

**ALZHEIMER'S DISEASE: THE STRUGGLE FOR
FAMILIES, A LOOMING CRISIS FOR MEDICARE**

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH CARE

OF THE

COMMITTEE ON FINANCE

UNITED STATES SENATE

ONE HUNDRED FOURTEENTH CONGRESS

SECOND SESSION

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**ALZHEIMER'S DISEASE:
THE STRUGGLE FOR FAMILIES,
A LOOMING CRISIS FOR MEDICARE**

WEDNESDAY, JULY 13, 2016

U.S. SENATE,
SUBCOMMITTEE ON HEALTH CARE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 2:47 p.m., in room SD-215, Dirksen Senate Office Building, Hon. Patrick J. Toomey (chairman of the subcommittee) presiding.

Present: Senators Grassley, Burr, Heller, Stabenow, Menendez, and Carper.

Also present: Republican Staff: Brad Grantz, Staff Director, Subcommittee on Health Care. Democratic Staff: Kim Corbin, Minority Staff Director, Subcommittee on Health Care.

OPENING STATEMENT OF HON. PATRICK J. TOOMEY, A U.S. SENATOR FROM PENNSYLVANIA, CHAIRMAN, SUBCOMMITTEE ON HEALTH CARE, COMMITTEE ON FINANCE

Senator TOOMEY. The Subcommittee on Health Care hearing will come to order.

Alzheimer's is in a category of its own in terms of its breadth, its lethality, the severity of this disease. We estimate that there are 5.2 million Americans with Alzheimer's. It is 100-percent fatal. It is the sixth leading cause of death, and the number of fatalities is likely to be underreported.

There is no cure. There is not even a treatment. The cause is still unknown. The toll on the lives lost, of course, is devastating, but the financial and emotional toll on caregivers is devastating as well, and there is a huge financial burden that the public pays.

The research by the Alzheimer's Association concluded that Alzheimer's disease is the costliest chronic condition in America, more expensive than any other disease. Medicare and Medicaid together will spend over \$160 billion a year, and while approximately 10 percent of Medicare beneficiaries have Alzheimer's, they consume about 20 percent of all Medicare dollars. This is a significant cost to Medicaid as well, as Medicaid provides long-term institutional care, and about half of nursing home residents have some form of dementia, many of them, of course, from Alzheimer's.

For many of us, this issue is very personal. My father was diagnosed 4 years ago. I had a grandmother who died of the disease. I can say firsthand how devastating it is to families.

I have been pleased to be able to work with a great bipartisan group of Senators and House members on advancing a Federal response to this. I am the co-chair of the bipartisan Congressional Task Force on Alzheimer's Disease, with Senators Markey, Collins, and Warner, and I have convened this hearing to explore further ways to strengthen Medicare and Medicaid, especially to support caregivers.

There are four big topics that I hope we will be able to pursue in some detail today. First is the fact that a lack of diagnosis hurts families. There is a report by the Alzheimer's Association that suggests that only about 45 percent of people with Alzheimer's disease or their caregivers are told their diagnosis by their doctor.

We need to ensure that physicians are aware of the value in communicating a diagnosis to the families. There are incredible advances in medical imaging technology that now allow a definitive diagnosis to be made prior to death. In 2013, Senator Hatch led several members of this committee, including myself, in writing to CMS in support of a national study on using PET imaging to diagnose Alzheimer's. CMS agreed, and we will hear today how that technology has helped families with loved ones who have Alzheimer's disease.

The second point that I want to address today is the importance of caregivers being fully engaged in the treatment plan. Caregivers face tremendous stress, and a care planning session can help connect the caregiver and the patient with resources and support. CMS has proposed a new billing code for 2017 for a care planning session, similar to the approach that Senator Stabenow's HOPE for Alzheimer's Act takes. I am pleased to announce today I will be a cosponsor of your legislation.

The third point is the huge long-term care costs for families. There are few viable long-term care options for many middle-class families, and it places a huge strain on caregivers, as well as on family finances. Many families end up spending down their assets and eventually qualify for Medicaid. In 2010, Congress reduced the value of the medical expense deduction, that is, the threshold above which medical expenses can be deducted. It was moved from 7.5 percent of income to 10 percent of income. I am grateful to Senator Coats for working with me to restore that deductibility at the lower level. The IRS determined that 86 percent of taxpayers claiming this deduction for extraordinary medical expenses earn less than \$100,000. This is an important deduction for them. I also hope we will get a chance to talk about long-term care insurance. It can be enormously helpful, but very few people really have long-term care insurance.

Finally, and maybe most importantly, we need a cure. One hundred and ninety Alzheimer's drugs have been tried, and they have failed in human trials. Companies have invested billions of dollars in searching for an effective treatment. About \$3 billion a year is spent, but none of that money changes the course of this disease. With the number of Alzheimer's patients projected to grow from over 5 million to nearly 14 million people in the foreseeable future, an effective therapy could yield enormous savings—most importantly, the immeasurable benefit of saving so many lives, but in ad-

dition, it could have huge financial benefit for those families that would otherwise be afflicted, and for Medicare and Medicaid.

There are other Federal issues outside the Finance Committee's jurisdiction that I think need to be addressed. One is the NIH allocation. I have sat down and met with NIH Director Francis Collins. The NIH budget is about \$32 billion a year. Alzheimer's research receives less than 3 percent of the funding. The fact is, there are other non-fatal and treatable diseases that receive far more resources in their research. I think we need to increase our Alzheimer's research, and we need to do it in a fiscally responsible way.

But I want to thank everyone for joining us today, including, especially, the Alzheimer's Association from the Delaware Valley chapter of southeastern Pennsylvania. I know you are very well represented here today. I appreciate that.

Now, let me recognize our ranking member, Senator Stabenow.

**OPENING STATEMENT OF HON. DEBBIE STABENOW,
A U.S. SENATOR FROM MICHIGAN**

Senator STABENOW. Thank you very much, Mr. Chairman. It is my pleasure to join with you in this hearing which is so important and, as we know, impacts so many people. I want to thank the three witnesses whom we have testifying before the subcommittee today, including Dr. Paulson from Michigan. We are glad to have you with us. Improving care for people with Alzheimer's is critically important to all of us, and it touches all of us in some way. So I am really looking forward to this hearing.

We do know the statistics. There are a lot of statistics that we could look at. But let me just mention a couple. The sixth leading cause of death in the United States is Alzheimer's disease. More than 5 million people are living with this disease in our country. Important for us on the Finance Committee is that 1 out of 5 Medicare dollars, all of Medicare, 1 out of 5 Medicare dollars goes to caring for those with Alzheimer's and related dementias. By 2050, it is estimated that 1 in 3 Medicare dollars will go toward Alzheimer's patients.

Alzheimer's is particularly devastating for women and for people of color. Women are two times more likely to face an Alzheimer's diagnosis than men. African-Americans are twice as likely to have Alzheimer's, and Hispanics are 1.5 times more likely.

We also know how critically important research is, because there is no known cure, and no cure for Alzheimer's disease means we have a lot of work to do on research. Right now, we have 1 in 3 seniors who are dying as a result of this disease. With this bleak outlook, it is no wonder that doctors delay diagnosis and begin some treatment without fully discussing the Alzheimer's diagnosis with individuals and families.

All of this is taking its toll on caregivers, the men and women, young and old, who love and care for a person with this awful disease. Nearly 16 million family members and friends care for those with Alzheimer's or a related dementia. These caregivers do this work out of love, but also at a significant financial and emotional cost to themselves.

In short, we need to do more. If we care about people with Alzheimer's disease and their loved ones, we need to do more. If we care about making sure Medicare is financially sustainable in the future, we need to do more.

There is good news. Since 2010, Senator Collins and I have sponsored a bill called the HOPE for Alzheimer's Act, which would empower those with Alzheimer's and their caregivers to take control of this diagnosis. With this bill, Medicare would reimburse for a comprehensive care planning service so that a person with Alzheimer's and their family can learn about the disease, gain access to much-needed support services in the community, learn about treatment and clinical trial options, and generally be better armed to face the diagnosis.

Six years later, we now have 57—with Senator Toomey, 58—cosponsors. I want to thank Senator Menendez, a long-time cosponsor of this legislation, for his advocacy. Not only has the Finance Committee been discussing this in its chronic care effort, the Appropriations Committee has included language to create a HOPE-like benefit in the current Labor, Health, and Human Services bill. So we are moving. And now the best news is that CMS has proposed creating a new Alzheimer's care planning code that could essentially implement the benefit that we have been working on in the HOPE Act.

So with that, as well as the additional dollars going into research, which is absolutely critical, we are seeing some things happen. But there is still a long way to go.

I am also very pleased to be the lead Democrat on a bill with Senator Capito, who has been very active with HOPE for Alzheimer's. I appreciate her partnership and working with me to place this language in the Appropriations bill. The new bill is called the Alzheimer's Beneficiary and Caregiver Support Act. This bill, which came together because of the advocacy of UsAgainstAlzheimer's, would create a 3-year Medicare pilot program to test the benefits, both financially and the health outcome for Medicare beneficiaries, of providing support services directly to caregivers of Alzheimer's patients.

So there is a lot happening. There needs to be a lot happening. We need to redouble our efforts, both in supporting families and caregivers and doing everything humanly possible to create the right kind of medications and a cure.

So I am pleased to be here today. I am looking forward to this hearing and what our witnesses have to say, Mr. Chairman.

Senator TOOMEY. Thank you, Senator Stabenow.

Senator Menendez, would you like to make an opening statement?

Senator MENENDEZ. Mr. Chairman, I will do it before my questions so we can get to the witnesses.

Senator TOOMEY. Senator Burr, likewise? Very well.

Then I will begin with the introduction of the witnesses. Senator Stabenow will introduce Dr. Paulson, but I will begin with an introduction of Dr. Ronald Petersen, director of the Mayo Clinic Alzheimer's Disease Research Center and the chairman of the Federal Advisory Council on Alzheimer's Research, Care, and Services.

Also joining us is Connie Bastek Karasow. Ms. Karasow is the wife and caregiver of Mark Karasow, both of Levittown, PA. She is also the executive director of a halfway house for 20 women recovering from chemical dependency.

Senator Stabenow, would you like to introduce Dr. Paulson?

Senator STABENOW. Thank you very much.

It is my great pleasure to introduce Dr. Henry L. Paulson, who is director of the Michigan Alzheimer's Disease Center and the Lucile Groff Professor of Neurology for Alzheimer's Disease and Related Disorders at the University of Michigan. Dr. Paulson received his medical and doctorate degrees from Yale University. After completing his residency and fellowships, he joined the University of Iowa in 1997 and joined the faculty at the University of Michigan in 2007.

In addition to his own research, since 2011 Dr. Paulson has served as the director of the Michigan Alzheimer's Disease Center. As director, he coordinates efforts between three major research universities in Michigan—the University of Michigan, Wayne State University, and Michigan State University—in order to better understand Alzheimer's disease. In addition to Alzheimer's research, the center promotes education and awareness about dementia and provides state-of-the-art clinical care.

We so appreciate your being here.

Senator TOOMEY. I would like to formally introduce into the record testimony from the Alzheimer's Association and also from UsAgainstAlzheimer's chairman George Vradenburg. Thank you to both groups in helping on this hearing.

[The statement appears in the appendix on p. 34.]

Senator TOOMEY. Dr. Petersen, you have 5 minutes for your testimony.

STATEMENT OF RONALD C. PETERSEN, Ph.D., M.D., CHAIR, ADVISORY COUNCIL ON RESEARCH, CARE, AND SERVICES, NATIONAL ALZHEIMER'S PROJECT ACT, ROCHESTER, MN

Dr. PETERSEN. Thank you. Good afternoon, Chairman Toomey, Ranking Member Stabenow, and distinguished members of the Health Subcommittee.

My name is Ron Petersen, and as Senator Toomey indicated, I chair the Advisory Council for the National Alzheimer's Project Act. I am also a professor of neurology at Mayo Clinic and direct the Alzheimer's Disease Research Center there. I sit on the World Dementia Council as well.

Alzheimer's disease is the most devastating disorder of our generation. It is estimated, as we have heard, that approximately 5.1 million people in the United States currently have the disease, and that is projected to rise to over 13 million by 2050. The Rand Corporation recently said that Alzheimer's disease is, in fact, the most costly chronic disease in this country, ranging around, from 2010 data, about \$200 billion a year at that point in time, as compared to heart disease, which was \$102 billion, and cancer \$77 billion. So in that comparison, staggering figures.

In 2011, President Obama signed the National Alzheimer's Project Act into law, and this required the Secretary of Health and Human Services to develop a national plan for addressing Alz-

heimer's disease. The first plan was published in 2012 and has been revised annually. There was also an advisory council appointed as part of the law, and the advisory council's charge, in addition to advising the Secretary, has been to generate a list of recommendations each year that are sort of unencumbered by fiscal restrictions and make recommendations to the Secretary and to Congress directly as to what it is going to take to fight this disease.

The primary goal of the national plan is to develop an effective treatment and perhaps prevention of the disease by 2025. One of the corresponding recommendations of the advisory council has been that the Federal Government should be spending at least \$2 billion a year to combat this disease. Currently, with the recent increase—thank you very much—in 2016 for Alzheimer's disease of \$350 million, we are now at \$991 million. But that is still not quite halfway to the \$2-billion goal recommended by the advisory council.

According to a recent report by the Alzheimer's Association, caring for persons, as of 2015, costs this country \$226 billion, two-thirds of which comes from Federal Government and State government dollars. By 2050, we will be spending \$1.1 trillion caring for individuals, unless something is done about this disease. The cumulative costs of caring for individuals between now and 2050 will approach \$20 trillion—so this almost becomes unsustainable—again, almost 70 percent of that coming from Medicaid and Medicare. So these numbers need to be addressed immediately, because this scenario is untenable for the country.

So putting this in the context of the primary goal of the national plan to effectively treat the disease by 2025, it has been estimated that if we develop a disease-modifying therapy, say, something that delays the onset of the disease by 5 years, we will reduce the number of people projected to have the disease in 5 years from 8.2 million down to 5.8 million. This will result in a savings of \$83 billion for that time frame. Projecting that out to 2050, where we are anticipating to spend \$1.1 trillion, that will be reduced to \$734 billion. So having a therapy that delays the onset of the disease by 5 years will have a tremendous impact on individuals, families, and on the health-care budget.

The research community is poised to make the necessary progress to make these treatment projections a reality with a disease-modifying therapy. The academic field is working on the notion of prevention of the disease, because, clearly, from a public health perspective, that is what we need.

So with recent advances, largely funded by the National Institutes of Health, such as the Alzheimer's Disease Neuroimaging Initiative, our work at Mayo in the Mayo Clinic Study of Aging, we are now able to identify individuals who have the underlying biologic causes of the disease earlier in life, even when they are asymptomatic.

The advantage of that is it affords us an opportunity then to develop treatments that are designed to have impact on those particular biologic characterizations. As we move toward earlier identification, it becomes imperative to take into account the impressions of not only the individual with the disease, but their caregivers as well. Recently, the Patient-Centered Outcome Research Institute,

PCORI, has funded an Alzheimer's effort designed to, again, assess the impact on individuals with the disease and caregivers.

So in closing, I would like to thank Congress for their proactive stance in funding research for Alzheimer's disease, but we are only halfway there. The time is now to act and to continue to increase the budget for NIH so that these therapies can, in fact, be developed, keeping in mind that this is the most costly disease with which we deal and small impacts on the disease will have enormous impacts on the health-care economy.

I would also like to commend both my Federal and non-Federal colleagues on the advisory council, individuals at the National Institutes of Health, and individuals at the Department of Health and Human Services, for working tirelessly on the execution of the national plan and its revision.

I appreciate this opportunity, and would be happy to answer any questions.

[The prepared statement of Dr. Petersen appears in the appendix.]

Senator TOOMEY. Thank you, Dr. Petersen.
Dr. Paulson?

**STATEMENT OF HENRY L. PAULSON, M.D., Ph.D., DIRECTOR,
MICHIGAN ALZHEIMER'S DISEASE CENTER, UNIVERSITY OF
MICHIGAN, ANN ARBOR, MI**

Dr. PAULSON. Good afternoon, Chairman Toomey, Ranking Member Stabenow, and members of the committee.

I am here today to express my support for the HOPE for Alzheimer's Act. I am a professor at the University of Michigan, where I direct the Michigan Alzheimer's Disease Center. I am honored to speak on behalf of my colleagues and our patients and their families to express a united vision for comprehensive care for those living with dementia. As director of our center, I speak for countless colleagues who care for those with dementia. Collectively, we recognize that the comprehensive care planning services provided by the HOPE Act will improve the lives of millions of American families confronting dementia.

This health impact is principally what drives our support. But by helping dementia patients and their families navigate the difficult road ahead, the HOPE Act also will reduce Federal health-care costs by nearly \$700 million over the next decade. It is no wonder this measure has garnered broad bipartisan support, and I applaud my Senator, Debbie Stabenow, and her colleagues for their vision in crafting and supporting this act.

Each day, over 1,000 Americans receive a diagnosis of dementia. Most often, the specific diagnosis is Alzheimer's, but other common dementias include Lewy body disease, frontotemporal dementia, and vascular dementia. As a doctor, I have seen the deep fear and uncertainty that can accompany this diagnosis. Busy, overworked health-care providers might only offer a simple fact sheet about the disease.

Too often, the future brought on by this progressive disease remains uncharted and frightening. And to someone receiving the diagnosis, the questions come fast and furious. What changes in my life do I need to make now? What kind of medical care do I need

and when? How do I connect with others who understand? To someone caring for a loved one, these same questions and others surface. How can I possibly cope with the new demands and stresses I am facing? What can we do to stay healthy and close as a family?

Sadly, too often patients and their families never get the chance to consider these questions, because the diagnosis is not provided to them. Astonishingly, two-thirds of seniors diagnosed with Alzheimer's are unaware of their diagnosis. We must do a better job of diagnosing dementia earlier in the course. Why? Earlier knowledge about the disease improves long-term outcomes for those with cognitive impairment.

The HOPE for Alzheimer's Act will ensure that patients' families receive the diagnosis and receive answers to these questions, allowing them to work with providers to optimize a plan for their future health and security. I cannot think of anything more pressing for our patients right now. Yes, many of us in the world are working hard to develop better therapies and ultimately a cure for Alzheimer's, and Senators Toomey and Stabenow and Dr. Petersen eloquently made the point that we are working toward that cure.

But we are not there yet. The HOPE Act makes a difference now. A few years ago, at Michigan, we realized that newly diagnosed patients and their families sometimes fail to receive all the information they need in a timely manner. So we piloted a new multidisciplinary program, a team approach to dementia that gives patients and caregivers the opportunity to meet with a neurologist, neuropsychologist, nurse practitioner, and social worker for an appointment during which we discuss test results, the diagnosis, and care planning.

This program has worked exceptionally well. Patients and caregivers overwhelmingly support our comprehensive approach, because they learn more about their disease sooner and have a greater awareness of community support and services. And in the process, we are continually reminded that each patient is unique. Care planning must be customized, taking into account the type of dementia, the stage of the disease, other chronic medical problems, and family dynamics, among other factors.

Unfortunately, few people who receive their diagnosis do it through a major research center like ours, where we can pilot a multidisciplinary approach. That is why the HOPE Act is so important. It will ensure comprehensive care planning for dementia across the country at all types of medical facilities.

Most of us, when we think of treatment, we think of medicines. But for dementia, the components that go into state-of-the-art care extend far beyond medicines. For example, recent studies show that exercise improves brain function. Careful attention to chronic illnesses, such as depression or diabetes, improves the lives of those encountering dementia. And access to support groups for patients and caregivers can be a lifesaver. Care planning through the HOPE Act will ensure that these and other vital components are offered to our patients.

I close on a personal note. When given the opportunity to direct our Alzheimer's Center 5 years ago, I jumped at the chance. Why? Partly because it is an exciting time. We are now testing potential

disease-modifying therapies. And partly because there is so much we still do not know and we need to figure out. But mostly, it is because this disease touches us all. I ask everyone in this room now to think of someone you know who has confronted dementia. I am thinking of a colleague, a brilliant physician, loved by his patients, who retired this year when he faced the earliest signs of Alzheimer's.

