

House committees to investigate new Alzheimer's drug approval

July 1 2021



(Healthday)—The U.S. Food and Drug Administration's controversial

approval of a new Alzheimer's drug, along with its high price, is now being investigated by two House committees.

"We have serious concerns about the steep price of Biogen's new Alzheimer's [drug](#) Aduhelm and the process that led to its approval despite questions about the drug's clinical benefit," House Democrats Carolyn Maloney and Frank Pallone Jr. said in statement from the Committee on Oversight and Reform and the Committee on Energy and Commerce, *CNN* reported.

"We strongly support innovative treatments to help the millions of Americans who suffer from Alzheimer's [disease](#), but Aduhelm's approval and its \$56,000 annual price tag will have broader implications for seniors, providers and taxpayers that warrant close examination," the statement read.

Although an FDA advisory [committee](#) concluded there wasn't enough evidence to support the effectiveness of the Biogen drug Aduhelm (aducanumab), the agency went ahead and approved the drug earlier this month, *CNN* reported.

Three of the advisory committee members resigned after the FDA approved the drug. Dr. Aaron Kesselheim, a Harvard Medical School professor and Brigham and Women's Hospital physician, was one of them.

In his [resignation letter](#), he called it "the worst drug approval in US history."

On the *CBS* show "This Morning," Kesselheim said the drug has "important side effects," such as brain swelling and bleeding, headache, falls, diarrhea, confusion, delirium and disorientation, *CNN* reported.

Most of the reviewers at the FDA who assessed the company's submissions for aducanumab did recommend approval, *CNN* reported.

"Alzheimer's disease is a serious condition and aducanumab, unlike other approved therapies, is targeted at an underlying, fundamental and defining pathophysiological feature of the disease, with the potential to alter the inescapable and relentless progression of this disease," the reviewers said.

The drug is infused once every four weeks. The wholesale cost is about \$4,312 per infusion.

Aduhelm is designed to clear Alzheimer's-associated deposits of amyloid beta from the brain. Biogen claims that treatment in the early stages of the disease could help prevent it from getting worse.

"We will of course cooperate with any inquiry we may receive from these committees," the company told *CNN*.

More information: Visit the Alzheimer's Foundation for America for more on [Alzheimer's disease](#).

Copyright © 2021 [HealthDay](#). All rights reserved.

Citation: House committees to investigate new Alzheimer's drug approval (2021, July 1) retrieved 21 September 2024 from <https://medicalxpress.com/news/2021-07-house-committees-alzheimer-drug.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.