

THE WAY FORWARD: AN UPDATE FROM THE ALZHEIMER'S STUDY GROUP

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

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WEDNESDAY, MARCH 25, 2009

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

The Committee met, pursuant to notice, at 10:36 a.m. in room SD-106, Dirksen Senate Office Building, Hon. Herb Kohl (chairman of the committee) presiding.

Present: Senators Kohl [presiding], McCaskill, Udall, Gillibrand, Martinez, Collins, Specter, and Graham.

OPENING STATEMENT OF SENATOR HERB KOHL, CHAIRMAN

The CHAIRMAN. Thank you all. Thank you all so much.

We do appreciate everyone's attendance here today, and today we will continue the discussion that we began last May concerning Alzheimer's disease and the crisis facing our Nation. At that time, two members of the Alzheimer's Study Group, Justice O'Connor and Speaker Gingrich, outlined plans to create a blueprint for tackling the largest problems associated with this disease.

Today, along with Senator Bob Kerrey, they will outline their national security plan to identify, examine, and mitigate Alzheimer's greatest challenges. We are happy to have them here and grateful for them to bring our attention to this issue.

The Committee has recently put forth several policy initiatives that complement the recommendations made in the study group's report. Senators Lincoln, Wyden, and Casey join me in introducing the Retooling the Healthcare Workforce for an Aging America Act, which would address our Nation's healthcare workforce shortage and provide support to the 44 million Americans who are caring for a family member, including those with dementia.

My colleague Senator Martinez and I also have a bill called the National Silver Alert Act. Similar to the successful Amber Alert for children, the National Silver Alert Act enables families in local, State, and Federal law enforcement to quickly coordinate a search when a senior with Alzheimer's or dementia has wandered away from home.

In addition to the members of the Alzheimer's Study Group, we are pleased today to welcome Maria Shriver and Larry Butcher, who have been tireless advocates on behalf of both their own family members as well as the millions of Americans living with this disease.

We are so happy to have this hearing today, and I would like to call on first Senator Specter for his remarks, then Ranking Member Senator Martinez, and then Susan Collins.
 Senator Specter.

STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Thank you, Mr. Chairman.

Thank you, Senator Martinez, for yielding to me for just a moment.

I want to welcome this extraordinarily distinguished group on such a very important subject and the large number of people who are filling this large hearing room.

There is no doubt about the tremendous impact that Alzheimer's has on the health of Americans and really worldwide. Having been chairman and now ranking of the Appropriations Subcommittee which funds the National Institutes of Health, I wanted to say a word of assurance of our concern for funding on Alzheimer's.

Senator Harkin and I, as you may know, have taken the lead on increasing the funding generally from \$12 billion to \$30 billion, and it is well known there was an additional \$10 billion added in the stimulus. The stimulus has been highly controversial, but I think few would deny the importance of that \$10 billion allocation.

The note that I wanted to sound this morning was to get the support of people who are here and other activists on medical research to put that \$10 billion in the base, not to have it as a one-shot proposition, but to start next year from \$40 billion, not \$30 billion.

I understand the allocation for Alzheimer's is not satisfactory. That has been left largely to NIH so it is nonpoliticized. But they take a suggestion or two every now and then from the appropriators. [Laughter.]

So stay tuned.

Thank you very much. [Applause.]

[The prepared statement of Senator Specter follows:]

The CHAIRMAN. Thank you very much, Senator Specter.
 Senator Martinez.

STATEMENT OF SENATOR MEL MARTINEZ, RANKING MEMBER

Senator MARTINEZ. Thank you, Mr. Chairman, and thank you for calling this very important hearing.

I want to welcome all of those who accompany us here today, especially our very distinguished panel.

With the number of Americans living with Alzheimer's disease expected to increase as our Nation's population becomes increasingly older, the need to address it has become more and more important. Almost half of all Americans who are 85 and older are afflicted with Alzheimer's disease. With no cure and limited treatment options, I am looking forward to hearing about how we might improve the ways we treat the disease and minimize its impact on our Nation and our families.

Because Alzheimer's is a progressive disease, its effects are often felt beyond households and the families where treatment is administered. In many cases, the effects can reach an entire community.

Finding ways to provide the special care and attention necessary for this devastating disease has been a primary goal of cities and

States across the Nation. Community organizations have sprung up to offer care, support, and education to patients, caregivers, medical professionals, and members of the community.

In my home State of Florida, officials at all levels of government have coordinated to develop a system known as "Silver Alert." Chairman Kohl mentioned our efforts in that regard at the Federal level as well. It helps to offer a uniform response and cater to the unique needs of individuals like those suffering from Alzheimer's. Silver Alert was issued in October 2008 and has since led to the direct rescue of nine elderly Floridians as of last week.

By knowing some of the symptoms of dementia like wandering and confusion, Florida communities have been able to work together to improve response and stand ready to assist seniors with special needs. States like Florida have become a model for the Nation to encourage other States to adopt similar programs.

As Senator Kohl mentioned, we have come together, the two of us, to sponsor this Silver Alert legislation at the national level. The legislation would improve coordination among law enforcement agencies across jurisdictions to find missing loved ones in need of special care. The bill has already been passed by the House and is currently before the Senate Judiciary Committee.

Support from the medical research community is another element critical to addressing Alzheimer's. Universities and other research institutions are working to improve understanding of the disease and are developing drugs, therapies, and other interventions to treat and slow the disease.

Healthcare communities have sought to establish best practices for working with patients and caregivers. Many include evidence-based models for patient care and caregiver support. As a result, some patients living with Alzheimer's are staying at home longer with family and loved ones.

Medical researchers have developed a number of the ways to relieve the burden placed on family caregivers and others with Alzheimer's. One of the ways is through the use of assistive technology. One example of this includes a talking alarm reminding the patient to take medication on time. Another is a scale hooked onto the Internet so that it can send weight and other vital signs to the providers.

Nationally, organizations have formed to provide information on advocacy, such as the Alzheimer's Association. These organizations help raise the Nation's awareness about the disease and support efforts at the Federal level to improve the care that patients receive.

For all of the advances that have been made to assist Alzheimer's patients, their caregivers, and loved ones, there is still much more that can be done. Right now, the U.S. does not have a coordinated system for long-term care. People seeking information or services are confronted with a disjointed and complex web of public and private options.

In some cases, they encounter criminals who know how to defraud a patient or family in crisis. These concerns are shared with those living with Alzheimer's and many American seniors.

I am looking forward to hearing the testimony from our witnesses today and want to thank them for being here.

I want to thank all the caregivers, health professionals, community leaders, and providers who are here with us today. Every day, you work to help our loved ones living with Alzheimer's receive the best care possible. I look forward to working together to find ways to understand a disease that affects so many families in our Nation.

Thank you, Mr. Chairman. [Applause.]

The CHAIRMAN. Thank you, Senator Martinez.

Senator Collins.

STATEMENT OF SENATOR SUSAN M. COLLINS

Senator COLLINS. Thank you, Mr. Chairman.

Mr. Chairman, thank you so much for holding this very important hearing that is of such tremendous interest, as you can see by this packed room.

Along with Senator Mark Warner, I have the privilege of co-chairing the bipartisan Congressional Task Force on Alzheimer's Disease. I am particularly interested today to hear about the new report released by the Alzheimer's Study Group, chaired by former Speaker Newt Gingrich and former Senator Bob Kerrey.

Alzheimer's is a devastating disease that takes a tremendous personal and economic toll on both the individual, the family, and our country. In my own family, we are all too familiar with the pain and hardship associated with Alzheimer's. In fact, Alzheimer's is so common in my own family that we refer to it as "the family illness."

We are not alone. An estimated 5.3 million Americans have Alzheimer's disease, more than double the number in 1980. In addition to the extraordinary suffering that Alzheimer's causes, Alzheimer's costs the United States just under \$150 billion a year, primarily in nursing home and other long-term care costs.

That figure will soar as the baby boom generation ages. As the baby boomers move into the years of highest risk for Alzheimer's, a strong and sustained research effort is our best tool to slow the progression and ultimately prevent the onset of this heartbreaking disease.

Our investments in Alzheimer's research have begun to pay dividends, and effective treatments are tantalizingly within our grasp. Unfortunately, however, while the number of Alzheimer's cases has continued to climb, funding has been flat over the past 5 years, and we cannot allow that trend to continue.

For every dollar that the Federal Government spends today on the costs of Alzheimer's care, it invests less than a penny in research to find a cure. That simply does not make sense. It is time for us to put our foot back on the accelerator and redouble our research efforts. [Applause.]

We really have only two choices. We can sit back and continue to pay the bills and endure the suffering, or we can aggressively pursue a national strategy aimed at preventing, delaying, and eventually curing this debilitating disease.

In addition to funding for research, we must also do more to support Alzheimer's patients and their families. I have sponsored legislation to provide a tax credit of up to \$3,000 to help families meet

the costs of caring for a loved one with a long-term chronic disease like Alzheimer's.

We also need to do more to encourage more Americans to plan for long-term care needs by providing a tax deduction to help them better afford to purchase long-term care insurance. As we look at comprehensive healthcare reform, we need to ensure that long-term care systems get equal treatment and should be part of the debate.

Mr. Chairman, in July 2007, I had the opportunity to join Speaker Gingrich and Senator Kerrey at a press conference to kick off this tremendous effort. They have done a fabulous job, and they have brought together an incredibly talented and diverse group of the best thinkers in our country, including Justice Sandra Day O'Connor.

I know that their effort, with our support, is going to make real progress. So thank you for your leadership.

Thank you. [Applause.]

The CHAIRMAN. Thank you, Senator Collins.
Senator McCaskill.

STATEMENT OF SENATOR CLAIRE MCCASKILL

Senator MCCASKILL. Thank you, Mr. Chairman.

I do not have a formal opening statement, but I want to recognize the distinguished panel. I want to, first, recognize the fact that on this panel is a woman who has been a role model for me for most of life.

At the point in time that she donned a black robe on the national scene, I was a very young lawyer right out of law school. At that point in time, the only women I had seen in a black robe were in the church choir. [Laughter.]

So, and I think she has been a model of the kind of public servant that all women strive to be, and it is an honor to have her here.

I also obviously want to recognize— [Applause.]

I want to recognize the first lady of California for all the work she has done and especially the influence she has had on the Governor of California. I think this is the perfect time for you to go to work on Newt Gingrich. [Laughter.]

If you could— [Applause.]

Since we have got him here, I think you can work your magic, First Lady.

Then the last recognition. I don't know you, Mr. Butcher, but I have to recognize the president of The New School because my daughter is a sophomore at The New School and called me the other night and said she was sick of it. Sick of school, that is—not The New School. She loves The New School. [Laughter.]

But has enjoyed her educational opportunities at your university and thinks you are doing many things the right way.

I want to just say that I think there are two issues that I would like to learn more about in the process of this hearing. One is are we doing enough to support the research community? Are we elevating science as we should in this area? Are we giving enough support to that area?

Because, clearly, this is a disease that is a heartbreaking disease, and so many diseases are painful, but this is a special, different

kind of pain. I think that it is incumbent on us in the Senate to find ways that we can better support the research community.

The other issue I think is the long-term care issue, and how well are we doing at the job of educating long-term caregivers for the particular needs of the Alzheimer's patient? I know that in some long-term care facilities, there are many rules and regulations, for example, about freedom of movement.

Well, this becomes a different issue with Alzheimer's patients in terms of their safety, but also their quality of life. Are we doing enough to educate and change and tweak our rules and regulations in the long-term care environment to make sure that the Alzheimer's patients are getting the kind of help and support they need?

Obviously, then the other issue for me in a State like Missouri is are we doing enough in the rural areas? I know that there are groups that gather and provide support and assistance in the urban areas of my State because there is a critical mass of families that are dealing with the same issues, and there are groups that get together and provide counseling. We have in Missouri done a rural outreach services and support pilot project with funding from the Federal Government.

But I look at the family in a rural community that is struggling with Alzheimer's, and the long-term care options are not good because, obviously, visiting the loved one is so important. So the long-term care options generally are not good, and there is not that support system.

So any information that you can give our Committee as it relates to what more we can do in rural communities to help those families suffering with Alzheimer's would be greatly appreciated.

Thank you all for being here today, and I look forward to your testimony. [Applause.]

The CHAIRMAN. Thank you. Thank you, Senator McCaskill. Senator Graham.

STATEMENT OF SENATOR LINDSEY GRAHAM

Senator GRAHAM. Thank you, Mr. Chairman.

This is an impressive display of speakers and support network, and the one thing I have been intrigued about in Congress is that diseases have the bigger sponsors you can get, the more money you will get. You know, when a movie star adopts a disease, it is amazing how Congress responds.

But look at the panel here. These are some of the most noteworthy people in the country speaking on behalf of the Alzheimer's Association. What I try to do is resist giving in because there are noteworthy people and a large crowd because there are a lot of diseases out there that nobody basically supports but are equally devastating.

But the one reason I wanted to come to this hearing, and I might have to leave in a minute to talk to Mr. Bernanke, is to say that this disease is unusual in the sense that it represents what I think is the biggest challenge to the country—demographic changes.

If we are going to get our fiscal house in order, we are going to have to deal with the fact that Americans, there are few workers

and a lot of retirees, and Americans are living a lot longer than any other time in our history. That is the good news.

But this is one disease that comes with aging, and it can hit pretty early on. But I think it would be smart for the Congress to listen closely and come up with basically a game plan, a war plan to combat diabetes and Alzheimer's. [Applause.]

Because diabetes, as the Speaker knows—you have been championing this for years—when you look at our Medicare expenses, if you could get a handle on diabetes, it would dramatically change the expenses that Medicare has to assume.

It is a preventable disease. It is devastating to people and has an enormous cost. This disease follows in that category, and the demographic changes in this country are real. This disease is tied to the demographic changes that we have to deal with. We have got to find a way to make sure that younger workers can support the systems that we are putting on their shoulders.

Money spent now on Alzheimer's, I think, will pay great dividends and will help young Americans realize the American dream, improve the quality of life for older Americans and their families. So God bless you for taking up this cause. [Applause.]

The CHAIRMAN. Thank you. Thank you, Senator Graham.
Senator Udall.

STATEMENT OF SENATOR MARK UDALL

Senator UDALL. Thank you, Mr. Chairman.

I want to welcome the panel. I look forward to this important and, I am sure, compelling testimony. I want to make my remarks very short.

My father, Morris Udall, who many of you knew and who served in the Congress, Mr. Speaker, with you, suffered from Parkinson's disease. So, this is personal for me, as it is for all of us.

I wanted to associate myself with Senator Graham's compelling statement as well. There is so much at stake here. Thank you for being here. We are going to get this right.

Thank you, Mr. Chairman. [Applause.]

[The prepared statement of Senator Udall follows:]

PREPARED STATEMENT OF SENATOR MARK UDALL

I want to thank Chairman Kohl and Ranking Member Martinez for holding this hearing to address such salient issues related to Alzheimer's and how we can best tackle the challenges ahead in battling this disease. I want to especially thank our distinguished guests for being here today and for the work you have done and continue to do on behalf of this important cause and the millions of Americans and their families who are affected by this devastating condition.

While the prevalence of Alzheimer's is, as you know, rising at an unsettling rate, the numbers are especially disturbing in my state of Colorado, which is projected to have one of the highest increases in diagnosis rates over the next decade. I am happy to say that the state-level response to this unwelcome trend has been promising, as evidenced by last May's creation of the 22-member Colorado Alzheimer's Coordinating Council. This group, which comprises representatives from industry, government, business, as well as the Alzheimer's community, had its first meeting this past Friday toward developing a comprehension plan for addressing our state's specific challenges, and I am excited to see the effort take off.

With this Council beginning its work in Colorado, I am especially looking forward to hearing this morning's testimony and to the findings of the national strategic plan being released later today. I trust that the report's broad-based goal to "accelerate and focus national efforts" will help bridge the divide between federal and in-

dividual state efforts across the country, allowing us to increase the efficiency, scope, and speed of our battle to reverse such an alarming trend.

The CHAIRMAN. Thank you very much, Senator Udall.
Senator Gillibrand.

STATEMENT OF SENATOR KIRSTEN GILLIBRAND

Senator GILLIBRAND. Thank you, Chairman Kohl and Ranking Member Martinez, for holding this important hearing today.

I want to thank these outstanding witnesses for their dedication and work on the significant issue that affects millions of families throughout the country.

In my home State, there are over 330,000 people suffering from Alzheimer's disease. Of course, we all know that when one of our loved ones is affected by a debilitating illness, it touches all of us.

It affects the lives of 650,000 unpaid family caregivers in New York who provide over 560 million hours of unpaid care, valued at \$6.2 billion each year. These caregivers struggle to care for their families and find the help they need to keep their relatives at home.

Sharon Boyd, senior vice president of the Rochester chapter of Alzheimer's Association, talked to me about cobbling together money and feeling like she was begging on a street corner to put together the funds she needed to provide comprehensive services to Alzheimer's patients and their families. Because of the lack of a coordinated effort and funding from the national level, Sharon does it on her own, combining different grants and donations from not-for-profits to serve the needs of her constituents.

She told one story of a woman from Naples, NY, who cares for her husband who is suffering from Alzheimer's and was diagnosed with her own health problems. She couldn't leave her husband alone to attend for her own doctor's appointments. The Rochester chapter organized respite care for her husband so that she could attend to her own ailing health and take time to travel to the doctor when she needed care.

Because of New York City's funding cuts to social model day programs, many of the programs have closed and can no longer offer scholarships. One woman from East Harlem attended a program from Monday to Friday, even showing up on the weekend, although it was closed. While she didn't know where she lived, she knew how to get to her daycare program. This program has been forced to close because of budget cuts, even as the number of people struggling with the disease continues to skyrocket.

These stories are similar to stories all around the country. Some are lucky enough to receive the help from organizations like the Rochester chapter, but others are not. We must do better for those suffering from this crippling disease. We must streamline the process and make sure that the resources that we have get to the people that need them the most.

I look forward to working with my colleagues to ensure that the patients and families have access to the services they need and that we provide the critical research dollars that are needed to fund the cure.

Thank you again. [Applause.]

The CHAIRMAN. Thank you. Thank you, Senator Gillibrand.

Now we get to our panel. We are happy to welcome first Sandra Day O'Connor back to this Special Committee on Aging as our Nation's first female Supreme Court justice. She spent 24 years on the court. Justice O'Connor began her work on the Alzheimer's Study Group in 2007.

Our next panelist will be former Speaker of the House Newt Gingrich. While serving in Congress, Speaker Gingrich co-chaired the Republican Task Force on Health for four years. Since leaving Congress, Mr. Gingrich has continued to work extensively on healthcare issues, and he is currently the co-chair of the Alzheimer's Study Group.

Our third panelist this morning is Senator Bob Kerrey.

After three years in the Navy, Senator Kerrey served as the Governor of Nebraska and then served as a Senator here in Washington for two terms. He is currently the president of The New School in New York City, and he is also the co-chair of the Alzheimer's Study Group.

Our next witness will be the first lady of California, Maria Shriver. She is an award-winning journalist, best-selling author, as well as the mother of four. As first lady, Ms. Shriver has used her voice to advocate on the behalf of women, the working poor, the mentally disabled, and families struggling with Alzheimer's disease.

Our fourth panelist will be introduced by Senator Martinez.

Senator MARTINEZ. Thank you, Mr. Chairman.

I would like to say a few words about Larry Butcher, who is the chair of the board of directors of Alzheimer's Community Care, Inc. Larry discovered the organization in late 1999 when, as an overwhelmed caregiver, he was able to find the kind of guidance and help that he desperately needed as he was caring for his beloved wife, who had been diagnosed in 1995 at the age of 55 with a form of Alzheimer's disease.

Larry has served on the board of directors of Alzheimer's Community Care since April 2001. He has served as chair of the board of directors since July 2007, was appointed by Governor Jeb Bush as a member of the Florida Alzheimer's Disease Initiative Advisory Council in 2005, and he served as chair of the advisory council in 2007 and 2008 and remains as a member.

Larry also facilitates a weekly support group that has average attendance of about 25 caregivers. So, Larry, thank you for joining us today. [Applause.]

The CHAIRMAN. Justice O'Connor.

**STATEMENT OF HONORABLE SANDRA DAY O'CONNOR,
FORMER SUPREME COURT JUSTICE, MEMBER OF THE ALZ-
HEIMER'S STUDY GROUP, WASHINGTON, DC**

Justice O'CONNOR. Thank you, Mr. Chairman.

This Committee provided a wonderful opportunity for Speaker Gingrich and me to say something about the problems presented by the Alzheimer's crisis before we began our study about a year ago. We have now completed that study, and we appreciate very much the chance to give you a brief rundown on what we have concluded. Thank you for that opportunity.

