

Policy Forum

# Developing a national Alzheimer's strategy equal to the epidemic

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## Be Heard Here First

### 1. Introduction

Alzheimer's disease (AD) is battering the United States as it destroys the lives of more than five million Americans and overturns the lives of their loved ones. These Americans suffer from its devastating impact without the prospect of reprieve or remission, and the toll will increase rapidly in the years ahead.

And yet, for all this, the United States federal government has no core strategy to guide its response to this crisis. The Office of Alzheimer's Research at the National Institutes of Health, established in 1986 to coordinate the government's AD efforts, was abolished in 1995. For the past 12 years, no senior government official has been charged with leading the government's battle against the disease.

Consequently, it should come as no surprise that the federal government's efforts toward dealing with AD are marked by wavering commitment, a misallocation of resources, and little collaboration among federal agencies. In short, we find precisely the passivity and bureaucratic drift one would expect, given the absence of a clearly articulated and vigorously implemented strategy.

The human scale of AD's impact makes the absence of a guiding National Alzheimer's Strategy disturbing. The mounting fiscal impact of this disease makes the government's passivity astonishing.

Alzheimer's disease is already the country's third most expensive condition, and because of the average age at onset, the obligation to pay for this burden rests to a large degree with the federal government. Alzheimer's disease

costs the Medicare and Medicaid programs more than US\$100 billion per year. Without medical breakthroughs, as the boomers pass through their elder years, federal spending on AD care will increase to more than US\$1 trillion per year by 2050 in today's dollars. That is more than 10% of America's current gross domestic product.

If the more than US\$100 billion in tax revenue that the federal government currently spends on this disease were compared with the revenue of America's Fortune 500 corporations, AD-related federal activities would, taken together, place it among the 10 largest corporations in the United States. Consider how much attention and energy these largest U.S. companies devote to ensure the consistent, coordinated pursuit of key strategic objectives. Senior executives and directors rightly regard strategy-driven leadership as their most important responsibility. Although AD poses a management challenge with comparable financial stakes and substantive complexity, it is worth repeating that not a single senior U.S. government leader in recent years has devoted sustained attention toward creating—let alone implementing—a comprehensive National Alzheimer's Strategy.

The consequences of this strategic vacuum are readily apparent upon even a cursory review of current federal efforts. For instance, for every dollar the federal government now spends through Medicare and Medicaid to help Americans cope with the impact of AD, it invests less than a penny to accelerate the discovery and development of effective therapies through the work of the National Institutes of Health (NIH) and the Food and Drug Administration (FDA).

This penny-on-the-dollar approach to AD is about as apt an example of a “penny wise, pound foolish” policy as one could imagine. The government underinvests in accelerating the search for effective therapies based on the argument that it cannot afford to do more. However, each day without such treatments leads the government to spend many, many times more than the debated amounts with which the NIH and FDA must cope, as best it can, with the devastating impact of AD.

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This example shows why such a comprehensive National Alzheimer's Strategy is necessary. The NIH, FDA, and Centers for Medicare and Medicaid Services (CMS) are all making extremely important contributions to the fight against AD within their own domains, led by highly talented and deeply committed public servants. But the heads of these agencies do not have the mandate to fix the kinds of strategic imbalances we have described, and it is unrealistic to expect these agencies to effectively “mind the gaps” between their organizations.

Challenges like these prompted Dwight Eisenhower to observe, “If you can't solve a problem, enlarge it.” The federal government has not followed Eisenhower's advice; rather than enlarging the problem, it has reduced it. Alzheimer's disease has been relegated to the purview of each individual agency to deal with, explicitly or implicitly, in a disconnected fashion. Of course, this approach has not reduced the impact of AD. Its impact has continued to grow, and at an increasing rate. It is past time for the federal government to follow Eisenhower's admonition and enlarge the perspective from which it plans on how to battle this rapidly escalating epidemic.

Over the years, many others have noted the pressing need for a national strategy to address the AD crisis. These same analyses pointed to both longstanding and emerging issues that need to be addressed in any such strategy. These considerations might be called the *substance* of a national strategy.

Two fundamental, institutional issues will also have to be addressed, however, if any such strategy is to have teeth and to shape federal policy meaningfully in the long term. In addition to grappling with substantive issues, a comprehensive strategy will have to resolve issues of *scale* and *structure*.

First, the federal government must appropriately measure the threat that AD poses to the nation, and consequently, the proper scale of the federal investment required to confront it.

Second, the federal government must find an appropriate managerial structure not only to implement a strategy, but also to ensure its long-term support and refinement, in keeping with rapidly evolving opportunities and conditions.

If the federal government's strategy focuses only on matters of substance, while adhering to the status quo on matters of scale and structure, even the best-crafted policy recommendations are unlikely to have more than a passing, marginal impact.

But if the government is willing to take a transformational approach to quantifying the threat posed by the disease, and to building the institutional capacity to meet that threat, our government may be able to substantially reduce the damage this disease will do to the country in the years ahead.

