

FasterCures

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Department of Health & Human Services

Via email: napa@hhs.gov

Re: National Plan to Address Alzheimer's Disease

To whom it may concern:

Thank you for the opportunity to comment on the draft National Plan to Address Alzheimer's Disease. We at *FasterCures* have been observing with great interest the development of this agenda for some time and were significantly engaged in providing feedback on its precursor, the plan of the Alzheimer's Study Group.

FasterCures' mission is to improve the medical research system irrespective of disease area, to speed up the time it takes to get important new medicines from discovery to patients. As a result, our concerns often relate to the importance of tackling problems with the research process as well as the science. While we might wish that the language in the Plan were a little bit stronger and more direct on this score, we are pleased that many of the process issues we care about and raised with the Alzheimer's Study Group are reflected in it, including:

- Promoting a more outcomes-oriented approach to research, particularly translation and drug development. (The Plan does not, however, offer specific ideas about the changes necessary for this to happen – e.g. how might this impact the traditional investigator-initiated model of grantmaking by the NIH?)
- Mapping the landscape of current Alzheimer's disease (AD) research, not just within federal agencies but by all players;
- Identifying priority areas for research investment;
- Encouraging and facilitating collaboration among sectors; and
- Building patient awareness of and participation in research.

There are other issues we see as critical to progress toward new treatments that we do not believe are adequately reflected in the Plan, including:

- **Creating shared resources available to AD researchers.** There are occasional references to this subject in a number of places in the plan, but we believe it should be an important focus. Any inventory of AD research investments should explicitly include resources such as databases, electronic health records collections, and tissue banks that already exist and should be shared, and any effort to identify research priorities should explicitly include new shared resources that need to be created.

- **Engaging regulators in strategizing about how to accelerate approval.** Again, the plan does mention FDA on occasion, but in our view there is not enough emphasis on the importance of this. Approval of new therapies can be significantly accelerated if regulators can be involved in discussions about clinical trials at early stages, so that time is not lost at the end of the process having to go back to the drawing board. The Foundation for the NIH's Biomarker's Consortium is an excellent example of the utility of involving FDA at the earliest stages of research.
- **Making sure that all existing federal efforts (not just those already specifically targeted at AD) are applying themselves to the challenges faced by AD.** For example, the new National Center for Advancing Translational Sciences (NCATS) at NIH, the FDA's focus on improving regulatory science at the agency, and the efforts of the Office of the National Coordinator for Health IT at HHS to accelerate the adoption of electronic health records and information exchange. These are significant efforts by the federal government that will have an impact on the research environment and should reflect the priority the federal government is placing on AD.
- **Examining the pipeline of clinical researchers in AD.** There is appropriate emphasis in the Plan on training of providers and caregivers, but not on the future research corps. AD already suffers from a shortage of clinicians trained in the complex care of elderly patients, and the shortage of clinical researchers in this area is probably even more dire. Attention should be paid to the recruitment and training of researchers capable of working in this field.

Thank you once again for the opportunity to comment on what we believe is a strong draft National Plan to Address Alzheimer's Disease. We are happy to discuss our views further with HHS or the Advisory Council on Alzheimer's Research, Care and Services at any time.

Sincerely,
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[FasterCures](http://www.fastercures.org) is a nonprofit, nonpartisan center of the [Milken Institute](http://www.milkeninstitute.org) dedicated to improving the medical research system so that we can speed up the time it takes to get important new medicines from discovery to patients. Through our programmatic activities, we work with many patient advocacy, venture philanthropy, and medical research organizations across the disease spectrum to improve the effectiveness and efficiency of the medical research enterprise, and transform the way we pursue, fund, and conduct medical research.