Now the statistics have not improved since we were last here. Alzheimer's disease is the sixth leading cause of death, and today

in this country, more than 5 million Americans have the disease. Our study shows that in the next 20 years, the numbers of people with Alzheimer's will increase more than 50 percent.

Without some basic action in this country, ultimately, 1 in 2 people over 80 are going to have this disease, and that is too many. We are living longer, and we just can't face that kind of personal tragedy and expense.

Now the disease is devastating for those who are afflicted, but their friends and family and caregivers as well. That is the problem. The costs of care are very substantial because at some point the person with the disease can't take care of himself or herself, and it typically takes at least two to provide round-the-clock care.

Our Nation has no real plan for a Federal effort to find a solution or to help manage the costs, and we need to do both. That kind of a solution is urgently needed. So we submit some specific recommendations.

First, I think we need a major prevention initiative to be developed with the goal of preventing the onset of Alzheimer's in most people. Based on the research that we heard about and the testimony that we heard, we think that prevention can be achieved within a reasonable time if it has the proper funding and support.

We are on the edge of being able to do that, but we really must get some funding and support. It requires both public-private joint ventures to do this with the scientific community, and it requires major data sharing, which is not happening at present.

Second, we need to reimburse the providers of health and social services to Alzheimer's patients for perhaps about 20 percent of those services. I don't think we can possibly do it all. But as you know, we work today under a fee-for-service reimbursement through Medicare and Medicaid for specific services. Alzheimer's patients don't need so much a specific "I have a cut, you need to sew it up" sort of service. It is a broader kind of a service of how do we provide more generalized care?

So, third, I think we need to start an Alzheimer's solutions project office within our Federal Government, find a focal point for this. That office can direct and implement the various care and improvement initiatives that Congress agrees should be undertaken. I am sure that within Congress itself, you can have a joint Committee or Subcommittee to supervise this.

Now our Nation has undertaken other specific initiatives and for particular diseases, not to mention going to the Moon. When we undertake as a Nation to do something like that, these have been some of our major successes as a Nation and our greatest contributions to the world. So developing better care for those afflicted by Alzheimer's and preventing and curing the disease are things that can, should, and, I think, must be undertaken.

We urge you to help with this very critical endeavor, and without the support of Congress, I think the costs of care are going to grow astronomically and will hinder our efforts to reduce our growing Federal deficit if we can't help with this.

Thank you very much for listening and for holding this hearing today.

Thank you, Mr. Chairman. [Applause.]

[The prepared statement of Justice O'Connor follows:]

**Statement of
Sandra Day O'Connor
Associate Justice, Retired
Supreme Court of the United States**

**Before the
Special Committee on Aging
United States Senate**

March 25, 2009

This Committee provided an excellent opportunity for Mr. Gingrich and me to speak about the problems presented by the Alzheimer's crisis before we began our study and the formulation of a plan of action. The Committee members indicated both a genuine interest in the problem and a willingness to consider the results of our study. We have now completed the study and we appreciate the chance to tell you briefly what we have concluded. We thank you for that opportunity.

The statistics have not improved since we were last here. Alzheimer's is the sixth leading cause of death. Today, more than five million Americans suffer from the disease. Our study shows that in the next 20 years the number of people with Alzheimer's will increase by more than 50%. Without urgent action, ultimately one out of every two Americans over 80 will have Alzheimer's.

Of course, the disease is devastating not only for those who are afflicted, but also their friends, family and colleagues. Two or more caregivers are required to provide round the clock care of those with severe symptoms. Alzheimer's also takes a tremendous financial toll. The costs of care are substantial, imposing a great burden on Medicare and Medicaid programs. That burden will grow at a staggering rate.

Our nation has no plan for a federal effort to find a solution or to help manage the costs. Such a solution is urgently needed. To that end, we submit our findings and our proposals. There are a number of very specific recommendations but there are three main ones I want to mention here today.

(1) We need a major prevention initiative to be developed as soon as possible with the goal of preventing the onset of Alzheimer's in most people. We believe based on our research and testimony that this can be achieved within a reasonable time with proper funding and support. It will

require public/private initiatives and major data sharing for scientific advances.

(2) We need to reimburse providers of health and social services to Alzheimer's patients for at least 20% of those services. Such value based payments will allow greater care, better coordination of that care, and a higher quality of life for Alzheimer's patients.

(3) We need to establish an Alzheimer's Solutions Project Office within our federal government to direct and implement the various care improvement initiatives. It would greatly help if Congress established a joint Committee to monitor the federal programs.

Our nation has undertaken other major projects that have succeeded in conquering disease. These initiatives are among our greatest successes as a country and our greatest contributions to the world's population. Developing more effective care for those afflicted by Alzheimer's and ultimately preventing and curing the disease are efforts that can, should, and must be undertaken. We urge you to help us with this critical endeavor. Without your support, the costs of care will grow astronomically, hindering our efforts to reduce our mounting deficit, and 50% of Americans at some point in their lives will face the suffering of Alzheimer's.

Thank you for listening.

The CHAIRMAN. Thank you very much.
Speaker Gingrich.

**STATEMENT OF HONORABLE NEWT GINGRICH, FORMER
SPEAKER OF THE HOUSE OF REPRESENTATIVES, CO-CHAIR,
ALZHEIMER'S STUDY GROUP, WASHINGTON, DC**

Mr. GINGRICH. Thank you very much for hosting us, and I want to thank you again for last year having hosted us, had been in May 2008.

I also want to thank Senator Collins because she and Senator Mikulski and Senator Burr and then-Senator Clinton, on July 11, 2007, actually helped us launch this entire project, which has now been underway for almost a year and a half.

On the Alzheimer's Study Group, Senator Kerrey and I have been very lucky to have very strong support. In addition to Justice O'Connor today, from our group, Meryl Comer, James Runde, and Dr. David Satcher are here, and Dr. Mark McClellan. So it was a very powerful group that really worked very hard.

I specifically want to thank Rob Egge, who was the Executive Director, and George and Trish Vradenburg. The Vradenburg Foundation, in many ways, conceptualized the study group. Harry Johns and the Alzheimer's Association has been tremendous in supporting it.

I want to thank the audience for being here today because I think they help drive home the human side of what we are talking about and the degree to which they have personal awareness and personal involvement with Alzheimer's.

I really want to start by pointing out that as we reached out very deliberately to neuroscientists and to try to develop an understanding of what was available, that part of what you have to take—and this is a little bit to pick up on what Senator Graham said—is the scale of what we are dealing with.

Every 70 seconds, someone in America develops Alzheimer's disease. By 2050, someone will develop Alzheimer's every 33 seconds. 5.3 million Americans currently suffer from Alzheimer's, 1 in 8 Americans over 65, and almost 1 in 2 over 85.

Ten million baby boomers will develop the disease. It is a family disease. As Senator Gillibrand pointed out, 9.9 million caregivers provide 94 billion hours of uncompensated care per year.

The healthcare costs for people with Alzheimer's disease are three times greater than for people with other diseases because of the complexity of dealing with someone who has dementia. In 2005, Medicare spent \$91 billion on beneficiaries with Alzheimer's and other dementias and is projected to spend \$189 billion by 2015.

Given the present trends, Alzheimer's will cost Medicare and Medicaid a projected \$19.89 trillion between 2010 and 2050. Because people tend to get Alzheimer's later in life, even a delay has a significant effect on lowering cost. A 5-year delay of onset would save \$8.51 trillion over the same period. I want to repeat that number—\$8.51 trillion by simply getting a 5-year delay.

The CDC, the Centers for Disease Control, lists Alzheimer's disease as the sixth leading cause of death. Today, there is no cure, no disease-modifying treatment, and no prevention. There is no sin-

gle breakthrough that would do more to lower the cost of entitlements than preventing the onset of Alzheimer's disease.

In the early 1950's, more than 50,000 Americans were infected with polio each year. Within years of the licensing of the Salk vaccine in 1955, polio was effectively eliminated in the United States. An Alzheimer's preventive would dramatically overshadow even that great scientific victory.

More importantly, there is no single breakthrough that would do more to improve the quality of life of older Americans and more to relieve their families and loved ones of pain and worry than to develop a breakthrough in treating or delaying the onset.

We have 16 specific recommendations, and for time reasons, I ask for permission for my entire presentation to be put in the record.

The CHAIRMAN. Without objection.

Mr. GINGRICH. But I want to focus—and Justice O'Connor has already emphasized several key points. I want to focus in on a fundamental change in budget and management of science.

We are going to get 4 to 7 times as much new science in the next 25 years. That science is going to change everything, from energy to the environment to national security to jobs to health. The specific example of Alzheimer's, we have approximately \$20 trillion on the table that we are going to spend between now and 2050.

If you took a business approach, and you said, "What would my return on investment be if I could get a breakthrough?" You would make a very substantial investment up front. You wouldn't start with an annual budget and say, "This is all I can afford," because you are already going to spend \$20 trillion.

So, our proposal in part is to take this kind of research off budget, to create a sinking fund, to pay for it with specific bonds that are Alzheimer's related bonds, and we have three Nobel Prize winners and 125 neuroscientists in the appendix who believe we can get the breakthrough by 2020.

Let us say they are off by 5 years, and it is 2025. People in this room can measure their own age and decide whether or not that relates to them. But I will tell you, for your children and grandchildren, this breakthrough would be unbelievably important. For the budget, it would be unbelievably important.

I think if you were to call together the leading neuroscientists and say what could you profitably use to maximize the rate of discovery, to maximize the chances of breakthrough, and then have it as part of the budget agreement that if we do get a breakthrough, the first cut of the savings goes to pay off the bonds that were used to launch the research.

You would have a closed system in which you would save trillions of dollars in out-year costs. You would get the breakthrough years faster, saving many human lives and much suffering, and you would have accelerated our ability to invest in science the way we should.

The last point I would make about this is that—and this is very controversial, even on our own panel. So let me be clear about that. I believe, and most of the neuroscientists we have talked with believe, that the project direction model used for the Human Genome Project is a much more powerful organizing system for this kind of

research than the traditional NIH individual researcher, application, peer review, annual budget, small building blocks.

That is very controversial, but I think it is worth this Committee and others hearing from neuroscientists about why that approach would be more powerful. If combined with Justice O'Connor's model of a public-private partnership, we believe it is realistic that sometime in the 2020 or 2025 range, we would have had fundamental and decisive breakthroughs and in the process not only affected Alzheimer's, but affected every brain science-related activity, including Parkinson's, including epilepsy, including mental health, such as schizophrenia.

So we think this is a very major zone to fundamentally rethink the budget act and to fundamentally rethink how we organize science.

I appreciate very much the chance to share this with you. [Applause.]

The CHAIRMAN. Thank you, Speaker Gingrich.

[The prepared statement of Mr. Gingrich follows:]

**Statement of
Newt Gingrich
Former Speaker of the House
U.S. House of Representatives
Co-Chair, The Alzheimer's Study Group**

**Before the
Special Committee on Aging
United States Senate**

March 25, 2009

Chairman Kohl, Ranking Member Martinez and Members of the Committee. Thank you for the opportunity to return to the Senate Special Committee on Aging to report on the key conclusions we have reached through our work as part of the Alzheimer's Study Group. It is a privilege to release our final report, *A National Alzheimer's Strategic Plan: The Report of the Alzheimer's Study Group*,¹ before a committee that has such a distinguished record of championing those issues that so profoundly affect not just older Americans, but our entire Nation as a whole.

I also want to take this opportunity to thank Senator Susan Collins from this committee. As a co-chair of the Senate Congressional Task Force on Alzheimer's Disease, Senator Collins joined with Senator Barbara Mikulski, Senator Richard Burr, and now Secretary Hillary Clinton on July 11, 2007 to launch the effort that we report on here today.

The issues of Alzheimer's disease also benefit from the tireless and extremely able advocacy of your colleagues in the U.S. House of Representatives. In particular I wish to recognize the generous support of Representative Ed Markey and Representative Chris Smith, co-chairs of the House Congressional Task Force on Alzheimer's Disease, for their support of the work of the Alzheimer's Study Group.

When we testified before this committee on May 14, 2008, Chairman Kohl, we were moved and inspired by the personal stories shared by the members of this committee about the terrible impact of Alzheimer's disease on their families and loved ones. It is, we have learned all too well through our work, increasingly the story of America as a whole. It is not just tragic. It is also a national crisis. And it is a crisis that grows with each year.

And so, we thank you for the opportunity to return before you with a plan and even a sense of optimism. We are convinced by our work that we have real, substantial opportunities to not only provide much more effective care and support for those with Alzheimer's disease and their families, but we also have the opportunity to substantially accelerate the arrival of new therapies that can start to turn the tide against this disease and, in time, defeat it.

¹ The report can be accessed at: www.alzstudygroup.org.

To that end, the key recommendation reached by the Alzheimer's Study Group is the United States should establish the Alzheimer's Solutions Project to accelerate and focus national efforts, reengineer dementia care delivery, and, ultimately, prevent Alzheimer's disease. This project we propose to you today has three pillars:

1. ***The Alzheimer's Prevention Initiative:*** As a national priority, urgently focus on developing the capability to delay and, ultimately, prevent Alzheimer's disease. This capability will depend on the advancement of development science as well as basic research.
2. ***The Alzheimer's Care Improvement Initiative:*** By 2012, use value-based payments to reimburse providers for at least 20 percent of health and social services for people with dementia, and for half of these services by 2016. Value-based payments will reward health care and social services professionals for providing the coordinated care dementia patients most need for better health and a higher quality of life.
3. ***The Alzheimer's Public-Private Partnership:*** By 2010, establish an outcomes-oriented, project-focused Alzheimer's Solutions Project Office within the Federal Government. Backed by an appropriate scale of funding and through active collaboration with other stakeholders outside the Federal Government, this office will lead the successful implementation of the Alzheimer's Prevention and the Alzheimer's Care Improvement Initiatives, together with supporting efforts.

The human pain and financial burden of Alzheimer's is so great and the potential breakthroughs in science are so encouraging that a "Manhattan Project," "Apollo Project," or "Human Genome Project" approach to ending Alzheimer's is more than justified.

The Alzheimer's Solutions Project is in the best American tradition of solving a big problem with a big vision and a big effort. A public-private partnership is the best collaborative approach to achieve that vision as rapidly as possible.

It is the combination of, first, the scale of the crisis and, second, the breadth of the new science which makes this focused, intense investment and project management approach worth implementing.

The Scale of the Alzheimer's Crisis

First, the scale of Alzheimer's as a crisis is something that is vivid and real to individuals and families dealing with the disease but because of its very nature has been consistently underestimated in our public policy.

Consider these facts, principally drawn from the Alzheimer's Association's report, *2009 Alzheimer's Disease Facts and Figures*:

- Every 70 seconds someone in America develops Alzheimer's disease—by 2050 someone will develop Alzheimer's every 33 seconds.
- 5.3 million Americans currently suffer from Alzheimer's—one-in-eight Americans over 65 and almost one-in-two over 85.
- 10 million baby boomers will develop the disease.
- It is a family disease—9,900,000 caregivers provide 94 billion hours of uncompensated care per year.
- Healthcare costs for people with Alzheimer's disease are three times greater than for people with other diseases.
- In 2005, Medicare spent \$91 billion on beneficiaries with Alzheimer's and other dementias and is projected to spend \$189 billion by 2015.
- Given the present trends Alzheimer's will cost Medicare and Medicaid a projected \$19.89 trillion between 2010 and 2050.
- Because people tend to get Alzheimer's later in life, even a delay has a significant effect in lowering costs. A five year delay of onset would save \$8.51 trillion over that same period.
- The CDC lists Alzheimer's disease as the 6th leading cause of death.
- Today there is no cure, no disease-modifying treatment, and no prevention.

There is no single breakthrough that would do more to lower the cost of entitlements than preventing the onset of Alzheimer's disease.

In the early 1950s, more than 50,000 Americans were infected with Polio each year. Within years of the licensing of the Salk vaccine in 1955, Polio was effectively eliminated in the United States. An Alzheimer's preventive would dramatically overshadow even that great scientific victory.

More importantly, there is no single breakthrough that would do more to improve the quality of life of older Americans and more to relieve their family's and loved ones of pain and worry than to develop a breakthrough in treating or delaying the onset of Alzheimer's.

The Scale of the Science and Research

Second, the exciting opportunity to create the capability to prevent Alzheimer's is created by the fact that the scale of the need in Alzheimer's is being matched by the scale of the scientific breakthroughs in our understanding of the human brain.

The enormous increase in our understanding of the brain creates a genuine possibility of "a world without Alzheimer's" – a view widely shared by leading researchers themselves. In just the past several weeks, almost 200 leading Alzheimer's research scientists have endorsed the goal of developing the capability to prevent Alzheimer's by 2020.

However, this goal is only 'realistic' if it is pursued realistically.

Tragically, the gap today between scientific potential and scientific resources is enormous. This gap ensures unnecessary suffering and unnecessary costs.

The efforts to develop the new knowledge and then to translate it into new medicines and new therapies are fragmented and underfunded. Mechanisms for sharing new knowledge are stunningly slow and inadequate. For example, the Institute of Medicine has estimated that it takes up to 17 years for a new breakthrough to reach every doctor. This applies to Alzheimer's fully as much as any other disease.

Thus even when the new science leads to new solutions, millions may suffer unnecessarily for years because the current health communications systems are so inadequate.

Every day that we fail to invest in the new science is a day Americans suffer unnecessarily. Today much more money is spent simply treating the complications that arise from Alzheimer's than is invested in developing a cure, better treatments or improved approaches to care.

What we need are a much larger investment in science, a strategy for coordinating the research, mechanisms for accelerating the translation of breakthroughs into practical treatments, and much better ways to reward those who deliver valuable care.

The Alzheimer's Solutions Project should be seen as both the biggest single humanitarian opportunity and the biggest single entitlement savings opportunity in America today.

The Alzheimer's Solutions Project fits both the human and fiscal needs of the American people in the next generation.

Steps to a Successful Alzheimer's Solutions Project

In the following report, the Alzheimer's Study Group has proposes a series of consensus recommendations to address these and other issues.

Immediately below are 16 specific steps, inspired by the report's consensus recommendations, that we, the co-chairs, believe will have the largest impact on our national effort to end the Alzheimer's crisis:

1. We encourage President Obama to make a major speech focused on communicating the facts of Alzheimer's to the American people and sharing with them the opportunity for an historic breakthrough that would improve the quality of life of millions of Americans and would provide help for people around the world. In this speech the President should outline the nature and structure of the Alzheimer's Solutions Project and urge Congress to adopt the Project as a major goal for the Nation.

2. Congress should pass implementing legislation to create a public-private partnership for the prevention of Alzheimer's and to implement better care models. This legislation should include a fundamental change in the science budgeting process. To reach a solution as quickly as possible, the public and private sectors must work together cooperatively.

3. The annual budget cycle based on immediate constraints should be replaced for Alzheimer's research with a new model based on the scale of potential savings. If there is already a projectable \$19.89 trillion dollar federal expenditure for Alzheimer's over the next generation then the scale of research investment ought to be measured against the money it will save rather than against other federal expenditure it would crowd out in a static budget. Seen in this light the logical upper bound for an investment budget to find an Alzheimer's solution is the amount scientific research could intelligently use for the foreseeable future. An annual public-private Alzheimer's research assessment (including the basic science in math, physics and chemistry which powers many of the breakthroughs in understanding the biology of the brain) should produce a five-year investment strategy which should be funded through a new generational budget outside the traditional budget limits. As National Institutes of Health Director Elias Zerhouni has testified to Congress, the \$10 billion invested in basic research on HIV/AIDS between 1985 and 1995 saved \$1.4 trillion in healthcare expenditures, a return on investment of 140-to-one. The prospects are that Alzheimer's research will pay dividends that dwarf those on HIV/AIDS because the scale of the challenge is so much bigger. The choice for our generation is not whether or not to spend the money on Alzheimer's. The choice for our generation is to invest the money early and save a lot of lives, pain and money later or to be foolishly cheap in the short run, minimize breakthroughs and maximize pain, suffering and cost.

4. Public investment in the Alzheimer's Solutions Project should be financed through the public sale of tax-exempt bonds. The bonds would be repaid through a sinking fund. Contributions to the sinking fund would be paid into by the Federal government as a percentage of the savings to the Federal Government that would follow the development of the capability to prevent Alzheimer's.

5. The President should appoint a new Chief Executive Officer to lead the public-private Alzheimer's Solutions Project. This CEO would report annually on the progress of the Alzheimer's Solutions Project and the steps necessary to maximize the speed of its completion.

6. The Congress should establish a Joint Committee on Alzheimer's Disease with unique authorizing and appropriating authority. Members of the Committee would be drawn from the appropriate appropriations and authorizing committees of the House and Senate. This Committee would have oversight of the Alzheimer's Solution Project and would propose such legislation and such appropriations as needed for its successful completion. The Committee would be disbanded when the three objectives for Alzheimer's had been developed and implemented.

