Currently, the NIH spends approximately \$6 billion on cancer research, \$3 billion on HIV/AIDS research, and a little over \$2 billion on cardiovascular disease. Yet, at present, the Federal research budget for Alzheimer's disease is less than one-half-billion dollars. Yet Alzheimer's disease may be the defining disease of our generation. In order to keep it from being the defining disease of 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 the disease.

Several other recommendations are worth noting. One involves the therapeutic pipeline. Another recommendation from the Advisory Council pertains to the compression of the therapeutic pipeline, or shortening of the extended period of time—often over ten years—it takes from the discovery of a molecule to the production of a drug for treatment.

This being a National Plan, along the same theme, the Advisory Council realizes that this is a National Plan and not a Federal plan. As such, we need to invoke assistance of many private part-

ners to come together to develop a therapeutic approach for the disease.

This is a global disease. We 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 other countries that have developed national plans prior to ours.

With the aging of America, we realize that the front line of evaluations for individuals at the early stage of 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. In addition, curricula designed for caring for individuals with Alzheimer's disease needs to be developed at all levels of care, including physicians' assistants, nurses, allied health care workers in skilled nursing facilities, and emergency department personnel to ensure uniform practices are undertaken for those affected with the disease.

I would like to close by thanking Congress and the President for the initial steps at increasing funding for Alzheimer's disease research. As Dr. Moulds indicated, the initial redirection of funds in fiscal year 2012 yielded two large clinical trials, one for prevention and one for treatment.

While we all recognize that these are very difficult times for the Federal budget, this is an issue that cannot wait. With the aging of the baby boomers, individuals turning age 65 at a rate of 10,000 persons per day, it is easy to see why this will be the defining disease of our generation. It will swamp other diseases and be the single most salient condition of aging. It is likely that everyone in this room has 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 that our children will not have to face the same situation. It will take a few courageous people, likely this committee, to make bold statements necessary to make it possible 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 Council.
[The prepared statement of Dr. Petersen follows:]

**Senate Special Committee on Aging
National Plan to Address Alzheimer's Disease**

Are We On Track to 2025?

April 24, 2013

Statement of

Ronald C. Petersen, Ph.D., M.D.

Director, Mayo Alzheimer's Disease Research Center

Mayo Clinic

Rochester, Minnesota

Statement of Ronald C. Petersen, Ph.D., M.D.
Senate Select Committee on Aging, April 24, 2013

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.

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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

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estimates of that level are \$2 billion 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, \$3 billion 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.

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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

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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

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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

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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

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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 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.

The CHAIRMAN. Dr. Hurd.

**STATEMENT OF MICHAEL D. HURD, PH.D., DIRECTOR, RAND
CENTER FOR THE STUDY OF AGING**

Mr. HURD. Chairman Nelson, Ranking Member Collins, members of the committee, thank you for the opportunity to testify before you today on a critically important topic, the monetary costs of dementia in the United States.

My testimony will be based upon work performed at the RAND Corporation and the University of Michigan by me, Paco Martorell, Adeline Delavande, Kathleen Mullen, and Kenneth Langa. It was published in the *New England Journal of Medicine* on April 4 of this year.

While our work is about the monetary costs of dementia, my co-authors and I recognized that the emotional costs of dementia are vast, indeed, as we have heard today. But in our data, we have no good way of measuring those emotional costs. However, even with the more modest goal of measuring the monetary costs, there are a number of challenges.

First, most people with dementia have a coexisting health problem, such as a history of stroke or a heart condition. These health problems would, by themselves, lead to higher costs. We wanted to separate out those costs so as to find the costs attributable to dementia, not the costs of health care of people with dementia.

A second difficult aspect concerns informal care, that is, unpaid care performed by a spouse, daughter, or other family member, or others. We already knew that the amount of informal care was substantial, so that the method of placing a monetary value on that care could cause our estimates to vary by a great deal.

We used the Health and Retirement Study. The HRS was first fielded in 1992, and since then, it has become the preeminent data source for general population representative studies of aging. Funded by the National Institute on Aging and the Social Security Administration, it provides a wide variety of data, including cognition, health care use, and costs and informal caregiving.

We estimated that the prevalence of dementia in the population 71 or older was 14.7 percent in 2010. We found that persons with dementia had about \$29,000 more in annual spending for health care than persons without dementia, after adjusting for coexisting conditions and demographic characteristics. The great majority of those costs were for nursing home stays and in-home care that was paid for. Adding in the costs of informal care increased the total annual costs due to dementia substantially. Depending upon the method of valuing informal care, the costs per person with dementia were between \$42,000 per year and \$56,000 per year.

We then used Census estimates of the age distribution of the population to estimate the total cost of dementia, that is, the total cost in the population. We found that attributable actual spending was \$109 billion in 2010. This cost places dementia as the most costly disease in the United States in terms of actual spending. Adding in costs for informal care increased this estimate to the range of \$160 billion to \$250 billion per year.

Because the prevalence of dementia sharply increases with age, the aging of the population itself, particularly when the baby boom

generation reaches advanced old age, will increase future costs. We calculated that by 2040, the costs for care purchased in the marketplace will more than double, from \$109 billion to \$260 billion in real terms. Adding in the costs of informal care increases the cost in 2040 to between \$380 billion and \$510 billion, depending upon the method of valuing informal care.

Our research shows that dementia is costly and that the costs will increase sharply, but we did not estimate the distribution of costs across households. Even within a year, these costs are unequally distributed, with some households spending nothing and others as much as \$100,000 per year.

We suspect that the costs are even more skewed when accumulated over many years because some people with dementia can be in nursing homes for five years or even more, or as Dr. Petersen suggested, even ten years. The accumulated costs can be financially devastating to some families. In principle, this risk could be reduced by long-term care insurance, but the products on the market are apparently not well designed. Only about 13 percent of persons age 55 or older hold this type of insurance.

In summary, dementia is very costly and will grow more costly unless we find ways of delaying onset. In the meantime, well-designed long-term care insurance could reduce the risk of catastrophic out-of-pocket spending.

Thank you for your attention.

[The prepared statement of Mr. Hurd follows:]

The Monetary Costs of Dementia in the United States

Michael D. Hurd

RAND Office of External Affairs

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Testimony presented before the Senate Special Committee on Aging on April 24, 2013

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The RAND Corporation

*The Monetary Costs of Dementia in the United States*²

Before the Special Committee on Aging
United States Senate

April 24, 2013

Chairman Nelson, Ranking Member Collins, Members of the Committee, thank you for the opportunity to testify before you today on a critically important topic: the monetary costs of dementia in the United States. My testimony will be based upon work performed at the RAND Corporation and the University of Michigan by me, Paco Martorell, Adeline Delavande, Kathleen Mullen, and Kenneth Langa. It was originally published in the *New England Journal of Medicine* on April 4 of this year.

Introduction: Dementia and Its Costs

Dementia, a chronic disease of aging characterized by progressive cognitive decline that interferes with independent functioning, affects a large and growing number of older adults. The National Alzheimer's Project Act seeks to improve the ability of the federal government to track monetary costs incurred by individuals and public programs, such as Medicare and Medicaid, that result from dementia. We believe that this work will contribute to that effort.

Our goal in this work was to estimate the monetary costs due to dementia, not all monetary costs of people with dementia. Accurately identifying the costs attributable to dementia is challenging for two reasons. First, persons with dementia are likely to have co-existing chronic health problems, meaning any effort to isolate the costs attributable to dementia must isolate them among other concurrent costs. Second, informal caregiving, the unpaid care provided by family and friends for assistance with activities of daily living, is an important component of the support required by persons with dementia, yet it is unclear how to attribute a monetary cost to an informal caregiver's time.

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² This testimony is available for free download at <http://www.rand.org/pubs/testimonies/CT386.html>.

Data Available for Estimation

To estimate costs associated with dementia, we used data from the Health and Retirement Study, or HRS. The HRS is a longitudinal survey; that is, it interviews repeatedly the same individuals over time, about 20,000 persons over the age of 50 every two years in the case of the HRS. The HRS was first fielded in 1992 and since then has become the pre-eminent data source for population-representative studies of aging. Funded by the National Institute on Aging and the Social Security Administration, it provides a wide variety of nationally-representative longitudinal data on persons, including cognitive assessments and data on the need for assistance in activities of daily living as well as on health-care and other costs. However, the HRS does not have a direct measure of dementia, but such a measure is available through the Aging, Demographics, and Memory Study, or ADAMS. The ADAMS is study of a nationally-representative sub-sample of HRS respondents who underwent a detailed in-home clinical assessment for dementia. Using data from the ADAMS, we constructed a statistical model to identify the probability that each HRS respondent over the age of 70 has dementia.

We assessed several categories of health-care spending: out-of-pocket spending, spending by Medicare, net nursing-home spending, and formal and informal health-care spending. Out-of-pocket spending includes any out-of-pocket health-care expenses for nursing-home or hospital stays, medical visits, outpatient surgery, home health care, special services such as outpatient rehabilitation, prescription drugs, and dental services. Medicare spending is available for HRS respondents who agreed to the linkage of their Medicare records and who were enrolled in fee-for-service plans, or approximately 70 percent of persons in our study population. Net nursing-home spending distinguished between rates paid by Medicaid and those paid by third parties. Formal health care includes paid care in home. Informal care includes unpaid care in home, most often provided by family members.

Individual Prevalence and Costs of Dementia

Overall, we found 14.7 percent of the population 71 years of age or older had dementia in 2010. Nonwhite, female, single, less-educated, and lower-income persons have an elevated probability of dementia, as do persons with a history of stroke, heart disease, or psychiatric conditions. Nonwhites, for example, are nearly twice as likely as whites to have dementia. Those who did not graduate high school were more than twice as likely as those who graduated college to have dementia, and those with household income of less than \$15,000 were more than four times likely to have dementia as those with household income more than \$75,000.

We distinguish between costs that flow through the marketplace such as spending for hospital stays, doctor visits, nursing homes, hired caregiving at home and so forth, and implicit additional costs that are due to informal care and result from caregivers withdrawing from the labor market. We found persons with dementia had \$33,329 more in annual health-care costs that flow through the marketplace than persons without dementia. Adjusting for coexisting conditions and demographic characteristics reduces this estimate to \$28,501. This is the average annual market cost attributable to dementia. Of the \$28,501 in these costs attributable to dementia, \$13,900 is for nursing-home care, \$6,200 is for out-of-pocket expenditure, \$5,700 is for formal home care; Medicare spent \$2,700 of the total.

Adding the cost of informal care boosts the total annual costs due to dementia to \$41,685 per person with dementia when based on the value of foregone wages. These costs would be \$56,290 per person with dementia when based on the valuation of replacement cost for the informal care. Put another way, the value of informal home care represents 31 percent to 49 percent of the costs attributable to dementia, depending on how such care is valued.

Population-wide Costs and Projections

To estimate the total cost of dementia to the U.S. economy now and in the future, we combined the adjusted cost per person with dementia with prevalence rates from the ADAMS and population estimates and projections from the U.S. Census. Multiplying the per-person costs for dementia by the estimated number of persons with dementia who were 71 years of age or older in 2010 indicates an annual population cost of \$109 billion for care purchased in the market. Including the estimated value of informal home care boosts this estimate to a range of \$159 billion to \$215 billion. The cost for care purchased in the market place (\$109 billion) places dementia as the most costly disease in terms of actual spending in the United States: according to tables based on the Medical Expenditure Panel Survey published by the Agency for Healthcare Research and Quality, heart disease cost \$102 billion in 2010 (adjusted from \$96 billion in 2008) and cancer cost \$77 billion in 2010 (adjusted from \$72 billion in 2008). Because neither heart disease nor cancer is likely to require the large amount of informal care that is required by dementia, accounting for informal care would increase the cost difference between dementia and those diseases even further.

Because of the aging of the population, the fraction of the population at advanced old age where the risk of dementia is greatest will increase. By 2040, assuming that prevalence rates of dementia at each age remain the same, our estimates suggest that the costs for care purchased in the market place will more than double from \$109 billion to \$259 billion in real terms. Adding in

the cost of informal care increases the cost in 2040 to \$379 billion to \$511 billion, depending on the method for valuing informal care.

