

**THE STATE OF ALZHEIMER'S RESEARCH:  
100 YEARS LATER**

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**HEARING**  
BEFORE THE  
SUBCOMMITTEE ON RETIREMENT AND AGING  
OF THE  
COMMITTEE ON HEALTH, EDUCATION,  
LABOR, AND PENSIONS  
UNITED STATES SENATE  
ONE HUNDRED TENTH CONGRESS  
FIRST SESSION  
ON  
EXAMINING THE STATE OF ALZHEIMER'S DISEASE RESEARCH  
100 YEARS LATER

MARCH 20, 2007

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## **THE STATE OF ALZHEIMER'S RESEARCH: 100 YEARS LATER**

**TUESDAY, MARCH 20, 2007**

U.S. SENATE,  
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,  
*Washington, DC.*

The subcommittee met, pursuant to notice, at 10:06 a.m. in Room SH-216, Hart Senate Office Building, Hon. Barbara A. Mikulski, chairman of the subcommittee, presiding.

Present: Senators Mikulski [presiding], Reed, Brown, Burr, Isakson, and Coburn.

### **OPENING STATEMENT OF SENATOR MIKULSKI**

Senator MIKULSKI. Good morning, everybody. The Subcommittee on Retirement and Aging will now come to order. This is a subcommittee of the Health, Education, Labor, and Pensions Committee. This will be a hearing on legislation to create a new framework for Alzheimer's. It will be a hearing devoted to listening to what the needs of families are, and how we can help families help themselves through being able to pay for long-term care but most of all, what we can do to help families with those who are affected by Alzheimer's.

Alzheimer's affects not only the person who has it but also the family that must endure it and the taxpayer who must pay for it. I'm going to thank all of our witnesses today that are here and I particularly want to thank the members of the Alzheimer's Association, who are here and a special hello, of course, to the Maryland Chapter, known for their verve, their vigor and their advocacy on this topic.

This is the 100th anniversary of the first diagnosis of Alzheimer's in Germany. Where have we come in 100 years? A greater awareness, a greater diagnosis but sadly, a greater number of people who have Alzheimer's.

We're going to hear as our first witness, a very dear friend and colleague on this topic, Senator Sue Collins, who is the co-chair of the Alzheimer's Caucus within the Senate. The other co-chair is Senator Hillary Rodham Clinton.

As we get ready to hear Senator Collins' testimony, though I want to say that I know that many of you, like myself, have been touched by Alzheimer's. More than 5 million Americans suffer from Alzheimer's. My father, my very dear father, was one of those 5 million Americans. I remember we tried to take care of him at home. We made sure he had the right diagnosis, that it wasn't that

he needed a different kind of medication, that maybe it was the wrong kind of medications. We all hoped that when we got his geriatric evaluation at Johns Hopkins, that they were going to tell us Dad needed vitamin B-12 and a cruise with my mother.

But unfortunately, that was not the case and we began, with our family, the long goodbye. Our mother was the primary caregiver and my sisters and my wonderful brother-in-laws helped. It was heartbreaking to my mother, heart-wrenching for my sisters and I because we knew what was happening to our father. Our father had already provided for us and our father had always protected us and now we wanted to do the same for him.

But though I was a U.S. Senator, there was very little that I could do. Though I lived within the shadow of the University of Maryland and Johns Hopkins, there again, was very little that could be done at that time. Eventhough I could reach a Noble Prize winner on the phone and have NIH in my own State of Maryland. Again, we knew that we needed more research. We needed more ideas and we needed more help.

Well, we've been working on that and I believe that Honor thy Father and thy Mother is not only a good commandment to live by, it's a good policy to govern by.

When my father passed away because of the complications of Alzheimer's, I knew that my father was a modest kind of guy. He just wanted to make sure my mother was taken care of and that my sisters and I had the kind of family and education where we could take care of ourselves. But I know what legacy—what he'd want. He wouldn't want a fancy tombstone or big memorials and so on. He would like me to do what I could do to help families that faced what we did, to help them be able to deal with this.

That's why we worked hard to establish the Anti-Spousal Impoverishment Program. That's why we worked to improve research and now experts have told us amazing things. We're on the verge of amazing breakthroughs. We have opportunities at a crucial point where NIH could make a tremendous difference, either in finding a cure or in coming up with those approaches that stretch out one's cognitive or memory ability.

This week, along with other colleagues, I introduced bipartisan legislation, the Alzheimer's Breakthrough and Family Assistance Act of 2007. Congressman Markey and the Alzheimer's Caucus leadership, Congressman Smith, are doing the same in the House. Senator Bond is the lead Republican co-sponsor here in the Senate. For all of you in this room, it's S. 898. The Alzheimer's Breakthrough Act and S. 897, the Family Assistance Act. I will talk more about what the legislation does as we move through our testimony but I know Senator Collins has other important responsibilities and we want to hear her testimony. But if the Senator will withhold, I'd like to hear from our Ranking Member and wonderful colleague, Senator Burr.

[The prepared statement of Senator Mikulski follows:]

PREPARED STATEMENT OF BARBARA A. MIKULSKI

Thank you to all of our witnesses today on our panel. I look forward to hearing about the state of Alzheimer's research, 100 years after the discovery of this disease. I am excited we are holding this

hearing during the Alzheimer's Association's annual public policy conference.

Your presence here today sends a loud message to Congress that Alzheimer's is an All-American disease that needs an all-American effort. I am happy to have so many constituents from the State of Maryland at the hearing today—welcome to you all. Thank you for your tireless advocacy.

The 2007 Alzheimer's Facts and Figures Report, released today by the Alzheimer's Association, is a wake-up call—we must respond! Many of you here today have been touched personally by Alzheimer's. Maybe it's someone you love. In fact, more than 5 million Americans suffer from Alzheimer's.

My own dear father was one of those 5 million Americans. I remember when I would go to visit him. It didn't matter that I was a U.S. Senator who represents NIH. It didn't matter that I could get Nobel Prize winners on the phone. The information that would have made his life easier just wasn't there. My family and I knew about the long goodbye—we lived the 36-hour day. It was devastating to him, heartbreaking to my mother, and heart wrenching for my sisters and me. There was no safety net for our family. What was difficult was not just the disease. We felt powerless. All we could do was make my father comfortable. There was no cure. There was no safety net for our family.

I vowed to do everything I could. Not just to support research, the search for a cure or a cognitive stretch out, but also to create a safety net for families. Because we know how hard it is. Ten million Americans have a family member with Alzheimer's. I believe "Honor thy mother and father" is not only a good commandment to live by, it's also a good policy to govern by.

I created the National Family Caregiver Support Program. This successful program helps people who help themselves with information, resources and respite care. I established the Spousal Anti-Impoverishment Program, which protects the income and assets of seniors who have spouses in nursing homes. This program has protected over a million seniors since it took effect in 1989.

The experts have told us: "we are on the verge of amazing breakthroughs;" "we will lose opportunities if we don't move quickly;" "we are at a crucial point where NIH funding can make a difference."

We need to do more and we need to do better. That's why last week, I introduced bipartisan legislation with my colleague Senator Bond, *The Alzheimer's Breakthrough Act of 2007* (S. 898) and *The Family Assistance Act of 2007* (S. 897). An identical House companion bill was introduced by Congressmen Markey and Smith. We ask that you connect with your congressional representatives to support these important bills.

Our bills do three things:

**1. Doubles funding for Alzheimer's research at NIH**, from \$640 million to \$1.3 billion. We need to give researchers the resources they need to make breakthroughs that are on the horizon in diagnosis, prevention and intervention. This can bring us closer to a cure and find early interventions for a cognitive stretch-out. We are on the verge of breakthroughs, however we must move at a faster pace.

**2. Creates a national summit on Alzheimer's** so the best scientists in the country can come together to look at the current state of research, discuss the most promising breakthroughs and chart the course for future research.

**3. Provides family support** because we know the family is always the first caregiver. We will provide "News You Can Use" for families and physicians. Incredible advances are being made every day—we need to get the word out about tools and resources. The legislation also creates a \$3,000 tax credit for families caring for a loved one with a chronic condition like Alzheimer's. This helps them pay for prescription drugs, home health care and special day care. It also includes a long-term care tax deduction, making long-term care insurance more affordable for people. This helps people help themselves as they plan for retirement and their future.

Today's hearing will focus on breakthroughs in Alzheimer's Research and care, providing news that people can use. We will hear facts about breakthroughs in diagnosing Alzheimer's disease with promising research pertaining to drugs and treatments; prevention techniques—what works, what doesn't work—and what research and programs mean for people with Alzheimer's and their caregivers.

Research that is going on right now is the master key that will one day open doors to finding a cure for Alzheimer's. Ninety-five percent of what we know about Alzheimer's disease we've learned in the past 15 years. We must stay the course and continue the investment. Expanding the cognitive stretch-out for people with this disease by 5 years could save billions. A 1-year delay in a nursing home placement could save \$12 billion annually in Alzheimer's care costs. Public investment will mean savings to Medicare and Medicaid.

I'm on the side of people with Alzheimer's and the families who love and care for them. I look forward to hearing from our witnesses today and getting facts about current breakthroughs in research, where we are today and the direction we need to head to make a difference in the lives of millions of people nationwide impacted by Alzheimer's.

#### OPENING STATEMENT OF SENATOR BURR

Senator BURR. Madam Chairman, let me thank you for the opportunity to be here and more importantly, I think everybody sees why she is a bulldog. She didn't even wait for me to start. I apologize for my tardiness and I welcome my colleague, Senator Collins.

Madam Chairwoman, I commend you for your leadership and support for Alzheimer's disease research at the NIH. You are passionate about the issue and I look forward to working with you this Congress.

Back in 1901, a German psychiatrist, Dr. Alzheimer, interviewed a new 51-year-old patient, Miss Augusta D. Her husband had brought her in because he could no longer care for her declining mental health. Dr. Alzheimer showed Augusta D. several objects and later asked her what she had been shown. She could not remember. Miss Augusta D. would be the first patient to be identified with what is now known as Alzheimer's disease.

In 2007, there are an estimated 5 million people in the United States living with the disease. In North Carolina alone, by 2010, there is projected to be 170,000 people living with Alzheimer's. Currently, age is the greatest risk factor. One out of eight people, age 65 and older, has Alzheimer's and nearly half over 85 have it.

Alzheimer's disease treatment is costly. In the United States, it's the third most costly disease to treat. In 2005, Medicare spent \$91 billion on beneficiaries with Alzheimer's and other dementias. With the aging of our population, the total is projected to double by 2015, to \$189 billion annually.

Academic, scientific and pharmaceutical institutions have been trying to identify and develop new treatments for Alzheimer's. North Carolina is home to one of the 31 Alzheimer's disease Research Centers funded by the National Institute of Aging, part of the National Institutes of Health. At Duke University, the Joseph and Kathleen Bryan Alzheimer's Disease Research Center focuses on early diagnosis and the development of treatments to delay or prevent the full onset of disease symptoms and disabilities. To aid in this research, the Bryan Center houses a Brain Bank, which includes tissue donated from individuals' autopsies.

Another exciting innovation in North Carolina comes from the growing biotech industry in our State. For example, a Winston-Salem-based company, Targacept, is working with AstraZeneca on the development of AZD 3480, a promising treatment for Alzheimer's disease.

So you see, we all have something to look forward to—exciting research that is being done, passion of the Chairwoman of this subcommittee and more importantly, the statistics that prove that this is one of the wisest investments we can make from a standpoint of taxpayers to make sure that in the future, we have a declining cost of treatment because we've either been able to cure or to stop the progression of a very debilitating disease in its tracks.

Once again, Madam Chairwoman, I thank you for the opportunity to be here.

Senator MIKULSKI. Thank you very much, Senator Burr. In respect for Senator Collins and her other duties, that's why I charged ahead. I knew you'd be here. Everyone should know that Senator Burr is an excellent participant in this hearing. We also welcome Senator Isakson and ask him to withhold his opening statement until we move on to the witnesses.

We have votes at 11:30 so we want to move pretty expeditiously so that we can hear from our witnesses and then can engage in a question and answer so we can hear the best ideas in the most affordable way to help the most people.

With that, I'd like to turn to Senator Sue Collins, a long advocate of this issue, who is, as I said, the co-chair of the Alzheimer's Task Force and she's been a very strong advocate for disease and research and also on how to find ways for people to be able to afford long-term care and has been a long advocate of looking at how we can give help to those practicing self-help.

Senator Collins.

## OPENING STATEMENT OF SENATOR COLLINS

Senator COLLINS. Thank you very much, Madam Chairman. I want to point out that not only do you have the Maryland Chapter here today but you also have some very fine representatives from the Maine Chapter of the Alzheimer's Association and I know that a Maine/Maryland combination is a powerful one to get things done.

I very much appreciate your invitation to participate in this morning's important hearing as well as your leadership in the battle against Alzheimer's. I also very much appreciate my colleagues being here today. This is an extraordinarily important issue.

As someone whose family has experienced the pain of Alzheimer's, I know there is no more helpless feeling than to watch the progression of this dreadful disease. It is an agonizing experience to look into the eyes of a loved one and to receive only a confused look in return.

As both you, Madam Chairman and the Ranking Member have mentioned, an estimated 5 million Americans have Alzheimer's, more than double the number in 1980. Moreover, Alzheimer's costs the United States just under \$150 billion a year, primarily in nursing home and other long-term care costs. This figure will increase exponentially as the baby boom generation ages.

As our generation moves into the years of highest risk for Alzheimer's, a strong and sustained research effort is our best tool to slow the progression and prevent the onset of this devastating disease.

Our investments in Alzheimer's research have begun to pay dividends. Effective treatments are tantalizingly within our grasp. Moreover, if scientists can find a way to even delay the onset of this devastating disease for even 5 years, our Nation will save more than \$60 billion every year in health and long-term care costs and an incalculable amount in human suffering.

If we are to keep up the momentum we have established, however, we simply must increase our investment in Alzheimer's disease research. Congress recently doubled over 5 years, the funding for the National Institutes of Health. As the Ranking Member noted, I can't think of a better investment for us to make. This is the largest increase in funding for biomedical research in our history and millions of Americans, including the families of Alzheimer's patients, are profoundly grateful. We have made considerable progress but now is no time to take our foot off the accelerator.

We have 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 even curing this devastating and debilitating disease. And that's why I'm so pleased to be an original co-sponsor of the Senator from Maryland's Alzheimer's Breakthrough Act of 2007, which would double the authorization levels for research at the NIH to \$1.3 billion.

In addition to increasing funding for research, we must also do more to support Alzheimer's patients and their families. Those of us who have had close relatives who have suffered from Alzheimer's know that it imposes an enormous burden, not just on the

patient but even more so as the disease progresses, on the family members and caregivers. I'm therefore also very pleased to be an original co-sponsor of the Alzheimer's Family Assistance Act, which will 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. The legislation also would encourage more Americans to plan for their future long-term care by providing a tax deduction to help them purchase long-term care insurance.

In the Homeland Security and Government Affairs Committee a few years ago, I was pleased to author the legislation, which had the Federal Government provide long-term care insurance to Federal employees and that is another step toward helping people plan for their future.

Again, Madam Chairman, I very much appreciate your inviting me here to testify about an issue that I care deeply about. It is wonderful to see advocates from all over the country gathered here today so that we put a human face on the statistics of this horrible disease. Working together, I am confident, with your leadership, the leadership of the members of this committee—Senator Bond, Senator Clinton and others—that we can have bipartisan support for the research that is necessary to find better treatments and ultimately, a cure. Thank you very much for the opportunity to be here today.

[The prepared statement of Senator Collins follows:]

#### PREPARED STATEMENT OF SENATOR COLLINS

Madame Chairman, as the Senate co-chair of the bipartisan Congressional Task Force on Alzheimer's Disease, I appreciate your invitation to participate in this morning's hearing.

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

An estimated 5 million Americans have Alzheimer's disease, more than double the number in 1980. Moreover, Alzheimer's costs the United States just under \$150 billion a year, primarily in nursing home and other long-term care costs. This figure will increase exponentially as the baby boom generation ages. As the baby boomers move into the years of highest risk for Alzheimer's disease, a strong and sustained research effort is our best tool to slow the progression and prevent the onset of this heart-breaking terrible disease.

Our investments in Alzheimer's research have begun to pay dividends. Effective treatments are tantalizingly within our grasp. Moreover, if scientists can find a way to delay the onset of this devastating disease for even 5 years, our Nation will save more than \$60 billion every year in health and long-term care costs and an incalculable amount in human suffering.

If we are to keep up the momentum we have established, however, we must increase our investment in Alzheimer's disease research. Congress recently doubled over 5 years the funding for the

National Institutes of Health. This is the largest increase in funding for biomedical disease research in history, and millions of Americans, including the families of Alzheimer's patients, are profoundly grateful. We have made tremendous progress; this is no time to take our foot off the accelerator.

We have 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 even curing this devastating and debilitating disease.

That is why I am pleased to be an original cosponsor of the Senator from Maryland's "Alzheimer's Breakthrough Act of 2007" to double the authorization levels for Alzheimer's research at the NIH to \$1.3 billion.

In addition to increasing funding for research, we must also do more to support Alzheimer's patients and their families. I am therefore also pleased to be an original cosponsor of the "Alzheimer's Family Assistance Act of 2007" which will 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. The legislation will also encourage more Americans to plan for their future long-term care needs by providing a tax deduction to help them purchase long-term care insurance.

Again, Madame Chairman, thank you for inviting me to participate in this morning's hearing, which I hope will generate increased support for the research that is necessary to find better treatments and ultimately a cure for this terrible disease.

Senator MIKULSKI. Thank you very much, Senator Collins, for your advocacy and we look forward to working with you.

[Applause.]

Senator COLLINS. Thank you.

Senator MIKULSKI. You know, we have questions but we'll be able to talk with you on the Senate floor and as the bill goes forward. I'd now like to also acknowledge that two colleagues have arrived, Sherrod Brown, our wonderful new colleague from Ohio and Senator Jack Reed, who has also had a longstanding interest in this issue.

You know, we're all so spread out. If you want to come closer, you can.

Senator REED. I can see you better from this angle.

Senator MIKULSKI. Oh, come on up. Now we'd like to be able to move our witnesses and we'll be calling them to the table. Will Mr. Johns, the President of the Alzheimer's Association, Dr. Albert, Dr. Gandy, Marilyn Blum, a homemaker and caregiver, and Mr. Robert Egge from the Center for Health Transformation come to the table.

