February 8, 2012

BY ELECTRONIC DELIVERY
NAPA@hhs.gov

Sherry Glied
Assistant Secretary for Planning and Evaluation
Room 415F
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Re: Draft Framework for the National Plan to Address Alzheimer's Disease

Dear Ms. Glied:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments on the Draft Framework for the National Plan to Address Alzheimer's Disease (the "Draft Framework"), released by the Assistant Secretary for Planning and Evaluation (ASPE) on January 9, 2012.[1] BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

As the representative of an industry that is devoted to improving health care through the discovery of new therapies, BIO believes that any framework for improving diagnosis and care for serious, complex illnesses, such as Alzheimer's disease, must include measures to provide access to innovative treatment options, including new drugs and biologicals. We are pleased that the Draft Framework specifically includes strategies for enhancing scientific research aimed at preventing and treating Alzheimer's disease, coordinating research with international public and private entities, and facilitating the translation of findings

[1] Draft Framework for the National Plan to Address Alzheimer's Disease, Jan. 9, 2012, http://aspe.hhs.gov/daltcp/napa/Framework-Draft.pdf.

into medical practice and public health programs.[2] We offer the following comments to make these strategies more effective.

1. **The Draft Framework Should Include a Strategy to Protect Patient Access to Innovative Therapies for Alzheimer's Disease**

The draft framework correctly recognizes that after research findings are published in the clinical literature, "additional steps are needed to highlight promising findings and to facilitate dissemination and implementation of effective interventions to the general public, medical practitioners, industry, and public health systems quickly and accurately."[3] In addition to being shared with patients, caregivers, and practitioners, new clinical evidence also must be adopted into health plans' coverage and payment policies in a timely manner to ensure that access and reimbursement is available for advanced treatment options and improved diagnostic tools that address the eight cognitive domains that may be impaired in Alzheimer's, as recognized in the NINCDS-ADRA Alzheimer's Criteria: memory, language, perceptual skills, attention, constructive abilities, orientation, problem solving, and functional abilities.[4] This is particularly important now because there are exciting new diagnostic tools and treatments for Alzheimer's disease on the horizon, at the same time our health care delivery system is undergoing dramatic change, from the creation of Accountable Care Organizations to increased packaging.

There are several ways the Centers for Medicare and Medicaid Services (CMS) can protect patient access to care. CMS should assign Healthcare Common Procedure Coding System (HCPCS) codes in a timely manner for new drugs and biologicals to facilitate claims processing and payment by all health plans. CMS also should expeditiously add new cognitive tests to Medicare's Annual Wellness visit so that beneficiaries will have access to this service on a regular schedule and without out-of-pocket costs. In addition, CMS should work with stakeholders to identify new preventive services and issue national coverage determinations that add those services to Medicare's preventive benefits. Other payers, including Medicaid and private insurance plans, as well as the state agencies that regulate health plans, will need to act promptly on similar matters to protect access to

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[2] Strategies 1.B., 1.D., and 1.E, id. at 1-2.
[3] Id. at 2.
[4] G. McKhann et al. Clinical diagnosis of Alzheimer's disease: Report of the NINCDS - ADRDA Work Group under the auspices of Department of Health and Human Services Task Force on Alzheimer's Disease. Neurology. 1984; 34:939-944.

innovative diagnosis and care for patients within their programs as well. CMS and other payers also may need to reconsider their current rules on coverage and payment to support adoption of new approaches to care, such as use of telehealth and increased participation in care by family members and caretakers, and to ensure that bundled payment systems do not discourage the use of novel therapies. BIO recommends that the Draft Framework be revised to explicitly acknowledge the need for prompt action by Medicare and other payers to provide comprehensive coverage, coding, and payment for new methods of preventing, diagnosing, and treating Alzheimer's disease to help meet the needs of this vulnerable patient population.

2. **The Draft Framework's Strategies Should Support the Development of Treatment by Facilitating Participation of Patients with Alzheimer's Disease in Clinical Trials**

BIO recognizes that no progress can be made without clinical research, yet we also realize that it is difficult for many older patients to participate in trials due to comorbidities and limited access to sites of care that offer trials. These obstacles are particularly significant for patients with Alzheimer's disease, who may have more difficulty deciding to participate in a trial or remaining in a trial unless they have strong support from their family members and caregivers and health care practitioners. The Draft Framework notes that "new partnerships and outreach efforts may be needed to ensure that enough people are enrolled in clinical trials to examine the effectiveness of promising interventions."[5] BIO believes these efforts are needed. Enhanced outreach is essential to increasing participation in clinical trials through educating patients' families and caregivers, facilitating their access to the patient's health information, and supporting their role in helping patients make treatment decisions. These efforts also need to be applied across all research efforts – in the U.S. or other countries, public or privately funded – to encourage optimal participation in these essential trials. BIO recommends that the Draft Framework specifically recognize the need for enhanced efforts to address the factors that frequently inhibit patients with Alzheimer's disease from participating in clinical research. To facilitate this, we recommend that the Secretary involve, consult and engage with industry to address those factors through "new partnerships and outreach efforts."

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[5] Draft Framework at 1 (emphasis added).

BIO appreciates this opportunity to comment on the Draft Framework. We look forward to continuing to work with ASPE to refine and implement this plan to improve diagnoses and care for Alzheimer's disease. Please contact me at (202) 962-9220 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Laurel L. Todd
Managing Director, Reimbursement and Health Policy