

2004 National Public Policy Program To Conquer Alzheimer's Disease

from hopeless to hopeful



alzheimer's  association

Ushering in a new era of progress and hope

2004 marks a new era in the fight against Alzheimer's disease. In 20 years, we have gone from hopeless to hopeful. Indeed, the last two decades have brought us to a point where the goal of a world without Alzheimer's is within reach. Working collaboratively, the federal government, the scientific community, the Alzheimer's Association and the pharmaceutical industry have made tremendous progress in the prevention, diagnosis and treatment of Alzheimer's disease. The breakthroughs include:

- Improved diagnostic tools that are helping providers to diagnose with more than 90 percent accuracy.
- Identification of genes that may put people at increased risk for the disease.
- Food and Drug Administration approval of medications that can alleviate the symptoms of Alzheimer's disease.
- The search for "anti-amyloid" therapies (including an "Alzheimer vaccine"). Recent research points to the accumulation of amyloid as the biological event that fosters the development of Alzheimer's disease. Treatments that can reduce the accumulation of this unwanted protein are essential.
- Increased knowledge of what we can do to stave off dementia. The Alzheimer's Association has launched a "Maintain Your Brain" campaign to alert every American that healthy brain aging is possible.



The goal of a world without Alzheimer's is within reach.

Our challenge: Taking advantage of a window of opportunity

Now, our great challenge is to forge a public policy program that lays the foundation for many more breakthroughs and, ultimately, a cure. The stakes couldn't be higher.

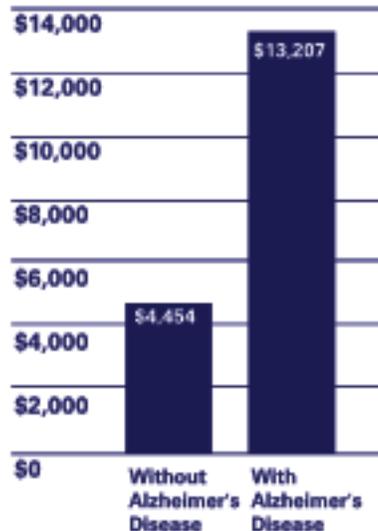
What will happen if we do not act: The number of Americans with Alzheimer's – 4.5 million today – will increase to between 11.2 million and 16 million by 2050.

Within a decade, total annual Medicare cost for people with Alzheimer's will increase by almost 55 percent to nearly \$50 billion. Medicaid health and long-term care expenditures will rise by 80 percent, to \$33 billion annually. Alzheimer's disease costs U.S. businesses \$61 billion in 2002, an amount equivalent to the net profits of the top 10 Fortune 500 companies. And the incalculable human costs will rise – the pain of seeing loved ones suffer, and the lost contributions of millions of older Americans who would otherwise enrich us as a people.

What will happen if we do act: Most scientists believe that discovering effective methods and treatments that will delay the onset and progression of Alzheimer's as well as prevent the disease are well within reach in the foreseeable future if the current pace and momentum of research is maintained.

Great opportunities are before us – if we can seize them.

Average Medicare Costs for Beneficiaries with Alzheimer's vs. All Beneficiaries



Source: Centers for Medicare and Medicaid Services, FY2000 Medicare claims data for a 5% random sample of Medicare beneficiaries.

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Our call to action

The Alzheimer's Association has a plan for the fight against Alzheimer's disease that includes a major mobilization of people and significant new resources. The Association is prepared to lead the fight, but the nation needs the leadership of the President and the Congress as well. We call upon the 108th Congress and the Administration to take action in three key areas:

CURE: Provide \$1 billion for basic and clinical Alzheimer research at the National Institutes of Health (NIH) to translate scientific discoveries into effective methods of prevention; to develop treatments that reduce the disabling impact of the disease on those already affected; and to finance focused studies of Alzheimer's disease in minority populations.

PREVENTION: Launch a "healthy brain" initiative in partnership with government agencies, including the NIH and the Centers for Disease Control and Prevention, to educate the American people about the ways they can maintain their brain as they age.