First, we're just really glad to have these witnesses and I'd like to just kind of tell the committee about who is here and tell you a little bit about them and then we will just start with Mr. Johns. Then we'll go to Dr. Gandy, then to Dr. Albert and then—is it Egg or Egge?

Mr. EGGE. Egge. Thank you.

Senator MIKULSKI. Egge.

Mr. EGGE. Yes.

Senator MIKULSKI. And we're glad to have your testimony. I know you were recommended by Senator Burr and we're very en-

thusiastic. And also then, Marilyn Blum, who will tell us really the family perspective, after we've heard the experts.

We're pleased that Harry Johns is here, who spent 23 years at various positions at the American Cancer Association. He is a long-standing advocate and I think he brings tremendous executive ability and passion to this. We're so pleased that the Alzheimer's Association has released a report that has kind of been a one-stop shop today, on everything the general public and policymakers need to know about it. We'd like to compliment you on that report but also, like the report, we don't want it to be like some national commissions. We want it to lead to action. So we thank you for that.

Also for Dr. Gandy, who is the Director of the Farber Institute of Neurosciences at Thomas Jefferson University, who has focused his career on studying how plaques can be found on the brain of Alzheimer's. He is the author of over 100 articles and a very often quoted researcher because he can talk about this issue—he's really the science advisor to the Alzheimer's Association in addition to his own gifted and talented research.

Ms. Marilyn Albert, of course, came from Harvard to Johns Hopkins and she is the Director of Cognitive Neuroscience and the Department of Neurology at Hopkins and is the co-Director of the Alzheimer's Disease Research Center. When I spoke about my dad, dad was really ill primarily during the mid-1980s and we had so little to turn to. There was pioneering work at Hopkins. Dr. Mason Ward, the social work approach and Mazi Rappoport, who was one of my mentors but now, there is just tremendous work going on at Hopkins and I might add, the University of Maryland and we're looking forward to hearing actually your ideas on cognitive stretch-out.

And last but not at all least, Marilyn Blum from Owens Mills, Maryland, who is a caregiver for her husband, Steve, who was diagnosed 2 years ago with Alzheimer's at age 60. Often we think of this as a disease of the people in their eighties. She is also taking care of her 92-year-old father. So you talk about caregiver stress and living the 36-hour day. Mrs. Blum certainly is—but Mrs. Blum, while we listen to your story, we really welcome what you think would be sound, affordable public policies.

Having said that, I really want to emphasize to all who are here, this is a bipartisan approach. I mean, Alzheimer's affects everybody equally. They don't know if you're a Democrat and they don't know if you're a Republican. They don't know if you're rich or you're poor, it just kind of takes your life away and so that's the way we're going to fight it, though, not only in a bipartisan basis but a nonpartisan basis. Nobody at this hearing has their party hats or their campaign buttons on. We wear the button of the Alzheimer's Association today.

So with that, I'll turn to Harry Johns.

**STATEMENT OF HARRY JOHNS, PRESIDENT AND CEO,  
ALZHEIMER'S ASSOCIATION, CHICAGO, ILLINOIS**

Mr. JOHNS. Thank you, Chairman Mikulski, Senator Burr and members of the committee. I really want to thank you and I appreciate you holding this hearing today and I especially want to thank

you, Senator Mikulski, for introducing with Senator Bond, the Alzheimer's Breakthrough and Family Assistance Acts.

You know, today, as you said, Senator, the Alzheimer's Association is releasing this report, facts and figures on Alzheimer's disease in America and this report really provides evidence that Alzheimer's Disease is a growing epidemic. Today, our national investment is not commensurate with the effect and the impact of the disease already in today's world and we are significantly underinvested in Alzheimer's for its future impact. So many more lives, our Federal budget and our overall economy have the potential to be so greatly affected.

I'd like to talk about some of our key findings that are in the report. As it's already been said, there are now 5 million people who have Alzheimer's disease in America. That's up at least 10 percent from the last time we reported these figures. Half a million new cases in the upcoming year alone will occur in America. That's 1 every 72 seconds.

Alzheimer's disease is not just a little memory loss. Alzheimer's disease kills. It's already the fifth leading cause of death among older Americans in America and growing. Death rates from this disease have risen 33 percent in the last 4 years. This is while death rates for other diseases, diseases in which we have invested heavily as a Nation, we can proudly say, are declining every year. In fact, our success at curing many cancers and at fighting heart disease are exposing our under-investment and our failures in addressing Alzheimer's disease in America.

People are surviving cancer only to face Alzheimer's disease. Left unchecked, Alzheimer's has the potential to wreck our economy. In fact, already today, Alzheimer's is costing almost \$150 billion a year. By 2015, Medicare costs and Medicaid costs will be as high as \$210 billion for beneficiaries with Alzheimer's disease alone. Within just 25 years, unchecked, the cost for Alzheimer's beneficiaries in Medicare alone could be as high as the total of the Medicare program today. This threatens our economy and the economic security of not only baby boomers but generations to come.

The human cost is even worse. There are at least 10 million caregivers carrying the burden of this disease for their loved ones and again, as you said, Senator, all of us who have been touched by this disease know that burden on a personal level. And again, Alzheimer's is not just a little memory loss. It kills. But before it does, it can rob people of all bodily functions.

Caregivers not only lose their loved ones before they physically die—caregivers are perpetually fatigued. They suffer physical injury, depression and not infrequently, premature death, pre-deceasing the Alzheimer's individual. It doesn't say so on the death certificate, caregivers know that Alzheimer's disease causes deaths among caregivers as well.

These statistics are a call for action. For the first time in history, there is real hope in emerging science that we can control this disease. There are several drugs in the final stages of clinical trials but no one expects these current drugs to cure the disease. We hope for disease modification as the researchers will tell you. So we have a problem. Without additional investments in research, we could see short-term progress and long-term gaps in gains.

With sufficient resources, we can find ways ultimately to prevent this disease in millions of Americans and for those who still get it, control the disease to make it a manageable and chronic illness. A modest investment in total Federal budgetary terms has the potential for enormous returns to our country.

To support the Alzheimer's Association's objective of providing access to effective treatments, we ask the Congress to support Senator Mikulski's legislation, the Breakthrough Acts, to substantially increase funding for Alzheimer's disease, funding and research at the NIH and we ask for an increase in the resources available to FDA to review new drugs as they become available and to support our objective for quality health care for people with Alzheimer's. We ask you to continue funding for proven programs serving Alzheimer's families—the Call Center, the Brain Health Initiative, Safe Return and the State Matching Grants program.

Senators, again, Alzheimer's disease is a growing epidemic. It is not just a little memory loss. Alzheimer's disease is fatal. Our success in curing cancer and other disease is exposing our Nation's failure in Alzheimer's and we can stop Alzheimer's disease but we need your help to do it and I very much appreciate your efforts, your leadership on Alzheimer's disease and the opportunity to speak to you here today.

[The prepared statement of Mr. Johns follows:]

PREPARED STATEMENT OF HARRY JOHNS

SUMMARY

Alzheimer's is the most under-embraced, serious health crisis our Nation faces today. It is undermining efforts to control health care costs, assure access to quality care, and protect the retirement security of generations to come. That is the undeniable conclusion of the report the Alzheimer's Association report on *Facts and Figures about Alzheimer's disease* in the United States. Summarizes key findings:

- 5 million people have the disease now (10 percent more than previous estimates.) By mid-century, as many as 16 million will have Alzheimer's.
- Half a million new cases will develop this year—one every 72 seconds.
- Alzheimer's is now the 5th leading cause of death in older Americans. Death rates from the disease have risen 33 percent in 4 years, at the same time that rates for other diseases common in the elderly are going down every year.
- Alzheimer's is costing the Nation \$148 billion a year. Medicare spend \$91 billion; Medicaid another \$21 billion.
- By 2015, Medicare and Medicaid will be spending \$210 billion on beneficiaries with Alzheimer's.
- Alzheimer's is overwhelming the health and long-term care system. Twenty-five percent of elderly hospital patients, at least 47 percent of nursing home residents and half of people in assisted living and adult day care have dementia.
- Yet 70 percent of people with Alzheimer's live at home where at least 10 million family members provide unpaid care. The annual value of the unpaid work Alzheimer caregivers do is valued at nearly \$83 billion.

These statistics are a call to action. For the first time in history there is real hope that we can get this disease under control. With sufficient resources, we will find ways to prevent this disease in millions of Americans and, for those who still get it, change it from a death sentence to a manageable chronic illness. A modest investment in total Federal budget terms has the potential for enormous returns. Within 5 years of the start of a breakthrough treatment, projected annual Medicare and Medicaid spending on Alzheimer's could decline by more than \$60 billion, with even larger savings every year thereafter.

Describes current collaborations of Alzheimer's Association with key Federal agencies—NIH, CDC, AOA, FDA. Presents key Alzheimer's Association legislative priorities for the 110th Congress:

1. To provide *access* to effective treatments, increase funding for Alzheimer research at NIH by \$125 million and provide adequate resources to FDA to expedite review of new drugs.

2. To ensure *quality* health care for people with Alzheimer's, add a targeted chronic care management benefit to Medicare and continue support for proven programs serving Alzheimer families—the Call Center, the Brain Health Initiative, Safe Return, and the State Matching Grants Program.

3. To protect *retirement security* of American families, enact long-term care financing legislation to help insure against the economic risk of Alzheimer's and increase funds for caregiver support programs.

Chairman Mikulski, Senator Burr, and Members of the Subcommittee. Thank you for holding this hearing, and for your persistent leadership in the fight against Alzheimer's disease.

It is an honor to appear before you, on behalf of people with Alzheimer's and their families—hundreds of whom are behind me here this morning. They have come to Washington at their own expense, from 48 States, to tell their Members of Congress about their own struggles with Alzheimer's, and to enlist them in an all-out war against this horrible affliction.

I especially want to thank you, Senator Mikulski, for introducing with Senator Bond the Alzheimer's Breakthrough Act and the Alzheimer's Family Assistance Act. Your legislation will help millions of families and caregivers and will speed the day that we have a world without Alzheimer's. We appreciate your commitment to act quickly on these important measures. I assure you that all of us in the Alzheimer's Association will do everything we can to help you.

Today, the Alzheimer's Association is releasing a comprehensive report on the latest Facts and Figures about Alzheimer's in the United States. We are issuing a wake up call to Congress and the Nation. Alzheimer's disease is exploding into an epidemic that will undermine all of our best efforts to control health care costs, assure access to quality care, and protect the retirement security of generations to come. Despite its devastating consequences, which you know all too well, it remains the most under-embraced, serious health crisis our Nation faces. I do not have time here to go over all of the data. I ask that the report be made a part of the record and will just note a few of its findings.

*[Editor's Note: Due to the high cost of printing, previously published material will not be reprinted. The report may be found at [www.alz.org](http://www.alz.org).]*

- More than 5 million people in the United States are living with Alzheimer's disease today. That is a 10 percent increase from previous estimates, but it is only the tip of the iceberg. By mid-century, as many as 16 million will have the disease. That is more than every man, woman, and child currently living in Maryland and North Carolina combined.

- We will see half a million new cases of Alzheimer's this year alone. That means someone in America is developing Alzheimer's disease every 72 seconds!

- A diagnosis of Alzheimer's is a death sentence. It is now the fifth leading cause of death in older Americans. Death rates from many diseases common in the elderly—like heart disease, breast and prostate cancer, and stroke—are declining every year. But the death rates for Alzheimer's disease went up 33 percent in just 4 years. The absence of effective disease modifying drugs, coupled with the aging of the baby boomers, makes Alzheimer's the health care crisis of the 21st century.

- Alzheimer's already costs the Nation \$148 billion a year. Medicare alone spent \$91 billion on beneficiaries with the disease in 2005 and Medicaid spent another \$21 billion. By 2015 those two programs will be spending \$210 billion just on people with Alzheimer's. And, by 2025, the cost of today's entire Medicare program will be consumed by Alzheimer's alone.

- The disease is overwhelming health and long-term care systems: 25 percent of elderly hospital patients, 47 percent of nursing home residents, and at least 50 percent of people in assisted living and adult day care have Alzheimer's or another dementia.

- This is true, even though 70 percent of people with Alzheimer's live at home, where at least 10 million family members provide unpaid care. In Maryland, these caregivers are providing over 145 million hours of care a year; in North Carolina, almost 270 million hours. Nationwide, the work Alzheimer caregivers are doing is valued at nearly \$83 billion.

These caregivers are the lifeblood of long-term care in the United States today. Our report documents the huge toll this is taking on families—in lost work, physical illness and injury, depression, even premature death. The term “help with activities of daily living” doesn't sound so bad, until you stop to think about what that means, day in and day out, for families struggling with Alzheimer's disease. It is a 70-year-

old woman getting her husband in and out of bed every day, an 80-year-old man who never gets a decent night's sleep because his wife wanders the house all night and he has to keep her from harm, a daughter changing her father's diapers and cleaning up after him, a son bathing and dressing his mother who no longer knows who he is.

This is the reality of Alzheimer's disease. It is not a pretty picture. But it is a picture that we can change. Today, there is real hope that we can get Alzheimer's under control, that we will find the ways to prevent millions from ever getting the disease, and that for those who do get it, we can change it from a death sentence to a manageable chronic illness. Other witnesses this morning will tell you about effective drug treatments on the horizon, new information on how to maintain our brains, and proven interventions that can reduce the burden of the disease.

We cannot win this fight against Alzheimer's without an all-out commitment from Congress and from every relevant part of the Federal Government—especially NIH, FDA, CMS, CDC, and AOA. The Association is working closely with all of these agencies to maximize our mutual efforts within the limits imposed by existing law and resources. We are proud of our longstanding partnership with the National Institute on Aging. We are gratified by the response of the Food and Drug Administration to our Effective Treatments Initiative, to increase its focus on Alzheimer's and to bring patients and caregivers into the drug review process. Our joint projects with the Administration on Aging are serving hundreds of thousands of Alzheimer families. We are excited about our new collaboration with the Centers for Disease Control to expand public understanding of Alzheimer's and ways to reduce personal risk and improve diagnosis and treatment.

We need your help as well. We are here on Capitol Hill to enlist the support of the 110th Congress on our three Key Legislative Priorities:

1. Provide access to effective treatments to prevent or slow the onset and progression of Alzheimer's, by increasing funding for Alzheimer research at the National Institutes of Health by \$125 million and by providing adequate resources to the Food and Drug Administration to expedite review of new drugs.

2. Ensure quality health care for people with Alzheimer's disease, by adding a targeted chronic care management benefit to Medicare and by continuing support for proven programs that are serving Alzheimer families—the Call Center, the CDC Brain Health Initiative, Safe Return, and the State Matching Grants Program.

3. Protect the retirement security of American families, by enacting long-term care financing legislation to insure against the economic risk of Alzheimer's disease, and by increasing funds for caregiver support programs.

These proposals require a modest investment in total Federal budget terms but, as the other witnesses in this panel will explain to you, they have the potential for enormous returns—in reduced health and long-term care costs to Federal and State budgets and in improved quality of life for millions of American families.

I would like to close on a personal note. We cannot forget the human faces behind all of the statistics. They are the faces of spouses, parents, children and grandchildren whose lives are being disrupted by Alzheimer's disease. I am now one of those faces. This past year, my mother was diagnosed with Alzheimer's. Each of us now lives with a new realization that, unless we deliver on the promise of research, our Nation's children and grandchildren may be facing a similar fate.

Please, help us make sure that does not happen. Thank you.

Senator MIKULSKI. Thank you very much for your call to action and now, let's get some ideas on the research and the breakthroughs. We'll turn to Dr. Gandy.

**STATEMENT OF SAM GANDY, M.D., Ph.D., DIRECTOR, FARBER INSTITUTE FOR NEUROSCIENCES, THOMAS JEFFERSON UNIVERSITY, CHAIR, MEDICAL AND SCIENTIFIC ADVISORY COUNCIL, ALZHEIMER'S ASSOCIATION, PHILADELPHIA, PENNSYLVANIA**

Dr. GANDY. Madam Chairwoman, Senator Burr and members of the subcommittee, I'm delighted to be here to report on the latest exciting developments in the field of Alzheimer's disease research. Senator Mikulski, you clearly understand the importance and promise of this research as evidenced by your Alzheimer's Breakthrough Act, which would commit Congress to the billion dollars for

Alzheimer's research and I'd like to begin my comments by applauding your efforts.

When my colleague, John Morris, appeared before the subcommittee 3 years ago, he was full of cautious optimism. Today, I can report genuine, tangible, quantifiable hope for effective prevention and treatment of Alzheimer's disease. Within the next 3 years, it is all but certain that we will have disease-modifying drugs that will fundamentally change the nature of the disease. For millions of Americans, a diagnosis will no longer be a death sentence but the beginning of a manageable chronic illness.

These new drugs are very different from the ones currently on the market. Currently available drugs treat the symptoms but leave the underlying disease untouched. The new drugs are designed to attack the disease directly.

Two of the most promising drugs which target the brain destroying amyloid plaques in the brain are well on their way to market. In controlled clinical trials, we've already proven they are safe, well-tolerated and have significant positive impact on slowing the progression of the disease. Higher doses or combination drugs might arrest the process completely. One of these drugs could go to the FDA for review as early as this fall with possible approval by next year.

Advances in genetics and imaging have brought us near the point where we will be able to identify persons at risk for Alzheimer's, diagnose it before symptoms appear and begin treatment in time to prevent development of dementia all together.

There is still a lot of work to be done. Alzheimer's is a complex puzzle and solving it will involve multiple strategies. Scientists are pursuing a number of other highly promising theories, including the chemical bases of tangles in the brain, the connection to heart, vascular disease and diabetes and the interaction of environment, genetics and lifestyle. If we can validate these theories through basic research, then every major pharmaceutical company will begin bringing new drugs into clinical trials. We have reached this stage because of your prior investments in NIH but we are now at risk of losing momentum. Alzheimer's research funding peaked at \$658 million in 2003 and has declined every year since, a 14 percent decline in constant dollars at the National Institute on Aging alone. This is already having an impact. NIA is funding less than 20 percent of the best research proposals it receives, down from 30 percent in 2003. The grants that are approved are funded at 20 percent below the recommended levels for the first year and have no inflationary adjustments for the out years.

This means that huge scientific opportunities are being left on the table. Exciting projects are taking longer to find results and some of those promising trials are being delayed or are scrapped altogether and we are losing a generation of scientists who are either choosing more traditional careers or leaving research altogether. These brilliant minds are our greatest resource and we should be applying them to this, our most difficult problem. These budget cuts are not only killing research, they are killing the minds of millions of Americans and they are killing your chances of getting health research spending under control.