Differences from Other Estimates and possible bias

A critical assumption in our estimates was that real costs per case will remain constant. This may be likely for care-giving, because wages of workers likely to provide care have remained stable or even decreased in real terms. It is less likely, however, for health-care spending such as that for hospital costs or medication costs. To the extent such costs continue to rise we are likely underestimating future costs of dementia. However, the amount of bias may be relatively small because between 75 percent and 84 percent of attributable costs are for care-giving, which has not been subject to the large increases in prices of health care services.

Our cost estimates are considerably lower than those reported by the Alzheimer's Association, which estimated that annual monetary costs alone were \$172 billion in 2010, compared with our estimate of \$109 billion. There are several reasons for this difference. The Alzheimer's Association estimate of cost per case was higher than ours, but it was based on a more severely-impaired population. Its estimated prevalence of dementia, which was higher than ours, was derived from a different population than the population that produced the cost per case. Prevalence came from a study of three Chicago neighborhoods. In that study the diagnostic criteria for dementia did not require the presence of a limitation in activities of daily living, as the ADAMS does, likely explaining why prevalence was higher. Finally, its cost estimate was not adjusted for coexisting conditions, as ours was.

Future Research

Considerable future research remains to be done on this topic. We did not address the distribution of costs, that is, who is likely to pay the costs of dementia, particularly at the household level. Most households will not incur large costs for dementia care: many patients will have their care covered by Medicaid or private long-term care insurance. Their nursing-home or hospitalization stays may be short and relatively affordable, or households will avoid serious hardship for some other reason. However, a minority of families will face financially-devastating costs because of very long nursing-home stays of five years or more. Research is needed to quantify the distribution of costs so that families will have a better understanding of the risks. Such research will also clarify the role of long-term-care insurance. This situation in which many families incur minor costs but a few incur very large costs ought to call for an insurance solution, one in which the costs of long-term care could be spread across the entire population rather than

being concentrated on the unlucky few. At the moment the long-term-care insurance products that are available apparently do not meet the needs of the older population as evidenced by the very low take-up rates, about 13 percent in the population age 55 or older. Better designed products to reduce the risk of very large out-of-pocket spending for long-term-care would help reduce a significant cause for concern of the older population.

Research Funding

This research was funded by a peer-reviewed grant from the National Institute on Aging.

The CHAIRMAN. Thank you, gentlemen.

Before I turn to Senator Collins, Dr. Petersen, would you explain what happens to the brain from a medical standpoint—the build-up of plaque, why do the neurons not fire, et cetera.

Dr. PETERSEN. In general, we call Alzheimer's disease a degenerative disease of the brain, and that means that the nerve cells are not working as well as they formerly did. We think that a leading hypothesis right now is this protein that you mentioned, Senator. Amyloid gets deposited in the brain and causes destruction to the nearby nerve cells. Then there is a cascade of events that occur. Inflammation, other proteins become involved.

And when that process begins in the memory part of the brain, so called the temporal lobe or the hippocampus, the person becomes forgetful. Then as the disease progresses that process spreads to other regions of the brain, those involved with language, ability to pay attention, concentrate, problem solve. And as that starts to spread, then other behaviors start to deteriorate. The person loses an ability to care for him or herself and the function deteriorates.

So it is a slow process that begins many, many years, maybe decades before the symptoms actually present themselves, and this degenerative process gradually progresses over time.

The CHAIRMAN. Is there a trigger that we know of that causes the build-up of the protein?

Dr. PETERSEN. It is a good question. In some instances, yes. In one form of the disease, so-called familial or truly inherited Alzheimer's disease, there is a genetic mutation. Dr. Moulds mentioned the study that is now being funded by the NIH to look at a family who has this particular genetic tendency. In those instances, the genetic tendency leads to the build-up of this amyloid protein. But that is perhaps only one percent of the disease.

In the much larger proportion, sort of late onset, more typical Alzheimer's disease, there still may be a familial tendency, meaning that it sort of runs in families. So there are what are called genetic susceptibility polymorphisms, a big term that means you just a risk, an increased risk because of a contribution of a variety of genes that will lead you to misprocess these proteins and develop the disease.

There still might be some environmental triggers that accentuate that, head trauma being one of them. So there are some environmental factors that bring it on, as well. But we do not fully understand why one person with the same genetic make-up may develop the disease, the next person not. So research underway.

The CHAIRMAN. Do we know the molecular structure of the protein?

Dr. PETERSEN. Absolutely. We know a great deal about the amyloid protein, the tile protein. Amyloid makes up the plaques in the brain. The tile protein makes up the tangles in the brain. The defining characteristics of the disease in the brain, plaques and tangles. So when someone passes away, has an autopsy, you look at the brain under the microscope. To call it Alzheimer's disease, they have to have these plaques and tangles.

We know a great deal about the make-up of these proteins, the genetic sequencing of them, when things get misprocessed, how they get misprocessed, the enzymes that cause the misprocessing,

et cetera. So we know a great deal about it, and that has resulted in many therapeutic attempts aimed at various aspects of that process. So we do know a lot about the basic biology of the disease.

The CHAIRMAN. But we have not found the molecules or the genes or the proteins that could reverse the process of the build-up of this plaque.

Dr. PETERSEN. Essentially, that is correct, meaning that we do not have a disease modifying therapy, meaning we do not—we are unable to get at the underlying plaque and tangle process and stop it. But that is a rich area of research right now. Many trials are underway, many approaches to doing that, either blocking the building up of the protein or enhancing the removal of the protein. All of these are possibilities, but we are not there yet.

The CHAIRMAN. Thank you for that explanation.

Senator COLLINS.

Senator COLLINS. Thank you, Mr. Chairman.

Dr. Petersen, noted neurologist and author Dr. Oliver Sacks has written about music's role and impact on patients with neurological disorders like Alzheimer's. I could not help but be struck by Ashley's poignant comment when she said her father is having a hard time remembering her name, and yet just a few moments before the hearing, I heard him playing the guitar, remembering very complicated musical sequences, singing with his daughter, and able to change chords and play significant portions of several of his songs.

Is there a neurological reason why music can have such a powerful effect on a patient with dementia and why the ability to remember and respond to music is retained even when the ability to remember the name of your daughter is not?

Dr. PETERSEN. It is a striking contrast in Mr. Campbell, his dense memory problem, as we have all seen, even manifesting in his inability to remember Ashley's name, and yet his ability to perform on stage. And, in part, there are neurologic explanations because of the parts of the brain that are involved in those different activities.

So, as I was mentioning to Senator Nelson that the brain—the disease starts in the memory part of the brain, and that is the part of the brain that sort of allows us to learn new information and recall recent information. Very old information—where we grew up, where we went to school—those kinds of events are often retained well into the disease.

In addition, the ability to play the guitar, which neurologists sometimes call procedural memory, motor skill memory, can be relatively preserved far into the disease process. So it is not an equal opportunity. The brain is not an equal opportunity organ to be affected by the disease. Certain regions are more susceptible to others.

So it is quite astounding that Mr. Campbell can be on the stage, can play music apparently fairly normally, really, things he has done many, many times going back literally decades. And if you prompt him with the lyrics of some of the songs with a teleprompter, it is business as usual. Mr. Campbell looks like the Mr. Campbell of years ago. Yet between songs, he may, as Ashley was indicating, he may wander around and then it becomes a little bit

of freeform as to what is going to happen next and we cannot necessarily predict, and he will have trouble with where he is going and what is happening next.

So it really involves the regions of the brain and the way the disease evolves over time.

Senator COLLINS. Thank you.

In addition to your role as a physician and as the Chair of the Advisory Council, you are one of the world's leading researchers on Alzheimer's through the Mayo Clinic. Could you tell us a little bit more about promising research that you are undertaking? I am hoping for everyone here, for all of us, that there are some promising developments or good news on the horizon. It has been a long time since there has been a breakthrough. I think it goes back to 2003, as I recall.

Dr. PETERSEN. Thank you, Senator. You have given me too much credit. I tend to work around a lot of bright people and they are the ones who are responsible for much of the progress in the disease.

I think there are some bright areas with respect to the disease itself and what we understand about it and getting ready to intervene. Some of the work that we are doing at the Mayo Clinic involves what we call the Mayo Clinic Study of Aging. Very briefly, this is a random sample of people who live in our region who are aging fairly normally. We have been able to evaluate these people ages 50 to 90, randomly sample them, bring them in, and study them thoroughly clinically. But we are also able to look at them with respect to what are called biomarkers, and by biomarkers, I mean images of the brain, MRI scans, PET scans. We can even image this protein in the brain called amyloid now when people are normal.

So we are poised to be able to characterize people, perhaps it is an overstatement to say a prediction formula, but that type of approach, risk profile of people based on their age, maybe their education, family history, some genetic features, maybe some of these biomarkers, that we will be able to say, you have a thus and so probability of developing the symptoms of Alzheimer's disease by a certain age.

That helps us, then, to have these individuals ready and poised to be able to take a therapy when that therapy—and I think it is “when,” not “if”—that therapy is, in fact, developed, so that we will be able to use that information regarding an individual's risk to dictate what kinds of therapies we use.

For example, what if an immunotherapy, an antibody or a vaccine, is developed? That is very promising, under investigation right now. It is likely to be expensive and maybe a little risky. So it may not be completely benign to give this. So we are going to need to know who is at the top third of the risk, who is in the middle, and who is in the bottom because we may want to expend those resources on individuals at the top end of it before they express the symptoms of the disease.

So I think that that type of work is out there. There is a great deal of work going on regarding the clinical characteristics and understanding of the disease. The therapy side is getting there but has not reached that pinnacle right now. But as soon as that hap-

pens, these two will merge and, hopefully, we will be able to have an impact on that disease.

Senator COLLINS. Thank you.

The CHAIRMAN. It is just amazing to me that with all of our ability to understand, that we cannot make the breakthrough here. We have not been able, for example, in others, such as ALS, Amyotrophic lateral sclerosis, Lou Gehrig's disease. And yet I think we are right on the cusp of the big breakthrough.

Dr. PETERSEN. I could not agree more, Senator, that I think we are just poised. The research community is anxious to be able to make those contributions. We cannot say yet today, tomorrow, where it is going to be. But I think so, and it is going to be a huge breakthrough when it happens.

The CHAIRMAN. Senator Whitehouse.

Senator WHITEHOUSE. First, let me thank Chairman Nelson for holding this hearing. This is such an important topic and I think you have done a really wonderful job of bringing very effective witnesses here. I also wanted—and the Ranking Member, as well. Thank you, Senator Collins.

I also wanted to thank the advocates who have been here today and compliment them on what I think is a really impressive piece of demonstrative literature that they brought with them. Donna McGowan and her husband, Bill, from Rhode Island came to visit me and they showed the graphic that you all have been handing out all day today, and it is really extraordinary when you look at the cost piled up in this huge line that Medicare and Medicaid will spend on this, not private insurance but just the Federal Government through Medicare and Medicaid, and then you compare what we are spending on research to try to avoid those costs. And if you do, you have got to look down to this little thing which you cannot even see out there. It is about as wide as my fingernail. This little speck is the amount that we are spending on NIH research to combat an illness that is creating that much cost.

As Ashley demonstrated so clearly, the cost of Alzheimer's is measured in a great deal more than dollars. But I think the case that has been made with this kind of material is really terrific and I look forward to working with my colleagues to make sure that that funding is protected and increased and we have a chance to get ahead of this illness.

One of the situations that emerges when a family is faced with this illness is the question of decisions that are going to be made as the illness progresses and how people wish to be treated. And it is incredibly important to make those decisions early on while the individual suffering from the disease still has the ability to make those decisions and determine what they want. And there are a great number of us on this committee—I know Senator Collins and Senator Nelson have been very active in this area—who want to improve the way in which Americans express their wishes about how they wish to be treated when their illnesses are advanced and make sure that living wills and advance directives and things like that are honored.

I would love to ask the panel what your experience has been at how effectively we are treating that goal with patients who have this illness and what kind of progress should we be making to

make sure that those choices are being driven by the wishes of the patient and the family and not just the grind of the health care system.

Mr. MOULDS. So, why don't I start and then Dr. Petersen, because he has obviously encountered this with patients in the course of his career, both as a researcher but also as someone providing care, medical care.

But there are a number of steps that are taken in the plan to provide information and encourage health care providers to have just the conversations that you are alluding to right now earlier on in the process. So care, planning, and coordination is incredibly important to this population. If ever there is a population where the case can be made that you need those elements in the provision of care, it is with patients with dementia.