Like you, I want to make a difference in the lives of those with dementia. Until we have cures for the dementias, we need to provide patients and families with the means to cope and reasons to hope for a better future. This is precisely what the HOPE Act will do.

I thank you for this opportunity.

[The prepared statement of Dr. Paulson appears in the appendix.]

Senator TOOMEY. Thank you, Dr. Paulson.

Ms. Karasow?

**STATEMENT OF CONNIE B. KARASOW, CAREGIVER,
LEVITTOWN, PA**

Ms. KARASOW. Mr. Chairman and members of the subcommittee, thank you for this opportunity to address the issues associated with being a care partner for individuals living with Alzheimer's disease and other dementias. It is an honor to represent the over 5 million Americans living with the disease and more than 15 million care partners who love them. Alzheimer's disease is not a respecter of role, rank, or relationship.

Those afflicted with Alzheimer's disease are adept at concealing their confusion, their embarrassment, frustrations, and fears, often before their partners begin to realize that there is a problem. That was certainly true in our case. The cues were subtle at first, and I had a demanding career. It was not until the notes were piling up, including cues written on his hands, that I suggested we see someone, half-jokingly saying, to eliminate the big "A" fear.

On November 11, 2010, after some seemingly simplistic tests, we were told by Dr. Weisman that my Mark, a 70-year-old proud man, devoted husband, and father, had Alzheimer's disease, a progressive, fatal disease of the brain. Based on these seemingly simplistic tests, we were told that Mark was on the bunny slope: we could expect a gradual decline. No direct diagnostic tests were available, and we were often told by others that no one really knows until they are dead and you can see it in the brain—painfully glib, but true at the time. Mark was prescribed medication to try to extend his memory, and we were sent on our way, stunned, reeling, and projecting scenarios we could never really fully appreciate.

Following Dr. Weisman's diagnosis, Mark experienced depression, anxiety, and obsessive-compulsive behaviors that led me to look for a geriatric psychiatrist, not an easy specialist to find. I found someone who was compassionate and intelligent, but untrained in dementia. She prescribed medication for Mark's symptoms, and at each session, she would give Mark a pep talk by saying "You are not typically Alzheimer's," an oxymoron that reinforced our hope and our denial.

If Mark was not typically Alzheimer's, what typically was he? And was he receiving the right protocols? We were recommended to another neurologist, who sent us to a clinical neuropsychologist for further testing. Mark endured 6 grueling hours of testing, including assessments that covered 12 functioning parts of the brain. Following this battery of tests, Mark's driver's license was revoked, and Mark left the session feeling traumatized, frustrated, and, not typically, angry.

The results indicated subcortical features; dementia appeared to be present, mild to moderate in severity. However, the precise nature of Mark's dementia was unclear from the test data alone. We went back to the referring neurologist, who, with a dismissive wave of his hand, declared that he did not agree with the diagnosis and that was all he could do. He never once asked me to meet with him separately from my husband so I could give him my input.

We went back to Dr. Weisman, who was clearly disturbed with what Mark went through. Knowing Mark's scientific curiosity, he suggested a clinical trial, the Imaging Dementia—Evidence for Amyloid Scanning, or IDEAS, study. The IDEAS study will determine the clinical usefulness on patient-oriented outcomes of a brain PET scan that detects amyloid plaques, a core feature of Alzheimer's disease. This study is particularly helpful at determining a diagnosis for people like my Mark who do not present with typical dementia or cognitive decline.

After our previous experience, it was so reassuring to know that there are doctors who care enough to help us pursue a firm diagnosis and understand how important it really is. When Mark had the PET scan that confirmed his diagnosis, all the debate, searching, and uncertainty were put to rest and the real work of living with the disease began.

Mark is willing to engage in other trials and wants to donate his body when he dies. It is his desire to establish something good from the nightmare of watching the disintegration of his mind and his life.

We joined an Alzheimer's Association support group, where we shared survival knowledge and survival skills. Issues for care partners have included our children's distrust based on fear; how to get rid of guns; stealth banking; thermostat wars; repetition, the date, family information, media, et cetera; hunger strikes; isolation; support; grieving; and survivor guilt. We had the opportunity to establish a durable power of attorney, medical directives, will, financial planning, medical equipment, shoes for his gait, bathing, diet, weight loss, family, and friends engagement.

For me, coping means trying to stay present with him in his space, as long as his mind allows me. The rate of stress and depression has been described as unique to caregivers. Everyone says it is hard, and that is the simple truth. The awareness that self-care of my mind, body, and spirit is critical to survival is growing faster than the resources that make that a reality for me.

Adult day care 2 days a week for my husband and me is expensive, and I know the costs will increase over time. My husband thought he was preparing to leave his family some financial security that will melt like the snow in spring. However, I am also concerned for the homeless poor and working poor who lack transpor-

tation and child care, let alone elder care. Without knowledge, health care, and case management resources, families living in the margins of our society cannot hope to manage the daily demands of those afflicted with Alzheimer's disease. Investment in Alzheimer's services can prevent the terrible social and fiscal costs in social services due to the dissolution of families.

Before Mark enrolled in the IDEAS study and was able to get an accurate diagnosis, I was asked, "What difference does a precise diagnosis make?" A fair question, since we know at that moment there is no cure.

Trying to express this is not easy. I looked up the quote, "Better the devil you know than the devil you don't." This is said when you think it is wiser to deal with someone, something familiar, although you do not like him, her, or it, than to deal with someone or something you do not know and might be worse. I believe there is power in naming. How can we cure something if we cannot even give it a name?

On a practical level, an early and accurate diagnosis of Alzheimer's disease affords the individual the opportunity, dignity, and respect of participation and involvement in financial and legal decisions with his or her family. Legislation like the HOPE for Alzheimer's Act, which allows individuals newly diagnosed with Alzheimer's or related dementias to have a care planning session with a health-care provider, would do just that. If HOPE had been around at the time of Mark's diagnosis, I am sure we would have felt much less alone in this fight.

Thank you again for the honor and the opportunity to testify today. I hope that I have been able to address the issues of caregivers and their loved ones with the respect and recognition they deserve. More importantly, I hope my message conveyed to you the exact nature of the problems through our eyes and perhaps has given you some insights on how your leadership can be instrumental in the current and future needs of our families and our communities.

[The prepared statement of Ms. Karasow appears in the appendix.]

Senator TOOMEY. Thank you, Ms. Karasow. And let me thank you for having the courage to share your personal experience. I know that must be a very difficult thing to do.

I would like to start the questions by directing one to Ms. Karasow. In your testimony, you indicated that the PET scan that Mark received detected the amyloid plaques, and that led to the definitive diagnosis of Alzheimer's. Is it fair to say that without that scan, your family would not have had the ability to properly chart the course of treatment and plan accordingly?

Ms. KARASOW. I would say yes, because I wasted an awful lot of time—I wasted 5 years after the original diagnosis then very quickly got the pieces of what we needed to do in place, as I testified.

Senator TOOMEY. Were there decisions that your family made that might have been easier or that you might have decided differently had you had the definitive, accurate diagnosis immediately?

Ms. KARASOW. One of the things that I would not have thought of—I have a good friend, who is our solicitor and our lawyer, and

she recommended that we very quickly revise our wills, update our wills, so Mark could have participation in that on behalf of his family, and that was very much appreciated.

Senator TOOMEY. Sure. Thank you.

Dr. Paulson, we all understand that we do not have a cure for the disease and the pharmacological treatments that are administered do not really fundamentally change the course of the disease. But nevertheless, you mentioned that there are important and effective treatments. Could you elaborate a little bit on what can be done in the absence of a curative treatment?

Dr. PAULSON. Absolutely; I would be happy to do that. I did mention a few things. I think we all know that exercise is good for the heart, and it is increasingly clear that aerobic exercise several times a week improves brain function in people who are beyond the age of 65, whether they have cognitive impairment or not. So it is one of the first things that I tell anyone who comes into my clinic who has dementia.

Adequate sleep makes all the difference in the world. The right kind of sleep can make a difference. We believe that maybe we rid the toxic proteins in the dementias by sleeping enough.

Being socially and mentally engaged in the world around you, the absolute opposite of a couch potato, is a very good thing to help brain function as we go forward.

Finally, diet probably makes a difference, although that is not as clearly worked out.

I think we need to, as we wait, as we work hard for those disease-modifying therapies—and I believe we will get there—we need to emphasize to people who have dementia that there are plenty of things that can be done proactively, non-medically, to help.

Cognitive training is another thing that makes a difference, as well. I am sure Dr. Petersen would have other things he would add to that.

Senator TOOMEY. Thank you very much.

Dr. Petersen, I would like to just explore with you a little bit some recent research into the underlying cause of Alzheimer's. In May, in fact, researchers from Harvard theorized, in an article that was published in the journal *Science Translational Medicine*, that some kind of pathogen and, specifically, maybe a virus, may be responsible for triggering Alzheimer's disease, and, specifically, that it may pass through the blood-brain barrier.

Here is a brief quote from a *New York Times* article on this research. "The brain's defense system rushes in to stop the pathogen by making a sticky cage out of proteins, called beta amyloid. The microbe, like a fly in a spider web, becomes trapped in the cage and dies. What is left behind is the cage, a plaque that is the hallmark of Alzheimer's."

The idea that is elaborated on in the article is that the plaque then sets off a formulation of the tau tangles, which then kill the nerve cells, inflame the brain, and hasten the death of more brain cells.

I guess my question is, could you comment on your opinion as to whether there is a consensus and, if so, the nature of the consensus about the initial first causes? Is it considered plausible that

there is some kind of pathogen that triggers the plaques that we associate with Alzheimer's, or are there other theories that you think are more widely accepted?

Dr. PETERSEN. It is a very intriguing hypothesis, and I think those investigators at Harvard have been working on this theory for quite a number of years, with some credible evidence that there is a role for either a precise pathogen like a virus or at least the role of the immunological system in the brain to combat it, and then the secondary inflammation that may arise and cause subsequent damage.

Unfortunately, it throws the whole picture of the role of amyloid in the brain, amyloid being the key protein in the brain, into question. What is its function? What does it do? We still do not know what the normal role of amyloid is in the brain.

So they are postulating that it may actually have a protective effect, and these plaques that we see on the PET scans that you mentioned actually may be sequestering some of the pathogenic material away. So that raises the question, if you have a drug then that goes after that plaque, removes the plaque or destroys the plaque, is that good or bad? And I think it throws a lot of things up in the air and makes us reevaluate what we are doing. I think we still think that the amyloid protein, and the tau protein that forms the tangles, are critical elements; in fact, they are the defining characteristics of the disease, as we heard, with regard to pathologies.

But I think we need to learn more about the disease, and clearly, as the NIH has expanded its research program, getting at some of these basic underlying mechanisms remains a high priority.

Senator TOOMEY. Thank you, Dr. Petersen.

Senator Stabenow?

Senator STABENOW. Thank you very much. Again, thank you to all of you for your testimony.

First, Dr. Paulson, as one of Michigan's top scientists working on Alzheimer's, you certainly know as much about the disease as anyone, and I know the University of Michigan's Alzheimer's Disease Center takes a multidisciplinary approach, as you were talking about. But most people in Michigan and certainly around the country who have Alzheimer's disease are probably unable to visit such a specialized facility.

So when we look at the fact that, according to the Alzheimer's Association, somewhere between 40 percent and 50 percent of people with Alzheimer's do not get early diagnosis and we hear from physicians that they are not sure it makes a difference diagnosing it, because they are not sure what they would do, that was one of the reasons that we put together HOPE for Alzheimer's, so that there would actually be a message to physicians that it would be something you could do in terms of care-giving sessions and working with families in developing a plan and so on.

But it is concerning to me that I do not know of any other top cause of death that is so severely undiagnosed as this. So I am just wondering if you might talk a little bit more about early and formal diagnosis of Alzheimer's and how important it is.

I know in talking to researchers in Michigan, they all indicate that the kinds of things they are working on, if they are going to

work, actual medications and so on, they involve early diagnosis. So it seems like being able to get that is a very important thing for a number of reasons, whether it is new drugs, whether it is supporting families and caregiver plans, or whatever.

But if you could talk a little bit more about that, early formal diagnosis—

Dr. PAULSON. Absolutely. It is a new era in Alzheimer's and related dementias. I think if you go back 20 years, it may have been fair to say there was nothing we could do. But at this point, that is clearly not the case. Connie eloquently described the difficulties of making a diagnosis and some of the ways that we can actually achieve now an earlier diagnosis.

Let me comment about why Alzheimer's, unlike heart disease or diabetes or depression, is less commonly a diagnosis that the family and the patient learn about. I think there are really two things driving it. One is that doctors are busy and they are moving from patient to patient, and they do not want to or have the time to sit down and discuss with a family and a patient what this means. That would change, I think, with the HOPE Act.

The second reason is, it is a difficult thing for a doctor to say to someone, "You have a disease that is progressive, that currently we cannot stop, and that is fatal." As Senator Toomey said, this is 100-percent fatal. It is hard to say that.

We need to change that sort of dynamic for doctors, and most of the diagnoses are not given by a specialist like me or Dr. Petersen; they are given by primary care doctors. So I think it is absolutely vital that we educate more primary care providers about how to achieve an earlier diagnosis and provide that information.

In terms of the therapies, yes, symptomatic therapies are modest, at best, right now, and the disease-modifying therapies are not there now. But I really believe that a sit-down with the family and with the patient—where you mention the diagnosis and say, these are the things we have to be thinking about, we have to plan for in the future; these are the things that will be an issue in 4 or 5 years, let us discuss them now; these are some things you can do to make your quality of life better now—is as important as any medication, frankly.

Senator STABENOW. Thank you.

Ms. Karasow, thank you for coming and sharing your story. There are so many people who share your story and need to have your voice here today speaking for them. I wonder if you might talk a little bit more about your husband's path with the disease and your experience as a family and a little bit more about what having an early, clear diagnosis would mean.

What could have happened differently for you?

Ms. KARASOW. Thank you for the question. Good question.

What happened was, we were very fearful and we relied on each other and we did not talk about it. We did not talk about it to the children, because we did not have anything definitive to tell them, and who wants to scare them, and everything that that implies?

If we had known sooner, we probably would have gotten into a family session and started planning as a family together. This way, we are doing everything catch-up and going back and doing things that perhaps we could have put in place sooner.

What it means is isolation. I have three sons—one is in Alaska and two are local—and they say, “Oh, sure, Mom, we will come by and we will stay with Dad anytime you want.” I hate to impose. And in the Alzheimer’s support group, it is hard to ask for help. It is hard to accept help when you and your husband are in a war against this big, ugly, 5,000-pound gorilla. It would be very helpful to have the kind of model that Dr. Paulson noted. And I understand there is another one in Pennsylvania, in Lancaster.

If there was a one-stop shop where you could have family sessions—here is the medication—if I had been able to compare with my sisters and brothers in the Alzheimer’s support group where they have gone—and we have helped each other enormously, and that is the wonderfulness of the support group—we would have been down the road a piece.

Maybe we would have taken vacations together while Mark was still able. He cannot walk. He is having neurological problems now. He is having delusions. Leaving him for an hour in the morning for a commitment is very difficult. It is very isolating. And you cannot get your family to come 24/7.

So them understanding that and knowing what you are going through and finding other ways to meet the needs and find a balance within all of the craziness of the disease is very, very useful.

Senator STABENOW. Thank you very much.

Thank you, Mr. Chairman.

Senator TOOMEY. Senator Menendez?

Senator MENENDEZ. Thank you, Mr. Chairman and Senator Stabenow, for holding this really important hearing today. I have many issues in the Senate, but this is an issue that is supremely personal to me, since my late mother suffered from Alzheimer’s for 18 long, difficult years, years when we watched her drift further and further away.

She was a courageous woman, a woman who saw her country in the midst of revolution and decided, against my father’s wishes at the time, to uproot her family and come to the United States in search of freedom and a better life for her children, which, at that time, meant my brother and sister, coming to a country where she had no one waiting for her, did not know the language, and had no real understanding of the risks she was taking. Courageous woman.

So when it first happened, I, of course, hoped for the best but, of course, expected the worst. And there were days at the beginning when my mother seemed just fine, when the lost moments became more pronounced, and when they began to last longer.

Now, there were times I wondered if she would recognize me the next time I walked into the room, and I wondered if all the memories of my youth and her life were in there somewhere or whether they were lost forever. For a while, it seemed she was as she was before, but then, as you know, it gets worse. She lost her cognitive powers, and then the time came when I realized she was really no longer with us, and then, mercifully, the long goodbye came to an end.

Now, the grand irony of it all is that often the toll Alzheimer’s takes on the family, on loved ones, and on caregivers can be worse even than on the person suffering with the disease.

I appreciate Ms. Karasow's personal testimony, and I appreciate her willingness to share it with us. I think about it in the case of my own sister. Her name is Caridad, which in Spanish means "charity." And she had an enormous amount of charity to give. She was a legal secretary who, during the day, worked as I paid for a home health-care aide because of our cultural belief that you just do not put Mom in a nursing home, and then would come back at the end of a long day—no vacations, no time off—and the only time she had off is the time that I could ultimately come and give to her.

And I think about the intergenerational challenges that we have with this disease, trying to give mom the dignity she deserves in the twilight of her life, taking care of the education of our children, trying to get them through college, and thinking about our own lives in the future, and I think of how many families across this country face that intergenerational challenge as a result of this disease.

So that is why I believe that we must ensure that, in addition to proper diagnosis, treatments, and eventually a cure, we support and give planning, supporting care to help families prepare for life with Alzheimer's.

I think Congress needs to aggressively fund the research for causes and cures, because if not, the long goodbye will be even longer for the Nation in costs and in heartache. So that is why I am a proud cosponsor of Senator Stabenow's HOPE for Alzheimer's Act, because I think it expressly provides for these planning services. And I am pleased to see that CMS has recently announced new billing codes to allow physicians to provide care planning to Medicare beneficiaries. I think that is incredibly important.

But one of the statistics that was mentioned in testimony today is that fully two-thirds of those with Alzheimer's disease do not know it. To me, that is a tragedy and a failure of our health-care system. Not only is it a failure to properly treat people, but it causes an undue and unnecessary burden on the health-care system, which is a good part of what this committee focuses on—certainly the human part of this particular disease, as with other diseases that we face, but the costs to the Nation collectively.

Since we know that early diagnosis leads to better long-term outcomes, which in turn lead to lower costs, it seems to me that any investment that we make in providing physicians with the time, with the resources, with the knowledge they need to better care for those with Alzheimer's will ultimately pay for itself many times over.

I want to follow up with one question I have for both Dr. Paulson and Dr. Petersen. I heard part of your response to Senator Stabenow, but from the perspective of a clinician, what is the root cause of this under-diagnosis? Is it simply, as you said, that doctors do not want to necessarily share a very difficult diagnosis with patients? There are many diseases, some of which are horrible, like certain forms of cancer, which I assume doctors would not want to give that diagnosis for, but nonetheless do, even though the results at the end of the day may not be what that family hoped for.

Is it that there is not one definitive test for Alzheimer's which can account for this major lack of timely diagnosis? Is it simply because of a lack of time and resources—which, of course, the HOPE

Act and CMS's new benefit would help address—or is it a larger misunderstanding and lack of knowledge about the disease more generally beyond specialists like yourselves?

Dr. PETERSEN. It is an excellent question, Senator Menendez.

Senator MENENDEZ. I only ask excellent questions. [Laughter.] I am just kidding. Just kidding.

Dr. PETERSEN. I wish I could give an excellent answer.

Senator MENENDEZ. None of my colleagues would say I always ask excellent questions, I can tell you that. [Laughter.]

Dr. PETERSEN. It is very important, and I think many of the issues you mentioned are all playing a part. I think there is the physician training part, how comfortable they are with making the diagnosis, because it is not a simple blood test; it is not a simple x-ray. It is a clinical judgment, but I think with some of the new techniques we have now, we can be more confident that, in fact, this person who meets the clinical syndrome of, say, dementia now has Alzheimer's disease as the underlying cause.