If we let the disease continue on its current trajectory, in less than 25 years, Medicare will be spending almost \$400 billion on 10 percent of its beneficiaries, those with Alzheimer's. That's almost as much as we are spending in the entire Medicare program today. Medicaid will be spending another \$50 billion on people with Alzheimer's. We can cut that spending in half, saving over \$200 billion annually with treatments to delay the onset and slow progression and we could keep nearly 400 million Americans from getting the disease.

Senators, we are in a race against time. With every year that passes, we risk losing that race. We urge Congress to add the funding we need to break through the finish line and eliminate this slow, cruel disease known as the Long Goodbye.

[The prepared statement of Dr. Gandy follows:]

PREPARED STATEMENT OF SAM GANDY, M.D., PH.D.

SUMMARY

For the first time in history, there is genuine widespread enthusiasm among scientists that effective ways to prevent and treat Alzheimer's are within reach. Within 3 years, it is all but certain we will have disease-modifying drugs that fundamentally change the nature of the disease. Within 25 years, we could save nearly half of projected Medicare and Medicaid costs on Alzheimer's—savings of over \$200 billion a year. We could keep nearly 4 million Americans from getting the disease.

Two of the most promising drugs, which target the brain-destroying amyloid plaques in the brain, are well on their way to market. In controlled clinical trials, we have already proven they are safe, well tolerated, and have significant positive impact in slowing progression of disease. Higher doses or combination drugs might arrest the process completely. One of these drugs could go to FDA for review as early as this fall with possible approval by next year.

Advances in genetics and imaging have brought us near the point when we will be able to identify persons at risk of Alzheimer's, diagnose it before symptoms appear, and begin treatment in time to prevent development of dementia altogether.

There is still a lot of work to be done. Alzheimer's is a complex puzzle and solving it involves multiple strategies. Scientists are pursuing a number of other highly promising theories including the chemical basis of tangles in the brain, the connection to heart and vascular diseases and to diabetes, and the interaction of environment, genetics, and life style. If we can validate these theories through basic research, then every major pharmaceutical company will begin bringing new drugs into chemical trials.

We have reached this stage because of your prior investments in NIH, but we are now at risk of losing momentum. Alzheimer research funding peaked at \$658 million in 2003 and has declined every year since—a 14 percent decline in constant dollars at the National Institute on Aging alone. This is already having an impact. NIA is funding less than 18 percent of the best research proposals it receives—down from 30 percent in 2003. The grants that are approved are funded 18 percent below recommended levels for the first year, with no inflationary adjustments in the out years.

This means that huge scientific opportunities are being left on the table. Existing projects are taking longer to find results. Some of the most promising clinical trials are being delayed or scrapped altogether. And we are losing a generation of scientists who are either choosing traditional careers or leaving research altogether.

This is killing research, it is killing the minds of millions of Americans, and it is killing your chances of getting health research spending under control.

The scientific community is in a race against time. I urge Congress to provide the funds needed to break through the finish line ahead of the baby boomers who are nipping at our heels.

Madam Chair, Senator Burr, and members of the subcommittee. I am delighted to be here to report on the latest exciting developments in the field of Alzheimer's disease research. Senator Mikulski, you clearly understand the importance and the promise of this research, as evidenced by your Breakthrough Act, which would commit Congress to the \$1 billion goal for Alzheimer research. I'd like to begin my comments by applauding your efforts.

When my colleague John Morris appeared before this subcommittee 3 years ago, he was full of cautious optimism. Today, I can report genuine, tangible, quantifiable hope for effective prevention and treatment of Alzheimer's disease. Within the next 3 years, it is all but certain that we will have disease-modifying drugs that will fundamentally change the nature of Alzheimer's. For millions of Americans, a diagnosis will no longer be a death sentence but the beginning of a manageable chronic illness.

These drugs are very different from the ones now on the market. Current drugs treat the symptoms of Alzheimer's but leave the underlying disease untouched. While they do help some patients temporarily, the predictable progression to death continues along the cruel path we know too well. The new drugs are designed to attack the disease directly. My own laboratory is involved in clinical trials of two drugs that target the brain-destroying amyloid plaques that are one of the two molecular hallmarks of Alzheimer's disease. Results to date are very encouraging. These drugs are safe. Patients tolerate them well. And they appear to show significant positive impact, slowing the progression of the disease. Higher doses or combination drugs might arrest the process completely. This drug could go to the Food and Drug Administration for review as early as this fall with possible approval by next year.

The other exciting news is that we are rapidly gaining knowledge about genetic and other risk factors of Alzheimer's disease, and developing techniques to detect early changes in the brain well before symptoms appear. These discoveries will let us identify persons at risk of Alzheimer's, diagnose presymptomatic disease, and begin treatment in time to prevent development of dementia altogether.

All of this good news is the direct result of your decision to double funding for the National Institutes of Health. The influx of resources moved Alzheimer research from a backwater of obscurity to perhaps the single most visible, most competitive, and most exciting field in the neurosciences. This is the key to drug discovery.

Drug development does not start or end with pharmaceutical companies. It begins at NIH-funded laboratories at academic health centers, where scientists uncover the molecular basis of the disease, identify treatment strategies, and develop the research methods and techniques that make clinical investigation possible. Clinical trials depend on the expertise of NIH-funded investigators, and many require direct NIH funding because the drugs under investigation are not protected by patent.

I emphasize this fundamental role of NIH funding because there is still so much work to be done. We are right to be excited about treatments that attack the amyloid plaques. But they will not likely be the complete answer. Like cancer and heart disease, Alzheimer's is a complex puzzle. Solving it will involve multiple strategies. We already have a number of other potential targets for intervention—including the chemical basis of the tangles in the brain that are the other hallmark of Alzheimer's, the relationship between heart and vascular disease and Alzheimer's, the connection to Type 2 diabetes, the role of nerve growth factors, and the interaction of environment, life style choices, and genetics in the development of disease.

If we can validate the prevailing wisdom about amyloid, and if we can refine these other theories, then every major pharmaceutical company will begin bringing new drugs into human clinical trials. That will not happen, however, unless Congress provides the funds to sustain the Alzheimer research enterprise.

In 2003, annual NIH funding of Alzheimer research peaked at \$658 million. We are living off the results of that investment, but we now risk losing our momentum. Since 2003, we have seen a slow steady decline in funding—down to \$643 million this year and even less if Congress approves the President's fiscal 2008 budget request. In constant dollars, the drop is devastating—a 14 percent decline in overall funding at the National Institute on Aging (NIA.)

This is happening at a time when the scientific opportunities have never been greater. There are more highly promising avenues of inquiry to explore than ever before. And we now have research tools at our disposal, involving genetics and imaging, that can help us get better, quicker answers. But we cannot use those tools without adding funds to existing projects.

The slow down in funding is already having an impact in the Alzheimer research community. NIA is funding less than 18 percent of the most highly rated investigator-initiated projects it receives—down from a 30 percent success rate in 2003. What is more, the first-year grants that are awarded are funded at 18 percent below the level recommended by NIA's own independent review panels. There are no inflationary adjustments in the out-years or for existing projects. This means that most scientific opportunities are left on the table, and the successful ones are being seriously under-funded. It also means that some of the most promising clinical trials—the way to translate basic research findings into effective treatments—will be delayed or scrapped altogether. And I can say with certainty that we are losing a gen-

eration of scientists, who are either choosing less traditional careers or else are leaving research altogether. These brilliant minds are our greatest resource, and we should be applying them to our most difficult problems.

Only money will bring them back.

These budget cuts are not just killing research projects. They are killing the minds of millions of Americans. And they are killing your chances of getting health care spending under control. If we let the disease continue on its current trajectory, in less than 25 years Medicare will be spending almost \$400 billion on 10 percent of its beneficiaries—those with Alzheimer's. That is almost as much as we are spending in the entire Medicare program today. Medicaid will be spending another \$50 billion on people with Alzheimer's disease.

We can cut that spending in half—saving over \$200 billion annually—with treatments to delay the onset of Alzheimer's and slow its progression. And we can also save millions of families from devastation. By 2030, there would be 1 million fewer cases of Alzheimer's in the United States than there are today—in spite of the rapid aging of the baby boomers. And among those of us who would still get it, most would never progress beyond the mild stages of the disease and could continue to live productively with our families in the community.

Senators, we are in a race against time. With every year that passes, we risk losing that race. We urge Congress to add the funding we need to break through the finish line ahead of the baby boomers who are nipping at our heels. Thank you.

Senator MIKULSKI. Thank you very much, Dr. Gandy.

Dr. Albert.

**STATEMENT OF MARILYN ALBERT, Ph.D., DIRECTOR, DIVISION OF COGNITIVE NEUROSCIENCE, DEPARTMENT OF NEUROLOGY, JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE, CO-DIRECTOR OF THE JOHNS HOPKINS ALZHEIMER'S DISEASE RESEARCH CENTER, BALTIMORE, MARYLAND**

Dr. ALBERT. Good morning, Madam Chair and Senator Burr and other members of the committee. I speak to you today both as a scientist and as someone who has worked with hundreds of patients with Alzheimer's Disease and their families for over 25 years.

This morning, I want to talk to you specifically about two important areas of Alzheimer's research: scientific progress and understanding lifestyle factors that may reduce the risk of developing Alzheimer's disease and evidence-based strategies to reduce the impact of Alzheimer's disease on patients and families, once it is developed.

At the last hearing on Alzheimer's disease before this subcommittee, you heard about the rapidly growing body of knowledge concerning the links between lifestyle factors and the risk of developing Alzheimer's disease, factors such as mental activity, physical activity, social engagement and risks for vascular disease.

There is great interest in this topic in the general community because most people now understand the awful consequences of having Alzheimer's disease and would like to reduce their risk for developing it. Based on what we know today, we can offer some general guidelines but we still don't know many important details. For example, what types of physical activity to recommend or when in the lifespan physical activity would be most effective at lowering risk.

Our challenge now is to continue this research so we can better understand how to lower risk for developing Alzheimer's disease. At the same time, it is important to educate the public and healthcare practitioners on what we've learned so far and we've begun to make some progress in this area. Just last year, work-

shops given by the Alzheimer's Association, known as Maintain Your Brain workshops, educated over 26,000 people across the country on this topic. Interestingly, many were baby boomers and nearly half came to these workshops with no prior, or family, or other experience with Alzheimer's disease. This confirms our impression that there is a great interest in brain health in the population at large.

A particularly important part of our educational efforts is the recent collaboration between the Alzheimer's Association and the Centers for Disease Control and Prevention. This collaboration, which began about a year and a half ago, was initiated by a small, Federal appropriation. This funding has permitted working groups organized by the CDC and the Alzheimer's Association to develop what is being called A National Public Health Roadmap on Cognitive Health. In addition, with support from the CDC, the Alzheimer's Association is now testing a program on brain health in two communities, a program particularly targeted to African-Americans. African-Americans were chosen because they have high rates of vascular risk factors such as high blood pressure, diabetes and obesity and these factors are now known to increase the likelihood of cognitive decline. A larger program along these lines could clearly have enormous benefits for public health.

At the same time that we're seeking to improve strategies for preventing Alzheimer's disease, we're also committed to reducing its impact on patients and families who are dealing with the disease now. A number of NIH funded studies have shown that relatively simple interventions, such as caregiver education, can reduce the behavioral and psychological symptoms of the patients. These programs also teach strategies for reducing stress and depression and have been shown to improve quality of life for both the patient and the caregiver. In fact, these strategies can even delay nursing home placement. One study found that the delay could be by as much as a year and a half.

The Alzheimer's Breakthrough Act, which you've sponsored, Senator Mikulski, is critical for all the ongoing efforts in Alzheimer's disease I've been talking about. It will lay the groundwork to increase funding at the NIH to pursue promising avenues in the prevention and treatment of Alzheimer's disease. It will also expand current efforts to translate research into practice. All of us who care for Alzheimer's patients and conduct research in the area believe that the scientific community is on the brink of finding answers to creating a world without Alzheimer's disease. We need your leadership and your support to make that goal a reality.

[The prepared statement of Dr. Albert follows:]

PREPARED STATEMENT OF MARILYN ALBERT

SUMMARY

At Johns Hopkins, with Federal funding from the National Institutes of Health, we are proud to be on the forefront of Alzheimer's research and we are as optimistic about the breakthrough drugs on the horizon. We are also just as concerned about reductions in NIH funding.

There is a rapidly growing body of knowledge about the links between cardiovascular risk and Alzheimer's and about the possibilities that exercise, diet and even social engagement might help reduce the risks of Alzheimer's and cognitive decline. However, we still don't know how much exercise, or which kinds of social en-

agement, or which specific dietary changes will have the greatest impact on the disease. But, the findings are strong enough that the Alzheimer's Association has launched its Maintain Your Brain Campaign® and in partnership with the Centers for Disease Control has initiated a new effort to address cognitive health. Maintain Your Brain® workshops educated 26,000 people in communities across the Nation last year. The average age of participants was 61 and many were baby boomers—program's target audience.

Another exciting development is the collaboration between the Alzheimer's Association and the Centers for Disease Control and Prevention. A National Public Health Roadmap to Cognitive Health is being developed which will provide guidance to government and the private sector on key steps to communicate the latest scientifically sound information, conduct and translate research on risk factors and strategies to maintain and improve brain health, on policy changes needed to support brain healthy behavior, and on better surveillance techniques to assess the burden of Alzheimer's disease and cognitive decline in communities nationwide. In addition, with support from the CDC, the Alzheimer's Association is now testing a program on brain health in two communities—southern California and the Greater Atlanta area—targeted to African-American baby boomers. Given the higher rates among African-Americans of cardiovascular disease, diabetes, obesity and high blood pressure, all of which are risks for Alzheimer's, a program targeted to this population could have enormous benefit for public health.

While we continue our work on strategies to prevent Alzheimer's disease, we are also learning a great deal about how to reduce its impact on patients and families. NIH-funded studies have shown that relatively simple interventions, such as caregiver education, can reduce the behavioral and psychological symptoms in people with the disease that create the greatest challenges for family caregivers and our health and long-term care systems. They can reduce depression, stress, burden and unmet needs in caregivers. They can improve quality of life for both the person with the disease and the caregiver. And they can delay nursing home placement, in one study by more than a year and a half.

The most exciting research findings are meaningful only if they are translated into practice, and if the benefits offered by State and Federal programs like Medicaid and Medicare are updated to incorporate these new and successful care strategies. That is why your proposed *Alzheimer's Breakthrough Act* is so important, Senator Mikulski. We have a strong foundation and the scientific community is well on its way to the answers needed to change a diagnosis of Alzheimer's disease from a death sentence to one of hope for generations to come.

Good morning Madame Chair and Senator Burr. My name is Marilyn Albert, and I am Director of the Division of Cognitive Neuroscience in the Department of Neurology at Johns Hopkins University School of Medicine and Co-Director of the Johns Hopkins Alzheimer's Disease Research Center. I am also a member of the national board of the Alzheimer's Association and former chair of the Association's Medical and Scientific Advisory Council. I speak to you today as a scientist and as someone who has worked with hundreds of people with Alzheimer's disease and their families for over 20 years.

At Johns Hopkins, with Federal funding from the National Institutes of Health, we are proud to be on the forefront of the research just discussed by Dr. Gandy. We are as optimistic as he is about the breakthrough drugs on the horizon. We are also just as concerned about reductions in NIH funding. Senator Mikulski, thank you for your support of Alzheimer's disease research and our efforts at Hopkins.

My reason for being here is to report ground-breaking results in two exciting areas of Alzheimer research: (1) scientific breakthroughs on lifestyle factors that could reduce the risk of developing Alzheimer's disease; and (2) evidence-based strategies to reduce the impact of Alzheimer's disease on individuals, families and our health care system. This progress is a direct result of prior investments Congress has made at the National Institutes of Health (NIH) and research supported by the Alzheimer's Association.

#### REDUCING THE RISK OF ALZHEIMER'S DISEASE

At this subcommittee's last hearing on Alzheimer's, you learned about a rapidly growing body of knowledge about the links between cardiovascular risk and Alzheimer's. About the possibilities that exercise, diet and even social engagement might help reduce the risks of Alzheimer's and cognitive decline. We have only scratched the surface of these issues and we still don't know, for example, how much exercise, or which kinds of social engagement, or which specific dietary changes will have the greatest impact on the disease. But, the findings are strong enough that the Alzheimer's Association has launched its Maintain Your Brain Campaign® and

in partnership with the Centers for Disease Control has initiated a new effort to address cognitive health. All of these public health initiatives are based on solid science. And, all provide hope that we may be able to someday prevent this terrible disease through lifestyle changes and pharmaceutical interventions.

Our challenge now is to continue the research and to educate the public and health care practitioners to act on this information. We have a lot of work to do. A recent national survey by the Alzheimer's Association found that most Americans are not aware of the progress being made against Alzheimer's and that only 14 percent are taking any action to reduce their risk for Alzheimer's disease.

We've begun to make some progress in this area. Just last year, the Alzheimer's Association's Maintain Your Brain® workshops educated 26,000 people in communities across the Nation. The average age of participants was 61 and many were baby boomers, the target audience for the program. Nearly half came to the workshops with no prior family or other experience with Alzheimer's disease, which means there is interest in brain health in the general population. We don't know whether participation in the Maintain Your Brain workshops have lead to changes in lifestyle or improvements in brain healthy behavior, but the first step in behavior change is knowledge and 90 percent said they learned something new and could apply this new knowledge.

But, the most exciting development began a year and a half ago with the collaboration between the Alzheimer's Association and the Centers for Disease Control and Prevention. With a small Federal appropriation, some big things have begun to happen. Most notable is the development of a National Public Health Roadmap to Cognitive Health, which will provide guidance to government and the private sector on key steps to communicate the latest scientifically sound information, conduct and translate research on risk factors and strategies to maintain and improve brain health, on policy changes needed to support brain healthy behavior, and on better surveillance techniques to assess the burden of Alzheimer's disease and cognitive decline in communities nationwide. This report will be released in June at the Alzheimer's Association's International Prevention of Alzheimer's Disease Conference here in Washington, DC.