We are pushing out through HRSA's Geriatric Education Centers—there are 45 of them over the country—as part of NAPA information to try to educate health care providers about best practices in dementia care, and part of that is having these care planning and coordination conversations in the doctor's office earlier in the process.

As for the question, the second part of the question, which is the question about advanced dementia care planning, that was, in fact, one of the recommendations that was made by the Advisory Council to the Secretary for inclusion in the 2014 Plan, so the second iteration of the Plan. All of those proposals or recommendations are before the Secretary at the moment. She is taking all of them very seriously, and we are happy to report back out, we expect that the second iteration of the Plan will be made public in May sometime, probably mid-May. There will be some discussion at the Advisory Council meeting on Monday, but we are happy to report further when she has made her decisions about the second iteration of the Plan.

Senator WHITEHOUSE. Thanks.

Dr. Petersen, anything to add in my remaining 38 seconds?

Dr. PETERSEN. Just a quick comment that it is increasingly important to do this. And I think our recommendations in the Plan have suggested that in geriatric education, because it is particularly important in this disease to do it earlier rather than later, because by the process of the disease itself, people lose the insight as to what is going on, because when the parts of the brain become involved with the disease that allow us to introspect and look at ourself, the people are no longer able to make those kinds of decisions. So emphasizing the importance of doing it early.

Senator WHITEHOUSE. Thank you.

The CHAIRMAN. Senator Donnelly.

Senator DONNELLY. Thank you, Mr. Chairman, and I want to thank all of our witnesses for all your hard work on this issue.

I also want to mention my former colleague in the House, Dennis Moore, who is dealing with this now, who is an extraordinary leader, extraordinary person, and so many Hoosiers who are here today for Alzheimer's.

Dr. Moulds, I wanted to ask, FDA recently approved a new diagnostic technology and it helps diagnose Alzheimer's. CMS is in the process of deciding whether it should be considered for national

coverage under Medicare and Medicaid. And I was wondering if you are working with CMS to ensure that all appropriate Medicare patients have access to technologies that can help with early diagnosis of Alzheimer's.

Mr. MOULDS. Sure. The short answer is that CMS has been quite engaged in this process. We have—I mentioned earlier in my opening remarks about the Interagency Working Groups that we established very early on. They are in three general areas, on the research side, clinical care, and then long-term care services and supports. CMS is chairing the clinical care subcommittee. There has been a good amount of conversation about diagnostics at CMS.

And more to the question about how to expedite the review of potentially helpful both diagnostics and, hopefully, going forward, therapeutics, there is a process that exists where that work can go on concurrently. CMS is reviewing, I believe, a number of diagnostic tools at the moment. I cannot speak to decisions—

Senator DONNELLY. Sure.

Mr. MOULDS [continuing]. But they go through the normal channels where they are reviewed by an external committee for efficacy and for the other considerations that go into making those decisions.

Senator DONNELLY. Thank you.

Dr. Petersen, I recently heard about an area called epigenetics and was wondering what you have seen in this area of almost—seeing its potential for treating Alzheimer's, what you think of it, what you know of it, and is this a path that seems to show promise.

Dr. PETERSEN. I think it might very well be promising insofar as that epigenetics refers to a trait of a particular disease that before the full expression of the disease appears. So, for example, if somebody has a genetic tendency to develop Alzheimer's disease by virtue of their genetic make-up, there may be signs that the disease is manifesting itself early.

So, for example, take imaging. Imaging—certain regions of the brain, as I was mentioning earlier, are preferentially affected by the disease. So there may be some signatures in the brain with shrinkage in certain parts of the brain that can be related to the genetic make-up of that individual and imply that this person is on the road to developing the disease.

Senator DONNELLY. And I certainly do not have your level of knowledge, obviously, but is that an area that could, in effect, turn it off at that point, turn off the Alzheimer's?

Dr. PETERSEN. It gives us an opportunity to pick up the disease process at an earlier point in time. So if we have effective therapeutics, we could intervene at that earlier point in time when that genetic signal, that epigenetic signal is there, and it gets to the issue of certain markers that characterize the disease and are they going to be therapeutic targets for the disease. We are not there yet, but that is where we are going.

Senator DONNELLY. And as we look at Alzheimer's and talk about 2025, do you have milestones that, as we look forward, here is where we hope to be by this time, here is where we hope to be by this time, so that we know either we are making progress or we are starting to fall behind from where we hope to be?

Dr. PETERSEN. A very timely question. With the Advisory Council meeting that is coming up on Monday that Dr. Moulds just referred to, we are going to be discussing just that issue, and our colleagues at the National Institute on Aging, Dr. Richard Hodes and his team, have developed a rather extensive chart of milestones mapping the plan, the plan that was translated into the research summit that was held at NIH last May, the recommendations coming out of that summit insofar as what are actual items that are actionable and when. So the grid has been divided into short-term goals, intermediate goals, long-term goals.

Senator DONNELLY. And I do not mean to interrupt you. I have ten seconds left. I just want to ask you, is the most important thing we can do to continue with the research funding?

Dr. PETERSEN. I am a little biased, but absolutely.

Senator DONNELLY. Okay. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Blumenthal.

Senator BLUMENTHAL. Thank you, and I want to join in thanking our Chairman and Ranking Member for having this hearing and also the advocates from all around the country who have been so steadfast and vigorous in championing this cause and also advocating for the kind of research that is necessary and caregiving to address this problem.

I want to begin with your testimony, Dr. Moulds, saying that the President's fiscal year 2014 budget includes a \$100 million initiative to fight this disorder through expanded research, improved supports for caregivers, and enhanced provider education and public awareness.

We have seen the charts. You know the numbers better than I. Is \$100 million really enough? I mean, does it even come close to being enough?

Mr. MOULDS. That is obviously a very difficult question to answer. What I can tell you is that the things that we are able to do with the investments that the President has identified, that we were able to do in 2012 and moving forward with both the insulin nasal spray trial and the trial in Colombia for early onset, were tremendously important activities.

I think if you were to ask anybody in the research community whether there are things beyond what you could fund with \$100 million that would be worthwhile research, the answer would almost certainly be yes. But if you think about the NIH budget and the way that it has been affected by sequester, the fact that we are moving forward with the research agenda this year, that the President has identified funds in 2014 reflects a tremendous commitment to fighting this disease.

Senator BLUMENTHAL. But I take it that if you had double or triple or a lot more money, there would be worthwhile research to be done.

Mr. MOULDS. So, to be clear, I am not an Alzheimer's researcher, so I would defer to people who are.

Senator BLUMENTHAL. I am happy for you to defer, but I think you know enough—

Mr. MOULDS. Yes.

Senator BLUMENTHAL [continuing]. I think almost everyone in this room knows enough to say, yes.

Mr. MOULDS. So, I would reiterate the answer that I gave earlier, which is that when you talk to researchers in the community and ask the question that you just put, the answer is, yes, there is more that can be done. There is a lot that can be done. We are making tremendous efforts to move this agenda forward. We did it last year. We are doing it this year. We will be doing it in 2014.

Senator BLUMENTHAL. Dr. Petersen, did you have anything you wanted to add?

Dr. PETERSEN. In my remarks, I indicated that the Advisory Council has recommended a research budget of about \$2 billion a year. A reasonable question, where did that number come from? Well, in fact, the Alzheimer's Association undertook an exercise during the development of the first plan and the recommendations surrounding the first plan asking experts in the research community, in your area of research, what are short-term goals, what are medium goals, and can you put a price tag on that?

As difficult as that is, in fact, many researchers came together throughout the entire spectrum of the disease, basic biology to treating patients, put numbers on their goal, what time frame and all, and, in fact, generated this \$2 billion. So I think, again, the community really can be receptive of that figure as being relatively solid.

Senator BLUMENTHAL. Thank you.

Well, I understand, Dr. Moulds, the limitations of what you can say and what your role is here. My question to Dr. Petersen was going to be about how that \$2 billion number is derived. You know, it could be \$20 billion. It could be \$100 billion. But \$2 billion seems to be the consensus number that the research community would pinpoint.

Mr. MOULDS. I mean, I think so. And, again, it is \$2 billion or more, because, in fact, to do a clinical trial in Alzheimer's disease may be \$100 million-plus to run it out. This is a chronic disease. It takes many people to test a particular therapeutic. So that is just one aspect. But there are a lot of other basic science questions that need to be answered, as well as clinical questions regarding the characterization of the disease. So I think that is a realistic number.

Senator BLUMENTHAL. Thank you.

One last question, if I may ask you, Dr. Hurd. We have not, in my view, developed the kind of private insurance tools that families need to deal with this problem. Could you give us some thoughts about whether you believe that there are private insurance policies and products available now to help families address the huge, humongous, often heartbreaking costs financially that they need to face in dealing with a family member afflicted with this disease.

Mr. HURD. Well, I think, indeed, it is a big lack in the insurance market and it exposes some families to tremendous financial risk, catastrophic risk, because of the chances—there are not large chances, but there are chances that they might have to support a family member in a nursing home for ten years, and we know the costs of one year in a nursing home are approaching \$100,000 per year. So you can see what the numbers are.

The main risky group would be where one spouse remains in the community and the other spouse is in the nursing home, because then the spending will come out of the family's resources and impoverish the person in the community.

Why are there not? So, we know that the products that are there are not satisfying to families because the take-up rate, as I mentioned, is 13 percent. Why are the policies unsatisfactory? It is difficult for the insurance companies to write kind of correct kind of policies. So the typical insurance policy has caps on the daily rate. It has caps on the lifetime amount that will be paid out. So the insurance policies do not address the extreme upper tail of costs, leaving families exposed to that cost.

That is the part that needs to be covered, because, after all, you do not need insurance—well, we have insurance for eyeglasses, but you really do not need insurance for eyeglasses. You need insurance when your house burns down, not when you scorch your rug. And that is the analogy.

But insurance companies do not know what that long-term, what that tail risk is, either, because, for example, suppose we have improvements in the ability to keep people alive with Alzheimer's. So rather than having ten years in a nursing home, it now goes up to 15 or 20. The insurance companies do not know how to price that. They do not know what the actuarial value is of that and they do not know what the risk of that happening is.

So there is a risk out there that nobody is willing to pick up and to bear, and we do not know the price of that risk. That was—the CLASS Act was supposed to address that issue, and, of course, the CLASS Act was not successful. But that is a gap in the insurance market that possibly public policy should be addressing.

Senator BLUMENTHAL. Thank you very much, and again, my thanks to the panel and to our Chairman.

The CHAIRMAN. And just to underscore what Senator Blumenthal has said, right now, this is about a \$140 billion a year problem, and in another 30 years, it is going to be a trillion dollar problem. And of that trillion per year, it is going to be about two-thirds of that paid by Medicare and Medicaid. So, Dr. Petersen, another reason for you all to find a cure, not even to speak of the heartbreak and the personal stories, the cost.

Now, Dr. Hurd, I want to ask you cost, but from a different angle. To take care of an Alzheimer's patient, it is usually about \$28,000 a year. A lot of the caregivers are the family members that are the same age, and the average household income of that age group over 65 is about \$35,000 a year. So how are the families going to manage the cost? Until we find the cure, is it that we are looking at bankruptcy?

Mr. HURD. The cost, of course, is spread over a number of payers, and families spend what they are able to. But we—families are facing bankruptcy. Families are facing catastrophic out-of-pocket spending for reasons that I mentioned previously. Right now, there is no effective way for families in particular situations to avoid that. There are no insurance products. There is really nothing that those families can do except do the best they can, and it is a situation—it is an insurable situation in principle where costs are enor-

mous for small numbers of people, less enormous for larger numbers of people. But we do not have those insurance products.

The CHAIRMAN. To underscore what Senator Whitehouse had said, we are spending over close to \$6 billion a year on cancer research and, of course, the budgets have been going backwards on Alzheimer's research. It was about a half-a-billion dollars. In the sequester, that was cut back. The President has come out with his proposal, which is about a \$100 million increase, which should take it somewhere in the range of \$600 million. But that is a far cry.

Some experts have said that if you really want to make some advances in finding the cure, that we ought to be spending \$2 billion a year on research. Does anybody want to comment on that?

Dr. PETERSEN. Well, I think that this is an appropriate observation, and the funding that has been expended on cancer research, on HIV/AIDS, on heart disease, presumably has been effective, because the annual mortality, number of deaths per year, in all of those disorders is, in fact, decreasing while the number of deaths due to Alzheimer's disease, related to Alzheimer's disease, is skyrocketing in the opposite direction.

