



## **Alzheimer's drug approved amid controversy: 'Reasonable chance' of benefit, says doctor**

Elissa Salamy

June 11, 2021

This week the US Food and Drug Administration approved the first Alzheimer's drug in 20 years, Biogen's Aduhelm, amidst controversy.

"Aduhelm is an antibody that was developed by Biogen that attacks the amyloid plaque that has been found to accumulate in the brains of people who have Alzheimer's disease," said Dr. Jeffrey Singer to The National Desk's Jan Jeffcoat. "The only problem is that there's still a lot of controversy among researchers as to whether or not those plaques, actually, are responsible for the dementia or are a byproduct of some sort of other inflammatory process that's going on that's causing the dementia."

Three members from the FDA's advisory panel have resigned over the decision to approve Aduhelm. According to Dr. Singer, the FDA has an accelerated approval process for drugs that can make them more readily available to people who don't have time to wait.

"Even though this panel of experts reviewed all of the clinical data, and concluded that despite the fact that plaque is being diminished, they're not convinced that it's had any impact on dementia," said Dr. Singer. "Under the approval process, they said well we're going to go ahead and approve it anyway because we think there's a reasonable chance that this will have benefit, and that's what the controversy is about."

Prior to 1962, Dr. Singer says, the FDA was not required to prove the efficacy of a drug, just safety, and proper labels.

"That's added, on average, about 10 years on the approval process a lot of people suffer waiting while the drug could be available elsewhere," said Dr. Singer. "Why don't we just go back to letting clinicians rely on their experience and review of clinical research and make their own decisions, because it's delaying getting these drugs to the patients."