

National Alzheimer's Project Act (NAPA)

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Editorial

Prospects for designating Alzheimer's disease research a national priority

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Abstract

This editorial evaluates the prospects of the National Alzheimer's Project Act (NAPA) succeeding to shape public policies that would substantially increase national expenditures for research on Alzheimer's disease. The essay identifies, in the context of 30-year history, some of the difficult challenges the NAPA Advisory Council must address and offers specific recommendations for an action plan by the Secretary, Department of Health and Human Services (DHHS).

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Keywords:

Alzheimer's disease; Research; Funding; Public policies; Strategic plan; Congress; Legislation; National Alzheimer's Project Act; PAD2020; Alzheimer's Association; Prevention; Treatment

1. Introduction

The aim of this perspective paper is to assess the potential impact of the National Alzheimer's Project Act (NAPA) on a *national strategic plan* for mobilizing research resources to alter the course of an impending public health catastrophe. The critical issue confronting us is whether this endeavor will at last deliver the "Promised Land of Milk & Honey" to the research community or become yet another "Bridge to Nowhere." We evaluate NAPA in the context of a 30-year effort to designate Alzheimer's research a national priority, asking what NAPA offers or pledges to the research community that will enable it to achieve this goal where past attempts have failed (Table 1). This essay will analyze the thorny scientific, administrative, and financial challenges that NAPA's Advisory Council on Alzheimer's Research, Care, and Services must address to bring about radical changes in current research paradigms aimed at preventing or slowing the progression of the disease.

The legislative mandate of NAPA covers a broad array of issues related to research, care, and services. This article, however, will focus on questions regarding public policy op-

tions and recommendations for significant expansion of national research capabilities.

In 2007, the Alzheimer's Study Group (ASG) was launched with support from the Alzheimer's Association (AA) and the leaders of the Congressional Task Force on Alzheimer's Disease. In 2009, the ASG, led by former Speaker of the House of Representatives Newt Gingrich and former Senator Bob Kerrey, published a report calling for the creation of a National Alzheimer's Strategic Plan by 2010; thus, the idea of a National Alzheimer's Project was born. Since then, the AA became one of the strongest supporters of the national strategic planning effort to address Alzheimer's disease (AD). The Association, along with other key stakeholders, actively collaborated with Congressional leaders at every step in the evolution of NAPA. The Act was passed by both houses of Congress and signed into law (PL 111-375) by President Obama on January 4, 2011, mandating:

- a. Creation of National Strategic Plan to address the Alzheimer's crisis
- b. Coordination of AD efforts across the federal government
- c. Formation of an Advisory Council and
- d. Annual reports to Congress, which will provide:
 1. Updates on the National Strategic Plan
 2. Recommendations for priority actions

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3. Evaluation of all federally funded efforts in Alzheimer's research

The role of NAPA's Advisory Council is to (a) make recommendations to the Secretary of the Department of Health and Human Services (DHHS), who has the ultimate authority for preparing the final National Strategic Plan; (b) coordinate federal agencies conducting Alzheimer's research; and (c) participate in the evaluation and strategic planning process.

The membership of the Advisory Council* has been constituted to reflect the diversity of constituencies involved in different aspects of research, care, and services. The heterogeneity of interests and the multiplicity of perspectives embodied by the Council are both a potential strength and a weakness. The "Achilles' heel" of this deliberative body is the possible danger that competing or narrow agendas of its members could weaken the actual advice given to the Secretary (DHHS). The propensity of focusing on the "trees" rather than "forest" was evident during discussions of the Council's inaugural meeting on September 27, 2011 in Washington, DC. For example, discussions at that meeting appeared to focus more on explaining or justifying current programs across federal agencies rather than outlining a forward-looking bold vision to solve the problem by answering questions such as what are some of the scientific obstacles that must be surmounted and the types of additional resources that will be required. The ultimate effectiveness and utility of the Council will depend on a set of recommendations to the Secretary (DHHS) that are transformative rather than those that promote business-as-usual solutions, aimed at protecting individual turfs.

2. Why NAPA is important for the future funding of Alzheimer's research

The great hope of the research community is that NAPA will finally succeed in designating Alzheimer's research a national priority. Potentially, PL 111-375 promises to create the same successes as have been demonstrated in the battles against other diseases, such as HIV/AIDS, influenza and pneumonia, and stroke. For the first time in the history of Alzheimer's research, NAPA will enable Congress, by the required annual review process, to assess whether the nation is meeting the challenges of this disease. This course of action will allow the public and Congress to determine each year whether research is making satisfactory progress in the fight against Alzheimer's.

