

A National
Alzheimer's Strategic Plan:
THE REPORT OF THE ALZHEIMER'S STUDY GROUP

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A NATIONAL ALZHEIMER'S STRATEGIC PLAN: THE REPORT OF THE ALZHEIMER'S STUDY GROUP

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I. AMERICA MUST ACT NOW: THE ALZHEIMER'S SOLUTIONS PROJECT

Alzheimer's disease poses a grave and growing challenge to our Nation.

Many experts already recognize that Alzheimer's will severely affect the lives of millions of Americans who either suffer from this disease or care for someone who does. Less appreciated are the grave economic consequences that Alzheimer's disease, with its cumulative costs, will impose on the country. Unless we take decisive action now, the Alzheimer's crisis could very easily surpass even the current economic crisis in the damage it inflicts on individuals and our economy.

The Alzheimer's crisis, like the disease itself, will unfold gradually, making it all too easy to ignore until we have little opportunity to alter its impact. The prospect of an overwhelming hurricane never became real enough to prompt the strengthening of New Orleans' levees; the result was \$82.2 billion in damage and almost 2,000 lives lost. Concerns about subprime lending never became urgent enough to prompt corrective regulatory actions; we're still tallying the cost of this crisis as job losses and bank failures mount and stock values plummet. If we fail to address the Alzheimer's crisis now, we face the prospect of losing lives and dollars on much larger scale.

The numbers alone tell a frightening story about the current impact of Alzheimer's, a terminal disease that has no cure:

- Alzheimer's disease afflicts more than 5 million Americans,¹ and is the Nation's sixth leading cause of death.²
- Alzheimer's disease is a family disease. This year 10 million caregivers will provide 94 billion hours of physically demanding and emotionally draining uncompensated care.³
- Alzheimer's disease is already the Nation's third most expensive disease,⁴ costing the Federal Government alone more than \$100 billion per year.⁵

If we fail to develop the capability to disrupt current trends, projections regarding Alzheimer's future impact are even more alarming:

- Alzheimer's cases will increase by more than 50 percent in 20 years and double again to as many as 16 million cases by 2050.⁶

- Over the next 40 years, Alzheimer's disease-related costs to Medicare and Medicaid alone are projected to total \$20 trillion in constant dollars, rising to over \$1 trillion per year by 2050.⁷

We still have an opportunity to take strong, decisive actions to rewrite this future. But it won't be easy. We will need to act boldly to develop the capability to prevent, cure, or delay Alzheimer's disease. We must also redesign the healthcare reimbursement system for Alzheimer's care, which too often fails people with the disease and their families. For instance:

- Fewer than half of people with Alzheimer's disease or other dementias have been officially diagnosed with the disease. These missed diagnoses impede the delivery of needed care and services.⁸
- The Medicare Fee-for-Service system, which covers more than 80 percent of Medicare enrollees,⁹ was designed to address acute conditions and rewards providers for a high volume of in-office services. This reimbursement policy effectively discourages the between-visit care and support most valuable to people with dementia and their family caregivers.
- There are interventions proven to increase quality of life for people with dementia while optimizing their healthcare utilization. Yet, many of the most promising interventions—including community-based psychosocial interventions¹⁰ and caregiver counseling programs¹¹—are not covered by Medicare Fee-for-Service.

If we hope to deliver higher quality care to people with Alzheimer's disease, the Medicare Fee-for-Service payment system must be reengineered so that payments are

more closely aligned with the activities that deliver the greatest value to people with Alzheimer's disease and other dementias.

These, then, are the dimensions of the national challenge: Alzheimer's is having a large and quickly growing medical and economic impact on the country, no significant medical treatments exist to halt this trend, and our healthcare system is not delivering adequate care to many of those with Alzheimer's and their caregivers. Consider these alarming trends:

- For every dollar the Federal Government spends on the costs of Alzheimer's care, it invests less than a penny in research to find a cure.¹²
- Reflecting broad trends at the National Institutes of Health, over the past 5 years federal research investment in Alzheimer's disease has declined by 15 percent in purchasing power even as the number of new cases has continued to climb.¹³
- Medicare Fee-for-Service for those with Alzheimer's has not changed meaningfully in the nearly 50 years since its creation, despite repeated documentation of its failure to provide responsive care or to effectively manage costs.¹⁴
- Despite the scale of the challenge—the millions of American lives and the billions of dollars—there is not now even the most rudimentary strategic plan to coordinate and direct the combined federal efforts.¹⁵

Judged in proportion to the scale of the challenge, these facts indicate that we have mustered, at best, token responses to this rapidly growing crisis.

In summary, then, the following are the primary findings underlying the recommendations contained in this report:

- Without a means of prevention, better treatment, or cure, Alzheimer's disease is projected to afflict 10 million Americans from the Baby Boom generation and contribute cumulative costs of almost \$20 trillion to Medicare and Medicaid between 2010 and 2050.
- The current Medicare Fee-for-Service system, designed in 1960 to address the acute care problems

that predominated at the time, regularly fails those with Alzheimer's disease and their families.

- Our national effort to address Alzheimer's disease has lacked coordination and focus, and has been woefully underfunded relative to the scale of the mounting crisis.

These findings, taken together, have led the Alzheimer's Study Group to the following lead recommendation:

Establish the Alzheimer's Solutions Project to accelerate and focus national efforts, reengineer dementia care delivery, and, ultimately, prevent Alzheimer's disease. The Alzheimer's Study Group urges America to embark on this bold project to contain the staggering impact of Alzheimer's disease. This project has three pillars:

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

The Alzheimer's Study Group believes that each of these three objectives is of critical importance and that the pursuit of these objectives will lead to a cascade of benefits for those with Alzheimer's and other dementias.

We believe the Alzheimer's Solutions Project should be established in the tradition of America's most successful ventures, such as the Apollo spaceflight program, a national goal-setting effort that culminated in 6 lunar landings over a 14-year period. That program, one of the great achievements in human history, is a clear illustration that Americans can accomplish great things when we set our minds to doing so.

The Alzheimer's Solutions Project is as urgent and inspirational as any national project our country has yet undertaken. If we succeed, we will improve the lives of millions of Americans and we will have shared a great gift with the world.

Now is the time to act.

2. THE CASE FOR ACTION: THE ALARMING DIMENSIONS OF A MOUNTING CRISIS

Alzheimer's disease will expand rapidly in the coming years as more and more Americans from the Baby Boom generation enter retirement. This demographic development poses a steadily escalating crisis for the Nation. Not only is it a crisis for individuals—Alzheimer's is a devastating condition for those with the disease and their families—but, because it is extremely costly, Alzheimer's is becoming a national economic crisis as well. Alzheimer's disease clouds our Nation's future.¹⁶

RAPID EXPANSION OF ALZHEIMER'S DISEASE CASES

America is growing older. The leading edge of the Baby Boom generation has already reached retirement. This generational milestone, coupled with increasing longevity, will bring with it significant challenges to the Nation in the years ahead. Within 25 years, 1 in 5 Americans will be age 65 or older.

Overall, Americans are aging more successfully than ever. For instance, the number of Americans over age 65 living with chronic disabilities has declined steadily, falling from 26.5 percent in 1982 to 19 percent in 2004.¹⁷

Longevity is increasing as well. Americans, on average, are living longer with every passing year. We are also becoming more successful at preventing many of the leading causes of death.

Statistics on Alzheimer's disease are the exception to these promising trends. All too often, this disease denies Americans the benefits of a longer, healthier—and less expensive—retirement.

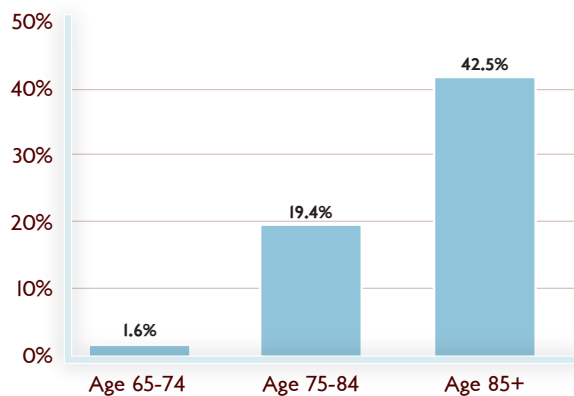
Percentage Change in Selected Causes of Death, 2000 and 2006¹⁸

Cause	2000	2006	Percentage Change
Heart Disease	710,760	629,191	-11.5
Breast Cancer	41,200	40,970	-0.6
Prostate Cancer	31,900	27,350	-14.3
Stroke	167,661	137,265	-18.1
Alzheimer's Disease	49,558	72,914	+47.1

Alzheimer's disease is predominantly a disease of aging. The odds of developing Alzheimer's double every 5 years after 65. This devastating disease strikes 1 in 8 Americans over age 65 and almost half of Americans over 85.

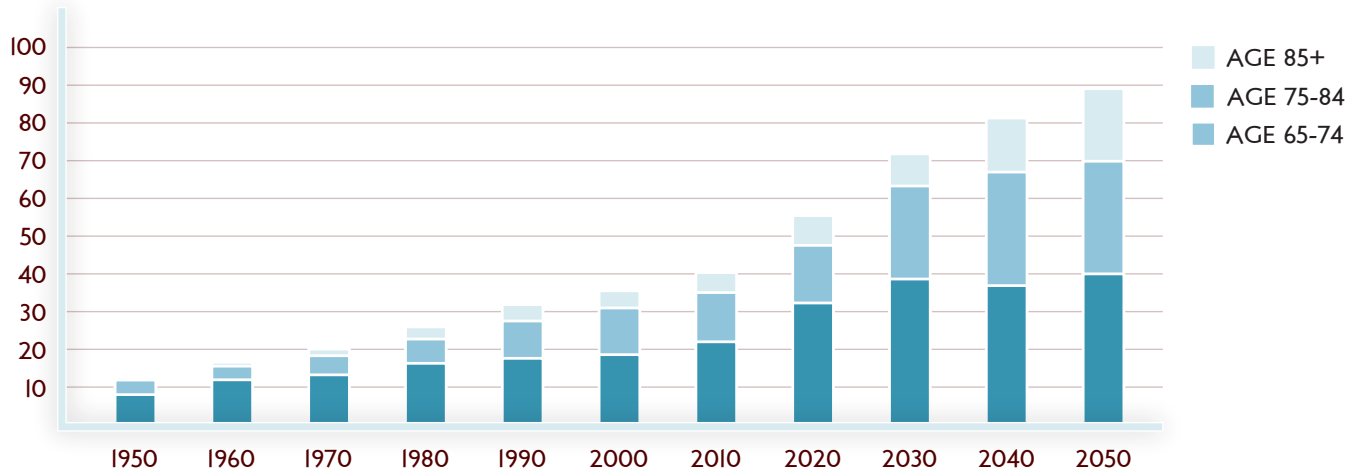
America is aging rapidly. The risk of developing Alzheimer's disease increases with age. Taken together, these two facts create a sobering outlook for the years ahead.

