In an unprecedented move hoping to quell criticism, FDA releases documents detailing messy internal debate over Biogen's dementia drug Aduhelm

[A] series of documents [were released June 22] by the FDA to explain its decision to use a truncated pathway, called accelerated approval, to approve Aduhelm.

The document dump follows weeks of bracing criticism of the FDA, which departed from regulatory precedent to approve Biogen's treatment. Instead of judging Aduhelm based on its effect on the progression of Alzheimer's, for which the evidence is debatable, the agency approved the drug based on its ability to remove brain plaques called beta-amyloid, which are believed to contribute to the disease. One agency adviser, resigning from his committee post in protest, called it "probably the worst drug approval decision in recent U.S. history."

"We strongly disagree with that characterization of our decision," said Patrizia Cavazzoni, director of the FDA's drug division, in an interview with STAT on [June 22]. "We think the decision is on very solid ground, that we are on very solid ground when it comes to the data and the rationale for utilizing accelerated approval to greenlight this drug."

Exacerbating the controversy was Biogen's decision to set a $56,000-a-year list price for Aduhelm. More than 1 million Americans are likely eligible for the treatment, making Biogen's product a potential budget-buster for Medicare.

Read the original post