So one would think that—again, I am not an economist, but the investment of around \$2 billion a year for research now would pay back so many times over in terms of the savings that Dr. Hurd has alluded to if, in fact, these costs could be reduced. It makes sense that this is the investment that needs to be made now.

The trouble is, this is a difficult time—you know better than I—to make these kinds of statements. But, in fact, the investment has to be made right now.

The CHAIRMAN. Presently, we have some assisted living facilities that offer specialized memory care units. Dr. Hurd, how do we go about having them properly regulated and how do we let people know what is appropriate?

Mr. HURD. Well, I wish I had the answer to that. You have asked me something out of my area of scientific expertise. I could give you an answer as an informed reader of the New York Times or Wall Street Journal, but not as a scientific effort, so maybe I should pass to Dr. Petersen or Dr. Moulds on that one.

Mr. MOULDS. I can take a little bit of a stab at it. So, assisted living facilities are regulated by States, which limits to a significant degree the Federal Government's ability to intervene in the way that they are run. We certainly engage in research in my office, for example, at the Administration on Community Living, looking at best practices in these facilities, looking at model regulatory policy. We share practices across States. So there are those possibilities, but it is one of those things that is largely controlled by States.

The CHAIRMAN. Do you think there is a Federal role for us to try to ensure that these residential facilities are providing the high-quality care?

Mr. MOULDS. I would say that, certainly, where we have levers, it would be an important area to be using those levers. As I said, we have limited levers available to us now. We can certainly share and push information and have not been shy about doing that.

The CHAIRMAN. Do we have any leverage?

Mr. MOULDS. As regulators, no, and there are—I mean, insofar as they are Medicaid beneficiaries and Medicare beneficiaries that live in some of these cases, we have—there are potentially some hooks there. But, again, the facilities themselves are regulated by the State.

The CHAIRMAN. Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman.

Dr. Hurd, I am very interested in the research that you have done on the costs, since many of us are aware of the emotional toll that Alzheimer's takes and the horrible suffering that the victims and their families endure. Around here, you also have to look at the economics of a disease.

Now, given that cancer and heart disease, cardiovascular diseases, are also age-related, could you give us a comparison of the trend lines for those diseases in terms of costs versus Alzheimer's.

Mr. HURD. I cannot give those directly. The cancer and the heart numbers that we came up with and cite in our paper come from studies of the medical expenditure panel survey, and I have not seen equivalent trends on those. But the defining aspect, of course, of the cost associated with Alzheimer's and dementia is it is age-related. Roughly speaking, the prevalence doubles every five years beginning among people in their 70s, and as the baby boom generation reaches those advanced old ages, then we see the very large increases in prevalence and, therefore, costs.

I would not think those same trends would pertain to cancer and heart, where the age prevalence is not nearly so strong and so striking, firstly. And, secondly, the baby boom generation, the extremely large generation associated with those birth years, will have passed through those critical years and now are approaching the ages when Alzheimer's and dementia is so prevalent.

Senator COLLINS. And, fortunately, and in part due to the investments that we have made in research for those diseases, we do have some treatments, means of delaying the onset, even in some cases cures, and that is what is so troubling on the Alzheimer's side, is that we can do so little.

Dr. Moulds, I cannot help but think that this is one of those classic cases where an investment up front is going to save our nation so much money in the long term, and when we have Federal health programs like Medicare and Medicaid already in financial trouble, already teetering in some cases, does it not make sense to make that kind of investment in the hopes that we can save money later in Medicare and Medicaid? I am just talking about the economics. I am putting aside the terrible human suffering right now.

Mr. MOULDS. Sure, and absolutely, and you would get a wholehearted agreement from both the President and the Secretary on that statement. It does make sense to invest in this now, which is why the President put forth the initiative a year and a half ago now and reiterated it in his 2014 budget.

I will also add that there are, in addition to investments in the research side, there are key investments on the caregiver side that are incredibly important. One of the things that we know, that the research has shown about caregivers—and keep in mind that the best outcome for everyone, for a person with Alzheimer's, for their loved ones and for the government, is to enable a person with the

disease to stay in their home, be cared for by their family or other loved ones as long as possible.

But what the research shows is that it is often fairly small things that make those arrangements impossible, that lead to a person with Alzheimer's disease needing to go into a nursing home. So it is a sprained ankle or a thrown back or the fact that they could not quite accommodate the job that they are doing at the same time. So strategically placed reinforcements for the people who are providing the care, very, very important, as well.

Senator COLLINS. Well, it is also why we should not be cutting home health care, because that can help people stay in their homes and avoid far more expensive institutional care, as well.

I guess my concern today is while I completely commend the President for increasing Alzheimer's research by \$100 million in his budget and paying attention to the caregiver side, as well, when we hear that the Council has advised that at least \$2 billion be spent, and I believe the number in the President's budget is \$564 million, we are a long ways away from the recommended amount.

Now, I am also very cognizant of the budget constraints that we are living under. But does the administration have a plan for ramping up the amount, the investment in Alzheimer's so that it is more on a pure level with the amount that we are investing in AIDS or cancer or other serious diseases?

Mr. MOULDS. I think you framed the challenges very well. Certainly, the President and the Secretary recognize that this is important on many different levels. They are absolutely committed to funding this research going forward. I cannot speak to Presidential budgets beyond the 2014 budget, obviously, but I can testify about the imperativeness that both of them see in moving forward with this agenda.

Senator COLLINS. When I look at the research levels, it seems to me that there are two areas that are really underfunded, and diabetes is one and Alzheimer's is another, when you look at the costs that they are imposing on Federal health care programs, not to mention the suffering they are imposing on families across this country.

Let me just ask a couple more questions, if I have the Chairman's indulgence.

The CHAIRMAN. Take your time.

Senator COLLINS. Thank you.

Dr. Petersen, one thing that we are going to hear is that, let us say we could magically wave a wand and produce the \$2 billion that has been recommended, which I would love to do. What we are going to hear is the question, can it be spent wisely? If the current funding level is around \$470 million, that is a huge leap, and we do not have—we cannot waste a single dollar nowadays. Are the projects out there? Are the clinical trials available? Would the money be well spent, or would it be more productive to have the money ramp up and have a plan over the next five years for what the funding level should be so that researchers like you can know what is coming and be prepared to spend this money very wisely?

Dr. PETERSEN. Well, I think that the research community is ready to be able to absorb that and move ahead. But toward that exercise, with the summit that was held at the NIH last May for

Alzheimer's disease, as I was indicating earlier, there was a prioritization and a categorization of research areas and what it would take in each of those fields. That has been translated at the National Institute on Aging into certain concepts that would be appropriate for research. That was approved by the National Council on Aging, the National Advisory Council on Aging, and that has been translated into RFAs, requests for applications to the research community. They have been put out and now there have been research grant applications that have come in in response to that.

On May 1 and 2 this year, there is going to be a similar summit for the non-Alzheimer's dementias, the frontal temporal, the dementia with Lewy bodies, vascular disease. The same exercise will be undertaken then, where the disease areas are being brought out, categorized, the experts are coming together, and a prioritization of research undertakings will be made such that if the funding were available, here is where it would go.

So I think the NIA is acting and the NIH is acting proactively as if. Now, if that does not come to be, we have got a problem. But I think people are thinking ahead because there is the hope that either the ramping up or a large bolus will come forward, and I think the research community would be able to march forward very rapidly.

Senator COLLINS. Thank you.

My final question, Dr. Moulds, Dr. Petersen referred to the international—I think there was an international conference that was held. If we can coordinate efforts around the globe for research, we have the potential to ensure that there is faster progress. Could you update us on what is being done to coordinate Alzheimer's research around the world as the National Alzheimer's Plan Act envisioned?

Mr. MOULDS. I would be happy to. As you know, because you were instrumental in its passage, the NAPA legislation directed us to develop structures to better coordinate these efforts internationally.

There are a couple of different efforts underway at the National Institutes on Aging. The first was the one that Dr. Petersen referred to, which was the symposium where we did international planning and looked at priorities in funding projects moving forward. They have also developed a tool that effectively allows countries and non-governmental entities to input work globally that is going on so that everyone is aware of work going on internationally.

There are a number of countries that have plans in place, so in England, it is the Prime Minister's Dementia Challenge. There has been an ongoing initiative in France. We have been contacted by the Japanese, who are working on a plan. The Koreans are working on a plan. This is an issue that is not constrained to our borders. Many of those plans also include research components and dollars that are dedicated to research.

So we are engaging at a couple of different levels. One is a multilateral level, which are the planning activities that I mentioned and the tools for engaging multilaterally. But we are also engaging in a bilateral way. So we have frequent conversations with the leaders of the plan.

In Britain, for example, many of the initiatives that are part of their initiatives are starting—they are doing both demonstrations and evaluations, so we share early results from initiatives that are underway. We have the leader of the British plan and the leader of the Canadian plan who are coming to testify at the Advisory Council on Monday.

So this is a very global effort. This type of coordination is going to be absolutely essential to maximize limited resources. But there are many partners in this because as populations age globally, this becomes more epidemic in all of the nations that are facing these aging challenges.

Senator COLLINS. Thank you.

I want to thank our witnesses today. You were all very illuminating and helpful to us. And most of all, I want to thank our Chairman for holding this very important hearing. I think it has been so heartening for the advocates who are here today to get this update on the plan and on our personal commitment, as well. I have worn this purple suit for many years during the annual day that the Alzheimer's advocates come to town, and I fear I am going to have to keep it around for many, many more years and I would like us to get a cure so that I can retire it once and for all.

[Laughter and applause.]

The CHAIRMAN. Well, it is very becoming.

Senator COLLINS. Thank you.

[Laughter.]

The CHAIRMAN. Dr. Moulds, we look forward to the receipt of the new plan. When do you think that will be coming?

Mr. MOULDS. So, we anticipate probably mid-May, but almost assuredly sometime in May. As I mentioned, the second—this is an annual process, so we are required by the statute to update on an annual basis. The Advisory Council is charged with providing recommendations to the Secretary, which we share with Congress, as well, and post on our Web site. We have tried to make this as both transparent and as public a process as possible for numerous reasons.

So the recommendations are with the Secretary. We are making great progress on the second iteration of the plan and we anticipate that it would come out shortly after the Advisory Council meeting, which is next week.

The CHAIRMAN. Well, we look forward to it, and if you would rap the knuckles of OMB for delaying your testimony to me for this hearing, I would appreciate it.

We are going to hold the record open for one week. There are many advocates that I know want statements entered into the record.

Anything more, Senator Collins?

Senator COLLINS. No. Thank you again, Mr. Chairman.

The CHAIRMAN. All right. Thank you.

The meeting is adjourned.

[Whereupon, at 3:43 p.m., the committee was adjourned.]

APPENDIX

*Chairman Bill Nelson opening statement
U.S. Senate Special Committee on Aging
Hearing: The National Plan to Address Alzheimer's disease: Are We on Track to 2025?
April 24, 2013*

Good afternoon everyone, and thank you for being here today as we discuss efforts to combat Alzheimer's disease.

Alzheimer's is the sixth leading cause of death in the U.S. overall, and the fifth leading cause of death for those above the age of 65. It is the only cause of death among the top 10 without a way to prevent it, cure it, or even slow its progression.

Today, 1 in 3 seniors dies with Alzheimer's or other types of dementia. And, with the aging of the baby boom generation, the number of Americans age 65 and over with Alzheimer's will increase dramatically unless we find a way to prevent or effectively treat the disease. If nothing is done to reverse this trend, the Alzheimer's Association estimates that up to 16 million Americans will be living with the disease by 2050.

In my own state of Florida, we've seen the number of Alzheimer's cases climb 25 percent over the past 10 years.

In response to these troubling numbers, the Department of Health and Human Services last May released the National Plan to Address Alzheimer's Disease. One of the plan's goals is to effectively prevent and treat the disease by 2025, and today we will be discussing how we can reach that goal.

So, we are up against a clock to make advances in the diagnosis, treatment, and care of those with Alzheimer's. While work is already underway around the country at places like the *University of South Florida's Byrd Alzheimer's Institute* and *Wien Center for Alzheimer's disease and Memory Disorders at Mount Sinai Medical Center in Miami*, there is still much to be done to meet the goal of finding effective treatments by 2025.