So I think we are getting there, and I think the IDEAS study that Connie mentioned is going to help us to convince CMS that, in fact, we should support the amyloid imaging component of the diagnostic process. So I think that is part of it.

I think there still is some therapeutic nihilism: there is nothing we can do about this disease, so why burden this patient with this kind of knowledge? And as Dr. Paulson has indicated, there are many things we can do about it.

But most of all, the patient and the family deserve to know what is going on. It is going to impact their decision-making process; it is going to impact what they do the rest of their life. And it is important, I think, for the physician—and we have been trying to bring this message home to physicians—that these individuals are often aging and they rarely have just Alzheimer's disease as a diagnosis. They may have diabetes, they may have hypertension, they may have heart failure.

The management of these other medical problems is complicated and compounded by the fact that they have Alzheimer's disease. So a person managing his or her own blood sugar—diabetes management becomes much more difficult when the person is having memory and thinking problems.

So I think for all of those reasons, it is important that we implore the physicians and the medical community out there to really get up to speed on what this diagnosis takes, what it means for the individuals, and what we can do about it.

Dr. PAULSON. I will follow up. The excellent question was followed by an excellent answer, and I will not reiterate what Dr. Petersen said, but let me make a couple of comments.

One, about the difficulty of diagnosis, Connie mentioned a doctor saying this is atypical; this is not typical. The reality is that with Alzheimer's and actually the whole range of dementias, it is a spectrum, and not everything is cookie-cutter. It is not at all that way.

Alzheimer's itself can take on many different flavors. It can involve the frontal lobe, it can involve the back of the brain, it often involves the memory, but it can involve the other areas as well. So there can be ways in which the diseases can trick us as well.

So, yes, in addition to this particular point, I think the fact that it is a complicated disease, the dynamic changes over time, contributes also to the failure of early diagnosis.

I just want to say I commend you for your comments about your mother. But the point you raised about your sister's involvement: the emotional and physical toll that occurs on families is huge, and that is a dynamic process too over time, and you eloquently described that.

Senator TOOMEY. Thank you.

Senator HELLER?

Senator HELLER. Thank you, Mr. Chairman and Senator Stabenow, for holding this particular hearing. I certainly appreciate it.

I am grateful to our witnesses for being here today and for your background and understanding and for the messages that you are sending to us.

I believe that talking about degenerative neurological diseases—Dr. Paulson, you talked about how it affects everybody. Everybody has a story. Everybody in this room has a story. I certainly do appreciate Senator Menendez's story about his mother.

My mother-in-law happens to have late stages of Parkinson's. Dr. Paulson, is that considered a degenerative neurological disease?

Dr. PAULSON. Yes, Senator Heller. Parkinson's disease is a degenerative brain disease, and, in fact, there is an overlap between Parkinson's disease and the dementias. In fact, over half of individuals who have Parkinson's disease in the late stages have dementia. So there is a Parkinson's disease dementia.

And I specifically mentioned the condition called Lewy body dementia or diffuse Lewy body disease, which is related to Parkinson's disease, because the same kind of protein abnormally accumulates. It is not the amyloid that Dr. Petersen spoke about. It is a different protein, but it has similarities, and in the same way that we are moving forward with new technologies and new ideas about therapies for Alzheimer's, we are doing the same for Parkinson's disease and, by extension, Parkinson's disease dementia and Lewy body disease.

Senator HELLER. The reason that I raise that issue is that she is in the late stages, and she was at a doctor's appointment last week. I went in with her, with my father-in-law, her husband, and the doctor asked, "Who are you with?" and she said, "My friend." So you can imagine the impact that that has on the family when she is at that stage and she does not realize and recognize her own husband of 60-plus years.

So having mentioned that, I want to talk a little bit to Dr. Petersen. You mentioned your organization, your work with the National Alzheimer's Project Act in Minnesota. How have you been able to expand this to telemedicine?

I come from the rural State of Nevada. We have the Lou Ruvo Clinic that is now working with the Cleveland Clinic. In fact, they had a fundraiser last week. They have raised over \$250 million for this specific purpose of these brain diseases and trying to find cures and help people who are moving down that road.

But the problem is, it is in Las Vegas, and telemedicine has become so important for a large State like Nevada that has—two-thirds of it is very rural.

How do you get to these rural towns? How do you get to the Elkos, the Winnemuccas, the Elys and try to make sure that those who are diagnosed in these stages and find it so difficult to travel are able to get the help and services that they need?

Dr. PETERSEN. Thank you for that question, because I think telemedicine is the wave of the future as to how to deal with a disease as widely prevalent as Alzheimer's disease, where everybody is not going to be able to make it to a specialty clinic, not make it to the Lou Ruvo Brain Institute, but is going to have to be seen by their primary care physician.

The telemedicine offers an opportunity for those physicians then to communicate with some of the specialists, to also deal with the problems of patients in their homes, and we have been dealing with that in Minnesota. Wisconsin has a program. I was recently in Texas; Texas is developing a program for telemedicine, same principal, with large spaces to deal with.

So I think that developing systems where we can communicate with the primary care physicians for specialist recommendations, but also then with the patients and families themselves in their home, will help a great deal at reducing the anxiety, reducing the co-morbidity that goes with it, and actually help the quality of life for individuals with the disease.

Senator HELLER. Dr. Petersen, thank you.

Ms. Karasow, thank you for your message to all of us. Like I said, it does make a difference. We need to hear these stories. My wife's family is going through similar circumstances, as I just mentioned. So it hits home.

Did you have Medicare services initially when your husband was diagnosed?

Ms. KARASOW. We had private insurance, Blue Cross/Blue Shield, and he had Medicare. He was on Social Security by the time he was diagnosed. Yes.

Senator HELLER. What services were available to you?

Ms. KARASOW. We were referred to the Alzheimer's Foundation. I am trying to think of where I found that out. Through Dr. Weisman, and that was it.

Senator HELLER. That was it. Okay. Thank you.

Mr. Chairman, thank you.

Senator TOOMEY. Thank you.

Senator Carper?

Senator CARPER. Thank you. I thank you, Mr. Chairman.

Welcome. It is good to see all of you. Thank you for being here and helping us with an issue that we struggle with as families and as States in this Nation.

My staff and I met earlier this week with some folks from the pharmaceutical industry. We probably spent, in a half-hour visit, at least half that time talking about Alzheimer's research, and several of the companies represented there are involved in projects with compounds or biologics trying to find the road to a cure. I was encouraged by the numbers of them that have paired up, so that you have several companies that are working in tandem with others—more sharing of information.

I do not know if any of you are up to date with what is going on on that front, but when we were facing the crisis with Ebola,

one of the ways we really focused on Ebola was coming up with a vaccine, coming up with some kind of medicines that could prevent it, that would help people get better. We are doing a similar kind of thing with Zika, the Zika virus.

Just give us an update, somebody, any of you, on what is going on on that front with respect to Alzheimer's.

Dr. PETERSEN. Thank you for the opportunity to chat on that, because that is a very important aspect of developing treatments for this disease. Academic medicine can identify the molecules, the targets, take it to a certain level. Small biotechs can introduce certain techniques. But ultimately, it is going to take major pharma to carry out these huge global phase 3 trials, and that is really what it is going to take.

I think almost all of the major pharmaceutical companies out there have a program in Alzheimer's disease and dementia right now, because the need is so great. Of course, the market is also great, but, in fact, I believe that they are actually dedicated to trying to help with this particular disease.

So much of the attention right now is focused on these proteins that we have identified and discussed a little bit this afternoon: the amyloid protein that is the component of the plaque, the tau protein that is the component of the tangles. So immunological approaches actually—antibodies, either active or passive, approaches to dealing with those two proteins—are actively being pursued.

The interesting feature of those is that, if successful, they afford an opportunity for prevention of the disease, because many times, these proteins appear in the brain before a person becomes symptomatic. That gives us a window of opportunity to intervene to try to prevent the clinical symptoms down the road.

There are several trials underway right now at various early stages in the disease process aimed at real prevention. But I must say, a major obstacle right now to the development of therapeutics is in clinical trial recruitment; that is, getting individuals to participate in these studies.

Senator CARPER. Really?

Dr. PETERSEN. It is a major, major problem right now, and I think it goes back to some of the issues we were discussing about physician awareness, family awareness, and patient awareness that clinical trials are available and are very effective at trying to combat this disease.

Senator CARPER. For my colleagues and I, that is actually something that is especially interesting. We all work—we have our own messaging operations, communication operations, some of which are old-fashioned: radio, TV, print. A lot of it is not old-fashioned. And the idea of using our collective resources to reach out and better inform our constituents across the country that there is this need, that could be very helpful.

Thank you. Please, go ahead.

Dr. PETERSEN. I just have one final comment.

Senator CARPER. Please, go ahead. And then I have another question.

Dr. PETERSEN. I mention in my testimony comments about PCORI, and I think PCORI is active in that area. The project they are funding now in dementia is exactly that, how we can bring in

particularly underrepresented groups to participate in clinical trials. So I think that this is a major effort. There is a large grant right now called the GAP that is at NIH being entertained to try to help recruitment in clinical trials.

This is a global issue as well. It is not just in the United States.

Dr. PAULSON. Senator, let me add a few things to what Dr. Petersen had to say. You talked about the partnership of industry, pharmaceutical companies working together.

I think it is important to recognize—and this is a very good thing—that there have been sort of public-private partnerships in the Alzheimer’s realm, and there have been real collaborations among centers across the country to move forward here.

The point I really want to make is, it gets back to this issue of nihilism and whether, in fact, we can get health-care providers to recognize that if you diagnose people earlier and you let them know about clinical trial opportunities, there is a chance to make a difference.

Why has cancer led to new therapies in cancer? It is because so often people who have been diagnosed with cancer are put into clinical trials. They sign up quickly. Doctors recognize the importance of that.

We need to change, again, the dynamic, and I think we are beginning to for Alzheimer’s.

Senator CARPER. Mr. Chairman, my time has expired. Could I ask unanimous consent for an extra 20 minutes? [Laughter.]

Senator TOOMEY. Objection is heard. But we are going to begin a second round.

Senator CARPER. That is great. I will come back.

Senator TOOMEY. I just have a brief question I am going to direct to Dr. Petersen, and then I know Senator Stabenow has a question.

I would like to touch on something that is a little bit disturbing. There is a natural tendency, I think, when faced with what seems to some to be a hopeless diagnosis to cling to a false hope, and there have been false cures that have been suggested.

I think we have heard that cookware can cause Alzheimer’s, that cinnamon can cure it, and some are suggesting marijuana is a cure, or there are certain games you can play on your iPhone. This must be extremely frustrating to the scientists who are with us, in particular, but it is terribly unfair to families and patients to have a false hope that has absolutely no basis in reality.

Do you have any advice for patients or for families, caregivers, about this notion of these false hopes?

Dr. PETERSEN. It is a huge industry out there to put out nutraceuticals, various supplements, medical foods, or “my brain game is better than your grain game”—huge industry out there.

I do some work with the Federal Trade Commission actually on products that are put on the market and are making egregious claims about what they might do for aging and memory and all that. So it is an active process. I am sure Dr. Paulson spends a good part of his practice as well sort of debunking some of these, because people will come in with printouts of these types of—there are websites out there that are credible. The Alzheimer’s Association, *alz.org*, is one of them that provides reliable information: what is good, what is not good, and what can be done.

So I think that, again, this is an educational activity that we can all participate in, trying to educate the physicians as well as the families and caregivers.

Senator TOOMEY. Senator Stabenow?

Senator STABENOW. Thank you very much. I just had one question, a follow-up with Dr. Petersen.

At the Finance Committee, as we look at some of the financial pieces of this, when we look at the health costs—you said that by 2050, we could face a 420-percent increase, basically top over \$1 trillion in costs for Alzheimer's disease. That is a big number.

So I am wondering, because we have jurisdiction over Medicare and Medicaid on this committee, what more should we be doing to combat the disease? What should we, from a Medicare and Medicaid standpoint, be looking at?

Dr. PETERSEN. Well, as we discussed earlier, I think the HOPE Act, if it is translated into its real promises of aiding people with a care plan going forward—so it is not just stop paying the physician at the time of diagnosis but there is an actual care plan that is compensated afterward—that will reduce costs down the road.

So the more knowledge, the more care planning—there have been a variety of studies, some done at the University of Pennsylvania actually, documenting that if you follow people when they get discharged from the hospital with dementia—they have other medical problems, get discharged from the hospital—if you follow up with them, you deal with them at home, you have a lifeline for them so that they can contact people about, “Is this part of my disease or is this something I need to be concerned about,” you can reduce the subsequent hospitalizations that can occur in people with Alzheimer's disease—not that we refuse their care, by any means, but we are dealing with it in a more educated fashion.

But I think the HOPE Act is one real tangible way that we will actually have a chance to remediate some of those costs with Medicare and Medicaid.

Senator STABENOW. Dr. Paulson, do you have anything to add to that in terms of anything else we should be specifically looking at in Medicare and Medicaid at this point?

Dr. PAULSON. I agree completely with Dr. Petersen. I love the fact that there would be comprehensive care planning. I actually would love to see that more than once. And the reality is, this disease changes over time. It is not the same disease in year 1 versus year 5.

I do not know the specifics of how Medicare and Medicaid should be involved in this, but I do believe that we need to look beyond that initial diagnostic period and the planning period and recognize that this is a progressive disease that lasts for years, if not decades, in every individual who has it, and we need to be thinking about the long-term approach.

Senator STABENOW. Thank you.

Senator TOOMEY. I want to thank our witnesses for joining us. Dr. Petersen, do you have one last comment?

Dr. PETERSEN. Just one short comment on that. With Medicare and Medicaid, CMS is already funding the IDEAS study that Connie mentioned, and that is tremendously important, because if

we demonstrated, in fact, that amyloid imaging helps the outcome of the patient, we may, in fact, reduce costs down the road.

So I think that investment is incredibly important. So thank you for that.

Senator TOOMEY. Thank you. Members of the committee will have 5 business days to revise and extend their remarks.

I want to thank our witnesses for their very, very helpful and valuable testimony. I want to thank Senator Stabenow for the really great work that she has been doing in this field.

I want to recognize Senator Carper.

Senator CARPER. Is this when I get my 20 minutes?

Senator TOOMEY. The clock is ticking.

Senator CARPER. I will be uncharacteristically brief. I would like to ask one question about cognitive screenings in Medicare annual wellness checkups.

One of the pieces of legislation I worked on in the Affordable Care Act, I think along with Senator Stabenow, was one to include cognitive screenings in Medicare annual wellness checkups. I think sometimes months, maybe even years can go by between the first signs of dementia and a medical diagnosis, even though early detection and treatment might mean better outcomes for the patients and better health outcomes, better experiences.

I just want to ask you this question. Do you know how often—do you have any idea how often Medicare beneficiaries receive these cognitive screenings as part of their annual wellness checkups? Do you have a feel for that? What can we do in Congress to help increase the rate of annual wellness checkups and cognitive screenings being provided to seniors?

What other approaches can physicians take to identify cognitive impairment and reduce the likelihood of a delayed diagnosis of dementia?

Dr. PETERSEN. Thank you. I think that was an incredibly important move forward with regard to the annual screenings.

Senator CARPER. Would you say that again? [Laughter.]

Dr. PETERSEN. I think it was very, very important, because it now puts cognitive evaluation on the radar screen like another vital sign. So in addition to knowing the heart rate, the blood pressure, the blood sugar, we now have an index of cognitive function. That is the good news, and I think that is a major step forward.

Where we are not as satisfied is in the uptake of visits. Dr. Shari Ling is a Federal member from CMS on the advisory council, and she has informed us on numerous occasions that the uptake has been disappointingly low, and I think that, again, this is another service that we can provide with education, and perhaps maybe the HOPE Act now is going to give the physicians a rationale for why they might want to identify cognitive problems sooner rather than later.

We can now do something. We can help the family and the patient. On our side, I must say that the legislation said there should be a cognitive assessment, and that is great, but now we have to let the primary care physicians know what is an adequate cognitive screen. Is it just saying, “Hey, how is your memory?” or do we do test A or test B?

So we have to demonstrate our best recommendations for the primary care physicians as to what tools to use and then, what do you do with the results of the tool?

So that is underway right now, and there are several exercises addressing that.

Senator CARPER. Does anyone else want to comment on that?

Dr. PAULSON. I completely agree with Dr. Petersen. I think you need to recognize that Dr. Petersen is one of the individuals who is primarily responsible for recognizing that you can find early cognitive changes, well before dementia, and that makes a difference.

So this kind of an effort, this kind of screening, must be implemented, and we are moving in that direction.

Senator CARPER. Mr. Chairman, thank you for those extra minutes.

Thank you all, again.

Senator TOOMEY. Thank you, Senator Carper.

Thank you all for your participation, and thanks to the many guests who came in attendance.

The hearing is adjourned.

[Whereupon, at 4:02 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF CONNIE B. KARASOW, CAREGIVER

Good afternoon, Chairman Toomey, Ranking Member Stabenow, and members of the subcommittee. Thank you for this opportunity to address the issues associated with being a care partner for individuals living with Alzheimer's disease and other dementias.

More than 5 million Americans are living with Alzheimer's, and without significant action, as many as 16 million Americans will have Alzheimer's disease by 2050. More than 10,000 baby boomers a day will turn 65 and as these baby boomers age, one in eight will develop Alzheimer's. This explosive growth will cause Alzheimer's costs to Medicare and Medicaid to increase from \$160 billion today to \$735 billion in 2050 (in today's dollars) and threatens to bankrupt families, businesses, and our health-care system. Unfortunately, our work is only growing more urgent.

It is an honor to represent the over 5 million Americans living with the disease and more than 15 million care partners who love them. Alzheimer's disease is not a respecter of role, rank, or relationship.

Those afflicted with Alzheimer's disease are adept at concealing their confusion, embarrassment, frustrations, and fears, often before their partners begin to realize that there is a problem. This was certainly true in our case. The cues were subtle, and I had a demanding career. It wasn't until the notes were piling up, including cues on his hands, that I suggested we see someone to eliminate the big "A" fear.

On November 11, 2010, after some seemingly simplistic tests, we were told by Dr. Weisman that my Mark, a 70-year-old proud man, devoted husband, and father, had Alzheimer's disease, a progressive, fatal disease of the brain. Based on those "simplistic" tests, we were told Mark was on the "bunny slope"—we could expect a gradual decline. No direct diagnostic tests were available, and we were often told, "no one ever really knows until they are dead and you can see it in the brain." Painfully glib, but true. Mark was prescribed medication to try to extend his memory, and we were sent on our way stunned, reeling, and projecting scenarios we could never fully appreciate.

Following Dr. Weisman's diagnosis, Mark experienced depression, anxiety, and obsessive-compulsive behaviors that led me to look for a geriatric psychiatrist, not an easy specialist to find. I found someone who was compassionate and intelligent but untrained in dementia. She prescribed medication for Mark's symptoms, and at each session she give Mark a pep talk by saying "you are not typical Alzheimer's," an oxymoron that reinforced our hope and denial.

If Mark was not *typical Alzheimer's*, what *typically* was he, and was he receiving the right protocols? Another neurologist was recommended. In August 2015, we met with a clinical neuropsychologist for further testing. Mark endured six grueling hours of testing, including assessments of intellectual functioning, behavioral observations, visual and verbal capabilities, memory orientation, concentration and working memory, verbal learning, language skills, motor and emotional functioning, and executive functioning. Following this battery of tests, Mark's driver's license was revoked, and Mark left the session feeling traumatized, frustrated, and "not typically" angry. The results indicated subcortical features, dementia appears to be present, mild-to-moderate in severity. However, the "precise nature" of Mark's dementia was "unclear" from the test data alone. We went back to the referring neurologist who,

with a dismissive wave of his hand, declared that he didn't agree with the diagnosis and that was all he could do.