CARE: Establish a targeted chronic care benefit within Medicare to control the high cost of care for beneficiaries with dementia and other complex chronic conditions. Implement the new Medicare prescription drug benefit. Preserve the Medicaid long-term care safety net by maintaining the federal entitlements and quality assurance provisions of current law. Enhance care and support services for persons with Alzheimer's by assuring that research findings are translated into improved care and treatments for patients.



Ninety-five percent of what we know about Alzheimer's we've learned in the past 15 years. Scientists are making great strides to find better treatments and precautions that may one day lead to a cure.

Action 1: Appropriate \$1 billion for Alzheimer research at the National Institutes of Health.

In 1983, when President Ronald Reagan first designated November as National Alzheimer's Disease month, the extent of the disease was not widely known, a definitive diagnosis could be confirmed only via an autopsy and there was no infrastructure for Alzheimer research.

Twenty years of investment in the National Institutes of Health combined with steady scientific progress have led to advances no one would have imagined in 1983. We are well into an era of discovery that has already brought us tangible benefits.

It is now possible to diagnose Alzheimer's with more than 90 percent accuracy. Understanding of the fundamental neurobiology of the disease and its impact on the brain is developing rapidly. Identification of potential points of therapeutic intervention has accelerated the search for new treatments. Several animal models mimicking some aspects of the disease are available to researchers, enabling scientists to narrow the targets for prevention and speed effective drugs to market. Five prescription medicines specifically approved to treat Alzheimer's are in pharmacies. Three genes that cause rare, early-onset forms of the disease and one risk gene for the more common, late-onset form have been identified. A nationwide research infrastructure that supports thousands of scientists with funding from the federal government, the Alzheimer's Association and pharmaceutical companies is in place.



Current research is focused on the importance of attacking Alzheimer's disease at much earlier stages, before the symptoms of the disease begin. Additional strategies for slowing the progression of the disease process – to postpone onset of and hopefully prevent full-blown Alzheimer's – are under investigation. Advanced technologies, including neuroimaging techniques such as magnetic resonance imaging (MRI), functional MRI and positron emission tomography (PET) are expanding possibilities for early detection and intervention.

The best treatment, for individuals, for the health care system and for the public health system, is prevention. If science could delay the onset of Alzheimer's by even five years, the number of individuals with the disease could be reduced by as much as 50 percent over time.

How additional resources will lead to more breakthroughs

The key to realizing a future without Alzheimer's disease is ensuring that the NIH has the resources it needs to fund promising research. These resources are needed to:

Maintain the pipeline of basic scientific discovery to develop additional targets for treatment. At current funding levels, NIH can support only about one in four research proposals that

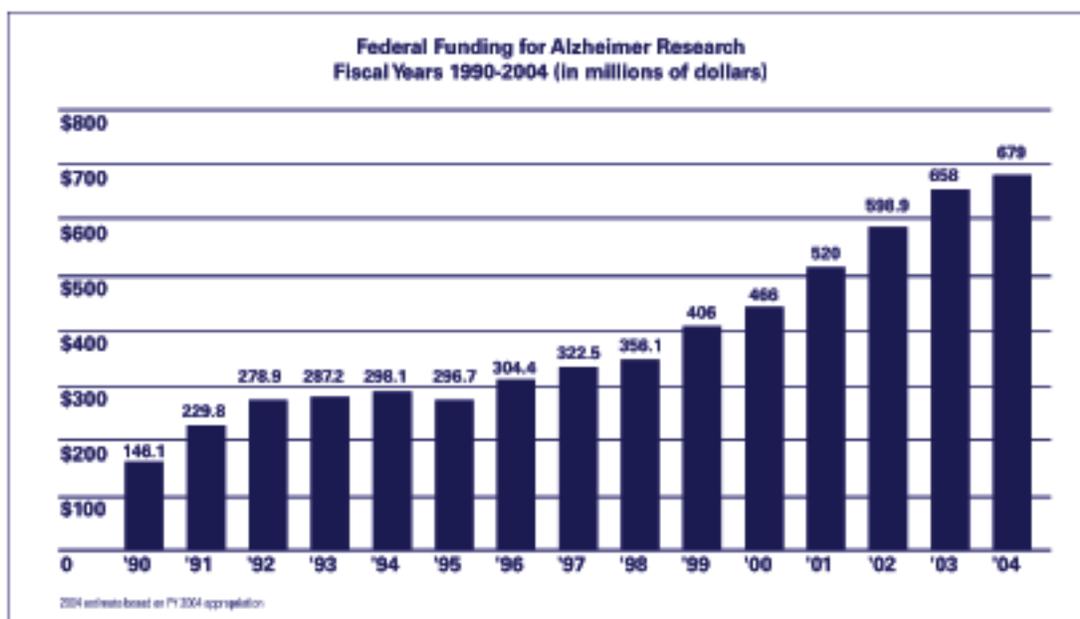
meet rigorous peer-reviewed standards. It would take an additional \$24.5 million for the National Institute on Aging (NIA) alone to fund another 10 percent of the most promising proposals submitted by scientists.