7. Create a new public-private Alzheimer Solutions Project Advisory Committee with representation from research, treatment, private industry, families, and government. The Advisory Committee would highlight bottlenecks and opportunities and would provide an independent judgment on the effectiveness of the Alzheimer's Solutions Project and the steps needed to accelerate its completion. Annually the Advisory Committee would issue a public report on progress, problems, and opportunities.

8. A public-private Alzheimer's Roadmap for Research and Development should be developed with a five year horizon and an annual update. The dramatic increase in research resources we are proposing should be matched by a systematic improvement in the ability to manage those resources in a coherent manner. This metrics-driven approach has proven its potential again and again. The achievement-oriented focus of the Manhattan Project, the Apollo Project, the Human Genome Project and the extraordinary speed of development in combating HIV/AIDS all stand in stark contrast to the highly decentralized and researcher—rather than research—centered model which has characterized much of the modern government funding process. We believe the potential for preventing Alzheimer's requires a much more sophisticated overview of research opportunities, much more transparency in research information dissemination and a more team focused and long term investment focused approach.

9. Biopharmaceutical research on preventive, disease-modifying and risk-reducing Alzheimer's therapies should be provided incentives equivalent to those in the Orphan Drug Act to maximize investment in new breakthroughs. Scientific research only reaches its full impact in helping people when it is translated into usable medications and usable technologies. Today the complexity of testing medicines for the brain has led to a substantial private sector underfunding of the very translational research that is needed. Furthermore the upcoming struggle over payment for drugs will further discourage investment in medications for Alzheimer's at the very time when we need to be deepening and accelerating the research. Placing Alzheimer's research under provisions equivalent to the Orphan Drug Act would attract a new generation of capital investment in seeking more effective medications.

10. A fundamental reform of the Food and Drug Administration process as it relates to approving drugs relating to Alzheimer's disease is vital. There are very useful proposals for saving as many as six to eight years of the approval time through sophisticated new approaches. These should be thoroughly explored. Every year lost in regulatory bureaucracy is a year of pain, suffering and cost for millions of individuals with Alzheimer's and the loved ones who are caring for them. Streamlining the regulatory process for approval is as important as any single step in getting new medications to help those who need them.

11. As a part of this more focused investment strategy, a series of Comprehensive Alzheimer's Disease Centers should be. Advancing the model established by the National Cancer Institute and the existing Alzheimer's Disease Centers, the objective is to streamline and broaden the scope of activities to include research on interventions, diagnosis, imaging, prevention trials, and other longitudinal studies that require long-term

support. There is an increasing need to identify individuals at high risk of AD for prevention trials and very early in the course of their illness for clinical trials of disease modification. The enhanced Centers Program will accelerate the development of knowledge needed to improve care, delay onset and ultimately prevent the occurrence of the disease.

12. New methods of paying for the care of individuals with Alzheimer's must be developed based on the straightforward premise of paying providers for delivering value to patients and their families. The current Medicare Fee-for-Service system actually discourages doctors from testing to see if their patient has Alzheimer's. Treatment, care management and care coordination are so underfunded that doctors find themselves burdened with liabilities without compensation. The result of the current system is consistent under diagnosis and under reporting of Alzheimer's, and the neglect of treatments and support that could immediately result in significantly improving the quality of life for those with Alzheimer's and their families. New models of payment based on value created, rather than services rendered (whether needed or not), need to be developed so doctors and other health providers will have adequate compensation for dealing with a complex, slowly progressing disease.

13. Because Alzheimer's takes effect over a very long time and often involves many other diseases (co-morbidities) and requires the collaboration of a number of care providers, a special effort should be made to develop electronic health records for individuals with Alzheimer's. This will lead to substantial savings in both time and money and to a substantial improvement in care. The first step might be to identify those institutions which have already developed such electronic health records for their own use.

14. The National Library of Medicine, the Institute of Medicine and the Agency for Health Research and Quality should collaborate with private sector systems to develop a real-time internet-based dissemination system for researchers, doctors, individuals with Alzheimer's and care giving families. The goal should be to translate new opportunities into available knowledge within weeks rather than years and to allow every concerned citizen to access the knowledge base. This Rapid Learning Network for Alzheimer's would revolutionize the transmission of knowledge to those who most need it.

15. A national online Registry for Early Detection and Treatment of Alzheimer's should be established for three reasons. First, to get doctors in the habit of looking for early signs of the disease (something many actually reject doing today). Second, to encourage individuals with Alzheimer's to make themselves available for scientific trials as new knowledge leads to new opportunities. The time and cost savings of developing a pool of willing research volunteers would more than pay for the cost of the Registry. Third, to enable the transmission of new knowledge to every person who registers and their caregivers so we can dramatically accelerate the translation of new knowledge to new treatments.

16. New community-based programs should be developed to take maximum advantage of the new technology and new communications systems to help caregivers and individuals with Alzheimer's cope with the diseases challenges with all the assets and capabilities a modern society can develop. Those who are willing to care for their loved ones should not be abandoned to obsolete technologies and inadequate information. We can do much better.

These 16 steps would represent one of the most comprehensive solution oriented efforts in American history.

Taken together these 16 steps meet the challenge of Alzheimer's and offers hope to millions both today and for the future.

Thank you.

Senator Bob Kerrey.

STATEMENT OF HONORABLE BOB KERREY, FORMER SENATOR, PRESIDENT, THE NEW SCHOOL, CO-CHAIR, ALZHEIMER'S STUDY GROUP, WASHINGTON, DC

Senator KERREY. Mr. Chairman and members of the Committee, I would like, first of all, just to ask that my full statement be included in the record.

The CHAIRMAN. Without objection.

Senator KERREY. Trying to build on what both Justice O'Connor and Speaker Gingrich has said, there is a case here to change the way we approach Alzheimer's disease, and it is a fairly simple case that it is a different kind of disease.

I mean, first of all, it is not the normal process of aging. It is a disease. But it is a disease unlike most others that produces, at some point, dependency—at some point, complete dependency. There is real cost attached to that dependency, both to the family, but also public costs, which is what Speaker Gingrich has been talking about.

There are real implications as our own population not just ages, but as we survive longer. So, there is a demographic issue here that is real. There is a social issue, and there is a cost issue. There is a case here to treat Alzheimer's differently.

I share Speaker Gingrich's evaluation of this, and I actually would slightly disagree with him and maybe substantially disagree with him. I don't think this is that controversial. You have differences of opinion on whether or not it ought to be project based, but I think the compelling argument is that it should be project based.

You can call before this Committee others who will disagree with that, but you have to make a decision. Because if you believe it is project based, then you have to create an entity inside the executive branch that can organize and direct that project, that gets the resources necessary to be able to pull people together.

Because if all it is is just another office of the Government without any funds attached, attached in a multi-year fashion, the way Speaker Gingrich was implying, you are simply not going to be able to get it done. It has to have resources. You have to believe that there is real savings and that it can be done.

If you believe it is project based, I am quite enthusiastic that the recommendations that we are making in this report will produce real results—that it will reduce suffering, that it will, at the very least, postpone the onset of Alzheimer's, and I think there is real promise, in fact, from the scientists that we have talked to that you could eliminate Alzheimer's as one of the things that you fear when you think about growing old.

So, Mr. Chairman and members of the Committee, I hope that this hearing will produce results. I very much appreciate your attention to it, your interest in it, your interest prior to this report. I am very hopeful that the recommendations that we make will become a part of a major project to eliminate this disease.

Thank you. [Applause.]

[The prepared statement of Senator Kerrey follows:]

**Statement of
Bob Kerrey
President, The New School
Co-Chair, The Alzheimer's Study Group**

**Before the
Special Committee on Aging
United States Senate**

March 25, 2009

Chairman Kohl and Members of the Committee, who among us does not know someone who has been diagnosed with Alzheimer's Disease? And who among us does not know someone who has provided care for a loved one with the disease?

Alzheimer's disease turns out the light of memory. For good and bad the victim becomes someone else. But the disease does more than destroy memory. It destroys the capacity for daily functioning. Dependency is a universal condition for those who suffer the disease's destruction of healthy brain tissue. Independent living is not possible following a steady decline in memory and mental abilities.

Alzheimer's disease is not a part of normal aging. It is a disease. Still, the risk of the disorder increases with age. About 5 percent of people between the ages of 65 and 74 have Alzheimer's disease, while nearly half the people over the age of 85 have Alzheimer's.

These two simple facts – universal dependency and high probability of acquisition beyond the age of 80 – combined with a growing number of Americans who will live that long or longer have profound significance for every member of Congress. For you have the responsibility every year of authorizing two programs – Medicare and Medicaid – which will be severely stressed by the mounting cost of this disease.

Alzheimer's is not just another disease that produces suffering. Victims of other well known and researched diseases very often function normally in all other respects other than their treatment and do not require the kind of intense and expensive dependent care that always accompanies Alzheimer's. Curing Alzheimer's will do more than save lives; it could save our health care system from financial collapse.

The sobering implications of this mounting Alzheimer's crisis led the Alzheimer's Study Group to this principal recommendation:¹

¹ This recommendation is from the Alzheimer's Study Group's report, *A National Alzheimer's Strategic Plan*, which can be accessed at www.alzstudygroup.org.

Establish the Alzheimer's Solutions Project to accelerate and focus national efforts, reengineer dementia care delivery, and, ultimately, prevent Alzheimer's disease.

The Alzheimer's Study Group urges America to embark on this bold project to contain the staggering impact of Alzheimer's disease. The project is composed of three initiatives:

1. ***The Alzheimer's Prevention Initiative:*** As a national priority, urgently focus on developing the capability to delay and, ultimately, prevent Alzheimer's disease. This capability will depend on the advancement of development science as well as basic research.
2. ***The Alzheimer's Care Improvement Initiative:*** By 2012, use value-based payments to reimburse providers for at least 20 percent of health and social services for people with dementia, and for half of these services by 2016. Value-based payments will reward health care and social services professionals for providing the coordinated care dementia patients most need for better health and a higher quality of life.
3. ***The Alzheimer's Public-Private Partnership:*** By 2010, establish an outcomes-oriented, project-focused Alzheimer's Solutions Project Office within the Federal Government. Backed by an appropriate scale of funding and through active collaboration with other stakeholders outside the Federal Government, this office will lead the successful implementation of the Alzheimer's Prevention and the Alzheimer's Care Improvement Initiatives, together with supporting efforts.

The Alzheimer's Prevention Initiative

Our consultations with the Alzheimer's research community have made two points clear to us:

- Many leading Alzheimer's researchers believe that we may be closing in on developing the capability to delay, and even prevent, Alzheimer's.
- However, developing this capability as quickly as possible will require us to abandon a "business as usual" approach to overcoming these challenges.

And this analysis led us to propose the Alzheimer's Prevention Initiative, the objective of which is developing the capability to delay and, ultimately, prevent Alzheimer's disease. This capability will depend on the advancement of development science as well as basic research.

The most important recommendations to advance in pursuit of this initiative can be summarized as follows:

1. ***Clarify and accelerate the development pathway for preventive and risk-reducing therapies.*** The Alzheimer's Solutions Project must work with a range of stakeholders to clarify and streamline the development pathway for preventive and risk-reducing therapies. This effort should aim to advance development science, including the improvement of disease models and qualification of biomarkers for clinical research. Additionally, incentives for exploring potentially significant lifestyle interventions, such as diet and exercise, are insufficient. Both pharmacological and behavioral interventions must be accelerated if we are to develop the capability to prevent Alzheimer's as quickly as possible.
2. ***Expand the volunteer research pool.*** Much larger numbers of volunteers—including study participants who have Alzheimer's and control group participants who do not—should be recruited for clinical trials and population-based longitudinal studies to build our understanding of the disease and validate potential interventions. Recruitment of pre-symptomatic and early-stage patients is especially critical to the development of preventive treatments.
3. ***Encourage rapid learning by linking databases and researchers.*** Create an Alzheimer's disease rapid-learning network that links all major research databases and researchers. Implement advanced analytical tools to support research and data mining using this new data-sharing infrastructure.

Many experts believe we may be on the cusp of developing the capability to prevent Alzheimer's disease. However, this goal will only be reached if we pursue it with discipline regarding the ends and innovation regarding the means.

The Alzheimer's Care Improvement Initiative

While we focus on the search for a cure, we must also vastly improve how we deliver Alzheimer's care. The most important lever for doing so, we have concluded, is payment reform.

Nothing shapes practice as profoundly as payments. From workforce recruitment and retention, to procedures and practice patterns, Medicare and Medicaid reimbursement schedules and methods have a significant effect on the care that patients do—or do not—receive.

This fact is at the root of a fundamental problem facing people with Alzheimer's disease or other dementias and their caregivers. Many of these families depend on Medicare Fee-for-Service to cover the costs of care. Unfortunately, Medicare Fee-for-Service leads to very poor care for people with Alzheimer's disease and other dementias.

Medicare Fee-for-Service rewards volume. The more patients a health professional can serve and the more services that professional can offer in a fixed amount of time, the higher his or her income will be. Yet, the best dementia care—and very likely the cheapest dementia overall as well—is low volume. The more time a health professional spends with patients and their caregivers, the better the care will be.

Medicare Fee-for-Service discourages coordinated care. Yet, people with Alzheimer's or other dementias require care coordination given the prevalence of co-morbidities and their diminished capacity to manage their own health.

Medicare Fee-for-Service currently provides low reimbursement—or no reimbursement at all—for services like counseling and medication management. Yet services like these best suit the needs of dementia patients.

Medicare Fee-for-Service discourages the use of community services and psychosocial interventions. Yet these services often provide the greatest value to dementia patients.

Perhaps the failure of the current system is best illustrated by the fact that fewer than half of those with dementia even have their condition noted on their medical records, despite the sweeping implications such a diagnosis should have on care plans, medications, referrals, and other issues. Health care providers fail to diagnose many cases of dementia for several reasons, but perhaps the most important is that they lack the financial incentive to do so. Not only is a diagnostic workup itself reimbursed poorly compared to many other Medicare services, but a diagnosis sets in motion a chain of other responsibilities that are also poorly reimbursed under Fee-For-Service.

Individuals with Alzheimer's disease or other dementias need a Medicare reimbursement system that rewards value, not volume. This new system should be based on a simple economic principle. Care providers—much like all providers of goods and services in the marketplace—should be rewarded for providing what is most valuable to dementia patients for better health and a higher quality of life.

Our challenge is to determine what dementia patients and their families value most, to develop systems to measure appropriate care delivery, and to reward providers for delivering such care.

In our report, the Alzheimer's Study Group has developed a range of recommendations aimed at reforming health and community care systems so they were more responsive to the needs of people with Alzheimer's and other dementias. The following points summarize the recommendations that should receive the highest priority as we work to fundamentally reform the payment system as a way to improve outcomes across health systems and communities:

1. ***Implement an electronic health records system.*** Such a system can be used to track the delivery of valued care and lower the cost of care coordination.

2. ***Develop quality care measures.*** These measures should be based on what people with Alzheimer's disease and their caregivers value most. Building on this work, begin to test value-based payments for dementia care based on a small number of indicators in pilot programs, followed by aggressive rollout as results warrant.
3. ***Encourage coordinated care.*** This care should include training and supporting family caregivers, who often bear the largest share of the caregiving burden today without compensation.

Our ultimate hope and ultimate goal is a world without Alzheimer's disease. While we work toward that goal, we also have a responsibility to create a system that delivers more valuable and efficient care for the 5.3 million Americans with Alzheimer's today, and the almost half a million additional Americans who develop Alzheimer's every year. In that effort, we must implement a value-based payment system that will drive change and spur care delivery innovation. Americans with Alzheimer's deserve much better care than they all too often receive today.

The Alzheimer's Public-Private Partnership

Despite the grave implications of the mounting Alzheimer's disease crisis for America's future, the Federal Government has no comprehensive strategy to guide its efforts against this disease. There is no integrated statement of the vision, assumptions, objectives, strategies, measures of success, assignment of responsibilities, timelines, and anticipated resource requirements to guide and explain the Federal Government's overarching efforts to address the Alzheimer's crisis. In fact, our review indicates that there exists nothing even close to the kind of planning document routinely employed to guide disciplined, comprehensive and sustained planning and implementation efforts.

The Alzheimer's Solutions Project will fill this void. Through the Public-Private Partnership, it will take a system-wide approach to planning and implementation that accounts not only for the various agencies and departments of the Federal Government, but will actively work to coordinate and align these efforts with those of other key stakeholders outside the Executive Branch.

In addition to an agile, project management approach, the Alzheimer's Solutions Project will require investment levels significantly above current levels. It should be noted, however, that these investment levels will almost certainly remain modest relative to the most appropriate financial reference points, such as the project's potential return on investment. That is, the appropriate comparison should be the potential of such an investment to offset the projected \$20 trillion Federal expenditure to pay for the care of people with Alzheimer's over the next generation.

This standard return on investment framework brings reasonable investment levels into clearer perspective. A total investment of \$50 billion over the course of the Alzheimer's

Solutions Project would pay for itself many times over even if it only managed to yield a 1 percent reduction in the projected \$20 trillion outlay. If it led to the capability to prevent Alzheimer's, it would prove to be one of the wisest and most profitable investments in the history of our Nation. And this is before even factoring in the improvements such an investment would bring to the quality of life of millions of Americans.

While the federal investment should be substantial enough to allow researchers to make significant progress toward Alzheimer's prevention and better care solutions, the Federal Government should not be the only contributor to this effort. Federal investment must be designed to attract, not crowd out, additional investments from other stakeholders. Just as they already do today, for- and non-profit sectors alike should be encouraged to continue to contribute to this effort, both in dollars and in expertise. Individuals employed within these sectors have already shown that they possess knowledge and experience that will be indispensable to the pursuit of solutions to important aspects of the Alzheimer's disease crisis.

The same is true of state and local governments. These governments are often ahead of the Federal Government in their efforts to address pressing issues such as the development of effective and sustainable community-based care models. In addition, states like Arizona, Florida, and Texas are spearheading the creation of innovative public-private research consortia that are already yielding impressive results.

Collaboration is also warranted on the international level. Global partners such as France, the United Kingdom, and Japan have engaged in national planning exercises that hold important lessons for U.S. efforts. The United States should actively engage with international partners through the G8, the World Health Organization, and other multilateral organizations.

The Alzheimer's Study Group believes that by 2010 Congress should establish an outcomes-oriented, project-focused Alzheimer's Solutions Project Office within the Federal Government. Backed by an appropriate scale of funding to finance projects and through active collaboration with other stakeholders outside the Federal Government, this office will lead the successful implementation of the Alzheimer's Prevention and the Alzheimer's Care Improvement Initiatives, together with supporting efforts.

The Alzheimer's Study Group has developed a range of recommendations regarding the appropriate governance structure for a sustained, appropriated funded effort to overcome the Alzheimer's crisis. In summary, the following recommendations are most important to successfully completing the Public-Private Partnership Initiative:

1. ***Create an Alzheimer's Solutions Project Office.*** This office should exist within the Executive Branch and should be led by a Chief Executive Officer. As its first order of business, the office should develop and publicly release a detailed Alzheimer's Solutions Project Implementation Plan. The plan should be publicly updated with accompanying progress reports no less than annually.

2. ***Put at the disposal of the office an Alzheimer's Solutions Project Investment***

Fund. Annual appropriations to the fund should be based on a multiyear investment budget that extends through at least a five year planning cycle. Appropriate funding levels should be revisited annually to address the rate of progress and changing conditions. The scale of Federal investment should be based on the savings that overcoming Alzheimer's would yield to the Federal government over the coming generation, implying a scale of annual investment many times greater than current levels.

3. ***Maximize public-private collaboration to speed progress.*** Building on current initiatives and existing efforts, maximize public-private collaboration wherever feasible. Quickly implement such initiatives while balancing the need for speed and innovation with the need for appropriate safeguards and controls.

The Alzheimer's Public-Private Partnership Initiative is a critical foundation for the successful execution of the other Alzheimer's Solutions Project initiatives. Implemented effectively, the project will allow the country to begin providing Alzheimer's and other dementia care much more effectively by 2012, and will provide the capability to prevent Alzheimer's as quickly as possible. Without this program infrastructure in place, however, these objectives will most likely remain out of reach.

Mr. Chairman and Members of this Committee, Alzheimer's disease has placed America's future at risk. Without substantial progress toward overcoming this disease, millions of Americans and their families will suffer the devastating, progressive loss that comes with Alzheimer's. In addition, all Americans will shoulder the fiscal burden of a costly disease that promises to substantially increase Medicare and Medicaid spending in the years ahead.

The Alzheimer's Study Group believes we can secure a much better future for our Nation. Through the implementation and successful execution of these initiatives, America will travel a path to a much better world—a world without Alzheimer's.