I'd like to take a moment to thank the Alzheimer's Association for their tireless work on behalf of those facing this devastating and debilitating disease. Today, the Alzheimer's Association had over 900 citizen advocates on Capitol Hill, including former Congressman Dennis Moore (D-KS) and his wife Stephene, who are here today. This turnout illustrates just how many people are impacted by this disease and are dedicated to finding a cure.

Like so many illnesses, Alzheimer's places emotional and financial strains not just on the patient, but on the caregivers and the entire family. I'd like to thank country music legend Glenn Campbell and his daughter, Ashley, for being here today to share their story with us.

In addition to the human suffering it causes, Alzheimer's places an enormous financial strain on families, the health care system, and on state and federal budgets. A recent RAND Corporation study found that Alzheimer's and other forms of dementia cost the U.S. more than

either cancer or heart disease. The report also found that each year the condition costs the country between \$159 billion and \$215 billion, a cost that could double by 2040. Dr. Michael Hurd, PhD and senior economist at RAND, was the lead researcher on this study and we are happy to have him with us today.

And, we will also hear from two witnesses on the federal government's efforts to combat Alzheimer's. Don Moulds, Acting Assistant Secretary for Planning and Evaluation at HHS, and Ronald Petersen, chair of the National Alzheimer's Advisory Council and Director of the Mayo Alzheimer's Disease Research Center, are with us today and we look forward to hearing their testimonies, as well.

I would now like to turn it over to Senator Collins for her opening remarks.

STATEMENT OF
SENATOR SUSAN COLLINS
SENATE SPECIAL COMMITTEE ON AGING

*"THE NATIONAL PLAN TO ADDRESS ALZHEIMER'S DISEASE: ARE WE ON TRACK
TO 2025"*

APRIL 24, 2013

Mr. Chairman, thank you for calling this hearing to examine the tremendous toll that Alzheimer's disease takes on our nation and to assess the progress since the enactment of the National Alzheimer's Project Act in 2011. Along with former Senator Evan Bayh, I am proud to have been the sponsor of that law, known as NAPA.

Alzheimer's is a terrible disease that exacts a tremendous personal and economic toll on both the individual and the family. As someone whose family has experienced the pain of Alzheimer's many times, I know that there is no more helpless feeling than to watch the progression of this devastating disease. It is an agonizing experience to look into the eyes of a loved one only to receive a confused look in return. It is equally painful to witness the emotional and physical damage inflicted on family caregivers, exhausted by an endless series of "36 hour" days.

And my family is by no means alone. An estimated 5.2 million Americans have Alzheimer's disease, more than double the number in 1980. Based on the current trajectory, as many as 16 million Americans over the age of 65 will have Alzheimer's disease by 2050.

Moreover, in addition to the human suffering it causes, Alzheimer's costs the United States more than \$200 billion a year, including \$142 billion in costs to Medicare and Medicaid. This price tag will increase exponentially as the baby boom generation ages. If nothing is done to slow or stop the disease, Alzheimer's will cost the United States an astonishing \$20 trillion over the next 40 years, according to the Alzheimer's Association.

It is estimated that nearly one in two of the baby boomers reaching 85 will develop Alzheimer's. As a consequence, chances are that members of the baby boom generation will either be spending their golden years with Alzheimer's or caring for someone who has it. In many ways, Alzheimer's has become the defining disease of my generation.

A strong and sustained research effort is our best tool to slow the progression and ultimately prevent the onset of this tragic disease. If we fail to change the current trajectory of Alzheimer's disease, our country will not only face a mounting national health crisis, but an economic one as well.

Despite all the alarming statistics, until now, there has been no national strategy to defeat Alzheimer's and our efforts to combat the disease have lacked coordination and focus. That is why the National Alzheimer's Project Act – or NAPA – creates a strategic national plan for combating Alzheimer's disease.

This National Plan, which will be updated annually, will help us focus our efforts and accelerate our progress toward better treatments, a means of prevention, and ultimately, even a cure for this devastating disease.

The annual review process required by the law is intended to help us to answer the simple question – have we made satisfactory progress this year in the fight against Alzheimer’s?

And that is why we are here today. The primary goal of the first National Plan to Address Alzheimer’s Disease released last May was “to prevent and effectively treat Alzheimer’s disease by 2025.” It is my understanding that the next version of the National Plan will be released next month. So this seems to be a perfect time for a progress check.

Thank you again, Mr. Chairman, for calling this hearing. Issues related to Alzheimer’s are near and dear to my heart, and I look forward to hearing from our witnesses.

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Senator Jeff Flake
The Special Committee on Aging
Questions for the Record

1. Question for Dr. Petersen on private partners role:

Dr. Petersen, you stated in your testimony that “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 the 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.”

Question: Can you speak more to what private partners have brought to the table or done to achieve the National Plan goals? Also, do you have any data on what the private sector has contributed financially towards achieving these goals?

Answer from RP: *There have been several efforts at convening groups in the private sector concerned with developing more effective treatments for Alzheimer’s disease. For example, the Alzheimer’s Association convenes the Alzheimer’s Association Research Roundtable twice a year to bring industry, academia and government officials together to discuss what can be done to facilitate the development of new therapeutics for Alzheimer’s disease. One example of this effort has pertained to how the various companies can work together in the pre-competitive space to achieve outcomes that would be useful for all of the companies when they develop their specific products. Another example of a public-private partnership pertains to the Alzheimer’s Disease Neuroimaging Initiative (ADNI). The ADNI is co-funded by the National Institute on Aging and the Foundation for the National Institutes of Health (FNIH). In the first phase of ADNI, from approximately 2004 through 2009, the NIA contributed \$40 million, and the FNIH contributed \$20 million. In the renewal phase of ADNI, once again, NIA contributed \$40 million, and the FNIH has contributed over \$20 million, trying to achieve a \$29 million contribution goal. This co-funding effort has been critical for the study since it includes over 1,000 subjects being followed longitudinally. The FNIH receives its funding from a combination of private partner sources such as pharmaceutical companies and diagnostic imaging companies. This has proved to be a very successful collaboration.*

2. Question for Dr. Petersen on the cost impact of new drug:

According to the Alzheimer’s Association, a drug that postpones the onset of Alzheimer’s by 5 years could save the health care system \$170 billion dollars a year by 2030. Do you agree that new treatments have the potential to offset the substantial direct and indirect costs of care?

Question: Dr. Petersen, do you agree that new treatments have the potential to offset the substantial direct and indirect costs of care?

Answer from RP: *Yes, preliminary estimates indicate that the potential savings to the health care system by reducing the number of individuals who would develop severe dementia would be substantial. The cost of caring for individuals with all stages of cognitive impairment is*

enormous, and Dr. Hurd in his testimony to the Senate Special Committee on Aging highlighted these figures. Projections indicate that, if we could postpone the onset of dementia and/or slow the progression of dementia, the cost savings would be significant. While this is not a simple calculation because there are other health care costs associated with longevity, the funds saved by reducing morbidity from Alzheimer's disease coupled with the maintenance of the integrity of an individual's identity and role within the family would be incalculable. We at the Mayo Clinic in conjunction with colleagues from the University of Southern California are working on a health economics model based on the Mayo Clinic Study of Aging that demonstrates the savings to be accrued to the health care system.

The Monetary Costs of Dementia in the United States

Addendum

Michael D. Hurd

RAND Office of External Affairs

CT-386/1

July 2013

Document submitted on July 12, 2013 as an addendum to testimony presented before the Senate Special Committee on Aging on April 24, 2013

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Michael D. Hurd¹
The RAND Corporation

*The Monetary Costs of Dementia in the United States
Addendum²*

Before the Special Committee on Aging
United States Senate

July 12, 2013

The subsequent questions and answers found in this document were received from the Committee for additional information following the hearing on April 24, 2013 and were submitted for the record.

**Senator Jeff Flake
The Special Committee on Aging
Question for the Record**

1. Question for Dr. Hurd on cost of treating Alzheimer's patients:

Dr. Hurd, in your testimony you talked about how your cost estimates assume that real costs per case will remain constant. You also mention within your testimony that this assumption will have little bias because care-giving accounts for a large cost of total costs.

Question: Could you elaborate more generally on this cost issue? I'm curious to know how today's cost compare to what they were 10, 20 or 30 years ago and if the ratio of care-giving required has changed over that same time period?

Response of Michael Hurd:

We have found consistent cost comparisons just going back to 1999.

The following table shows Medicaid payment rates for nursing home rooms both in nominal terms and in real terms (adjusted for general inflation). The average payment rate increased at a faster rate than inflation, on average about one percent per year

¹ The opinions and conclusions expressed in this testimony are the author's alone and should not be interpreted as representing those of RAND or any of the sponsors of its research. This product is part of the RAND Corporation testimony series. RAND testimonies record testimony presented by RAND associates to federal, state, or local legislative committees; government-appointed commissions and panels; and private review and oversight bodies. The RAND Corporation is a nonprofit research organization providing objective analysis and effective solutions that address the challenges facing the public and private sectors around the world. RAND's publications do not necessarily reflect the opinions of its research clients and sponsors.

² This testimony is available for free download at <http://www.rand.org/pubs/testimonies/CT386z1.html>.

	Nominal	Real (\$2010) using CPI
	Average Medicaid Payment Rate	Average Medicaid Payment Rate
1999	\$108	\$141
2000	\$109	\$139
2001	\$118	\$145
2002	\$124	\$150
2003	\$129	\$153
2004	\$142	\$163
2005	\$145	\$162
2006	\$150	\$163
2007	\$156	\$164
2008	\$164	\$166

Source: A report on Shortfalls in Medicaid Funding for NH Care Eljay, LLC, 2010

Medicaid rates and private rates differ as to both level and trend. The following table shows private pay rates for both semi-private and private rooms. Private pay rates are higher for a semi-private room than what Medicaid pays. For example in 2008, Medicaid paid \$164 and the private pay rate was \$191. Over the 10 years shown, private pay rates increased after adjustment for general inflation by about 0.6% per year for a semi-private room and by 0.4% per year for a private room.

	Nominal		Real (\$2010) using CPI	
	Semi private	Private	Semi private	Private
2002	\$143	\$168	\$173	\$203
2003	\$158	\$181	\$188	\$215
2004	\$169	\$192	\$195	\$222
2005	\$176	\$203	\$197	\$227
2006	\$183	\$206	\$198	\$223
2007	\$189	\$213	\$199	\$224
2008	\$191	\$212	\$193	\$215
2009	\$198	\$219	\$201	\$223
2010	\$205	\$229	\$205	\$229
2011	\$214	\$239	\$207	\$232

Source: MetLife Market Survey of Nursing Home, Assisted Living, Adult Day Services, and Home Care Costs, various issues

In our current cost estimates these variations in cost over time were taken into account. But to the extent that nursing home costs continue to increase at a faster rate than general inflation, our forecasts of costs in the future will be underestimates.

As for the second part of the question (ratio of care giving required), I have no information on that issue.

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Testimony of the Alzheimer's Association
 Hearing on The National Plan to Address Alzheimer's Disease:
 Are We On Track to 2025?

Special Committee on Aging
 United States Senate

May 1, 2013

Mr. Chairman, Ranking Member Collins and members of the Committee, the Alzheimer's Association appreciates the opportunity to submit a statement for the record on the state of the National Alzheimer's Plan. Additionally, the Association would like to thank the Committee for focusing on Alzheimer's, an escalating national epidemic, by holding the first hearing on the progress of implementing the first-ever *National Plan to Address Alzheimer's Disease*. The first year of the *National Plan to Address Alzheimer's Disease (The Plan)* has included significant steps toward changing the trajectory of Alzheimer's disease, but there is still much work to be done. To implement the Plan, it is critical that Congress support the President's FY 2014 budget request for the activities in the Plan, including \$100 million for Alzheimer's research, education, outreach, and caregiver support activities.

State of the Disease

Alzheimer's is a progressive brain disorder that damages and eventually destroys brain cells, leading to a loss of memory, thinking and other brain functions. Ultimately, Alzheimer's is fatal. Currently, Alzheimer's is the sixth leading cause of death in the United States and the only one of the top ten without a means to prevent, cure or slow its progression. Over five million Americans are living with Alzheimer's, with 200,000 under the age of 65. While deaths from other major diseases, including heart disease, stroke and HIV continue to experience significant declines, those from Alzheimer's have increased 68 percent between 2000 and 2010.

