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VIA ELECTRONIC FILING – NAPA@hhs.gov

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
U.S. Department of Health and Human Services
c/o HHS Office of the Assistant Secretary for Planning and Evaluation Room 424E,
Humphrey Building
200 Independence Avenue S.W.
Washington, DC 20201

Re: Comments on Draft National Plan to Address Alzheimer's Disease

Dear Secretary Sebelius:

Merck & Company, Inc. appreciates the opportunity to comment on the Draft National Plan to Address Alzheimer's Disease. Merck is an innovative, global health care leader that is committed to preserving and improving human life. We continue to focus our research on conditions that affect millions of people around the world.

We commend you and the Advisory Council on the first Draft of the National Plan. The plan is comprehensive in scope and addresses many of the most significant challenges to changing the course of Alzheimer's disease in the US and globally. As indicated in the Draft Plan, we encourage you to make subsequent iterations of the Plan far more specific, and to give a practical sense of what can be accomplished not only through government action but by bringing government, industry, and academia together to align and build on each other's already substantial activities on Alzheimer's disease. We applaud the government's leadership in organizing and hosting the Alzheimer's Disease Research Summit in May to bring a wide array of stakeholders to the table, and we look forward to participating in this meeting.

The Importance of Goal 1

We are particularly pleased with the first Goal of the Draft Plan: to prevent and effectively treat Alzheimer's disease by 2025. Only by setting such a challenging goal and by allocating sufficient resources and aligning critical partners can we hope to achieve such an important global public health outcome.

Broad Collaboration Needed

This is not a goal the US federal government can accomplish solely through its own actions or by directing the actions of others, particularly in light of the limited resources currently at its disposal. Rather this is a goal that all of us committed to a breakthrough in Alzheimer's disease must share; and must, indeed, share with our colleagues around the world. It will take a true partnership of research, business, advocates, health care and government and the combined resources of all parties to develop and apply the needed therapeutics at the rate required to attain this goal.

Leadership is critical, and the government, through this Plan and its funding and convening powers, can do much to provide that leadership. Achieving key milestones in advancing therapeutics will require a collaboration of government, academia, and industry.

Industry Partnership Is Essential

In Streamlining Regulatory Pathways

While the Draft Plan proposes a number of areas in which greater collaboration with industry can be productive, there are a number of proposed actions where more constructive engagement of industry could be helpful. Specifically, Action 1.E.1 to identify ways to accelerate time to market, should engage industry as a full partner in identifying ways to simplify the approval process, provide greater clarity and predictability in validation and application of diagnostics and biomarkers and in the selection of endpoints.

In Establishing New Approval Standards

Currently, efficacy can only be established in large and lengthy clinical trials. Advances in knowledge of disease pathophysiology, risk factors, and disease biomarkers through academic, government and industry sponsored research is critical to develop more efficient new approaches for clinical trials. Industry should be directly involved in an ongoing dialogue with the FDA on how to translate the rapidly evolving science of Alzheimer's disease into standards for establishing safety and efficacy of treatments. Developing new approaches that can be used to shorten this timeline and remove risk earlier will require the combined efforts of industry and the FDA. Collaboration with the EMA and other major regulatory bodies will be essential as well to ensure global consistency in the translation of science into regulatory pathways to get therapeutics to patients.

In Accounting for Different Disease Segments

Imaging and biomarker development in Strategy 1 C should contribute to clear differentiation by the FDA of segments of disease -- prevention, early treatment and later treatment -- which have different issues and may have different pathways for approval. For each segment, the FDA will need to provide guidance on acceptable diagnostic criteria and clinical end-points needed to prove efficacy.

In Designing and Conducting Clinical Trials

Clinical trial design and conduct is another area where much can be gained from a true partnership with academia and industry. Action 1.B.5 proposes that HHS, VA, and NIA develop and fund clinical trials on the most promising therapeutics. This Action does not account for the amount of time and effort, and the amount of uncertainty that is involved in finding safe therapeutic candidates and testing these mechanisms in trials. Nor does it acknowledge the existence of the substantial infrastructure that exists in industry for discovering promising new agents for trials and the relationships that already exist with regulators to ensure that medicines are approved. This is an infrastructure today fully engaged in developing the more than 100 Alzheimer's disease candidates currently in the pipeline.

Efficiency Needed in Research

It is important in Strategy 1 B in expanding the research aimed at preventing and treating Alzheimer's disease, to ensure the most efficient use of all partners and resources, and make the best use of the limited number of patients that will be available for clinical trials. Studies need to be adequately powered, with agents that effectively test mechanisms and produce evidence of brain target engagement to avoid studies that confuse the field and do not advance the state of knowledge, in order to make the best use of patients that enter clinical trials.

Again, we commend you on the progress to date on this important project. We appreciate the opportunity to provide comments on the Draft National Plan to Address Alzheimer's Disease. We look forward to the opportunity to remain fully engaged in this important mission of developing an effective prevention and treatment for Alzheimer's disease by 2025.

Sincerely,

Darryle D. Schoepp

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Senior Vice President and Franchise Head, Neuroscience