US congressional report slams FDA approval of Alzheimer's drug

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The US Food and Drug Administration's approval process for a

controversial drug used to treat Alzheimer's was "rife with irregularities," a congressional report said Thursday.

An 18-month investigation into the FDA's green-lighting of the drug, Aduhelm, also criticized its manufacturer, biotechnology company Biogen.

The Cambridge, Massachusetts-based Biogen set an "unjustifiably high price" for Aduhelm of $56,000 a year to "make history" with the first drug approved in decades to treat Alzheimer's, the report said.

Aduhelm received "accelerated approval" from the FDA in June despite the fact that an independent panel advising the US drug regulator had found insufficient evidence of its benefit and some experts had raised concerns about inconsistency in the drug's clinical data.

At least three of the 11-member independent committee that voted unanimously against recommending the drug to the FDA subsequently resigned.

According to the congressional investigators, the FDA "considered Aduhelm under the traditional approval pathway used for most drugs for nine months, before abruptly changing course and granting approval under the accelerated approval pathway after a three-week review period."

They found that FDA interactions with Biogen were "atypical" and included a failure to properly document contacts between agency staff and the drug maker.

The FDA and Biogen had also "inappropriately collaborated" on a joint briefing document for a key advisory committee.

"FDA's approval process was rife with irregularities," the report said.

As for Biogen, the report said the company "viewed Aduhelm as an unprecedented financial opportunity—estimating a potential peak revenue of $18 billion per year."

It quoted a September 2020 presentation to the Biogen board as saying: "Our ambition is to make history" and to "establish Aduhelm as one of the top pharmaceutical launches of all time."

'Wake-up call'

Carolyn Maloney, chairwoman of the House Oversight and Reform Committee, said she hoped the report's findings "are a wake-up call for FDA to reform its practices."

Frank Pallone, chairman of the House Energy and Commerce Committee, said the report "documents the atypical FDA review process and corporate greed that preceded FDA's controversial decision to grant accelerated approval to Aduhelm."

"While we all support the search for new cures and treatments to address devastating diseases like Alzheimer's, we must ensure that expediency does not take precedence over protocols," Pallone said. "Patient safety and drug efficacy must remain at the core of our nation's pharmaceutical regulatory review process."

In a statement, the FDA said it "remains committed to the integrity of our drug approval process, which includes ensuring that safe and effective new treatment options are available to the millions of people with Alzheimer's disease."

Biogen said it "stands by the integrity of the actions we have taken."

"Biogen has been committed to researching and developing treatments for Alzheimer's disease for more than a decade," the company said.

"We have been focused relentlessly on innovation to address this global health challenge, and have adapted to both successes and setbacks."