

March 30, 2012

Advisory Council on Research, Care, and Services C/O Helen Lamont, Ph.D. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation Room 424E, Humphrey Building 200 Independence Avenue, SW Washington DC, 20201

Dear Members of the Advisory Council on Research, Care, and Services:

Leaders Engaged on Alzheimer's Disease (LEAD) commends the Inter-Agency Working Group of the Department of Health and Human Services (HHS) for developing a solid first draft of a National Plan to Address Alzheimer's Disease, a draft that includes goals and actions dealing with the most pressing issues facing people with Alzheimer's disease and their families. LEAD is pleased that a number of priority recommendations previously submitted by the coalition are included in the draft plan.

Organizations from all segments of the Alzheimer's-serving community participated in developing these comments, including nonprofits and for-profits, research-oriented and care-oriented, academic and advocacy, among others. LEAD believes strongly that achievement of the goals of preventing and effectively treating Alzheimer's by 2025 and improving the quality of care and of life of Alzheimer's victims and their families will require an National Alzheimer's Team using an 'all hands on deck' approach. LEAD and its participating organizations are prepared to step up as a full member of that Team.

Attached please find LEAD's comments on the first draft of the National Plan. We have organized our comments in the categories of research and drug discovery, clinical care, and long-term care support and services. We hope the Secretary will give strong consideration to including these recommendations in the final National Plan.

Comments provided in this document seek to strengthen the goals, strategies, and actions within the draft plan. As noted in earlier comments, LEAD believes that these goals can be achieved only with a significant increase in investment from the public, private, and non-profit sectors. It is imperative that the actions within the national plan be monitored and tracked to assess the impact of the action steps as well as progress toward the Plan's goals. While we are pleased that HHS will evaluate the data and infrastructure required for implementation of the plan, it is important that there is a model for assessing the impact that strategies within the national plan have on progress toward the desired goals. To that end, LEAD recommends that immediate action be taken to develop a model this year that will allow HHS to accurately assess the impact of the action steps in the national plan and identify areas for course adjustments. We, as a nation, should not pursue implementation steps that are not clearly moving toward our goals. We cannot waste time and resources going down blind alleys. In that regard we recommend that each goal and strategy set forth in the final national plan include a budget, clear milestones and quantifiable metrics to achieving the desired outcome.

LEAD members have also identified a set of other actions within the draft plan that should be implemented immediately, without the need for a national plan. These include activities that are already being undertaken or that leverage current resources and materials. Many of these actions are critical to the success of implementing long-term goals and strategies. Specifically they include disseminating existing tools and guidelines to help healthcare professionals diagnose and care for people with Alzheimer's and their families, as well as expansion of successful interventions that are already proven to improve quality of life for people with Alzheimer's. These actions are highlighted at the end of each section of comments.

Should you have questions or require additional information about this document, please contact Sally Sachar, Chief Operating Officer of USAgainstAlzheimer's at (202) 360-2043, <u>ssachar@usagainstalzheimers.org</u>, or Eric Sokol, Vice President of Public Policy at the Alzheimer's Foundation of America, at (202) 466-0590, <u>esokol@alzfdn.org</u>. We look forward to working with you on this important effort.

Respectfully,

George Vradenburg Chair & Co-Founder USAgainstAlzheimer's Eric J. Hall Founding President & Chief Executive Officer Alzheimer's Foundation of America

LEAD Participating Organizations

AHAF Alzheimer's Disease Research Alliance for Aging Research Alzheimer's Drug Discovery Foundation Alzheimer's Foundation of America Alzheimer's Research and Prevention Foundation American Academy of Neurology American Association for Geriatric Psychiatry American Association for Long Term Care Nursing American Life Science Pharmaceuticals. Inc. Banner Alzheimer's Institute **Baylor College of Medicine Critical Path Institute** Cure Alzheimer's Fund Direct Care Alliance Eisai Co., Ltd. Elan Eli Lilly & Company Geoffrey Beene Foundation

Inspire Janssen Alzheimer Immunotherapy R&D LLC Mayo Clinic Memory Enhancement Centers of America, Inc. Merck & Company, Inc. National Alliance for Caregiving National Association of Area Agencies on Aging National Association of States United for Aging and Disabilities National Council on Aging National Family Caregivers Association Parkinson's Action Network Pfizer Inc. Project Lifesaver The Gerontological Society of America University of Washington USAgainstAlzheimer's Visiting Nurse Associations of America Volunteers of America

In developing these comments LEAD established three workgroups -- one each in the areas of research and drug development, clinical care and long-term care support and services -- representative of the sentiment and unique needs of the entire Alzheimer's-serving community. Participation in LEAD or in the development of these comments does not constitute an endorsement of each of the recommendations within this document by any particular organization.