*The federal representations on the Advisory Council include Administration on Aging, Agency of Healthcare Research and Quality, Centers for Disease Control and Prevention, Centers for Medicare and Medicaid Services, Department of Veterans Affairs, Food and Drug Administration, Indian Health Service, National Institutes of Health (NIH), National Science Foundation, and the Surgeon General. The nonfederal representations (two each) include AD caregivers, AD patient advocates, health care providers, researchers with AD experience, state health departments, and voluntary health associations.

Questions regarding the potential significance of NAPA for future prospects of funding Alzheimer's research should be weighed against a 30-year history of similar efforts within the DHHS, NIH, and National Institute on Aging (NIA). Since 1978, with the inception of NIA's efforts to develop national programs of research on brain aging and AD, there were numerous efforts and initiatives launched with the same laudable intentions of designating Alzheimer's research as a high-priority national goal; calling for substantial increases of funds [1]. Unfortunately, virtually all of these initiatives during the past 3 decades failed to fulfill the expectations of the Alzheimer's research community. For example, during the period of 1984 to 1994, a series of "reports" known as *Alzheimer's Disease: Report of the Secretary's Task Force on Alzheimer's Disease* offered specific action plans with budget recommendations to the Secretary (DHHS). These reports, which reflected the collective advice of key opinion leaders in Alzheimer's, were largely ignored by DHHS/NIH [2]. Some of the factors that contributed to the lack of success of these earlier efforts are informative lessons for the NAPA initiative. These include:

- The scientific community was fragmented into groups with mixed loyalties, different interests, and no overriding interest in advocating for public policy.
- Despite NIA's effort, successive Directors of NIH did not explicitly support or endorse the idea of designating Alzheimer's a high priority for NIH or DHHS.
- Alzheimer's advocacy was Balkanized and was not effective in mobilizing grassroots support and speaking with one voice.

In contrast to earlier efforts, NAPA has the best chance to succeed because it has (a) at least the nominal support of Congress, the President, and the Secretary of the DHHS (and therefore the NIH); (b) the unanimous support of all constituencies; and (c) a research community that has become engaged in the planning process.

Recognizing the history of disappointments, this author, along with the AA, the Campaign to Prevent Alzheimer's Disease by 2020 (PAD2020),[†] and the research community,

[†]PAD2020 is a Maryland-based, 501(c)(3) nonprofit corporation (www.pad2020.org). PAD2020 executive committee members are Zaven S. Khachaturian, PhD, President, Potomac, MD; Virginia Lee, PhD, University of Pennsylvania, Philadelphia, PA; Ronald Petersen, MD, PhD, Mayo Clinic, Rochester, MN; Peter Snyder, PhD, Lifespan Affiliated Hospitals, Providence, RI; John Trojanowski, MD, PhD, University of Pennsylvania, Philadelphia, PA; Ara S. Khachaturian, PhD, *Alzheimer's and Dementia: Journal of the Alzheimer's Association*, Rockville, MD; and Stanley Prusiner, MD (Noble Laureate), University of California San Francisco, San Francisco, CA.

PAD2020 is affiliated with the AA through a "Memorandum of Understanding." All PAD2020 work groups and "Think Tank" meetings will be organized in collaboration with the AA. The strategic plans and policy recommendations of PAD2020 will be implemented through the Public Policy Office of the AA.

Table 1

Thirty-year chronology of some key “Strategic Plans,” “Task Force Reports,” “Directives,” and “Editorial” calling for the designation of Alzheimer’s research as a national priority (“Those that forget the lessons of history tend to repeat the mistakes of the past”)