Develop better animal models to test potential new treatments more quickly and at a fraction of the cost of human trials. It could take as little as \$50 million to get the next generation of animal models in the hands of the scientific community.

Accelerate the investment in clinical trials to test prevention targets in non-cognitively impaired persons to determine whether early use of these compounds can have a protective effect. Each of these prevention trials will cost between \$25 and \$30 million. To reap the greatest reward, the trials should start as rapidly as targets are identified.

Invest in more new biological assays and imaging techniques to monitor changes in the brain that indicate progression of the disease and to provide accurate, earlier diagnosis. When more effective medications are available, it will be necessary to intervene as early as possible, and the Imaging Initiative currently underway at the NIA is designed to make this possible. It will cost an estimated \$60 million to fully implement.

Speed the discovery of risk factor genes for late-onset Alzheimer's, the most common form of the disease. Discovery of risk factor genes will help illuminate the underlying disease processes of Alzheimer's disease, open up novel areas of research and identify new targets for drug therapy. The NIA and the Alzheimer's Association are in the process of recruiting at least 1,000 families over the next three years to create the nation's largest repository of genetic material from families affected by late-onset Alzheimer's disease. NIA needs an estimated \$60 million to complete the genetics initiative.



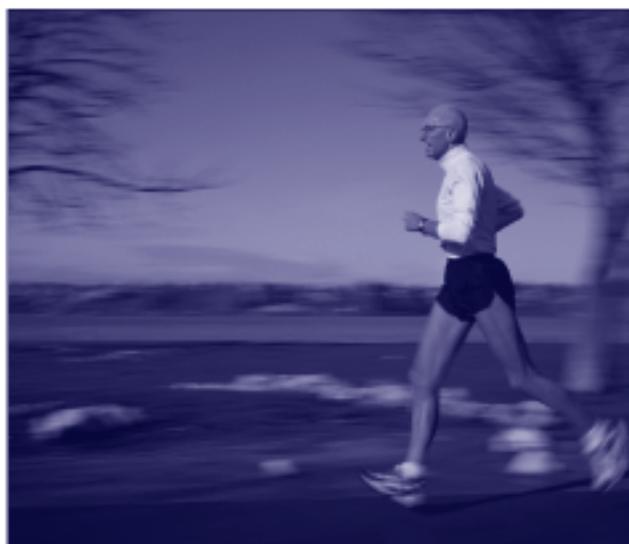
Congress and the Administration must remove a roadblock to progress

Only Congress and the President, through a significant addition of new funding, can assure that we realize the unprecedented opportunities in Alzheimer research. Minimal increases in funding for the NIH are not enough to support additional clinical trials and maintain the pipeline of basic scientific discovery. Failure to provide the large funding increases that will help keep pace with inflation will destroy the momentum gained over the past five years. Inadequate funding increases mean that less money will be available to support new research grants and clinical trials, delaying scientific discoveries and resulting in lost opportunities.