Goal 1: Prevent and Effectively Treat Alzheimer's Disease by 2025

LEAD fully supports this bold goal, with the hope that the goal can be achieved even more rapidly with the right plan and resource commitment. And LEAD is pleased that the Advisory Council has included a number of recommendations submitted by the coalition under Goal 1. Specifically we are pleased that the Advisory Council recommends a strategic approach to focus efforts and resources on "the most promising pharmacological interventions" as well as accelerating efforts to "identify early and presymptomatic stages of Alzheimer's disease." In addition, we are pleased that there is greater emphasis on international coordination and collaboration with commercial and nonprofit partners. However, it is imperative that any goal to prevent and effectively treat Alzheimer's disease include research investments in non-pharmacological treatments. Non-pharmacological approaches to Alzheimer's treatment can improve relevant outcomes including improved behavior and delay of institutionalization.

Below please find LEAD's comments and recommendations for Goal 1 of the draft National Plan:

Action 1.B.5: Conduct clinical trials on the most promising pharmacologic interventions

Strategies to expand research aimed at preventing and treating Alzheimer's disease should reference the very significant contribution that will be made by industry in conducting clinical trials. Strategies should build on the infrastructure that exists in industry for discovering promising new agents for trials and their existing working relationships with regulators to ensure that safe and effective medicines get approved. Strategies should include a statement of what each Federal and industry partner can contribute and where the cost and time of the clinical trial process can be reduced consistent with standards of safety and efficacy.

Action 1.C.1: Identify imaging and biomarkers to monitor disease progression

To further support a strategy to identify early and presymptomatic stages of Alzheimer's disease, government, industry, and patient advocacy organizations should work together to develop a large-scale, open-source patient registry of subjects that can be approached for recruitment in prevention trials, including specifically under-represented ethnic and other sub-populations. Trials focused on identifying early stages of Alzheimer's disease should be based on accepted quantitative clinical trial models designed for studies in early Alzheimer's disease.

Action 1.C.2: Maximize collaboration among federal agencies and with the private sector

With the levels of funding now dedicated by government, academia, and industry to Alzheimer's disease research, it is important to make the most efficient use possible of all partners and resources – and make the best use of the limited number of patients available for clinical trials. Studies need to be adequately powered, with agents that effectively test mechanisms of action, produce clear evidence of brain target engagement, and really help to advance the state of knowledge. Private industry is ready to support the 2025 goal and should be engaged as a full and equal partner with government and the research community in its achievement.

Action 1.E.1: Identify ways to compress the time between target identification and release of pharmacological treatments

LEAD recommends that this Action include consideration of a uniform patient consent and centralized Institutional Review Board (IRB) to review all multi-center Alzheimer's disease trials to decrease the time for trial start-up and protocol amendments.

Action 1.E.2: Leverage public and private collaborations to facilitate dissemination, translation, and implementation of research findings

Public-Private Partnerships provide an opportunity to overcome many of the challenges associated with taking a basic scientific discovery through development and regulatory approval of a medical product. Partnerships between the private sector, regulatory and other government agencies, academic institutions, nonprofit organizations, and patient groups represent a new model offering innovation and efficiencies in drug development. Many Public Private Partnerships exist around Alzheimer's disease and have helped to overcome barriers to research and drug development. Such partnerships include: the Alzheimer's Disease Neuroimaging Initiative, Coalition Against Major Diseases, FNIH Biomarkers Consortium and the Alliance for Aging Research's ACT-AD Coalition.

LEAD recommends increased support for these partnerships as they seek to establish publicly accessible clinical trial databases that can be mined for information on biomarkers and disease progression. Drug companies can contribute data and conduct prospective trials that may be required to provide the regulatory levels of evidence to assure qualification of new drug tools. Academics can also provide clinical data and analysis to identify optimal biomarkers for qualification. Further as additional data gaps are identified, pre-competitive partnership collaborations can accelerate the pathway toward development of Alzheimer's disease modifying therapies.