In 2013, America is estimated to spend \$203 billion in direct costs for those with Alzheimer's, including \$142 billion in costs to Medicare and Medicaid. Average per person Medicare costs for those with Alzheimer's and other dementias are three times higher than those without these conditions. Average per senior Medicaid spending is 19 times higher. A primary reason for these costs is that Alzheimer's makes treating other diseases more expensive, as most individuals with Alzheimer's have one or more co-morbidity that complicate the management of the condition(s) and increases costs. For example, a senior with diabetes and Alzheimer's costs Medicare 81 percent more than a senior who only has diabetes.

If nothing is done, as many as 16 million Americans will have Alzheimer's disease by 2050 and costs will exceed \$1.2 trillion dollars (not adjusted for inflation), creating an enormous strain on the healthcare system, families and the federal budget. In fact, an NIH-funded study in the *New England Journal of Medicine* confirmed that Alzheimer's is the most costly disease in America, with costs set to skyrocket at unprecedented rates. The expense involved in caring for those with Alzheimer's is not just a long-term problem. As the current generation of baby boomers age, near-term costs for caring for those with Alzheimer's will balloon, as Medicare and Medicaid will cover more than two-thirds of the costs for their care. Smart investments in scientific research have proven to pay big dividends, as demonstrated by recent reductions in mortality rates for conditions such as cancer, HIV/AIDS, cardiovascular disease and diabetes. In sum, Alzheimer's disease is the costliest disease in America, and is set to increase like no other -- but we can change this with the proven policies that have led to progress against other major diseases.

the compassion to care, the leadership to conquer

With Alzheimer's, it is not just those with the disease who suffer -- it is also their caregivers and families. In 2012, 15.4 million family members and friends provided unpaid care valued at over \$216 billion. Caring for a person with Alzheimer's takes longer, lasts longer, is more personal and intrusive, and takes a heavy toll on the health of the caregivers themselves. More than 60 percent of Alzheimer's and dementia caregivers rate the emotional stress of caregiving as high or very high, with one-third reporting symptoms of depression. Caregiving also has a negative impact on health, employment, income and finances for countless American families. Due to the physical and emotional toll of caregiving on their own health, Alzheimer's and dementia caregivers had \$9.1 billion in additional health costs in 2011.

Changing the Trajectory

Until recently, there was no federal government strategy to address this looming crisis. Advocates for the Alzheimer's community fought for years to ensure a robust and coordinated federal strategic plan to tackle the problems associated with Alzheimer's and other dementias. In 2010, thanks to bipartisan support in Congress and the tireless work of our dedicated advocates, the National Alzheimer's Project Act (NAPA) (P.L. 111-375) passed unanimously. NAPA mandated the creation of a strategic national plan to address Alzheimer's disease.

The Plan is required to include an evaluation of all federally-funded efforts in Alzheimer's research, care and services -- along with their outcomes. In addition, the Plan must outline priority actions to reduce the financial impact of Alzheimer's on federal programs and on families; improve health outcomes for all Americans living with Alzheimer's; and improve the prevention, diagnosis, treatment, care, institutional-, home-, and community-based Alzheimer's programs for individuals with Alzheimer's and their caregivers. NAPA will allow Congress to assess whether the nation is meeting the challenges of this disease for families, communities and the economy. Through its annual review process, NAPA will, for the first time, enable Congress and the American people to answer this simple question: *Did we make satisfactory progress this past year in the fight against Alzheimer's?*

On May 15, 2012, the U.S. Department of Health and Human Services (HHS) released the first-ever *National Plan to Address Alzheimer's Disease*. The Plan established goals and action steps in the areas of research, care, support and public awareness in order to prevent and effectively treat Alzheimer's disease by 2025. We are pleased that the Plan includes such a specific and important goal that, when successfully achieved, will deliver critically needed progress in the fight against Alzheimer's disease.

Prior to the release of the Plan, the Alzheimer's Association convened public input sessions across the country to allow affected individuals to share their insights, concerns and hardships in facing Alzheimer's disease. The result of those sessions was a report, *Alzheimer's from the Frontlines: Challenges a National Alzheimer's Plan Must Address*, which included input from more than 43,000 individuals from across the country. We were pleased to see many of these concerns addressed in the first iteration of the Plan.

Over the past year, the Plan has made progress in the fight against Alzheimer's including:

- Creating a blueprint for Alzheimer's research at the National Institutes of Health (NIH), a much needed first step in setting priorities for Alzheimer's research.
- Expediting Food and Drug Administration (FDA) approval of drugs for early-stage Alzheimer's.
- Developing quality measures for dementia care in nursing homes.
- Enhancing dementia training for healthcare professionals.
- Promoting resources for caregivers through the creation of www.alzheimers.gov.

Yet, despite this progress, there are still things that have yet to be accomplished. Immediately following the release of the Plan, we applauded actions taken by the President and NIH to shift an additional \$50 million in existing funds toward new Alzheimer's research. We were also grateful for the inclusion of an additional \$100 million in funding for Alzheimer's research as well as education, outreach and support in the FY 2013 budget request. However, because of challenges experienced during last year's appropriations process, Congress was unable to provide this additional funding that is so desperately needed. For two years, the Advisory Council on Alzheimer's Research, Care and Support has recommended a rapid ramp-up in Alzheimer's research to at least \$2 billion a year. In Fiscal Year 2013, NIH is expected to spend only \$484 million on this research. This means that for every \$29,000 Medicare and Medicaid spends caring for individuals with Alzheimer's, the NIH spends only \$100 on research to find treatments for Alzheimer's.

Quality care is dependent on an individual being diagnosed and receiving care planning. The Plan has not done enough to ensure that Medicare is addressing these needs, nor has it led to the creation of a more comprehensive and effective strategy to train healthcare professionals to provide this service. Additionally, the Plan has not begun to address the home- and community-care needs of individuals with the disease and their caregivers. Recommendations made in January by the Advisory Council on Alzheimer's Research, Care and Services would take steps to address these shortcomings, and we support their inclusion in the next version of the Plan as HHS prepares its release in the coming weeks.

Understanding current gaps in research and provider training, the President's FY 2014 budget requests funds to implement the Plan, including \$80 million for Alzheimer's research and \$20 million for education, outreach and support. These funds are a critically needed down payment for research and services for Alzheimer's patients and their families.

With these funds, states will be able to improve dementia care services and supports, create greater public awareness campaigns to connect caregivers to community resources and provide better provider education and training. These steps will better prepare individuals with the disease and their caregivers while lengthening the ability to provide care in the home and community setting.

Research funding is the key to unlocking a means for earlier diagnosis, preventive treatments or even a life-saving cure. We have seen the smart investments in research yield treatments that have saved individuals and the health care system millions while creating research and clinical jobs. If a treatment were developed that delayed the onset of Alzheimer's by just five years, it would cut government spending on care for people with Alzheimer's nearly in half. But to do so, we must give the scientists funds to do the job.

That is why Congress must provide the resources necessary to implement the Plan, and should support the President's budget request for \$100 million for implementation.

Conclusion

The Association would like to thank the Committee again for the opportunity to share our support for the work being done to address Alzheimer's disease. We would also like to express our gratitude to the Committee for holding last week's important hearing on the implementation of the Plan and for inviting our advocates, including Glen Campbell and his family, to participate. We strongly believe in the Plan and the goal of preventing and effectively treating Alzheimer's disease by 2025. The Association strongly supports the President's budget request of \$100 million to ensure implementation of the Plan. We urge Congress to move quickly to pass legislation which implements this request.

The already high cost of Alzheimer's will skyrocket as the baby boomers age.
* Adjusted for inflation to 2010 dollars. Source: Alzheimer's Association, "The Economic Burden of Alzheimer's Disease."

Year	Estimated Cost (\$ Billion)
2010	150
2015	200
2020	250
2025	350
2030	450
2035	600
2040	800
2045	1100
2050	1500

NIH research investments in other conditions, shown below, are paying off. This proven approach should be applied to Alzheimer's.
(The Example Budget Request for FY 2011)

Condition	Estimated NIH Investment (\$ Billion)
Cancer	28
HIV/AIDS	12
Cardiovascular	10
Diabetes	5
Alzheimer's	2

"... Alzheimer's is the most expensive malady in the U.S. ..."
Source: New York Times, "Alzheimer's Disease: A New Reality," April 1, 2011.

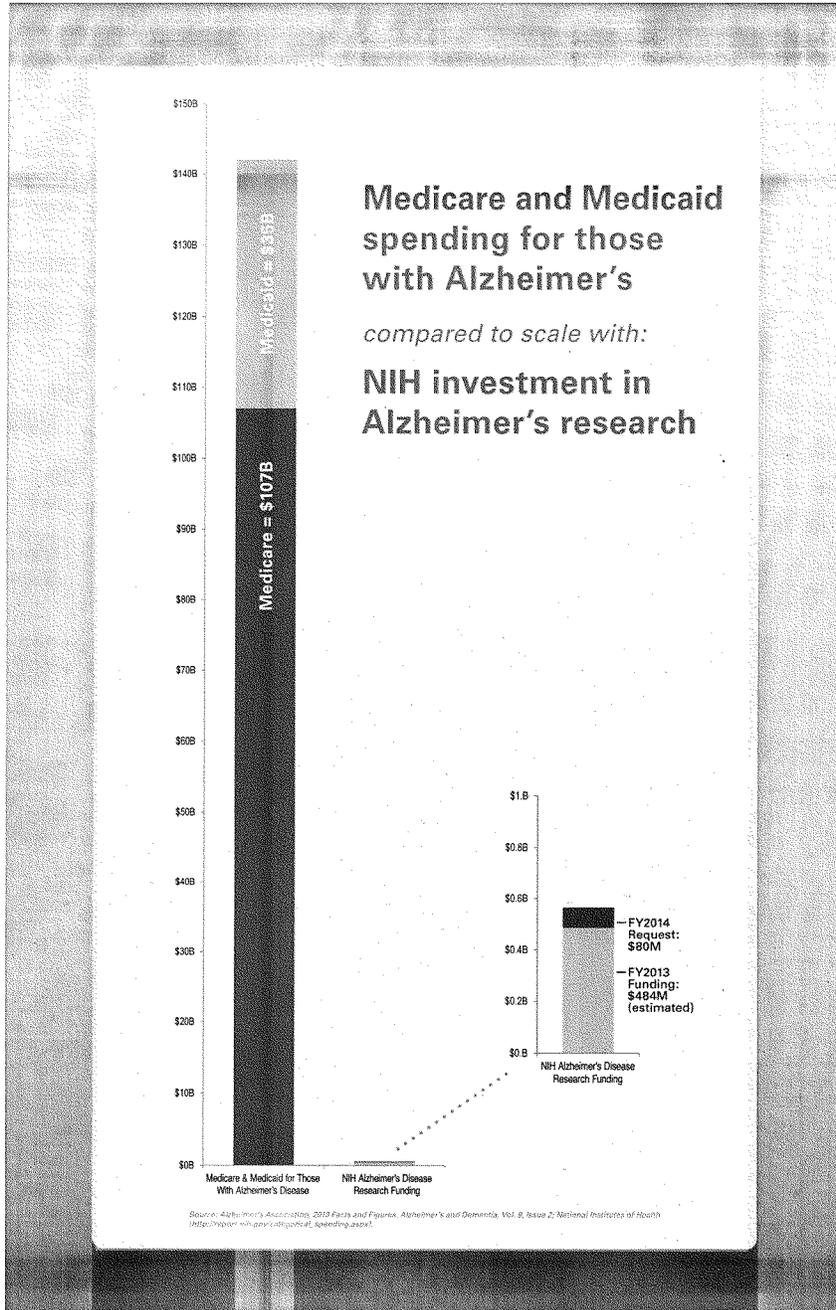
"... exceeding that for heart disease and cancer ..."
Source: New York Times, "Alzheimer's Disease: A New Reality," April 1, 2011.

"... skyrocketing at a rate that rarely occurs with a chronic disease."
Source: New York Times, "Alzheimer's Disease: A New Reality," April 1, 2011.

SO, WHERE DO YOU STAND?