Action 2—Prevention: Launch a “healthy brain” prevention initiative in partnership with government agencies.

A growing body of evidence making the connection between known risk factors for heart disease (including high blood pressure and high cholesterol) and risk factors for Alzheimer’s opens the door to opportunities for preventing or delaying onset of dementia. New research indicates that controlling weight and blood pressure and cholesterol levels may be as good for the head as they are for the heart. Maintaining the brain by remaining intellectually and physically active and socially connected may also help stave off dementia.

The Cognitive and Emotional Health Project (CEHP), a major effort to identify factors for maintenance of cognitive and emotional health in adults, has been undertaken in a joint venture of three Institutes - the NIA, the National Institute of Mental Health (NIMH) and the National Institute of Neurological Disorders and Stroke (NINDS). The overarching goal of this trans-NIH initiative is to determine how cognitive and emotional health can be maintained and enhanced as people grow older by unearthing the risk and preventive factors for cognitive and emotional dysfunction.



*Exercise your body and brain.
Manage your blood pressure, weight
and cholesterol. What is good for the
heart is good for the head.*

Maintain your brain: Ways to potentially ward off dementia

Research advances have proven that Alzheimer's disease is not a normal part of aging. Preliminary studies suggest that some of the same strategies that preserve overall health may also help prevent or delay Alzheimer's disease.



Epidemiological studies have revealed that individuals taking anti-inflammatory drugs to treat conditions such as arthritis appear to have a lower-than-expected occurrence of Alzheimer's disease. Scientists have launched several clinical trials to investigate specifically whether use of anti-inflammatory drugs may reduce the risk of Alzheimer's.

The first clinical trial designed to test the effects of statins (drugs prescribed to lower blood cholesterol levels) is underway as ongoing basic

research seeks to clarify the biological links between vascular disease and Alzheimer's disease. Confirming and clarifying a vascular/Alzheimer's connection raises the exciting possibility that well established strategies for reducing the risk of heart disease, such as exercising, paying attention to diet, avoiding smoking and controlling blood pressure and cholesterol levels may also have value in preventing Alzheimer's.

Research published in the last year found that:

Weekly consumption of fish may reduce the risk of developing Alzheimer's disease, according to a report in the *Archives of Neurology*. Study participants who consumed fish at least once per week had 60 percent less risk of developing Alzheimer's compared with participants who rarely or never ate fish. Further research, including controlled clinical trials, to understand the apparent protective benefit of diets high in omega-3 fatty acids is needed.

Significantly overweight women at age 70 have a substantially increased risk of developing Alzheimer's, according to a long-term study reported in the *Archives of Internal Medicine*. The average size of the women in the study was on the borderline between normal and overweight, suggesting that even moderate, common-sense weight control may help lower risk of Alzheimer's disease.

Research advances prove that Alzheimer's disease is not a normal part of aging.

Mentally stimulating activities, such as reading a magazine, may reduce the risk of developing Alzheimer's and other forms of dementia, according to a study published in *Neurology*. This study found a 19 percent decrease in the annual rate of cognitive decline for every 1-point increase in the cognitive activity score.

Older adults who have had a stroke have a higher risk of developing Alzheimer's disease than those who have not had strokes, according to a study in the December 2003 *Archives of Neurology*. Alzheimer risk increased even more for individuals who also had high blood pressure, diabetes or heart disease in addition to a history of stroke. In the absence of stroke, none of those factors except diabetes appeared to increase Alzheimer risk in this study. Although this study adds to a growing body of evidence that there is a relationship between vascular factors and Alzheimer's disease, it also illustrates that the relationship is not a simple one, and that more research is needed to clarify and understand it.

Three institutes at the NIH (NIA, NINDS, NIMH) are working together to determine the current state of knowledge in this area and to recommend future studies that are needed. The CDC's National Center for Chronic Disease Prevention & Health Promotion has identified healthy aging for older adults as a major focus area for future research and action.