In addition, with support from the CDC, the Alzheimer's Association is now testing a program on brain health in two communities—southern California and the Greater Atlanta area—targeted to African-American baby boomers. Given the higher rates among African Americans of cardiovascular disease, diabetes, obesity and high blood pressure, all of which are risks for Alzheimer's, a program targeted to this population could have enormous benefit for public health. At this time next year, this exciting demonstration project will be reporting initial results.

The CDC is also working with organizations, such as the AARP, the American Society on Aging and National Council on the Aging to educate professionals and the public about cognitive health. Some programs are targeted to school age populations in the hopes of starting at the youngest age to address brain healthy behavior.

#### REDUCING THE IMPACT OF ALZHEIMER'S DISEASE

While we continue our work on strategies to prevent Alzheimer's disease, we are also learning a great deal about how to reduce its impact on patients and families. We now have strong evidence from randomized clinical trials that coordinated medical and community care for people with dementia and counseling and support for family caregivers can stretch out the time that people with Alzheimer's can live successfully in the community.

These NIH-funded studies have shown that relatively simple interventions, such as caregiver education, can reduce the behavioral and psychological symptoms in people with the disease that create the greatest challenges for family caregivers and our health and long-term care systems. They can reduce depression, stress, burden and unmet needs in caregivers. They can improve quality of life for both the person with the disease and the caregiver. And they can delay nursing home placement, in one study by more than a year and a half.

Through the Alzheimer Demonstration Grant Program at the Administration on Aging, States are matching modest Federal grants and are developing practical ways to incorporate evidence-based programs to help patients and caregivers into their health and long-term care systems. For example, North Carolina developed a guide for families and a companion manual for nurses to improve hospital care for people with dementia. Georgia developed a mobile day care program to bring these important services to rural areas that did not have the resources to support a full program on their own. Maryland extended caregiver outreach services into rural and underserved minority communities. California developed a model to mobilize community resources to support Alzheimer families in underserved areas, starting first

in a Latino community in Los Angeles and then adapting the program for African-American and Asian communities.

TRANSLATING RESEARCH TO PRACTICE

In the end, the most exciting research findings are meaningful only if they are translated into practice, and if the benefits offered by State and Federal programs like Medicaid and Medicare are updated to incorporate these new and successful care strategies.

That is why your proposed *Alzheimer's Breakthrough Act* is so important, Senator Mikulski. It would provide the authority and resources to deliver on the exciting promise of the Alzheimer's Association/CDC Brain Health Initiative, the Maintain Your Brain®, and the community demonstrations with African-American baby boomers. And it would extend the opportunity to develop innovative Alzheimer programs under AOA's Demonstration Grant Program to all 50 States. And, perhaps most important, it will lay the groundwork to increase funding at NIH to pursue the many promising avenues in Alzheimer research.

We have a strong foundation and the scientific community is well on its way to the answers needed to change a diagnosis of Alzheimer's disease from a death sentence to one of hope for generations to come. With your continued support and leadership, we can create a world without Alzheimer's.

Senator MIKULSKI. You know, that's what all of you said so far but particularly focusing on Drs. Albert and Gandy. What amazing gains have been made, even in the last 5 years and this is why, I think, the impetus of the breakthrough is so important.

Let's turn to Mr. Egge because I know you have ideas on promoting research and also the affordability aspects of this as well.

**STATEMENT OF ROBERT EGGE, PROJECT DIRECTOR, CENTER FOR HEALTH TRANSFORMATION, WASHINGTON, DC.**

Mr. EGGE. Thank you very much, Madam Chair, Senator Burr, members of the subcommittee. Thank you for this opportunity to testify regarding the significant challenge that Alzheimer's disease poses to our Nation and to the importance of responding to this growing crisis with a bold strategy that emphasizes research and innovation.

My name is Robert Egge. I am a Project Director at the Center for Health Transformation, where I lead the Center's Alzheimer's Disease Project. The Center is a collaboration of more than 90 organizations from all segments of the health sector, including some of America's largest healthcare providers and employers.

As we have already heard this morning, every 72 seconds, another American develops Alzheimer's disease. That's 50 more Americans during the course of this hearing, five more in the course of my remarks. Based on this present reality and future projects, that's certainly a cause for grave concern. But as we have also heard, when we survey the exciting progress being made in our Nation's laboratories, we find reason for cautious optimism. What we will not find anywhere, however, is an excuse for complacency. America must work both quickly and effectively to meet the challenge Alzheimer's poses to our country and to do so, our efforts must be guided by a comprehensive, coherent strategy. What is alarming is that based even on a cursory review of our current Federal efforts, the evidence suggests that such a strategy is now lacking.

America has two fundamental objectives with respect to Alzheimer's. The first objective, as we heard and as I've described in

greater length in my written testimony, is to develop therapies that will end this epidemic.

The second objective is to support those now coping with Alzheimer's devastating impact, to help reduce the pain and exhaustion they face daily until the day comes when medical advances make Alzheimer's care giving no longer necessary.

Both are essential goals and one might reasonably assume that the Federal Government is putting roughly comparable resources behind each of them. In fact, however, the current imbalances in investment are startling. For every dollar the government now spends through Medicare and Medicaid to help Americans cope with Alzheimer's impact, it invests less than a penny to find a cure through the work of the NIH and the FDA.

This penny on the dollar approach might be called America's Katrina strategy for Alzheimer's disease. As we now know, policy-makers long neglected funding the work required to repair and to strengthen the levies that might have saved New Orleans from the worst of Katrina's impact. And so, after the hurricane, more than 100 times this amount will have to be spent to repair the damage done to the city after the levies failed.

So long as the government's current reactive posture toward Alzheimer's continues, we are at risk of repeating this tragic misjudgment of Katrina every 72 seconds, as another American braces their personal hurricane with no levies, no disease disrupting therapies to shield them.

Far from sensationalizing the present situation, in one very significant regard, this Katrina analogy still understates the deficiency of current Federal approach toward Alzheimer's disease. For however slowly, the fact remains that New Orleans is now being rebuilt. That city is recovering from the mistake of neglect of its levies but until effective therapies are in hand, we simply have no way to even begin to restore the lives that are now being lost to Alzheimer's.

However, we do know how to go about this the right way. Our national response to HIV/AIDS, for instance, shows what can be accomplished when our Federal Government mobilizes around a coherent, aggressive, innovation-oriented strategy. In the mid-1980s, projections for the future impact of the AIDS epidemic were of a scale that is now similar to what we face from Alzheimer's disease. In a recent interview in Health Affairs, NIH Director Zerhouni recalled his experience as a doctor at Johns Hopkins in the mid-1980s, a time when there was not yet, like now with Alzheimer's, an effective treatment available for the disease. Half of all beds at that time were being used to care for terminally ill AIDS patients and Dr. Zerhouni and his colleagues projected that within a decade, 80 percent of their beds would be used to care for those dying from HIV/AIDS. However, through a combination of strong research funding and accelerated FDA review, a pre-emption strategy has yielded dramatic results. In just 5 years, between 1995 and 2000, deaths fell 70 percent and survival rates increased by 10 years. Results continue to improve this decade. While much more remains to be done within the United States, HIV/AIDS diagnosis is increasingly regarded as a chronic disease rather than death sentence.

The fiscal impact of these new therapies have been equally dramatic. In his testimony before both the Senate and the House last year, Dr. Zerhouni explained how a \$10 billion investment in basic HIV/AIDS research between 1985 and 1995 has saved \$1.4 trillion in healthcare expenditures, a return of \$140 for every dollar invested.

It is time for America to learn from our past successes and to act in similarly bold, strategic and compassionate manner, revitalizing our commitment to defeating Alzheimer's disease through research and innovation. If we do, I'm hopeful that in 20 years time, a future NIH director will use Alzheimer's disease to illustrate how smart, aggressive action changed the course of the Nation and immeasurably improved the lives of millions of Americans. Thank you.

[The prepared statement of Mr. Egge follows:]

PREPARED STATEMENT OF ROBERT EGGE

Chairwoman Mikulski, Senator Burr, and members of the Senate Subcommittee on Aging and Retirement, thank you for this opportunity to testify regarding the significant challenge that Alzheimer's disease (AD) poses to our Nation, and to the importance of responding to this growing crisis with a bold strategy that emphasizes the role of research and innovation.

My name is Robert Egge. I am a project director at the Center for Health Transformation, where I lead the Center's Alzheimer's Disease Project. The Center is a collaboration of more than 90 organizations from all segments of the health sector, including some of America's largest healthcare providers and employers.

THE MOUNTING IMPACT OF ALZHEIMER'S DISEASE

As documented in the Alzheimer's Association's *Alzheimer's Disease Facts and Figures 2007* report released today, Alzheimer's strikes 1-in-8 Americans over age 65 and almost half of Americans over 85. The likelihood of developing Alzheimer's essentially doubles every 5 years beyond age 65. Every 72 seconds another American develops Alzheimer's disease—50 more Americans during the course of this hearing.<sup>1</sup>

There are no cures for Alzheimer's and no remissions. It is a condition that, once begun, always leads inexorably to death—on average within 8 years. These are long, exhausting, and painful years, described as “the funeral that never ends.”<sup>2</sup> One caregiver recounted her experience since the onset of her husband's condition:

Twelve years later, my own vision has forever been clouded by seeing my husband's brilliant mind unravel, his eloquence turn to gibberish, my name and our life together lost in the tangles and plaques that clog his brain. His identity has been stolen forever by this cruelest of disease, yet his body lingers intact because it never got the message from the brain that it is time to shut down. So together we are trapped in the endless wasteland of Alzheimer's disease that offers no mercy to its victim or the caregiver or the family.<sup>3</sup>

The impact of Alzheimer's, on a national scale, is just as alarming. The Alzheimer's Association now estimates that more than 5 million Americans suffer from this brain-crippling disease. With the aging of the baby boomers, this number is set to nearly triple in little more than a generation.<sup>4</sup>

Because Alzheimer's steals independence and complicates the treatment of comorbidities, it is already America's third most expensive disease.<sup>5</sup> Claims for Medi-

<sup>1</sup> Alzheimer's Association, (2007), *Alzheimer's Disease Facts and Figures*.

<sup>2</sup> Ballenger, J., (2006). *Self, Senility, and Alzheimer's Disease in Modern America: a History*. Baltimore: The Johns Hopkins University Press, as cited in, Comer, Meryl, “Be Heard Here First: A Strategic Voice for Alzheimer's Advocacy,” *Alzheimer's & Dementia* 3 (2007) 58–61.

<sup>3</sup> Comer (2007) 59.

<sup>4</sup> Hebert, LE; Scherr, PA; Bienias, JL; Bennett, DA; Evans, DA, (2003) “Alzheimer Disease in the U.S. population; Prevalence Estimates Using the 2000 Census.” *Archives of Neurology*. 60 (8): 1119–1122.

<sup>5</sup> Koppel, R, (2002). “Alzheimer's Disease: The Costs to US Businesses in 2002.” *An Alzheimer's Association commissioned report*.

care beneficiaries with Alzheimer's disease, for instance, are three times larger than the claims of those without.<sup>6</sup> Estimates of the disease's current cost to the Nation range as high as \$200 billion per year. This year the Federal Government will likely spend more than \$120 billion of this amount through the Centers for Medicare and Medicaid Services (CMS).<sup>7</sup>

Looking ahead, however, this \$120 billion tab is only a fraction of what awaits our Nation. Without medical breakthroughs, as the boomers pass through their elder years Federal spending on Alzheimer's care will increase to more than \$1 trillion per year by 2050 in today's dollars.<sup>8</sup> That's more than 10 percent of America's current gross domestic product. With this amount of money on the table, the Government simply will not be able to solve its looming fiscal problems if it fails to address this growing epidemic.

Yet as daunting—and, in personal terms, tragic—as this portrait is, we also have sound reason for optimism about what can be accomplished if our Nation commits to supporting the development of more effective therapies, guided by a bold but balanced Alzheimer's strategy. This optimism is important, because while complacency is a grave danger, so is resignation.

#### A RECORD OF U.S. BIOMEDICAL PROGRESS: PAST AND PRESENT

Our Nation's mounting Alzheimer's crisis is largely a result of our past biomedical accomplishments. Alzheimer's grows more common with age, and we have been remarkably successful at extending the average American's lifespan. The life expectancy of Americans expanded by three decades over the course of the 20th century alone, increasing from 47 to 77 years of age.<sup>9</sup>

Steady progress has continued in recent decades even as the biomedical community has shifted its attention to the more complicated constellation of diseases associated with aging. In fact, according to the most recent statistics available from the CDC, the age-adjusted death rate for 9 of the top 10 causes of death in America fell from the prior year, including for cardiovascular disease and cancer.<sup>10</sup>

As it happens, the only one of these top 10 causes of death to increase was Alzheimer's disease. And it will continue to increase, in step with our aging population, unless and until an effective, disease-modifying therapy becomes available.

The good news is that Alzheimer's disease is now receiving steadily increasing attention from our biomedical research community. One accepted way to gauge the growth of scientific activity within a field is through the volume of studies on the subject published in research journals. Less than 100 articles were published on Alzheimer's disease during the 1960s. During the 1990s, almost 25,000 such articles were published. This represents a seven-fold increase, decade on decade, over the latter half of the 20th century.<sup>11</sup>

This rapid increase in research activity continues. Nearly 52,000 scientific articles related to AD have been indexed in the PubMed database since the first such publication in 1949. Remarkably, about half of these articles have been published since the start of the new millennium, vividly illustrating the stunning acceleration of AD research.

Alzheimer's research is not just rapidly expanding in its own right. It is also beginning to close a once large gap with other biomedical research fields. The comparison with cancer research is typical. From 1950 to 1980, oncology researchers published approximately 1,000 papers for every one on Alzheimer's disease. By the 1990s, however, that gap had closed to a much closer ratio of 25 to 1, and so far this decade the ratio is just under 20 to 1.

This upswing in Alzheimer's disease research activity tracks closely with the commitment to significantly expand support for Alzheimer's research through the National Institutes of Health. In particular, the rapid "catching up" in the 1980s corresponds with President Reagan's initiation of a serious, directed effort to fund AD research through the NIH. This linkage suggests that Federal Government support for basic research can indeed trigger a dramatic expansion of research activity and of new knowledge.

<sup>6</sup>Lewin Group, (2004). "Saving Lives, Saving Money: Dividends for Americans Investing in Alzheimer's Research." *An Alzheimer's Association commissioned report.*

<sup>7</sup>Lewin Group, (2004).

<sup>8</sup>Lewin Group, (2004).

<sup>9</sup>National Center for Health Statistics, (<http://209.217.72.34/aging/TableViewer/tableView.aspx?ReportId=357>).

<sup>10</sup>Miniño, Arialdi M., M.P.H.; Melonie P. Heron, Ph.D.; and Betty L. Smith, B.S. Ed., (2006). "Deaths: Preliminary Data for 2004," *National Vital Statistics Reports*, Vol 54, No 19.

<sup>11</sup>Ballon, Daniel, Ph.D., (2007). Correspondence.

For all the increased effort, however, AD research has not been easy work, and it's not likely to become so anytime soon. Like many other neurodegenerative conditions, Alzheimer's disease is extremely complex. Our neuroscience community has learned much about the brain, the central role it plays in regulating almost all aspects of health, and the profound disruptions to its activity associated with plaques and tangles. But those discoveries only skim the surface of the mysteries that remain.

Nevertheless, our neuroscientists are meeting this challenge, systematically unlocking the brain's complexities with ever greater strides in scientific capabilities and sophistication. Never before in human history have so many scientists worked so productively, routinely employed such sophisticated instrumentation, collaborated worldwide so effectively, and developed their discoveries so efficiently.

One result of the rapid expansion of research described above has been a series of specific, cumulative breakthroughs in our understanding of Alzheimer's mechanisms, and in the creation of novel strategies to disrupt them—with almost all these advances occurring within just the past 20 years. At the moment there are more than 250 active Alzheimer's disease trials underway as listed on [clinicaltrials.gov](http://clinicaltrials.gov). These trials are all designed to test critical aspects of our understanding of AD, helping us to put together the pieces of the puzzle that explain this disease.

These trials, as well as the underlying research strategies, have been supported by rapid advances in instrumentation and platform technologies. Some of these essential tools and methods include:

- *Imaging.* Advances in brain imaging technology—in particular, functional magnetic resonance imaging (fMRI) and positron emission tomography (PET)—are providing important clinical diagnostic aids for AD research. Particularly encouraging is the development of novel PET scan probes/tracers that permit real-time visualization. Similar tracers are under development for use with fMRI.<sup>12 13</sup>

- *Biomarkers.* Extensive efforts are underway to identify AD-specific biomarkers that reliably and non-invasively track AD onset and progression so that, among other uses, these markers can indirectly measure drug response and help optimize treatment regimens. Researchers are currently working to identify superior markers using technologies from genomics, proteomics, metabolomics, computational and systems biology, and mathematical modeling.

- *Screening Methodologies.* A candidate therapy's performance is routinely measured using a variety of techniques including cell-based (in vitro) assays and animal models (in vivo assays). While the animal models are the gold standard, they are time consuming and extremely costly. Recently, the development of automated, high-throughput assays has greatly enhanced in vitro approaches to screening. Scientists are currently developing new computer-assisted (in silico) or virtual techniques to analyze and model the physicochemical properties of a compound in order to predict how it would behave in a complex system like the human body.

- *Animal Models.* Better understanding of the mechanisms underlying AD, coupled with advances in the fields of genetics, bioinformatics, and molecular biology, has led to substantially improved AD animal models. A major limitation of the early mouse models of AD was that the mice only developed some of the hallmark pathologies of the disease. Researchers recently addressed this problem by creating a triple transgenic mouse model that progressively developed both plaques and tangles, and demonstrated cognitive defects.<sup>14</sup> This particular transgenic mouse promises to be a valuable animal model for evaluating potential AD therapeutics.

- *Genome-Wide Association Studies.* Rapidly evolving technologies—such as computerized databases containing reference human genome sequences and tools that can rapidly identify genetic variations—are equipping neuroscientists to employ new investigative methods such as genome-wide association studies (GWAS).<sup>15</sup> For instance, one such study reported earlier this year uncovered that faults in the SORL1 gene are associated with an increased risk of late-onset AD, providing promising new avenues for follow-on research.<sup>16</sup>

<sup>12</sup>It is important to note that the development of these tracers, however, is comparable in process, time scale, and financial investment to the development of AD therapies themselves.

<sup>13</sup>Not only are these advances in imaging technology extremely important for research, but continued increases in capabilities with declining costs may eventually enable wide-scale, routine screening to detect AD upon onset when therapies are likely to be more effective.