## **2. Scale: Rigorously building the case for making substantial investments in the battle against AD, and for projecting the value of strategic options**

Federal policymakers are constantly besieged by advocates seeking additional funding. Consequently, it is extremely difficult to build and sustain long-term support for an ambitious strategy without an unimpeachable analysis to support it. Commitments can swiftly be swept away by the cause or crisis of the moment.

The Alzheimer's Association and other groups have commissioned many studies documenting the threat that AD poses to America. As invaluable as these have been, however, the regrettable fact is that within the Beltway, projections from only two organizations—the Congressional Budget Office (CBO) and the Office of Management and Budget (OMB)—dominate all others in shaping federal AD policy.

If federal policy toward AD is to change substantially, than this CBO-OMB dominance over Congressional and administration policymaking will have to change as well.

The CBO and OMB exert tremendous influence over federal policymaking through their role in budgetary and appropriations decisions. They “keep score” of the near-term budgetary impact of proposed legislative and administrative programs. What these financial scores cannot tell policymakers, however, is whether these proposals are good investments.

The most fundamental problem is that, by design, CBO and OMB scoring deliberately ignores what most would agree should be the primary objective of health policy: saving lives. If two proposed programs are judged to have the same budgetary impact but one would save many lives and the other none, they would nevertheless be given the same score by these institutions. Only the federal budget impact matters within these models. Clearly, while these approaches may be useful for answering a range of narrow, fiscal questions, they do not provide the right framework to dictate policy regarding a deadly disease claiming hundreds of thousands of lives each year.

More generally, CBO and OMB scores do not distinguish between expenditures that are simply costs and those that are strategic investments. For instance, a dollar invested in basic research through the NIH is simply scored as a dollar spent. It is not balanced against anticipated future returns from that research. According to NIH Director Elias Zerhouni, analysis has shown that US\$1.4 trillion in HIV/AIDS-related healthcare expenditures were avoided due to US\$10 billion invested in basic research at the NIH from 1985–1995, for a return on an investment of 140 to 1. The CBO and OMB would record the \$1 cost. They would not attempt to account for the \$140 saved.

As a first order of business, a National Alzheimer's Strategy should commission a more appropriate, authoritative analytical model to help policymakers come to terms with the current and projected future costs that AD will

impose on the country, and the true expected value—including lives saved, return on investment, and other factors—of various strategic options.

This is a realistic charge. American corporations routinely use sophisticated financial modeling tools to choose between strategic options that require substantial immediate investments in exchange for future return. Even in some other branches of the federal government, cost-benefit analysis is routinely employed to guide decision-making. The Environmental Protection Agency, for instance, uses modeling that explicitly accounts for the value created through better health and longer lives.

The AD advocacy community knows what is at stake for the country if America does not effectively confront this swiftly expanding epidemic. What this community should now insist on, in order to build the analytic foundation for a sustained, intense, strategically driven assault on AD, is that the federal government explicitly and openly quantifies its assumptions about the threat this epidemic poses to the country, and the scale of investment that is therefore justified to ward off its looming future impact. Advocates both within and outside government will need this analysis in place to sustain a long-term, consistent commitment to any National Alzheimer's Strategy.

### **3. Structure: Creating the institutional leadership and management capacity to sustain implementation of a comprehensive and suitably aggressively National Alzheimer's Strategy**

Much as an effective National Alzheimer's Strategy will rigorously and authoritatively quantify the personal and financial cost that AD imposes on the country, it will also define a management structure capable of ensuring the strategy's successful implementation and ongoing oversight.

That capability does not now exist. Not a single individual on the entire senior staff of the Department of Health and Human Services (HHS) has been tasked with focusing on this disease. Even within the department's various agencies, one typically has to move several levels down the hierarchy before identifying the senior-most official exclusively focused on AD, if such a person is to be found at all.

This is in stark contrast with accepted practices of the best-run nonprofits and corporations that address challenges of a similar scale and complexity.

Similar to how the HHS has organized its agencies around various functions—the NIH for biomedical research, the FDA for translation, and so on—corporations are typically organized around functions such as research and development, marketing, and finance. But these larger organizations also balance this functional management structure with senior executive teams that shepherd particular products, services, or brands through these departments. Their responsibility is to ensure that each department's decisions advance the overarching strategies and objectives for that

initiative. While the details of this matrix management structure vary from organization to organization, it has long been a ubiquitous management practice for the simple reason that it works.

At least with regard to AD, the HHS is lagging four decades behind accepted management practices. The department has no one individual—let alone a senior management team—to coordinate the fight against AD across the federal government as a whole. A national strategy must charge someone with overseeing its implementation—someone who will not only mind the gaps between agencies like the NIH, FDA, and Centers for Disease Control, but who can push for an invigorated, coordinated approach both within these agencies and within HHS' Office of the Secretary.

Creating a management structure to implement a comprehensive National Alzheimer's Strategy will not ensure success. But neglecting to do so will almost certainly ensure such a strategy's failure.

### **4. Substance: Identifying the policy changes and innovations that must be made to best wage America's war against AD**

Sustained support and strong management will only deliver results if they are employed to advance sound policy. And so the substance of a National Alzheimer's Strategy, together with establishing scale and building structure, is also critical.