We went back to Dr. Weisman, who was clearly disturbed with what Mark went through. Knowing Mark's scientific curiosity, he suggested a clinical trial—the Imaging Dementia—Evidence for Amyloid Scanning (IDEAS) study. The IDEAS study will determine the clinical usefulness on patient-oriented outcomes of a brain PET scan that detects amyloid plaques, a core feature of Alzheimer's disease. This study is particularly helpful in determining a diagnosis for people like Mark who do not present with typical dementia or cognitive decline. After our previous experience, it was so reassuring to know that there are doctors who care enough to help us pursue a confirmed diagnosis and understand how important this really is.

When Mark had the PET scan that confirmed his diagnosis, all of the debate, searching, and uncertainty was put to rest and the real work of living with the disease began. Mark is willing to engage in other trials and wants to donate his body when he dies. It is his desire to salvage something good from the nightmare of watching the disintegration of his mind and life.

We joined an Alzheimer's Association support group where we shared knowledge and survival skills. Issues for care partners have included: our children's distrust based on fear; how to get rid of guns; stealth banking; thermostat wars; repetition, the date, family information, media, etc.; hunger strikes; isolation; support; grieving; and survivor guilt. We established a Durable Power of Attorney, Medical Directives, wills, financial planning, medical equipment, shoes for his gait, bathing, diet, weight loss, and family/friends engagement.

For me, coping means trying to stay present, with him, in his space as long as his mind allows me. The rate of stress and depression has been described as "unique" to caregivers. Everyone says "it's hard" and that is the simple truth. The awareness that self care of my mind, body, and spirit is critical to survival is growing faster than the resources to make it a reality.

Adult day care two days a week for my husband, and me, is expensive, and I know the costs will increase over time. My husband thought he was preparing to leave his family some financial security that will melt like the snow in spring. However, I am also concerned for those homeless, poor and working poor, who lack transportation and childcare let alone eldercare. Without knowledge, health care, and case management resources, families living in the margins of our society cannot hope to manage the daily demands of those afflicted with Alzheimer's disease. Investment in Alzheimer services can prevent the terrible social and fiscal costs in social services due to the dissolution of families.

Before Mark enrolled in the IDEAS study and was able to get an accurate diagnosis, I was asked, "what difference would a precise diagnosis make?" A fair question since we know at this moment there is no cure. Trying to express this isn't easy.

I looked up the quote "Better the devil you know (than the devil you don't)." This is said when you think it is wiser to deal with someone or something familiar, although you do not like him, her, or it, than to deal with someone or something you do not know that might be worse.

I believe there is power in naming; how can we cure something if we don't even know its name?

On a practical level, an early and accurate diagnosis of Alzheimer's disease affords the individual the opportunity, dignity, and respect of participation and involvement in financial and legal decisions with his or her family. Legislation like the HOPE for Alzheimer's Act, which allows individuals newly diagnosed with Alzheimer's disease or a related dementia to have a care planning session with a health-care provider, would do just that. If HOPE had been around at the time of Mark's diagnosis, I am certain that we would have felt much less alone in this fight.

Of the more than 5 million American seniors currently living with Alzheimer's disease or another dementia, only 33 percent are aware of the diagnosis. Studies show that one of the reasons doctors do not disclose an Alzheimer's diagnosis is insufficient time and resources to provide support to patients and caregivers at the time of diagnosis. The HOPE for Alzheimer's Act works by incentivizing health-care practitioners to: (1) dedicate time and resources to fully inform a beneficiary about the diagnosis; (2) have a meaningful discussion of treatment and support options; (3) develop a care plan specific to the beneficiary, accounting for all other conditions;

and (4) document the diagnosis and care plan in the patient's medical record that is shared with all providers treating the individual.

Following a diagnosis, care planning is crucial to improving outcomes, maintaining quality of life, controlling costs, and planning appropriately for the future. The HOPE for Alzheimer's Act builds on existing Medicare coverage of a diagnosis to provide individuals with Alzheimer's and their caregivers comprehensive care planning services, including information on medical and non-medical options for ongoing treatment, services, and supports. The HOPE for Alzheimer's Act would also allow the care planning discussion to occur with or without the beneficiary present, allowing for the facilitation of more effective communication between the health-care provider and the beneficiary's family, caregivers, or personal representative.

Additionally, the HOPE for Alzheimer's Act ensures documentation of a diagnosis and the care plan in the beneficiary's medical record. Although Medicare requires documentation of a diagnosis for purposes of reimbursement, there is no requirement for a diagnosis to be documented within an individual's medical record. Documentation is critical to ensuring effective management of comorbidities (such as heart disease and diabetes) by an individual's care team and allows for care coordination among treating physicians.

Finally, by requiring a provider outreach campaign upon implementation, the HOPE for Alzheimer's Act also helps ensure beneficiaries have access to these services by educating appropriate providers about the benefit and its elements. The HOPE for Alzheimer's Act is also consistent with the National Plan to Address Alzheimer's Disease, which calls for educating health-care providers as well as supporting individuals and families upon diagnosis to prepare for care needs.

The HOPE for Alzheimer's Act may also work to reduce the disparity between costs for Medicare beneficiaries with Alzheimer's disease and those without. More than 85 percent of people with Alzheimer's and other dementias have other comorbid chronic conditions, and they are about 4 times more likely to have six or more chronic conditions, adding to the complexity of their care. Consequently, hospitalization rates are twice as high and costs are nearly three times as high for Medicare beneficiaries with Alzheimer's compared with other beneficiaries. A recent analysis of the HOPE for Alzheimer's Act by HealthSperien, which is comprised of former CBO staff, revealed that this legislation would lead to reductions in hospitalizations and emergency room use as well as improved management of comorbid chronic conditions and better management of medications for those receiving the benefit. As a result of the legislation, net federal health spending would decrease by \$692 million over a 10-year period.

Until a scientific breakthrough leads to an effective treatment or cure for Alzheimer's disease, we must work to improve the Medicare system to provide better care for American families facing this diagnosis. The HOPE for Alzheimer's Act is a win-win: it will improve the quality of care and quality of life for Medicare beneficiaries and families facing Alzheimer's disease, while reducing Medicare utilization and spending for those who receive the benefit.

Thank you again for the honor and opportunity to testify today. I hope that I have been able to address the issues of caregivers and their loved ones with the respect and recognition they deserve. More importantly, I hope my message conveyed to you the exact nature of the problem through our eyes and perhaps has given you some insights on how your leadership could be instrumental in the current and future needs of our families and communities.

PREPARED STATEMENT OF HENRY L. PAULSON, M.D., PH.D., DIRECTOR,
MICHIGAN ALZHEIMER'S DISEASE CENTER, UNIVERSITY OF MICHIGAN

Good afternoon, Mr. Chairman, ranking member, and members of the committee. I flew here today from Michigan to express my support for the Health Outcomes, Planning, and Education for Alzheimer's Act, also known as the HOPE for Alzheimer's Act, that was introduced by my Senator Debbie Stabenow. I am currently the director of the Michigan Alzheimer's Disease Center at the University of Michigan where I am also the Lucile Groff Professor of Neurology and co-director of the U.M. Protein Folding Diseases Initiative. I am honored to speak on behalf of my colleagues, our patients, and their families to express a united vision for comprehensive care and compassion for those who are living with dementia.

As director of the Michigan Alzheimer's Disease Center, a Center that links the three major research universities in Michigan, I bring with me the support of countless colleagues across our State who provide care for those with Alzheimer's and other forms of dementia. Collectively, we recognize that the comprehensive care planning services provided by the HOPE for Alzheimer's Act will improve the lives of millions of American families confronting dementia. This impact is principally what drives our support: through the HOPE Act, we will provide better care that makes a real difference in the lives of many. By addressing this critical medical need and helping dementia patients and their families navigate the difficult road ahead, the HOPE Act also will reduce Federal health care costs associated with this devastating disease by nearly \$700 million over the next decade. It's no wonder that this measure has garnered broad bipartisan support. It's the kind of legislation that will inspire a new generation of hope, and I applaud Senators Stabenow and her colleagues for having the vision to craft and support this act.

Each day, over a thousand Americans receive the diagnosis of dementia. Most often, the specific diagnosis is Alzheimer's, which currently affects more than 5 million Americans. Other related dementias, including Lewy body dementia, frontotemporal dementia, and vascular dementia, affect millions more. As a neurologist who cares for persons with dementia, I have seen the deep fear, anxiety, and uncertainty that can accompany this diagnosis. Busy and overworked health care providers may only be able to offer a simple fact sheet about the disease or provide a prescription for a medication. The future brought on by this slowly progressive disease too often remains uncharted and frightening.

To someone newly receiving the diagnosis, the questions come fast and furious:

What does my future hold?
 What changes in my life do I need to make now?
 How do I prepare for these inevitable changes as my disease progresses?
 What kind of medical care do I need and when?
 Who will help my family?
 How do I connect with others who understand?

To someone caring for a loved one, these same questions, and others, surface:

Where can I turn for help?
 How will I be able to provide care while also working or managing the household?
 How can I possibly cope with the new demands and stresses I'm facing?
 What can we do to stay as healthy as possible and close as a family?

Sadly, too often patients and their families never get the chance to consider these questions because the *diagnosis is not provided to them*. Astonishingly, approximately two thirds of seniors diagnosed with Alzheimer's are unaware of their diagnosis. In no other common disease affecting seniors—cancer, heart disease, hypertension—are so many unaware of their disease. We must do a better job of diagnosing dementia earlier in the course, and making our patients and their family caregivers aware of the diagnosis. Recent evidence shows that early knowledge about the disease improves long-term outcomes for those with cognitive impairment.

The HOPE for Alzheimer's Act will ensure that patients and families receive answers to these questions, allowing them to work with health-care providers to develop a proactive plan to optimize their health and security as they deal with the changes wrought by dementia. I cannot think of anything more pressing for our patients right now. While we in the field are working hard to develop better therapies and ultimately a cure for Alzheimer's, we are not there yet. The HOPE Act will make a difference *now*.

A few years ago we at the University of Michigan realized that, even at a major research university like ours, newly diagnosed patients and their families sometimes fail to receive all the information they need in a timely manner. Thus, we piloted a new program, the Multidisciplinary Diagnostic Medical Visit—a "team" approach to dementia that gives patients and caregivers the opportunity to meet with a neurologist, neuropsychologist, nurse practitioner and social worker for a comprehensive appointment during which we discuss test results, diagnosis, and care planning. Our pilot program also shortens the time from first contact to disclosure of a diagnosis. In short, the program has worked very well: patients and caregivers overwhelmingly support our comprehensive approach, and feel they have a much greater awareness of community support and services as a result. Care planning also allows us to address critical issues that families might not otherwise raise—for example, is it safe for my loved one to keep driving? Or to live alone? In the

process, we are continually reminded that each patient is unique. Comprehensive care planning must be customized, taking into account the specific type of dementia, stage of disease, other chronic medical disorders, and family dynamics, among other factors.

Unfortunately, only a small percentage of persons with dementia receive their diagnosis through a major research center such as ours, where we have the privilege to pilot a multidisciplinary approach. That is why the HOPE Act is so important: it will ensure comprehensive care planning for dementia across the country at all types of medical facilities, small and large.

When we think of disease treatment most of us think, first, of medicines. But for dementia, the various components that go into state-of-the-art care extend far beyond medicines. We now know, for example, that non-pharmacologic interventions play a vital role in brain health. Recent studies show that regular aerobic exercise improves cognitive function. Adequate sleep, and the right kind of sleep, may help rid us of the toxic proteins that accumulate in dementia. Cognitive training can make a difference. Careful attention to other chronic illnesses, such as depression, diabetes or heart disease, improves the lives of those encountering dementia. Finally, access to support groups, for patients and caregivers alike, can be a life saver. Access to comprehensive care planning will ensure that these vital components are offered broadly to all of our patients.

I close on a personal note. Throughout my career, I have sought to understand the mechanisms underlying brain diseases so that we might develop cures. When given the opportunity to direct the Michigan Alzheimer's Disease Center 5 years ago, I jumped at the opportunity. Why? Partly because it's an exciting time in the field; our understanding of dementia has advanced to the point where we are now testing promising, potential disease-modifying treatments. Partly because there's so much we still don't know, and need to figure out. But mostly because this disease, by affecting millions of Americans, touches us all—whether through a family member, a friend, a neighbor, a colleague. There are so many faces to this disease. I ask you now to think about someone you know who has confronted dementia. I am thinking of a colleague, a brilliant physician loved by his patients, who retired this year when he faced the earliest signs of Alzheimer's. Like you, I want to make a difference in the lives of those with dementia. Until we have a cure for Alzheimer's and other dementias, we need to provide patients and families with the means to cope and the reasons to hope for a better future. This is precisely what the HOPE Act will do.

Thank you for the opportunity to speak to you today. I am deeply encouraged by the HOPE Act, and personally, I have great hope for the future of those with Alzheimer's and other dementias. I look forward to getting back to Michigan to continue our work toward that better future and would be happy to answer any questions that the committee has for me.

PREPARED STATEMENT OF RONALD C. PETERSEN, PH.D., M.D., CHAIR, ADVISORY COUNCIL ON RESEARCH, CARE, AND SERVICES, NATIONAL ALZHEIMER'S PROJECT ACT

Good afternoon, Chairman Toomey and Ranking Member Stabenow. 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. Recently, I was appointed to the World Dementia Council by United Kingdom Prime Minister David Cameron.

Alzheimer's disease is the most devastating disorder of our generation. We are all familiar with persons who suffer from the disease, as well as families and caregivers of those individuals who are keenly aware of the urgency in addressing this disease now.

It is estimated that there are over 5.1 million people currently in the United States with Alzheimer's disease, and that number is projected to exceed 13 million by 2050. A recent research project from the RAND Corporation published in the *New England Journal of Medicine* based on data from 2010 indicated that the cost to the U.S. healthcare and long-term care systems for Alzheimer's disease was between \$159 billion and \$215 billion. This is in comparison to similar 2010 data for heart disease estimated at \$102 billion and cancer at \$77 billion. As such, this was the first documentation that Alzheimer's disease is, in fact, the most costly disease to the U.S. health economy.

In 2011, President Obama signed the National Alzheimer's Project Act into law. This law required the Secretary of Health and Human Services to develop the first U.S. Plan to Address Alzheimer's Disease. The first Plan was published in May of 2012, and it has been revised annually. The law also required the appointment of an advisory council to advise the Secretary on the development and revision of the Plan, and the Advisory Council, which I chair, has been meeting quarterly since 2011. The law also required that the Advisory Council generate a separate set of recommendations that would go directly to the Secretary and to Congress outlining our opinions and necessary steps for treating Alzheimer's disease and related dementias. These recommendations are not constrained by any current fiscal considerations.

The primary goal of the National Plan is to effectively treat and prevent Alzheimer's disease by 2025. One of the corresponding recommendations that the Advisory Council has put forth to the Secretary and Congress urges the Federal Government to allocate at least \$2 billion a year for research in Alzheimer's disease. Currently, with the recent increase in the FY 2016 budget, the Federal allocation is \$991 million. We are making progress, but we have a long way to go.

According to a report from the Alzheimer's Association, caring for persons with Alzheimer's disease in 2015 cost the United States \$226 billion, 70% of which came from Medicare and Medicaid. This means that approximately one in five Medicare/Medicaid dollars was spent on Alzheimer's disease. By 2050, that annual cost is estimated to be greater than \$1.1 trillion. This represents a 420% increase over that timeframe and indicates that, by 2050, we will be spending one in three Medicare and Medicaid dollars on Alzheimer's disease. The cumulative costs from now until 2050 will be over \$20 trillion, again 70% of which will be covered by Federal and State governments. Therefore, if we were to be successful at addressing the primary goal of the Plan, to develop an effective treatment by 2025, these figures may become modifiable. We need to act now to avert this untenable scenario for our country.

Putting this in the context of the primary goal of the National Plan, if we were to develop by 2025 a disease-modifying therapy that delayed onset of the disease by 5 years, this would reduce the number of individuals with Alzheimer's disease over the succeeding 5 years, from 8.2 million to 5.8 million. This would result in a savings of \$83 billion from \$451 billion to \$368 billion. If you project these numbers out to 2050, at which time we indicated that we would be spending \$1.1 trillion without a disease-modifying therapy, that number would be reduced to \$734 billion.

Without an effective treatment, cumulatively over the 10 year period from 2025 to 2035, Federal and State governments would pay an estimated \$3.2 trillion. Again, assuming a disease-modifying therapy by 2025 over the ensuing 10 years, Federal and State governments would appreciate a cumulative savings of \$535 billion. Even in the first year following a disease-modifying therapy, we would be saving \$3 billion. I do not mean to inundate you with statistics, but the numbers are impressive that, for as little of an investment of \$2 billion a year for Federal research, the impact in savings to the Federal health-care system would be enormous.

So, are we there? As I mentioned, the current Federal budget for Alzheimer's disease research is approximately \$991 million. In 2014, Congress passed the Alzheimer's Accountability Act which required the National Institutes of Health to generate an annual Professional Judgment Budget, also called a bypass budget, to estimate what the annual costs would be to reach the goal of the plan by 2025. Last year, Dr. Francis Collins, Director of the National Institutes of Health, announced the first bypass budget for FY17 at the Advisory Council's summer meeting. He estimated that the recommended increase in the budget for FY17 would be \$323 million. He and his staff are currently working on the 2018 bypass budget.

The research community is poised to make the necessary progress to make these treatment projections a reality with the disease-modifying therapy by 2025. The academic field is working on the notion of prevention of Alzheimer's disease. By prevention, we mean a delay in the onset or the slowing of progression of the disease, which is entirely realistic. Through recent research advances funded largely by NIH, such as the Alzheimer's Disease Neuroimaging Initiative and our Mayo Clinic Study of Aging, we have become able to identify the underlying disease process causing Alzheimer's disease in cognitively normal individuals. This research opens the door for designing more efficient and effective clinical trials.

As we move toward earlier and earlier identification of the disease through the use of clinical tools and biomarkers, we are developing better techniques to assess

individuals. The Patient Centered Outcome Research Institute (PCORI) has focused a recent dementia initiative on evaluating clinical measures from the patients and, and very importantly, from caregivers, to assist in the development of these new therapies.

In closing, I would like to thank Congress for its proactive stance in addressing these issues. The time is now to act at continuing to increase the budget for Federal funding of research for Alzheimer's disease because the consequences of these projections are otherwise unsustainable. Alzheimer's disease is the most costly disease in this country and will become increasingly so unless we develop these effective therapies.

I would like to commend both my Federal and nonfederal colleagues on the Advisory Council for Research, Care and Services for the National Alzheimer's Plan as well as our colleagues in the Department of Health and Human Services, most notably in the office of the Assistant Secretary for Planning and Evaluation and the National Institutes of Health. Our work is just beginning. I appreciate the opportunity to share these thoughts with you this afternoon and would be happy to entertain questions. Thank you.

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October 3, 2016

Patrick J. Toomey
U.S. Senator
United States Senate
Washington, DC 20510

Dear Senator Toomey:

I would like to thank you for the opportunity to testify before the Senate Finance Subcommittee on Health Care on "Alzheimer's Disease: The Struggle for Families, a Looming Crisis for Medicare" on July 13, 2016. I was pleased to share my views with you and the committee and greatly appreciate the venue to discuss this looming crisis.

I recently returned from Australia where I toured the country, discussing Alzheimer's research and policy issues in the United States. Since Australia is developing a national strategy, they were primarily interested in our approach to the U.S. Plan to Address Alzheimer's Disease. I spoke at the Australian National Press Club on World Alzheimer's Day, September 21, and entered into a rich discussion following the presentation. I cited many of the statistics for them that I had presented to your subcommittee.

I appreciate the opportunity respond to Senators Grassley and Burr that you requested. I will address them as enclosures.

Senator Toomey, I again want to express my appreciation to you for my opportunity to respond to you and Senators Grassley and Burr. Please do not hesitate to contact me at any time.