The Odds of Developing Alzheimer's Disease Double Every 5 Years Beyond the Age of 65¹⁹



Over the next 20 years, the number of Americans over age 65 with Alzheimer's will increase by more than 50 percent, from approximately 5 million today to about 7.7 million in 2030.

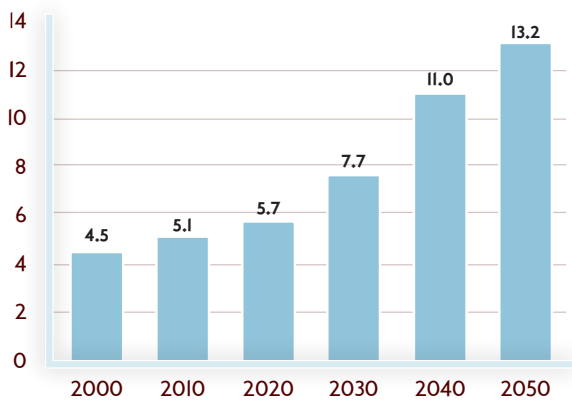
U.S. Population 65 and Over by Age: 1950 to 2050 (in millions)²⁰



By 2050, there may be as many as 16 million Americans with Alzheimer's disease.

Until we have the capability to prevent or greatly delay Alzheimer's disease, these trends will accelerate in the coming years.

Projected Prevalence of Alzheimer's Disease Cases in the U.S. from 2000 Through 2050 (in millions)²¹



ALZHEIMER'S TOLL ON INDIVIDUALS AND FAMILIES

Even though Alzheimer's disease is associated with aging, it is not a normal part of the aging process. Alzheimer's is a devastating, degenerative condition that progressively shuts down the brain over the course of years as each region of the brain is clogged with misfolded proteins.

First, Alzheimer's disease strips away memories. Next, its victims lose their independence, and then their very personalities. Finally, people with Alzheimer's cannot even control their most basic bodily functions, such as speaking, walking, and eating. Many victims succumb to complications of the disease, including deadly infections. For those who avoid these complications, life ends with a final act of forgetting: the brain simply forgets how to breathe.

There are no Alzheimer's disease survivors. Unlike cancer, cardiovascular disease, and many other chronic conditions, Alzheimer's disease always ends in death. We cannot halt or reverse it. Nor do we yet understand how to prevent or delay it.

The individual with Alzheimer's disease is not the only one affected by the disease. Because Alzheimer's is a family disease, it places a long-term, progressive burden on those who care for people with the disease.²² Seventy percent of individuals with Alzheimer's disease are cared for by their families in their homes. Many of these caregivers

are spouses who are in declining health. Children also assume many caregiver duties.

Recent studies have documented the harm that Alzheimer's disease caregiving does to the caregiver. The disease can affect a caregiver's health, resulting in a measurable reduction in the caregiver's own life expectancy.²³ It can also affect a family's economic security, as spouses and children are forced to leave their jobs to care for an aging relative with the disease.

From the point of disease onset to the point of death, an average family can expect to spend \$215,000 to care for a relative with Alzheimer's. Up to \$40,000 of this total expenditure can be attributed to direct costs, such as purchasing medications and procuring outside assistance with caregiving tasks. The balance—up to \$175,000—can be attributed to the indirect cost of quitting one's job to provide uncompensated care at home.

Average Per Person Payments by Source for Healthcare and Long-Term Care Services, Medicare Beneficiaries Aged 65 and Older With and Without Alzheimer's and Other Dementias, 2004²⁴

	Beneficiaries with no Alzheimer's or other dementia	Beneficiaries with Alzheimer's or other dementia
Medicare	5,272	15,145
Medicaid	718	6,605
Private Insurance	1,466	1,847
Other Payers	211	519
HMO	704	410
Out of Pocket	1,916	2,464
Uncompensated	201	261
Total Payments*	\$10,603	\$33,007

ALZHEIMER'S TOLL ON THE NATION

The burden that Alzheimer's disease places on individuals and families should be enough to justify immediate, decisive action to conquer this disease once and for all. But there is yet another important reason to act now. Alzheimer's disease brings with it staggering economic costs. It is already the country's third most expensive disease, and its economic impact will only increase with its mounting prevalence.²⁵

At the root of Alzheimer's high cost is the fact that almost all of its older victims suffer from other medical conditions that become more difficult and expensive to treat because of the presence of Alzheimer's. Ninety-five percent of Medicare beneficiaries aged 65 and older with Alzheimer's disease have at least one co-morbid condition.²⁶ The task of managing these other conditions becomes increasingly difficult for Alzheimer's patients as their dementia progresses. For example, medications management for Alzheimer's patients is a major cause for concern. Patients who don't remember to take critical medications run the risk of developing otherwise preventable conditions that require ongoing and expensive treatment. Patients taking medications for multiple conditions run the risk of drug interactions that could lead to costly hospitalizations and health complications. Managing and responding to these risks drives up health-care costs.

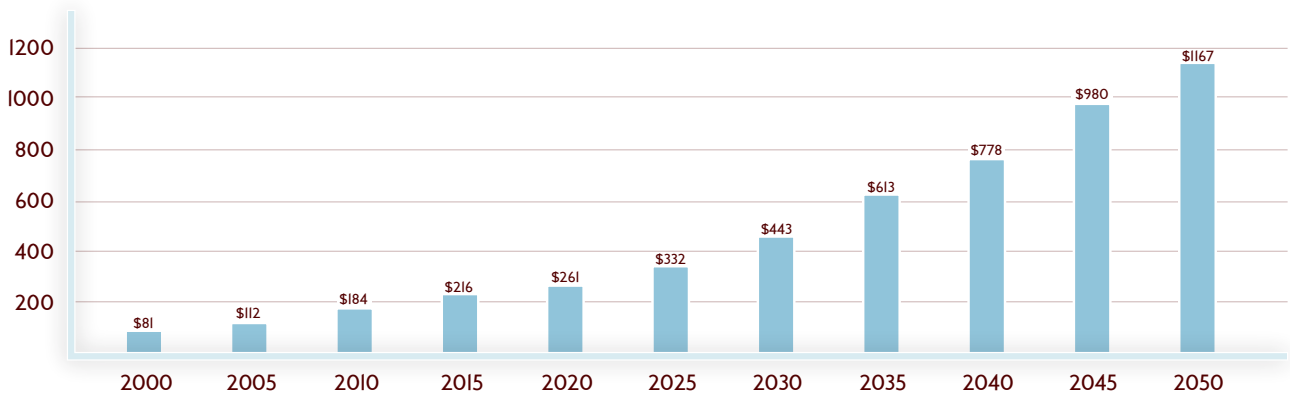
A newly released analysis of health and long-term care utilization by individuals with Alzheimer's and other forms of dementia demonstrates how expensive these conditions are to families and the Nation. The average annual cost of health and long-term care for people with Alzheimer's is \$33,007 per year, more than 3 times the average cost of \$10,603 incurred by individuals 65 and older without this condition.²⁷

When aggregated across the 5.3 million Americans with Alzheimer's disease, this cost differential places an immense strain on our Medicare and Medicaid programs. This year, the Federal Government will spend more than \$100 billion through Medicare and Medicaid to care for those struggling with Alzheimer's. This figure would be far higher if we did not rely on family members to bear so

much of the Alzheimer's caregiving burden through their time and out-of-pocket expenses.

Unfortunately, this is not the end of the story. The government's current \$100 billion Alzheimer's bill only foreshadows what awaits our Nation. Following current trends, federal spending on Alzheimer's disease will increase to more than \$1 trillion per year by 2050 in today's dollars. With this amount of money at stake, the government simply will not be able to solve its looming fiscal problems if it fails to address the growing Alzheimer's disease crisis. The cumulative cost to Medicare and Medicaid programs between 2010 and 2050 is projected to be \$20 trillion, measured in today's dollars.

Medicare and Medicaid Spending for People with Alzheimer's Disease (in billions)²⁸



3. THE ALZHEIMER'S SOLUTIONS PROJECT: RALLYING THE NATION

The Alzheimer's Study Group believes that the path to a better future for America—a future free from Alzheimer's—must begin with the establishment of a bold, challenging, and yet feasible set of objectives that are designed to change America for the better. These objectives are contained in two major recommendations.

RECOMMENDATION 1: THE ALZHEIMER'S SOLUTIONS PROJECT

Establish the Alzheimer's Solutions Project to accelerate and focus national efforts, reengineer dementia care delivery, and, ultimately, prevent Alzheimer's disease. The Alzheimer's Study Group urges America to embark on this bold project to contain the staggering impact of Alzheimer's disease. This project has three pillars:

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

These three initiatives emerged from consultations with more than 100 distinguished Alzheimer's disease researchers, clinicians, care providers, and policy experts who are well-versed in the technical challenges that must be addressed to accomplish these objectives. These consultations convinced us that these are challenging but feasible goals. Additional experts have since conveyed their support for these objectives.²⁹

While our Nation's success in meeting these objectives is by no means guaranteed, the Alzheimer's Study Group believes that adopting an ambitious mission will serve to rally the country and earn the sustained commitment of its policymakers and citizens. Together, Americans have pursued other great national goals, such as the Transcontinental Railroad, which connected the Atlantic and Pacific coasts for the first time; the Apollo Program, which culminated in 6 lunar landings over a 14-year period; and the Human Genome Project, which identified all of the approximately 25,000 genes in human DNA. All of these projects were similarly daunting when first proposed. Yet, in all cases, America proved itself capable of accomplishing great missions when those efforts were backed by a sustained commitment, entrepreneurial spirit, and sufficient resources. Each of these great projects strengthened our physical and scientific infrastructure and profoundly transformed our Nation.³⁰

Great American Projects

Great American Projects	Champion	Initiated	Success	Duration
Transcontinental Railroad	Abraham Lincoln	1862	1869	7 years
Panama Canal	Theodore Roosevelt	1904	1914	10 years
Manhattan Project	Franklin D. Roosevelt	1939	1945	6 years
Apollo Program	John F. Kennedy	1961	1969	8 years
Human Genome Project	William Clinton	1990	2000	10 years
<i>Alzheimer's Solutions Project</i>		2009		

Some Alzheimer's Study Group members disagree with the use of the projects on this list as appropriate precedents for the AD Solutions Project for reasons stated in endnote 30.