New models of Public-Private Partnership cooperation and funding are needed, within or possibly outside of NIH, especially for non-profit organizations, collaborative platforms, and those working toward improving the process of drug development and regulatory review. Infrastructure support for such Alzheimer's partnerships could be provided through HHS or other governmental agency appropriations. Because these partnerships rely upon multi-stakeholder collaborations, it is critical that oversight be provided through multi-stakeholder governance mechanisms to represent the broad spectrum of the various entities (industry, regulatory agencies, government funding, non-profits, academic experts, and patients).

<u>New Recommendation:</u> Address the unique circumstances of individuals with Alzheimer's disease and their ability to provide informed consent for clinical trial participation

LEAD recommends that the final plan includes a process for developing a standardized informed consent to allow participants in clinical trials to authorize their de-identified data be used for research purposes broader than a single study in order to advance understanding, treatment and prevention of Alzheimer's disease. We recommend allowing pooling of individual de-identified data into larger Alzheimer's disease databases to allow data mining and to increase statistical significance, provide information on the natural history of Alzheimer's disease, identify promising biomarkers and response or non-response to treatment. This database would need to address privacy, HIPPA, informed consent and liability issues and need a mechanism to protect proprietary and confidential data. Research activities involving human participants will continue to be conducted in a way that promotes their rights and welfare but include a feature for allowing Alzheimer's patients to opt in and contribute their de-identified data for research as in public databases or opt out for those who do not want to allow their data to be used for research purposes.

<u>New Recommendation:</u> Develop data standards to ensure a uniform approach for collection, transfer, analysis, reporting and archiving of data.

The National Plan should encourage all new and ongoing federally-funded and industry-sponsored Alzheimer's disease clinical trials to use the same Alzheimer's disease data standards developed by the Clinical Data Interchange Standards Consortium (CDISC). Data standards provide a uniform approach for collection, transfer, analysis, reporting and archiving of data. The benefits of using common data standards include improved learning and knowledge generation and a reduction in time, resources and costs. Using these standards will facilitate data sharing and review by the FDA and EMA. In addition, Alzheimer's disease clinical trials data, including data in failed trials, data with respect to dormant drugs, and data rich in biomarker information, should be remapped to the same common Alzheimer's disease CDISC data standards and any federally-funded and industry-sponsored Alzheimer's disease clinical trials data recorded should be shared in a common Alzheimer's disease database for qualified research use.

Actions to be implemented immediately:

Action 1.A.1: Convene an Alzheimer's disease research summit with national and international scientists to identify priorities, milestones, and a timeline

LEAD recommends that all findings from the May research summit be shared with the public for comment and that "strategies and milestones for an ambitious plan to slow progression, delay onset, and prevent Alzheimer's disease" be established within six months of the summit to ensure continued momentum and coordination with the National Plan. LEAD recommends that continuing research summits be conducted every other year in order to monitor progress and adjust priorities in light of funding conditions.

Action 1.A.2: Solicit public and private input on Alzheimer's disease research priorities

The NIA should issue an RFI within six months of the summit as noted above and information be captured and evaluated and considered as the NIA develops priorities for future years.

Action 1.B.3: Increase enrollment in clinical trials and other clinical research through community, national, and international outreach

Within the year HHS should convene representatives from across the federal government, state and local governments, academic medical research institutions, and the private sector to create an action plan for increasing enrollment in clinical trials, including through the building of registries.

Goal 2: Enhance Care Quality and Efficiency

LEAD is pleased that the draft plan includes the goal to enhance care quality and efficiency. A national plan for Alzheimer's disease should focus on developing and continuously improving the care of our citizens in home or community settings by offering the best risk management, prevention strategies, early detection, precise diagnosis, and long-term management available. The strategies outlined for Goal 2 in the draft plan will provide a platform for ensuring that all Americans requiring care for Alzheimer's disease are able to access quality care across various care settings. Below are comments from LEAD regarding the draft plan:

Action 2.A.1: Educate Healthcare Providers

Improved emergency department and inpatient hospital care can be achieved by enhanced recognition of Alzheimer's disease in acute care settings. A key element to achieving this objective is providing information and training for physicians, nurses, nursing aides, and other staff to help manage patient care. This should include psychiatric care for patients with escalating levels of depression, agitation or psychosis, and hospital care for acute agitation or psychosis in public and private hospital settings. Additionally, psychosocial support services must be available to families that allow for the continued home-care of loved ones when illness or other emergency strikes the primary caregiver.