Allow me to close with a quote of Albert Einstein:

"A human being is part of a whole, called by us the Universe, a part limited in time and space. He experiences himself, his thoughts and feelings, as something separated from the rest a kind of optical delusion of his consciousness. This delusion is a kind of prison for us, restricting us to our personal desires and to affection for a few persons nearest us. Our task must be to free ourselves from this prison by widening our circles of compassion to embrace all living creatures and the whole of nature in its beauty."

Much the same needs to be done with our collective effort to find a cure for Alzheimer's. We must free ourselves from the prison of the status quo in order to create the possibilities of a different way of growing old.

Thank you.

The CHAIRMAN. Thank you very much, Senator Kerrey.
Ms. Shriver.

**STATEMENT OF MARIA SHRIVER, FIRST LADY OF CALIFORNIA,
CAREGIVER AND ADVOCATE, SACRAMENTO, CA**

Ms. SHRIVER. Thank you.

I would like to thank the Alzheimer's Study Group for their incredible service, and I want to thank the Committee for asking me to come here today, even though I wish I didn't qualify.

Good morning. I am Maria Shriver, and I am a child of Alzheimer's. For many years, my father, Sargent Shriver, would come here to the Hill himself to testify before Committees like this. He came to get increased funding for his beloved Peace Corps and for all the war on poverty programs that he started, including Head Start, VISTA, Job Corps, and legal services for the poor.

My dad was legendary for the way he worked this building. He knew every Senator and every congressman by name. He knew their careers, their interests, their politics, and of course, their soft spots. Sargent Shriver was an idealistic, intelligent, optimistic public servant—sharp, witty, a walking encyclopedia, his mind a beautifully tuned instrument that left people in awe.

That was then. Today, he doesn't even know my name. To be honest, that is still really difficult to wrap my own mind around, but that is the heartbreak and the reality of Alzheimer's. A reality that is terrifying and incomprehensible.

When my father was first diagnosed in 2003, everybody in my family felt confused, powerless, and alone. There was little information and even less hope. My mother, my four brothers, and I felt we were entering a world that was dark, depressing, and scary. When people talked about Alzheimer's, they whispered about it. It was a diagnosis shrouded in shame.

We struggled, like so many families here, with learning about medication and care giving, with issues of our father's diminishing independence, trying to explain to him why he could no longer drive, trying to tell him why he could no longer give speeches about public service.

I know that when many people look at Alzheimer's families from the outside, they see dependent, childlike parents now cared for by their offspring or their loved ones, and it seems so often that the roles are simply reversed. That is not so.

The truth is, no matter what our age, we all feel like children. No matter who you are, what you have accomplished, what your financial situation is, when you are dealing with a parent with Alzheimer's, you, yourself, feel helpless.

The parent can't work. They can't live alone and is totally dependent like a toddler. As the disease unfolds, you have no idea what to expect. As a doctor once said to me, once you have seen one case of Alzheimer's, you have seen one case of Alzheimer's.

In fact, back then, there was so little information about the disease that I wrote a book myself, called "What Is Happening To Grandpa?" At the time, I wrote it to help my children understand what was happening to their grandfather. But in truth, I actually wrote it to explain it to myself.

When I wanted to turn it into a television special, because I was a working journalist, nobody wanted to do it because they said it wasn't a hip enough, big enough disease.

Then almost out of nowhere came what I call the Alzheimer's turning point, when the New York Times reported that the number of people with Alzheimer's was ballooning, rising by 10 percent in just the previous 5 years. They reported, and you have heard some of the figures this morning, that fully 13 percent of Americans had Alzheimer's. That meant that 1 in 8 people over the age of 65, and they said that unless a cure was found, the numbers would balloon by 2050.

That was, I believe, the wakeup call that baby boomers needed. After all, we are the generation who believed our brain span should match our lifespan. But now we are confronted with an epidemic, an epidemic that is not just happening to "those people." It is an epidemic that is happening to us, and we are scared to death.

All of a sudden, it seemed to me that people really started paying attention to Alzheimer's. It became front-page news. HBO came to me at the time and said, "We want to do an in-depth look at this disease, and we want you to be involved." So starting on Mother's Day, May 10, HBO will air the most comprehensive television event ever about Alzheimer's disease. It is called "The Alzheimer's Project."

There will be four broadcasts and a companion book focusing on the cutting-edge science, the issues of care giving, and how one lives with the disease and how it affects children and grandchildren. I am excited to be involved in this project with HBO's Sheila Nevins because I truly believe that it will change the way we look at Alzheimer's, and I think it is time for this attention.

Because fully a third of Americans, and I know many of you, have direct relationship to this disease. Believe it or not, there is about half a million kids, close to half a million kids actually babysitting grandparents at home, more than perhaps are actually babysitting little kids.

Most of the unpaid care giving in this country is being done by women. But luckily, that is also changing. Increasingly, men are stepping up to the plate. Which brings me back to my own brothers, one of whom, Timothy, is here today.

I am in awe of what they and so many of these families do. They take my dad out to Orioles games. They sit and joke with him. They talk "guy talk" to him. They take him to their children's games and their piano recitals.

Or former Peace Corps volunteers and OEO members will come up to him, knowing he has Alzheimer's, and still talk to him and tell him stories. It doesn't matter that he doesn't know who they are. It doesn't matter that he doesn't even remember the Peace Corps. What matters is that he is comforted by the warmth of human connection. I know that for sure.

I also know that, all in all, my family is one of the lucky ones. We are blessed to be able to keep our dad at home. We are blessed to have the resources to pay for patient and loving caregivers, two of whom are here with me today, who help us take care of my father.

But millions of others are not as lucky. Many are forced to quit jobs to stay home or go through the wrenching process of sending a parent away to a facility, feeling judged and mortified and ashamed that they can't take care of their loved one at home.

But for so many of the people in this room, the financial, emotional, and spiritual costs are way too much to bear. My hope is that as the veil is lifted, as information and funds are made available, they will understand that they are not alone and that there is nothing to be ashamed of, and that there is hope out there because we are finally, at long last, making Alzheimer's a national issue.

I believe, and I know many of you share this belief, that we have to put Alzheimer's on the front burner because if we don't, Alzheimer's will not only devour our memories, it will cripple our families, devastate our healthcare system, and decimate the legacy of this generation.

Let me end with my father. At the age of 93, he still goes to Mass every day. Believe it or not, he still remembers the Hail Mary. But he doesn't remember me, Maria. I would be lying if I didn't admit that that still makes me cry.

But even so, in the past 6 years, I have gone from hopelessness to hope. I have hope because things are changing. I have seen intergenerational daycare centers where toddlers and Alzheimer's patients spend the day together. They eat together. They dance together, and they have story time together. It is moving.

I have hope because public hearings like this, high-profile work like the Alzheimer's Study Group and the coverage this is getting, and I hope the television special will take Alzheimer's out of the back room and into all of our living rooms.

Most of all, I hope that this Committee will do the bold thing, the courageous thing, and use the Alzheimer's Study Group report as a blueprint for the real legislation we need to stem the tide of what promises to be a horrific epidemic—the disease itself and its impact on our families and the healthcare system.

I know many of you know someone close to you or maybe even in your own family who is struggling with this disease. I know you have seen the pain and you have watched in the eyes of someone who sits powerlessly as their loved one dies on the installment plan. That is why I know you will have the courage to do the right thing. Make no mistake, I know it will take courage to implement some of these bold recommendations.

But I know for sure that if you do make that major commitment to the brilliant scientists like the ones I have met in laboratories across this country, they will produce the drugs to slow Alzheimer's down and maybe even prevent it.

So I hope you will get busy right now and do what we have to do to spare millions of Americans the future and the pain of watching someone they love and feeling powerless. If you do, I am convinced, truly convinced that we baby boomers will be the generation who gets to tell our grandchildren that, believe it or not, there once was a time when there was no cure for Alzheimer's.

Thank you. [Applause.]

[The prepared statement of Ms. Shriver follows:]

**Maria Shriver
TESTIMONY
3-25-2009**

I'd like to thank the Alzheimer's Study Group for their service -- and the committee for asking me to speak here today -- even though I wish I didn't qualify.

Good morning. I'm Maria Shriver -- and I am a child of Alzheimer's.

For many years, my father, Sargent Shriver, would come here to The Hill HIMSELF to testify before congressional committees. He came to get increased funding for his beloved Peace Corps -- and for all the War On Poverty programs he started, including Head Start, Vista, Job Corps, and Legal Services for the Poor.

My father was legendary for the way he worked this building. He knew every Senator and Congressman by name. He knew their careers, their interests, their politics . . . AND their soft spots.

Sargent Shriver was an idealistic, intelligent, OPTIMISTIC public servant -- sharp, witty, a walking encyclopedia -- his MIND a beautifully-tuned instrument that left people in awe AND inspired.

That was then . . . TODAY he doesn't know my name or who I am. To be honest, that's still really difficult to wrap my OWN mind around. But that's the heartbreak and the REALITY of Alzheimer's. A reality that's terrifying AND incomprehensible.

When my Dad was first diagnosed in 2003, I felt confused, powerless, and alone. There was little information -- and even less HOPE.

My mother, my four brothers and I felt we were entering a world that was dark, depressing, and scary. People didn't TALK about Alzheimer's -- they WHISPERED about it. It was a diagnosis shrouded in shame.

We struggled with learning about medication and care-giving -- with issues of our father's diminishing independence. Trying to EXPLAIN to him why he could no longer drive. Trying to TELL why he could no longer do many of the things he loved MOST in this world, like giving speeches about public service. When the invitations came in, we'd just send his regrets.

I know that when people look at Alzheimer's families from the outside, they see the dependent, childlike PARENTS now cared for by their OFFSPRING -- and it seems that the roles are simply REVERSED. Not so.

The truth is, no matter what our age, we feel like CHILDREN. No matter who you are, what you've accomplished, what your financial situation is -- when you're dealing with a parent with Alzheimer's, you YOURSELF feel helpless.

The parent can't work, can't live alone, and is totally dependent, like toddler. As the disease unfolds, you don't know what to expect.

As a doctor once told me, "Once you've seen one case of Alzheimer's . . . you've seen one case of Alzheimer's."

In fact, back then, there was so little information about the disease that I wrote a book myself, called, *"What's Happening to Grandpa?"* At the time, I said I wrote it to help my children understand what was happening. In truth, I wrote it to explain Alzheimer's to myself.

But when I wanted to turn it into a television special -- to shine some light on this subject -- no one was interested. I was told Alzheimer's wasn't BIG enough -- it was just "an old person's disease".

As my father's situation deteriorated, my brothers and I felt we wanted to do something that captured who our father was and told his story.

Along with the Chicago Video Project, I executive-produced a film called "The American Idealist", about his life and legacy in government -- so that people would remember his intellect, energy and passion -- even if HE couldn't.

Then almost out of nowhere, came what I call The Alzheimer's Turning Point. It happened in March, 2007, when the New York Times reported that the number of people with Alzheimer's was **BALLOONING** -- rising by 10% in just the previous five years. They reported that fully 13% of Americans had Alzheimer's -- that meant one in EIGHT people over the age of 65. And UNLESS a cure were found, there would be more than 13 MILLION people with Alzheimer's by 2050. The number, as you've heard this morning, has been revised even further upward since then.

THAT was the wakeup call Baby Boomers needed. After all, WE'RE the generation who believed our BRAIN-span would match our LIFE-span.

But now we were confronted with an EPIDEMIC -- an epidemic that wasn't just happening to "THEM". An epidemic that would happen to "US", too. And that scared us to death.

All of a sudden, it seemed to me that people REALLY started paying attention, and Alzheimer's became front-page news.

And that's when HBO came to me and said, "We need to take an in-depth look into Alzheimer's disease, and we want you to be involved."

So, starting on Mother's Day, May 10th, HBO will air the most comprehensive television event ever about Alzheimer's disease. It's called the Alzheimer's Project. There will be four broadcasts and a companion book -- focusing on the cutting-edge SCIENCE -- the issues of CARE-GIVING -- how one LIVES with the disease -- and the CHILDREN AND GRANDCHILDREN of Alzheimer's.

I'm excited to be executive producing this project along with HBO's Sheila Nevins -- because I truly believe it will change the way we look at Alzheimer's.

It's TIME for all this attention. Fully a THIRD of Americans now have direct experience with this disease. People come up to me all the time to ask for advice and guidance.

And believe it or not, there are getting to be almost as many kids actually "babysitting" a grandparent with Alzheimer's at home -- as are babysitting for little kids. THAT'S where we are.

Of course, most of the unpaid care-giving is done by women -- but luckily, THAT'S also changing. Increasingly, men are stepping up to the plate.

Which brings me back to my brothers. I'm in AWE of what they do. My brothers take my Dad out to the Orioles games. They sit and joke with him, talk guy-talk to him. They take him to their kids' piano recitals and basketball games. Former Peace Corps volunteers will see him, know he has Alzheimer's, and still come up to him. They take his hand, and tell him stories.

It doesn't matter that he doesn't know who they are -- or that he doesn't even REMEMBER the Peace Corps. What matters is that I know for sure he's comforted by the warmth of the human connection.

I know that all in all, my family is one of the lucky ones. We're truly blessed we're able to keep our Dad at home.

We're blessed to have the resources to pay patient and loving caregivers, who help us take care of our Dad and make him feel loved. I'm in awe of THEM, too.

But millions of others aren't as lucky. Many are forced to quit jobs to stay home -- or go through the wrenching process of sending the parent away to a facility -- feeling judged and mortified and ashamed that they can't care for their loved one themselves. For so many, the financial, emotional, and spiritual cost is just way too much to bear.

My hope is that as the veil is lifted, as information and funds are available, they'll see that they're not alone -- that there's nothing to be ashamed of, that there's hope out there, because we're FINALLY making Alzheimer's a national issue.

We HAVE to put Alzheimer's on the front burner, because if we DON'T, Alzheimer's will not only devour our memories -- it will cripple our families, devastate our health care system, and decimate the legacy of our generation.

But let me get back to my father. At the age of 93, my Dad still goes to Mass every day. And believe it or not, he still remembers the Hail Mary. But he doesn't remember ME ... Maria. I'd be lying if I didn't admit that that STILL makes me cry.

But even so -- in the past 6 years, I have gone from hopelessness to HOPE.

I have hope, because things are CHANGING out there:

I've seen inter-generational day care centers -- where toddlers and Alzheimer's patients spend the day together. They eat together, they dance together, and have story-time together. It's quite moving to behold.

And we're building inter-generational PLAYGROUNDS in California, so Sandwich Generation people like ME -- who are taking care of kids AND parents -- can go to one place with both of them.

I've ALSO gotten hope from my OWN children. I watch how they talk and laugh with my father. They don't get bogged down in the sadness. My kids and my nieces and nephews ALL accept my Dad for who he is today -- and that's been a lesson for me.

I have hope because public hearings like this -- high-profile work like the Alzheimer's Study Group report -- the coverage we'll get today -- and the TV shows and books we're doing ... are bringing Alzheimer's out of the BACK room and into the LIVING room of our nation.

And most of all, I have hope that this committee will do the BOLD thing, the COURAGEOUS thing -- and use The Alzheimer's Study Group's report as a roadmap for the real legislation we need, to stem the tide of what promises to be a horrific epidemic -- the disease itself, AND its impact on our families and our health care system.

I know many of you know of someone -- or even know someone CLOSE to you -- who's struggling with this disease in their family. I know you've seen the pain in the eyes of someone who has to watch powerlessly as it takes their loved one down ... and sometimes even tears at the fabric of the family itself.

That's why I know you'll HAVE the courage to do the right thing. And make no mistake, I know it'll TAKE courage to implement some of these BOLD recommendations.

But I know for SURE that if you MAKE that major commitment to brilliant scientists like the ones I'VE met in laboratories around the country -- they WILL produce drugs to slow Alzheimer's down -- and maybe even prevent it.

So let's get busy NOW and do what we have to do -- to spare millions of Americans in the future the PAIN of watching someone they love die a mysterious death on the installment plan.

If we DO -- I am convinced -- TRULY convinced -- that we Baby Boomers WILL be the generation who tells our GRANDchildren . . . that believe it or not, there ONCE was a time . . . when there was NO cure for Alzheimer's.

Thank you.

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The CHAIRMAN. Thank you, Ms. Shriver.
Mr. Butcher.

STATEMENT OF LARRY BUTCHER, CHAIR, BOARD OF DIRECTORS ALZHEIMER'S COMMUNITY CARE, WEST PALM BEACH, FL

Mr. BUTCHER. Thank you, Chairman Kohl.

The CHAIRMAN. Tough act to follow, Mr. Butcher. We will give you a lot of leeway. [Laughter.]

Mr. BUTCHER. It is a tough act to follow, sir.

Chairman Kohl, I thank you and Ranking Member Martinez this morning and the other members of the Committee, for the opportunity to be here.

My name is Larry Butcher. I live in Stuart, FL. I speak to you today as the husband and caregiver of my wife, Jeannette. She was diagnosed with Alzheimer's at the young age of 55. Since then, she has suffered just about every one of the disease's cruelties. She is now bedridden and in the care of hospice.

I also speak today as board chair of Alzheimer's Community Care, a remarkable, community-based provider of care and support for Alzheimer's patients and their families in Palm Beach, Martin, and St. Lucie Counties in Florida. There is nothing else around quite like it, and Mary Barnes, Alzheimer's Community Care's founding CEO, is the reason why. She is here with us today.

The organization's success has drawn State and national attention, including the National Institutes of Health, the National Library of Medicine, which piloted an information outreach program with us.

Jeannette and I recently celebrated our 48th anniversary. She didn't know it, and she doesn't know me. This vibrant and loving woman once thrived on motherhood, family, and our community. She was full of life, and our good future was ours for the taking.

If I might, sir, my oldest son from Tampa, FL, happened to be in town for other business, and he joined us here in the room this morning. I am really pleased with that.

Once she was afflicted, though, the good judgment I had relied upon vanished. She became angry, belligerent, a very different person. Erratic and full of rage and resentment, Jeannette seemed as much possessed as diseased. I really felt like a bystander at a car wreck. Good information was very difficult to find. Her doctor gave me very little support. I guess he felt that wasn't his job.

Pieces of my heart broke every day as our future as husband and wife dissolved. Eventually, the only emotions we shared were depression and fear. Then almost by accident, I heard about Alzheimer's Community Care. Jeannette entered one of their day programs, and we have been in the embrace of the wraparound model of family care ever since.

Speaker Gingrich's report reads like the operator's manual for Alzheimer's Community Care. The study describes what we already do. Your care manager nurse is our family nurse consultant. An R.N., she is my friend, my advisor, my guide, and sometimes my therapist. She is our integrator of specialized care, the one person who connects all the dots between Jeannette's care, my needs, and

the available services. She remains a steadfast advocate for our best interests.

Our nurse consultant pushed me through the door into an Alzheimer's support group, where I discovered I was not alone. Here, I found the smarts to make some of the hard decisions like taking away car keys, protecting her from wandering, and tips on daily details of care at home.

I learned this was a long, hard haul, that I would need all the physical and emotional stamina I could muster. They sure got my attention when they told me that Alzheimer's caregivers are at risk of dying sooner than caregivers of loved ones with other killing diseases. I vowed not to be one of them.

The need for caregivers and support is huge. Experts say that in our State of Florida alone, Alzheimer's and related disorders afflict more than 800,000 people. There is an estimated 107,000 people in our three-county service area. For each one, there are 19 others affected. Do the math. The numbers are absolutely astounding.

No entity is prepared to take it all. ACC is but a single dim light in a bleak landscape. We have 11 daycare programs that are scattered across three counties. We lease neighborhood church fellowship halls where the at-home setting, the spirit, and the rent is right for our purposes.

Most caregivers work. So we are open 10 hours a day, Monday through Friday. Nurses and nurse assistants staff each site, a ratio of about 1 to every 5 patients. With volunteers, the ratio drops to 1 in every 3 patients. Our results are unmatched. Caregivers live longer. Hospital stays are far less than traditional Government-funded models, and the need for medications for patients is lessened.

ACC's model is cost effective, just under \$1,500 a month. By contrast, conventional institution care pushed \$5,000 a month or more. We are the most significant stakeholder in our service area. Our annual education conference draws 600 attendees, and they tell us the ripple effect is improving dementia care across the region.

Still, it comes down to people just like Jeannette and me. Before we found ACC, we were frightened and full of pain, but that has been lessened. Though our destination remains certain and unforgiving, we approach the end blessed with lives filled with quality, dignity, and love. There is no cure for Alzheimer's disease, but we believe we have found the cure for despair.

I want to thank the Committee for allowing ACC's light to shine a little bit brighter today. If you decide to see what the study group's ideas look like in action, come see for yourselves. Alzheimer's Community Care is really where the rubber hits the road.

Thank you. [Applause.]