Containing the staggering human and economic impact of Alzheimer's disease is an appropriate national goal for this generation of Americans. We also believe that, just as with the Nation's other monumental undertakings, the pursuit of each of the Alzheimer's Solutions Project initiatives will build our national infrastructure. For example:

- The Alzheimer's Prevention Initiative will spur the growth of our scientific and medical research infrastructure, one of the most important economic sectors in the 21st century.
- The Alzheimer's Care Improvement Initiative will develop new methods to provide superior coordinated chronic disease care to Americans. These new methods have important benefits for all people who suffer from chronic conditions, in addition to those who have dementia.
- The Alzheimer's Public-Private Partnership will serve as a laboratory for project-focused, outcome-oriented government.

The outcomes we achieve through the Alzheimer's Solutions Project will be even more important than the infrastructure created. This is a mission we must embrace for the sake of millions of Americans and their families and for the fiscal strength of the Nation in the decades ahead. The alternative—to resign ourselves to a future overshadowed by Alzheimer's disease—is unacceptable.

RECOMMENDATION 2: RALLY SUPPORT

Rally the Nation to support the Alzheimer's Solutions Project. The President of the United States should address the Nation to explain the growing dimensions of the Alzheimer's crisis, declare the prevention of Alzheimer's disease to be a national priority, and explain key elements of the Administration's plan for accomplishing these goals through the creation of the Alzheimer's Solutions Project.

Half a century ago, on May 25, 1961, President John F. Kennedy unveiled his vision for the Apollo manned spaceflight program in an address to Congress. During that address, President Kennedy set in motion the eventual success of the Apollo mission. By leading the effort, and putting the full support of his presidency behind it,

the President secured the enduring commitment of the American people. Two administrations later, on July 20, 1969, Neil Armstrong set foot on the Moon.

Timing also played an important role in the Apollo program's success. In 1961, the Apollo program was the right mission to spearhead our exploration of the great frontier of outer space. Today, the United States faces another great opportunity of scientific exploration—the human brain—which is, essentially, as much a frontier to neuroscientists and clinicians today as outer space was to astronomers and engineers 50 years ago. Today, overcoming Alzheimer's disease is the ideal mission to spearhead a new era of exploration of the human mind, with great potential benefits across the entire spectrum of human health and activity.

Following in the footsteps of John F. Kennedy, America's new President has the opportunity to play an indispensable role in leading and directing this mission by creating the Alzheimer's Solutions Project. Most Americans recognize the devastating impact that Alzheimer's disease and other dementias have on individuals and their families. However, relatively few Americans understand the dramatic impact that Alzheimer's will have on our aging Nation in the decades to come. Most importantly, few Americans understand the monumental opportunity we have to take decisive action now that will secure a much brighter future for our country and the world.

Mobilizing the Nation in support of the Alzheimer's Solutions Project will take a persuasive leader. We believe the President is exceptionally qualified and uniquely positioned to perform this critical national service.

4. THE ALZHEIMER'S PREVENTION INITIATIVE: OVERCOMING ALZHEIMER'S IN AMERICA

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

- *Many leading Alzheimer's researchers believe that we may be closing in on developing the capability to delay, and even prevent, Alzheimer's.³¹*
- *However, developing this capability as quickly as possible will require us to abandon a "business as usual" approach to overcoming these challenges.*

Business as usual would not have opened the West to rail travel and trade in 1869. Business as usual would not have put a man on the Moon by 1969. Business as usual would not have transformed our knowledge of DNA through the mapping of the human genome. Likewise, business as usual will not give us the capability to prevent Alzheimer's disease as soon as possible. Now is the time to set aside business as usual. Now is the time to pursue the prevention of Alzheimer's disease with a disciplined and comprehensive strategy backed with sufficient public and private investment.

THE ALZHEIMER'S PREVENTION INITIATIVE'S OBJECTIVE

As a national priority, urgently focus on developing the capability to delay and, ultimately, prevent Alzheimer's disease. This capability will depend on the advancement of development science as well as basic research.

PRIORITY RECOMMENDATIONS

The Alzheimer's Study Group has developed a number of detailed recommendations related to Alzheimer's disease research and development. These recommendations are included in Technical Appendices B and C of this report. The most important recommendations for this initiative can be summarized as follows:

1. *Clarify and accelerate the development pathway for preventive and risk-reducing therapies.* The Alzheimer's Solutions Project must work with a range of stakeholders to clarify and streamline the development pathway for preventive and risk-reducing therapies. This effort should aim to advance development science, including the improvement of disease models and qualification of biomarkers for clinical research. Addition-

ally, incentives for exploring potentially significant lifestyle interventions, such as diet and exercise, are insufficient. Both pharmacological and behavioral interventions must be accelerated if we are to develop the capability to prevent Alzheimer's as quickly as possible.

2. *Expand the volunteer research pool.* Much larger numbers of volunteers—including study participants who have Alzheimer's and control group participants who do not—should be recruited for clinical trials and population-based longitudinal studies to build our understanding of Alzheimer's disease and validate potential interventions. Recruitment of pre-symptomatic and early-stage patients is especially critical to the development of preventive treatments.
3. *Encourage rapid learning by linking databases and researchers.* Create an Alzheimer's disease rapid-learning network that links all major research databases and researchers. Implement advanced analytical tools to support research and data mining using this new data-sharing infrastructure.

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

5. THE ALZHEIMER'S CARE IMPROVEMENT INITIATIVE: REINVENTING DEMENTIA CARE BY 2012

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

This fact is at the root of a fundamental problem facing people with Alzheimer's disease or other dementias and their caregivers. Many of these families depend on Medicare Fee-for-Service to cover the costs of care. Unfortunately, Medicare Fee-for-Service leads to very poor care for people with dementia.³²

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

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

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

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

Perhaps the failure of the current system is best illustrated by the fact that fewer than half of those with dementia even have their condition noted on their medical records, despite the sweeping implications such a diagnosis should have on care plans, medications, referrals, and other issues.³³ Health care providers fail to diagnose many cases of dementia for several reasons, but perhaps the most important is that they lack the financial incen-

tive to do so. Not only is a diagnostic workup itself reimbursed poorly compared to many other Medicare services, but a diagnosis sets in motion a chain of other responsibilities that are also poorly reimbursed under Fee-For-Service.

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

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

THE ALZHEIMER'S CARE IMPROVEMENT INITIATIVE'S OBJECTIVE

By 2012, use value-based payments to reimburse providers for at least 20 percent of health and social services for people with dementia, and for half of these services by 2016. Value-based payments will reward health care and social services professionals for providing the coordinated care dementia patients most need for better health and a higher quality of life.

PRIORITY RECOMMENDATIONS

The Alzheimer's Study Group has developed a range of recommendations aimed at reforming health and community care systems so they were more responsive to the needs of people with Alzheimer's and other dementias. These recommendations are included in

Technical Appendices D and E of this report. The following points summarize the recommendations that should receive the highest priority as we work to fundamentally reform the payment system as a way to improve outcomes across health systems and communities:

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

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

6. THE ALZHEIMER'S PUBLIC-PRIVATE PARTNERSHIP: AN IMPLEMENTATION INFRASTRUCTURE BY 2010

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

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

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

This standard return-on-investment framework brings reasonable investment levels into clearer perspective. A total investment of \$50 billion over the course of the Alzheimer's Solutions Project would pay for itself many times over even if it only managed to yield a 1-percent reduction in the projected \$20 trillion outlay. If the total investment led to the capability to prevent Alzheimer's, it would prove to be one of the wisest and most profitable investments in the history of our Nation. And this is before even factoring in the improvements such an investment would bring to the quality of life of millions of Americans.

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

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

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

THE ALZHEIMER'S PUBLIC-PRIVATE PARTNERSHIP INITIATIVE'S OBJECTIVE

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

PRIORITY RECOMMENDATIONS

The Alzheimer's Study Group has developed a range of recommendations regarding the appropriate governance structure for a sustained, appropriately funded effort to overcome the Alzheimer's crisis. These recommendations are included in Technical Appendix A of this report. The following points summarize the recommendations most important to successfully completing the Public-Private Partnership Initiative:

1. *Create an Alzheimer's Solutions Project Office.* This office should exist within the Executive Branch and should be led by a Chief Executive Officer. As its first order of business, the office should develop and publicly release a detailed Alzheimer's Solutions Project Implementation Plan. The plan should be publicly updated with accompanying progress reports no less than annually.
2. *Put at the disposal of the office an Alzheimer's Solutions Project Investment Fund.* Annual appropriations to the fund should be based on a multiyear investment budget that extends through at least a 5-year planning cycle. Appropriate funding levels should be revisited annually to address the rate of progress and changing conditions. The scale of Federal investment should be based on the savings that overcoming Alzheimer's would yield to the Federal government over the coming generation, implying a scale of annual investment many times greater than current levels.

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

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

7. CONCLUSION

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

The Alzheimer's Study Group believes we can secure a much better future for our Nation. We recommend the establishment of The Alzheimer's Solutions Project as a way to provide a path toward overcoming the challenges posed by Alzheimer's. This will be accomplished through three core initiatives, which are supported by additional recommendations. These initiatives, and their corresponding objectives, are:

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

Through the implementation and successful execution of these initiatives, America will travel a path to a much better world—a world without Alzheimer's.

TECHNICAL APPENDIX A: THE ALZHEIMER'S PUBLIC-PRIVATE PARTNERSHIP INFRASTRUCTURE

The Alzheimer's Study Group urges America to embark on a bold program, called the Alzheimer's Solutions Project, to overcome Alzheimer's. To maximize its prospects of success, a governance infrastructure should be implemented to manage this project with the same speed, discipline, and collaboration that characterize the best run large-scale projects in the public and private sectors. The project must be supported by a scale of investment commensurate with the scale of the crisis it is designed to avert.

RECOMMENDATION A1

Create an Alzheimer's Solutions Project Office and appoint a Chief Executive Officer to manage the effort.

The Alzheimer's Study Group recommends that the President create an Alzheimer's Solutions Project Office as an independent government entity led by a Chief Executive Officer. An accomplished executive of national stature should be appointed as soon as possible to fill the role. The Chief Executive Officer will oversee the execution of the Alzheimer's Solutions Project and ensure coordination within the Federal Government and collaboration with other key stakeholders. The Chief Executive Officer should immediately be provided with the staff and resources deemed necessary to accomplish the mission of the office. In addition, the Alzheimer's Solutions Project Office should be governed by a Board of Directors appointed by the President of the United States.

The success of the Alzheimer's Solutions Project will depend on the personal commitment and material support of the President and the Congress, as well as on the President's ability to recruit and appoint a world-class leader to direct this decade-long mission to its successful completion. This executive should demonstrate a proven capability to direct complex, large-scale scientific and engineering projects that integrate essential contributions from both public and private stakeholders. The Chief Executive Officer should be given the mandate and resources to accomplish the mission with which he or she is charged.