Sincerely,

Ronald C. Petersen, Ph.D., M.D.
Professor of Neurology
Distinguished Mayo Clinic Investigator
Cora Kanow Professor of Alzheimer's Disease Research
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October 3, 2016

Charles E. Grassley
U.S. Senator
United States Senate
Washington, DC 20510

Dear Senator Grassley:

I would like to thank you for your insightful comments regarding the status of funding for Alzheimer's disease and other dementias. I appreciated the opportunity to testify before the Senate Finance Subcommittee on Health Care on July 13, 2016, and greatly appreciate your interest.

The issues you raise regarding Alzheimer's disease funding and its impact on citizens of Iowa and the country are particularly germane. With respect to your specific question on the potential of the EUREKA prize, I will offer the following.

A substantial prize such as \$10 million for Alzheimer's disease would be particularly exciting. While there are many endeavors that could be addressed, I believe that early recognition of the diagnosis, and most importantly, identifying those at risk for developing the disease in the future would be most productive. Due to the magnitude of the problem, I do not believe we can wait until people become clinically symptomatic to institute treatment. Rather, from a public health perspective, we need to prevent the disease. As such, there has been a great deal of work on identifying early biomarkers of the disease, even when people are clinically normal, and I believe that this is an urgent need. I would invest in increased development and validation of biomarkers for Alzheimer's disease that we could employ in the population as early as possible. Preferably, these would be relatively inexpensive and noninvasive to be maximally useful, but in the interim, we need to validate current sets of biomarkers. When this work is completed, intervention with disease modifying therapies could be employed at the appropriate time in the disease process.

I realize that this is just one opinion, but I think it reflects a great deal of activity currently underway in the field of Alzheimer's disease research. Again, I would like to thank you for your keen interest in the topic and your proposal to establish a EUREKA prize.

Sincerely,

Ronald C. Petersen, Ph.D., M.D.
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Distinguished Mayo Clinic Investigator
Cora Kanow Professor of Alzheimer's Disease Research
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October 3, 2016

Richard Burr
U.S. Senator
United States Senate
Washington, DC 20510

Dear Senator Burr:

I would like to thank you for the opportunity to testify before the Senate Finance Subcommittee on Health Care on July 13, 2016, regarding Alzheimer's disease. I found the questions and the subsequent exchange to be extremely valuable, and I was impressed with the committee's commitment to this topic.

With respect to the specific questions that you have raised following the hearing, I would like to offer these responses.

Question 1: What is the state of the research in developing more effective diagnostic tools for this disease?

I believe the field is advancing very rapidly with respect to the development of diagnostic tools for Alzheimer's disease. In particular, formerly, one could not make the diagnosis of Alzheimer's disease until the individual had passed away and an autopsy on the brain was performed. At the time of autopsy, the two signature proteins, amyloid comprising the neuritic plaques and tau comprising the neurofibrillary tangles, were sought. The field has progressed sufficiently such that we can now identify these two proteins, amyloid and tau, in living individuals using positron emission tomography (PET) scanning techniques. We can also detect their presence during a lumbar puncture to obtain cerebrospinal fluid. This is a tremendous advance in the field since, as therapeutics are developed, they can be targeted specifically toward these proteins and their effect on the proteins can be measured using these new detection techniques.

Consequently, as a clinician at the Mayo Clinic, I am much more confident in making my diagnoses using these tools to aid in our clinical assessment. Biomarkers will become increasingly valuable as therapies evolve.

Question 2: What is the timeline for development of a game-changing drug for patients with Alzheimer's disease?

At any given time, there are more than 50 potential therapeutic candidates under investigation around the world. However, relatively few make it to Phase 3 of FDA testing. Currently, one Phase 3 result will be reported later this year pertaining to the anti-amyloid antibody, solanezumab. This compound produced by Eli Lilly and Company has been tested in two previous trials which have not proved successful. However, using the new imaging techniques described above in response to Question 1, the proponents are now confident that they are using the potential therapy in appropriate participants, *i.e.*, individuals who have demonstrated the amyloid protein in their brains. As such, this will be a realistic test of this particular compound.

On a related note, another anti-amyloid antibody, aducanumab, has demonstrated in Phase 1 results that it can, in fact, lower the amyloid levels in the brain over the course of treatment for 12 months. These data have been reported in a prominent journal just recently and indicate that the antibody strategy does, in fact, work at removing the amyloid. Since this was only a Phase 1 study, the study was not statistically powered to detect clinical effects, but the group of subjects who responded to the compound by demonstrating a reduction in amyloid over the 12 months also had stabilization of their clinical symptoms. This is very encouraging for the field, and two large global Phase 3 trials have been launched.

All this is to say that the development of therapeutics is a very active area in the field of Alzheimer's disease research, and we are increasingly hopeful that a positive result will appear in the next few years.

Question 3: What can be done to accelerate these processes in order to reach the goals of effective treatments and cures more quickly?

This is a particularly important issue with respect to the development of effective therapeutics. A major barrier to the development of effective therapeutics revolves around the issue of subject recruitment for randomized controlled trials. That is, when a clinical trial for a therapy is designed, the recruitment phase is projected. However, almost always, the proponents need to extend the recruitment phase because the participants are reluctant to join the trial or, more likely, are unaware of the trial's existence. As such, there are major efforts underway currently to increase enrollment in randomized controlled trials. It is not uncommon for a person with a difficult-to-treat cancer to enroll in a clinical trial, and we need to raise the awareness of the general public and practicing physicians. If the physicians were more informed on the availability of clinical trials for Alzheimer's disease, we would be able to develop effective therapies much more efficiently and economically. As such, enrollment in clinical trials is a major area of concern.

I need to disclose that I have consulted both for Eli Lilly and Company and Biogen, Inc., with respect to the development of therapeutics for Alzheimer's disease. The two compounds I mention above are sponsored by these two companies. However, since I do a great deal of work in this area as a clinical investigator, I do not think these involvements alter my perception of the field. Nevertheless, I wanted you to be aware.

Again, thank you so much for your interest in the field, and I would be happy to expand upon any of these issues at a future point in time.

Sincerely,

Ronald C. Petersen, Ph.D., M.D.
 Professor of Neurology
 Distinguished Mayo Clinic Investigator
 Cora Kanow Professor of Alzheimer's Disease Research
 Cadieux Director, Mayo Alzheimer's Disease Research Center
 Director, Mayo Clinic Study of Aging

SUBMITTED BY HON. PATRICK J. TOOMEY, A U.S. SENATOR FROM PENNSYLVANIA

PREPARED STATEMENT OF GEORGE VRADENBURG, CHAIRMAN AND FOUNDER,
 USAGAINSTALZHEIMER'S

Chairman Toomey, Ranking Member Stabenow, and members of the subcommittee:

On behalf of UsAgainstAlzheimer's, a relentless patient-centered force committed to ending Alzheimer's disease by 2020, I applaud you for holding this hearing on this most important issue. While a number of congressional committees have held hearings examining Alzheimer's from a number of angles, this session is particularly powerful because it focuses explicitly on the devastating economic impact this disease has on families and our Medicare program.

Multiple studies in recent years have placed the annual total cost of our Nation's Alzheimer's epidemic in excess of \$200 billion. Notably, a 2013 report by the RAND Corporation placed the direct medical costs of Alzheimer's disease care at \$109 billion (compared to cancer at \$77 billion) and at \$159 billion to \$215 billion annually when the value of informal care services is included.¹

Furthermore, estimates indicate that 70 percent of the total national costs of Alzheimer's disease are shouldered by taxpayers through the Medicare and Medicaid programs. For 2016, this would amount to about \$160 billion. To put this in perspective, \$160 billion is about 24 percent of the estimated \$673 billion the chief actuary estimates will be spent in 2016 on the entire Medicare program.²

¹Michael D. Hurd, Ph.D., Paco Martorell, Ph.D., Adeline Delavande, Ph.D., Kathleen J. Mullen, Ph.D., and Kenneth M. Langa, M.D., Ph.D., *N. Engl. J. Med.*, 2013, 368: 1326–1334, April 4, 2013.

²See FY 2016 HHS Budget in Brief: <http://www.hhs.gov/about/budget/budget-in-brief/cms/medicare/index.html>.

Beyond the United States, global costs of this disease in 2015 were estimated at \$800 billion, or over 1 percent of global GDP. As the prevalence of the disease triples in the coming decades with its attendant rapid increase in global burden, entitlement costs around the world will put increasing pressure on global balance sheets and sovereign debt quality. A particularly troubling statistic, according to Alzheimer's Disease International, is that by 2030 63 percent of the global population living with Alzheimer's or other forms of dementia will reside in low- and middle-income countries, a percentage that will rise to 68 percent by 2050.³

While the primary focus of this hearing is rightfully the impact of this disease on American families and on Medicare, a full discussion on Alzheimer's and dementia cannot occur without touching on research. In recent years, thanks to the leadership of many in this Chamber, Congress has allocated increased resources to support Alzheimer's research at the National Institutes of Health (NIH). While the recent and ongoing efforts must be applauded vigorously, the reality is that today we are committing less than \$1 billion to Alzheimer's research—about 1/6 of 1 percent of what our government programs are spending each year in care costs to address this disease. Increasing levels of research investment into the broad promising scientific opportunities in attacking this disease hold the promise of reducing this burden. We have seen time and again, particularly in the fields of cancer, cardiovascular disease and HIV/AIDS, that focused and intensive commitments to research can crack heretofore vexing scientific challenges and lead to breakthroughs in how we treat and manage a condition. We need this same commitment, right now, to Alzheimer's disease. The fact is that Alzheimer's is a cancer-size or greater problem demanding a cancer-size or greater solution.

Over the past several years, I have been privileged to serve as an inaugural member of the World Dementia Council to help drive forward global action to address Alzheimer's and dementia. Over the past few years, this panel and other experts have begun to coalesce around the notion that a nation should commit at least 1 percent of care costs to research efforts aimed at developing therapies and cures.

Of course, many factors play into making such research decisions including the state of the science, the opportunities available and the quantity of high-quality and meritorious science being proposed. I would submit that Congress and the NIH consider the 1 percent market as a short-term target to inform research prioritization. If we fail to set priorities that are informed by the most significant current and looming threats to the physical and financial well-being of our families and the Nation overall, our future will be one of lives lost and of fiscal ruin.

As the agency that is responsible for covering these costs, the Centers for Medicare and Medicaid Services (CMS) needs to play a significant role in leading our national efforts to prevent and effectively treat Alzheimer's by 2025. Perhaps the most important action the agency can take is to provide greater levels of support and services to beneficiaries with Alzheimer's through their caregivers. Doing so is another short term strategy to equip caregivers to keep their loved ones at home and out of residential care homes for longer periods of time and also reducing emergency room and avoidable hospital admissions or readmissions. Such action would reduce the care costs that are burdening Medicare and delay or reduce the institutional care costs that are challenging Medicaid.

Some significant developments to achieve these goals have occurred during the past few weeks and are examples of issues within the Finance Committee's jurisdiction.

Last month, the Senate Appropriations Committee advanced a fiscal year 2017 Labor, HHS Appropriations Act that included the Health Outcomes Planning and Education or HOPE For Alzheimer's Act, a piece of legislation long-championed by Ranking Member Stabenow and Senator Susan Collins, Chair of the Special Committee on Aging. This bill, if enacted, would help ensure Medicare beneficiaries with Alzheimer's disease receive timely and accurate diagnoses as well as critically important guidance and direction to access a range of care planning services.

UsAgainstAlzheimer's knows far too many patients and family members who struggled for years to obtain an accurate diagnosis as well as those who, once diagnosed, were told there is simply nothing that could be done for them. While no disease-modifying or slowing drug has been approved as of today, we do know that a number of lifestyle modifications, co-morbidity management, and supportive services can

³Alzheimer's Disease International: *World Alzheimer's Report 2015: The Global Impact of Dementia; An Analysis of Prevalence, Incidence, Cost, and Trends*, <https://www.alz.co.uk/sites/default/files/pdfs/world-alzheimer-report-2015-executive-summary-english.pdf>.

make a difference in helping patients and their families maintain their quality of life and plan for the future.

I urge the members of this committee to do everything you can to enact the HOPE Act into law this Congress, through the appropriations process or as a stand-alone bill.

More recently, just last week Ranking Member Stabenow joined Senator Shelley Moore Capito—who lost both of her parents to Alzheimer’s disease—in introducing S. 3137, the Alzheimer’s Beneficiary and Caregiver Support Act. This bill would pick up where the HOPE Act leaves off by authorizing Medicare to evaluate promising counseling and supportive interventions that, when delivered to the informal or non-paid caregivers of persons with Alzheimer’s and dementia have been shown to improve the caregiver’s health and well-being, thus enabling them to care for their loved one for longer periods of time and reduce utilization of the health system.

A major driver of the Alzheimer’s cost burden is the cost of care, particularly institutional care, with Medicaid being the largest payer of such care. One such model, developed by a team at New York University and evaluated over decades, found that targeted in-person and telephonic counseling and supports delivered to family caregivers helped delay placement of the person with Alzheimer’s in an institutional care setting by about 18 months compared to the control groups.

Given the cost of nursing home care—1 year in a semi-private room costs nearly \$75,000 on average according to *LongTermCare.gov*—such a model could realize significant savings to individual families and to our Federal healthcare budget. ***The time is ripe for CMS to conduct such an evaluation, and I urge all members of this subcommittee to cosponsor S. 3137 today.***

I thank you for calling this important hearing, and I urge you and this committee to continue the focus on the impact Alzheimer’s will have on the Medicare program going forward. There is much that CMS can and should be doing to blunt this threat, and I look forward to working with all of the members on these issues going forward.

COMMUNICATIONS

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The Honorable Pat Toomey Chairman Senate Finance Subcommittee on Health Care 248 Russell Senate Office Building Washington, DC 20510	The Honorable Debbie Stabenow Ranking Member Senate Finance Subcommittee on Health Care 731 Hart Senate Office Building Washington, DC 20510
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Chairman Toomey, Ranking Member Stabenow, and committee members:

Thank you for the opportunity to speak in support of the needs of caregivers. I serve as the Director of the Aging Institute of UPMC Senior Services and the University of Pittsburgh where we are fervent in our focus on the core needs of the older adult and the very real struggle for families and caregivers, particular those providing care for an individual with Alzheimer's Disease, or related dementia. We have developed programs and initiatives designed to provide one-on-one supports and education for both caregivers, as well the health professionals that provide additional services.

In short, the needs of caregivers are great. For those providing care for an individual with cognitive changes including Alzheimer's Disease or related dementia and other memory disorders, there are the additional complexities such as wandering, cognitive and functional decline, and behavioral disturbances that heighten the demands on caregivers. Becoming a caregiver is associated with increased depression, poor self-care, and increased chronic illness, and many of these caregivers must manage difficult symptoms and problematic behaviors in addition to the physical, emotional, and financial challenges of caregiving in the home. Moreover, becoming a caregiver is also associated with social isolation. Caregivers must deal with changes and challenges in their emotions, energy, living patterns, finances, and roles. Over time, heavy duty caregivers decline more rapidly than non-caregivers, and caregiving itself is a risk factor for mortality.

The demands of this group have been a particular concern in Pennsylvania, which has the country's fourth oldest population. Older adults have a disproportionately higher burden of disease, utilization of health care services, and the need for both family caregiving as well as professional health care supports. In addition, according to the Alzheimer's Association, there are more than 400,000 individuals, throughout the state of Pennsylvania, living with Alzheimer's Disease and related dementias with approximately 669,000 family caregivers providing 760 million hours of unpaid service throughout the state each year. The financial burden is also significant where nationally, more than \$214 billion, which represent one dollar out of every five spent by Medicare and Medicaid goes to treat Alzheimer's Disease. Fifteen million individuals provided 17.4 billion hours of unpaid care, with 60% rating the emotional stress of caregiving as high or very high, and one-third to two-thirds reporting high levels of depression. In response to this growing need, the Pennsylvania Alzheimer's Disease Planning Committee and the Pennsylvania Long-Term Care Commission were developed, both of which brought together legislators, medical professionals, and individuals living with Alzheimer's disease throughout the state to create comprehensive reports outlining recommendations from the respective committees. Enacted legislation such as the Caregiver Advise Record and Enable Act, re-

ferred to as the CARE Act or Act 20, is a common sense solution—integrating health and social services—that supports caregivers when loved one is hospitalized by encouraging a more formalized provision of instructions for medical tasks upon their loved one's return to home. In addition to the CARE Act, recently proposed legislation such as the Alzheimer's Beneficiary and Caregiver Support Act underscore the recommendations from these committees and outline a strong focus and plan for supportive action:

Recommendation—PA State Plan for ADRD: Enhance support for family and nonprofessional caregivers and those living with ADRD.

Recommendation—PA Long-Term Care Commission: Enhance services provided to unpaid caregivers.

How can we prevent caregivers from feeling burdened while sustaining and assisting them in meaningful and positive aspects of caregiving? The approach should include not just the individual and family counseling, participation in support groups, and telephone contact discussed later in this testimony. It can also include tailoring multi-component interventions in a more individualized manner. As such, more intensive support strategies that combine education, support, and respite into a single, extended service offered more long-term have proven efficacy. An example of this type of approach is found in the Resources for Enhancing Alzheimer Caregiver Help, referred to as the REACH and REACH II protocols currently utilized by the Allegheny County Department of Aging for their funded program called Caregiver First Initiative through Family Links. A somewhat different approach than the New York University's Caregiver Intervention, which the Alzheimer's Beneficiary and Caregiver Support Act is modeled after, the REACH and REACH II protocols merit attention due to emerging results of improving caregivers' quality of life and serve as a first-rate example of a local effort bringing evidenced-based practice into service delivery. Of note, REACH II was designed to address the needs of culturally diverse caregivers of persons with dementia, including White, Hispanic, and African-American caregivers and has been able to show that it improves caregiver quality of life, and was found to show benefits to White, Hispanic, and African-American caregivers.

In addition, the following initiatives are offered free of charge to those in the community and serve as a bridge to science, education, and service to deliver care that is both evidenced-based and efficient. They reflect the mission of the Aging Institute by providing integrated, comprehensive, and timely access to a full range of services for older adults, their friends, caregivers, family members, and healthcare professionals without financial restriction.

Education—In 2013, the Aging Institute developed the INSPIRE (Inspiring New Solutions and Providing Individualized Resources and Education) Advanced Caregiver Series. Through six weekly sessions, personalized, comprehensive, and individualized support as well as in-depth dementia education is provided to long-term caregivers, particularly those providing in-home care to older adults. Core course content includes:

- Managing the disease's progression;
- Identifying and responding to behavioral issues;
- Dealing with depression; and
- Crisis resolution.

Pre-course and post-course one-on-one sessions are conducted with participants to further emphasize the course content.

Help and referral line—The Aging Institute hosts a free call-line that serves as a community-benefit with no restrictions on geographical location or insurance affiliation. Callers are connected with a health professional trained to provide older adults, caregivers, and members of the community with supportive resources based upon their needs. These call-line supports have been extended into a physical location at a nearby community hospital through the Aging Institute at UPMC McKeesport Resource Center. This center provides a physical location where individuals from the community can walk in and work with a health professional to obtain information and connections to community resources. The space also houses educational sessions and support group sessions of the Alzheimer's Association.

Website (*aging.upmc.com*)—The Aging Institute seeks to provide helpful aging-related information to health care professionals, students, researchers, and the community at large and contains a feature where users can submit aging-related questions to be answered either virtually or via phone by the call-line staff. A dedicated

section contains resources for caregivers and important information on topics such as advanced care planning, and social and emotional supports.

Employer/Employee Supports—The Aging Institute and UPMC has partnered with the United Way of Allegheny County on the United for Caregivers Initiative designed to stimulate both employer and employee engagement and to increase the supports available to employees who also serve as caregivers. American businesses lose \$29 billion each year due to employees' need to care for loved ones, and many caregivers in the workforce are also members of the "sandwich generation" characterized as providing caregiving needs to both the older adult and younger children at home. Through this initiative, a survey was created and disseminated to staff at eight companies to better understand the distribution of employees that identified themselves as caregivers within the workforce and to identify needed resources for this group.