In our judgment, some of the most important substantive issues with which a National Alzheimer's Strategy will have to contend are the following:

- *Defining a national research agenda that appropriately encourages public-private partnerships and collaboration.* The eradication of a complex and widespread disease requires a focused effort across the scientific community, within both the public and private sectors. The collective efforts against HIV/AIDS are an instructive example of this. In the war against AIDS, the government, regulatory agencies, scientists in industry and academia, and patient groups worked hand-in-hand to characterize the nature of the disease, develop new therapies, and evaluate them as rapidly as possible. The results were dramatic: within 6 years of the identification of the disease, a breakthrough medication was available to help people manage their symptoms. A similar crash program is yielding encouraging results in the race to develop effective therapies in the event of an influenza pandemic. This same urgency ought to drive our research efforts to develop disease-modifying therapies for AD.
- *Aggressive support for diagnostic developments and enhancing early detection.* Advances in brain imaging technology—in particular, functional magnetic resonance imaging (fMRI) and positron emission tomog-

raphy (PET)—are serving as important clinical diagnostic aids in AD research. Particularly encouraging is the development of novel PET scan probes/tracers that permit real-time visualization. Similar tracers are under development for use with fMRI. Accelerating the development and approval of these technologies should be a priority for the NIH and FDA. As crucial as these technologies are for the discovery and development of new treatment options, however, economics will likely prevent this imaging technology from being widely used as a routine screening tool for years to come. Because new therapies are likely to be most effective when administered as early as possible in the progression of AD, the federal government should also aggressively support the identification of biomarkers that could lead to wide-scale, routinely administered screening tests (i.e., an equivalent of the “prostate-specific antigen test” for AD).

- *Accelerating the evaluation of therapeutic treatment options for those with AD.* An analysis of regulatory approval timelines for existing AD therapies as compared with those of drug categories identified as high-priority by the FDA indicates that the FDA has not reviewed therapies for AD as expeditiously as it has therapies for HIV/AIDS and selected cancers. Clearly, the FDA’s focus on cancer and HIV/AIDS as health-care crises appropriately resulted in increased agency attention to the importance of making therapeutic treatment options available to patients and their families and caregivers. Given the pending AD crisis, similar attention appears warranted. In the aviation industry, as soon as best practices are identified, they become the expected practices. Given that the FDA is capable of approving therapies more quickly when “fast tracked,” why do we even tolerate a slow track for candidate AD treatments? Similar to its use in the airline industry, the fast track should be the default track, and the FDA should work relentlessly to reduce evaluation times ever further. In turn, the administration and Congress should provide the FDA the funds needed to do so.
- *Ensuring adequate access to new AD therapies through Medicare.* Because of the potentially high cost of novel, large-molecule therapies, the coverage and reimbursement decisions will likely be dependent on various cost-control mechanisms. Chief among these mechanisms are new technology-specific, decision-making tools created through new national coverage decision guidance recently released by the CMS. This guidance creates conditional coverage for new therapies, and requires that additional data continue to be gathered for a period of time until Medicare is satisfied that the data warrant full coverage and reimbursement. Policymakers should aggressively explore creative strategies for the program expansion issues

that will arise as Baby Boomers age and become Medicare-eligible.

- *Providing additional support for caregivers.* Family caregivers currently face immense physical, emotional, and financial challenges when they opt to care at home for family members with AD. The federal government should systematically survey a range of emerging, assistive technologies that would place these caregivers in closer contact with medical support, and assist with some of the more physically demanding activities. In addition, the government should examine policies that discourage family caregivers from providing this support, and perhaps provide additional financial support if such home care can be demonstrated to save Medicare expenditures overall.

### **5. Bringing together scale, structure, and substance to create a National Alzheimer’s Strategy that holds the potential to deliver significant results**

The cost incurred by AD makes a comprehensive strategy prudent. The suffering caused by AD makes a comprehensive strategy essential. America must create and implement a National Alzheimer’s Strategy to meet the grave challenge posed by this disease.

Administration and Congressional leaders have the opportunity to set things right. This strategic void was not created by today’s leaders—there has never been a National Alzheimer’s Strategy worthy of the name. Now, however, government leaders can demand and, in a meaningful fashion, support its creation and implementation.

The United States government, led by the HHS, has shown it is fully capable of this kind of effort when it believes the stakes warrant such action. Just under 2 years ago, President Bush announced an aggressive federal effort to prepare the nation for a potential influenza pandemic. The federal government has since produced a comprehensive strategy that coordinates action across various departments and HHS agencies, and that is backed by extensive supporting activities and regular implementation progress reports.

This example of prudent and impressive planning demonstrates that the federal government is fully capable of preparing a National Alzheimer’s Strategy. But it also raises a pressing question. Given that this current effort was warranted for a potential epidemic, how much more appropriate is it for an epidemic already upon us, an epidemic of the tremendous societal scale and impact of AD?

America must develop a suitably bold and comprehensive National Alzheimer’s Strategy marked by transformational and substantive solutions, on an appropriately ambitious scale of investment, and with a strong managerial structure to oversee its implementation and ensure ongoing support. One more American develops AD every 72 seconds. Such a strategy is already long overdue.