RECOMMENDATION A2

Create and publicly release the Alzheimer's Solutions Project Implementation Plan.

The Alzheimer's Study Group recommends that as a first order of business the Chief Executive Officer oversee development of a comprehensive, integrated Alzheimer's Solutions Project Implementation Plan. The implementation plan should specify the major steps required to accomplish the Alzheimer's Solutions Project's initiatives, strategies for accomplishing these steps, measures for evaluating success, roles and responsibilities for implementing strategies, execution timelines, and a financial budget that extends through at least a 5-year planning cycle. The plan should include and put into context all significant federal efforts related to Alzheimer's disease across all departments and agencies. It should be completed and publicly available by January 1, 2010. No less than annually thereafter, the Chief Executive Officer should release a progress report together with updates to the plan.

The first task of the Alzheimer's Solutions Project must be to create an implementation plan that encompasses both the Alzheimer's Value-Based Payments Initiative and Alzheimer's Prevention Initiative, together with additional, reinforcing objectives, which are outlined in Technical Appendices B through E of this report. Given the scope and scale of the Alzheimer's crisis, this plan must be equal to the best planning efforts executed within and outside of the Federal Government. The Alzheimer's Solutions Project Chief Executive Officer must have the resources required to complete this planning effort.

The American people will be asked to make a significant investment in this initiative. Therefore, it is essential that the initial plan, and progress reports on its execution, be publicly available for review and debate.

RECOMMENDATION A3

The President should work with the Congress to establish an Alzheimer's Solutions Project Investment Fund.

The Alzheimer's Study Group recommends that the President transmit to the Congress a legislative proposal to establish an Alzheimer's Solutions Project Investment Fund to be administered by the Alzheimer's Solutions Project's Chief Executive Officer. The fund would be used to address critical needs and invest in opportunities that advance Alzheimer's Solutions Project objectives. The fund would also be governed by the Alzheimer's Solutions Project Board of Directors.

Federal health agencies already have established missions that they must address through their current budgets. Were these agencies assigned the additional mandate of supporting the Alzheimer's Solutions Project, their existing efforts would risk being compromised. It is important that the Alzheimer's Solutions Project not divert resources and thereby undercut these agencies' progress in pursuing other priorities.

The Alzheimer's Solutions Project should have an independent investment fund to cover its own obligations without requiring other agencies to reallocate funds originally intended to fund other programs. The Alzheimer's Solutions Project Investment Fund could be used to cover the cost incurred by other federal health agencies as they carry out initiatives requested by the Alzheimer's Solutions Project. The fund could also be used to directly commission and fund projects that fall outside the mission, expertise, or operational tempo of these agencies.

All investments made through the Alzheimer's Solutions Project Investment Fund should be subject to the governance of the Alzheimer's Solutions Project's Board of Directors and subject to congressional oversight. Furthermore, all investments made by the fund should be

publicly disclosed, along with the ongoing progress and outcomes of such investments as they become available. The public has the right to know how its resources are being spent and the outcomes of these investments.

RECOMMENDATION A4

Convene an Alzheimer's Solutions Project Advisory Committee to provide independent counsel to the President and to the Secretary of Health and Human Services.

The Alzheimer's Study Group recommends that the Secretary of Health and Human Services convene an external advisory committee composed of independent experts from outside the Federal Government. The committee's primary responsibility should be to publicly issue an independent, annual assessment of the progress made by the Alzheimer's Solutions Project in meeting the objectives contained in its Alzheimer's Solutions Project Implementation Plan.

The advisory committee should also identify and address key challenges and opportunities that would inform the pursuit of Alzheimer's Solutions Project objectives. The committee should be authorized and supported with sufficient funding and staff to enable execution of the above responsibilities.

RECOMMENDATION A5

Create a streamlined mechanism for congressional oversight of the Alzheimer's Solutions Project.

The Alzheimer's Study Group recommends that the Congress create a Joint Committee on Alzheimer's Disease that is vested with authorizations and appropriations authority over the Alzheimer's Solutions Project. Members of this joint committee should be drawn from relevant appropriations and authorization committees in both the House and Senate. The joint committee should focus exclusively on oversight of Alzheimer's Solutions Project operations and the appropriations actions required to ensure the program's success. Each hearing would be a focused and rigorous review of the Administration's progress in meeting its goals and of the supporting steps that could be taken by the Congress to further improve performance.

A disease that permanently disrupts the lives of 5 million Americans and their families and that costs the Federal Government alone more than \$100 billion per year in expenditures justifies the creation of a dedicated congressional committee for oversight and appropriations.

This Joint Committee on Alzheimer's Disease should directly link its oversight and subsequent appropriations decisions to the Alzheimer's Solutions Project's performance in meeting its objectives as defined in its implementation plan. Under this new approach, hearings would be focused reviews of the Alzheimer's Solutions Project's plans and performance.

In addition, the committee would offer Alzheimer's-related guidance to the relevant House and Senate appropriations committees regarding department and agency funding levels. The joint committee would have direct appropriations authority for the Alzheimer's Solutions Project and its investment fund. For these program-specific appropriations, the joint committee would pass and submit an annual investment budget, crafted on a full 10-year basis to provide the program with a time horizon corresponding to its duration. The investment budget would be modified annually if warranted by changing conditions. This budget, scored separately from the current expenditures budget, would be submitted directly to the House and Senate Budget committees.

RECOMMENDATION A6

The Congress should immediately increase funding for federal Alzheimer's disease and dementia programs.

The Alzheimer's Study Group recommends that the Congress immediately increase funding for Alzheimer's and dementia research at the National Institutes of Health to \$1 billion per year, with commensurate increases for Alzheimer's and dementia programs at other federal health agencies. This increased funding should be from additional appropriations. It should not be through reassignment from other objectives.

Current federal funding levels for Alzheimer's and dementia programs are extremely low relative to the national burden attributable to the disease. Therefore, the Congress should immediately begin to build capacity for

Alzheimer's research within these agencies while planning work for the Alzheimer's Solutions Project is underway.

While the details of the Alzheimer's Solutions Project Implementation Plan will not be known until the planning effort is completed, the success of this effort will depend on the resources and expertise found within America's federal health agencies. The demands that the Alzheimer's Solutions Project places on these agencies must enhance, rather than detract from, the many other important health priorities assigned to them. Likewise, these agencies must have the capacity to meet these new demands without being required to reallocate resources from other priorities and commitments.

In recent years, federal funding for Alzheimer's and dementia biomedical and caregiving research has declined while the national burden imposed by Alzheimer's has continued to increase. This decline, reflecting trends across the National Institutes of Health, should be reversed as soon as possible. The federal investment in Alzheimer's biomedical research reached a high of \$658 million in 2003. Since then, funding has fallen back to \$645 million in 2007 in nominal dollars. Accounting for biomedical inflation as calculated by the U.S. Government, federal funding has eroded by 17.5 percent since 2003.³⁴

RECOMMENDATION A7

Investment levels called for in the Alzheimer's Solutions Project Implementation Plan should be commensurate with the burden of the disease upon the Nation, and should be no less than the amounts that could be productively invested to successfully execute the Alzheimer's Solutions Project initiatives.

The Alzheimer's Study Group recommends that when determining the scale of investment warranted for the Alzheimer's Solutions Project, future budgetary planning should be based on the scale of the opportunity before the Nation rather than past budgetary levels. Practically speaking, it will be all but impossible to overinvest in this program as long as these investments are put to productive use. Rather, the practical funding constraints will be the absorptive capacity of our scientific, biomedical, and clinical research infrastructure to put investments to productive use, and

our ability to establish financial controls to ensure funds are invested appropriately.

Without medical advances that disrupt current trends, the U.S. Government will spend a projected \$20 trillion on Alzheimer's-related expenses through Medicare and Medicaid by 2050. The amount the Federal Government currently spends each year to speed the development of breakthroughs is well under \$1 billion per year, or about 0.005 percent of the projected Federal Government's entitlement liability through 2050 attributable to Alzheimer's.

As stated above, the Federal Government's practical challenge will be to ensure that federal Alzheimer's funds are invested effectively. Investments must be accompanied by fiscal controls to ensure that funds are spent as intended and subject to public review without unduly constraining the project from making swift investments that will lead to rapid progress.

TECHNICAL APPENDIX B: BUILDING THE FOUNDATION FOR BREAKTHROUGHS

The Alzheimer's Study Group recommends that emphasis be placed on basic and applied Alzheimer's and dementia research because it is the foundation for new therapies and better care models. Most fundamentally, the Nation must continuously attract and develop scientific and medical researchers who will dedicate their careers to overcoming the challenges posed by Alzheimer's. These scientists and clinicians should be encouraged and equipped to collaborate with one another more efficiently. In that effort, we must critically reassess boundaries that discourage the swift and open exchange of scientific findings and data among researchers working in different sectors and in different countries. In addition, we must provide these researchers with the integrated data-sharing platforms and advanced analytical tools they need to carry out collaborative research efforts. Finally, we should build on existing programs and capabilities to create a national network of Comprehensive Alzheimer's Disease Centers that will foster the systemic integration of research, whether that research involves the basic sciences, clinical investigation, practical delivery of care, or community interventions. Such integration holds great promise for spurring the discovery of new solutions.

RECOMMENDATION B1

Support the next generation of academic investigators.

The Alzheimer's Study Group recommends that the National Institutes of Health, the National Science Foundation, the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, the Department of Veterans Affairs, and other government agencies that support academic research and training allocate sufficient research budgets to fund new and early-stage investigators, in the context of overall research budget expansion. These efforts should be measured and evaluated against two goals: (1) increasing the number of new investigators and clinicians actively pursuing careers in Alzheimer's disease and dementia research; and (2) assuring long-term stability of their research careers through ongoing support that includes increasing mid-career development awards.

Supporting next-generation American scientists, engineers, physicians, and social science researchers should be a national priority. We must ensure a continuous infusion of fresh thinking and new ideas in Alzheimer's disease research and other disciplines by attracting a steady stream of new investigators to basic and applied science, just as

we must in a number of other medical disciplines such as geriatrics, mental health, and nursing.³⁵

As new areas of healthcare and health policy research emerge, they create opportunities for the inflow of new talent. These new areas include comparative effectiveness research, design of innovative care models, research on quality of care that establishes care measurements needed to enable value-based payments, and cross-disciplinary geriatric medicine research.