Charles F. Reynolds III, M.D.

Director, Aging Institute of UPMC Senior Services and the University of Pittsburgh
UPMC Endowed Professor in Geriatric Psychiatry

Director, NIMH Center of Excellence in Late-Life Depression Prevention and Treatment

Director, John A. Hartford Foundation Center of Excellence in Geriatric Medicine,
School of Medicine, University of Pittsburgh

STATEMENT SUBMITTED BY MICHAEL ELLENBOGEN

My name is Michael Ellenbogen, and I live in Jamison, PA 18929. I am living with Alzheimer's and have become a world renowned advocate for this cause. Below are the issues and actions that need to be addressed as I see them if we are going to help people and their families deal with this devastating disease. Implementation of the following will lead to future savings to government and the public sector. The government loses so much money today because of this disease, including many things that are not even being considered under the actual cost of the disease; *i.e.*, loss of revenue from taxes from the individuals who no longer work, and the added cost of SSDI and unemployment supplements. To keep it simple I will make this in bullet form. For more details look at my other attachment. Keep in mind I have AD so don't expect perfection.

LACK OF FUNDING is one of the biggest issues we face. If we were to fund research for Alzheimer's like we fund other major disease research, we would find ways to slow it down and even a possible cure.

AWARENESS AND EDUCATION must be increased. Not only do we need to remove the stigma around this disease, most people including medical staff do not understand this disease. Although NAPA was created about 4 years ago there has been no real public awareness on the disease to better educate the public. One way to help with this is to also support and push for involvement for Dementia Friendly America.

MEDICAL PROFESSIONALS: Through my experience with medical staff and hospitals, I have learned that in order to educate them about this disease we will need to make training mandatory by insisting they take CEU's related to dementia training. Without it I can assure you it will not happen. I have been told this by high level professionals in the field. In my opinion hospitals should play a key role in advancing such training.

If we want doctors to actually diagnose people with dementia we need to ensure that people's rights are not taken away just because they receive this diagnosis. People lose their drivers' license in some states. Some judges take away the individual's right to maintain control of their own finances and most importantly we do not get the same rights as someone who is disabled—especially at policy forums like the NAPA Advisory Council. If NAPA does not provide appropriate accommodations for people living with dementia, how are we going to set an example for others to follow?

Given the ever-increasing number of individuals who need to be diagnosed, gerontologists and geriatricians are critically important. Unfortunately we have a serious issue because there are fewer doctors choosing this field due to the lack of financial reimbursement. Doctors need to spend additional time with these patients in order to determine a proper diagnosis. Additional financial incentives are needed for new doctors to get into this field.

We also need to change the laws so that physicians can oversee, and be paid for, at-home care so people with dementia can live in their homes longer. That will lead to a savings to all and better outcomes for those patients.

MEANINGFUL ENGAGEMENT: We need to find meaningful things to do for individuals with dementia who no longer can work. The labor laws prohibit our volunteering. If we were able to volunteer, it would delay the progression of the disease and we would function longer before needing care.

RESOURCE DATABASE: Today there is no system in place to give help to the people who need it when they need it. I believe a database can be created to do just that. It would help people get the answers they need to help them take care of their love one and would delay placement in a residential facility or the need to go to a hospital emergency room. So many caregivers are thrown into the fire of taking care of others without any tools or directions on what to do or where to go.

These are what I consider the critical issues that will lead to the most success in helping to deal with the escalating challenges our nation faces from an ever-growing aging population living with dementia. Thanks.

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July 12, 2016

The Honorable Patrick J. Toomey
Chairman
U.S. Senate Committee on Finance
Subcommittee on Health Care
248 Russell Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
Ranking Member
U.S. Senate Committee on Finance
Subcommittee on Health Care
731 Hart Senate Office Building
Washington, DC 20510

Dear Senators Toomey and Stabenow,

Thank you for allowing me to participate in this critical conversation on “Alzheimer’s Disease: The Struggle for Families, a Looming Crisis for Medicare.” As the President and CEO of the nonprofit Jewish Association on Aging in Pittsburgh, Pennsylvania, I am acutely aware of the ravages of this disease and applaud you for bringing this difficult and important conversation to the forefront.

The impact of Alzheimer’s in both quantitative and qualitative terms on the population we serve cannot be overstated. The illness has a devastating impact on individuals, their caregivers, families, the economy, the healthcare system, and the community at large. In 2015, the Alzheimer’s Association reported 270,000 individuals living with Alzheimer’s in the state of Pennsylvania, with the number projected to increase by 18.5 percent to 320,000 by 2025. On a national level, an astonishing 1 out of 3 people are affected by this disease—either by a personal diagnosis or a diagnosis of a family member—in this country.

The mission of the JAA is to honor and enhance the lives of older adults by providing a continuum of individualized quality care consistent with Jewish values and tradition. For 110 years we have been committed to providing long-term care and shelter to the region’s elderly population. Today the JAA offers a full range of comprehensive care programs to keep seniors active, safe, independent, and connected to the community through services to **seniors of all faiths, backgrounds, and financial means, including seniors who no longer have the ability to pay for their own care.** In fiscal year 2016, we served more than 3,000 seniors and their families throughout our continuum and provided more than \$2.8 million in uncompensated care services and charity.

Since 2012 the JAA has embarked upon a culture change journey throughout our continuum to enhance the lives of seniors in our community with greater opportunities for independence and social engagement. We have several Alzheimer's programs across our continuum, including 48 skilled nursing and personal care rooms for those suffering from Alzheimer's and dementia. Our Anathan Club Adult Day Service has a growing registry of more than 45 individuals and we recently launched a Nighttime Memory Care Program—the only facility in the state—that cares for those suffering from Alzheimer's and dementia during the evening hours when they are the most restless, giving caregivers a much needed respite. But that just touches the surface as **we project that approximately 80% of the elderly we serve across our entire continuum of health care services have some form of dementia** with varying degrees of the progression of the illness. Combine these compelling statistics with the fact that Western Pennsylvania is home to the second largest population of adults over 65 in the country, second only to Dade County, Florida, and we need no other motivation for our community to prepare for the “silver tsunami” and the surge of services that we will need to offer best-in-class care for our elders, their families and the community at large.

I wanted to take a few moments to tell you what I, our caregivers, and volunteers encounter every day with our Alzheimer's patients. There's Marialyce, who walks through the halls with her daughter listening to an iPod and laughing at silly, sometimes coarse, jokes. There's Edward who cannot recall his wife's name or her smile, but knows he loves her. And there's Joel, an esteemed former physician who after his diagnosis remained uncommunicative for hours but has suddenly found a new passion for painting in one of our art classes offered at our Adult Day Service. But for every one of the Marialyces, Edwards and Joels, we do, sadly, hear of stories of elderly men and women who battle this disease alone with no support and without even a sliver of the care they need. We also hear stories of the stress of caregivers, who before they discovered our services, found themselves alone, abandoned by friends when their loved one's diagnosis became public. This is a disease that people are terrified of, and this fear of the unknown leads to misunderstanding.

We now take it upon ourselves to battle that fear and we hope Congress will support patients and families affected by Alzheimer's by supporting the types of services the JAA provides.

At the JAA we have a long-range goal of developing creative and cost-effective solutions to address the escalating number of older adults expected to suffer from Alzheimer's and dementia over the next 30 years. Last year, we launched our commitment to be the premiere memory care specialists in Western Pennsylvania. The JAA has begun training staff under the Boston, Massachusetts-based Hearthstone Institute's “I'm Still Here” comprehensive transformation training program, which offers innovative memory care techniques through agency-wide culture change. This is a philosophy of understanding and caring for individuals with Alzheimer's disease and other dementias through practical application of a proven methodology. This methodology is based on the “I'm Still Here” approach of Harvard-educated Dr. John Zeisel that **despite the diagnosis of Alzheimer's, those affected and their families can still find meaning and purpose and have excellent quality of life for many, many years.** The stigma of this disease is so pervasive in our community it prevents people seeking treatment and living life to the fullest in spite of the disease. We were compelled to invest in this groundbreaking socially responsible program that will educate family members, staff and the public at large to **change the conversation about Alzheimer's as a disease of “disability” to one that emphasizes “ability.”**

Make no mistake. Funding these programs are a challenge for us. But we believe it is a priority, not only for us but for our community and nation as a whole.

Alzheimer's disease and the stress it places on patients, families and society cannot be ignored. As much as we as a small nonprofit in Western Pennsylvania can do, we need support from our local, state and national representatives to join us in combating this disease by funding important programs such as ours and making sure that our parents and grandparents have all the tools at their disposal so they don't have to feel like they are suffering alone. Together, we can beat this disease and its stigmas.

Thank you for your time and dedication.

Sincerely,

Deborah Winn-Horvitz
President and CEO

ELI LILLY AND COMPANY

Chairman Toomey, Ranking Member Stabenow, and distinguished members of the subcommittee, thank you for the opportunity to submit written testimony on the widespread impact of Alzheimer's disease—a condition that devastates the lives of millions of Americans and their families each year.

Indeed, the growing impact of Alzheimer's disease has led many economists, the health-care industry, and communities across the country, to sound the alarm about this enormous public health threat—and rightfully so, as the statistics are as staggering as they are daunting.

For example, there are currently 5.4 million Americans who are living with Alzheimer's disease. With an aging baby boomer population, coupled with longer life spans, that number will nearly triple to 13.8 million by 2050.

Alzheimer's disease will cost Americans \$236 billion this year alone—and this is projected to swell to \$1.1 trillion by 2050. But the disease reaches much further, with an acute burden placed on the families of patients as well. It is estimated that more than 15 million caregivers provide an estimated 18.1 billion hours of unpaid care to patients each year.

On this path, the burden on families will only amplify for generations to come, and the disease will inflict serious trauma on the American health care system. Yet, as of now, we currently have no means to prevent, slow or cure the sixth leading cause of death in the United States.

Of course, while a cure for the disease remains elusive, over the course of the last 50 years, scientists—including those at Lilly—have gained a better understanding of how the disease affects the brain, which, in turn, has helped improve care for millions of people. And while the statistics currently related to the disease are sobering, there remains hope on the horizon.

After decades of research and determination, scientists have moved closer to innovative new therapies. The possibility of real breakthroughs are within our grasp. For Lilly's part, we have invested 28 years and \$3 billion in research and development on new medicines to treat this devastating disease.

Just last month, we were excited to announce the launch of the Alzheimer's Readiness Project. The mission of this project is to inspire action by fostering a deeper understanding of Alzheimer's, its evolving science, and the public health crisis it poses.

The project will combine efforts to advocate on behalf of those with the disease, encourage effective and efficient research and ensure a regulatory system that reflects the best science and thinking we have. With this initiative, we will support policies and laws that recognize innovation and investment that will make a real difference for those impacted by the disease.

Building off of ongoing partnerships, public education efforts and events, we will provide a platform where people come together to discuss solutions and raise awareness of the need for and value of advancements in the fight against Alzheimer's disease.

Those engaged in the fight against Alzheimer's—from researchers and physicians to advocates, business leaders and Congress—have set a goal to prevent or effectively treat Alzheimer's by 2025. The fact is: we can't meet the goal if we don't act now. Which is why we have ramped up our efforts and the intensity of our focus.

However, while we continue our research, there are conclusions we have already drawn that should be considered. For example, we need to increase emphasis on early detection and diagnosis of Alzheimer's disease—diagnosis and treatment in the early stages is paramount to stopping the disease before it does irrevocable damage.

We need to encourage the development of innovative treatments. New approaches to treating Alzheimer's disease will play a vital role in preventing and effectively treating Alzheimer's. However, the path from basic research to new medicines is extremely complex with challenges along the way. When those new treatments do become available, timely and appropriate reimbursement decisions will need to be made.

We also need to improve the efficiency of clinical trials. A limiting factor to advancing research is the challenging process of conducting clinical trials, including recruitment of participants.

We also would encourage community action strategies. Communities across the nation are facing the fiscal and societal impact of Alzheimer's. Implementation of the U.S. National Alzheimer's Plan, as well as individual state and community-based plans, are critical.

And an often forgotten component is the need to enhance public awareness and engagement. Significant misperceptions about diagnosis lead to stigmatization and delayed treatment. Since early detection and diagnosis is critical, education about the disease is paramount.

We have learned a great deal about Alzheimer's, and a tremendous amount of effort by many has occurred. But we can do better, and doing better means laying the groundwork today for the change we want to see in the future. Of course, scientific breakthroughs often involve years of research, trials, errors and, sometimes, setbacks. But armed with a united desire to make life better for people in this country and around the world, we can—and must—continue the fight.

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Statement of Mark Covall, President and CEO

Mr. Chairman and members of the Subcommittee, I want to thank you for holding this hearing on "Alzheimer's Disease: The Struggle for Families, a Looming Crisis for Medicare."

On behalf of our member organizations, we are pleased to provide our insights on the need for Medicare modernization that could play a critical role in improving the lives of millions of Americans who live with symptoms of a serious mental disorder. We are very concerned about patients with Alzheimer's disease and would like a Medicare system that fits the 21st century.

The National Association of Psychiatric Health Systems (NAPHS), which was founded in 1933, advocates for behavioral health and represents provider systems that are committed to the delivery of responsive, accountable, and clinically effective prevention, treatment, and care for children, adolescents, adults, and older adults with mental and substance use disorders. NAPHS members are behavioral healthcare provider organizations that own or manage more than 800 specialty psychiatric hospitals, general hospital psychiatric and addiction treatment units and behavioral healthcare divisions, residential treatment facilities, youth services organizations, and extensive outpatient networks.

Medicare Modernization Is Necessary

As you know, Medicare was established in 1965 when our healthcare delivery system and insurance system were very different than today's. This was before Alzheimer's disease was declared the most common form of dementia and a substantial public health challenge by the neurologist Dr. Robert Katzman in a 1976 editorial.

In 1965, most care for people living with mental illnesses was provided in state mental hospitals. Inpatient stays were counted in months and years, and much of the care was custodial in nature. So when Congress was considering establishing the Medicare program, this was the framework that Congress had to work within in establishing coverage for mental illnesses. This resulted in a very limited benefit for mental illnesses under the original Medicare program and a benefit that provided much less coverage compared to that for other medical disorders. The benefits for mental illnesses included just inpatient hospital and outpatient office-based visits, but more importantly these benefits had limits in duration, scope, and cost-sharing. For example, outpatient psychiatric care had a 50% cost-sharing requirement (compared to an 80% cost-sharing requirement for all other Medicare outpatient services). Also, inpatient psychiatric care provided in freestanding psychiatric hospitals was limited to 190 days during the lifetime of a Medicare beneficiary.

These discriminatory benefits for mental illnesses remained in place until 2008 when Congress made the first change in mental health coverage since 1965. In 2008, Congress changed the cost-sharing for outpatient mental health services from 50% to 80% (phased in over several years) to make cost-sharing for mental health

just like that for all other Medicare outpatient services. Yet the Medicare 190-day lifetime limit for inpatient psychiatric care in freestanding psychiatric hospitals remains unchanged to this day. (However, the 190-day lifetime limit does not apply to Medicare beneficiaries receiving treatment in a psychiatric unit in a general hospital.)

During the 1980s, there was a growth in the number of community private psychiatric hospitals that provided short-term, acute, inpatient psychiatric care. At the same time, the downsizing and closing of state mental hospitals intensified. During this period, diagnosis and treatment of mental illnesses dramatically improved, and new medications became available. This resulted in briefer inpatient stays compared to the longer-term care that was provided in the 1960s when Medicare was first established. The 1990s saw a decline (more than 30%) of the overall inpatient psychiatric bed capacity. The decline in beds was in all settings, including state mental hospitals, community private psychiatric hospitals, and general hospitals' psychiatric units. Today, many communities do not have enough inpatient psychiatric beds—leading to an increase in emergency room visits, longer time spent in the emergency departments, and patients needing to travel long distances to receive inpatient psychiatric care.

In 2008, Congress passed landmark legislation called the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act (MHPEA). This legislation changed the landscape of coverage for mental and addictive disorders by requiring private commercial health plans that offered coverage for mental health and addictive services to provide that coverage on par with all other medical disorders. However, the major governmental health insurance program for seniors and the disabled—the Medicare program—still has discriminatory coverage for inpatient psychiatric care. It is long past due to bring the Medicare program up to the standard of all other insurance plans and to—once and for all—eliminate Medicare's 190-day lifetime limit for inpatient psychiatric care delivered in community private psychiatric hospitals.

The need to get rid of this long-standing discriminatory provision for inpatient psychiatric care is not just about fairness and equity, but it is about real people who are dealing with debilitating Alzheimer's disease, who so desperately need this care.

Who Are These Medicare Beneficiaries? Why Is Elimination of the 190-Day Lifetime Limit Critical?

The Medicare Payment Advisory Commission¹ has outlined key characteristics of Medicare beneficiaries who receive inpatient psychiatric care.

Unlike beneficiaries seen in other types of hospitals, most Medicare beneficiaries treated in inpatient psychiatric facilities (known as "IPFs") qualify for Medicare because of disability.

As baby boomers have aged, the number of IPF beneficiaries between the ages of 45 and 64 has grown, rising 18% between 2002 and 2009.

More than a quarter of Medicare beneficiaries (29%) have a cognitive/mental impairment.²

Medicare is a critical safety net for those who have long-term mental disabilities, but who have the ability to participate in the community throughout their lives given adequate support.

These demographics provide a picture of Medicare beneficiaries who have symptoms of a serious mental illnesses (such as Alzheimer's disease) and who are living with these disorders. Alzheimer's is a chronic disease and will require ongoing treatment and care over lifetimes, including hospitalization when in crisis.

Care for these sickest patients continues to have unnecessary complexity and barriers that don't exist for other complex or chronic illnesses. These Medicare beneficiaries can easily exceed the 190-day lifetime limit because the chronicity of their illness.

The 190-day lifetime limit restricts access to critical, life-saving treatment just when it is most needed.

¹ Medicare Payment Advisory Commission (MedPAC). "Inpatient psychiatric care in Medicare: Trends and issues." Chapter 6 in *Report to Congress*. June 2010. See http://www.medpac.gov/chapters/Jun10_Ch06.pdf.

² Henry J. Kaiser Family Foundation. "FACT SHEET: Medicare at a Glance," #1066-12, January 2010. www.kff.org/medicaid/upload/4091_06.pdf.

The 190-day lifetime limit also impacts the continuity of care for people living with Alzheimer's disease. Just when they need crisis stabilization in a hospital setting, they may not be able to go to the hospital and doctors who have been treating them for many years because of the arbitrary lifetime limit.

Legislation has been introduced in previous Congresses to eliminate the 190-day lifetime limit, and it has been both bipartisan and supported by broad coalition of national organizations.

In closing, the science and expertise about mental illnesses has grown exponentially in recent years. These illnesses can be diagnosed and treated effectively. People can recover their memory. What we need to do as a society is to give people the hope and help they deserve—just as we would for someone who has a heart condition or cancer.

Eliminating the 190-day lifetime limit will equalize Medicare mental health coverage with private health insurance coverage, expand beneficiary choice, increase access for the most seriously ill, improve continuity of care, and create a more cost-effective Medicare program.

Mr. Chairman, again, thank you for holding this very important hearing. We look forward to working with you and the entire Subcommittee to ensure that Medicare beneficiaries living with Alzheimer's disease are able to have coverage that is comparable to what is available for all other Medicare beneficiaries.