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- 1980: *Department of Health, Education and Welfare (HEW) Health Research Planning—A Report of the HEW Steering Committee for the Development of a Health Research Strategy*. July 1980. Part 2, Chapter 6: Alzheimer’s Disease and the Dementias of Aging, pages 218–31.
- 1982: President Reagan signs a resolution declaring “November” as Alzheimer’s disease month.
- 1981: *White House Conference on Aging*—see recommendations for Alzheimer’s disease.
- 1984: The Secretary of the Department of Health and Human Services (Margaret Heckler) established Secretary’s Task Force on Alzheimer’s (Chaired by Robert Katzman, and later by John Blass).
- 1984: Office of Technology Assessment (OTA) report on *Technology and Aging in America* (see pages 33–61), chapter *Selected Chronic Conditions, Technology and Biomedical Research*. U.S. Congress. BA-264, June 1984. Library of Congress Catalog Card No. 84-601137.
- 1984: *Alzheimer’s Disease: Report Prepared by the Subcommittee on Investigation and Oversight, Committee on Science and Technology*. House of Representatives. 98th Congress, 2nd Session, Serial 00. December 1984.
- 1985: James Wyngarden, Director of National Institutes of Health, established the Office of Alzheimer’s Disease Research (OADR),* at the NIA as the coordinating center for all National Institutes of Health (NIH) research on Alzheimer’s; Zaven Khachaturian was appointed as the Director of OADR; however, this Office did not have any budget authority.
- 1987: OTA report, *Losing a Million Minds: Confronting the Tragedy of Alzheimer’s Disease and Other Dementias*. U.S. Congress, OTA-BA-323 (Washington, DC: U.S. Government Printing Office), April 1987. NTIS order #PB87-183752.
- 1990: *Decade of the Brain*, an interagency strategic planning initiative.
- 1992: Editorial, *The Five-Five, Ten-Ten Plan for Alzheimer’s Disease*; a call to arms intended to mobilize the federal government, academia, the pharmaceutical industry, the general public, and family support groups behind a concerted and integrated effort aimed at discovering treatments for AD. (Khachaturian ZS. *Neurobiol Aging* 1992;13:197–8).
- 1993: U.S. Senate Committee on Appropriations (for the Departments of Labor, Health and Human Services, and Education, and related agencies) in its report on the FY 1994 Appropriations Bill directed the NIA to develop a long-range plan for taking advantage of scientific opportunities in Alzheimer’s disease research. Congress noted several extremely important scientific advances during the past few years that had provided new leads concerning the etiology of AD and had thus created targets for drug development.
- 1994: Scientific communities’ consensus report on *Scientific Opportunities for Developing Treatments for Alzheimer’s Disease: Proceedings of Research Planning Workshop* (see Khachaturian ZS. *Neurobiol Aging* 1994;15:11–17).
- 1997: The Ronald and Nancy Reagan Research Institute’s strategic plan *Prospects for Preventing Alzheimer’s Disease*. Testimony by Khachaturian ZS at a hearing on Alzheimer’s disease research. Senate Committee on Labor and Human Resources. Washington, DC. June 5, 1997.
- 2002–2003: Alzheimer’s Disease Research, Prevention, and Care Act of 2002 & 2003 (107th & 108th Congress). [This was an “Authorization Bill”; it had no impact on “appropriation” of funds for Alzheimer’s research]
- 2004–2005: Ronald Reagan Alzheimer’s Breakthrough Act of 2004 & 2005 (108th & 109th Congress). [This was an “Authorization Bill”; it had no impact on “appropriation” of funds for Alzheimer’s research].
- 2007: *Developing a National Alzheimer’s Strategy Equal to the Epidemic*—perspective paper by Speaker Newt Gingrich and Robert Egge makes the case for the creation of a federal Alzheimer strategy article in *Alzheimers Dementia* (July 2007).
- 2007–2011: *Alzheimer’s Breakthrough Act of 2007, 2009 & 2011* (110th; 111th & 112th Congress). [This was an “Authorization Bill”; it had no impact on “appropriation” of funds for Alzheimer’s research].
- 2008: *A roadmap for the prevention of dementia*—consensus recommendations of Leon Thal Symposium (LTS’07). See Khachaturian et al. *Alzheimers Dement* 2008;4:156–63.
- 2009: Alzheimer’s Study Group (ASG), a bipartisan group of prominent, former government officials, led by Newt Gingrich and Bob Kerrey, delivered a report to the 111th Congress on March 24, 2009, calling for the creation of a National Alzheimer’s Strategic Plan by 2010. On release of the report, the Alzheimer’s Association pledged to seek enactment of the core recommendations.
- 2009: In June 2009, *The Campaign to Prevent Alzheimer’s Disease by 2020 (PAD2020)* was launched to maintain the momentum of the ASG report (ASG report, which incorporated many of the recommendations for an action plan suggested by the Leon Thal Symposium [LTS’08]—the precursor “think tank” to the PAD2020—was delivered to the 111th Congress on March 24, 2009. Some of the recommendations from the LTS’08 think tank were also adopted by the Alzheimer’s Breakthrough Act of 2009.)
- 2009: *The Alzheimer’s Breakthrough Act of 2009*—S 1492/HR 3286, 111th Congress, 1st Session, 2009. This was an *Authorization Bill* that had no impact on any *appropriation* of funds for Alzheimer’s research.
- 2010: *National Alzheimer’s Project Act of 2010 (PL 111-375)*.
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*OADR was abolished by the National Institute on Aging (NIA) in 1995.