[The prepared statement of Mr. Butcher follows:]

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United States Senate
 Special Committee on Aging
 Wednesday, March 25, 2009
 Testimony Presented By
 Larry Butcher, Chair
 Prepared By
 Mary M. Barnes, President and CEO
 Alzheimer's Community Care, Inc.

Thank you, Senator Herb Kohl, Senator Mel Martinez, and your distinguished committee and panel of caregivers. As an American I could not be prouder that we are discussing the growing crisis that Alzheimer's disease poses to our nation.

It has only been these past 15 years that Alzheimer's disease and the related disorders have been acknowledged as debilitating diseases that affect two people – the caregiver and the person who is diagnosed.

In the state of Florida, which is my family's home, it is projected that there are in excess of 500,000 patients diagnosed with Alzheimer's disease. When the other related disorders are factored, in such as Lewy Body Disease, Pick's Disease, Vascular Disease and Parkinson's, that number climbs to over 800,000. In our service area that encompasses Palm Beach, Martin, and St. Lucie counties, the projected number of patients suffering with Alzheimer's disease or a related disorder is over 107,000. For every person diagnosed 19 people in the community are affected.

When my loving wife of 35 years, Jeannette, was diagnosed with a strain of Alzheimer's disease at age 55, it quickly made her a different person. Before the affects of the disease took hold, she thrived on being a mother and an active community leader. She turned into someone who was angry, belligerent, had no sense of judgment, and was resentful of me. This was heartbreaking at the time, because I was not aware of all the emotional aspects of the disease process. I continued to believe it was my fault that she was acting out the way she was. Her doctor gave me very little support. She progressed quickly and we both became very depressed. At the lowest ebb of my life, by accident I found Alzheimer's Community Care and immediately became enveloped by their "model of care."

The Family Nurse Consultant became my best friend; the study calls her a care manager nurse. As a registered nurse certified in dementia specific care, she is well aware of when a disease is evident and is the integrator of specialized care that administers support, guidance, and advocacy throughout all stages of the disease. Every service and resource, including

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support groups, was instrumental in providing me with the knowledge, strength and stamina to make the hard decisions when it was necessary, such as taking away the car keys early; 60% of patients will wander at least once during the disease process. Removing the keys was for her safety. These resources also taught me the importance of taking care of myself; 63% of Alzheimer's disease and related disorders caregivers are at risk of death before other caregivers. Because of their commitment and services to me I became a volunteer and an advocate for the organization and now proudly serve as the Chair of the Board of Directors.

Alzheimer's Community Care is unique and unlike any other organization in the country. The mission of Alzheimer's Community Care is to promote and provide specialized quality compassionate care to Alzheimer's disease and related disorders patients and caregivers within a community-based environment. They are where "the rubber hits the road" and innovation is their hallmark.

Traditional funding for services under the Older Americans Act is for persons 60 years of age or older which is limiting to the point that it is not disease specific nor is this considered a resource for patients diagnosed at a younger age. As diagnostic capabilities become more sophisticated, and with an estimated 10 million baby boomers developing the disease in their lifetime, the impact of Alzheimer's disease is of significant concern and one which Alzheimer's Community Care is prepared to embrace.

Alzheimer's Community Care is one such organization that works with both the patients and caregivers, from the initial indication of dementia, referrals for appropriate medical diagnosis, and planning and assisting with the patients and caregivers every step of the way. Patients are being diagnosed at a younger age and caregivers have had to adapt to their changing roles and relationships without forewarning or preparation. All staff of Alzheimer's Community Care is trained and receives dementia certification. Community resources used in the provider network and through information and referral must meet standards of practice for dementia care. Alzheimer's Community Care has included cognitive screenings and measurements in their assessment tools recognizing that assessment forms used in aging programs generally concentrate only on the physical deficits in the aging process. The cognitive assessment includes the Mini Mental State Examination, safety concerns - wandering and Alzheimer's proofing the home, financial planning, specialized disaster preparedness, and legal issues, such as living will and advanced directives. Also used during the assessment process is the Caregiver Strain Index that assists both the Family Nurse Consultant and the caregiver to determine the level of caregiver burden and the appropriate mode of service to assist with caregiver relief.

Alzheimer's Community Care's "Model of Care" provides therapeutic interventions targeted at community-based services by well trained staff during the continuum of the disease process. Community partnerships and collaborations have been beneficial with successful outcomes. Training with law enforcement for appropriate recognition of signs of Alzheimer's disease diminishes inappropriate interpretations of behavior and prevents unsuitable incarceration. The specialized Alzheimer's day services provided by Alzheimer's Community Care have been proven to reduce health care costs by providing health care monitoring, preventative health care, and timely provision of primary care.

The findings in an independent evaluation conducted by the University of South Florida regarding the Florida Medicaid Alzheimer's Home and Community-Based Waiver Program, which Alzheimer's Community Care is one of three participants in the state, reported the

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program is an effective resource for caregivers to Medicaid recipients, improved their personal quality of life and delays institutionalization for the patient. The report concluded that overall the Medicaid Alzheimer's Program represents a multi-service intervention that targets not only the problems of the Medicaid recipient with Alzheimer's disease (e.g., medication use, wandering, provision of stimulation and social contact), but also the problems and issues faced by the caregiver (need for general assistance in care provision, respite, information about the provision of care to an individual with Alzheimer's disease, etc.). The results demonstrate that a specialty program such as the Alzheimer's waiver program can have a positive impact on the well-being and trajectories of enrollees with Alzheimer's disease and their caregivers.

Caregivers and families express a high satisfaction with service provision. Service providers are trained and resourceful on dementia specific needs and their delivery of those services and resources applies to the ever changing needs driven by stages of the disease's progression.

Alzheimer's Community Care has established 11 specialized Alzheimer's day care service sites, 8 of which operate in church fellowship halls and 3 in other community based settings. We sponsor an annual Alzheimer's educational conference that brings national, state, and local presenters to speak on research, care techniques, legal, and safety issues. Last year, of the 534 attendees half were caregivers. We are projecting over 600 attendees this year.

In our service area, over 167 cultures are represented, all of whom have needs for our services. Hispanics will exhibit the symptoms of Alzheimer's disease 5 to 8 years sooner than Caucasians. Recognizing this need, Alzheimer's Community Care has operated a Spanish speaking specialized Alzheimer's day care center for six years. African Americans will suffer longer with vascular dementia because of complications from co-morbid illnesses, such as hypertension and diabetes. 55% of all caregivers who have their loved ones in our 11 specialized service sites are employed. On average the day care centers operate for 10 hours each day to accommodate working caregivers. We provide a staff to patient ratio of 1 to 5. With volunteers it is 1 to 3. The longevity of caregivers has increased and both caregiver and patient hospital stays are far less than other traditional government funded models of care. Institutionalization is delayed for 2 to 4 years and many never require placement.

The average cost of this service is under \$1,500 monthly. Institutional care is \$4,000 to \$5,000 monthly.

Alzheimer's Community Care is our community's stakeholder.

I am a living testament of this model of care provided by Alzheimer's Community Care. It is not the retirement years that I had envisioned for myself and the love of my life, Jeannette, but I now have a quality of life that allows me to live in dignity as well as oversee and be a part of her care with the knowledge that I am doing the right thing each step of the way. I have not been relieved of my pain, but it is being shared with those who truly care, who understand, who are knowledgeable and compassionate so I am not isolated or ever alone.

Thank you for allowing me to give my personal testimony on behalf of a model of care that needs to be made available to the millions of others that cope every day with Alzheimer's disease and the related disorders throughout our great country.

The CHAIRMAN. Thank you very much, Mr. Butcher.

Speaker Gingrich and Senator Kerrey, could you tell us a little bit more about the study group, how it has been functioning? How many members do you have, and what are your most promising recommendations?

Mr. GINGRICH. OK. Well, the actual members of the study group are Dr. Christine Cassel, who is the Geriatrician and President of the American Board of Internal Medicine; Meryl Comer, who is President of the Geoffrey Beene Foundation Alzheimer's Initiative; Steve Hyman—Dr. Steve Hyman, provost at Harvard University; Henry McCance, who is the Chairman of Greylock Partners; Dr. Mark McClellan, Director of the Engelberg Center for Healthcare Reform at Brookings; Justice O'Connor; James Runde, who is a Special Advisor at Morgan Stanley; Dr. David Satcher, Director of Center of Excellence on Health Disparities at Morehouse School of Medicine; and Dr. Harold Varmus, President of Memorial Sloan-Kettering Cancer Center.

So that is the core group that met regularly and worked on this project together, along with Senator Kerrey and myself as the co-chairs. It was funded from a variety of sources. I should say that Booz Allen Hamilton and Susan Penfield in particular gave us extraordinary support as part of their commitment to this. They used their models of how you structure large intellectual projects in a way that I think Rob Egge would tell you was very helpful.

The Center for Health Transformation provided the basic staff and provided housing for the project. Most of our meetings were there. The Vradenburg Foundation, as I said earlier, was invaluable. Alzheimer's Association was invaluable. The Dwyer family, Pfizer, McCance Foundation, and Wyeth were all very, very helpful.

More than half the funding came from nonprofits, and no funders received any particular input or access compared to anybody else. Our primary model, again with the guidance from Harry Johns and from George Vradenburg, was to reach out to the scientific community, and I must say that Justice O'Connor arranged for some meetings in Arizona that were very impressive, where they have a very substantial State-level commitment in research.

We were trying to find whether or not you could create a common understanding of the potential for a breakthrough, and then, second, led by Meryl Comer and others, we were looking at what can you do to dramatically improve the way in which Alzheimer's in the interim is dealt with by the Government and dealt with by the private sector.

I think both the testimony of Larry Butcher and of Maria Shriver gave you some sense. We both need improvements in the short run, and then we need breakthroughs in the long run to change it. That was our focus, but Senator Kerrey may want to add to that.

Senator KERREY. Mr. Chairman, the report has a number of recommendations. I would actually focus on almost two sides of it, and again, to repeat, you have to believe that there is a case here, that this disease is different. It is a different kind of disease, that the implications are different than other diseases.

You do have to believe that, at the very least, the onset can be delayed and connected on such that a real savings occur on the public side if you accomplish that objective.

I happen to believe that it could be prevented, that a project that had that as an objective could, over a relatively short period of time, prevent the onset of the disease itself. But you have to have that underlying belief. Otherwise, it is very difficult to get anywhere with it.

I happen to have that belief. With that, I would respectfully say to the Committee, focus on two sides of the problem. One is the prevention effort itself, and the other is the care. So on the prevention side, we are recommending the creation of a projection office with a CEO and resources.

I will leave it to you to decide where it belongs and how to make certain that the overhead is as low as possible, that the incentives are there to create the public-private partnerships, that the incentives are there to bring other areas of the Government, whether it is NIH or NSF or other entities, bring them into it as well.

But unless it has not just authority, but funding, it is going to be exceptionally difficult to get the job done. There are a number of things beyond that that we are recommending. There is a need to clarify and accelerate the development pathway for preventive and risk-reducing strategies. There is a need to expand the pool of volunteers that are willing to be a part of these therapeutic tests.

There is a need to encourage very rapid learning, and we are recommending the linking of databases as well as the linking of researchers in this effort. So there are a number of things on the research side that we are recommending that we think will both increase the chances that the onset is delayed or increase the chances that prevention itself is ultimately achieved.

On the care side, Mr. Chairman, you heard Justice O'Connor make this point. Unfortunately, under the Medicare and Medicaid system, but primarily Medicare we are talking about here, the reimbursement is done on a fee-for-service basis. What that means is there is an incentive to oftentimes do the thing that the patient doesn't need.

Lots of individual services, the higher your income—the more visits you make, the higher your income. The less amount of time you spend with a patient, more likely it is that your income is going to be higher if you are the provider, whereas, oftentimes, what the patient needs is just the opposite—a longer amount of time on task.

What Larry Butcher is describing is exactly what we envision with our recommendations, and specifically, what you could do is ask CMS to do some pilots. To first consult with the community to find out how they measure quality and then try to get reimbursements out there that achieve that. Do a few pilots, and where the pilots work, then aggressively implement where the success occurs.

The CHAIRMAN. Thank you so much.

Senator Martinez.

Senator MARTINEZ. Mr. Chairman, thank you. Thank you, sir.

You have spoken about the disease being different, and as someone who is fairly new to understanding this, how do you mean it

is different, and what are the implications of that difference as it relates to policy?

Senator KERREY. The three differences, actually two differences of the disease and the other one is just a demographic fact. We are all getting—we are living longer.

So the two big differences are it leads to dependency, near total dependency and significant dependency. It is not just I have lost one activity of daily living. I have to be supervised. I need somebody providing direct care. It is 100 percent.

In most other diseases, that isn't the case. You have limitations. When you are going through treatment, you have limitations oftentimes as a consequence of what the disease is doing to your body. It doesn't produce that certainty of dependency.

The dependency is connected to the public programs that we have in place, Medicare and Medicaid. The cost of providing the dependent support, even when it is done incorrectly, as I think as the current rules of Medicare provide oftentimes incorrect kinds of reimbursement. So that is the first substantial difference, it seems to me.

The second is though it is not a normal process of aging, there is a correlation. Nearly half of everybody over the age of 80 will get this disease. So that correlation with the third one, which is the demographic, which is we are all getting—we are living longer, creates, I think, a different set of circumstances.

But again, you have got to believe, and I do, when you listen to the scientific community that if we organized ourselves differently that, at the very least, we could prevent the onset. What Speaker Gingrich said earlier is very important as you are making this case. You can produce almost half the savings just by delaying the onset 5 years. There is very little dissent on the question of whether or not that can be accomplished.

Senator MARTINEZ. What would be the key—please.

Ms. SHRIVER. Could I just add something? When you talk about differences, I think when you talk about cancer and diabetes and many other diseases that come before you, there are survivors. There are—with Alzheimer's, there are no survivors. There is nobody walking around in remission. There is nobody who gets a diagnosis and then goes back to work and thrives.

Alzheimer's not only affects the person who is diagnosed, and very often there are people who are diagnosed well before they are 80. They are in their 60's, many of whom are here today, in their 70's. They not only have to quit their job. Their children have to quit their jobs to take care of them, the loss of income.

There is no knowledge about how to take care of them. The entire family is totally involved in this disease. It is like everybody has it. So it is completely different. You don't even—at these marches, you don't see survivors walking around. I think that is the big difference.

When Senator Collins was talking about tax breaks for caregivers, I think if you talk to all the people here or many of the people in this country who are caregivers, that is welcome news. But everybody will talk to you that they do believe that funding of the research, streamlining the process and funding of these scientists

is the only answer because it is not what we eat. We are not going to be able to do enough crossword puzzles.

People who get this disease, like my father was one of the smartest human beings on the planet. So we don't even know what causes it, what we can eat to prevent it. When someone gets it in your family, the whole family starts going this way.

Senator MARTINEZ. There are health disparities in our country, and I know one of the members of the commission apparently has expertise in this area. I didn't see anything in the report relating to disparities by ethnicity or race. Is there anything you can share with us about any findings along those lines?

Mr. GINGRICH. I think that we made a conscious decision—and Dr. Satcher may want to comment or may want to supply more material later. Our commitment is that if we can find a way to have the breakthrough, that it ought to be a breakthrough for 100 percent of all Americans.

I think the impact of this disease today, partly because of the difference in how many people live to certain ages, I don't think you have the same pattern of disparity. This is a disease we, frankly, don't understand why it hits people the way it does, and it seems to hit people across the board of all ethnic backgrounds.

I think that our goal is to find a breakthrough in such a way that you would apply that breakthrough to everybody across the whole country, and I don't know any other way to approach it.

Senator MARTINEZ. Mr. Butcher, I just wanted to ask if there was anything you can share with us about what is available in the way of services that you have found particularly helpful, valuable? Then the opposite of that, which is what would you say is the most needed service that is not available?

Mr. BUTCHER. Thank you, Senator Martinez.

I think the idea of a family nurse consultant or the nurse care manager is probably one of the most effective things that we can do. It seems that when you go to the doctor and you get a diagnosis, the major problem that most of the physicians have, neurologists and so on, the caregiver is going to ask, "OK, now what do I do?" Many times, that doctor is going to say, "I don't know." Because it has been mentioned here, there is no effective treatment. The disease process may be from 2 to 20 years. Many of those people in the middle stages of the disease are going to require someone to be with them 100 percent of the time.

I had the experience in the moderate portion of my wife's disease where she would go to the freezer and take something out of the freezer and take it in and put it in her lingerie drawer. I better be watching, or I am going to have a problem in the house.

The wandering of those patients. They require someone with them 100 percent of the time, and that is unlike many other diseases. If we look at heart disease, if you are diagnosed with heart disease, there is a protocol that you go into, and the doctors are going to send you into that protocol.

If you have cancer, there is a protocol that you go into, and the doctors are going to send you into that protocol. As was mentioned, there are some cures out of that. There are people walking around surviving that. With Alzheimer's disease, there is no protocol. There is no pattern.

So what we are looking at is the only thing that we know how to do in our area right now is provide care for the patient as much as we can through the family nurse consultant and also give the caregiver the support that we can through the support groups, through advice where the resources are.

I think that is the positive and the lack of those services is the negative.

Senator MARTINEZ. Thanks.

The CHAIRMAN. Thank you very much, Senator Martinez.

Senator McCaskill.

Senator McCASKILL. Thank you, Mr. Chairman.

I would like to try to focus on some of the pragmatic recommendations, the challenges pragmatically with some of the recommendations that you have made. There are some bold recommendations here. I think creating a joint Committee with unique authorizing and appropriating authority. I mean, the building is shaking with those words being said out loud, and I know that both the Speaker and Senator Kerrey appreciate how bold that particular recommendation is in the reality of Congress and how it operates.

I would like to talk about the money. In the recommendation, you talk about a logical upper bound for an investment budget. What is that? In terms of the scientific community being able to swallow in a way that is efficient and effective, what is the upper bound of investment that would be necessary if we were going to do a cost-effective approach by realizing that what we invest now is going to save big-time public dollars 10, 20, 30 years down the line?

Mr. GINGRICH. Let me take a first stab at it, and let me say—and Senator Kerrey can either dissociate himself if he wants. One of the reasons that he and I wanted to put in the joint Committee idea is to raise tentatively the notion with our former colleagues that the Congress is in as deep a need to rethink how it operates as the executive branch, and it is much harder because the Congress would have to operate on itself.

It is quite cheerful about reorganizing the executive branch. Much harder to get the Congress to rethink itself. I think we both thought this was a legitimate opportunity to just gently raise that notion as a general principle.

What I would encourage you to do—and we have not done this yet. But what I would encourage you to do is to actually ask the scientific community to develop a strategic architecture for research in the neurosciences and in particular in Alzheimer's.

The reason I suggest that is that if you look at how the one group that does this pretty well are the astronomers because astronomy is such a very expensive system that they actually get together on a regular basis and talk about what should be the roadmap for astronomy because they know there are going to be very big, very expensive projects. They have huge intramural fights over what should you focus on.

Our proposition is slightly different than that. I would argue that this is much more like the World War II use of science. We made enormous strides in 4 years. The entire war for us is 3 years and 8 months. The speed with which we developed, for example, at the

radiation labs at MIT or in the Manhattan Project or in a variety of other places, we really moved ideas, and we really moved science very fast.

Because we didn't say to the scientists, "Here is your annual budget." We said to the scientists, "Tell us what you are trying to achieve. Tell us the resources you need to get it done. Now go do it."

I would suggest if we went out—and particularly because if you really want to build a momentum of research, you are talking about graduate students. You are talking about people who decide this is their career. So annual budgeting is a terrible way to do science because it sends exactly the wrong signals.

So, I would urge you to actually challenge the scientific community to come back with a science-led budgeting proposal, which would be very daring and very different. Then particularly, I would urge you to appeal to scientists under 40. It is quite clear, if you read Kuhn's "The Structure of Scientific Revolutions," that very often the next generation of scientists—and this is part of the challenge of peer-reviewed application is that the very people most likely to have bold, breakout ideas are the least likely to get through a peer review process.

You can see this, for example, with Einstein, who clearly—who himself said if he had ever been on a faculty, he never would have come up with relativity because it would have been socially so unacceptable. Only the fact that he couldn't get a job as a teacher and had to work as a clerk at the Patent Office gave him the freedom to actually think up one of the two greatest revolutions in physics in the 20th century.

So what I would ask you to do is you all have the status, you could literally ask—and we would be glad to help organize it—for a group of scientists to come in as a panel and present you with a very bold proposal for how one might finance and structure science.

Senator McCASKILL. So, basically, what you are saying is the NIH model is not going to cut it as it relates to researcher based, as opposed to, "Here is the problem. What do you need? Go."

Mr. GINGRICH. Yes, we are saying two things. The first is you ought to measure the amount of money to be spent on Alzheimer's research against the \$20 trillion you are going to spend. Therefore, you would spend vastly more than you are spending right now.