The Alzheimer's Association recommends that Congress establish and fund a program through the CDC to educate members of the public about ways they can maintain their brain as they age, based on the current review being undertaken by the NIH, and to encourage state public health departments to launch prevention/early identification and intervention programs with particular attention to the link between Alzheimer's disease and co-morbidities such as diabetes and vascular disease.

Action 3 – Care: Establish a targeted Medicare chronic care benefit; implement the new Medicare prescription drug benefit; preserve the Medicaid long-term care safety net; continue collaborations between the Alzheimer's Association and government to enhance care and support services for persons with Alzheimer's.

Because of their impaired memory, judgment and reasoning ability, Medicare beneficiaries with advanced Alzheimer's disease or another dementia cannot completely manage or direct their own care. As Alzheimer's progresses, individuals with the disease cannot follow the medication instructions or nutritional regimes prescribed by their doctors nor can they recognize symptoms that their condition may be getting out of control. Individuals with dementia need



ongoing care management to monitor their health status and prevent the acute care crises that are driving up Medicare costs today.

Alzheimer's disease is a major contributor to rising Medicare costs. A closer look at the numbers illustrates how Alzheimer's disease contributes to Medicare expenditures:

- Individuals with dementia cost Medicare three times more than other beneficiaries — \$13,207 versus \$4,454 annually.
- 95 percent of all beneficiaries with dementia have at least one other chronic health condition common in the elderly — 30 percent have coronary heart disease, 28 percent have congestive heart failure and 21 percent have diabetes.
- Hospital, home health care and skilled nursing facility costs are three times higher for beneficiaries with dementia.
- Medicare costs for beneficiaries with dementia and other chronic conditions such as coronary heart disease, congestive heart failure or diabetes are twice as high as costs for beneficiaries with chronic conditions who do not have dementia.



Restructuring Medicare: Shifting the focus to chronic care

One of the most effective ways to restructure Medicare in the short term is to establish a care coordination benefit targeted to individuals with complex chronic conditions, including Alzheimer's or other dementia.

The Alzheimer's Association has collaborated with health care providers and managed care organizations to demonstrate that simple interventions, including early identification of dementia, consultation among care providers and ongoing support for caregivers, can reduce hospitalization and delay nursing home placement, lower overall costs and result in better health outcomes for the individual with dementia. A Medicare chronic

care benefit should include: payments to the beneficiary's primary health care provider for an initial assessment; development of a coordinated care plan; care management activities including coordination of clinical care across providers, medication management, multidisciplinary care conferences and ongoing consultation with the beneficiary and his/her caregivers. Care

coordination is very different from disease management programs that focus on managing only one aspect of an individual's overall health status at a time. Care coordination focuses on managing an individual's care needs across various health settings and among different providers to avoid adverse medical events exacerbated by the presence of multiple chronic conditions.

Efforts to restructure Medicare should also focus on making the program more responsive to the needs of beneficiaries with Alzheimer's disease. Medicare coverage policies and regulations should ensure fair and equal access to benefits currently provided by statute and remove barriers, such as inappropriate denials of mental health services and restrictions on rehabilitation therapies, that are obstacles to good Alzheimer's care.

Prescription drug coverage: A good first step

Passage of the Medicare Prescription Drug & Modernization Act will, for the first time, provide Medicare beneficiaries with Alzheimer's disease critically needed coverage for prescription drugs. This is a historic accomplishment that provides both up-front and catastrophic coverage and offers subsidies to help protect low-income beneficiaries.

The Alzheimer's Association believes that the addition of the prescription drug benefit moves the Medicare program in the right direction. The Alzheimer's Association, however, will be vigilant in overseeing the implementation and evaluation of the "premium support" demonstration to ensure that it will not place beneficiaries with Alzheimer's at risk by destabilizing the traditional, fee-for-service Medicare system or penalize older, sicker beneficiaries who tend to have higher health care costs.

