Rules must evolve to allow new drugs for early Alzheimer's

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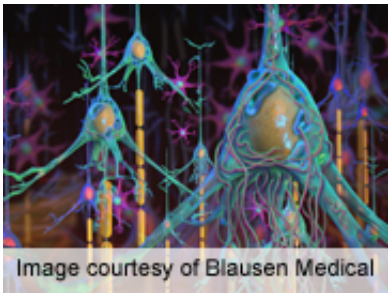

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(HealthDay)—Given the shift in the focus of drug development for Alzheimer's disease toward earlier disease stages, before the onset of dementia, regulatory guidelines need to evolve, according to a perspective piece published online March 13 in the *New England Journal of Medicine*.

Noting that in reviewing new-drug applications for the treatment of Alzheimer's disease, the U.S. Food and Drug Administration has maintained that improved cognition should be accompanied by evidence of improvement in function, Nicholas Kozauer, M.D., and Russell Katz, M.D., from the FDA in Silver Spring, Md., discuss the implications for drugs designed for use in the early stages of Alzheimer's disease.

According to the authors, drug development is increasingly shifting to earlier stages of Alzheimer's disease, before the onset of overt dementia. In recognition of this, the FDA has developed guidelines for conducting clinical trials for patients who do not present with dementia. The guidelines suggest use of a single scale that combines cognition and function. For patients with disease at an early clinical stage, before functional impairment, this might allow approval of a drug based on cognitive outcome alone. Accelerated approval of such drugs could be conditional on post-approval studies, which would verify the clinical benefit.

"As the focus of drug development has shifted to earlier stages of Alzheimer's disease, many new and challenging scientific questions have emerged, and the regulatory framework under which such therapies are evaluated should evolve accordingly," the authors write.

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