The second is that you ought to do it in a directed way with a multi-year plan because you want to build the momentum, which is antithetical to the NIH current model.

Senator KERREY. I will attempt to get my talk button on and add simultaneously two things. One is that the recommendation for a joint authorizing appropriation Committee actually was a bit connected, more than a bit, was connected to the experience of the 9/11 Commission, where what we saw was very difficult oversight process, to put it in gentle terms, if not a dysfunctional oversight process.

So I appreciate how difficult it would be to vote on something like that, but I felt and Speaker Gingrich agreed that changing that oversight process is a very important thing to do. For those few brave souls in the Congress willing to be advocates of it, they

need some outside validators who are willing to validate that that is an essential part because there isn't a silver bullet here. There isn't one thing that you can do in this congressional session that is going to solve the problem.

It is going to require the kind of oversight that we are seeing here today, where there is good attendance at the meeting, there is a lot of people in the room. There is a lot of attention being done to it, but this Committee doesn't have the kinds of authority that it needs, frankly, it seems to me.

So I will just leave that one out there because it is not a small recommendation. I know it is a difficult recommendation to give to Congress, but I think it would provide tremendous change not just for the way we would analyze Alzheimer's, but in many other areas as well.

Secondly, spend some time looking at the difference between a project model, which is what we are recommending, and a traditional NIH or NSF or other model, where you go in and try to get a peer-reviewed grant approved. A project model means you have got to have a project director with authority and resources to manage that project, as we did with the Genome Project.

There is some controversy on that, but in my view, it is just a difference of opinion. You will have a number of people who will say you shouldn't do it that way, and that is up to you. You have got to make that decision. I don't know how you get from where we are to where we could be, let alone where we ought to be, unless you organize it as a project-based effort.

Thank you.

Senator McCASKILL. Thank you.

Thank you, Mr. Chairman.

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

Senator COLLINS.

Senator COLLINS. Thank you. Thank you, Mr. Chairman.

Speaker Gingrich, just yesterday I met with a group of neurologists from Maine, and they talked to me about the need to have a patient-centered reimbursement system under healthcare rather than a procedure-centered system. Justice O'Connor, in her testimony, made exactly that point that Alzheimer's patients don't need a lot of procedures, but they need time with their healthcare providers. They need counseling. They need advice, as do their family members.

Senator Kerrey also referred to a recommendation in this area. It is my understanding that one of the major recommendations that the study group has come up with is the need to develop what you are referring to as "value-based payments." That sounds very similar to what the neurologists were talking to me about patient-centered care rather than procedure-centered care.

Mr. Speaker, could either you or Senator Kerrey or Justice O'Connor expand on what you envision when it comes to value-based payments?

Senator KERREY. Well, first of all, I would recommend that if you have an interest in this to call Dr. McClellan up at some point to have him talk you through this because he started doing this when he was the director of CMS.

What it requires is either you directing CMS to do it or CMS working with you to get it set up, but it requires pilots. The pilot begins with a conversation to assess what are the quality measures? How do you measure quality?

Then you set the pilot up based upon reimbursing for quality rather than reimbursing for procedures or visits. As I said, the current fee-for-service not just in this areas, but in lots of other areas as well, you have got a problem in that the system tends to reimburse for care that is different than what the individual patient actually wants.

So I would talk to Dr. McClellan about it because he has a lot of experience in this area, and I think it has a tremendous amount of opportunity because the community is saying this is what we want. In many cases, you don't find that. In this case, the community is saying identify what the quality issues are and reimburse based upon quality.

There are number of other things, Senator, that I think you have got to have if you are going to be able to have an impact in this area. I do think electronic medical records are a key part of it. It is very difficult to coordinate care unless you have it. Very, very difficult, in my view, to get to where you need to be unless you have that kind of electronic medical system because people are just getting lost.

I mean, there is a very large number of people with Alzheimer's that haven't even been diagnosed with it. There is no record of the fact that they have got it, and those where the diagnosis occurs, the records are not connected. You don't know where they are, and it produces a tremendous problem for the research community because they simply are unable to put together the groups that they need to try something out, to test something to see whether or not an idea, a procedure that they have got in mind will work.

Senator COLLINS. Thank you.

Yes, Mr. Speaker?

Mr. GINGRICH. Can I build on that very briefly? First of all, I think Larry Butcher's testimony is a key example. If you were to go out and find the 10 or 15 best facilities in the country and figure out how they organize and how they pay, you would find it was radically different than a fee-for-service model.

Again, if you think about it, the morning somebody is diagnosed with Alzheimer's, you know you have a lifetime contingency. So the idea that you would then try to deal with that on a fee-for-service model is utterly irrational. It is a hangover from an earlier and simpler era and makes no sense in the modern world. So, first of all, I would look at places actually doing it.

Second, Don Fisher at the American Medical Group Association, which is the Mayo Clinic and the Cleveland Clinic and institutions of that caliber, they have been working for three years on new payments models because they decisively believe that the fee-for-service model actually produces bad medicine and that you don't have people with continuity. You don't organize the care not just for Alzheimer's, but across the whole system.

Third, I would look at the work that is being done right now at Intermountain Health, where they are very systematically looking at very new models, and I would look at the work being done at

Virginia Mason in Seattle, where they had the ironic moment of—they actually send 20 key people at a time to Japan to work in the Toyota factories, to learn the Toyota production system, to apply it to health.

They discovered they could take an amazing amount of waste out of the system, and they almost went broke because it turned out the waste they were taking out was the billing points. They literally faced a crisis that if they only did the things that were technically right, they couldn't have enough billing points to survive as a medical group. Virginia Mason is worth your looking at.

This is a much—first of all, we think that Alzheimer's is absolutely unequivocally clear, you should go to a continuum of care model based on value and not a fee-service model. But second, I would urge you to look at all of Medicare and Medicaid in the same pattern and all of Federal employee health benefit.

Because the current way we pay for it guarantees the maximum number of short interventions with the minimum amount of cohesive, long-term, coordinated care, and that is exactly backwards. So, I think you have raised a very important topic.

Senator COLLINS. Thank you.

The CHAIRMAN. Thank you. [Applause.]

They just called a vote on the floor, but we have a little bit more time.

Senator Gillibrand, do you want to take minute or two?

Senator GILLIBRAND. Thank you, Mr. Chairman.

I would like to direct a question to Ms. Shriver and Mr. Butcher. From your personal experiences as caregivers, what do you think are the most important things that Congress can do to help caregivers nationwide? More specifically, how can the Federal Government play a larger role in coordinating the care that has fallen to the local municipalities and not-for-profits?

Ms. SHRIVER. Well, I think one of the things, as I said, Senator Collins talked about, many of the caregivers—we have childcare tax credits. Many of the people who are doing this full time, we have heard some of the figures that the uncompensated care that is going on is in the billions and billions of dollars. So that might be something to look at, a caregiver's tax credit.

I think many of the things that have been—I think, No. 1, funding the research would give caregivers hope. I think, you know, establishing an office, funding it, coordinating, streamlining it, and caring. Those are the four things that I think would be really fantastic, that all the people in this room—and really, this is the number-one disease feared by people over 55 in this country. I am sure there is nobody on the panel that is 55.

But 55 years in age up, people are terrified of this disease. They want to know that their Government cares about it, that it is a priority, that it will be funded, that the work will be streamlined and coordinated, and that we will solve this problem. We will solve Alzheimer's. We must solve Alzheimer's.

I think, in the meantime, that caregivers feel that there are organizations out there where they can go, as Larry can talk more about it, for support, that they can get a tax credit if they have to lose, change their job, that there is support out there, and that they are able to afford to keep their loved one at home.

Mr. BUTCHER. Thank you.

I think, as I look at it, I would certainly agree with Ms. Shriver on many of the major points. One of the things that I look at, when my wife was affected, I was unaware that there were any daycare programs out there. It required me to quit my job in order to stay home and take care of her. That certainly had an impact as we look at the fact that now she has been in the nursing home 8½ years, and the cost of that is astronomical.

One of the things that we might look at is funding or tax credits for people being put into daycare. As I mentioned, we do have some—many of our caregivers who are working. They are able to put their loved one in a care facility during the day. They can still maintain their work. They get to work five days a week and then they get to work the next two days as a full-time caregiver.

We need to look at that model. I would want to look at the fact that hospice, Medicare funds hospice. Now hospice is continued on sometimes for much, much longer than six months. If we could get Medicare funding to help some of the daycare, even if it was for one or two days a week, it would give the caregiver or the family an opportunity to have a life. I think that is extremely important.

I might add one other thing. When Senator Kerrey was talking about the project-type funding and also it was mentioned earlier about the Moon landing program. We didn't fund that to go half way. We funded it as a project to go all the way to the Moon, and that is the way we need to look at this disease.

Thank you. [Applause]

The CHAIRMAN. Thank you. Thank you.

Senator GILLIBRAND. May I follow up? I would like to follow up with our working group members. You mentioned Medicare, and one of the plans of our new President is to focus on healthcare reform. So, I would like your thoughts.

One of the recommendations that I particularly appreciated—both Speaker Gingrich and Senator Kerrey, you had it in your remarks—was focusing on healthcare IT. That there should be a focus on developing a record, an electronic record of care for Alzheimer's patients from the early stages through their whole life and the development of the disease, but also getting a link of data bases and researchers so that you are having the ability to track this information so it helps us in research.

I would like you to talk just for a moment about as the President reforms healthcare and as we look at what role Medicare will play, can you please give your thoughts on some suggestions with healthcare IT and other ways to provide better delivery of care more cost efficiently?

Senator KERREY. Senator, I would just add to what—repeat actually what I said earlier. I don't think you can do this without electronic health medical records.

I just don't think, particularly in rural areas, you simply can't either develop the kind of quality of care nor can you develop a better system of doing the research.

Because the research community is very, very frustrated at their inability to be able to put together their own project. So I just don't think you can do it. I think it is a very critical piece to be able to get it done.

In addition, another thing I think about, as you asked a very important question about what do you do in rural areas? I really would look—I would get CMS and I would spend time with CMS and talk to them about this quality care initiative. Because I am sure in New York, there are community-based groups that are frustrated with this payment system and would benefit, I think, from getting some attention paid to reimbursing based upon quality.

Then, last, I would just—you probably already know this, but there are some very exciting social networks that are already developing on the Internet of community groups that if you just follow those networks, it will lead you to community leaders like Larry, who are working on this and who are going to have a lot better ideas about how to do it right than I do.

The CHAIRMAN. Thank you so much. Go ahead.

Mr. GINGRICH. Could I just add one quick thing?

The CHAIRMAN. Quickly, yes.

Mr. GINGRICH. Because I think that you have touched a very important point. I am very supportive of the President's initiative in allocating \$17 billion for health information technology. Candidly, it is something I tried to get the last administration to do for 6 years and failed, and I think it is absolutely essential.

However, the great fear I have is that they will now internalize health information technology into the Government bureaucracies. We have two clear track records in America. When you have an agency like the Defense Advanced Research Projects Agency, which spends all of its money out of the agency, you get a breakthrough like the Internet, the rise of the home computer, an amazing number of things happen because you are accelerating the access to resources of entrepreneurs.

When you have the process the Department of Energy tried to use in the last few years to create a green coal plant, they so internalized it that their 2003 commitment to build a plant by 2008 is now a 2016 commitment, and I doubt if they will ever get it done because it is totally wrapped up in their own bureaucracy.

I would hope that the Senate and the House will look very carefully and will urge the President very strongly to externalize most of that \$17 billion so that it is spent in the private sector in a very decentralized way to allow continuous evolution because you do not want to get trapped either with bureaucratic red tape or get frozen into a technology which becomes obsolete within 3 years.

So it is exactly the right direction. But if they do it wrong downtown, they will actually retard the rate at which we are able to get to health information technology.

The CHAIRMAN. Thank you.

Thank you so much, Senator Gillibrand. [Applause.]

We want to thank our panelists for being here today. You have given us a great update on where we are today and where we yet need to get to. So we thank you so much for coming here and sharing your information and your knowledge with us.

There is going to be a post hearing press briefing for those of you who want to stick around. It will take us just a minute or two to set up for it. But we thank you all for being here today, and we look forward to continuing to work with you.

Thank you so much.

[Whereupon, at 12:10 p.m., the hearing was adjourned.]

A P P E N D I X

PREPARED STATEMENT OF SENATOR ROBERT P. CASEY, JR.

I would like to thank Chairman Kohl for scheduling this important hearing on Alzheimer's disease. We first heard from some members of the Alzheimer's Study Group last May and I look forward to hearing their updates today and their recommendations for moving forward. I would also like to welcome our distinguished panel of witnesses and thank them for taking the time to be here today and share their experiences with us.

Alzheimer's disease is a progressive brain disorder which kills brain cells creating difficulties with memory and behavior that can impact every aspect of an individual's life. It is estimated that as many as 5.3 million people live with Alzheimer's today. In Pennsylvania it is projected that by next year 280,000 people will have Alzheimer's disease.

Age is the number one risk factor for Alzheimer's disease. As our nation continues to age, and Pennsylvania has one of the highest percentages of older citizens in the nation, we can expect to see the number of new cases increase every year. Indeed the 2009 report of the Alzheimer's Association projects that in 2010 there will be nearly 500,000 new cases diagnosed every year and by 2050 that number will double to almost one million.

Alzheimer's disease is a fatal disease. It is the sixth leading cause of death in the United States and the fifth leading cause for people over the age of 65. Between 2000 and 2006 the number of deaths from Alzheimer's disease increased by 47.1 percent. To put this in perspective, over the same time period deaths from heart disease decreased by 11.5 percent, deaths from stroke decreased by 18.1 percent, deaths from breast cancer decreased by 0.6 percent and deaths from prostate cancer decreased by 14.3 percent. While many other diseases are seeing significant progress, Alzheimer's disease is moving backwards. I look forward to hearing what the Alzheimer's Study Group suggests we do to reverse this trend.

Alzheimer's disease impacts many people. Of course anyone with the disease is impacted most of all, but family members and caregivers share the burden. In 2008, 9.9 million family members, friends and neighbors provided unpaid care to individuals with Alzheimer's disease. These caregivers do many tasks including shopping for groceries, meal preparation, managing finances, assisting in activities of daily living such as bathing or dressing and helping with medication management. In Pennsylvania alone 532,589 unpaid caregivers assisted individuals with Alzheimer's and that care was valued at \$4,114,860,553. Over four billion dollars. That's a huge number and that's just in Pennsylvania. Nationally the figure is over \$94 billion.

The cost of this caregiving cannot just be measured in dollars. The physical and emotional toll on the caregiver has an impact as well. Approximately one third of family caregivers for individuals with Alzheimer's have symptoms of depression. Unpaid caregivers are more likely to report their health as fair or poor. One study found that 57 percent of these caregivers are employed full or part time and two thirds of those said they needed to go in late, leave early or take time off because of their caregiving duties. These are also costs that must be taken into consideration when we discuss the full impact of Alzheimer's disease.

In closing, Mr. Chairman, let me again thank you for bringing us together again on this important issue. I look forward to hearing the testimony of the witnesses and the recommendations from the Alzheimer's Study Group and to working with them and my colleagues.



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

**Statement by Eric J. Hall, President and Chief Executive Officer
Alzheimer's Foundation of America**

**Hearing by the United States Senate Special Committee on Aging
"The Way Forward: An Update from the Alzheimer's Study Group"**

March 25, 2009

Chairman Kohl, Ranking Member Martinez and distinguished Committee members:

On behalf of the Alzheimer's Foundation of America (AFA), thank you for holding this important hearing on "The Way Forward: An Update from the Alzheimer's Study Group." We are pleased to submit this statement in support of the Committee's efforts to raise awareness about Alzheimer's disease in general, as well as AFA's efforts to promote early detection of memory problems and to serve as the national face of care for individuals and loved ones affected by the disease in particular.

Introduction: Our Shared Mission

According to the National Institute on Aging, an estimated 2.4 million to 4.5 million Americans have Alzheimer's disease—a progressive, degenerative disorder that attacks the brain's nerve cells, resulting in loss of memory, thinking and language skills, behavioral changes, and, ultimately, death. Alzheimer's disease recently surpassed diabetes as the sixth leading cause of death among American adults. Notably, mortality rates for Alzheimer's disease are on the rise, unlike heart disease and cancer death rates which are continuing to decline. It is therefore critical that we all stand together for care as the incidence from this devastating disease continues to climb.

AFA (www.alzfdn.org) is a national, nonprofit 501(c)(3) organization that focuses on providing optimal care to individuals with Alzheimer's disease and related illnesses, and their families. While we hope for a cure, with none on the horizon, our objective is to address the educational, emotional, medical, practical and financial needs of the millions of Americans dealing with the brain disorder on a daily basis, as well as to raise awareness of the disease and the needs of the dementia population through our own advocacy efforts and in collaboration with other organizations.

We achieve these goals through myriad programs and services available at our national headquarters in New York—such as a toll-free hotline, counseling by licensed social workers, bilingual educational materials, respite care grants and a free caregiver magazine—and groundbreaking national initiatives spearheaded by AFA, including the AFA Quilt to Remember, Dementia Care Professionals of America,

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and National Memory Screening Day as part of a wide-ranging campaign to promote early diagnosis and treatment. In addition, we unite nearly 1,000 member organizations nationwide that provide hands-on programs and services in local communities that help improve quality of life for those with the disease and their families; these organizations continue to operate independently while benefiting from being part of a larger network, including the opportunity for nonprofit members to apply to AFA for grants to develop or enhance programs and services in their local communities.

AFA believes that America needs a consumer-centered long-term care strategy for dementia that can serve the aging baby boomer population until hypothesized disease modifying interventions are available and widely deployed. Most long-term care is provided at home by family members—middle age and older women are the backbone of the caregiver work force. According to the Centers for Medicare and Medicaid Services (CMS), an estimated 70 percent of nursing home residents have some degree of cognitive impairment, and studies show that at least half of all assisted living residents aged 65 and older have dementia or a related illness. Nursing home placement often results from hospital care of demented inpatients where hospital staff is often ill-equipped to mitigate functional decline during hospitalization. Optimal use of community resources such as faith-based organizations is sporadic.

AFA's long-term care policy incorporates several basic concepts articulated by our members. First, the best long-term care option is the kind that you never use. Second, effective long-term care requires a combination of high tech and high touch. Third, quality assurance, transparency, and consumer empowerment are essential components to promote both cost efficiency and improvements in care.

I. Reducing the Burden of Chronic Disease

AFA considers the focus on chronic disease management of the Committee as an important effort at reducing the risk of dementia or lengthening the duration of time to onset of disease. To this end, AFA is engaged in a number of efforts:

- Aggressive management of cardiovascular risk factors, mental and physical activity, good nutrition, stress reduction and medication compliance are important components of the AFA prevention program, outlined on our new prevention Web site, www.alzprevention.org.
- AFA is the leading advocacy organization for promoting early detection of Alzheimer's disease and related dementias through memory screening.
- AFA serves as a strong voice in support of a care coordination Medicare benefit.

The Importance of Early Detection

One of the main arguments in favor of memory screening is that there are serious deficiencies in the health care system's ability to recognize dementia. A 2006 editorial in the *Journal of the American Geriatric Society* estimated that missed diagnoses are greater than 25 percent of the dementia cases and may be as high as 90 percent.¹ Not surprisingly, individuals with mild dementia are more likely to go unrecognized by physicians than persons with moderate to severe dementia²; however, most researchers agree that most available medications are best given earlier in the disease when the individual has mild symptoms.³⁻⁴ In

¹ Freund B, "Office-based evaluation of the older driver," *Journal of the American Geriatric Society*, 2006, Issue 54, pages 1943 to 1944.

² Borson S, Scanlan JM, Watanabe J, Tu Sp, Lessig M. Improving identification of cognitive impairment in primary care. *Int. J Geriatr Psychiatry*. 2006 Apr;21(4):349-55.

³ Hogan DB, Bailey P, Black S, et al. Diagnosis and treatment of dementia: 4. Approach to management of mild to moderate dementia. *CMAJ* 2008 Oct 7;179(8):787-93.

addition, while close friends and family can play an important role in detection of dementia, many elderly live alone and have limited contact with distant relatives or friends.

There are additional barriers⁵ to early detection⁶ of dementia:

- Individuals are often unaware, deny or minimize the severity of symptoms, or are concerned about stigma.
- Access to quality care is a key issue for all individuals with dementia and for those of minority racial and ethnic backgrounds in particular.
- Clinician evaluation may be time consuming and not well reimbursed.
- Many, especially minority populations, believe that memory loss and cognitive decline are a normal part of aging.