<sup>14</sup>Oddo S et al. Triple-Transgenic Model of Alzheimer's Disease with Plaques and Tangles: Intracellular Ab and Synaptic Dysfunction. *Neuron*, 2003;39:409–421.

<sup>15</sup><http://www.genome.gov/20019523>.

<sup>16</sup>"The neuronal sortilin-related receptor SORL1 is genetically associated with Alzheimer disease." *Nature Genetics* 39, 168–177 (01 Feb 2007).

The range of these research breakthroughs and others like them indicates the complexity of the task we have set before the neuroscientists in our research institutes and industry laboratories. It's as if we've asked them to build a house, but to do so they also have had to invent and fabricate all the tools needed for construction along the way. They are proving more than equal to this challenge.

Even with rapid advances in our understanding of the disease and in the tools available to neuroscience researchers, though, the development of therapies—bringing them from the point of discovery to the moment of delivery—remains a high-risk enterprise. AD drugs have low clinical success rates, similar to those of other central nervous system (CNS) drugs (~8 percent).<sup>17</sup> Approximately 60 percent of drugs targeting the CNS successfully complete phase I clinical trials. Of these, ~40 percent successfully complete phase II clinical trials, and ~50 percent of these successfully complete phase III clinical trials. Finally, only ~70 percent of those that progress past phase III trials will become registered.

The new instrumentation and methodological options described above should improve these attrition levels. However, AD therapy development will remain daunting for the foreseeable future. It will continue to require substantial investments to be made by biopharma and medical device companies far in advance of what are, at best, uncertain prospects at the close of their development cycles.

#### STILL NEEDED: A ROADMAP TO GUIDE OUR ALZHEIMER'S DISEASE EFFORTS

So today, as we look at the national projections for Alzheimer's disease, we find cause for grave concern. As we survey the progress being made in our Nation's laboratories, we find reason for cautious optimism. What we will not find anywhere, however, is an excuse for complacency.

America must work both quickly and effectively to meet the challenge Alzheimer's poses to the country. And to do so, our efforts must be guided by a comprehensive, coherent strategy. What's alarming is that based even on a cursory review of our current Federal efforts, the evidence suggests such a strategy is lacking.

We have two fundamental objectives with respect to Alzheimer's. One objective, as described above, is to find therapies that will derail this disease. The second objective is to support those coping with Alzheimer's devastating impact. The first is to deliver a decisive medical solution. The second is to help reduce the pain and exhaustion, however inadequately, until medical advances make caregiving no longer necessary.

Both are essential goals and one might reasonably assume that the Federal Government is putting roughly comparable resources behind each of them. In fact, however, the imbalance in investment is startling. For every dollar the Government spends through Medicare and Medicaid to help Americans cope with Alzheimer's impact, it invests less than a penny to find a cure through the work of the National Institutes of Health and the Food & Drug Administration.

This penny-on-the-dollar approach might be called America's Katrina Strategy for Alzheimer's disease. As we now know, policymakers long neglected funding the work required to repair and strengthen the levees that might have saved New Orleans from the worst of Katrina's impact. And so, after the hurricane, a hundred-fold more had to be spent to rebuild the devastated city after the levees failed.

So long as the Government's current, reactive posture continues, we are repeating the tragic misjudgment of Katrina every 72 seconds as another American faces their personal hurricane with no levees to shield them.

Far from sensationalizing the present situation, in one very significant regard this Katrina analogy understates the deficiency of our current Federal approach toward AD. For, however slowly, the fact remains that New Orleans is now being rebuilt. That city is recovering from the mistake of neglecting its levees. But until effective therapies are in hand, we simply have no way to even begin to restore the lives of those now gripped by Alzheimer's.

However, we do know how to go about this the right way. Our national response to HIV/AIDS shows what can be accomplished when our Federal Government mobilizes around a coherent, aggressive, innovation-oriented strategy. In the mid-1980s, projections for the future impact of the AIDS epidemic, absent effective treatments, were of a scale similar to what we now face from Alzheimer's disease.

In a recent interview in *Health Affairs*, NIH Director Elias Zerhouni recalled his experience as a doctor at Johns Hopkins during the mid-1980s, a time when there was not yet an effective treatment available for the disease.<sup>18</sup> Half of all beds were

<sup>17</sup>Kola I and Landis J. Can the pharmaceutical industry reduce attrition rates? *Nature Reviews Drug Discovery*, 2004;3:711–715.

<sup>18</sup>*Health Affairs*, 25, no. 3 (2006): w94–w103.

being used to care for terminally ill AIDS patients, and Dr. Zerhouni and his colleagues projected that within a decade, 80 percent of their beds would be used to care for those dying from HIV/AIDS.

However, through a combination of strong research funding and accelerated FDA review, a preemption strategy yielded dramatic results. In just 5 years between 1995 and 2000, deaths fell 70 percent and survival rates increased by 10 years. Results continue to improve this decade. While much more remains to be done, within the United States an HIV/AIDS diagnosis is increasingly regarded as a chronic disease rather than a death sentence.

The fiscal impact of these new therapies has been equally dramatic. In his testimony before both the Senate and the House last year, Dr. Zerhouni explained how this innovation-focused strategy has saved \$1.4 trillion in healthcare expenditures,<sup>19</sup> on the basis of \$10 billion invested in basic research between 1985 and 1995; a return on investment of 140 to 1.

It is time for America to once again act in a similarly bold, strategic manner, revitalizing our commitment to defeating Alzheimer's disease. If we do so, I am hopeful that in 20 years' time a future NIH Director will use Alzheimer's disease to illustrate how smart, aggressive action changed the course of the Nation and immeasurably improved the lives of millions of Americans.

Thank you.

APPENDIX 1.—PREPARING THE COUNTRY FOR THE ALZHEIMER'S EPIDEMIC: A VIEW FROM SCIENCE, BUSINESS, GOVERNMENT, AND CAREGIVERS; NEWT GINGRICH, FOUNDER, THE CENTER FOR HEALTH TRANSFORMATION (EXCERPTED REMARKS)<sup>20</sup>

This particular conference was inspired in part by an article in the Washington Post called "Open the Door to Curing Alzheimer's: Why this Research Must Become an Urgent Priority," by Bob Essner at Wyeth. It really led me to ask the question, "Are we at a turning point where the scientific knowledge base makes it plausible that you could design a roadmap of extraordinary power that could in fact provide dramatically better futures for people?"

The breakthroughs for this disease are real and they're extraordinarily exciting, and they are driven by fundamental breakthroughs in science. I want to suggest to you that we are at the edge of an opportunity that is truly extraordinary, but that requires a willingness to think beyond the normal.

If you were to look at what the cost would have been to have fixed the levees prior to Katrina and what the cost has been since then, you would see a perfect case study of prevention and failure. And one of the great challenges for the Congress and the President to confront is that if we allow annual budgeting to define our investment strategies, we guarantee in the baby-boomer retirement years catastrophic disasters, because you never generate the resources to make the breakthroughs to avoid the catastrophes, and this has been very evident in the last 5 or 6 years. I mean, it is a process; it literally fits the model of penny wise and pound foolish from the 18th century phrase that you should never try to save a penny if it cost you a pound in British terms. In our case, it is million-dollar wise and trillion-dollar foolish. And it's just utterly irrational. And yet it requires you to say, "okay, what would an investment strategy approach look like?"

Let me also say that one of the things that is most stunning—if you take the 5-year cost of a breakthrough—if you could get a research advance that would delay the onset of Alzheimer's by 5 years, which is not complete victory, but a non-trivial breakthrough, the difference would be a 40 percent reduction and prevalence—5.3 million lives saved, a \$444 billion annual Medicare saving, a \$70 billion annual Medicaid savings, and a total \$515 billion savings for the Center for Medicaid and Medicare services. You can multiply that number by about seven to get the private savings for human beings who are using their own money today to deal with the challenge of Alzheimer's in their family. That's what just a 5-year delay means as a difference.

I believe that the scale of change we need—and I'm just going to go over this very briefly but I want to set a stage here—the scale of change we need starts with how do you maximize the evolution of imaging capabilities so that you can have a very inexpensive real-time capability on a routine basis. Ultimately, in the long-run, you want brain scans to be comparable to getting your teeth X-rays, and that's largely a research—it's a combination of the National Science Foundation, NIH, Siemens, General Electric, and other systems that focus on it. But that's a box that has to be dealt with.

<sup>19</sup><http://olpa.od.nih.gov/hearings/109/session2/testimonies/nihbudget.asp>.

<sup>20</sup>[Complete remarks available at [www.healthtransformation.net](http://www.healthtransformation.net)]

The second box is to design both basic and applied research tracks to essentially try to figure out what are the six or eight or nine biggest breakthroughs we need? And what level of resourcing does that require, and what level of access to data does that require? We're entering a world where if you look at Kaiser Permanente, the Veterans Administration, a number of other fairly large systems, we have over 30-million electronic health records today. We have a potential capacity to build Framingham-style studies to give you the epidemiology of a wide range of things, and we don't use them very well because we don't think like that. And so you want to look at could you identify every person who is in an early onset Alzheimer's situation out of the 30 million we already have electronic health records for and how could you knit them together into a learning system?

But this whole notion, we have to fundamentally reassess what do we mean by basic and applied research in the information age. And how do we maximize the rate of change and maximize the rate of discovery? And how do we bring together—it's very parallel to what Andy began doing at the National Cancer Institute in trying to accelerate the evolution with cancer. We need the same kind of pattern and we need to recognize, because of the emergent nature of brain science, which is at a much earlier stage than oncology, that you really want a lot more National Science Foundation involvement, because a fair amount of this is physics and mathematics; and you want NIH involvement and you want the corporations. And you want some kind of public/private research partnership to build a very high-tempo process.

The third thing you want to do, frankly, if I can take a few seconds to preach in public here, is we need an FDA brain science model of operation. Brain sciences are different. They're going to cut across all sorts of existing FDA systems. They require a level of sensitivity and intuitiveness, because today, it is my understanding as a non-scientist, we actually determine for sure you have Alzheimer's during the autopsy. Well, that defies all the FDA requirements for figuring out who the subjects are. And so we really need to fundamentally from the ground up erase the blackboard and say, "okay, in this newly emergent science involving one of the two or three largest items facing the American people, what is it we need to understand to maximize the rate of testing and maximize the rate"—and again, I want total Federal testing from a human safety standpoint, but I want it done in a brand new kind of framework.

This is particularly important because—my sense, again, as a non-scientist but as a historian who looks at the evolution of technology—my sense is you're going to see three parallel patterns going on simultaneously. You're going to see symptom management where you get a breakthrough that is partially palliative. It makes a huge difference if you can manage the symptom. You're going to get actual disease management. How can you in fact suppress the effect of it, make it better? And third, you are eventually going to start getting disease prevention or literally disease suppression. Now, those three tracks need to simultaneously be coordinated because you want to make progress on all three, and you don't want to give up any one of those waiting for some kind of magic breakthrough.

Fourth, I think the Center for Medicare and Medicaid Services and public policy in general, including the Veterans Administration and the Federal employee health benefit plan and Tricare should all be looking from the [caregiver] side back. What is the optimum way to help people be good caregivers? What is the optimum public policy to maximize the opportunity for families to have decent lives while struggling with this terrible disease? What is it we can do, for example, we should have a center which is developing the maximum number of tools that would help people who are caregivers.

Alzheimers Disease is a newly emergent problem that is no different than the epidemics of the 19th century or the famines of the 18th century or the industrial-era diseases of the 20th century. It's something we're going to have to learn to solve. We have to be practical about it. And the more aggressive we are and the more innovative we are, the faster we'll be successful.

And so I'm thrilled to have a chance on behalf of the Center for Health Transformation to thank all of you for being involved and to say that we very much want to work with you.

APPENDIX 2.—PREPARING THE COUNTRY FOR THE ALZHEIMER'S EPIDEMIC: A VIEW FROM SCIENCE, BUSINESS, GOVERNMENT, AND CAREGIVERS; SAMUEL GANDY, M.D., PH.D., DIRECTOR, FARBER INSTITUTE FOR NEUROSCIENCES (EXCERPTED REMARKS)<sup>21</sup>

This is the first time in medical history we can actually contemplate rational therapy for Alzheimer's disease. One of the numbers that you might or might not have heard before, but just to reinforce—half of the over-85 population has a dementing illness. That is, if both parents live to 85, statistically the likelihood is that they will—one of them will have Alzheimer's disease; will have a dementia, usually Alzheimer's disease.

So here's my title, "A Pivotal Moment is Within Reach" and that's absolutely certain; there's no doubt about that. We are now entering human clinical trials that will tell us if what we are fairly certain is true about Alzheimer's disease is in fact provable in humans.

Alzheimer's is really characterized by three key criteria. The first is the characteristic change in memory, typically the inability to form and retrieve new short-term memories. Equally frequent, patients with Alzheimer's may present with changes in personality. Eventually, all of the outside surface of the brain, all of the cerebral cortex, the part that's responsible for thinking, all of that part of the brain degenerates and patients die bed bound in what we call a vegetative state.

There is very early on a profound loss of a chemical called acetylcholine. This is a chemical that nerve cells use to talk to each other called a neurotransmitter. The currently approved medicines, at least three of the four, all target this deficiency; that is, they help the brain to compensate at the very earliest stages of the disease. However, for these medicines to be effective, intact nerve cells are required. So once nerve cells become impaired to the point of degenerating, those medicines that we currently have wear off. So these medicines don't appreciably slow the progression of the disease and don't really attack the underlying pathology. And that's what I'm going to talk about—the accumulation of the abnormal, gummy structures. This is really what's been the heart of the advances in Alzheimer's science.

This is what has the scientific community so excited about Alzheimer's disease—amyloid plaque, a clump, a build-up of a gooey material in between nerve cells. These plaques are composed of a protein called the beta amyloid peptide. So the real problem in Alzheimer's disease, in particular, and in other aggregation diseases, is that normal proteins, proteins that are always with you all throughout life, somehow, for reasons that are often mysterious—not always—change their shape, and in this altered shape, they then clump. And that's really the bottom line.

Within the past few years, we've now been able to develop—we the field; we, not me—have been able to develop PET scans that allow the visualization of amyloid buildup in the brain during life. So for the first time in a living human, you can watch amyloid buildup.

This is an incredibly important breakthrough and is being evaluated worldwide now, especially for the testing of new medications because now, for the first time, we can see the target; we can see what we are aiming our drugs at because we're developing these anti-amyloid drugs, and most peripheral markers have not been satisfactory. This particular imaging tool is being added to a large international initiative called the Alzheimer's Disease Neuroimaging Initiative and these particular scans are supported by a project from the Alzheimer's Association.

You will hear that there's a controversy over amyloid. Is this a cause or an effect? And the likely answer is both, because we know there is some instances in which the disease begins with amyloid and we know that there are other forms in which we can't trace the exact beginning. But all the evidence indicates we are better off without this misfolded form.

Even if amyloid is not the whole story in common Alzheimer's, we know very well that these clumps in nerves, and if we look at nerve cells in a dish, are poisonous. So this is not good. The only way now we can really resolve how much of the dysfunction in Alzheimer's disease is due to amyloid is in human clinical trials in which we develop successfully anti-amyloid agents, purge the brains of humans so there's no amyloid left, and see what happens cognitively. Ideally, we'd like to actually be in the prevention mode so that we identify ways to screen people, begin anti-amyloid interventions, and prevent the scenario from ever happening. But we won't know how bad amyloid really is until we purge it completely and follow the clinical outcome.

All the strategies that are currently being tested really fall into one of three categories. The first is the immunotherapeutic approach, the vaccine. The second is a

<sup>21</sup>[Complete remarks available at [www.healthtransformation.net](http://www.healthtransformation.net)]

new group of compounds called plaque busters (anti-aggregation drugs) And the third category are drug-like structures that could totally block amyloid formation.

This is really the state of Alzheimer's research. Mouse models of Alzheimer's amyloid can be caused with these amyloid-parent protein genes and cured with either vaccines, anti-aggregates, or these scissors modifiers. The real question that we're now answering in clinical trials, because these medicines are already being given to humans, is will (what we've seen in the mouse model) arrest or prevent the dementia with humans with Alzheimer's?

So I think that gives you a bit of an overview of the dramatic progress we've been able to make in the last 20 years in Alzheimer's. And the pivotal moment now is having these anti-amyloid medicines in human trials, washing the humans with these plaque-low PET scans to see if the anti-amyloid medicines work and following them with cognitive exams to see if they will stabilize or ideally, improve. And this is exactly where we are at this moment.

APPENDIX 3.—PREPARING THE COUNTRY FOR THE ALZHEIMER'S EPIDEMIC: A VIEW FROM SCIENCE, BUSINESS, GOVERNMENT, AND CAREGIVERS; ROBERT ESSNER, CEO AND CHAIRMAN, WYETH (EXCERPTED REMARKS)<sup>22</sup>

It's really a pleasure for me to be here today and share some thoughts on the intersection between science and patient care—in other words, how Wyeth and the private sector research-based pharmaceutical industry are trying to harness science to overcome Alzheimer's disease.

I'm pretty certain that still the population at large does not really see Alzheimer's disease as an epidemic, at least not yet. Last year, I spoke at the White House Conference on Aging, and pointed out that if you were to say the word epidemic then—and maybe still today—I bet most people would immediately think about avian flu, the so-called bird flu that's on the front pages of newspapers still all the time. And it's received massive attention in the media and people are genuinely and understandably frightened about the possibility of this new disease sweeping the world. But with all the intense interest around avian influenza, I sometimes think we've lost sight of the fact that this disease or potential disease, scary as it is, is only a potential threat, and that we may or may not actually have to deal with it.

The next disease probably most people would think about as an epidemic is HIV/AIDS. Reports in the 1980s of the devastation of AIDS quickly garnered widespread attention. The fear factor of this new disease with dramatic mortality rates was extraordinary. Scientific advances and a significant amount of effort across a multiplicity of stakeholders have rendered the threat of AIDS today to be very different than the way it was 10 or 20 years ago. While AIDS does continue to ravage many developing countries, in many parts of the world today, a diagnosis is no longer an automatic death sentence. Although much remains to be done in that field, in many ways, this is kind of a miraculous fact. And I think it feeds the imagination of a world in which AIDS is no longer an epidemic, but a manageable chronic illness. Unfortunately, obviously the same cannot be said about Alzheimer's disease.