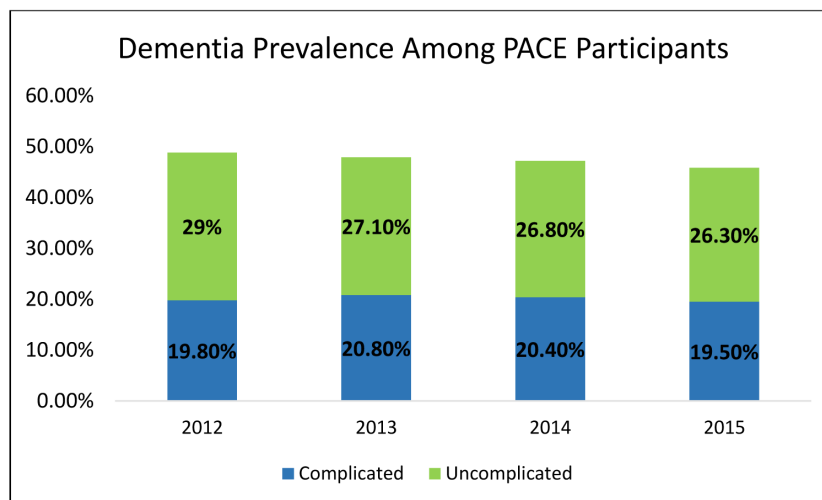
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The Program of All-Inclusive Care for the Elderly (PACE) is a proven care model that provides high-quality, community-based, integrated care to some of our nation's frailest, most vulnerable citizens—those over the age of 55 who need a nursing home level of care but seek to remain in their own homes. Studies show that people receiving care from PACE organizations live longer, are in better health, have fewer hospitalizations and spend more time living in their homes than those receiving care through other programs. PACE is an evidence-based program in which nearly half of the people who receive care and support have been diagnosed with dementia. As described in the chart below, PACE programs have a long history of serving patients with dementia, along with additional complex chronic conditions.

Today, it is possible to enroll only those individuals who meet their state's eligibility criteria for nursing home care. Once enrolled, PACE programs provide and are responsible for all care needed by enrollees, this includes long-term services and supports and acute services. There are 119 PACE programs operating in 31 states, serving approximately 40,000 participants—and this number continues to grow each year.

As a result of bipartisan legislation passed by Congress and signed into law by the President last year, the PACE Innovation Act of 2015, PACE has additional opportunities to serve those with intellectual disabilities, dementia, and Alzheimer's. The Centers for Medicare and Medicaid Services (CMS) now has additional authority under the ACT to pilot the PACE model with new populations, including people younger than 55 and those with complex care and support needs who do not yet meet their state Medicaid agency's criteria for needing a nursing home level of care. These pilots have the potential to expand the availability of PACE and PACE-like services to a greater number of people with Alzheimer's, their families and their friends, thereby providing them access to a care option that addresses the serious gaps in our current health and long term care delivery systems. The pilots would enable PACE organizations to offer high-quality, fully-integrated care that allows people with Alzheimer's who do not yet meet traditional PACE eligibility criteria to maintain their optimal health, receive much-needed services, and live independently in the community.



Not far from where this committee meets, the lives of two individuals and their families provide compelling examples of the difference access to a PACE program could make through a pilot program.

Serving People Under the Age of 55: Jim G.

Jim G. is a 54 year old Virginia resident who was diagnosed with early-onset Alzheimer's disease. Although Jim was initially enrolled in clinical trials to combat his illness, he recently ceased all treatment as his memory—and his health—deteriorated. Jim tried to enroll in the local PACE program, but was unable to because he was not yet 55 and therefore did not meet the program's current age eligibility requirements.

Jim was hospitalized in 2014 for a lung infection caused by "silent aspiration," which occurs when the swallowing function is weakened by Alzheimer's. A once vibrant athlete, Jim lost almost 40 lbs. Initially, Jim stayed home alone during the day, where he was isolated and struggled with activities of daily living, such as personal grooming, household chores, and child care. Karen, his caregiver, struggled to care for Jim and tend to her school-aged children, while also holding down a full time job, but eventually had to quit her job to care for him full time. Unfortunately, Karen discovered that his needs were more than she could handle. Following a psychotic break and a week as a psychiatric inpatient, Jim was permanently placed in a memory care unit near their home. Karen had to use "crowd-sourcing" to raise funds for Jim's treatment.

This heartbreaking situation might have been avoided had Jim been able to enroll in PACE. Jim could have received day-time support that would allow him to continue to live at home with his family. He could have received therapies to help him stay physically strong, and primary care to help avoid silent aspiration and other health complications. PACE has significant experience with dementia, and might have been able to avoid or better manage his psychiatric deterioration. And Karen and her family would have received much needed respite services, emotional and social support, and peace of mind, perhaps helping her maintain her employment.

Serving People At-Risk of Nursing Home Placement: Terry B.

In testimony before the District of Columbia's Council, Terry B. described her work as an enrollment coordinator at a PACE program as "the most rewarding job I ever had in my life. I was able to help older adults and their families find a solution to some very heartbreaking issues and could substantially see the huge difference this program made in their lives—from being totally at the bottom of despair to living a full life and thriving in their final years."

At the age of 56, Terry was diagnosed with younger onset dementia, and has now reached the point where she can no longer work. She recently completed her term as a member of the national Alzheimer's Association Early-Stage Advisory Group,

helping the Association provide the most appropriate services for people living with early-stage dementia, raise awareness about early-stage issues and advocate with legislators to increase funding for research and support programs.

Terry observed that she is “not yet ready nor qualified to need the PACE program, but when I do I know they will be there for me and my family.” Through a pilot program, Terry and her family would be able to access the PACE program when they determine they need its support and integrated care rather than waiting until Terry meets the state’s nursing home level of care criteria. This earlier access to PACE can support Terry’s continued quality of life, in a home setting that also strengthens the caregivers in her life.

Providing Access to PACE for People With Alzheimer’s

The pilots made possible by the PACE Innovation Act of 2015 would help Jim, Terry and others like them. These pilots would allow CMS to test and adapt the PACE model for individuals under the age of 55 and those who are not yet in need of a nursing home level of care but whose care delivery systems and supports are being strained as they strive to maintain their quality of life.

But providing care to individuals with dementia is nothing new. Specifically, the following are benefits that PACE has, and will continue to provide, to people with Alzheimer’s, their families, and policymakers seeking to improve their care options:

- **Access** to team based, disability competent care for an underserved, high cost population.
- **Improved care coordination with timely and accessible primary care** reducing unnecessary emergency, inpatient and long term care utilization.
- **Reduced nursing home utilization** enabling nursing home eligible individuals to live independently in the community.
- Competent, consistent and **quality attendant care services** for activities of daily living.
- **Social network of care** with innovative physical and virtual day programs to enhance independence and employability.
- **Extensive use of adapted technologies**—computing, telehealth, social networking, environmental controls, mobility—to increase independence, provide enhanced abilities at reduced cost.
- **Significant savings to Medicaid and Medicare**—payments to PACE programs are less than Medicaid would pay for a comparable population in its other programs and PACE provides savings to the Medicare program.
- **Relocation of individuals from nursing homes** into community settings by partnering with state and local housing organizations to fund development of accessible, affordable and safe housing.

Below is an example of a participant who has benefitted from the PACE model of care.

Serving People With Dementia: Anna M.

Anna M., or “Gramma” as she was affectionately called, was a 103-year-old Virginia resident who joined PACE once community adult-day care support alone was insufficient to address her needs. She suffered from dementia, experienced a steady cognitive and functional decline, and could no longer converse in English, but rather spoke in her native Italian.

When she joined PACE, Gramma was very agitated and combative, often hitting or spitting at PACE staff and, to a lesser degree, other participants. She was very territorial over her space and her possessions and rather inflexible in her routines. At the very beginning, the only activity she would engage in when she began with PACE was manically cutting up newspapers and magazines.

In PACE, Gramma worked closely with the entire interdisciplinary team (IDT) of PACE professionals, particularly with dementia experts to help her transition to PACE. The IDT quickly realized that she thrived with routines, familiar environments, and caregivers. So, Gramma was set up with a very consistent routine, which she followed daily with regular and consistent staff.

With some support, Gramma began to participate in a dozen different activities that she enjoyed and looked towards each day. The PACE program was able to transition her away from using scissors to more benign tasks such as folding laundry and sorting cards. Gramma expanded beyond her initial sphere of activity and there were even times when she would join in during group activities and interact with her peers at the PACE center. Beyond group activities, the PACE program developed tailored strategies to support Gramma. They used a colored plate during meal-time

to increase intake (low vision is often a problem with dementia and poor visual contrast of, for example, white food on a white plate leads to decreased intake because the person can't see the food vs. white food on a blue plate). They would also sweeten her food with strawberry syrup because people with dementia lose their sense of taste and eventually only taste sweet foods, not to mention Gramma loved the color red.

The PACE staff were keen to keep the overall distractions and noise level low, provided appropriate activities, and provided direct one-on-one care. The PACE staff ensured that she was actively engaged in a meaningful activity to reduce the risk of falls and minimize agitation. Additionally, the PACE team provided ample training and education. They hosted a caregiver training series focusing on caring for loved ones with dementia.

By working with Gramma and her caregivers, her family noted a number of improvements in her quality of life, including:

- Decreased agitation and aggression and overall improved mood;
- Increased participation in a large variety of activities;
- Increased intake;
- Decreased caregiver burden and stress; and
- Increased caregiver competence.

Her family was happy that after joining PACE Gramma began eating dinner again with the family. She began sleeping at night and she was again enjoying her family's company. Gramma passed away in her home, surrounded by her family. PACE supported her and her family throughout the end of her life.

Without PACE, Gramma's family said, they simply would not have been able to achieve so much.

Congress can advance a proven, cost-effective care model that will help achieve the goals of better care coordination, and higher quality of life by supporting the expansion of PACE programs both through new pilots as well through additional legislative and regulatory opportunities. In particular, updating the 2006 regulation, currently under review by the OMB, would greatly improve access to PACE with the potential to support more and faster growth.

Thank you for the opportunity to provide this testimony. We would be happy to provide any additional information that would be of use to the committee as it considers how to support the care needs of people with Alzheimer's and their families. Please contact Peter Fitzgerald, Executive Vice President, Policy and Strategy at the National PACE Association with any questions or if we can be of assistance. Mr. Fitzgerald can be reached at 703-535-1519 or peterf@npaonline.org.

STATEMENT SUBMITTED BY REGINA A. SHIH¹
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In 2013, my colleagues at RAND published an estimate of the cost of dementia to millions of families and the United States more broadly, reporting it to be the most costly condition in America.³ The team found that the vast majority of dementia costs are attributable to long-term services and supports (LTSS), rather than medical care. The number of Americans who will need LTSS is expected to double by the year 2050. As the nation's population grows grayer, the costs of dementia LTSS will only soar.

Following RAND's landmark research estimating the extraordinary monetary costs of dementia, RAND researchers challenged themselves to answer the question: "What can be done about this?" I led a team that interviewed key representatives of national, state, and local stakeholder groups. Their views, combined with research

¹The opinions and conclusions expressed in this testimony are the author's alone and should not be interpreted as representing those of the RAND Corporation or any of the sponsors of this research.

²The RAND Corporation is a research organization that develops solutions to public policy challenges to help make communities throughout the world safer and more secure, healthier, and more prosperous. RAND is nonprofit, nonpartisan, and committed to the public interest.

³Michael D. Hurd, Paco Martorell, Adeline Delavande, Kathleen J. Mullen, and Kenneth M. Langa, "Monetary Costs of Dementia in the United States," *New England Journal of Medicine*, Vol. 369, No. 14, 2013, pp. 1326-1334.

on existing national dementia and long-term care reports, were evaluated to identify policy options that have the greatest impact on improving dementia LTSS. This policy evaluation was the first to examine promising LTSS policy solutions specifically for those living with Alzheimer's and other related dementias (referred to hereafter as dementia) and culminated in the RAND report, *Improving Dementia Long-Term Care: A Policy Blueprint*.⁴

To inform today's subcommittee hearing on the impact of Alzheimer's disease on families and Medicare, I present the following statement for the record that integrates key findings from RAND's dementia LTSS policy blueprint and other relevant research publications.

Costs of Dementia

In a study published in the *New England Journal of Medicine*, my RAND colleagues reported that the costs of care for seniors in the United States with dementia are expected to more than double by 2040.⁵ In that study, the RAND team estimated that about 9.1 million people ages 70 and older will be suffering from Alzheimer's disease or another dementia by 2040. That study estimated that in 2010, Americans spent \$109 billion for dementia care purchased in the marketplace, like skilled nursing facilities. When informal care provided by family members or others outside of institutional settings is factored in, the total cost of caring for individuals with dementia in 2010 grew to between \$159 and \$215 billion.

As the U.S. population ages in the coming decades, we can expect those costs to continue to escalate. Even if dementia's prevalence stays at the current rate and the cost of care does not rise, RAND's research showed that by 2040, total costs will have soared to as high as \$511 billion.⁶ The vast majority of costs associated with dementia among those ages 70 or older are attributable to LTSS, rather than medical services. Unfortunately, the LTSS system has typically not been well aligned with the needs of persons with dementia.

The Current State of Dementia Long-Term Services and Supports

The costs of LTSS for persons with dementia are high, and they increase sharply as cognitive impairment worsens. LTSS can be provided by formal or informal caregivers. According to RAND estimates, the expense of in-home assistance provided by families accounts for approximately 50 percent of the total costs of dementia care.⁷

The Burden on Family Caregivers is Unsustainable

Informal care, which we refer to as family care, is unpaid care that usually consists of assistance from a relative, partner, friend, or neighbor. The vast majority of dementia LTSS are provided by family caregivers, as much as 80 percent by one estimate.⁸ More than 15 million Americans currently provide care to family members or friends with dementia.⁹ These family caregivers shoulder a heavy burden; nearly 40 percent reported quitting jobs or reducing work hours to care for a family member or friend with dementia. Many of these caregivers also experience negative physical and mental health effects. At the same time, family caregivers often report being inadequately educated about the trajectory of dementia and the scope of available respite/adult day care resources that could alleviate the stressors of providing care, even 1 year after a dementia diagnosis has been made.¹⁰

Demographic trends suggest that the current heavy reliance on family caregiving is unsustainable. Our RAND research has shown that compared to cognitively normal adults, persons living with dementia or cognitive impairment are more likely

⁴ Regina A. Shih, Thomas W. Concannon, Jodi L. Liu, and Esther M. Friedman, *Improving Dementia Long-Term Care: A Policy Blueprint*, Santa Monica, CA: RAND Corporation, RR-597, 2014.

⁵ Hurd et al., 2013.

⁶ Hurd et al., 2013.

⁷ Hurd et al., 2013.

⁸ L. Harris-Kojetin, M. Sengupta, E. Park-Lee, and R. Valverde, *Long-Term Care Services in the United States: 2013 Overview*, Hyattsville, MD: National Center for Health Statistics, 2013.

⁹ Alzheimer's Association, "2013 Alzheimer's Disease Facts and Figures," *Alzheimer's and Dementia: the Journal of the Alzheimer's Association*, Vol. 9, No. 2, 2013, pp. 208–245.

¹⁰ M.L. Laakkonen, Raivio, M.M., Eloniemi-Sulkava, U., Tilvis, R.S., and Pitkälä, K.H., "Disclosure of Dementia Diagnosis and the Need for Advance Care Planning in Individuals With Alzheimer's Disease," *Journal of the American Geriatrics Society*, Vol. 56, No. 11, 2008, pp. 2156–2157; and Allison K. Gibson and Keith A. Anderson, "Difficult Diagnoses: Family Caregivers' Experiences During and Following the Diagnostic Process for Dementia," *American Journal of Alzheimer's Disease and Other Dementias*, Vol. 26, No. 3, 2011, pp. 212–217.

to receive care from daughters.¹¹ This is alarming on several fronts: family sizes are shrinking, the number of women in the labor force is growing,¹² and women are more likely than men to suffer negative employment and health consequences associated with family caregiving for dementia.¹³ As the median age of the U.S. population continues to trend upward, there will be a growing imbalance between the number of people needing care and family caregivers available to deliver it.¹⁴ These changes suggest that in the future, more people living with dementia will need to turn to formal care in lieu of or in support of family caregiving.

Public Programs Cover Some Costs, but the Middle Class is Most Vulnerable

With respect to formal LTSS, Medicaid is the largest payer.¹⁵ Medicaid can cover skilled nursing facility care and paid care provided in the home or community, as well as assistance with personal care. In contrast, Medicare covers only hospice costs and a portion of short-stay, post-acute care for Medicare beneficiaries. Medicaid eligibility rules in many states require that individuals have assets no greater than \$2,000, and this restriction results in significant gaps in risk protection from LTSS costs. People with adequate resources who plan early enough turn to private long-term care (LTC) insurance or out-of-pocket resources for financing, while lower-income individuals are covered through Medicaid. The middle class is at greatest risk for significant and possibly catastrophic LTSS costs, given the lack of readily available resources to finance their dementia LTSS.

Medicare Post-Acute and Hospice Benefits Are Limited and Differentially Affect Those With Dementia

Persons with dementia would benefit from the expansion of several Medicare eligibility requirements. First, traditional Medicare covers skilled nursing facility care, if needed after a hospital stay, for patients who are hospitalized for at least 3 consecutive days. However, patients who are placed under observation status are not considered hospitalized.¹⁶ Therefore, individuals who have been hospitalized for 3 consecutive days but under observation for some or all of their hospital stay would not meet the 3-day inpatient hospitalization requirement for subsequent skilled nursing facility coverage, thus incurring significant out-of-pocket financial costs. Additionally, some individuals who require intensive health and therapeutic services after a hospitalization may prefer to receive care in their community rather than at a skilled nursing facility. Adult day services are emerging as a key community-based provider of short-term rehabilitation and transitional care following hospital discharge and could provide some specialized services for people living with dementia who have been discharged from a hospital stay, instead of a skilled nursing facility. Under current Medicare policy, however, such community-based care is not reimbursable.

Second, Medicare home health benefits currently require a beneficiary to be deemed “homebound” in order to access covered in-home care. Yet, while persons living with dementia may not always have physical limitations that make them homebound, their mental and other functional limitations may still require the same level of in-home care.

Third, the lifetime course of dementia symptoms can be characterized by long periods of stability punctuated by steep declines and occasional recovery. The average length of stay for beneficiaries with dementia who are receiving Medicare hospice

¹¹ Esther M. Friedman, Regina A. Shih, Kenneth M. Langa, and Michael D. Hurd, “U.S. Prevalence and Predictors of Informal Caregiving for Dementia,” *Health Affairs*, Vol. 34, No. 10, 2015, p. 1637–1641.

¹² Jonathan Vespa, Jamie M. Lewis, and Rose M. Kreider, “America’s Families and Living Arrangements: 2012,” in *Current Population Reports 2013*, Washington, DC: U.S. Census Bureau, 2013.

¹³ Family Caregiver Alliance National Center on Caregiving, “Fact Sheet: Caregiver’s Guide to Understanding Dementia Behaviors,” web page, 2016; and Erin DeFries Bouldin and Elena Andresen, *Caregiving Across the United States: Caregivers of Persons With Alzheimer’s Disease or Dementia in 8 States and the District of Columbia, Data From the 2009 and 2010 Behavioral Risk Factor Surveillance System*, McLean, VA: Alzheimer’s Association, 2014.

¹⁴ Donald Redfoot, Lynn Feinberg, and Ari Houser, “The Aging of the Baby Boom and the Growing Care Gap: A Look at Future Declines in the Availability of Family Caregivers,” in *Insight on the Issues*, Washington, DC: A.P.P. Institute, 2013.

¹⁵ Carol V. O’Shaughnessy, *The Basics: National Spending for Long-Term Services and Supports (LTSS) 2013*, Washington, DC: National Health Policy Forum at George Washington University, 2013.

¹⁶ Centers for Medicare and Medicaid Services, “Chapter 8: Coverage of Extended Care (SNF) Services Under Hospital Insurance,” in *Medicare Benefit Policy Manual*, Baltimore, MD: Centers for Medicare and Medicaid Services, 2014.

care in skilled nursing facilities has increased over time,¹⁷ and the per-person hospice care payments across all beneficiaries with dementia were 10 times higher than average per-person hospice payments for other Medicare beneficiaries.¹⁸ At the same time, the ability of physicians to predict 6-month mortality for persons with dementia is constrained by great variation in decline and recovery.¹⁹ Medicare currently requires a 6-month prognosis in order to qualify for hospice care, but this may not be easy to determine for those in the late stages of dementia.