Alzheimer's Association is a 501(c)(3) nonprofit organization. We are not a government agency. We do not have a political agenda. We are not affiliated with any political party. We are not a religious organization. We are not a trade association. We are not a labor union. We are not a professional association. We are not a consumer organization. We are not a public utility. We are not a financial institution. We are not a health care provider. We are not a health care payer. We are not a health care regulator. We are not a health care researcher. We are not a health care educator. We are not a health care advocate. We are not a health care lobbyist. We are not a health care policymaker. We are not a health care reformer. We are not a health care innovator. We are not a health care entrepreneur. We are not a health care investor. We are not a health care manager. We are not a health care leader. We are not a health care role model. We are not a health care hero. We are not a health care legend. We are not a health care icon. We are not a health care symbol. We are not a health care emblem. We are not a health care logo. We are not a health care trademark. We are not a health care service mark. We are not a health care copyright. We are not a health care patent. We are not a health care trademark. We are not a health care service mark. We are not a health care copyright. We are not a health care patent.

alzheimer's association
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ALZHEIMER'S FOUNDATION OF AMERICA

*Our mission is "to provide optimal care and services to individuals confronting dementia,
and to their caregivers and families—through member organizations dedicated to improving quality of life."*

SENATE SPECIAL COMMITTEE ON AGING

"The National Plan to Address Alzheimer's Disease: Are We On Track to 2025?"

April 24, 2013

Submitted for the Record

TESTIMONY OF THE ALZHEIMER'S FOUNDATION OF AMERICA

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The Alzheimer's Foundation of America (AFA) is grateful that the United States Senate Special Committee on Aging is focusing its lens on Alzheimer's disease (AD)—a horrific brain disease that unfortunately has come to define the current generation of aging baby boomers. Raising the visibility of AD via this influential committee and before other Congressional forums helps validate the urgency of addressing and halting this public health crisis. It is a crisis hitting hard, without discrimination and without boundaries. And it must end.

There is no doubt that we are beginning to make progress. Our nation is starting to chip away at barriers that prevent Americans from getting the care they need and the cure they deserve.

AFA commends President Obama, U.S. Department of Health and Human Services (HHS) Secretary Kathleen Sebelius, National Institutes of Health (NIH) Director Dr. Francis Collins and Congress for uniquely recognizing and responding to the implications of the AD epidemic through the mandate under the National Alzheimer's Project Act (NAPA) for a national plan and HHS' subsequent release of the historic "National Plan to Address Alzheimer's Disease" in May 2012. This recognition is essential for action, and their courage and commitment have forged enormous opportunity to address this chronic disease with urgency.

President Obama's ongoing commitment, including a proposed \$100 million increase in Alzheimer's disease research and care-related programs, and a proposed \$110 million for the BRAIN (mapping) Initiative, speaks to these efforts toward progress. As well, Dr. Collins' recent decision to use \$40 million in his discretionary budget as a buttress against automatic spending cuts that threaten Alzheimer's disease research will protect these promising projects and keeps research funding on a growth path during this time of fiscal restraint.

The national Alzheimer's plan provides solid stepping stones toward substantial change. It paves the way for transforming how our nation and the world view Alzheimer's disease, altering the trajectory of this tragic disease and changing lives forever. It substantiates the plight of millions of Americans and validates the concerns of generations to come. For the first time, we are making progress toward defeating this escalating public health crisis.

The plan sets out laudable goals for clinical research, compressing clinical pathways, developing better training of healthcare professionals and best practices for family caregivers, and enhancing public awareness. It calls for greater collaborative efforts among federal government agencies and new partnerships between public and private entities.

Many of the plan's initial strategies have been implemented or are underway. Among them, there is now greater intergovernmental agency cooperation and meetings concerning the issue. The federal government has undertaken a public awareness campaign that centers on a new comprehensive government Web site, Alzheimers.gov. HHS, related agencies and their private and public partners are developing initial training materials.

However, more needs to be done. And given the enormity of this disease state, the federal government must take the lead. Alzheimer's disease research must be a priority and necessary

resources must be dedicated if we are to make progress, as the national plan states, toward preventing and effectively treating Alzheimer's disease by 2025.

Now Congress must add its weight. It must reinforce its passage of NAPA with funding to push it to the next level. Despite fiscal impediments, today's investment toward the goals contained in the national plan, toward a cure and care-related relief, will pay off multi-fold in cost savings to families, government and society. Researchers, organizations and individuals stand ready with commitment, passion and innovation. With funding, their resolve can get us to where our nation needs to go.

WHAT IS ALZHEIMER'S DISEASE

Alzheimer's disease is an irreversible, progressive brain disease that slowly destroys memory and thinking skills, and eventually even the ability to carry out the simplest tasks. As many as 5.1 million Americans may have Alzheimer's disease. A recent study shows that as baby boomers age, the number of Americans with Alzheimer's disease is expected to triple to 13.8 million by 2050.

Alzheimer's disease is the sixth leading cause of death in America. It is also the only growth category in the Centers for Disease Control's top ten causes of death and the only condition with no cure or treatment to reverse or slow its progression.

Individuals with Alzheimer's disease use a disproportionate amount of health care resources; for instance, they are hospitalized two to three times as often as people the same age who do not have the disease. Similarly, nearly half of all nursing home residents have Alzheimer's disease.

A recent RAND study of adults aged 70 and older found that total economic cost of dementia in 2010 was estimated to be \$109 billion for direct care—higher than heart disease and cancer; and \$159 billion to \$215 billion when cost of informal care is included. The per-person cost of dementia was \$56,290 or \$41,689. Medicare paid about \$11 billion of dementia-related costs. In 2012, the direct costs of caring for people with Alzheimer's disease or other dementias to American society will total an estimated \$200 billion, including \$140 billion in costs to Medicare and Medicaid. These costs will soar to a projected \$1.1 trillion (in today's dollars) by 2050. This dramatic rise includes a 500 percent increase in combined Medicare and Medicaid spending.

For each person with Alzheimer's disease, there are multiple caregivers, who respond to 24/7 needs related to activities of daily living. Caregiving duties often fall on family members who are overwhelmed both emotionally and physically, and whose health and well-being often suffer as they fulfill this role. These caregivers are of all ages, including children and teens who take on very adult responsibilities. There is a higher incidence of sickness and mortality among Alzheimer's disease family caregivers, compared to other caregivers.

In 2011, family caregivers provided an estimated 17.4 billion hours of unpaid care, a contribution to the nation valued at more than \$210 billion.

NATIONAL PLAN TO ADDRESS ALZHEIMER'S DISEASE

The National Alzheimer's Project Act (NAPA) (P.L. 111-375) was passed unanimously by both houses of Congress and signed by President Obama in January 2011, and calls for creation of a national strategic plan to address the rapidly escalating Alzheimer's crisis and to coordinate Alzheimer's disease efforts across the federal government.

The first-ever "National Plan to Address Alzheimer's Disease" was released in May, 2012. It was developed with help from the Advisory Council on Research, Care and Services, which was established by NAPA to provide recommendations and advice on a national plan.

The plan is comprehensive. It touches on five major issue areas: research, clinical care services, long-term services and supports, awareness and accountability measures to track progress. In addition, it sets a goal for preventing and effectively treating Alzheimer's disease by 2025.

It is a national plan, not a federal plan. The plan recognizes that progress against Alzheimer's disease will require the active engagement of public and private sector stakeholders. The success of some long-term goals will be contingent on resources, scientific progress and focused collaborations across many partners. Over time, HHS will work with the Advisory Council and other partners to assess progress and make additional recommendations.

The plan is a living document to be updated annually. A revised national Alzheimer's plan is expected to be released in mid-May, 2013.

HIGHLIGHTS OF AFA'S 'TIME TO BUILD' REPORT

AFA has provided substantial input into the development of the "National Plan to Address Alzheimer's Disease." AFA's suggestions have included input from its prestigious Medical and Scientific Advisory Board and Memory Screening Advisory Board, strategic partners, member organizations and other AD stakeholders. Many of AFA's recommendations were included in the original historic plan.

In anticipation of the new version of the national plan, AFA in December 2012 released a white paper, "Time to Build" (www.alzfdn.org/Publications/TimeToBuild_final.pdf), which chronicles implementation of the national plan, identifies gaps in policy and provides critical, potentially life-changing recommendations for the revised "National Plan to Address Alzheimer's Disease". Some of these recommendations include:

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

- Develop more efficient and expeditious methods to determine diagnosis, prognosis and response to therapies using appropriate biomarkers and genetic markers.
- Convene a working meeting of public, private and industry partners to develop a realistic roadmap for Alzheimer’s disease research.
- Encourage development of “coopetition”—a strategy in which industry competitors share certain knowledge and research among research industry partners that compete for market share.
- Develop proper standards and measures to be incorporated into research proposals to ensure quality research.
- Establish large-scale patient registries to facilitate faster and less expensive clinical trial recruitment.
- Call on public and private sectors to work together to address the unique circumstances of individuals with Alzheimer’s disease and their ability to provide informed consent for clinical trial participation.
- Encourage all new and ongoing federally-funded and industry-sponsored Alzheimer’s disease clinical trials to use the same Alzheimer’s disease data standards developed by the Clinical Data Interchange Standards Consortium (CDISC) in order to facilitate data sharing and review by the FDA.
- Adopt the term “presymptomatic Alzheimer’s disease treatment” to refer to interventions that are initiated before a person’s apparent cognitive decline and that are intended to reduce the chance of developing Alzheimer’s disease-related symptoms.
- Establish a central Alzheimer’s disease research coordinating entity within the NIH that has the authority and ability to convene inter-agency and non-government constituencies, both domestically and internationally.
- Develop an international Alzheimer’s plan that will standardize biomarkers and surrogate end-points, coordinate drug surveillance and enhance global regulatory cooperation.
- Establish an international fund to collect revenues to support Alzheimer’s disease clinical research.
- Endorse efforts to increase research collaboration, compress clinical trial pathways and disseminate research findings to Alzheimer’s stakeholders and the general public.

Goal 2: Enhance Care Quality and Efficiency

- Strengthen efforts to build a high quality dementia care workforce by:
 - making student loans for geriatrics and gerontology eligible for federal loan forgiveness;
 - urging CMS to require geriatric competencies and dementia training for primary care clinicians;
 - requiring certified nursing aides and home care aides and their supervisors to take at least 120 hours of training, including explicit geriatric care and gerontological content;

- funding nursing home staff training related to behavioral interventions; and
- establishing a government-funded 24-hour call center specifically for dementia healthcare professionals.
- Expand memory screening efforts and promotion of the benefits of memory screening and early detection of Alzheimer’s disease by CMS and its partners, as well as provided individuals who are ultimately diagnosed with access to federal health programs for proper treatment and supportive services.
- Institute a new benefit for Medicare beneficiaries for diagnostic and care planning services specifically for Alzheimer’s disease and related dementias
- Provide additional initiatives to support family caregivers in the revised national Alzheimer’s plan, including:
 - adoption of family-friendly workplace policies, with federal incentives to carry them out;
 - availability of federal tax credits for family members who are primary caregivers and tax deductions for out-of-pocket costs used for reasonable and necessary long-term care services, including premiums paid for long-term care insurance;
 - greater access to home- and community-based care services under both Medicare and Medicaid to allow individuals with Alzheimer’s disease to stay in the home setting as long as possible;
 - increased funding of Administration on Aging (AoA) programs, like respite care and caregiver training, that help reduce the burdens on family caregivers; and
 - extension of Medicare benefits and AoA program eligibility to all those with Alzheimer’s disease, regardless of age.
- Expand publicly-funded “participant-directed” (aka “consumer-directed,” “cash and counseling,” “self-directed care”) programs that allow participants to hire family members—including spouses, adult children and even teens—as paid caregivers.
- Make adult day services a mandatory benefit under Medicaid.
- Develop high-quality care measures that are culturally competent and tailored to each stage of the disease and each type of care setting.
- Reimburse healthcare professionals more adequately under federal health programs for services such as longitudinal evaluations and management services, acute and chronic psychiatric management, evaluation of cognitive functioning, and caregiver education and counseling.
- Specify a target number of demonstration projects for CMMI to implement new care models for Alzheimer’s disease which will shed light on the best models for different populations and provide a substantial caseload to generate data to adequately measure costs and utilization.
- Establish dementia-specific protocols for emergency rooms, as well as for patients that will decrease length of hospital stays and lower readmission rates.
- Establish regional Memory Evaluation and Treatment Centers through public-private partnerships that focus on developing, improving and disseminating best practices for clinical care for persons with Alzheimer’s disease and their family caregivers.