In addition to educating healthcare providers, LEAD recommends that both government and private agencies that regulate, accredit, license and certify residential care and community care providers require training for health and social service professionals caring for people with Alzheimer's disease and other dementias. Such providers should include directors of nursing, nurse supervisors, nursing assistants and respite caregivers. The settings requiring certification should include assisted living, adult day care, nursing home and home care. The training should be based on evidence-based guidelines that have been developed through a consensus processes that includes providers, family caregivers, other advocates and people with dementia.

Action 2.A.3: Collect and disseminate dementia-specific guidelines and curricula for all provider groups across the care spectrum

LEAD recommends that this action be combined with Action 2.D.1 "Explore dementia care guidelines and measures." Both recommendations require input from experts to develop dementia-specific guidelines for dissemination.

Action 2.A.5: Strengthen state aging workforces

LEAD applauds the efforts to strengthen state aging workforces that are "capable and culturally competent" through the Administration on Aging (AOA). While implementing this action, it is important that efforts to improve state strategies do not further burden states' abilities to apply for and utilize funds from AoA. States should maintain flexibility to implement strategies that address the unique needs of the state populations through their state infrastructures.

Action 2.C.2: Enhance assistance for people with AD and their caregivers to prepare for care needs

LEAD recommends that people with Alzheimer's disease and their families are educated about palliative and hospice care by healthcare professionals. Palliative care is specialized medical care provided by a team of doctors, nurses, social workers and other specialists who work collaboratively to provide the best possible quality of life for people facing the pain, symptoms and stresses of serious illness, including Alzheimer's disease. Palliative care relieves suffering while affirming life, regards dying as a normal process, and intends neither to hasten nor postpone death. The integration of the psychological aspects of patient care offers a support system to the patient and, when in need, to help the family cope during the bereavement process.

Action 2.D.1: Explore dementia care guidelines and measures

The Advisory Council should consider merging Action2.D.1 with Action 2.A.3, which calls for the dissemination of "dementia-specific guidelines and curricula for all provider groups across the care spectrum." Both Actions require the convening of an expert panel to develop dementia care guidelines for care providers.

Action 2.F.2: Implement and evaluate new care models to support effective care transitions for people with Alzheimer's disease

To improve coordination of care and to share information on Alzheimer's disease care and best practices, the draft Plan should consider the creation of regional Memory Evaluation and Treatment Centers that leverage existing infrastructure

and resources. Memory Evaluation and Treatment Centers should focus on developing, improving and disseminating best practices in clinical care for people with Alzheimer's disease and family caregivers. The Centers are necessary to ensure translation of clinical research into practice. There should be particular focus on advances related to identification of persons with genetic mutations and persons with genetic, biological and environmental risk factors and to the implementation of biomarker-based risk assessments. Such centers would also serve to mobilize assessed populations for clinical trials of new prevention and disease modifying treatments.

<u>New Recommendation:</u> Ensure people with Alzheimer's disease and their families have access to new Alzheimer's therapies

As biologic therapies are approved for Alzheimer's disease, the Centers for Medicare and Medicaid Services (CMS) should consider policy safeguards ensuring Medicare beneficiaries have access to these therapies as health care reform provisions are implemented. This will be particularly important as CMS improves upon the Accountable Care Organization (ACO) program within Medicare. Under current regulations, ACOs will be allowed to share savings with the government to the extent they can achieve savings from an historic baseline trended forward for ACO patients within Parts A and B of Medicare. Due to the absence of any current spending on biologic therapies for Alzheimer's disease in an ACO's benchmark baseline, ACO's may be "penalized" for providing a new treatment to patients. To address this problem, LEAD recommends that CMS create a process under which stakeholders would be able to identify certain high cost or high volume, break-through treatments and request that CMS make a special adjustment to ACO baselines that would remove incentives to underuse those new treatments.

<u>New Recommendation</u>: Primary Care Doctors, Geriatricians, Geriatric Psychiatrists and Neurologists should be adequately reimbursed for patient care and the evaluation of cognitive function including psychometrics and caregiver education and counseling.