Also, most people are not inclined to discuss memory concerns with their doctors. A survey conducted during AFA's 2007 National Memory Screening Day found that 68 percent of respondents had concerns about their memory. However, while more than 80 percent had visited their primary care physician within the last six months, fewer than one in four of those with self-identified memory problems had discussed the issue with their physician.⁷

A memory screening is a simple and safe evaluation tool that assesses memory and other intellectual functions and indicates whether additional testing is necessary. Memory screening can be done in a medical environment (e.g. dementia clinic, physician's office) or in a community setting (e.g. senior center, pharmacy).

Several screens have adequate sensitivity and specificity to serve as routine, cost-worthy evaluations. In fact, validated memory screening instruments demonstrate 80 percent to 90 percent or higher sensitivity and specificity in reviewed studies⁸—similar to other established screening tests such as a mammography⁹ and Pap smear.¹⁰

Age is the biggest risk factor for Alzheimer's disease. Based on the fact that the incidence of dementia doubles every five years between 65 and 95, some experts recommend that annual memory screening is beneficial for everyone 75 and older, and for people 65 and older with a family history or other risk factors.¹¹ Other important risk factors are genotype and concurrent medical conditions.

⁴ Doody RS, Stevens JC, Beck C, et al. Practice parameter: management of dementia (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2001 May 8;56(9):1154-66.

⁵ Solomon PR, Murphy CA. Should we screen for Alzheimer's disease? A review of the evidence for and against screening for Alzheimer's disease in primary care practice. *Geriatrics*. 2005, 60(Nov): 26-31.

⁶ Knopman D, Donohue JA, Guterman EM. Patterns of care in the early stages of Alzheimer's disease: impediments to timely diagnosis. *J Am Geriatr Soc*. 2000 Mar;48(3):300-4.

⁷ <http://www.alzfdn.org/MediaCenter/073008.html>

⁸ Solomon PR, Murphy CA. Should we screen for Alzheimer's disease? A review of the evidence for and against screening for Alzheimer's disease in primary care practice. *Geriatrics*. 2005, 60(Nov): 26-31.

⁹ National Cancer Institute. Breast Cancer Screening Modalities.

¹⁰ <http://www.nci.nih.gov/cancertopics/pdq/screening/breast/HealthProfessional/page5>.

¹¹ Kulasingam SL, Hughes JP, Kiviat NB, et al. Evaluation of human papillomavirus testing in primary screening for cervical abnormalities: comparison of sensitivity, specificity and frequency of referral. *JAMA*. 2002 Oct 9;288(14):1749-57.

¹² Ashford JW, Borson S, O'Hara R, et al. Should older adults be screened for dementia? It is important to screen for evidence of dementia! *Alzheimer's & Dementia*. 2007;3:75-80.

The main arguments against memory screening are the unsubstantiated assertions that there are many potential adverse consequences.¹² However, **screening is neither a diagnostic or case finding process.**

Screening tests in general simply help determine whether diagnostic tests should be considered. A “positive” result from a memory screening should never be interpreted as a diagnosis of Alzheimer’s disease or a related illness or other illnesses—no more than a “positive” mammogram means an individual has breast cancer.

National Memory Screening Day

Memory screenings are one of the major focal points of the AFA’s national initiatives. For the past six years, AFA has sponsored National Memory Screening Day (NMSD), www.nationalmemoryscreening.org, annually in collaboration with community organizations to promote early detection of memory problems as well as Alzheimer’s disease and related illnesses, and encourage appropriate intervention. *AFA is particularly grateful for Chairman Kohl’s efforts to encourage Americans to be screened and to increase public awareness of National Memory Screening Day in 2008.*

In November 2008, qualified health care professionals at more than 2,200 sites nationwide offered free educational materials about dementia and successful aging to an estimated 54,000 participants. The goal of NMSD is to steer individuals toward proper diagnosis and treatment in order to improve quality of life for themselves and their families.

Qualified health care professionals—including social workers, pharmacists, physician assistants, nurse practitioners, and doctors—provide the screenings. The face-to-face screening takes place in a private setting in such venues as Alzheimer’s agencies, senior centers, long-term care facilities, doctors’ offices and pharmacies; only the individual being tested and the clinician are present. The screening usually takes less than 15 minutes on average and consists of a series of questions and/or tasks designed to test memory, language skills, thinking ability, and other intellectual functions.

A memory screening is not used to diagnose any particular illness and does not replace consultation with a qualified physician or other health care professional. The person who administers the screening reviews the results with the person screened, and suggests whether follow up with a physician or other health care professional for more extensive testing is necessary. Those with abnormal scores and those who still have concerns are encouraged to pursue further evaluation. The person who was screened will receive the screening results to bring to their health care professional. Screening sites also provide information about successful aging, including the benefits of proper diet, physical exercise, mental stimulation, socialization, and stress management.

Highlights from National Memory Screening Day 2008:

- Nearly 2,200 sites in all 50 states, Washington, DC, Guam, Puerto Rico and the Virgin Islands held confidential face-to-face memory screenings at no charge as part of 2008 NMSD. The record number of participating sites represented a 10 percent increase over 2008; for the first time, screenings were held in all 50 states.
- In addition, the entire chain of Kmart pharmacies—1,100—in the U.S. and territories participated. Based on its success with memory screenings on NMSD in past years and at other times of the year, Kmart changed its Gold K Day to coincide this year with NMSD.

¹² Ashford JW, Borson S, O’Hara R, et al. Should older adults be screened for dementia? It is important to screen for evidence of dementia! *Alzheimer’s & Dementia*. 2007;3:75-80.

- States that had the largest number of participating sites were Florida (189); Michigan (132); California (124); Pennsylvania (121); and Ohio (115).
- Some sites reported very large turnouts. For example, Oaklawn, Goshen, IN, 106 participants; Senior Day Services of El Dorado County, Placerville, CA, 104; Suma Health System, Cuyahoga Falls, OH, 103; Mercy Ridge Retirement Community, Timonium, MD, 91; Inter Valley Health Plan at Ontario Senior Center, Pomona, CA, 84; Brevard Alzheimer's Foundation, Melbourne, FL, 80 (site: Cocoa Beach Public Library); Riverglen House of Littleton, NH, 79; Princeton Senior Resource Center, Princeton, NJ, 73; Humboldt Senior Resource Center, Eureka, CA, 75.
- The majority of people screened were 65+, fairly evenly split between 65 to 74 and 75 to 84.
- Venues included local Alzheimer's organizations, long-term care facilities, senior centers, private doctors' offices, universities, hospitals, research labs, hospice, government agencies, churches, councils on aging, and pharmacies.
- In a partnership with Center for Medicare & Medicaid Services, several State Health Insurance and Assistance Programs SHIPs (funded by CMS) participated in NMSD, viewing it as a vehicle to reach hundreds of prospective Medicare beneficiaries to inform them about Medicare, open enrollments for Medicare Part D and Low-Income Subsidy, and Prescription Advantage. Three SHIPs supported by the Boston Regional Office — Connecticut, Massachusetts and New Hampshire — participated in NMSD with representatives at 18 sites.
- More than 20 national organizations supported the event, including: Alliance for Aging Research, American Academy of Nurse Practitioners, American Geriatrics Society, AGS Foundation for Health in Aging, American Medical Women's Association, American Pharmacists Association, American Psychiatric Association, American Public Health Association, Geriatric Mental Health Foundation, Mental Health America, National Asian Pacific Center on Aging, National Association of Chain Drug Stores Foundation, National Association of Social Workers, National Conference of Gerontological Nurse Practitioners, National Council on Aging, National Gerontological Nursing Association, National Hispanic Council on Aging, National Hispanic Medical Association, SEIU Healthcare, The Gerontological Society of America, and The National Caucus and Center on Black Aged, Inc.

Beginning in January 2009, AFA began listing year-round memory screenings on its www.nationalmemoryscreening.org Web site. AFA will hold National Memory Screening Day 2009 on November 19.

“Memory Matters” Study

In early December, building on the momentum of National Memory Screening Day, AFA released “Memory Matters,” a report that shatters unsubstantiated criticism related to memory screenings and instead emphasizes the safety and cost-effectiveness of these tools and calls on Congress to develop a national dementia screening policy. The *Associated Press* devoted its health column to the study release. I have attached the study and AP column for your reference.

Care Coordination

Once an individual is diagnosed, geriatric assessment and care coordination services are essential to care and cost savings. According to CMS, 95 percent of Medicare beneficiaries with Alzheimer's disease have one or more other chronic conditions, such as coronary heart disease, congestive heart failure, diabetes, and COPD. Outpatient and inpatient medical care must be adjusted to meet the special needs of persons with cognitive disabilities. Studies have shown that healthcare expenditures for this population can be reduced,

quality of care improved, and health outcomes enhanced when care is delivered in a coordinated fashion. Geriatric assessment and care coordination services are essential to the care of these older adults. When a comprehensive geriatric assessment is combined with coordinated care, studies have shown improved or stabilized function, reduced mortality, and changed patterns of healthcare utilization.

Unfortunately, the current Medicare program does not pay healthcare providers for care coordination. Instead, physicians are paid only for episodic face-to-face care, not the continuous care, occurring both during and between visits that is required to effectively manage multiple chronic conditions. Passage of the *Geriatric Assessment and Chronic Care Coordination Act*, sponsored by Senator Blanche Lincoln and Senator Susan Collins, and the *Independence at Home Act*, sponsored by Senator Ron Wyden, will create a patient-centered approach under Medicare that will benefit patients with multiple chronic conditions and lower their healthcare utilization rates and we thank them all for their leadership.

II. Strengthening the Workforce

AFA encourages the Committee to continue its groundbreaking focus on workforce availability and competency issues that impact long-term care. The impending national health care manpower shortage has been a focus of the Committee and most studies that examine challenges to long-term care. AFA is involved in a number of activities to strengthen the geriatric workforce:

- AFA is proud to be a new member of the Eldercare Workforce Alliance and strongly supports the *Retooling the Health Care Workforce for an Aging America Act*, sponsored by Senator Herb Kohl and co-sponsored by Senators Lincoln, Wyden and Casey.
- AFA has begun to address workforce competency for care settings through its Excellence in Care evaluation program and training programs for family caregivers and long-term care staff via its division, Dementia Care Professionals of America (DCPA).

The Value of Dementia Training

Long-term services and support quality and accountability is particularly important to AFA and to individuals with Alzheimer's disease and related dementias, and their loved ones, because they make up the majority of consumers who use such services. According to the Centers for Medicare and Medicaid Services (CMS), an estimated 70 percent of nursing home residents have some degree of cognitive impairment, and studies show that at least half of all assisted living residents aged 65 and older have dementia or a related illness. Nursing home placement often results from hospital care of demented inpatients where hospital staff is often ill-equipped to mitigate functional decline during hospitalization.

AFA believes strongly that the healthcare system could improve their dementia care through pre-employment initial training as well as ongoing in-service training. AFA offers two national training programs that are specifically designed to raise the bar on dementia care in the United States:

- AFA developed Excellence in Care, www.excellenceincare.org, to partner with care settings in the establishment of a nationwide standard of excellence in care for individuals with Alzheimer's disease or related dementias. Excellence in Care offers the opportunity for facilities to ensure that their dementia care settings meet the optimal care needs of their residents/clients. The program, created with the Avila Institute of Gerontology and other industry experts, consists of a comprehensive on-site evaluation and consultation on strategies to achieve the established standards for quality of care and to sustain performance. Key areas of review include: environment, education, staff-client interaction and programming. Care settings

that successfully reach the standards established by this initiative will earn the status of Alzheimer's Foundation of America Excellence in Care Dementia Program of Distinction.

- Dementia Care Professionals of America (DCPA) is a division of AFA, www.careprofessionals.org, and offers membership, training, qualification and other benefits to individual healthcare professionals involved in dementia care such as: physicians; psychiatrists; geriatric professionals; nurses and nursing home, assisted living, and adult day program staff; physician assistants; dentists and pharmacists; home health and personal care aides; physical, recreational, and occupational therapists; nutritionists, dieticians, social workers, and case managers; and owners, directors, presidents and administrators from long-term care, home health, hospital, adult day, and counseling industries. DCPA provides practical training to healthcare professionals, sets standards of excellence through our AFA qualification program, keeps professionals abreast of emerging breakthroughs in treatment and care, and supports professionals as they support those in need.

As a practical matter, we believe key areas for improvement in dementia care training include the following:

- Individuals with dementia have intellectual and psychiatric symptoms produced by damage to the brain. It is crucial that professional care providers understand these basic elements of dementia, as well as the impact of dementia on functioning, thought and behavior.
- Dementia also causes the loss of many functions, including the skills involved in activities of daily living. Correct care during these daily activities can increase the quality of life for individuals and reduce risks to care providers during these close interactions.
- Individuals with dementia commonly experience behavioral problems, including aggression, hostility, nighttime wandering, and sexually inappropriate behavior. Effective management of these problems can improve the individual's comfort, the safety of professional care providers and the environment of the residence.
- Older individuals typically have other health problems in addition to dementia, making them vulnerable to health emergencies, injuries, abuse, and neglect. Understanding these principles can help ensure a person's safety and reduce stress on the health care professional.

III. Investing in Technology

AFA also believes in the value of investing in long-term care technology. Simple devices can be very cost-effective and widely utilized. For example, 60 percent of individuals with Alzheimer's disease and related illnesses are likely to wander from their homes, and up to half will become seriously injured or die if they are not found within 24 hours. The average search and rescue time for a missing person with dementia is 9 hours and costs law enforcement agencies \$1,500/hour. Project Lifesaver International, www.projectlifesaver.org, places personalized radio transmitters on the wrist or ankle of identified persons. These transmitters are waterproof and cannot be removed. Average search and rescue time on more than 1,850 recoveries is less than 30 minutes. Project Lifesaver is available in 915 agencies (Law enforcement, Fire, Emergency Services and more) in 45 states, the District of Columbia and Canada.

Other monitoring, assistive, or information technologies for home based care, long term facility based care and caregiver support may improve care and avoid accidents. For example, on-line caregivers may work with impaired patients who live at home alone using sophisticated monitoring and sensing devices.

Appropriate oversight and funding depends on quality assurance. State by state and regional variations requires a bottom-up strategy for quality measures based on a broad framework set at the national level. Consumer and family input is essential to assure that the “customer” has a voice in this process. CMS should expand consumer input into regulations at the national level. All state regulatory agencies supported by CMS must have direct consumer input. CMS regional offices must expand or solicit opinions from the citizens in their region.

IV. Improving Quality

The nursing home industry has changed dramatically in the 21 years since the enactment of the landmark Nursing Home Reform Act of 1987 (OBRA '87). According to a September 23, 2007 *New York Times* investigation, “Byzantine” structures, such as those employed by global private equity investors and large chains, have frustrated the efforts of state regulators to hold long-term care facilities accountable for the quality of care they provide.

The next Administration should support passage of the *Nursing Home Transparency and Improvement Act*—sponsored by Senator Herb Kohl and Senator Charles Grassley—a good-government, no-cost bill that would increase public transparency and accountability of nursing home owners and operators by requiring them to disclose the corporate entities that own nursing homes and the affiliated entities that operate, manage or control them. Even CMS has testified it does not know who owns all nursing homes in this country—despite the fact that the industry receives \$75 billion a year in public Medicare and Medicaid funding. Through additional reporting requirements on nursing staffing levels, turnover and retention patterns, and the amount of Medicare dollars spent on direct care, the bill will provide American families and policymakers critical new information in evaluating the quality of services that are provided in nursing homes across the country.

The measure also calls for establishment of a national independent monitoring program to look closely at the performance of multi-state nursing home companies, allowing state and federal regulators to take timely action to effect corrections in those chains that have a pattern of poor care, and/or that abuse public funds. Additionally, the bill requires facilities of all sizes to include dementia management and abuse prevention training as part of pre-employment training, which is critical because individuals with dementia make up the majority of consumers who use such facilities.

V. The Biggest Hurdle: Cost

We must ensure that all Americans have access to long-term care financing in their time of need. Public and private financing should work together to enhance individual choice about care options and settings, improve quality, reward innovation, and demonstrate fiscal responsibility.

One of the greatest fears of aging is the loss of independence. With help, many long-term care patients can thrive at home. But, Medicare doesn't cover most long-term care expenses and Medicaid only helps after patients exhaust their financial resources. The existing assortment of public and private options to pay for long-term care is nearly impossible for most people to understand, let alone navigate. Private long-term care insurance exists, but premiums are too expensive for most families. Affordable financing options for long-term care are a necessity.

The cost of nursing homes and assisted-living facilities and lack of community-based options means that many older Americans must rely on family and friends to provide care at home. Most long-term care

(about 80%) is provided in the home by unpaid family members and friends. Family caregivers are the backbone of long-term care in the U.S., providing unpaid care at an estimated value to the U.S. economy of \$350 billion in 2006.

Caregivers, particularly women and members of low-income families, are faced with tremendous stress. Families and friends who provide this unpaid care often do so at the expense of their own health and financial well being. U.S. business productivity losses related to family caregiving have been estimated as high as \$33.6 billion per year. Many get caught in a difficult spiral. They are forced to take time off from work, forgo promotions, and maybe even drop out of the workforce altogether to care for elderly relatives. Consequently, they work less and earn less, which reduces the Social Security and pension benefits they receive. And women, who generally live longer than men, must stretch their meager resources much further.

We need to work on multiple solutions to help family caregivers aid the ones they love:

- Family friendly workplace policies
- Tax credits for individuals with substantial long-term care needs or for their caregivers
- Parity for home and community based care with the eligibility levels for nursing home care
- Full funding for the Lifespan Respite Care Act
- Adequate funding for the National Family Caregiver Support Program

Conclusion

Our nation faces a looming crisis in long-term care, which must be addressed before it spirals out of control. The crushing burden of an epidemic of chronic disease is falling squarely on the shoulders of family caregivers, who lack the resources to effectively manage it. Federal leadership is desperately needed to support investments in training, technology and quality improvement in partnership with the grassroots efforts of family caregivers and patient advocates at the state and local level.

Statement of Cure Alzheimer's Fund on Alzheimer's Study Group's Alzheimer's Prevention Initiative

"This report provides a solid framework for a strategic national plan to combat the growing crisis of Alzheimer's disease. It is clear that all involved in this report worked hard to develop a comprehensive strategy for the treatment and care of the more than 5.2 million Americans already battling Alzheimer's and the 10 million caregivers across the country grappling with the challenges of caring for a loved one with the disease.

"However, while we believe in the basics of this report, we also believe we must be more aggressive and ambitious in defining a research agenda and timelines for development of effective therapies in our battle against this devastating disease. The last two decades have shown that understanding the causes and genetic risk factors for Alzheimer's is absolutely critical to determining the disease models on which effective treatments and a potential cure should be based. We believe that with appropriate funding of approximately \$50 billion over the next decade, and with the strong organizational and care-focused recommendations of the Alzheimer's Study Group, early prediction and early prevention can be achieved for the vast majority of those who might otherwise fall prey to the disease.

When President Kennedy challenged our nation to land on the moon by the end of the 1960s, he gave us a challenge and a deadline for success. We met that challenge with fervor. Finding a cure for Alzheimer's is no less daunting and reaching that bold goal is critical to the health of our nation.

Cure Alzheimer's Fund™ is a 501c3 public charity established to fund targeted research with the highest probability of slowing, stopping or reversing Alzheimer's disease. For more information, please visit <http://www.curealzfund.org>.

The Cure Alzheimer's Fund National Alzheimer's Disease Research Strategy

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Introduction

Alzheimer's disease (AD), the most common form of dementia in the elderly, was first described roughly 100 years ago by Dr. Alois Alzheimer. AD is a progressive and fatal neurodegenerative disease that impairs memory and cognition. There are more than five million AD patients in the U.S., and the number of new cases will grow by more than 10% per year.

Almost half of people aged 85 and older have the disease. AD will become a certain epidemic as the baby boomers enter the age range in which Alzheimer's is most prevalent.

In 2004, 25% of the combined Medicare and Medicaid expenses (about \$122 billion) was spent on AD care. AD alone could single-handedly bankrupt Medicare and Medicaid within the next decade if left unchecked.

While the AD research community has traditionally received support from both public and private sources, federal funding for research into the causes of AD has significantly decreased over the last several years.

We propose that over the next decade, funding in the range of five billion dollars per year will be necessary to achieve the goal of eradicating AD by 2020 based on a program of early prediction, pre-symptomatic detection, and early prevention.

History has dictated that this goal will require the identification, validation, and characterization of all of the genes involved in AD susceptibility. Obtaining the complete set of all AD genes will not only enable the reliable prediction and diagnosis of AD, but also guide the discovery of novel therapies for treatment and prevention.

In addition to establishing the full cadre of AD genes, it will also be necessary to develop highly sensitive and specific biomarkers, imaging, and other early detection modalities to assess and monitor the disease process prior to the onset of symptoms. Early detection tools will also be necessary for monitoring disease progress in clinical trials.