In addition, the Food and Drug Administration's Critical Path Initiative should receive funding to encourage young and mid-career investigators to conduct research and training in predictive disease models and related aspects of product development science applicable to Alzheimer's disease. Selected areas, such as lengthy, multidisciplinary training in geriatric medicine, should also qualify for loan forgiveness in the face of the approaching Alzheimer's disease care crisis.

RECOMMENDATION B2

Enable federal research agencies and universities to interact better with industry and private funders to facilitate translation of basic research into applications.

The Alzheimer's Study Group recommends that the Institute of Medicine or another independent organization conduct a study within 12 months to reevaluate existing laws, regulations, guidelines, contracts, and principles, including conflict-of-interest provisions. The Institute of Medicine should then develop clear protocols to enable productive public-private exchange of ideas and talent and to promote joint funding of projects. Additionally, this study should propose specific collaborative guidelines that can be applied to the Alzheimer's Solutions Project's Public-Private Partnership Initiative.

It is important to work to keep academic biomedical research free of commercial and political bias. At the same time, it is frequently useful for scientists engaged in basic and translational research to gain a deeper understanding of how their work will be used by others to deliver improved clinical solutions for patients. Optimal interaction between academic and industry researchers, including the ability to participate in joint projects, can spur applied biomedical breakthroughs.

Existing guidelines, including conflict-of-interest provisions that govern the National Institutes of Health, the Food and Drug Administration, and other Department of Health and Human Services agencies, while useful in certain instances, can act as powerful deterrents to public-private interaction involving these organizations. Increased and timely application of joint funding through the National Institutes of Health Foundation, the Reagan Udall Foundation, and other potential channels could improve scientific exchange, especially in translational research areas, and could have a significant impact on making breakthroughs in many disease areas including Alzheimer's disease.

As noted above, the Alzheimer's Study Group recommends that the Institute of Medicine or another independent organization conduct a study to evaluate the effect of existing regulations and guidelines on public-private partnerships in biomedical research and development. The report should identify existing barriers to cross-sector collaboration, prioritize these barriers by level of impact, and propose ways to address these barriers while continuing to protect the integrity of academic science. The report should address data ownership, rights to

publication, liability, and other relevant issues; it should identify best practices and specific partnership models deemed successful; and it should create model principles that can be adopted by research institutions. Additionally, the report should propose the specific guidelines that should govern collaboration conducted under the auspices of the Alzheimer's Solutions Project's Public-Private Partnership Initiative.

RECOMMENDATION B3

Establish a national data-sharing infrastructure to accelerate scientific advances.

The Alzheimer's Study Group recommends that the Department of Health and Human Services establish a national framework for collaborative Alzheimer's disease research data sharing. This framework should enable the inclusion of all federally supported clinical study results; support confidential and anonymous Alzheimer's disease patient registries that include linked electronic health records, genetic data, biospecimens, and other information; sponsor an Alzheimer's disease rapid-learning network that links all major research databases and researchers; and implement advanced analytical tools to support research and data mining using this new data-sharing infrastructure. Public digital libraries should be supported to ensure broad public access to the results of this collaborative research.

Large datasets already generated by Alzheimer's disease researchers should be aggregated and combined with the wealth of clinical data in patients' medical records to enable initial, rapid testing of new scientific hypotheses. This framework should also include data from large etiologic cohort studies, which follow cognitively "normal" individuals through onset of disease. The approach to building this integrated data source should be carefully planned, and it should be properly funded and supported to ensure its usability.

Patient privacy, intellectual property protection, and other legal and regulatory elements must be part of the framework's blueprint. The Department of Health and Human Services should capitalize on the knowledge and common datasets and methods derived from existing Al-

Alzheimer's disease efforts to design the optimal data-sharing framework. These datasets include the Alzheimer's Disease Neuroimaging Initiative, the National Alzheimer's Coordinating Center, and the biomedical databases at the Department of Veterans Affairs. The framework also should capitalize on standards development efforts already underway in several areas of health information technology and establish programs that train technical specialists to appropriately navigate and analyze the resulting datasets.

Broad access to these data and the resulting research findings would improve the diffusion of knowledge both across scientific disciplines and to the diverse stakeholders engaged in resolving the Alzheimer's crisis. Those stakeholders include patients and families, healthcare providers and social workers, caregivers, policymakers, and private investors in research and development, and the international research community. Open-access sharing of findings would increase access to the most current peer-reviewed scientific information and discoveries by the public who, as taxpayers, have contributed to funding this research.

Funders of research should encourage publication of findings in open-access journals, such as Public Library of Science journals. The cost of publishing these journals is covered by individual authors, through their research grants. This allows the journals to operate without selling subscriptions and to make their articles immediately available through free, public digital libraries. Further, researchers should receive additional support and infrastructure to enable timely sharing of the research data that support each publication. In the immediate future, articles in subscription-based journals should be made available through PubMed Central within six months from date of publication.

RECOMMENDATION B4

Enhance the Comprehensive Alzheimer's Disease Centers infrastructure.

The Alzheimer's Study Group recommends that the National Institute on Aging support and fund a network of Comprehensive Alzheimer's Disease Centers where basic research, clinical and translational

research, clinical care, and community education take place in an integrated environment. This effort will provide the optimal setting for crosscutting research and will create unique opportunities to better translate scientific discoveries into development of new clinical therapies and applied clinical care.

The existing Alzheimer's Disease Cooperative Study consortium and the Alzheimer's Disease Research Centers and Centers of Excellence infrastructure should serve as foundation to create centers like the National Cancer Institute's Comprehensive Cancer Centers. These centers would incorporate and support efforts focused on establishing a national registry for longitudinal studies, qualifying biomarkers, developing therapies, conducting research on models of care, carrying out community-based research and education, and training and retaining new investigators.

The Comprehensive Alzheimer's Disease Centers' infrastructure would enable integration of research from basic discovery through delivery of care. It would also enable new areas of investigation, such as research on a comprehensive model of quality care for individuals with Alzheimer's disease or other dementias, as well as educational and psychosocial interventions. In developing the network of Comprehensive Alzheimer's Disease Centers, it will be important to maintain a broad geographic reach and establish access mechanisms for individuals who reside in underserved areas. It may also be advisable to pilot and refine a single comprehensive center and then use this experience in a subsequent expansion of the Comprehensive Alzheimer's Disease Centers infrastructure. This expansion phase will require incremental funding to avoid dilution of ongoing Alzheimer's research efforts.

TECHNICAL APPENDIX C: TRANSLATING KNOWLEDGE INTO INTERVENTIONS

The Alzheimer's Study Group recommends changes to the treatment development enterprise that will speed the flow of innovative therapies from laboratories to individuals with Alzheimer's and other dementias. Because discoveries can languish in the development gap between academia and industry, additional government grants and contract funds should be available to sustain the most promising approaches. Translation of knowledge into interventions should also be spurred through the development of advanced development tools, such as biomarkers, and through the focused collaboration of stakeholders to establish a clear development path for prevention and risk reduction therapies. Because translation also depends on clinical trials, enrollment in these trials should be encouraged and supported through outreach, education, and tools to reduce the burden of participation. Finally, more private capital should be sought for the development process through the extension of market exclusivity in proportion to the hurdles involved in developing preventive, risk-reducing, and disease-modifying therapies.

RECOMMENDATION CI

Bridge the funding gap between basic research and commercial development of new Alzheimer's disease treatments and technologies.

The Alzheimer's Study Group recommends that federal and state governments increase the targeted grant and contract funding available to companies pursuing the development of treatments, therapies, diagnostics, and medical devices for Alzheimer's disease patients. Additional approaches to bridge the gap between basic research and commercial development include funding translational research programs within government and academic organizations.

Incentives will stimulate the translation of academic research on Alzheimer's disease into new treatments and will commercialize innovative technologies that can benefit individuals with Alzheimer's disease and their families. Uncertainties about the regulatory approval process for new Alzheimer's disease therapies and diagnostics can make companies reluctant to invest their resources in this complex therapeutic area. This investment gap is especially pronounced in the period between a basic scientific discovery and the early-stage commercial development of new treatments. Academic grants are typically not designed to fund therapy development efforts and they

stop short of funding the demonstration of drug efficacy in animal models. Yet, industry investment is unlikely to start until a clinical proof-of-concept is established. The resulting gap is estimated, on average, to be 2 to 4 years of late preclinical and early clinical development, and \$3 million to \$10 million for each drug candidate.

Increased funding by such entities as the Small Business Innovation Research program could encourage private investment and greater industry involvement in the early-stage translation of innovative Alzheimer's disease therapies. Such funding increases should be commensurate with the success of these entities in advancing targeted technologies. This is a critical step in encouraging innovation in a business sector where a high likelihood of failure is the norm and the length of the product development cycle often approaches the duration of patent exclusivity. Small Business Innovation Research and other government programs can limit private investment risk by providing non-diluting investment for innovative technology companies.³⁶ These bridge-funding programs should allow private co-funding and encourage industry collaboration. With the addition of industry's valuable resources, Alzheimer's research and drug development can be bridged. Public-private collaboration has the potential to reduce the time, costs, and risks associated with biomedical product innovation.

Additional ways to bridge the funding gap for innovative Alzheimer's products include tax incentives to companies willing to take on this development risk. These incentives might include refunds of net operating losses, research and development tax credits, and reduction of capital gains tax on invested funds.

RECOMMENDATION C2

Encourage the development of biomarkers for use in Alzheimer's clinical trials and other applications.

The Alzheimer's Study Group recommends that the biopharmaceutical industry, the Food and Drug Administration, the National Institute on Aging, and the patient advocacy community accelerate collaborative efforts to develop and qualify for use the most modern tools and methods for drug development. These tools and methods should then be publicly available to all medical product developers. This collaborative effort should include sharing clinical trial data and other information to create quantitative disease models and predictive biomarkers for subsets of patient populations, with the goal of enabling the research community to structure new clinical trials most effectively.

Biomarkers are biological features that help identify the presence, type, and stage of disease progression, as well as an individual's predisposition to develop a disease. Because biomarkers can serve as an indirect measure of disease severity, they may be useful in monitoring patient response to treatment and optimizing treatment regimens. Biomarkers may also facilitate identification of Alzheimer's disease and other dementias—potentially many years before the onset of behavioral symptoms—when preventive and risk-reducing interventions might be most effective.

The use of qualified biomarkers could also potentially improve how researchers conduct clinical trials by allowing them to reduce trial size and duration. More fundamentally, qualified biomarkers enable a much more practical exploration of approaches to develop innovative therapies.

Diagnosis and treatment of Alzheimer's disease could be greatly improved by the discovery of biomarkers. Yet, development of novel biomarkers and their qualification for use in the clinical environment or as tools for drug development is a laborious and costly process.