Unless doctors are appropriately reimbursed, the complex needs of individuals with Alzheimer's disease will not be addressed. Anticipatory care planning and comprehensive treatment management in a setting where transitions and treatable concomitants of Alzheimer's disease are understood will result in better care. Such practices may delay the onset and progression of disabling clinical symptoms, and allow meaningful function, reduce healthcare costs, and improve the quality of life for individuals with the disease and their family caregivers.

New Recommendation: Develop Quality Care Measures for People with Alzheimer's and their Family

HHS should convene a panel of experts to develop Alzheimer's disease specific quality care measures. Information on these measures should be captured through the use of Health IT tools to track care quality and outcomes.

Actions to be implemented immediately:

Action 2.A.3: Collect and disseminate dementia-specific guidelines and curricula for all provider groups across the care spectrum

HHS should convene a panel of experts to develop guidelines that can be provided to provider groups.

Action 2.B.2: Identify and disseminate appropriate assessment tools

Similar to Action 2.A.3 HHS should quickly convene a panel of experts to develop consensus for appropriate assessment tools and identify strategies for dissemination.

Action 2.C.2: Enhance assistance for people with AD and their caregivers to prepare for care needs

HHS should compile an inventory of tools to assist caregivers from federal and state agencies as well as patient advocacy organizations and make these tools readily available within the next year through the state aging networks.

Action 2.F.1: Identify and disseminate models of hospital safety for people with AD

HHS should convene stakeholders to develop guidelines for hospital safety for people with Alzheimer's and disseminate guidelines through national associations and hospital systems.

Goal 3: Expand Supports for People with Alzheimer's Disease and Their Families

LEAD applauds the draft plan for including goals and strategies that will improve quality care and expand support for people with Alzheimer's disease and other dementias and their families. Specifically, we are pleased that the plan includes recommendations from LEAD to expand proven programs that are in place at the federal, state and local levels that provide adequate care and support for people with Alzheimer's and other dementias and their families. Moving forward it is important that the plan provide adequate resources to be available to support the implementation of these strategies. Below are LEAD comments on Goal 3 of the Draft Plan:

Action 3.A.3: Utilize informatics for caregivers and persons with AD

LEAD recommends that the word "informatics" in the title of this Action be changed to "Health IT" to be consistent with the accompanying language. Identifying and capturing information about caregivers, in particular family caregivers, by health IT applications will help to better coordinate care of both the person with Alzheimer's or other dementias and the caregiver. Capturing information about the health of family caregivers on medical records has an added benefit of supplying data for metrics that can be used to track the impact of programs on both family caregivers and their care recipients. Data would allow for the comparison of patients with and without family caregivers as well as track health impacts on family caregivers.

Action 3.B.3: Review the state of the art of evidence-based interventions that can be delivered by community-based organizations

LEAD recommends that this Action include identifying interventions that are successful in improving the health and wellness of people with Alzheimer's disease and other dementias. Many successful evidence based programs have been proven to work for both people with Alzheimer's and other dementias so it is important that the evaluation of such programs is not limited to only Alzheimer's specific interventions.

Action 3.E.1: Explore affordable housing models

LEAD recommends that this Action include the evaluation of innovative interventions aimed at helping people with Alzheimer's and other dementias remain in the community rather than in long term care or other institutional settings.

<u>New Recommendation</u>: Ensure adequate resources for programs and services supported by AoA's Alzheimer's Disease Supportive Services Program (ADSSP)

ADSSP's focus is to expand the availability of diagnostic and support services for persons with Alzheimer's disease and other dementias and their caregivers, as well as to improve the responsiveness of the home and community-based care system to persons with dementia. The program focuses on serving hard-to-reach and underserved persons using proven and innovative models. In order to achieve Goal 3 in the Draft Plan, funding for ADSSP should be increased rather than reduced so that evidence-based programs can continue to support the growing number of people with Alzheimer's disease and other dementias and their families at the community level.

New Recommendation: Include services for mental and behavioral health services

Mental and behavioral health services must be included in the wide array of needed health services available to individuals with Alzheimer's and other dementias. Mental and behavioral health providers should be represented on interdisciplinary health care teams that work with these individuals, their families and caregivers in primary care, long-term care and community and home-based settings. Cognitive impairment alone does not preclude the ability to benefit from various forms of effective behavioral and mental health interventions.

