Research Subcommittee

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Issues and considerations for discussion

Introduction

- One overall goal, three strategies
  - Strategy 3 is very much in development
- Some of the action steps have consensus, others are being developed

Issues and considerations for discussion

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Overall Goal

To prevent, effectively treat, substantially delay the onset, or slow the progression of AD

- The implications of setting a 2020 vs. 2025 target date are being discussed

Issues and considerations for discussion

Strategy 1

- Commit aggressive resources, with appropriate accountability, to Alzheimer's Disease research to match the current and growing impact of the disease on society

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Action 1A

- Immediately increase annual federal research funding investment to a minimum of $2 billion in targeted, outcome-oriented Alzheimer's research initiatives spanning basic, translational and clinical research, and hold recipients of funding accountable for progress toward the overall stated goal.
  - Federal members can't opine on allocation of resources
  - A systematic review of resource needs is currently underway by the Alzheimer's Association

Issues and considerations for discussion

Action 2A

- In order to achieve the goal, HHS should be required to develop, execute and regularly update a scientific research plan and priorities to accelerate breakthroughs in AD research, a review of research infrastructure including public/private partnerships, and provide programmatic recommendations for achieving these targeted research opportunities through sustainable higher levels of annual funding

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Action 3A

- A person or office should be identified who has responsibility and accountability for execution of, and advocacy for, all aspects of the National Plan, including responsibility for issuing reports to Congress and the Advisory Council
  - We share the desire to not add layers of bureaucracy but believe strongly in the need for accountability

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Strategy 2

- Accelerate public access to new therapeutic interventions by compressing the current average time in the process of identification of therapeutic targets, validation of those targets, development of interventions, testing of efficacy and safety, and regulatory review.
  - We are working on clarification of the component steps involved in therapy development and potential interventions

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Action 2A

- Develop behavioral and biological markers for potential therapeutic targets or surrogate endpoints
  - This is a common focus with framework

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Action 2B

- The HHS Secretary, in consultation with the private sector, the research community and NGO's, should by year-end 2012 model and prioritize the action steps needed to reduce the time for moving therapies from target identification and validation through regulatory approval and thereafter to implement or cause to be implemented such action steps.

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In undertaking the above, might include:

- Repurposing exiting drugs
- Develop and require adoption of clinical terminology and disclosure standards for use in all new and ongoing Alzheimer's clinical trials (Federally-funded and industry-supported) to build an open source database for qualified research use.
- Remap or otherwise integrate data from completed Federally-funded and industry-sponsored Alzheimer's clinical trials, including data from failed clinical trials
- Develop common data standards and measurements for questionnaires used to assess cognition and functional status.
- All Alzheimer's-related standardized data standards should promote interoperability between clinical research and healthcare information systems.

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Action 2C

- Develop a process by which research priorities would be set, including input from scientific experts

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Action 2D

- In order to address disparities, activities aimed at translation of research findings into medical practice and to the public should include specific targets for outreach to racial/ethnic and socioeconomic groups who have been shown to be at the greatest risk for developing AD

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Action 2E

- Develop metrics for assessing the effectiveness of therapies on the healthcare economy
  - Caregiver burden

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Strategy 3

- Explore the possibility of providing incentives to private industry to invest in disease-modifying interventions
- A panel of experts from private industry will be convened to help determine the nature of possible incentives that would accelerate discovery. They may include:
  - Tax reform/incentives to drive greater investment
  - Patent law reform to include pharma incentives
  - Enhanced market exclusivity

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Next Steps

- Conference calls & meetings
- Incorporation of feedback from research community and public comments

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