Once a biomarker is established and accepted by the Food and Drug Administration, it can be used by all medical product developers. Thus, development of new biomarkers is best accomplished before associated products go to market and with broad participation from companies engaged in the development of treatments for Alzheimer's and other neurological diseases. The Food and Drug Administration and patient advocacy groups are critical participants in this effort and should be part of any collaborative effort to develop and qualify biomarkers. The Food and Drug Administration's Critical Path Initiative is uniquely positioned to support such collaborations, and should be appropriately funded to enable the advancement of development science.

As part of preparation for biomarker-driven development of new therapies, the Food and Drug Administration should assess and report to the Congress the level of internal resources required to conduct a timely evaluation of submissions that use biomarker tools in clinical trials. Careful consideration should be given to both the number and the required specialty training of Food and Drug Administration reviewers, as well as to optimal and timely coordination among the Food and Drug Administration centers responsible for medical product approval.

RECOMMENDATION C3

Establish a clear development path for prevention and risk-reduction therapies.

The Alzheimer's Study Group recommends that patient advocacy groups, physicians, academic scientists, pharmaceutical and biotechnology company personnel, the Food and Drug Administration, and other stakeholders reach consensus on a clear and innovative development path for preventive therapies for Alzheimer's disease. The guidelines should include risk-benefit profiles, risk populations, clinical measures, clinical trial design, surrogate markers, minimum standards for clinically meaningful effects, prod-

uct labeling, and payer coverage. This effort should also include data sharing and collaborative research to develop and validate quantitative disease models and biomarkers that predict onset, progression, and response to treatment in relevant patient subgroups.

In addition to the common challenges of bringing innovative therapies to market, developers of preventive treatments face additional hurdles, including the current dearth of tools for early detection of Alzheimer's disease. The ability to treat individuals who exhibit minimal symptoms of the disease, or no symptoms at all, is critical. This ability, however, is limited by regulatory and ethical concerns regarding acceptable risk-benefit tradeoffs. Alzheimer's patients and families, and especially individuals known to be at risk for the disease, must share their perspectives on this issue and work actively with science policymakers to define the level of risk that is acceptable to them in light of the devastating nature of the disease and its long-term effect on patients and families.

RECOMMENDATION C4

Increase the participation of volunteers in clinical trials and population-based longitudinal studies.

The Alzheimer's Study Group recommends that the Alzheimer's Solutions Project Office collaborate with the Secretary of Health and Human Services to execute a properly resourced effort that promotes participation in clinical trials and population-based longitudinal studies. This effort should promote to the public and to the primary care physician community the importance of participation in clinical trials and other research studies. It should also include the development of a supporting infrastructure to provide education services and decision tools that match volunteers with trials and other opportunities in their local area.

Patients are critical contributors to clinical development. These patients must be made aware that they can speed the search for new treatments by enrolling in clinical trials, contributing tissue samples, and allowing the use of their medical records for research. The need to recruit a wide range of Alzheimer's patients for clinical trials

is becoming increasingly urgent as a large percentage of Americans reaches the age where they are at higher risk of developing Alzheimer's. A national initiative to encourage and coordinate enrollment in clinical trial and population-based longitudinal studies can accelerate the process of finding a means of prevention or cure for this devastating disease.

Any campaign to promote participation in clinical trials should issue a call to action to the public and the primary care physician community while providing the infrastructure and organization to support that call. For example, regional call centers could provide individuals with information on what trial participation is really like and which trials are actively recruiting in their area.

RECOMMENDATION C5

Extend market exclusivity for Alzheimer's disease therapies.

The Alzheimer's Study Group recommends that the Food and Drug Administration grant extended market exclusivity to new therapies that target Alzheimer's disease. This policy would provide an incentive to the biopharmaceutical industry to increase investment in Alzheimer's drug development. The duration of exclusivity should be proportional to the development hurdles for disease-modifying, disease-slowing, and preventive therapies, and should be reexamined when the current disincentives for Alzheimer's therapy development have been addressed or significantly diminished.

Alzheimer's disease and other neurodegenerative disorders typically present more difficult hurdles for drug developers than many other diseases. Insufficient understanding of the basic biology of Alzheimer's, lack of development tools such as biomarkers, and slow disease progression make clinical development of innovative treatments a long and prohibitively costly process. These challenges increase substantially in the area of preventive treatments.

It is important to provide incentives that encourage industry investment in therapy development for Alzheimer's disease, especially in light of the rapidly approaching explosion of Alzheimer's cases among the Baby Boomer

generation. Those incentives must be proportional to the disincentives that drug developers encounter today. Making the minimum market exclusivity requirement proportional to the hurdles that companies face would mean providing longer extensions for preventive therapies.

While several incentive options are available, the Alzheimer's Study Group believes that extension of market exclusivity is the most feasible option. Compared to extending patent protection, additional market exclusivity could be provided with less risk of unintended legislative implications for unrelated industry sectors that are driven by different business models and risks.

TECHNICAL APPENDIX D: DELIVERING IMPROVED DEMENTIA CARE

The Alzheimer's Study Group urges the Nation to make a swift transition to a healthcare system that encourages and rewards the provision of quality care to those with Alzheimer's disease. To function effectively, this system must be built on an interoperable electronic health information infrastructure. This infrastructure, in turn, will facilitate the development and collection of dementia-related, quality-of-care measures that can be adapted and applied across care settings and disease stages. This infrastructure, matched to appropriate care measures, will enable a much-needed transition away from reimbursement based on a fee-for-service model and toward reimbursement that rewards healthcare professionals based on the quality of dementia care they provide. This system will also require an available and adequately trained workforce of health professionals who have the equipment and incentive to provide collaborative, team-based care.

RECOMMENDATION D1

Build the electronic infrastructure for 21st-century, coordinated dementia care.

The Alzheimer's Study Group recommends that the Congress fund and federal agencies prioritize implementation of the President's call to invest \$50 billion over next 5 years to modernize the Nation's healthcare system through the broad adoption of interoperable, standards-based electronic health information systems and health records. More specifically, the National Coordinator for Health Information Technology should use Alzheimer's disease as a "value case" for chronic disease management when designing and implementing this national health information infrastructure. This value case should integrate systems to enhance the interoperability of electronic health records across traditional healthcare providers and with community agencies that provide key services to individuals and their caregivers.

Because the U.S. healthcare system was designed to support acute care, it works poorly for chronic care and is particularly inadequate for those with Alzheimer's disease and related disorders. Better care for people with dementia requires a coordinated, team-based approach that emphasizes long-term support rather than rigid procedures carried out through a series of intermittent, disconnected interventions. As noted by the Medicare Payment Advisory Commission, interoperable, standards-based electronic health information systems and health

records are a critical infrastructure for delivering such care. However, it is essential that this infrastructure be designed to effectively address the challenges that health professionals encounter when providing care to patients with dementia.

RECOMMENDATION D2

Develop and track quality-of-care indicators for people with Alzheimer's and other dementias.

The Alzheimer's Study Group recommends that the Department of Health and Human Services work with quality-of-care coalitions and other stakeholders to prioritize and actively support creation of a set of indicators that measure the quality of care provided to people with dementia and their family caregivers. This set should include indicators that apply in specific settings, such as the home, physician's offices, assisted living facilities, long-term care facilities, hospitals, and hospices, as well as indicators that apply to transitions between these care settings.

Evidence-based dementia care guidelines should be translated into quality indicators that can drive the delivery of better care to people with Alzheimer's disease and related disorders. Clinical studies have already supported creation of guidelines for important issues, including detection and diagnosis of dementia and appropriate treatment for behavioral disturbances. Where evidence-based guidelines already exist, identified gaps should drive clinical research to develop additional indicators.

Development of dementia quality-of-care indicators presents significant challenges. These challenges include the difficulty of measuring quality of care in the context of a disease characterized by progressive deterioration at widely varying rates, attributing quality effects to specific providers in team contexts, and customizing indicators for varied care settings. While some indicators will take years to develop, other important indicators can be developed and implemented quickly. These include indicators for dementia case finding and diagnosis, and indicators for referrals to supporting community services.

RECOMMENDATION D3

Begin testing the use of a subset of quality-of-care indicators in reporting and value-based payment pilot programs.

The Alzheimer's Study Group recommends that the Centers for Medicare and Medicaid Services implement a demonstration program to study the application of dementia quality-of-care indicators. Initial pilot programs should begin with the promotion of improved dementia detection and with referrals to supporting services. The use of dementia quality-of-care indicators should be expanded through additional demonstration projects as warranted.

It will take years to develop full sets of quality-of-care indicators. Likewise, it will take years to implement many of these indicators. Development efforts will most likely progress on a staggered basis from initial implementation, to public reporting, and then to value-based payment programs for different sets of indicators.

The Centers for Medicare and Medicaid Services should initiate pilot programs as soon as possible to address relatively straightforward elements of quality dementia care, such as case finding and referrals to supporting services, which set in motion important care processes that are likely to result in better outcomes for those with dementia.

RECOMMENDATION D4

Create new jobs and strengthen existing ones to better assist those with dementia and their families.

The Alzheimer's Study Group recommends that federal and state policymakers implement recommendations contained in the Institute of Medicine's 2008 report, *Retooling for an Aging America: Building the Health Care Workforce*. This report addresses the severe shortage of healthcare personnel who are trained to care for older adults, including those with dementia, in the healthcare and long-term care systems.³⁷ Individuals who provide healthcare and long-term care to older adults should receive relevant instruction that will help them understand dementia, deal with challenging behavior, develop communication skills, work with family caregivers, ensure the physical health and safety of people with dementia, and other related topics.

The Institute of Medicine report, *Retooling for an Aging America: Building the Health Care Workforce*, convincingly documents the inadequacy of the workforce of healthcare and long-term care professionals trained to provide competent care for older Americans. Based on current trends, the Institute of Medicine predicts that this workforce will be woefully inadequate to meet future demands as the Baby Boom generation reaches retirement age. For this reason, the Alzheimer's Study Group supports the recommendations included in the Institute of Medicine's report aimed at addressing this need. Health and long-term care professionals and workers should also receive incentives to pursue this important work.

Moreover, the Alzheimer's Study Group anticipates a critical need for training the health and long-term care workforce in dementia care and geriatric medicine. It recommends that policymakers address this need through targeted training and certification requirements for the relevant professional groups.

RECOMMENDATION D5

Improve coordination of dementia care regardless of setting.

The Alzheimer's Study Group recommends that the Centers for Medicare and Medicaid Services collaborate with the Agency for Healthcare Research and Quality to strengthen coverage, reimbursement, and training policies for health professionals. This includes nurse practitioners, social workers, and other allied health workers who assist with detection, ongoing medical management, coordination of medical and non-medical community care, and care transitions for people with dementia. Strengthening these policies will help to make dementia care a viable career field that attracts and retains talented and compassionate individuals and provides them with the skills they need to coordinate care for individuals with dementia and their caregivers, regardless of care setting or place of residence.