Actions to be implemented immediately:

Action 3.A.1: Identify culturally sensitive materials and training

Within the year HHS should convene an expert panel to develop an inventory of culturally sensitive materials and trainings available and identify gaps that should be filled by government and patient advocacy organizations.

Action 3.A.2: Distribute materials to caregivers

Utilizing its current inventory of federal agency programs and materials, HHS should make these resources readily available to all caregivers through the state aging programs.

Action 3.B.3: Review the state of the art of evidence-based interventions that can be delivered by community-based organizations

HHS should convene a meeting of partner organizations to identify successful evidence based interventions by community based organizations and quickly work to ensure that more people with Alzheimer's and their families have access to successful programs as identified in Action 3.B.4. There are already programs exist that LEAD recommends that HHS should expand as part of this effort:

- Older Americans Act Reauthorization of this legislation would ensure grants to states for community planning and social services, research and development projects, and personnel training in the field of aging.
- Lifespan Respite Care Act Reauthorization of this legislation would authorize grants to statewide respite care service providers. Grants can be used for various purposes, including training and recruiting workers and volunteers, training family caregivers and providing information about available services.
- National Family Caregivers Support Program At a minimum, funding levels should meet the recommended levels of the President's FY12 budget (\$192 million). This program provides grants to states and territories to pay for a range of programs assisting family and informal caregivers to care for loved ones at home and for as long as possible. In addition, this program should add the family caregiver assessment to the list of services for which states can use program funds.

Action 3.B.6: Share lessons learned through VA caregiver support strategies with federal partners

LEAD recommends that the quarterly meetings identified in this action step commence as soon as possible so that important information is gathered and shared among federal programs and with community based providers.

Goal 5: Improve Data to Track Progress

<u>New Recommendation</u>: Establish a coordinating entity specifically for Alzheimer's disease care, research, and education within the federal government

LEAD members strongly recommended that there be a permanent office or other coordinating entity specifically for Alzheimer's care, research, and education within the federal government. An office in the White House, like that established for HIV/AIDS, would be in a position to coordinate efforts across HHS, DOD and the VA as well as the Departments of Treasury and State and the Office of Management and Budget, in order to assure comprehensive coordination of a national and international effort to prevent and effectively treat Alzheimer's by 2025. Section 2c of the National Alzheimer's Project Act lays the groundwork for a coordinating function with HHS itself by establishing in the Office of the Secretary of Health and Human Services that:

- 1. the Secretary or the Secretary's designee be responsible for the establishment and maintenance of an integrated national plan to overcome Alzheimer's; (and)
- 2. Provide information and coordination of Alzheimer's research and services across all Federal agencies.

Both the Act itself and those volunteering their time and expertise on the Advisory Council, its work groups, and those assembled by supporting private entities such as LEAD, have envisioned a lasting presence to drive and coordinate Federal and private efforts to defeat Alzheimer's. We recommend that a permanent role be established within the White House as well as in the Office of the Secretary of HHS at the Deputy Assistant Secretary level as National Coordinators of Alzheimer's Plan Implementation. These individuals will be responsible not only for reporting on the progress of the National Plan as provided by the National Alzheimer's Project Act, but also for driving forward aggressive coordination and rationalization of Federal resources with private and global efforts to defeat Alzheimer's by 2025.

The National Alzheimer's Project Act, with bi-partisan support from the Congress, places the responsibility for this function with the office of the Secretary of HHS. A separate person within that office reporting to the Secretary may have a "bully pulpit" but would not have the administrative apparatus to function effectively. Ideally, this role would fall to an official whose full time job is pursuing an end to Alzheimer's in as highly placed a position as possible.

Similarly, locating this HHS responsibility elsewhere within HHS could dilute its importance. The National Institutes of Health, for example, focus on research, not care or education. The Administration on Aging focuses on care and education, not research.

The office of the Assistant Secretary for Planning and Evaluation has begun the implementation of the Plan efficiently and in good time. The professional staff has the institutional knowledge and, all indications are, commitment to the Plan to move it forward. What remains is the appointment of an individual within that office and at the level of a deputy assistant secretary whose full time responsibility is to fulfill the aspirations of the Act, the Advisory Council, Congress, and others who support it.