

Controversial Alzheimer's drug approval sparks surprising impact

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When the U.S. Food and Drug Administration gave controversial accelerated approval to the first Alzheimer's drug in nearly 20 years, it had a surprising impact on attitudes about research into the disease. A

survey by University of California, Irvine neuroscientists has found news coverage of the FDA's decision made the public less willing to volunteer for Alzheimer's pharmaceutical trials.

The study was conducted by the UCI Institute for Memory Impairments and Neurological Disorders, known as UCI MIND. It appears in the *Journal of Alzheimer's Disease*.

The UCI team performed the survey in tandem with the FDA's spring 2021 consideration of aducanumab. The monoclonal antibody reduces [brain plaques](#), an Alzheimer's hallmark, in people with the condition. A panel of outside experts advised the FDA against approval, saying aducanumab's ability to decrease plaques hadn't shown an impact on the disease's clinical progression. The agency's controversial go-ahead and further disaccord over the [drug's](#) labeling and price captured widespread media attention.

The UCI MIND researchers conducted their study among people aged 50 to 79 who had expressed willingness to take part in drug research. Two weeks before the FDA's decision, UCI MIND asked respondents if they would be interested in enrolling in a hypothetical four-year study of a plaque-reducing monoclonal antibody and a plaque-preventing drug known as a BACE inhibitor. Eight days after the FDA gave aducanumab the [green light](#), UCI MIND sent survey participants a similar questionnaire with a new section about the monoclonal antibody and its approval.

"We found those who had heard about the FDA decision before our follow up became less willing to take part in a drug trial," said neurobiology & behavior graduate student Marina Ritchie, corresponding author of the paper. "The people who learned about it from our materials demonstrated absolutely no change in their willingness."

UCI MIND Director Joshua Grill added: "This is surprising, because it goes against some of our previous data showing people are generally more willing to take part in studies involving approved drugs compared to investigational ones. We believe it could be evidence of the powerful influence of [media coverage](#) of science."

The survey's findings may offer important insights for Alzheimer's disease researchers. "Alzheimer's is the most important medical condition society faces and we need an army of citizen volunteers to participate in drug trials," said Grill, a professor of neurobiology & behavior and psychiatry & human behavior. "Anything that diminishes credibility in [scientific research](#) impedes our progress. Media coverage has the potential to influence people's choices. That can hold us back or push us forward."

The findings also show researchers need to be aware of sample bias. It occurs when people with certain characteristics participate in a study at a higher rate than others without those traits or if some research population segments are not fairly represented.

"It's crucial for trial participants to reflect the scope of people affected by the disease," Ritchie said. "One thing we don't know is whether the impact of media attention may be more or less important for particular groups, especially groups underrepresented in research."

The UCI MIND team plans to conduct further research into the issue, with emphasis on learning how to better ensure diverse populations are part of Alzheimer's clinical trials. "We need to understand what barriers to trust may exist and overcome them so our research is inclusive and applicable to everyone," Grill said.

More information: Marina Ritchie et al, Effect of Aducanumab Approval on Willingness to Participate in Preclinical Alzheimer's

Disease Trials, *Journal of Alzheimer's Disease* (2022). [DOI: 10.3233/JAD-220801](https://doi.org/10.3233/JAD-220801)

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