is committed to making NAPA a successful venture. This will require that the final strategic plan delivers (a) specific actionable plans and/or public policy changes and (b) radical changes in the management and funding of Alzheimer’s research within DHHS. The ultimate importance of NAPA will be defined by the scope, quality, and the final outcome of the Advisory Council’s recommendations for priority actions. Presently, PL 111-375 is merely an important promissory note for a radical shift in public policies on national priorities. Ultimately, the only deliverable that counts is a credible plan of action that calls for significant and systematic increases in the

allocation of resources and funds for Alzheimer’s research.

The value of the Advisory Council to a large measure will be determined by the question of whether the NAPA planning process will tackle an array of thorny challenges that are hindering progress in research and development, particularly in the discovery and development of interventions to prevent disability. It remains to be seen whether the Advisory Council will be willing and able to take on the difficult issues in the world of research, or whether it will seek politically expedient cosmetic solutions to controversial issues (e.g., organizational and administrative changes at NIH).

3. What are some of the decisive challenges for NAPA?

3.1. An overall unifying strategic goal

The adoption of strategic goals within the framework of a public health problem and health care will be an important challenge. For example, a consensus on the global strategic goal of reducing the prevalence of AD and other brain disorders that affect memory, movement, and mood by 50% within the decade would provide a unifying framework for the entire NAPA planning process, including research, care, and services.

A national strategic goal to prevent AD within a decade will be difficult. However, the challenges confronting such an ambitious mission are no less daunting than other great human endeavors of the past, such as the Transcontinental Railroad, Panama Canal, Manhattan Project, Apollo Program, and the Human Genome Project. The strategic goal of prevention should be framed not as a promise or a guarantee for disease eradication, but rather as the acceptance of a national goal to mobilize coordinated efforts and a commitment to focus resources toward such an achievement. Such a vision by NAPA will provide a framework for strategic planning and will encourage stretch goals from researchers.

3.2. A strategy for sustained (10-year) systematic investment in research

A critical rate-limiting factor that is hindering the search for cures is the gross inadequacy of funds allocated to Alzheimer's research.* The doubling of NIH budget during the period 1998 to 2003 did not have a commensurate impact on the budget for Alzheimer's research. The urgent need for a national goal of preventing the disease is in jeopardy because of inadequate and dwindling resources to support the necessary work. Neuroscience research is extremely costly and highly technical. The cost of conducting research continues to rise with technological advances.

Research funds are not available to begin new initiatives or attract new investigators from other fields. This is particularly important now, as their expertise is most urgently needed to explore new therapeutic targets. Scarcity of funds, combined with arcane and prolonged decision-making processes for funding research, has greatly disincentivized the exploration of new and potentially good ideas for prospective therapies. The NIA, which supports a substantial portion of AD-related research, can fund only very small number of approved proposals with exceptional scientific merit. High-risk, high-reward projects are often passed over, and those applicants fortunate enough to be funded routinely see their budgets cut at various points in the 9-month-long review process. In the end, scientifically meritorious projects often are

forced to limit the scope of the work or abandon valuable avenues of exploration because of the lack of dollars.

Many investigators, even those at the world's leading research universities, are seriously constrained by the lack of easy access to essential resources. New instrumentation to permit measurement of biologic processes that were previously impossible to assess, is expensive and often requires highly trained scientists and technicians, which adds additional cost.

The proposed national strategic goal of prevention will require an unprecedented level of financial commitment from both the public and private sectors. The success of a prevention initiative hinges on an unwavering national commitment to allocate appropriate levels of funding during the next decade. NAPA's plan should target significant and systematic increases in funds to be allocated for research and development in prevention. A sustained investment of \$1 billion per year in new funds over current expenditures for the next 10 years will be required. This recommendation is based on the premise that substantially increased funding and investment in brain research is the only cost-effective means to address a pending health care crisis brought on by the exponential increase in the prevalence of neurodegenerative disorders and the ever-increasing lifespan.