Making Medicare more responsive to the needs of beneficiaries with chronic conditions is only part of the challenge facing the U.S. health care system. We must also improve care in hospitals, nursing homes and assisted living facilities. Quality improvement efforts in various health care settings are currently underway by the federal government and several regulatory agencies. These quality improvement initiatives will miss the mark if they fail to consider the demands that Alzheimer's places on the health care system. The Alzheimer's Association strongly encourages federal agencies responsible for quality care programs to incorporate dementia care benchmarks in all quality initiatives.



Preserving the long-term care safety net

Medicaid is the single largest public payer for long-term care services in the United States and a last resort for persons with Alzheimer's who have no other way to pay for the help they need. Half of all Medicare beneficiaries with Alzheimer's also receive Medicaid to help pay for long-term care, prescription drugs and other medical care because they have "spent down" their own resources and qualify for assistance. In 2000, Medicaid spent an estimated \$18.2 billion on nursing home care for people with Alzheimer's. Medicaid expenditures for persons with Alzheimer's are projected to rise to \$33 billion by 2010 – an 80 percent increase over current spending.

In the absence of a better national long-term care program, Congress and the President must preserve the long-term care safety net that Medicaid provides. This includes maintaining or improving the federal entitlement to benefits, and preserving existing nursing home quality standards as well as protections against spousal impoverishment. Reform proposals that cap Medicaid funding as a method of giving states more flexibility regarding benefits and services will leave many of society's most vulnerable citizens in jeopardy.

Preserving the long-term care safety net also includes making continued improvements in the quality of care in long-term care facilities. These improvements include maintaining sufficient staffing levels, adequately compensating staff and providing dementia-specific training. There is a heavy reliance on institutional care, but family caregivers continue to be the backbone of the long-term care system, especially for persons with Alzheimer's. It is essential that Congress provide at least current-level funding for the National Family Caregiver Support Program to maintain this integral part of the nation's long-term care system.

Enhance support services for persons with Alzheimer's

More than two decades of collaboration between the Alzheimer's Association and the federal government has created unique programs to enhance care and support services for persons with Alzheimer's and their families. We are proud of these partnerships and urge support from Congress to assure their continuation.

Through our partnership with the U. S. Department of Justice, we are operating the Safe Return program, a nationwide system to register and identify persons with Alzheimer's disease who are at risk of wandering and to locate and return them home when they are lost. We urge Congress to provide \$900,000 for Safe



safe
return
alzheimer's association

There is now real hope for a future without Alzheimer's disease

Return, the same as current funding, to increase awareness of the program, train law enforcement personnel about Alzheimer's disease and assure the safety of persons with the disease.

Through our partnership with the Administration on Aging (AoA), we are helping states and communities extend culturally appropriate family support services to underserved minority populations and rural communities. We urge Congress to appropriate \$25 million to expand this program to all 50 states and to disseminate best practices. In addition, we urge Congress to appropriate \$1 million for continued expansion of the national Alzheimer's Call Center to provide support services to caregivers 24 hours a day, 7 days a week.

With backing from the NIH, much has been learned about how to improve care and support for Alzheimer patients. These findings need to be disseminated to clinicians caring for patients on a daily basis. We urge Congress to appropriate the funds necessary to enable key government agencies, such as the Centers for Disease Control & Prevention and the Health Resources & Services Administration, to conduct and disseminate research on quality health care for people with Alzheimer's disease and other dementia.

Shaping a better tomorrow

There is now real hope for a future without Alzheimer's disease. Greater understanding of the disease, improved care and treatment, and unprecedented scientific opportunities for delaying onset and preventing the disease can all lead to a future where Alzheimer's is just a memory. Imagine the billions in savings to Medicare and Medicaid if scientists were able to develop a presymptomatic diagnostic technique and a preventive therapy that did not allow the disease to occur. But none of this will happen if we do not take action. Research and discovery can save Medicare and Medicaid and we can protect state and federal budgets if we commit the resources necessary to get Alzheimer's under control.

An investment in Alzheimer
research and care will create
a better tomorrow for all
Americans – of all ages.



the compassion to care, the leadership to conquer

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