

ResearchersAgainstAlzheimer's

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

[Docket No. FDA-2013-D-0077]

Draft Guidance for Industry on Alzheimer's Disease: Developing Drugs for the Treatment of Early Stage Disease

ResearchersAgainstAlzheimer's supports adoption of FDA's "Draft Guidance for Industry on Alzheimer's Disease: Developing Drugs for the Treatment of Early Stage Disease".

ResearchersAgainstAlzheimer's is a network of 350 prominent researchers. We believe that it is possible to prevent and effectively treat Alzheimer's disease within our lifetimes, but only if our nation does what is necessary – this includes both increased funding for research and institutional reforms. We believe that this guidance is an important step to meet the national goal of finding an effective treatment for Alzheimer's disease by 2025.

ResearchersAgainstAlzheimer's agrees with the importance of diagnosis and treatments at much earlier stages of Alzheimer's disease. This draft guidance is based on the emerging understanding of Alzheimer's research that treatments aimed at people showing overt functional impairments due to dementia won't work because the damage to the brain may be too extensive at that point in the progression of the disease. Therefore, the appropriate response to this recently-developed understanding is, as noted in the well-considered draft guidance document of the FDA, to rely on a demonstration of a positive impact on cognitive decline along with evidence of the engagement of the underlying disease pathology.

ResearchersAgainstAlzheimer's strongly support the analysis of the draft FDA guidance.

If you have any questions, please contact Dave Morgan, Lead Representative of ResearchersAgainstAlzheimer's and CEO of the Byrd Alzheimer's Institute at the University of South Florida at dmorgan@ResearchersAgainstAlzheimers.org.