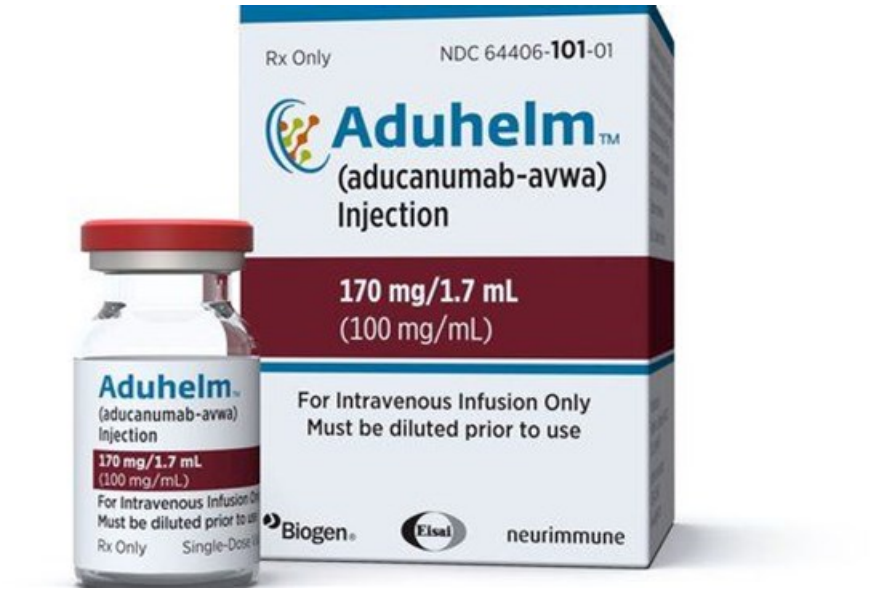
Questions raised on FDA's approval of Alzheimer's drug, Aduhelm

The controversial approval of a new Alzheimer's drug by the Food and Drug Administration (FDA) apparently revolves around the fact that US regulators believe it is the only one that could treat the underlying disease, rather than just managing symptoms.



Source: Twitter

The drug, known as Aduhelm (scientific name: aducanumab) has been developed by the Cambridge, Massachusetts based company Biogen together with Japanese company Eisai Co.

> *Today, FDA posted the Office of Neurology's summary reviewmemo which describes our extensive reviewof the Aduhelm (aducanumab) application and the basis for approval: https://t.co/QPh3zZJZ88 pic.twitter.com/863jhI7uYs— FDA Drug Information (@FDA_Drug_Info) June 22, 2021*

However, independent advisors to the FDA have warned that the treatment has not conclusively been shown to slow the progression of dementia. The drug does not reverse mental decline, and only one study seems to have indicated that it may slow it. The FDA is requiring that the drug-maker conduct further studies to confirm the benefit of the drug for patients. If it fails to prove effective, it could be pulled from the market.

The purpose of the drug is to clear harmful accumulations of a protein called beta-amyloid from the brain. This naturally-occurring protein appears to be abnormally high in the brains of Alzheimer's patients, causing it to clump together to form plaques that collect between neurons and disrupt cell function, which in turn leads to cell death. Initially, Alzheimer's disease tends to destroy neurons and their connections in parts of the brain used for memory. It later affects areas in the cerebral cortex responsible for language, reasoning, and social behaviour. In the long term, many other areas of the brain are damaged, leading to the patient losing their ability to function independently.

> *Opinion: The FDA's approval of Aduhelm raises more questions and creates more problems than a newdrug approval should. Here are six ways the approval does more harm than good.https://t.co/qkkoI2Y4cB— STAT (@statnews) June 19, 2021*

Price tag

Aduhelm comes with an eye-watering price tag of $56,000 a year, according to a report in *US Today*. In addition, experts say patients will need expensive tests to verify they have the underlying sticky clumps of protein the drug targets in the brains of Alzheimer's patients. Patients could see other bills from doctors, as well as from facilities that administer the drug via IV and imaging centres for MRIs to monitor common side effects such as brain swelling and bleeding, the report said.

Why approve a drug without proof of efficacy/

The FDA believes that the potential benefits outweigh the risks, because there is such a great unmet need for effective Alzheimer's treatments. According to *Alzheimer's News Today*, there are an estimated 44-million people worldwide living with Alzheimer's disease or a related form of dementia. Reports from America's National Institute on Aging indicate that one's chance of Alzheimer's doubles every five years after age 65. However, around one in 20 people with the disease are under 65. Early-onset Alzheimer's can affect people as young as 40. American statistics show that more than half of people over age 85 living in the USA suffer from dementia.

If these statistics do not seem alarming enough, consider that the [[https://alzheimersnewstoday.com/alzheimers-disease-statistics/ global cost of Alzheimer's disease and dementia is estimated to be $605bn, which is equivalent to one percent of the entire world's gross domestic product.