Many people do not know that Alzheimer's disease is the third-most costly disease to treat in the United States right now, and most do not know that annual medical care costs for beneficiaries with Alzheimer's are expected to increase 75 percent over the next 5 years, and that Federal and State Medicaid spending for nursing home care alone for Alzheimer's patients is expected to nearly double by the year 2025.

The costs of Alzheimer's disease don't strike governments alone; they also strike individual families and businesses like ours. Over the course of the disease, Alzheimer's patients and their families spend more than \$200,000 on healthcare for a patient, and employer's use approximately \$60 billion a year on lost productivity as adult caregivers are forced to leave their jobs, either permanently or on a temporary basis to care for a family member with the disease. I think you get the picture.

What is so horrifying about Alzheimer's is not just that it kills, but that it is debilitating and dehumanizing. Alzheimer's essentially eats away at the very essence of its victims, not just their physical and mental capabilities, but also, as you saw, their personalities and the qualities that I think we all believe make us human. Yet the general public still does not, by and large, consider Alzheimer's disease to be an epidemic, but the world's scientists are not just sitting by and watching the devastation approach. Efforts to respond to the epidemic of Alzheimer's are underway across academia, industry, and government.

We at Wyeth are trying to do our part. Wyeth has been researching innovative treatments for Alzheimer's for more than 15 years now. We have more than two dozen projects in our pipeline, and have over 350 people in our research group who

<sup>22</sup>[Complete remarks available at [www.healthtransformation.net](http://www.healthtransformation.net)]

work exclusively on Alzheimer's disease today. And we have projects ranging from very early development through later-stage clinical trials. Our projects today use all of our available technology platforms, drugs, biotech skills, and vaccines because we want to explore every option available to us.

Wyeth is not alone obviously on this path to trying to find a solution to Alzheimer's. There are other companies at work, as well as scientists and academia and research institutes, who are making their strong contributions. The scientific, pharmaceutical, and research communities have been seeking to identify and develop new therapeutic targets that could dramatically alter the treatment for Alzheimer's. There are a lot of people on this path, and a few dozen programs each have the potential to fundamentally transform the treatment of this disease.

So why, given all the attention across various stakeholders, does the war against Alzheimer's disease continue to progress so slowly? I consider the greatest challenge facing Alzheimer's is the lack of a coherent strategy to respond to this disease. Unlike my examples of AIDS and avian flu, there is no global or even national focus on Alzheimer's. Scientific work and drug development go on, but at too slow a pace. Public health agencies are perhaps understandably engaged in dealing with the current devastation of the disease as much as working towards its cure, and regulatory agencies sometimes deal with Alzheimer's in the cautious way they do with diseases where major therapeutic options already exist. On the regulatory front alone, worldwide cooperation between reviewers and researchers could significantly improve the probability that we will succeed and reduce development times by years.

The reality is that our efforts against Alzheimer's are moving at a pace that is in no way commensurate with the problem that we're all trying to solve. What we need is a sense of urgency analogous to what arose around AIDS.

What we also need is a sense of urgency driving a coordinated response to this disease. Scientists and academia, government and industry must work hand in hand with regulators, healthcare providers, and patients and caregivers. We need the kind of bold innovative effort that has been generated in the past, and the AIDS story I think is instructive and inspirational. If we approach Alzheimer's with the same fervor, we'll be able to harness the potential of scientific advances and truly alter the course of this epidemic.

APPENDIX 4.—PREPARING THE COUNTRY FOR THE ALZHEIMER'S EPIDEMIC: A VIEW FROM SCIENCE, BUSINESS, GOVERNMENT, AND CAREGIVERS; ANDREW C. VON ESCHENBACH, M.D., COMMISSIONER OF THE U.S. FOOD AND DRUG ADMINISTRATION (EXCERPTED REMARKS)<sup>23</sup>

Listening to the Video and Dr. Gandy's scientific presentation took me back to my roots. My roots at M.D. Anderson, where I spent 26 years living with this dual reality, which on one hand allowed me to be a part of what have been some of the most profound breakthroughs in biomedical research in science and in technology, and yet at the same time every single day being confronted with the suffering and death and the ravages due to a disease like cancer.

And I knew that those two realities needed to be and could be reconciled; that all of that progress, the kind of progress that Dr. Gandy talked about this morning, could now lead us to a point where we no longer had to witness and tolerate that suffering and death, whether it was a disease like cancer or the ravages of Alzheimer's. That is within our grasp. That is our opportunity. That is why this meeting and your involvement and participation are so important.

Almost 5 years ago, I had the privilege to come to Washington to lead the National Cancer Institute with that vision, with that passion and with that commitment, and set a goal that we would focus and commit our effort to eliminate the suffering and death due to cancer, and bring that about by the year 2015.

I would present that same perspective to you this morning, that as you are engaged passionately and appropriately in seeking and driving for a solution to the problem of Alzheimer's, you also are involved and a part of a larger transformation, a transformation in health, in healthcare, and in fact in our healthcare delivery system.

We are together collectively cooperatively in the midst of being able to change the entire future of health and healthcare. By embracing and fully developing across the continuum of discovery, development, and delivery the new molecular reality and the molecular opportunity. And it holds the promise for being able to radically conquer diseases like Alzheimer's. Not only is the magnitude of change that significant, but the pace of change is equally significant, such that we no longer need to think

<sup>23</sup>[Complete remarks available at [www.healthtransformation.nets](http://www.healthtransformation.nets)]

of time horizons that are something in decades and centuries away as we did in the past, but to see this as not evolution but revolution in medicine.

As we look at this new future of discovery and development and delivery, I now have the privilege to have moved from the National Cancer Institute, where we had the opportunity to drive the agenda of our understanding of molecular mechanisms of a disease process like cancer, and begin to think about that disease not as an event but as a process in which those genetic and molecular and cellular events occurred over a period of time, and offered us ample targets for intervention that could preempt its outcome, the suffering and death.

And one listens to this morning's presentations and recognizes that that is exactly the same paradigm for Alzheimer's. It is a disease process that occurs over time, and as we understand the fundamental mechanisms, as outlined by Dr. Gandy, we can begin to develop interventions, as presented by Bob Essner, that could be prevent or preempt, or modulate that disease process in a way that we eliminate the outcome, that tragic, horrible outcome that we witnessed on that video.

The FDA is positioned as the bridge that needs to be responsible for making certain that all of the fruits of that discovery and that development come to be applied to patients who are in need. And it is the FDA's commitment to be that bridge, to be that bridge not of the past, but to be that bridge of the future. And for that, like you, and like every other part of this equation, FDA must change. It has a proud record over the past hundred years of being the world's gold standard, but the FDA of the past is not adequate or equipped for this new reality, and therefore it must change, and it must change not in isolation, but in context and in collaboration and integration with all of the other parts and pieces of the equation.

And so we have embarked upon an opportunity to look internally about what those transformations are that must occur within the agency itself, and what those opportunities are to collaborate and integrate both on the discovery and development end of the continuum, as well as on the delivery end of the continuum to bring that process about.

For example,

- Critical path—and the need to fully implement many of the strategic initiatives in critical path so that we bring the new science that is making possible discovery and development into the regulatory process;
- The use of biomarkers instead of simply waiting for the kinds of outcomes that were alluded to earlier this morning having to do with autopsy findings;
- The ability to completely revamp our clinical trials process and to begin to look at different adaptive trial designs and models that are adapted to the new realities;
- To begin to bring tools of modern information technology and bio-informatics into the regulatory process; and
- To collaborate and cooperate with the industry in being able to assure that we are effectively, proactively facilitating the development of these new interventions in ways that assure not just their efficacy but their safety, and to be able to stay invested not only on the front end of their development, but also to continue to monitor and modulate the behavior once they are being applied to much larger populations.

One of the things that we have done is to begin to look at ways in which we can bring the advocacy groups more actively into the process. The patient consultant program will of course include the ability to bring advocate participation into FDA's regulation and development of new treatments for serious neurological diseases, and the patient representative program will welcome your participation in advisory committees.

We have created an FDA interagency, neurology working group that will enable us to integrate across the entire portfolio of the FDA—our opportunities to begin to look at use of neurologic diseases, like Alzheimer's, as a model, just like we can look at cancer as a model through the activities that we have around the interagency oncology taskforce to drive this integrative and collaborative process.

There is much for us to change and much for us to do. This meeting typifies what we need. We need knowledge coming from scientists. We need commitment coming from the developers of these interventions. We need visions coming from public leaders, like the Center for Health Transformation, and we need leadership, and advocacy, and passion coming from you. And collectively, cooperatively, together, we will create a new world, not just for Alzheimer's or cancer, but also for everyone. You have the opportunity to help make that happen.

Senator MIKULSKI. Well done. Now we'd like to turn to Marilyn Blum of Owings Mills, Maryland, because as we've heard now from the experts, the real expert is always the family who must live

through this. We really thank you for speaking to so many people in the room because so much of the advocacy comes from people who have been touched by this disease. So there are several hundred here and we're gratified for that but we'd like you to give voice to what you think, as policymakers, we need to hear from the family.

**STATEMENT OF MARILYN BLUM, OWINGS MILLS, MARYLAND**

Ms. BLUM. Good morning, Senator Mikulski and Senator Burr. My name is Marilyn Blum and I represent one of the millions of family caregivers who struggle daily with the challenges of Alzheimer's disease. I am also here to tell you that Alzheimer's disease is no longer just our parents' disease. It has hit the baby boomers and it is not going away.

My husband, Steve, is just one of the people under age 65 with early onset Alzheimer's disease. He was diagnosed at age 60, a diagnosis that was not a surprise, given his family history. His father was diagnosed with dementia in his forties and died about 10 years later.

Steve's memory problems began when he was a very successful CPA, employed as the Chief Financial Officer of a Public Relations firm. The CFO job was demanding but Steve had always been able to handle the job. Suddenly, he started going to the office 7 days a week because he said his assistant had been let go.

He also got lost in familiar places. When we drove somewhere together, I had to give him specific directions like turn right at the stop sign or watch out for the red light. He gave wrong answers when asked about money, which was odd for a CPA. He also stopped doing maintenance on the house and cars, which was unusual. That led to later challenges for me because I had to play catch-up on things that weren't done timely, one of which caused our basement to flood.

Eventually, Steve's company was bought by a larger company and he was laid off. It was a blessing because in reality, he could not do the job. This gave us a chance to focus on dealing with his memory problems. We made an appointment with his internist and mentioned that Steve's father had been diagnosed with dementia at a young age but the internist repeatedly dismissed our concerns. The internist diagnosed depression and put Steve on anti-depressants. I wasn't happy with the doctor's diagnosis so I found a good therapist through a friend.

Steve began seeing the psychotherapist who suggested he get further tests. Numerous tests followed and then the diagnosis of cognitive impairment with probable AD. The diagnosis turned our lives upside down. Steve had to relinquish responsibility for our checkbook, a major blow to the CPA who had always handled our finances. He also had to give up driving, which was perhaps the most painful loss.

We were referred to the local Alzheimer's Association Chapter, which has been terrific. No matter how many friends and family members you have to help, no one can give you support like the Alzheimer's Association.

Through the Association, we attended four different support groups before we finally found one that focused on the issues we

were facing, including loss of income, social isolation and lack of meaningful activities for younger persons. We enrolled in an 8-week pilot program for individuals with early onset AD. The program was a lifesaver for both of us. I learned from other caregivers how to tackle the daily challenges of being an Alzheimer's caregiver. Steve spent time with people like himself and made new friends. I also heard about the Association's Help Line that is available 24 hours a day, 7 days a week to offer counseling in crisis situations or just listen if I need someone to talk to. Doctors can help deal with the medical aspects of Alzheimer's but you can't call them at 11 p.m. when your husband is yelling at you because he can't remember where he put the television remote.

I also learned what I could do to help keep Steve occupied. Being with him 24 hours a day, 7 days a week was emotionally and physically draining. The Association suggested I enroll him in an adult daycare program. He now goes to daycare 5 days a week and thinks of it as his volunteer job. With Steve at the daycare center, I don't have to worry that he is home alone and I can continue looking after my 92-year-old father who has health problems of his own. But I'm very aware that our future is uncertain so I applied for the Maryland Respite Care Program. I recently learned that unfortunately, there is a greater demand for respite services than funds available so I'm on a waiting list.

I am determined to keep Steve at home but I can't do it alone. We must continue programs that support caregivers. We have to increase funding for research to find better treatments and we need greater awareness about early onset AD and better tests to identify the disease at the earliest stages.

I'm so grateful to you, Senator Mikulski, for introducing the Alzheimer's Breakthrough and Family Assistance Act and for your outstanding leadership on Alzheimer's issues. I want Congress to pass your bill as soon as possible so I can tell Steve that his daughter, granddaughter and grandson on the way will not have to confront what I'm dealing with today. Congress should pass this bill, not just for my family but also for the millions of other families who are represented in this room. Thank you.

[Applause.]

[The prepared statement of Ms. Blum follows:]

PREPARED STATEMENT OF MARILYN BLUM

SUMMARY

My husband Steve is one of as many as half a million people under age 65 who have early onset dementia. He was diagnosed 2 years ago at age 60, although his memory problems started even earlier. Steve's father was diagnosed with dementia in his forties and died in a State mental institution 10 years later, while Steve was still in college.

Steve had been a very successful CPA and chief financial officer of a public relations firm. His memory problems were already noticeable when his firm was downsized and he was laid off. He declined considerably after he retired.

Steve's internist dismissed our concerns about Alzheimer's, even when we told him about Steve's father. He diagnosed depression and prescribed antidepressants. I wasn't satisfied. We found a psychotherapist who agreed this was not depression. After extensive tests, we got the diagnosis of probable Alzheimer's.

Steve has suffered huge personal loss because of his Alzheimer's. He had to give up our personal finances—a major blow to a successful CPA. He had to give up driving. Because we were younger than most couples dealing with Alzheimer's, we faced unique problems—loss of income, social isolation, and lack of meaningful activities.

Our best source of help has been the Alzheimer's Association. Through them we found a program organized for people with early-onset disease, which included educational sessions and separate counseling sessions. Both Steve and I found new friends there who understand what we are going through and share ideas about how to tackle our daily challenges.

The 24/7 helpline has been a godsend. Doctors can help with medical issues, but they are not available at 11 at night when your husband is yelling at you. The Alzheimer's Association's Call Center is.

It was not safe for Steve to be at home alone. For nearly 2 years, I was working 24 hours a day, 7 days a week to keep him socially stimulated and engaged in day-to-day activities. At the same time, I was looking after my 92-year-old father who has health problems of his own. When I reached the end of my rope, I enrolled him in an adult day program, which he attends 5 days a week. He thinks about it as his volunteer "job."

I am determined to keep Steve at home as long as possible but like all caregivers, I need help. I urge Congress to continue its support of programs like the 24/7 helpline. We also need greater awareness, standard procedures to recognize early onset Alzheimer's and better tests to diagnose the disease at its earliest stages.

I urge you to increase funding for Alzheimer research to find better treatment and prevention. I want to be able to tell Steve that his daughter, his granddaughter, and the grandson on the way will not have to face what I am dealing with today.

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Good morning Senator Mikulski and other distinguished guests. It is an honor to be here. My name is Marilyn Blum and I live in Owings Mills, Maryland. I represent one of the millions of family caregivers who struggle daily to confront the challenges of this terrible disease. I am also here to tell you that Alzheimer's is no longer just our parent's disease. It has hit the baby boomers and it is not going away.

My husband Steve is one of the 200,000 to 500,000 people under age 65 with early onset Alzheimer's disease or other dementias. We found out that he had probable Alzheimer's disease 2 years ago at age 60 a diagnosis that was not a surprise given Steve's family history. His father was diagnosed with dementia in his 40's and was eventually placed in a State mental hospital after he became violent. He died in the State institution about 10 years later, while Steve was still in college.

When Steve's memory problems first started, he was a very successful CPA employed as the chief financial officer of a public relations firm. The CFO job was demanding but Steve had always been able to handle the workload. Suddenly he started going to the office 7 days a week. He said it was because his assistant had been let go and he had to do her work as well as his. He also started getting lost in familiar places. Whenever we drove somewhere together I had to give him specific directions like "turn right at the stop sign" or "watch out for the red light". He gave wrong answers when asked questions—particularly about money—which was odd for a CPA. Although I didn't know it at the time, he also stopped doing maintenance on the house and cars, which was not normal for him. That led to later challenges for me, because I had to play "catch up" on things that weren't done timely, one of which caused our basement to flood.

Steve's memory problems continued for several months. Eventually the PR firm was bought by a larger company who downsized the firm. Steve was laid off—a development that turned out to be a blessing because it was becoming increasingly obvious to Steve's superiors that he could not perform the duties of his job. The layoff allowed Steve to end his career with dignity and helped him accept that retirement was the next logical step.

Steve declined considerably after he lost his job. We immediately made an appointment with Steve's internist. During the consultation we mentioned that Steve's father had been diagnosed with dementia at a young age but the internist repeatedly dismissed our concerns. The internist diagnosed depression and put Steve on antidepressants. I wasn't happy with the doctor's diagnosis so I found a good therapist through a friend. Steve began seeing the psychotherapist who realized that the memory problems were not depression. After an extensive round of tests, we found out that Steve had cognitive impairment with probable Alzheimer's disease.

The diagnosis turned our lives upside down. I had to convince him to relinquish responsibility for our personal finances. That was a major blow because as a CPA he was always on top of our financial situation and suddenly we had to hire an accountant for the first time in our lives. He also had to give up driving which was perhaps the most painful loss. We always loved to drive and kept our cars in spotless condition—we joked about what good prices we got when we sold cars, because

he kept them so well. He has gradually come to accept that I don't want him to drive, but we have daily conversations about him buying a new car.

We were referred to the local Alzheimer's Association chapter which has been the absolute best source of help and support over the last few years. No matter how many friends and family members there are to help, no one can give you support like the Alzheimer's Association because they are the experts. Through the Alzheimer's Association we attended four different support groups before we finally found one that met our needs. Most of the support groups were geared toward older people who were not dealing with the same issues that we were facing including loss of income, social isolation and lack of meaningful activities for younger persons. We eventually enrolled in an 8-week pilot program for individuals with early-onset Alzheimer's. The program included educational seminars about the basics of Alzheimer's disease, as well as separate counseling sessions for caregivers and individuals with the disease. The program was a lifesaver for both of us. Steve got to spend time with people like him and make new friends. I met people who knew what I was going through and learned from other caregivers how to tackle the daily challenges of being an Alzheimer caregiver. I heard about the Association's helpline that is available 24 hours a day, 7 days a week to answer questions about the disease, provide information about available services, offer counseling in crisis situations or just listen if I need someone to talk to about my fears and frustrations. Doctors can help deal with the medical aspects of Alzheimer's but you can't call them at 11 p.m. when your husband is agitated and yelling at you because he can't remember where he put the television remote.