The present national commitment to discover a solution to this public health problem is approximately \$1 for every \$310 AD is now costing society, which is grossly inadequate. An investment of \$10 billion dollars to solve the most urgent looming public health problem is not too high a cost.

3.3. Streamline the research support systems

The administrative structure for funding research should be modernized to function more effectively. The current model for supporting research cannot meet the needs of rapidly evolving dynamic fields of research. Procedures for identifying cutting-edge ideas, creative investigators, and new scientific opportunities are woefully inadequate. It is well known that often the most important breakthroughs in science have come from unconventional thinkers; however, the present decision-making system frequently fails to accommodate risk-taking on truly imaginative ideas. There is a need to replace current cumbersome traditions with a streamlined system that supports rapid decision making and is flexible enough to handle unexpected opportunities and breakthroughs and allow greater risk-taking on projects with longer-term public health goals.

Scientific orthodoxy is a major obstacle to the advancement of knowledge on AD, tending to narrow the field of vision and inhibit exploration of novel avenues of research. The conventional model for disease research—searching for causes and cures—is too limited for a chronic, end-of-life condition like AD, for which clinical trials may last 10 years. This debilitating, long-term illness requires different approaches, involving not only the traditional biomedical strategies of developing symptomatic treatments, but also

*<http://www.nia.nih.gov/AboutNIA/NACA/MeetingInformation/>; <http://www.nia.nih.gov/AboutNIA/BudgetRequests/>; <http://report.nih.gov/>; <http://report.nih.gov/rcdc/categories/>; <http://www.nih.gov/about/almanac/appropriations/index.htm>.

other approaches such as those of public health and prevention strategies.

3.4. Restructuring “indirect costs” and NIH budget

In the present climate of economic uncertainty, and in light of the ongoing political controversies concerning the federal budget, it is not realistic to expect any dramatic increases in the funds appropriated for research. However, the NAPA Advisory Council could recommend two specific actions to the Secretary (DHHS) that could effectively increase the allocation of funds within DHHS: (1) reallocate funds among institutes and/or the Public Health Service, and (2) renegotiate lower indirect cost on funded research grants with academic institutions. Although these bold actions would be drastic and controversial, President Obama has called for all segments of the nation to share the burden of economic vows of the country. These policies will provide universities the opportunity to step forward and help in the effort to solve the public health problem of AD.

3.5. Forge strategic alliances and expand the role of industry

No single entity has the necessary scientific knowledge, technical capabilities, or resources to develop effective interventions to slow the progression or prevent neurodegeneration in AD. It is therefore imperative that NAPA forge collaborative research and development agreements among all stakeholders (e.g., government, academia, industry, non-governmental organizations, and voluntary health organizations), focusing on the long-term, 10-year objective of discovering and developing interventions that will delay or prevent the onset of disease.

NAPA must develop a paradigm for government–industry–academia collaborations. The new agreement must eliminate organizational, administrative, social, and legal barriers by reengineering the structures and the processes for collaborations in research and development across the full spectrum of activities, from early discovery to clinical validation of interventions. At present, the competing priorities, missions, agendas, and perspectives of stakeholders lead to program initiatives that are at cross-purposes or are duplicative. The NAPA agreement must develop reasonable and fair financial incentives to industry partners, both to expand research on new treatments and to collaborate with academic and government research on these projects.

The AA in partnership with PAD2020 is committed to ensuring that the full potential of NAPA is realized. Through a memorandum of understanding, PAD2020 and AA are cooperating in creating a platform, through virtual workgroups or “think tanks,” to engage the vast network of scientists in the planning process. The goal is to tap the expert knowledge of the research community to help shape the principles, concepts, and recommendations that should be included in the

final National Strategic Plan. These virtual “think tank” deliberations and work products will be modeled on the Leon Thal Symposia [3–9].

4. Summary/Conclusion

The success of NAPA will be assured, provided its National Advisory Council prevails in directing the Secretary of the DHHS to adopt the same approach to project management as other great American projects mentioned previously. The key elements are as follows:

- Defining clear and specific objectives of the mission.
- Establishing an efficient organizational and management system with a single centralized administration and coordination center.
- Developing realistic research and implementation plans with timelines and deliverables.
- Adopting a systems approach to the planning and execution of the effort.
- Establishing decisive leadership that will promote changes in the governance and organization of research.
- Investing resources and funds over a sustained period in support of the mission, that is, a 10-year commitment of \$1 billion per year.
- Sustaining an unwavering national commitment to support this mission until completion.

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