

## FDA approves first Alzheimer's drug in nearly 20 years — but some experts say there's not enough evidence it actually works

[On June 7, the FDA approved Alzheimer's drug aducanumab,] the first drug cleared that is designed to alter the course of the disease by slowing the deterioration of brain function — not just to ease symptoms. No Alzheimer's treatment has been approved since 2003, reflecting the extraordinarily high failure rate of drugs developed for the illness.

But in a nod to the controversy surrounding the drug, the FDA is directing the manufacturer, the biotech giant Biogen, to conduct a post-approval study confirming that the medication works. The requirement, part of a program called accelerated approval, is designed to allow for earlier approval of drugs that treat serious or life-threatening conditions and meet an unfilled medical need.

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Supporters of the medication have predicted that FDA approval would stimulate newfound interest and investment in researching therapies for the progressive, terminal illness. Biogen says the medication, by slowing the disease, gives patients valuable time to be with their families and to perform everyday tasks such as cleaning and shopping.

But critics have argued that data on the drug's effectiveness is weak and that FDA approval represents a dangerous lowering of standards in response to pressure from patients and advocacy groups.

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