The Alzheimer's Study Group has concluded that current evidence remains insufficient to definitively specify the best approaches to managed care under different circumstances. However, we believe that the costs associated with uncoordinated care, especially for people with dementia, are readily apparent. Too often, our current systems fail to carry out even rudimentary elements of coordinated care, such as referrals to community services, medication management among different providers, and appropriate transitions from one care setting to another. There is good evidence to suggest that these failures may substantially increase overall treatment costs for individual patients and lead to a lower quality of life. For this reason, the Alzheimer's Study Group recommends that the Centers for Medicare and Medicaid Services work with the Agency for Healthcare Research and Quality, private health plans, patient advocacy groups, and other stakeholders to identify and address opportunities to improve coordination through pilot programs that link value-based payments to appropriate quality indicators.

TECHNICAL APPENDIX E: EMPOWERING FAMILIES THROUGH COMMUNITY CARE

The Alzheimer's Study Group urges that communities improve services to enable those with Alzheimer's disease and other dementias to live longer in their homes and neighborhoods, if they wish to do so. As a foundation for this effort, policymakers should use surveys to assess the burden of dementia in specific communities and should inventory existing psychosocial programs to identify successful programs that could be replicated in other locations. Family caregivers, who now bear much of the burden of caregiving, should receive training that shows them how to provide more effective and less burdensome care, and they should be equipped with cost-effective, evidence-based, low- and high-tech assistive technologies. In particular, Internet-based tools should be developed that provide scalable, cost-effective support to these families.

RECOMMENDATION E1

Develop a more accurate understanding of the burden that dementia places on communities and the implications for federal, state, and local planning.

The Alzheimer's Study Group recommends that state and local governments use surveys and surveillance systems to track the impact of Alzheimer's disease and other dementias on communities. Health survey tools, particularly those administered by federal agencies, should routinely include questions about the impact of Alzheimer's disease on individuals, families, and communities. This survey data will provide a greater understanding of the challenges facing communities, will enable better program development and planning, and will help track the progress of interventions over time. Information collected from such surveys should be disseminated to additional governmental agencies and advocacy groups to improve messaging, outreach, and availability of information to people with Alzheimer's disease and their families.

Alzheimer's disease remains a condition that is often ignored and misunderstood. Factors such as the systematic under-diagnosis of the disease mean that most state and community governments have only a vague understanding of the impact of dementia on the quality of life of their citizens. Currently, surveillance tools that rely on a formal medical diagnosis, such as traditional disease registries, are unlikely to effectively identify dementias. However, if appropriate questions regarding dementia

were added to such national survey tools as the Agency for Healthcare Research and Quality's Medical Expenditure Panel Survey, and the Centers for Disease Control and Prevention's Behavioral Risk Factor Surveillance System and National Health Interview Survey, they could provide a very helpful assessment of dementia's impact at the community level. State and local governments, together with other community stakeholders, should ensure they receive these data and should use them as the foundation for appropriate planning efforts and program funding decisions.

RECOMMENDATION E2

Invest in community programs that enable individuals with dementia to continue living lives that are as rich as possible for as long as possible.

The Alzheimer's Study Group recommends that the Secretary of Health and Human Services designate a lead agency responsible for the development, translation, and implementation of effective evidence-based community programs for people with dementia, including adult day services and various kinds of respite. This designated agency should work with other federal agencies, state and local governments, patient advocacy groups, private health plans, and health and social service providers to quickly implement a series of community-based demonstration projects based on the most successful programs now operating in a diverse range of communities. These demonstrations should be rigorously evaluated based on consistent

criteria; successful programs should be replicated in communities across the Nation.

Community-based programs can improve the quality of life for people with Alzheimer's disease and related disorders, particularly in early- and mid-stages of dementia. In addition to improving quality of life, existing evidence indicates that the best of these interventions can lower overall costs to public and private payers.³⁸ Exemplary programs—particularly those that have survived over time without exceptionally large funding commitments—should be studied, adapted, and replicated in communities across the country.

RECOMMENDATION E3

Provide training and support to family caregivers.

The Alzheimer's Study Group recommends that the Centers for Medicare and Medicaid Services provide coverage for programs that train family caregivers who assist persons with dementia. These programs should be based on caregiver counseling programs that have demonstrated in randomized controlled trials that they improve caregiver and care recipient well-being and reduce overall healthcare costs.

Alzheimer's disease directly affects individuals but inevitably becomes a family disease. Frail spouses, contending with their own health challenges, often devote tremendous energy to caring for their loved ones with dementia. These family caregivers provide this care without compensation and often at measurable cost to their own health and longevity. Although randomized controlled trials are always difficult to conduct, they have demonstrated that caregiving counseling programs can both reduce overall healthcare costs and improve the quality of life for individuals with Alzheimer's disease and related disorders and their caregivers. The Federal Government should work with other stakeholders to ensure that caregivers receive appropriate training and support.

RECOMMENDATION E4

Develop and deploy both low- and high-tech assistive technologies in homes.

The Alzheimer's Study Group recommends that the Centers for Medicare and Medicaid Services encourage the use of cost-effective, evidence-based assistive technologies in the home. Encouraging the use of these technologies will often entail reimbursement not just for the purchase of the technologies, but also for installation and training. Non-profit organizations and the healthcare industry should offer grants and prizes to encourage the development of new, breakthrough assistive technologies for dementia patients and others with cognitive impairments.

Commonplace assistive technologies for frail elderly people living in their homes—including grab bars and elevated toilet seats—are particularly important for those with Alzheimer's disease and related disorders, since their symptoms often include increasing disorientation and reduced coordination over time. Relatively inexpensive assistive devices, when purchased and properly installed, can often help people with dementia avoid trips to the hospital that can lead to additional health difficulties.

Ubiquitous wireless connections, home networking, and inexpensive monitoring devices can offer people with dementia radical new models for assessment, monitoring, and anticipatory interventions. The current approach to tracking an individual's condition—intermittent, episodic visits to an office or clinic scheduled at the convenience of the healthcare system to collect medical histories—is a particularly poor system for older Americans contending with Alzheimer's disease, increasing frailty, and other medical conditions. In-home monitoring, combined with privacy safeguards and the automated interpretation of collected data, represents an entirely new and much more cost-effective healthcare paradigm for those with Alzheimer's disease and related disorders. While such approaches do not yet have an evidence base to justify reimbursement, they certainly warrant targeted innovation fueled by grants and prizes.³⁹

RECOMMENDATION E5

Increase the use and improve the effectiveness of Internet-based tools.

The Alzheimer's Study Group recommends that the information technology community, the healthcare industry, and patient advocacy organizations form a coalition to accelerate the creation of Internet-based support tools for people with dementia and their family caregivers. These tools should provide peer-to-peer support, appropriate elements of patient navigation services, caregiver training and support tools, voluntary matching to appropriate clinical trials, and referrals to local community services.

Few developments have reshaped American life as quickly as Internet-based tools. Members of the Baby Boom generation, unlike many in their parents' generation, are comfortable with such tools and able to use them effectively. This presents a powerful opportunity to offset, at least partially, the shortage of health and social work professionals and the challenges associated with care coordination. Pioneers are already using e-mail list serves and websites to share critical information on disease progression and caregiver training, and to offer support and encouragement to online neighbors. Such tools will continue to evolve with time. Our Nation should spur the development of these tools, given their potential to improve lives and reduce costs. Government has a role to play in this work, but success will ultimately depend on the combined efforts of visionaries and entrepreneurs from a variety of stakeholder groups. The Alzheimer's Study Group calls for such collaboration and commends these efforts as critically important to success in weathering the coming Alzheimer's crisis.

APPENDIX F: RESEARCHERS SUPPORTING AN ALZHEIMER'S PREVENTION INITIATIVE

The following Alzheimer's disease researchers endorse the goal of developing the capability to prevent Alzheimer's disease by 2020 provided, in keeping with the recommendations in this report, that the effort is backed by sufficient funding and pursued with an appropriate, disciplined strategy.⁴⁰

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APPENDIX G: OVERVIEW OF THE ALZHEIMER'S STUDY GROUP

The Alzheimer's Study Group was established on July 11, 2007 under the auspices of the Congressional Task Force on Alzheimer's Disease with the charge of creating a National Alzheimer's Strategic Plan to overcome America's mounting Alzheimer's crisis. With the delivery of this plan on March 25, 2009, the members of Alzheimer's Study Group ended their service together.

ALZHEIMER'S STUDY GROUP MEMBERS

Co-chaired by former Speaker of the House Newt Gingrich and former U.S. Senator Bob Kerrey, the Alzheimer's Study Group included 11 distinguished national leaders with careers in government, law, business, medicine, and academia. In turn, these members and the Alzheimer's Study Group's staff worked with hundreds of other experts to address specific issues.

The Alzheimer's Study Group members were:

Christine Cassel, M.D.

Geriatrician and President
American Board of Internal Medicine

Meryl Comer

President
Geoffrey Beene Foundation Alzheimer's Initiative

Newt Gingrich (co-chair)

Founder
Center for Health Transformation

Steven E. Hyman, M.D.

Provost
Harvard University

Bob Kerrey (co-chair)

President
The New School

Henry McCance

Chairman
Greylock Partners

Mark McClellan, M.D., Ph.D.

Director
Engelberg Center for Health Care Reform, Brookings
Institution

Sandra Day O'Connor

Justice (retired)
U.S. Supreme Court

James Runde

Special Advisor
Morgan Stanley

David Satcher, M.D.

Director
Center of Excellence on Health Disparities
Morehouse School of Medicine

Harold Varmus, M.D.

President
Memorial Sloan-Kettering Cancer Center

Among its members were former heads of the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services, and the U.S. Public Health Service.

The Alzheimer's Study Group's executive director was Robert Egge. Project management support and subject matter expertise were provided by Booz Allen Hamilton under the direction of Susan Penfield, Lucy Stribley, and Oxana Pickeral, Ph.D. Michelle Stein and Katie Varney from the Center for Health Transformation served as Alzheimer's Study Group's media director and project coordinator, respectively.

SUMMARY OF WORK

As a foundation for creating the National Alzheimer's Strategic Plan, the Alzheimer's Study Group commissioned Booz Allen Hamilton to prepare an assessment report, publicly released on March 11, 2008, and available on the Alzheimer's Study Group website.⁴¹

Building from this assessment, the Alzheimer's Study Group moved to the next task of identifying the leading challenges impeding progress against Alzheimer's. Alzheimer's Study Group staff received input and guidance from the following sources:

- Online engagement with approximately 125 experts.
- More than 80 in-depth interviews with experts on specific topics.
- Literature review (peer reviewed journals, research studies, and policy reports).
- Additional submissions from individuals and organizations.