I also learned what I could do to help keep Steve socially stimulated and engaged in day-to-day activities. When I reached the end of my rope after being with Steve 24 hours a day, 7 days a week for nearly 2 years, the Association suggested I enroll Steve in an adult daycare program. At first, Steve refused to participate. However, I read a book that said to tell Steve that going to the daycare center was a volunteer job. Steve now volunteers at the daycare center 5 days a week and it makes him feel like he still has a job. With Steve at the daycare center I don't have to worry that he's home alone and I can continue looking after my 92-year-old father who has health problems of his own. However, I'm very aware that our future is uncertain so I applied for the Maryland respite care program. I recently learned that unfortunately there is a greater demand for respite services than funds available so I am now on a waiting list.

I am determined to keep Steve at home as long as possible but I can't do it alone. We must continue programs that support caregivers, including the Alzheimer's 24/7 helpline and we have to increase funding for research to find better treatments. We also need greater awareness and standard procedures in place to recognize early-onset Alzheimer's disease and better tests to identify the disease at the earliest stages. That is why I'm so grateful to you, Senator Mikulski, for introducing the "Alzheimer's Breakthrough Act" and for your outstanding leadership on Alzheimer's issues in the Senate. I want Congress to pass the "Alzheimer's Breakthrough Act" as soon as possible so I can tell Steve that his daughter, granddaughter and grandson on the way will not have to confront what I'm dealing with today. Congress should pass this bill not just for my family but also for the millions of other families who are represented in this room. Unless we act now, another generation of Americans will become the newest set of statistics to fill the pages of a report about Alzheimer's. We can avoid this horrible scenario but only if policymakers make Alzheimer's an urgent national priority. Thank you again for inviting me here today.

Senator MIKULSKI. Thank you very much, Mrs. Blum. Thank you very much. I'm proud to have you as a constituent and we're certainly on the same side here. We're now going to go to questions but I would like to just kind of lay out quickly where we are and then we'll move into questions.

For those in the audience, there are two issues here: something called an authorization and something called an appropriation. Now for all these years and all your years of advocacy, we haven't just been sitting on our hands. We have been doing things, working to double the funding at NIH, looking at strengthening programs like the Call Center, the Alzheimer's Demonstration Grant Program and so on. But as Mr. Egge said, it's been a bit piecemeal,

uneven and even news that you could use often does not get out to those in clinical practice.

What we do know, though, is that we need to be focusing on two things. One, moving this year's appropriations to make sure that there is enough to keep hope and help alive while we work on the authorization legislation, which is S. 898, which will double the funding at NIH.

But to talk about doubling the funding is really an abstraction. What we face now, though, is that our legislation would double what we spend at NIH now, from \$640 million to \$1.3 billion. OK? Then we would also call for a summit to be run by NIH to look at breakthrough research. However, while we've been busy doubling the funding of NIH, which we completed in 2003, what we see is that Alzheimer's research has been actually cut since 2003, it has been cut a total of \$155 million. So we've been losing ground while we've been making headway in research.

What I want to do and I think we'll do on a bipartisan basis, is remember—look at this year's appropriations but we really need your help to go to every single member you know to co-sponsor this bill if, in fact, you are in support of it.

Well, let's go to what money will buy. I'd like to turn to Drs. Albert and Gandy because you've talked about the need to do more but tell me what you think about passage of this legislation, because we're calling it breakthrough legislation. Too often we've heard about the melancholy situation where it's hopeless, we can't make gains, et cetera. What would the increased funding, do you think, enable us to do that we are not doing or what would it do to accelerate what we are now doing? Dr. Gandy, you're the science advisor to the Association.

Dr. GANDY. Every clinical trial costs about \$50 million. So that's testing one medicine from start to finish. We believe that once we have these disease modifiers, we will now want to test medicines in pairs and in trios. We think that a cocktail of medicines will be the most effective way to arrest Alzheimer's. This is the strategy that has been successful with cancer, when we identify several pathways along the way and then develop medicines that block them one, two, three, four. That's where we need to go now. We need to be able to not only test these medicines one by one but in combination.

Senator MIKULSKI. Dr. Albert.

Dr. ALBERT. In addition, we need to be able to identify people as early as possible in the course of the disease when we do have effective medicines. We're not going to want to wait until the kinds of difficulties that Mrs. Blum has just been describing. We're going to want to intervene earlier, when the disease is just developing in the brain. So there are lots of strategies that need to be explored to improve early diagnosis so we can have early treatment. And as I was mentioning earlier, we also need to think about lowering risk. We need to learn much more about how we can delay the onset of the disease, prevent the disease, perhaps entirely by a variety of things. Right now, we've been focusing on—

Senator MIKULSKI. Could you elaborate on that? Because I think what struck Senator Burr and I while you were talking was these low-tech approaches. While we're looking for breakthrough drugs,

which is as you said, \$50 million for a trial. It has to be tested to be sure it not only has efficacy but it's safe. But right now, there seems to be a body of knowledge that is coming out of research even like yours, Dr. Albert, that are low-tech recommendations, kind of news you can use at the family level, at the community center level, on cognitive stretch-out, preventive kinds of diet things. Could you tell us maybe because not everything is high-tech drugs, though this is obviously very promising?

Dr. ALBERT. I think the most important thing we know for sure is the impact of vascular risks on cognitive decline. We all know that high blood pressure, diabetes, obesity, and smoking puts us at risk for heart disease and what we now know for certain is that it also puts us at greater risk for brain disease and cognitive decline. If that kind of information could get out to the community with programs such as the Alzheimer's Association has been developing with the CDC, that could have immediate impacts on public health because I think it could convince people that they should engage in these strategies of risk protection not only for their heart but for their brain.

In addition, we're learning that things like physical activity likely are very beneficial to the brain but we need to learn much more about that. So we need to have more research in order to know what to recommend to people.

Senator MIKULSKI. Mrs. Blum, you've talked about your life with your husband who really sounds like one swell guy and he still is a swell guy and you've lived the 36-hour day. Could you tell us what that means and therefore, what other public policies would have been helpful to you? You talked about a clinician who couldn't diagnose this. You talked about really, it was the Alzheimer's Association that was your friend and chief source of information. Then, of course, there is the financial stress. Could you share that with us and then we'll be turning to others for questions.

Ms. BLUM. I think, for one thing, it would be helpful if doctors could be educated that younger people can suffer from this type of disease. It just really threw a roadblock into Steve's getting a good diagnosis when his internist, whom we had confidence in, said that there was basically very little wrong with him. She actually said, every time a couple comes in here, the wife says the husband can't remember a thing she says to him and sort of made a little joke about it and this was no joking matter. Fortunately, we did get to see a good psychotherapist who recognized maybe there was something more serious going on and convinced him to be tested, to have his memory tested and then he was diagnosed.

Another, I think, critical area, as Dr. Albert mentioned, is educating caregivers on how to deal with it. This disease is like nothing you've ever experienced. Everybody here in this room knows that and you can't use your normal coping skills in dealing with your loved one because they are not the same person that they used to be and you really have to learn a whole new way of communicating with them, of dealing with crisis situations and I think caregivers need to be educated to learn how to do that.

Senator MIKULSKI. Where did you get your education? You said at this 8-week program that you went to.

Ms. BLUM. Yes. From the Alzheimer's Association, from reading everything I could get my hands on, from talking to other caregivers but certainly the Association is a major help.

Senator MIKULSKI. Was the Office on Aging or the Research and Information Service of any help to you?

Ms. BLUM. I don't think I ever used any of their resources.

Senator MIKULSKI. Well, you live in Baltimore County—

Ms. BLUM. Yes.

Senator MIKULSKI. Which has one of the really most outstanding senior programs. They win all kinds of awards but we're trying to look at also, how do we get the information that we now know out to the broader public? So I think you've offered us insights.

My time has expired. I'd like to now turn to Senator Burr.

Senator BURR. Thank you, Madam Chairman. Mr. Johns, thank you for what the Association does for so many afflicted by the disease and their families around the country. Ms. Blum, thank you for your very personal testimony today and your willingness to share that with us.

If I could, Dr. Gandy, let me focus on the two disease modifying drugs that you talked about. You said that they are now safe and effective. Are either one of those drugs on the fast track at FDA?

Dr. GANDY. Well, we're waiting for this summer's Alzheimer's Association Prevention Conference for the data to be laid out and at that point, the FDA will be able to make a decision as to what other information it requires to consider fast tracking either of those. I'm giving you sort of a preview of what is going to be released this summer.

Senator BURR. And my hope is that we can work in a bipartisan way up here to redefine for the future what fast track is. Fast track should start when we identify an epidemic and not necessarily at some point in the drug development process, do we now say, "Gee, this might be helpful. Let's speed it up." We've heard all the numbers from you, from the Association and I think from Mr. Egge. Nobody disputes the numbers. This is in the best interest of the patient, the families and the country that whatever our definition is of fast track, it should be let's get it as soon as we possibly can and my hope is that we'll work with you to try to achieve that.

How close are we potentially for big pharma, for biotechnology firms, for some of the companies independently to say, we know enough now that we're willing to invest our private sector money and we really begin to leverage that Federal investment? Not to diminish what we need to do on the Federal side but have we reached that critical mass in the private sector yet?

Dr. GANDY. I would say that every major pharmaceutical company has a program in Alzheimer's disease but many—actually most, are waiting for the very first effective medicine to be proven. Because then, they'll all agree that this is the right approach, that we're on the right track and things that are on the shelves now will begin to be tested.

Senator BURR. I think history has proven to us that we really need those private sector companies. They are the ones that have done most of the research on HIV/AIDS as it relates to the combination drug results and outcomes.

Let me turn to Mr. Egge for a second. In your testimony, you described a few recent biomedical advances in Alzheimer's disease, including brain imaging technology, animal models, specific biomarkers that track the onset and the progression of Alzheimer's, but you stated the development of therapies based upon these exciting initial discoveries has not been successful. Share with us, if you will, what you think the Federal Government can do to be a better partner with the private sector, to speed up translational advanced research that can turn promising basic research into actual therapies and treatments.

Mr. EGGE. Thank you, Senator. I think we can learn a lot, for instance, from what you did last year with some legislation, which was a very interesting look at a very pressing problem and it had very distinctive characteristics but it looked at how we could integrate it across the different functions of government, how we could work with the private sector very effectively. I think in the case of Alzheimer's disease, it's just the thing that has already been alluded to, where we need to look at this as a disease. I think our current leadership within HHS is exceptional and the people who oversee the different agencies are doing an extremely good job of overseeing what they asked to oversee, which is to look at it from an organizational or you might call it a horizontal perspective. But diseases don't strike that way. They come at us across the continuum.

So I think that's why we need to look at how we can work on just this translational point and maybe with some of the work we've done with the Cancer Society—the Cancer Society has done in working with government. It could point the way in some regards. For instance, there was active collaboration between NCI, where the current FDA Commissioner was leading the NCI and FDA to work on an integrative program so that there was as smooth a handoff as possible between the NIH and the FDA. So I think it is exactly that kind of approach that would be helpful here as well.

Senator BURR. Well, as we all know, this is not a phenomena just of Alzheimer's disease. I guess I would ask this question—do any of you share my frustration that eventhough innovation and technology has accelerated at a phenomenal rate, and the capabilities of bench research and the investment in the brain power is beginning to pay off, but we still have a system primarily at the FDA that moves at the same pace that it did 20 years ago because the designs never change. It is time we, in a bipartisan way, begin to look at how the design should change while still maintaining our safety and efficacy Gold Standard?

Mr. JOHNS. I certainly do, Senator. I know in talking to Commissioner von Eschenbach, he is interested in that very approach because he believes that the FDA needs to modernize to address these kinds of technological improvements. As you say, across different kinds of medical research, we've seen that we've got advancements in technology that can't be absorbed by the existing systems. We've used the great brain power and ability of the American public and researchers to move these things along but now we can't absorb them fast enough because of systems at FDA and otherwise.

But we are gratified by the work we've done with the FDA and that they have done with us in terms of including Alzheimer's individuals and caregivers on the panels and also for putting a focus on Alzheimer's disease neurological issues in the FDA. But we would agree with you completely that we need a bipartisan approach to advancing those systems to allow those technologies to move even faster.

Senator BURR. Thank you. My time has expired.

Senator MIKULSKI. That was an excellent line of questioning and I think something this committee will be taking up in the FDA reform. I think it is an excellent challenge.

Let's turn now to Senator Isakson from Georgia, also the home of the Center for Disease Control that has played such an important role in disseminating information on this.

Senator Isakson.

#### STATEMENT OF SENATOR ISAKSON

Senator ISAKSON. Thank you very much, Senator. Let me—I might break a rule here but I'm going to do it anyway. I want to acknowledge—I just noticed a minute ago in the audience, Matt McNair is here, right over here at the end of this row. He is a special friend to me for a number of reasons. He is a distinguished veteran of the U.S. military. He was a Republican candidate for governor in 1994 and today, he is the caregiver for his beautiful wife. He lives in a facility that my brother developed, having gone through the experience that he and I went through, taking care of my mother who died of Alzheimer's in 1998, which is why I am so supportive of S. 897 in particular because of what it does for the caregivers. Mack—I've seen him on many occasions at Park Springs at Stone Mountain, taking care of his lovely wife in an environment where he can still do it and everything we can do to promote the benefits to allow caregivers to be able to do that, just like Mrs. Blum, will be a tremendous advantage for the families and a tremendous advantage for those that suffer from what is a very devastating and terrible disease. So Mack, thank you for being here.

Senator MIKULSKI. Why don't you stand up because I think it's important we acknowledge the role of men in caregiving well—

[Applause.]

Senator ISAKSON. Mr. Johns probably knows this but Mack is probably the most significant fundraiser in the State of Georgia on behalf of raising money for the Alzheimer's Association and does a wonderful job of advocacy in terms of doing that.

As a son to a mother who had Alzheimer's and passed away from Alzheimer's, I'm interested in two things. First of all, Dr. Gandy, I'm interested in diagnosing those at risk early and you made in your comments, statements about advancements that are being made in that area. Would you elaborate on that for just a second?

Dr. GANDY. Sure, thank you, Senator. The way we envision the future is that there will be brain scans that we're beginning to develop now that will be applied the way colonoscopies, mammograms, PSAs are applied now in middle life so that we can determine whether the changes of Alzheimer's are already present. We believe that those changes that we can detect certainly under the

microscope and we believe, with these x-rays, with this brain scans, begin at least 10 years before the very first psychological or memory change.

So the idea is to use these brain scans to identify who is at risk or who is already on the way and when we have these effective medicines, begin those and that will then prevent this person from ever getting the disease. Sequential scans will be done to follow and be sure that the medicines are working.

Senator ISAKSON. That leads to my second question. Dr. Albert, you talked about Maintain your Brain exercises. I want to get a list of all of those, personally but I would suppose—

Senator MIKULSKI. We're going to give them out to both caucuses.

[Laughter.]

Senator ISAKSON. Yeah, right. I would suppose that as Dr. Gandy's early diagnosis bears itself out and is reliable that the first prescription in early diagnosis would be things like Maintain your Brain exercises, is that correct?

Dr. ALBERT. Absolutely. But we would want—we would hope that people would do that even without an early diagnosis. What we're learning is that the kinds of risk factors that I—the kinds of lifestyle changes that I mentioned, such as mental activity and physical activity and lowering vascular risks are beneficial even if people start doing them in middle age. There are large groups of individuals who've been followed from middle age to old age and it is clear now that when their lifestyle is already in this direction, it lowers their risk for developing Alzheimer's disease later on. So I would hope that this—we need much more information about specific activities that people can engage in to lower risk but my ultimate hope would be that all of us would engage in these activities starting at a much younger age.

Senator ISAKSON. I want to tell Dr. Gandy, who I believe is moving to Emory University soon, is that not correct?

Dr. GANDY. That's correct, yes.

Senator ISAKSON. Emory University is where my mother was diagnosed—we were very frustrated with her condition in 1992 and it was Emory that finally diagnosed my mom in 1993 and gave her tremendous support and care at that early stage of the diagnosis. So we'll welcome you to come to Georgia and come to Emory University.

Dr. GANDY. Thank you.

Senator ISAKSON. Thank you, Madam Chairman.

Senator MIKULSKI. Very good and again, we thank you for your active participation. We'd now like to turn to Senator Coburn from Oklahoma. Senator Coburn is also a physician and brings great insight into this and we turn to you, Senator.

Senator COBURN. Thank you, Madam Chairman, and thank you for having this hearing. I apologize, I had another hearing so I didn't get to hear all of the testimony. I have a couple questions for Dr. Gandy and also for Dr. Albert. Would you talk a little bit about beta-secretase and the inhibition drugs that are out there? I'm very involved with the Oklahoma Medical Research Foundation and they have a drug undergoing human trials right now. Would you talk about that because I see tremendous hope there?

Dr. GANDY. Absolutely. Beta-secretase is a chemical enzyme in the body that is really the rate limiting step that heads down the pathway, the bad pathway for creating the amyloid peptide. The idea then is to develop a medicine that will specifically block beta-secretase. That's been a favorite target since that enzyme was discovered in 1999.

There have been challenges so far for two reasons. One, because the catalytic site is very large and it is difficult to get something that will permeate the blood brain barrier and because the medicines that have been tried so far have been toxic. It's a favorite target and using genetic manipulations, looks very effective and looks like a safe target. But it has been very challenging to get a medicine that will do what we want. There are other strategies that seem safer but also are moving forward a bit faster than beta-secretase inhibitors.

Senator COBURN. Dr. Albert, any comment?

Dr. ALBERT. I would just reiterate what Sam said earlier, that all of the major pharmaceutical companies are trying extraordinarily hard to find medicines that will do just what he was describing. But they are only putting partial effort into this. They are waiting to see whether or not some drug will be truly disease modifying and the moment that that happens, I think, there will be an explosion.

Senator COBURN. I think there is no doubt that people in this country would love to see us double up our research again at NIH, which would imply a much larger portion of money going to dementia and Alzheimer's work, but what we often hear is we don't have the money for it. The thing that I'm struck by—I'm struck by it up here in the political sense but I'm also struck by it by all the disease advocacy groups, is that we have plenty of money to do it. But Congress doesn't have the courage to find the money.