We propose a national research strategy that is based on the fact that AD is a highly genetically driven disease. The proposed research strategy is endorsed by the fact that over the past two decades, the vast majority of investigation aimed at understanding the causes of AD and developing novel therapies for treatment and prevention has been based primarily on studies of the four known AD genes.

Specifically, we are proposing a pharmacogenomic (or personalized medicine) approach to the eradication of AD, based on "early prediction-early detection-early prevention".

Our strategy includes the following four steps (Figure 1):

1. Identify all genes contributing to risk for or protection from AD (foundational research);
2. Determine how AD genes contribute to the disease process and which subgroup of genes comprises the most promising therapeutics targets (translational research);
3. Discover therapies that can slow down, stop, or reverse AD progress (drug discovery) using the targets provided by AD gene identification and characterization;
4. Develop a subgroup of the safest and most effective drugs for the treatment and prevention of AD in nationally coordinated clinical trials (drug development).

Foundational Studies

While age is the strongest risk factor for AD, second is family history; up to 80% of AD cases involve a genetic component. Of the four established AD genes, three (APP, PSEN1, PSEN2) can carry any of over 200 mutations that directly cause early-onset (<60), familial AD with virtual certainty when inherited. These mutations account for only ~two percent of AD cases.

A variant (E4) of another gene called APOE increases risk for roughly half of the more common, late-onset cases of AD, but does not guarantee onset.

Together, these four genes account for about 30% of the genetic basis of AD. Meanwhile, 70% of AD genetics still remains to be determined.

History has documented that each newly identified AD gene can provide a unique window into the cause of AD thereby leading to novel targets for innovative drug discovery. In fact, the vast majority of ongoing AD research and drug discovery would not be possible without the information garnered from studies of these four AD genes.

Thus, a national AD research strategy should support the continuation of intensive studies of the four known AD genes to better understand their role in AD pathology, together with the identification and characterization of the remaining genes that influence susceptibility for AD.

To find the remaining AD genes accounting for the other 70% of the genetic basis of AD, labs around the world have been carrying out genome-wide association scans of DNA from thousands of AD patients and families.

A major effort in this area is our "Alzheimer's Genome Project" (AGP)[™], which is based at Massachusetts General Hospital and funded by the Cure Alzheimer's Fund. The AGP has recently reported four novel late-onset AD genes based on studies of over 1300 AD families.

This discovery was named a "Top Ten Medical Breakthrough of 2008" by Time magazine. In addition, the AGP has identified over 60 additional novel AD gene candidates that are currently being further studied and validated.

Translational Studies

The second step in a national AD research strategy involves "translational" studies aimed at determining how defects in the known and novel AD genes lead to brain pathology. As studies of these genes lead to a better understanding of the molecular mechanisms of neurodegeneration in AD, new targets for drug discovery are made possible.

Based on studies of the four original AD genes, it has become increasingly clear that excessive accumulation in the brain of a peptide (small protein) called the amyloid beta peptide (A-beta), is a key pathological event in the disease process. The balance between A-beta production versus clearance in the brain determines how much A-beta will accumulate and form toxic beta-amyloid aggregates that can impair neurotransmission and kill nerve cells.

Hand in hand with the accumulation of toxic aggregates of beta-amyloid are the neurofibrillary tangles consisting of aggregated tau protein that chokes and kills nerve cells. Current clinical trials of drugs aimed at retarding disease progression in AD involve therapies that curb the accumulation of A-beta in the brain by either promoting its clearance or turning down its production. Other therapies are aimed at preventing the conversion of tau protein into neurotoxic tangles.

Many of the most promising clinical trials would not have been possible without the identification and characterization of the first four known AD genes, and particularly the three genes causing familial early-onset AD. For example, specific protease inhibitors, e.g. gamma-secretase modulators and beta-secretase inhibitors, which lower cerebral A-beta levels are based on studies of the early-onset familial AD genes.

While there are several promising drugs currently in clinical trials, we do not know whether any one of them, alone, or in combination with others will have a significant effect in stopping, slowing or reversing AD.

Thus, it will be important to have a deep pipeline of as many gene-based targets as possible for additional drug discovery and development. The more shots on goal, the higher the probability of scoring a victory in the treatment and prevention of AD.

As novel AD genes are validated, "translational" studies will be necessary to determine whether they cause AD in the same manner as the four original AD genes. While we expect that many novel AD genes will also affect cerebral A-beta levels and tangle formation, many genes may function in alternative biochemical pathways.

We also expect to find genes that interact with environmental and life-exposure factors to influence susceptibility for AD. For example, traumatic brain injury (TBI) and stroke are strong risk factors for AD as are cardiovascular risk factors, e.g. high cholesterol. Physical exercise has also been shown to protect against Alzheimer's disease.

Translational studies will be required to elucidate the molecular and biochemical basis for how these and other non-genetic risk factors work together with one's genome to influence risk for AD.

As we gain a clearer understanding of the mechanisms by which the known and novel AD genes cause neural dysfunction and death, we can begin to design well-informed platforms for novel drug discovery.

Drug Discovery

The third step of a national AD research strategy is drug discovery based on the knowledge gained from "translational" (functional) studies of AD genes. This will most likely require close collaboration between academic groups and industry (pharmaceutical and biotechnology companies).

Through translational studies addressing how defects in AD genes lead to aberrant biochemical activities in the brain, we can garner critical information regarding what is "broken" in the AD brain and then devise therapies to "fix" it.

Translational studies of AD genes tell us which biochemical pathways should be targeted in high-throughput drug screens aimed at identifying "small molecules" and "biologicals" that can be used to treat and prevent AD.

Thus, the third step of a national AD research strategy should include implementing what is learned from genetic, molecular, and biochemical studies of AD genes to design novel drug screening strategies for therapeutic intervention in AD.

The majority of translational research has been carried out in academic institutions with federal and private foundation funding. For drug discovery, translational findings usually need to be carried over from academia into industry where drug discovery can be carried out based on molecular mechanisms elucidated by validated AD genes. However, some drug discovery can also be carried out at academic institutions.

It is worth noting that some of the most recent drug trials in AD that have failed, particularly those targeting beta-amyloid, have not adequately addressed what we now know about the biological and pathological activities of the known AD genes and have consequently involved flawed therapies.

As we generate more basic and translational data about the known and novel AD genes, we will be better equipped to design *smarter* drug screens necessary to engender therapies that will effectively treat and prevent AD.

Drug Development

The fourth step in a national AD research strategy will require novel drug candidates to undergo “drug development”. Drug development includes initially a pre-clinical step in which novel therapies are tested in cellular and animal models so that they can be prepared for safe and efficacious use in humans.

Next, novel drugs and therapies are tested in human clinical trials for safety and efficacy in treating and preventing AD.

While pharmaceutical companies generally carry out clinical trials, academia can help by concurrently working on the “mechanism of action” by which a novel drug works to treat the disease. Such information can greatly accelerate the approval of a novel therapeutic.

Academia can also facilitate drug trials by devising tools for the early detection of AD, prior to symptoms. These tools include biomarkers, imaging protocols, and other early detection tools. Early detection of AD is helpful at several different levels.

First, it can assist in the accurate diagnosis of AD. This is essential for clinical trials that need to recruit *actual* AD patients and not those suffering from other forms of dementia.

Second, it can identify pre-symptomatic subject suitable for prevention trials.

Third, it allows for additional outcomes to be measured in AD clinical trials beyond improvements in cognition, which can take up to a year to properly assess. In contrast, changes in validated biomarkers and other early detection measures can allow for much earlier assessments, e.g. two months, thereby providing an earlier window into the progress of a novel therapy in a clinical trial.

Currently, the most promising biomarkers include A-beta and tau levels in cerebrospinal fluid. Imaging, e.g. for volumetric changes in specific brain regions or for beta-amyloid deposition, can also facilitate early detection, diagnosis, and monitoring of the progress of a novel therapeutic in an AD clinical trial.

Clearly, successful clinical trials will require early, pre-symptomatic detection of AD based on imaging, biomarkers, and other early detection diagnostic tools. Much of this information will likely be derived from federal and privately funded studies in academia together with efforts in industry.

Summary

Studies of the four known AD genes have already provided an unprecedented window into the molecular underpinnings of AD.

Prior to the discovery of the four known AD genes, the field was limited to merely guessing at the causes of AD with little, if any, success. All four of the known AD genes have pointed to the excessive accumulation of the neurotoxic peptide, A-beta, in brain as the primary cause of AD, although the route to nerve cell death also involves tangle formation. Accordingly, most ongoing clinical trials aimed at modifying disease progression (as opposed to just treating the symptoms) are targeted at lowering A-beta and/or tau accumulation in the brain.

The overarching goal of the proposed national AD research strategy is to reach a cure by 2020 based on early prediction, pre-symptomatic detection, and early prevention.

History has shown us that this goal will require an acceleration of studies aimed at identifying and investigating all genes that influence susceptibility to AD, placing highest priority on those that will provide the promising biological targets for drug discovery and development.

Over the next decade, the influx of roughly 50 billion dollars into AD research should allow for the identification, validation, and characterization all of the genes involved in AD susceptibility. These funds will also be implemented to investigate AD-associated defects in these genes. The resulting data can be employed to guide and accelerate novel therapeutics that can prevent AD.

It should be noted that this strategy will require firm genetic discrimination laws protecting employment, health insurance, life insurance, and long-term care in order to guarantee genetic privacy.

In conclusion, we propose a national research strategy for AD that will enable the reliable prediction of AD (based on genetics), the early (pre-symptomatic) detection of AD, and the development of novel therapies that can prevent the disease process based on the knowledge gained from intensive studies of AD genes. These components will need to dovetail over the coming decade to ultimately enable a pharmacogenomic (personalized medicine) approach to AD, characterized by "early prediction, pre-symptomatic detection, and early prevention". With sufficient funding, this could be achieved by 2020.

National Alzheimer's Disease Research Strategy

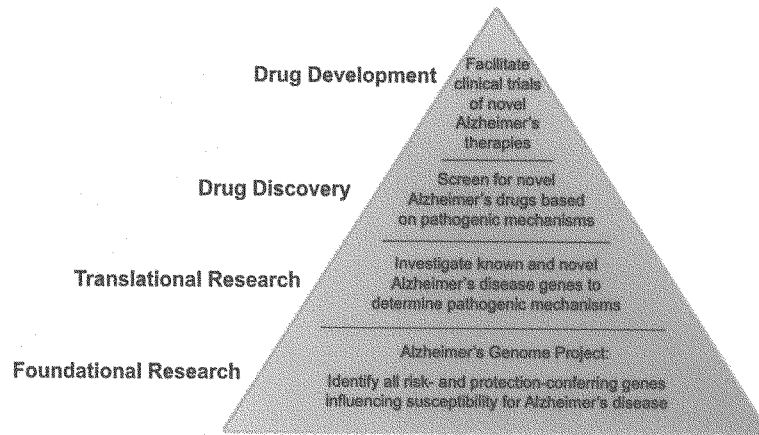


Figure 1. National Alzheimer's Disease Research Strategy. "Foundational Research" begins with the identification of the complete set of genes influencing susceptibility for AD (likely dozens). A subset of these genes will then be chosen based on strength of the genetic findings and suitability for drug discovery to proceed to "Translational Research". AD genes will then be biologically characterized to determine which biochemical pathways are impacted by AD-associated gene defects. This information will then be used for a smaller subset of genes to guide "Drug Discovery" efforts including high-throughput screening for small molecules as well as "biological" therapies, e.g. recombinant proteins that can effectively treat and prevent AD. The most promising therapeutics will then proceed to "Drug Development" efforts based on an even smaller subset of suitable AD genes. Successful clinical trials will require the use all AD genes for early prediction of risk, early (pre-symptomatic) detection of AD based on imaging, biomarkers, and other early detection tools, and effective therapies that can prevent disease progression, particularly in those with highest genetic susceptibility. With sufficient funding, this approach should ultimately allow for the future eradication of AD based on a "pharmacogenomic" or "personalized medicine" approach of "early prediction, pre-symptomatic detection, and early prevention" of AD by 2020.

MARY T. NEWPORT, M.D.

WRITTEN TESTIMONY FOR HEARINGS OF SPECIAL COMMITTEE ON AGING
HELD MARCH 25, 2009

Alzheimer's Disease currently affects 5.3 million Americans, including nearly 50 percent of the population over age 85. Additionally, there are increasing numbers of people battling dementia and similar memory disorders. Millions more are directly affected as well—the caregivers and family members of those suffering from these degenerative and debilitating diseases.

There is currently no treatment for Alzheimer's disease, resulting in an estimated health care cost upwards of \$148 million per year. But there is a treatment on the horizon that shows incredible promise for prevention, stabilization and improvement in this disease. The following will illustrate the urgent need for additional funding for the production of a **ketone body ester**—the most efficient delivery method of ketone bodies available.

Recently published research has found that Alzheimer's disease appears to be the result of a kind of "brain starvation" or a form of insulin resistance in which certain brain cells are unable to use glucose, the brain's usual source of energy. These brain cells begin to die off at least 10 to 20 years before symptoms appear. (8)(9) A similar process occurs in other types of neurodegenerative diseases, including Parkinson's, Huntington's, ALS/Lou Gehrig's, as well as multiple sclerosis, Duchene muscular dystrophy, some forms of autism, Down's Syndrome, and traumatic brain injury, (11) as well as a number of rare diseases involving enzyme deficiencies mostly affecting children. In Type I and Type II diabetes multiple organs are damaged due to the body's inability to process glucose normally. In addition, traumatic brain injury is very common cause of death and serious long term complications for our military forces.

Brain cells are able to use one other type of fuel—**ketone bodies**. Ketone bodies are taken into a cell using a different pathway than glucose and do not require insulin regulation. People do not normally have ketone bodies circulating unless they have been starving for more than two days or they are on a very low carbohydrate diet, called the "ketogenic diet." The average person in the U.S. consumes a relatively high carbohydrate diet and therefore would not produce ketones on a regular basis.

A **ketone body ester**, D-β-hydroxybutyrate, which can be given orally or intravenously, has been produced and studied in the lab of Dr. Richard Veech of the NIH/NIAAA in Rockville, Maryland. A research team from NIH and Oxford University was funded by DARPA, with \$12 million over 4 years, to produce a diet that would increase the physiological performance of soldiers without impairing cognitive performance. A diet of 30 percent ketone ester was produced, and it did increase the physical and cognitive performance of rats by about 30 percent. The diet is stable over time, shows no animal toxicity, and has GRAS status from FDA. It will be tested for human toxicity in April, 2009 and tested for its effects on physical and cognitive performance in humans in Oxford beginning in July, 2009. In addition, improvement of Alzheimer's Disease pathology has been demonstrated in cell culture models.

The "ketogenic diet" has been shown to result in cognitive improvement in persons with Alzheimer's and Parkinson's disease, and has been used since the 1920's to successfully treat childhood epilepsy. This diet is extremely high in fat (more than 80 percent of its calories are from fat) and most people find it very difficult to stay on such a diet for the long term. This type of diet may also increase cholesterol to unacceptable levels.

Mild increases in ketone bodies can be accomplished by eating medium chain triglyceride oil (MCT oil), or foods containing medium chain fatty acids, which are converted directly by the liver to ketone bodies. There are now research studies (6) and individual

reports (4) of improvements in cognitive function from consumption of medium chain triglycerides in persons with Alzheimer's and Mild Cognitive Impairment, Age-Related Memory Impairment (6) (which we will all develop if we live long enough), and Type I Diabetes (7).

The preferred mode of treatment for all of these diseases, and also to improve performance of our fighting forces, would be the **ketone body** ester, a powder that can produce 20-times the ketone blood levels obtained with MCT oil. The ketone body ester would also enable those suffering from these diseases to reap the benefits free of the additional calories and side effects related to the fat content from ingesting large amounts of MCT oil.

Dr Veech has also demonstrated in his lab very recently that brain peptides, including Nerve Growth Factor and Brain Derived Neurotrophic Factor are significantly increased when ketones are added to the diet in rats, compared to a high carbohydrate or high fat diet.

Currently 4 kilograms (about 9 pounds) of ketone esters are being produced at NIH per week in the labs of Dr. Richard Veech, which is sufficient for human toxicity studies and studies of Oxford rowers. An increase in production by a pilot plant to 50 kg per week is required to:

- a) Complete studies of ration formulation for war fighters,
- b) Test efficacy of ketone ester diet on treatment of Parkinson's and Alzheimer's disease, and
- c) Determine the efficacy of IV D-β-hydroxybutyrate on traumatic brain injury, the major cause of mortality and morbidity of troops in Iraq and Afghanistan.

The cost of a pilot plant is estimated to be \$15 million over 4 years. There could be significant cost savings if an ethanol plants is converted to production of the ketone body ester, since it is produced by a very similar process. The operation of just one of these plants would also result in the creation of a substantial number of jobs, potentially in a rural area, hard hit by the current economic conditions.

Continuation of funding for the DARPA ketone project is required to produce the pilot plant and fund the completion of these studies. We are asking you, as Members of the Special Committee on Aging, to assist in any way you can, to obtain the appropriations to continue this very promising **ketone body research** that has the potential to provide significant improvement, stabilization, and even prevention in a wide spectrum of diseases that involve the problem of insulin resistance and inability of cells to use glucose. The ketone body ester, produced in the NIH lab of Dr. Richard Veech, can serve as "alternative fuel" for cells that cannot use glucose, a very simple concept with very profound ramifications for the millions who suffer from these diseases, as well as their families.

I am concerned about issue because my 59 year old husband suffers from early onset Alzheimer's disease. In addition, I have lost two grandparents and my maternal aunt to this disease and my husband's 86 year old parents both suffer from dementia. Steve and I were present for the live testimony of the Hearing of the Special Committee on Aging on March 25, 2009. Former Speaker Newt Gingrich stated that one goal was to achieve a treatment that would prevent Alzheimer's disease by the year 2020. If ketone ester research is funded, this goal could be achieved by 2010.

I also ask the Special Committee on Aging to assist with public awareness of the potential of the "ketogenic" diet, and the consumption of oils with medium chain triglycerides to bring about stabilization and improvement in some persons with Alzheimer's disease, while awaiting clinical trials of the ketone ester.

Thank you for your urgent attention to this matter.

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Reference List

1. Veech, R. L., Chance, B., Kashiwaya, Y., Lardy, H. A., and Cahill, G. F., Jr. (2001) *IUBMB. Life* **51**, 241-247
2. Veech, R. L. (2004) *Prostaglandins Leukot. Essent. Fatty Acids* **70**, 309-319
3. Kashiwaya, Y., Takeshima, T., Mori, N., Nakashima, K., Clarke, K., and Veech, R. L. (2000) *Proc. Natl. Acad. Sci. U. S. A* **97**, 5440-5444
4. Hosley-Moore, E. (2008) Doctor says an oil lessened Alzheimer's effects on her husband. St Petersburg, FL. St. Petersburg Times, October 29, 2008. www.tampabay.com/news/aging/article879333.ece
5. VanItallie, T. B., Nonas, C., Di Rocco, A., Boyar, K., Hyams, K., and Heymsfield, S. B. (2005) *Neurology* **64**, 728-730
6. Henderson, S.T., "Ketone Bodies as a Therapeutic for Alzheimer's Disease," J American Society for Experimental Neurotherapeutics, Vol 5., 470-480, July 2008
7. Page, K.A., Williamson, A., Namyi Yu, McNay, Dzuira, J., McCrimmon, R.J., Sherwin, R.S., "Medium Chain Fatty Acids Improve Cognitive Function in Intensively Treated Type 1 Diabetic Patients and Support *in vitro* Synaptic Transmission During Acute Hypoglycemia," American Diabetes Association, Inc., 2009
8. O'Connor T, Sadleir KR, Maus E, Velliquette RA, Zhao J, Cole SL, Eimer WA, Hitt B, Bembinster LA, Lammich S, Lichtenthaler SF, Hébert SS, De Strooper B, Haass C, Bennett DA, Vassar R., "Phosphorylation of the translation initiation factor eIF2alpha increases BACE1 levels and promotes amyloidogenesis." *Neuron*. 2008 Dec 26;60(6):988-1009.
9. Klein, W.L., De Felice, F., Lacor, P.N., Lambert, M., and Zhao, W., "Why Alzheimer's is a Disease of Memory: Synaptic Targeting by Pathogenic A β Oligomers (ADDLs)," *Synaptic Plasticity and the Mechanism of Alzheimer's Disease*, Springer-Verlag Berlin Heidelberg, 2008
10. Mayumi L Prins, "Review Article: Cerebral metabolic adaptation and ketone metabolism after brain injury," *Journal of Cerebral Blood Flow & Metabolism* (2008) **28**, 1-16
11. Alan H Nagahara, et. al., "Neuroprotective effects of brain-derived neurotrophic factor in rodent and primate models of Alzheimer's disease," *Nature Medicine*, Vol. 15 No. 3, March 2009, p. 331-337

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