The result of this process was the identification of more than 300 distinct challenges on a range of issues and at various levels of detail and specificity. Based on this review, Alzheimer's Study Group members focused their attention on four themes as focal points for their recommendations development work:

- Encouraging information sharing and rapid learning across the Alzheimer's disease community.
- Improving Alzheimer's disease clinical trials.
- Improving Alzheimer's disease community-based care models.
- Creating an effective governance structure to guide Alzheimer's disease efforts.

A summary of findings is available in a report, *A Source Document on Thinking about Alzheimer's Disease*, publicly released on August 28, 2008 and also available on the Alzheimer's Study Group website.⁴²

In the final phase of its work, beginning with its final Alzheimer's Study Group working session held in Washington, DC, on October 20, 2008, the Alzheimer's Study Group moved to recommendations development

and the drafting of the National Alzheimer's Strategic Plan.

During this final stage of its work, Alzheimer's Study Group members and staff consulted with more than 500 experts from government, industry, and the non-profit sectors for the vetting and refinement of these findings and recommendations.

FINANCIAL AND IN-KIND CONTRIBUTIONS OF SUPPORT

All members of the Alzheimer's Study Group volunteered their time, serving without compensation.

In addition, the work of the Alzheimer's Study Group was made possible by the financial contributions of the Alzheimer's Association, the Dwyer family, Pfizer-Eisai, the McCance Foundation, the Vradenburg Foundation, and Wyeth. Following the direction of the Alzheimer's Study Group co-chairs, more than half of the Alzheimer's Study Group's total financial support came from non-profit contributors.

The Alzheimer's Study Group was directed and managed through the Center for Health Transformation as an in-kind contribution. The effort also received an in-kind contribution of project management and research support from Booz Allen Hamilton.

In addition, as described above, the work of the Alzheimer's Study Group was only possible due to the generous contribution of time and expertise by hundreds of experts. A partial list of these contributors is available at the Alzheimer's Study Group website.

For more information, visit the Alzheimer's Study Group website at www.alzstudygroup.org.

END NOTES

- 1 Alzheimer's Association. *2009 Alzheimer's Disease Facts and Figures*. Chicago: Alzheimer's Association; 2009.
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- 3 Alzheimer's Association. *2009 Alzheimer's Disease Facts and Figures*. Chicago: Alzheimer's Association; 2009.
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- 6 Hebert, LE; Scherr, PA; Bienias, JL; Bennett, DA; Evans, DA. "Alzheimer Disease in the U.S. population; Prevalence Estimates Using the 2000 Census." *Archives of Neurology*. August 2003; 60 (8): 1119–1122.
- 7 Lewin Group, The. "Saving Lives, Saving Money: Dividends for Americans Investing in Alzheimer's Research." *An Alzheimer's Association commissioned report*. 2004.
- 8 Boustani M, Callahan CM, Unverzagt FW, et al. "Implementing a screening and diagnosis program for dementia in primary care." *J Gen Intern Med* 2005 Jun; 20(6):572-7.
- 9 Centers for Medicare and Medicaid Services, Medicare Advantage, Cost, PACE, Demo and Prescription Drug Plan Contract Report – Monthly Summary Report (Data as of May 2007). Data accessed at: <http://slides.kff.org/chart.aspx?ch=141> on 27 February 2009.
- 10 Burgener, S, et al. "Review of Exemplar Programs for Adults with Early-Stage Alzheimer's Disease." *Research in Gerontological Nursing* Vol. 1 No. 4 October 2008.
- 11 Mittelman, M.S., et al, "Improving caregiver well-being delays nursing home placement of patients with Alzheimer's disease." *Neurology* 2006 67:1592-1599.
- 12 To calculate this number, the Alzheimer's Study Group used data from the Lewin Group's 2004 *Saving Lives, Saving Money* report to determine Alzheimer's cost to Medicare and Medicaid and divided this number by Alzheimer's funding through the National Institutes of Health (\$412 million for FY2008) with a generous margin for programs funded at other federal health agencies. The figure for Alzheimer's disease funding at the National Institutes of Health is available at <http://report.nih.gov/rcdc/categories/>.
- 13 Annual National Institutes of Health funding levels for Alzheimer's disease are available at: <http://report.nih.gov/rcdc/categories/>. The Biomedical Research and Development Price Index is available at: http://officeofbudget.od.nih.gov/UI/GDP_FromGenBudget.htm.
- 14 See, for instance, Fillit, H. "Excess Costs in Dementia Care and Impact of Comorbidities: A North American Perspective." Presentation accessed at <http://www.ipecad.org/data/pdf/Fillit%20-%20ipecad%20comorbidities%20final.pdf>.
- 15 Alzheimer's Study Group staff conclusion based on expert interviews, literature reviews, and responses to information requests.
- 16 For a comprehensive overview of the issues raised in this section, please see: Booz Allen Hamilton, "Assessment of the State of Alzheimer's Disease in the United States of America." Prepared for the Alzheimer's Study Group by Booz Allen Hamilton. 2008. Report accessed from: <http://www.alzstudygroup.org/>.
- 17 Manton, KG, et al. "Change in chronic disability." *PNAS*. November 2006: 103:18374-18379.

- 18 Alzheimer's Association. *2009 Alzheimer's Disease Facts and Figures*. Chicago: Alzheimer's Association; 2009.
- 19 Hebert, LE; Scherr, PA; Bienias, JL; Bennett, DA; Evans, DA. "Alzheimer Disease in the U.S. population; Prevalence Estimates Using the 2000 Census." *Archives of Neurology*. August 2003; 60 (8): 1119–1122; National Academy on an Aging Society. "Alzheimer's Disease and Dementia: A Growing Challenge." September, 2000.
- 20 Projections for 2010 through 2050 are from: Table I2. Projections of the Population by Age and Sex for the United States: 2010 to 2050 (NP2008-T12), Population Division, U.S. Census Bureau; Release Date: August 14, 2008. The source of the data for 1900 to 2000 is Table 5. Population by Age and Sex for the United States: 1900 to 2000, Part A. Number, Hobbs, Frank and Nicole Stoops, U.S. Census Bureau, Census 2000 Special Reports, Series CENSR-4, Demographic Trends in the 20th Century. This table was compiled by the U.S. Administration on Aging using the Census data noted.
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- 22 See for instance: Harris Interactive. "MetLife Foundation Alzheimer's Survey: What America Thinks." A MetLife Foundation commissioned report. 2006.
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- 24 Payments by source do not equal total payments exactly due to the effect of population weighting. Created from data from Bynum, J. Characteristics, Costs, and Health Service Use for Medicare Beneficiaries With a Dementia Diagnosis: Report 1: Medicare Current Beneficiary Survey (Lebanon, N.H.: Dartmouth Institute for Health Policy and Clinical Care, Center for Health Policy Research, January 2009). As cited in Alzheimer's Association. *2009 Alzheimer's Disease Facts and Figures*. Chicago: Alzheimer's Association; 2009.
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- 26 Bynum, JPW; Rabins, PV; Weller, W; Niefeld, M; Anderson, GF; and Wu, AW. "The relationship between a dementia diagnosis, chronic illness, Medicare expenditures and hospital use." *Journal of the American Geriatrics Society* 2004; 52:187-194.
- 27 Alzheimer's Association. *2009 Alzheimer's Disease Facts and Figures*. Chicago: Alzheimer's Association; 2009.
- 28 Lewin Group, The. "Saving Lives, Saving Money: Dividends for Americans Investing in Alzheimer's Research." *An Alzheimer's Association commissioned report*; 2004.
- 29 See Appendix F.
- 30 Some Alzheimer's Study Group members take exception to the comparison between the challenge of overcoming Alzheimer's described in this report and several of the past "great projects" referenced in the text. They caution such analogies can prove harmful by creating a false impression regarding the state of the science, by encouraging unrealistic expectations of progress, and by distorting research priorities before a foundation of knowledge is in place to best guide and inform such decisions.
- 31 See Appendix F.
- 32 This report will often refer to "dementia care" because many of the characteristics of good dementia care remain consistent regardless of the dementia's cause.
- 33 Boustani M, Callahan CM, Unverzagt FW, et al. Implementing a screening and diagnosis program for dementia in primary care. *J Gen Intern Med* 2005 Jun; 20(6):572-7.

³⁴ At the request of the Congress, the National Institutes of Health has implemented a new method of calculating its investment in various diseases called the Research, Condition, and Disease Categorization (RCDC) system. Using this revised methodology, Alzheimer's investments in Fiscal Year 2007 were revised downward from \$645 million, using the historic methodology, to \$411 million using the revised methodology. Data accessed from; <http://report.nih.gov/rcdc/categories/>.

³⁵ See Recommendation D4.

³⁶ "Non-diluting funding" is funding that does not require that ownership shares in the concern be transferred in exchange of investment funds.

³⁷ Institute of Medicine of the National Academies, *Retooling for an Aging America: Building the Health Care Workforce*. Washington, DC: The National Academies Press; 2008.

³⁸ Burgener, Sandra, et al., "Review of Exemplar Programs for Adults with Early-Stage Alzheimer's Disease." *Research in Gerontological Nursing*, Vol. 1, No. 4, October 2008.

³⁹ The Alzheimer's Study Group is indebted to correspondence with Jeffrey Kaye, Director of the Oregon Center for Aging & Technology, for these insights.

⁴⁰ This specific goal, to "Prevent Alzheimer's Disease by 2020," was proposed to the Alzheimer's Study Group by Zaven Khachaturian, Ph.D. & Ara Khachaturian, Ph.D., and the participants in the Leon Thal Symposium, 2009. For more information, see: Khachaturian ZS, Khachaturian AS. Prevent Alzheimer's disease by 2020: A national strategic goal. *Alzheimers Dement* 2009;5(2):81-84; and, Khachaturian ZS, Snyder PJ, Doody R, Aisen P, Comer M, Dwyer J, et al. A roadmap for the prevention of dementia II: Leon Thal Symposium 2008. *Alzheimers Dement* 2009;5(2):85-92.

⁴¹ Booz Allen Hamilton, "Assessment of the State of Alzheimer's Disease in the United States of America." Prepared for the Alzheimer's Study Group by Booz Allen Hamilton. 2008. Report accessed from: <http://www.alzstudygroup.org/>.

⁴² *A Source Document on Thinking about Alzheimer's*. Prepared for the Alzheimer's Study Group. 2008. Report accessed from: <http://www.alzstudygroup.org/>.