Let me explain. Last year, we demonstrated in one subcommittee of the Homeland Security and Government Affairs, \$200 billion—\$200 billion in waste, fraud, abuse or duplication inside the discretionary budget of the Federal Government. That's \$200 billion out of a trillion. That's 20 percent waste, fraud, abuse or duplication. And yet, there is no action in Congress to eliminate any of that so we could take NIH from \$28 billion to \$56 billion next year.

What you continually hear is well, it's a matter of prioritizing for the money. It's not. It's a matter of priority for Congress to do its job to get rid of the waste, fraud, abuse and duplications so we can put the money where it needs to be. So what I would like to ask each of you, will you help me put the pressure on Congress so that we get rid of the things that aren't giving us results so we can put money where it is truly needed? Any comments on that?

[Applause.]

Mr. JOHNS. Well, certainly Senator, certainly any of us as taxpayers favor our dollars going to what are the most effective kinds of things that our government can fund for this country and we certainly are believers that Alzheimer's disease is one of those things and as you indicate, the entirety of the medical research enterprise is something that is critical to this country going forward. As many of us have stated here earlier today, the returns on investments in medical research have such huge potential for this country to avoid

future costs in Medicare costs, in Medicaid costs and again, simply the cost in human lives and human suffering that is being endured today and will be endured to much more greatly beyond.

One of the things we haven't said here yet today is that today, there are 5 million people who have Alzheimer's disease. In the future, by 2050, if we don't check it, there would be as many as 16 million people who have Alzheimer's disease and again, the potential for that to have a devastating effect on not only the Federal budget but the entire American economy is significant. So I do believe that anything we can do to invest in medical research, as several of you have said, the potential of raising the entire NIH budget and doing what we believe is correcting an error in under-investment in Alzheimer's disease would be much advantageous.

Senator COBURN. I want to—one last question for Dr. Albert. The idea of prevention—Senator Burr and I tomorrow are going to be introducing a global healthcare bill and one of the hallmarks of that is prevention. We know that when we really spend dollars properly on prevention in this country, we save tons of money and the money we're going to save is basically for our children and our grandchildren. But I'd like to see—the thoughts of educating the American public on what you can do to prevent Alzheimer's—that ought to be out there and it ought to be out there in a way where we can receive it. Just like what you can do to prevent colon cancer. But we spend almost \$8 billion a year on prevention in this government in 27 different agencies and yet, we don't have a good, comprehensive message on prevention.

So I would love to have your help as we try to develop that and push this, putting this money all together and saying, there's going to be a concentrated, coordinated plan for prevention, not just of Alzheimer's but of everything else that we know is preventable. That's a legitimate roll for the Federal Government, which we have neglected by not putting it together and not coordinating it. So I'd love to have your help on that.

Dr. ALBERT. That's why we think that the collaboration between the CDC and the Alzheimer's Association is so important. There has never been a campaign by the CDC about brain health. This would be the first. We know that there are things that people can do and we just need to figure out how to inform them and then with the help of the CDC, figure out what gaps in knowledge there that we could then provide additional funds for.

Senator COBURN. You know, it doesn't take much in terms of national television advertising dollars to get that message out. As far as what we're spending on prevention, we could cut colon cancer in half, we could markedly reduce the IBs, we could prevent Alzheimer's, a good portion of it, if we would just market that message. And yet, we're doing it through all these government programs, regulations and everything else rather than having great consumer advertising saying here's what you need to know. So I look forward to working with you. I thank the Chairwoman for this hearing. I think it is creeping upon us that as we age, prevention is the key for us in terms of affording the healthcare in the future but also research is the key and I will say today, I'm committing myself to double the funding at NIH over the next 5 years from the present number to \$70 billion so that we can actually put the

money into the disease prevention and the treatment. And I'm not one known for spending a lot of money up here.

Senator MIKULSKI. No, you're not.

[Laughter and applause.]

I think we all agree that this is really a public investment that not only helps families but the cost, as Mr. Egge said, we could be heading to a Katrina year.

I'd like to just summarize a few things and then see if colleagues have any followup questions before we break for the votes.

First of all, when we talk about the bill S. 898 that is pending, there is an effort in terms of what we call not only prevention but news you can use, which would put into an authorization a program that is currently in existence at CDC for public education about prevention techniques that could help people maintain a healthy brain at all ages. It also authorizes the Alzheimer's 24/7 Call Center, which provides crisis assistance and decisionmaking support.

Now, I was struck by Mrs. Blum and others who we have talked to where they don't often know where to go even to begin and even their clinicians sometimes don't know where to go to identify a 60-year-old man with lethargy and memory loss—that does have some of the same symptomology as depression. Could you tell me, Mr. Johns, why you think the funding for the Call Center is so important? You've advocated for it in your testimony.

Mr. JOHNS. Absolutely, Senator Mikulski. It is absolutely crucial, we believe, because we know from the research that we have done that people across America do not understand Alzheimer's disease. When they confront it, as we've heard here today, oftentimes docs don't make the diagnosis. We've got a lot of work before us at the Alzheimer's Association and we think at the Federal Government level, too, to get those messages across this country.

We are about to embark on an advertising campaign to raise attention to Alzheimer's disease and to move more people to that Call Center so that they can, in fact, get the information they need at that critical moment when they need it. Without that kind of information, you've heard here today that individuals can suffer needlessly, not only the individual with the disease but the families who provide the caregiving. I've talked to people—you know, I sit on an airplane and I sit next to someone who says, "I just don't know what to do about this and I don't understand what to do." It's possible for us to help them understand what to do and we do that every day, 365 days a year, 24 hours a day and even at those worst moments when people need us most. It's a critical support mechanism for people who are suffering from this disease.

Senator MIKULSKI. Senator Burr, do you have any further questions and Mr. Isakson and then I'll kind of summarize before we conclude.

Senator BURR. Madam Chairman, I want to thank you for calling this hearing but more importantly, I want to say to all five of our witnesses, we can't thank you enough, not only for your testimony today but for the great knowledge that each one of you bring to the table. I think that it's evident that we've got a lot of work to do and it's not limited to this disease category. As Dr. Coburn said, this is about how we change the model in America to one where

prevention and wellness is the first thing that is promoted in healthcare coverage. It is the educational piece that we go out with, regardless of what the disease is and that we take to the next generation and we ingrain in them that prevention and wellness is the focus that they must have, relative to their health. We do that at a time where we try to provide the breakthroughs that Alzheimer's needs, and that other disease categories desperately need. My only suggestion today is that we can be successful at the research bench and we can still fail, if we can't expedite those safe and effective and promising breakthroughs to where they are used by patients and they are done quickly because of the timelines that we're up against.

You know, the amazing thing about HIV/AIDS was that the commitment was laid beside the timeline and the short timeline was one that really was devastating, as Dr. Zarhouni said when he was in Baltimore. There is no doubt in my mind that we've got to lay a timeline down. That timeline may be different but I would suggest to you today, the timeline is not necessarily the result of Alzheimer's or the result of HIV/AIDS. It's the result of us not changing our healthcare model. It's the continued deterioration of healthcare dollars that we've got available to treat the entire healthcare system.

So as Mr. Egge talked about, prize payments—it doesn't matter whether it's prize payments in the industry for somebody to get a breakthrough, the question is, get the breakthrough. We can't be held up at FDA because we haven't determined yet whether this meets the classification of fast track, any drug that shows safety, any drug that shows efficacy in a disease category that we would list as epidemic should be fast track. I think that Alzheimer's presents a great opportunity for us to implement a lot of these external things that we know have an impact today on people who are affected by this disease. I thank you, Madam Chairman.

Senator MIKULSKI. Mr. Isakson, did you want to have any comment?

Senator ISAKSON. Yes, thank you very much for your leadership, Senator Mikulski and thank all our panelists for being here today and especially all the advocates who came to support those who testified today. They were just as important.

Senator MIKULSKI. I too, want to extend my gratitude to both the leadership of the Alzheimer's Association, and their organization of an excellent public policy framework but also to all of the people who are here today, and those who couldn't come because of either the responsibilities of caregiving or other demands in their lives.

We know that many of the advocates in this room, in fact, most of you, that you're doing it on your own time and on your own dime and we know that you put in three shifts. Many of you put in one shift in the marketplace earning a living or supporting a family, trying to hope that you have benefits in the workplace that would help you with caregiving and then you put in another shift with your own family and then the third shift here with the Alzheimer's Association. So we really thank you for your civic engagement and we need you to really then move this legislative framework forward.

I think what we've learned from both the testimony today and also the other experts and the Alzheimer's Associations' excellent report and I'd commend it to all that Alzheimer's is really a continuum. It's not like you catch it like an infectious disease. You don't catch Alzheimer's the way you might have malaria. You don't catch it the way you might develop polio. You don't catch it, unfortunately but it evolves. Therefore, what we need are those strategies that look at it as a continuum, pretty much the way we looked at diabetes years ago when it was diabetes, yes or no, insulin, yes or no but now, thanks to the breakthrough in medication, the whole issue of diet and lifestyle, the focus on prevention, then when medications—to go from insulin resistance all the way through to perhaps being insulin dependent. But there were so many interventions along the way. I remember years ago that when my own mother, who was a diabetic, was on oral insulin at age 40. Yet in a family with that propensity, there are over 300 medications that help from insulin resistance to others. This is where we're heading with Alzheimer's. First of all, prevention—diet, exercise certainly affects the vascular and other complications. The second thing is, cognitive stretch-out. We know just as you do physical exercise, you've got to use the mind and be active in that way. But these are all those wonderful ideas and then to be able to do the breakthrough kind of research that would help either with the cure or the memory stretch-out and to work on a bipartisan basis to move the research into clinical practice.

We're going to do this together and at the same time, we want to focus on the Call Center. We think you need news you can use. This is why we want to promote the Call Center and the efforts of the Center for Disease Control, to get out those kinds of things that help you be you.

We're going to have two other hearings on this topic. One on the further exploring of research, where we'll hear from the Head of the Institute on Aging at NIH as well as other researchers so that the committee grasps the full range of what's going on. This was just a cameo and we thank you. And at the same time, to listen to the private sector on how they think we can be an innovation-friendly government to move the ideas out because it's great to do the research but we can't wait 5 years, 10 years, as Mr. Egge said, the levies are starting to really crack, and then we will also hold a second hearing on the whole issue of caregiving. What do caregivers need in terms of again, their continuum? How do you help keep a loved one at home and what should government do to be able to support that? What about the continuum of care from adult daycare to assisted living to other types of help because no one family can deal with this all by themselves.

But you know, each and every one of you is already making a difference. We're going to work together and we're going to make the change. So God bless you today for your hard work and let's keep on fighting.

[Applause.]

You're welcome. I also want to acknowledge that Senator Jack Reed and Sherrod Brown were here. Senator Brown will have a statements for the record.

[The prepared statement of Senator Brown follows:]

## PREPARED STATEMENT OF SENATOR BROWN

Thank you, Madam Chair.

And thanks to Senator Collins and our other witnesses for joining us this morning.

Today's news underscored the significance of Alzheimer's research: more than 5 million Americans are living with Alzheimer's disease today and at least 7.7 million are expected to have the disease by 2030. Unless scientists find a way to prevent or reverse Alzheimer's, that number could reach 16 million by 2050.

According to researchers, the increase in Alzheimer's does not reflect an acceleration in the incidence of the disease in any particular age group. Instead it's a function of longer life expectancies fueled by advances in the prevention and cure for other major diseases.

It's useful to know that longer life expectancies are fueling the increase, but it doesn't make the increase in cases any less alarming.

We need to take action.

There are promising medicines in the pipeline that could delay the onset of Alzheimer's, and there are excellent programs throughout the country that provide comprehensive, state-of-the-art care to Alzheimer's patients—like the University Memory and Aging Center, a collaboration between University Hospitals and Case Medical Center in Cleveland, Ohio.

But it is clearly in the public interest to redouble our efforts to prevent this disease and lessen its symptoms.

Alzheimer's robs individuals of their identities and families of their loved ones.

The costs—both the human costs and the budgetary impact—of not addressing Alzheimer's are staggering. As it stands, the cost of treating individuals with Alzheimer's and other forms of dementia is nearly three times the cost of care for other Medicare beneficiaries.

Medicare spending for these patients is expected to reach \$189 million by 2015.

We can predict what the future holds if we don't overcome Alzheimer's, Parkinson's Disease and other illnesses, the prevalence of which are growing as the population ages.

More suffering and an increased strain on families, communities, the health care system, and public and private payers.

It is in the public interest to invest in embryonic stem cell research and other avenues that hold promise for tackling medical conditions that undermine human capability and breed human suffering.

I want to commend Senator Mikulski and Senator Bond for their hard work on behalf of Alzheimer's patients and families, and for introducing the Alzheimer's Breakthrough Act. It is a blueprint for progress, and I fully support it.

I am looking forward to working with colleagues on both sides of the aisle to respond to this hearing's call to action.

Senator MIKULSKI. That concludes the hearing.

[Additional material follows.]

## ADDITIONAL MATERIAL

## PREPARED STATEMENT OF SENATOR CLINTON

I would like to thank Chairman Mikulski and Ranking Member Burr for convening today's hearing on the current state of Alzheimer's disease research, and the pressing need for research and program funding. I would also like to express my appreciation to the Alzheimer's Association for their continued leadership.

I would like to extend a special thank you to Senator Collins for her leadership on issues related to Alzheimer's disease and aging more broadly, and for partnering with me on numerous pieces of legislation and initiatives related to these and other important health issues.

For the past 3 years, Senator Collins and I have co-chaired the Senate Alzheimer's Task Force, hosting six Congressional events, which have highlighted a variety of issues, including: the importance of early detection of Alzheimer's; helping people suffering from Alzheimer's and providing support services for their families and caregivers; and promising research findings that suggest that healthy diet, regular exercise, as well as social and mental activity may help to decrease the risk of Alzheimer's. I am pleased that today's witness panel includes Dr. Marilyn Albert, who has been a panelist at several Alzheimer's Task Force events over the years and who most recently presented a wonderful overview of the current state of research on preventive lifestyle measures at a December 2006 Alzheimer's Task Force event.

But even as our understanding of this disease grows—so does the toll of the disease. We cannot lose sight of the struggles of approximately 4.5 million Americans suffering from Alzheimer's—and the countless husbands, wives, sons, daughters, loved ones and caretakers who watch the disease unfold in a family member, friend, patient.

This hearing provides an opportunity to express our commitment to providing scientists with the resources needed to: identify the factors that contribute to Alzheimer's; recognize the warning signs of Alzheimer's; and make strides in treatment. I am a long-standing supporter of greater research funding at the National Institutes of Health, among other steps, to put our best ideas and brightest minds to work on this heart rending disease.

Today's hearing is not only a reminder of the importance of committing the resources necessary to both aggressively pursue a cure for Alzheimer's, but also as a call to action to responsibly provide the care that its present victims require. The majority of caregivers have outside employment in addition to their caregiving responsibilities at home. Research tells us that, because of the lack of support services, most caregivers either miss work or quit their jobs in order to meet the health needs of their family members. Respite care services provide temporary relief for caregivers and decrease the likelihood of formal long-term care, thereby resulting in significant savings for the healthcare system and taxpayers. Further, respite care also provides family caregivers with the relief necessary to maintain their physical and mental health, as well as bolster family relationships.

Last December, the *Lifespan Respite Care Act* was finally enacted after a long, bipartisan effort. This law will have a real and meaningful impact on millions of Americans who struggle everyday to provide care for a family member with a chronic illness or disability so they may remain at home and out of more expensive institutional care. Senator Warner and I, along with 22 of our fellow Senators, are currently fighting to obtain the authorized funding, which would be nearly \$300 million over 5 years.

This fight for funding is a bipartisan effort, because all of us recognize the financial pressure that will be placed on our healthcare system in light of the fact that older adults are the fastest growing segment of the U.S. population. And we realize that as the Baby Boomer generation ages, there will be a dramatic increase in the number of Alzheimer's cases in the Nation. By the year 2050, if we do not make headway, up to 16 million Americans are expected to suffer from this devastating disease.

For the people that will confront this disease in their own lives, this increase is more than statistics: the increase represents an emotional struggle, a tremendous financial burden, a new strain on our already stressed healthcare system, particularly for Medicaid and Medicare costs.

I congratulate Senator Mikulski for her tireless efforts to raise awareness and support for Alzheimer's disease. I am proud to have been an original co-sponsor of the Ronald Reagan Alzheimer's Breakthrough Act last Congress, and now an original co-sponsor of both the *Alzheimer's Breakthrough Act* and the *Family Assistance Act* that Senators Mikulski and Bond introduced last week. I am delighted that these bills have garnered bipartisan support.

I also applaud Chairman Mikulski and Ranking Member Burr for using this hearing to highlight the importance of programs such as the 24/7 Alzheimer's Call Center and the CDC "Brain Health Initiative." Last year, I worked with Senators Mikulski and Collins to restore funding for critical seniors and Alzheimer's programs, and I will continue to advocate for these programs' continuation.

Diseases such as Alzheimer's can contribute to depression and anxiety for both those who suffer from the disease as well as their caretakers. That is why Senator Collins and I are working to improve access to mental health services for our Nation's seniors by integrating mental health services into primary care and community settings. In last year's reauthorization of the Older Americans Act, we successfully enacted Title I of the *Positive Aging Act of 2005* which authorized grants for the delivery of mental health screening and treatment services for older adults and grants to promote awareness and reduce stigma regarding mental disorders in later life. While this took an important step toward improving mental health services for older adults, significant efforts are necessary to ensure comprehensive geriatric mental health care. Senator Collins and I will soon introduce the *Positive Aging Act of 2007*, which will support integration of mental health services in primary care settings and authorize grants for community-based mental health treatment outreach teams, among other provisions.

Again, I would like to thank both Chairman Mikulski and Ranking Member Burr for holding this hearing, which reminds us that we must remain focused: to ensure we fully explore the potential

for prevention, treatment, and cure; that we do all we can to improve the lives of those suffering; and that we take steps now to lessen the future burden and improve the quality of life for our Nation's current and future seniors. The more we know, the closer we are to achieving a world without Alzheimer's—and we know that we cannot afford to wait.

I look forward to working with my colleagues on the committee and the Alzheimer's Task Force to highlight the need for more funding for Alzheimer's research and support programs. Thank you.

[Whereupon, at 11:35 a.m., the subcommittee was adjourned.]