Policy Options for LTSS and Dementia

Given the mounting toll dementia will place on our nation's families, LTSS, and health-care systems, RAND interviewed 40 stakeholders across seven groups (patients/public, providers, purchasers, payers, policymakers, product makers, and principal investigators), representing multiple perspectives on dementia care, research, and policy, to identify potential policy options. The RAND dementia blueprint reports the independent evaluation of the policy options across 14 feasibility and impact criteria, ultimately arriving at 25 high-impact policy options. For the purposes of this hearing, I discuss the high-impact policy options in that report related to Medicare and those that could aid family caregivers.

Support Family Caregivers

Family caregivers face a host of challenges caring for loved ones, and the federal government could implement new, or improve existing programs to assist these caregivers.

One option could be to offer business and individual tax incentives to provide family caregiving. This approach could include tax breaks for individuals who are family caregivers, which would provide some compensation for their caregiving time. The incentives could also target businesses to promote provision of adult day care centers on site, expansion of dependent care accounts to incorporate more LTSS costs, and more paid time off and/or flexible work hours to allow for more and varied caregiving.

Another option would be to expand financial compensation programs to family caregivers. The RAND dementia blueprint report recommends increasing the availability of compensation programs for lost wages and caregiving work (e.g., through Medicaid programs) and expanding these programs to all states. Such programs are often referred to as "participant-directed services" or "cash and counseling." While some persons with dementia may already have access to these programs, they are not available in all states and are restricted to persons with limited assets (primarily those on Medicaid). This solution would expand access to such programs to subsets of the population who currently cannot access them and increase awareness of existing compensation programs among those who are already eligible.

A third option is to provide dementia-specific training and information about resources to family caregivers and volunteer groups. Interventions aimed at providing dementia-specific education, skill training, support, and counseling to family caregivers have successfully deferred skilled nursing facility placement for persons with dementia and decreased depression and distress among caregivers.²⁰ Additional

¹⁷Susan C. Miller, Julie C. Lima, and Susan L. Mitchell, "Hospice Care for Persons with Dementia: The Growth of Access in U.S. Nursing Homes," *American Journal of Alzheimer's Disease and Other Dementias*, Vol. 25, No. 8, December 2010, pp. 666–673; Centers for Medicare and Medicaid Services, 2014.

¹⁸Julie Bynum, tabulations based on data from the Medicare Current Beneficiary Survey for 2008, Dartmouth Institute for Health Policy and Clinical Care, Dartmouth Medical School, November 2011.

¹⁹Susan L. Mitchell, Susan C. Miller, Joan M. Teno, Roger B. Davis, and Michele L. Shaffer, "The Advanced Dementia Prognostic Tool: a Risk Score to Estimate Survival in Nursing Home Residents with Advanced Dementia," *Journal of Pain and Symptom Management*, Vol. 40, No. 5, November 2010, pp. 639–651; Susan L. Mitchell, Joan M. Teno, Susan C. Miller, and Vincent Mor, "A National Study of the Location of Death for Older Persons With Dementia," *Journal of the American Geriatrics Society*, Vol. 53, No. 2, 2005, pp. 299–305; and Greg A. Sachs, Joseph W. Shega, and Deon Cox-Hayley, "Barriers to Excellent End-of-life Care for Patients with Dementia," *Journal of General Internal Medicine*, Vol. 19, No. 10, 2004, pp. 1057–1063.

²⁰M.S. Mittelman and S.J. Bartels, "Translating Research Into Practice: Case Study of a Community-Based Dementia Caregiver Intervention," *Health Affairs*, Vol. 33, No. 4, 2014, pp. 587–595; K. Hepburn, M. Lewis, J. Tornatore, C.W. Sherman, and K.L. Bremer, "The Savvy Caregiver Program: The Demonstrated Effectiveness of a Transportable Dementia Caregiver Psychoeducation Program," *Journal of Gerontological Nursing*, Vol. 33, No. 6, 2007, pp. 30–36; and S. Belle, L. Burgio, R. Burns, D. Coon, S.J. Czaja, D. Gallagher-Thompson, L.N. Gitlin, J. Klingler, K.M. Koepke, C.C. Lee, J. Martindale-Adams, L. Nichols, R. Schulz, S. Stahl, A. Ste-

Continued

training and information could be provided to volunteer groups with access to persons with dementia and family caregivers, so that these groups may be better informed about the needs of persons with dementia. We also recommend wide dissemination of educational materials about providing care, hands-on training, and availability of formal LTSS resources available to family caregivers (*e.g.*, respite care, community services) that may help make caregiving easier and more manageable. Combined, these policy recommendations are likely to reduce caregiver burden and potentially lessen or delay individuals' reliance on formal care often paid for by the federal and state governments. The legal and political feasibility of the option to expand financial compensation programs is likely to be higher than the option to provide tax incentives because the latter involves high costs to the federal government and businesses. Ideally, all three options would be packaged together, so that policies to provide monetary incentives to provide family care would be coupled with LTSS and dementia-specific LTSS training for family caregivers.

A Comprehensive National Financing Solution Is Needed for LTSS

As already discussed, the costs posed by dementia are only going to increase in the coming years, and many families are ill prepared to face those costs. A broad LTC insurance solution is needed to address high out-of-pocket costs for LTSS and the high proportion of older adults afflicted with dementia, and the federal government could help craft a national solution.

One option would be to create a national, voluntary opt-out LTC insurance program through a public-private partnership, which would build upon the structure of the private health insurance system, while having a public wraparound of secondary insurance. Insurance provided by the private LTC insurance industry allows for market competition and consumer choice. Making the program opt-out would encourage greater uptake, which in turn could encourage more private insurers to enter the LTC insurance market. A large insurance pool would limit exposure to the insurers and also improve efficiency by reducing overhead and underwriting risk.

Another option would be to adopt a national single-payer LTC insurance system that is financed through taxes and provides coverage for all citizens. The LTSS benefit could be a basic package or a comprehensive coverage built into Medicare or a new program. While LTC insurance coverage would be funded through the government, services could be provided by private organizations or other contractors.

While both of these options would increase LTSS access and utilization, they also face challenges. Such programs would require substantial implementation costs, creating a significant practical as well as political barrier. I note that both the Commission on Long-Term Care's 2013 report and the alternative report by the dissenting members agreed that an element of public financing is needed, but they disagreed on the extent to which a social LTSS insurance system should be publicly financed.²¹ Future quantitative analyses that examine different financing options for public programs, tax credits for saving for LTSS costs, and private LTC insurance will inform the development of a comprehensive LTC insurance program. This is especially critical given the expected rise in dementia prevalence and associated high costs of care to the federal government and families.

Refine Medicare Post-Acute Care and Hospice Benefits

Medicare post-acute and hospice benefits are limited, and persons with dementia would benefit from the expansion of eligibility requirements. The following options could be considered.

- *Refine the three-day hospital stay requirement for skilled nursing facility care.* This would extend coverage for skilled nursing facility care by allowing outpatient observation days to count toward the three-day inpatient hospitalization stay required before skilled nursing facility care is covered.
- *Allow payments for adult day care instead of a skilled nursing facility.* For beneficiaries who prefer to go home after a hospitalization rather than to a skilled nursing facility, Medicare could cover some specialized adult day

vens, L. Winter, S. Zhang, and Resources for Enhancing Alzheimer's Caregiver Health II Investigators, "Resources for Enhancing Alzheimer's Caregiver Health (REACH) II Investigators: Enhancing the Quality of Life of Dementia Caregivers From Different Ethnic or Racial Groups: A Randomized, Controlled Trial," *Annals of Internal Medicine*, Vol. 145, No. 10, 2006, pp. 727–738.

²¹ Commission on Long-Term Care, *Report to the Congress*, Washington, DC: U.S. General Accounting Office, September 30, 2013; and Long-Term Care Commission, *A Comprehensive Approach to Long-Term Services and Supports*, Washington, DC: U.S. General Accounting Office, September 23, 2013.

care services at potentially lower cost than through a skilled nursing facility.

- *Expand eligibility of hospice benefits to include dementia as a qualifying event.* This change would mean that persons with dementia could receive hospice care before they are diagnosed as terminally ill with a life expectancy of six months or less. Doing so would give persons with dementia more options for palliative care.
- *Reconsider the homebound requirement for receiving home health services under Medicare.* Expanding eligibility to consider persons with dementia as homebound would allow persons with dementia to have access to in-home care and would help them remain at home longer.

Expansion of these Medicare eligibility criteria for benefits and qualifying events would likely increase LTSS availability and use. Patient safety and patient and caregiver satisfaction would also likely increase with more access to post-acute care. While these recommendations would increase Medicare costs, they may be offset by savings to Medicaid and out-of-pocket spending for potential future LTSS, such as institutionalized care. Future cost analyses could further quantify the implications of these policy options on costs to Medicare.

I appreciate the opportunity to provide a statement for the record for today's hearing. I would be happy to answer any follow-up questions that may arise in response to this statement.

UNIVERSITY OF PITTSBURGH ALZHEIMER DISEASE RESEARCH CENTER (ADRC)

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July 11, 2016

The Honorable Patrick J. Toomey
Chairman
U.S. Senate Committee on Finance
Subcommittee on Health Care
248 Russell Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
Ranking Member
U.S. Senate Committee on Finance
Subcommittee on Health Care
731 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Toomey and Ranking Member Stabenow,

On behalf of our colleagues at the University of Pittsburgh Alzheimer Disease Research Center (ADRC), we are pleased to submit this written testimony for consideration at this week's aptly titled hearing, "Alzheimer's Disease: The Struggle for Families, a Looming Crisis for Medicare."

As researchers at one of the nation's 31 federally funded Alzheimer's Disease Centers we interact regularly with scientists from around the globe who share our passion and commitment to improving our understanding of and discovering new treatments for Alzheimer's disease and related disorders (ADRD). Indeed, we are drafting this statement of record for your subcommittee just as we are preparing ourselves to present our latest research at the upcoming Alzheimer's Association International Conference (Toronto, CA, July 24-28). Meeting with and hearing from other leading experts from around the world at scientific conferences like this is always a highly energizing experience. These meetings give us fresh perspectives on the most innovative ideas for advancing the diagnosis and treatment of Alzheimer's disease, which in turn, fuels our drive to move forward our own research projects as well as to support and facilitate the research of other scientists through our leadership roles at the ADRC.

Yet, following each of these inspiring meetings, we return to western Pennsylvania and are quickly reminded of the sobering realities of the current state of clinical care for individuals with dementia. While we know firsthand that scientific progress

is accelerating and offers great hope for future generations of patients, we are faced with frustration as we currently have so few treatment options for patients and families who are in the throes of the disease today. Patients and families come to Centers like ours seeking the most cutting edge diagnostic procedures and treatments that experts have to offer. At the time of an initial diagnosis of Alzheimer's disease or a related disorder, we see patients and their family members struggling to understand the illness and its implications for their futures. More than anything, they want to know what can be done to slow the course of the disease. Sadly, the answer to that question has been unchanged in 13 years (when the Food and Drug Administration last approved a new treatment for AD); and for all practical matters, the answer has been the same since each of us encountered our first patient in clinical practice, "We will do everything we can to manage the symptoms of this disease, but there is no cure available."

While the standard of practice for treating Alzheimer's disease has been unchanged in years, what has changed dramatically are the record numbers of individuals affected by the disease and the soaring costs of caring for them. Estimates from the Alzheimer's Association indicate that more than 5 million Americans are currently living with Alzheimer's disease or a related dementia, making these conditions as common as heart failure, which the CDC estimates to affect 5.7 million Americans. However, dementia disorders are especially costly (Kelley et al., 2015). While the annual costs of heart failure are estimated at \$32 billion (including healthcare services, medications and lost productivity), the care of persons with dementia is projected to cost the nation a staggering \$236 billion in 2016. The nature of and payers for these costs are varied, but there is no question that Medicare related expenses are a major contributor to the overall economic impact of the disease on our society. Even other diseases become more costly to treat on a backdrop of dementia. For example, recent reports indicate that when an individual with dementia is hospitalized for an acute illness, they are more likely to have complications which, when present, cause dementia patients to incur double the costs for a hospitalization as compared to patients without dementia who are hospitalized for the same condition (Bail et al., 2014).

The high costs of dementia care, relative to other disease, are also documented at the level of out-of-pocket spending among families. A recent examination of data from the Health and Retirement Study found that out-of-pocket costs to families were 81% higher for patients with dementia than for those without dementia. Compounding these out-of-pocket costs to family caregivers are lost wages as caregiving demands lead many individuals to reduce the amount of paid work in which they can engage, yielding long-lasting negative effects on overall wealth.

Given the immensity of the toll that Alzheimer's disease and related disorders are exacting upon the Medicare system and on American families, we commend you for taking the important step of holding this hearing. It is most promising that this hearing comes on the heels of the House and Senate appropriations committee proposals for historic and vitally needed increases in federal funding for research on AD.

Our personal commitments to conducting research on Alzheimer's disease are strong, unwavering, and all the more encouraged by announcements of such progress at the legislative level. In terms of our own work, our pioneering research led to the development of the first chemical agent to detect, in the brain of a living person, one of the hallmark proteins associated with Alzheimer's disease. This agent, known as "Pittsburgh Compound-B or PiB" is now the gold standard for detecting this protein, beta-amyloid, in research studies around the world. We have authored some of the first reports on what it is like, from the patient's perspective, to experience the uncertainty of early cognitive changes and come to terms with planning for a likely course of progressive cognitive decline (while setting aside other hopes and dreams for old age). As leaders at the Pittsburgh ADRC we work with our colleagues to maintain the overall infrastructure of the Center as a resource for a multitude of research studies ranging from laboratory based genetic studies to clinical trials and caregiving studies.

Despite these efforts at our Center and others across the country, we must humbly acknowledge that even under the best case scenario of a new, course altering treatment for Alzheimer's disease within the next 5 years, far too many individuals will continue to suffer the direct and indirect effects of this disease. We therefore urge your committee to identify new strategies for curbing the devastating impact that ADRC are having on patients and families who are living with the everyday realities of this disease while the world awaits a breakthrough in prevention or treat-

ment approaches. The inclusion of the Health Outcomes, Planning, and Education (HOPE) for Alzheimer's Act (S. 857/H.R. 1559) in the Senate Labor, Health, and Human Services Appropriations Committee FY 2017 Funding Bill is certainly a welcome and positive step. The HOPE Act would increase access to information on care and support for newly diagnosed individuals and their families, but we must go further. We need not only to increase access to these existing forms of care and support; we need to improve the existing options and capacity for care and support.

It is widely recognized that hospital based care and long term institutionalization are not the answers for providing compassionate and dignified care to persons with advanced dementia. Our colleagues in health services research indicate that there is much promise in innovative approaches to home and community based care. One example is the Aging Brain Care (ABC) program, a team based medical home model of care for persons with dementia and depression developed at Indiana University. This program takes a holistic approach to managing the biopsychosocial needs of both patients and their family caregivers through community based primary care and has been shown to reduce emergency department visits and hospitalizations, yielding annual cost savings of thousands of dollars per patient (French et al., 2014).

Similar demonstration projects are needed, but they will require financial support. Currently, groups of experienced care-professionals are meeting as part of the Alzheimer's Association "Care and Support Operational Task Force." In a manner analogous to the process that set milestones and a budget for basic and clinical research under NAPA, these professionals are developing milestones for the enhancement of care and support in our country. A budget will also be eventually attached to these care and support milestones and, like the recent increases both realized (FY 2016) and proposed (FY 2017) for basic and clinical research, this care and support funding will need champions in Congress to become reality.

Even in a difficult economic climate, the recent funding increases prove that this can happen when our nation and our lawmakers establish the struggle our families currently endure as a priority. We hope such champions arise from this week's hearing, "Alzheimer's Disease: The Struggle for Families, a Looming Crisis for Medicare."

Thank you for the opportunity to submit this statement of record.

Sincerely,

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Center Director

William Klunk, M.D., Ph.D.
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Jennifer Lingler, Ph.D., CRNP
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WOMEN AGAINST ALZHEIMER'S NETWORK

Statement of Jill Lesser, President

Chairman Toomey, Ranking Member Stabenow, and Members of the Subcommittee:

On behalf of Women Against Alzheimer's, a network of Us Against Alzheimer's, I commend you for convening this hearing and for your specific focus on the unique and difficult impact of Alzheimer's on women and families. Our growing network of women believes that Alzheimer's is one of the biggest economic justice issues and a growing health crisis for women in America and around the world. Our work is driven by passion and we are committed to finding new collaborative and innovative approaches to funding, research, and advocacy to bring Alzheimer's out of the shadows and into the spotlight.

Approximately 5.4 million Americans have Alzheimer's, and there are over 15 million unpaid caregivers of Alzheimer's patients within the United States. The number of individuals with Alzheimer's is expected to almost triple, approaching 13.5 million, in the next few decades. Without a cure, Alzheimer's is expected to cost the United States \$2 trillion by 2020 and have a devastating impact on families who often bear the brunt of the disease.

Alzheimer's is the 5th leading cause of death among women in the United States. Of the 6.4 million Americans with Alzheimer's disease, 4.2 million or two-thirds are women. Recent studies suggest that men and women may be affected by Alzheimer's differently. Perhaps partially as a result of the increased likelihood of women developing Alzheimer's and other chronic diseases that increase the risk of developing dementia over their longer lifespan, women are much more likely to suffer from severe depression. However, recent research suggests there may be biological pathways that lead to greater cognitive impairment in females. Emerging science indicates that hormonal changes and sex differences in gene expression are potential explanations. And, Women Against Alzheimer's believes that the time is now for a commitment to sex and gender differentiated research—whether in basic, translational or clinical research.

Given the rapid increase in the population of older Americans, the number of women with dementia and those serving as informal caregivers will escalate and cost the economy a cumulative \$5.1 trillion (in 2012 dollars) through 2040. This is according to "The Price Women Pay for Dementia: Strategies to Ease Gender Disparity and Economic Costs," a new report recently released by the Milken Institute. We are proud to be partnering with the Milken Institute on the distribution of their groundbreaking report and on future research into the economic impact of Alzheimer's disease on women as caregivers and people more likely to live with the disease.

A key driver of the devastating impact of Alzheimer's disease on Women is our role as caregivers. Women make up the majority of informal caregivers, often as family members of dementia patients who need around-the-clock assistance with the most basic needs. Significantly, approximately 70% of Alzheimer's and dementia caregivers are women. Half of women caregivers alter or have to stop working due to the demands of caregiving for their loved one. In addition, 75% worry about caregiving's toll on their own health.

Due to the time-consuming nature of dementia care, many women drop out of the labor market, reduce work hours, or incur lost workdays and productivity losses. All of these adversely affect the economy in general and women's and families' economic security, in particular. With women's participation in the labor force expected to rise in the future, the impact on the economy will undoubtedly be magnified. Identifying ways to support them is critical.

For these reasons, we support several important Alzheimer's initiatives before the Finance Committee and we urge the committee to continue its investigation into innovative solutions to relieve the economic burden of this disease to American families. Specifically, we urge the Finance Committee to explore new programs that support beneficiaries with Alzheimer's and their caregivers, the vast majority of whom are women. And, we applaud new approaches already being identified. On July 7, 2016, Ranking Member Stabenow and Senator Capito introduced S. 3137: the Alzheimer's Beneficiary and Caregiver Support Act. This bill would provide Alzheimer's disease caregiver support services to informal or non-paid caregivers to both keep patients in the home setting for longer periods of time and improve the quality of life of caregivers, ultimately resulting in lower Medicare and Medicaid program costs.

We urge the members of the Senate Finance Committee to cosponsor this important legislation and we look forward to working with you to enact this bill.

Ultimately, as WomenAgainstAlzheimers—waiting is not an option. In May of this year, we officially launched our We Won't Wait Campaign—a multi-faceted campaign joining together advocates for women's health and economic security to fight for a path to a cure—one that puts women front and center as patients and caregivers alike. We look forward to working with all of the members of the Committee to alleviate the burdens of Alzheimer's disease on a growing number of American families.