- Develop a specialized palliative care program under Medicare and Medicaid for persons with Alzheimer's disease and related dementias.
- Expand all federal programs associated with Alzheimer's disease treatment, care and support to serve to all persons with Alzheimer's disease, regardless of age.

Goal 3: Expand Supports for People with Alzheimer's Disease and Their Families

- Require licensure and/or accreditation of facilities that care for, treat and support people with dementia.
- Expand and provide adequate funding for federal programs that help family caregivers, which include:
 - Older Americans Act – provides grants to states for family planning and social services, research and development projects, and training in the field of aging;
 - Lifespan Respite Care Act – provides grants to support statewide respite care service providers, and training, recruiting and outreach;
 - National Family Caregivers Support Program – provides grants to help families pay for myriad support services for family and informal caregivers; and the
 - Missing Alzheimer's Disease Patient Alert Program – provides grants to help local communities and law enforcement officials quickly find persons with Alzheimer's disease who become lost and reunite them with their families.
- Adopt transparent training requirements for crisis call centers that serve individuals with Alzheimer's disease and their caregivers, and require that referrals must be non-exclusive.
- Adopt federal incentives to purchase long-term care insurance, including tax credits or premium support models that will encourage younger individuals to enter the market.
- Require accountants, financial planners, estate managers and CPAs who provide financial, estate planning and investment services to people with Alzheimer's disease and their families to have specialized training through the AoA.
- Increase oversight of all institutional facilities (not just nursing homes) that use antipsychotic medications to control behavioral symptoms in people with dementia.
- Undertake further research regarding antipsychotic medications, with an eye on a careful clinical decision-making process that takes into account the risk-benefit ratio per individual.
- Encourage HUD and other Alzheimer's stakeholders to develop new, cost-effective transitional housing models for people with Alzheimer's disease as an alternative to more expensive institutionalization.

Goal 4: Enhance Public Awareness and Engagement

- Expand the new Alzheimer’s Awareness Campaign to a more comprehensive campaign utilizing multi-media platforms, and kick off a parallel awareness campaign geared to physicians and other healthcare professionals about the benefits of early detection.
- Promote the Medicare Annual Wellness Visit as a vehicle for healthcare professionals and individuals to talk about memory problems and cognitive function.

Goal 5: Improve Data to Track Progress

- Compile basic, reliable statistics on the scope of Alzheimer’s disease, its demographics, economic impact, caregiver demographics and cost of services.

CONCLUSION

To remain relevant and responsive, the “National Plan to Address Alzheimer’s Disease” needs to adapt to the changing landscape in research, clinical and caregiving trends. We must cultivate and collect continued input from healthcare professionals, clinicians, researchers, people with Alzheimer’s disease, family caregivers and other stakeholders.

Their voices must be heard, and their participation is vital to the process. As the voice of individuals with Alzheimer’s disease and related dementias and their caregivers, AFA holds to its mission to solicit comments and help shape their messages into practical recommendations. AFA will continue to act as this conduit between Americans who deal with the challenges of this disease, day in and day out, and policymakers tasked with developing a comprehensive and effective national strategy. Only by working together will the plan’s action steps be fully implemented and the overall goals to tackle this crisis achieved.

Implementation to date of existing action steps is impressive and marks an important first step in establishing a comprehensive national strategy. With the required annual iteration of the national Alzheimer’s plan giving us the opportunity to reach even further, we now must continue to act on the input, experience and voice of the Alzheimer’s community.

We need to further shape and refine a national approach to this devastating disease. It’s time to build.

AFA looks forward to working with Congress, the Administration and Alzheimer’s disease stakeholders to ensure that increased Alzheimer’s disease funding becomes a reality in FY2014 and moves us closer to attaining the ambitious yet essential goals of the “National Plan to Address Alzheimer’s Disease.”

□ Cleveland Clinic

Jeffrey L. Cummings, M.D., Sc.D.

April 29, 2013

Donald J. McCaffrey
President and CEO
Resverlogix Corporation
279 Midpark Way SE, Ste. 202
Calgary, AB T2X 1M2

Re: Congressional support for advancing new therapeutics for Alzheimer's disease

Dear Mr. McCaffrey:

I would like the following to be entered as a written comment to the Senate hearing on Advancing Therapeutics for Alzheimer's disease.

Thank you for considering this submission.

Sincerely,



Jeffrey L. Cummings, M.D., Sc.D.
Director, Cleveland Clinic Lou Ruvo Center for Brain Health
Camille and Larry Ruvo Chair for Brain Health

NEW THERAPEUTIC APPROACHES TO ALZHEIMER'S DISEASE

Alzheimer's disease (AD) affects 5.3 million Americans and is projected to rise to a staggering 13 million, costing one trillion dollars annually by 2050 if means of abating this tragic illness are not identified. Current therapies for AD offer temporary, modest improvement and short term delay in decline. There is an increasing effort to identify disease-modifying therapies that will prevent or delay the onset, arrest the progression or ameliorate the decline in the clinical features of AD.

Increasingly detailed understanding of the biological basis of AD, along with the evolution of new biological markers, such as amyloid imaging, have accelerated the search for disease-modifying agents. So far, all attempts at disease modification have failed. Drugs such as the vaccine AN1792, the monoclonal antibodies bapineuzumab and solanezumab, as well as the gamma-secretase inhibitors, have all failed to interrupt the course of AD or have increased cognitive impairment. There is an urgent need to identify new therapeutic approaches for AD.

Among the most promising of alternative therapeutics for AD are agents such as RVX-208 that approach AD from a neurovascular perspective. RVX-208 is an agent that increases Apolipoprotein A-1, a core component of high density lipoproteins (good lipoproteins). These drugs act to reverse atherosclerotic plaques in cardiovascular disease. Importantly, they also appear to reduce the amyloid protein that accumulates in the brain of patients with AD, impact the neurovascular components that frequently complicate AD, reduce inflammation in the brain, and improve cognition.

RVX-208 is currently in a clinical trial to determine its effect on cardiovascular risk. Information is accumulating on its safety and tolerability which will be very useful in terms of developing future clinical trials for patients with AD.

Development of alternatives for the therapy of AD and increasing the "number of shots on goal" is very important for a successful drug development enterprise. The United States' economy as well as the United States' citizens will benefit from advancing the fight against AD through supporting the development of many approaches to treatment.

**Testimony of George Vradenburg
Chairman, USAgainstAlzheimer's**

**For the Record of the Senate Special Committee on Aging
The National Plan to Address Alzheimer's Disease: Are We on Track to 2025?
April 24, 2013**

Chairman Nelson, Ranking Member Collins, and members of the Committee. Just shy of one year ago, our nation made history when it adopted the National Plan to Address Alzheimer's Disease, a plan required under the landmark National Alzheimer's Project Act enacted by Congress in early 2011. While a number of other countries beat the U.S. to the punch in authoring Alzheimer's and dementia plans of their own, the U.S. took a bold step by establishing the first-ever time-based goal of preventing and effectively treating Alzheimer's disease by 2025.

Embracing this goal is an action that I, as an advocate and as a member of the Advisory Council on Alzheimer's Research, Care and Services, championed vociferously. While some pushed back on this notion, I believed and continue to believe that only a time-bound goal will be effective. Such a goal was critical in driving U.S. efforts to land a man on the moon, in mapping the human genome and in achieving other momentous breakthroughs. The time is now for a bold goal to stop Alzheimer's disease. Setting such a target took leadership and courage, but achieving this goal will require resolve and commitment.

I commend the leaders of this committee for calling this important hearing to measure the progress we are – or are not – making that will enable us to be successful. A bold goal may be one thing, but without the follow-through commitment, its value is worth nothing more than the paper on which it is written. I will focus my testimony on three elements that are critical to our ability to achieve success in preventing and treating Alzheimer's disease by 2025. But before I do so, I want to offer a word of praise and gratitude to Glen Campbell, his daughter Ashley for her moving testimony, and for the entire Campbell family.

As was mentioned at the outset of the hearing, far too many families with an Alzheimer's diagnosis opt to recede from the world, an action that can be devastating to family members, particularly the primary family caregivers, who can face depression, isolation, and other challenges. The Campbell family has courageously opted to be very public and candid about the ravages of Alzheimer's disease on both the individual and family. While this can be tremendously painful, it is helping raise public awareness and attention as to the severity of this disease and the need to make stopping it a national and an international priority. I applaud you for taking the time to testify before this committee and for staying visible despite the immense challenges you are facing.

With regard to the national plan and goal of preventing and treating Alzheimer's by 2025, three indispensable elements are:

- 1) Adequate resources, both public and private;
- 2) Measurement of progress and clear accountability; and
- 3) National and international collaboration and coordination.

Adequate Research Resources

With regard to resources, I am well aware of the fiscal challenges that continue to impact our nation. But at the same time, the nation does not have a choice as to whether or not it will pay for Alzheimer's disease. We are paying for Alzheimer's, to the tune of \$140 billion this year alone in Medicare and Medicaid costs attributable to this disease. The choice is whether we will allow these expenses – both public and private – to continue to mount with each passing year, or if we will commit ourselves to the research necessary to achieve the scientific breakthroughs necessary to develop effective treatments, therapies, and means of prevention.

As was noted by many during the hearing, U.S. funding for Alzheimer's research remains woefully inadequate compared to the threats posed by Alzheimer's to the nation's health and finances. Leading researchers believe that achieving the 2025 goal is possible with the appropriate commitment of public and private resources to Alzheimer's research. At the public level, the researchers believe this figure must be \$2 billion annually. Today, we spend about 25 percent of this amount.

The President has recently proposed to increase Alzheimer's research funding, which now lingers below \$500 million, by \$80 million in FY 2014. Even though such an increase will not put us anywhere close to the \$2 billion mark, it is a step in the right direction and one USAgainstAlzheimer's strongly endorses. I urge all members of the Senate Special Committee on Aging, particularly those who also serve on the Appropriations Committee, to include this funding in the FY 14 Labor, HHS and Education appropriations bill.

Measurement & Accountability

While adequate funding is necessary, so is a system to measure progress and hold all stakeholders accountable for their progress. Since the release of the National Plan, Administration officials have been clear that this document and its goals are a national plan, not a federal plan. This means all stakeholders – governments at all levels, the private sector, non-profit organizations, and others – must do their parts.

To hold all stakeholders accountable, we need clear metrics and milestones. The first iteration of the National Plan included some initial high-level milestones, but I believe a far more detailed and comprehensive set are necessary, particularly to measure whether or not research and drug development efforts aimed at developing treatments, therapies, and means of prevention are on track. The Advisory Council has spent a significant amount of time developing some model milestone tables, and I strongly urge that the next iteration of the plan include this level of detail to maximize our chances of achieving our goals.

National & International Collaboration

One of my top concerns is that our research activities are nowhere near as coordinated as they should be. I have heard multiple researchers say far too many research projects are unnecessary for the simple reason that the hypothesis has already been tested – and failed – but the results have yet to be publicized. This situation wastes resources at a time when we can ill afford to do so. To stop this nonsense, we must drive greater levels of research collaboration domestically and internationally.

Part of this solution means embracing tools and mechanisms, such as earlier disclosure of research findings – including failures – that can eliminate wasteful spending and speed progress. Another part of the solution is greater levels of collaboration and coordination between the growing body of national, sub-national, and regional plans to combat Alzheimer's, particularly in the areas of Alzheimer's research. It is impressive that so many nations and even multi-lateral organizations like the European Union are tackling Alzheimer's, but it is discouraging that many of these efforts may be occurring in silos.

The National Plan recognizes the need for greater levels of collaboration and coordination, particularly among countries with national plans. Some groundwork has been laid in this area, and I am pleased that the leaders of the Alzheimer's plans in Canada and the United Kingdom will be appearing before the next advisory council meeting. Ultimately, we must move with alacrity to the point in which we can harness the power of the many national plans to develop and implement a Global Alzheimer's Action Plan.

Alzheimer's – like HIV/AIDS and other deadly diseases – respects no national borders. It is a global health, economic and fiscal crisis and requires a global response. The time is now to take the same leadership the U.S. applied to HIV/AIDS and other diseases and apply it to Alzheimer's by developing a Global Alzheimer's Action Plan within the next year.

I thank you, again, for convening this important hearing, and I thank you for allowing me to submit this testimony.