Why Is Everyone So Mad About Aduhelm?

By Simon Spichak, MSc | January 17th, 2022

It seems like, following the FDA's controversial July 2021 approval of Biogen's Alzheimer's drug Aduhelm, everyone is mad at someone. Here are the main reasons why.

Alzheimer's Association	Biogen	Food & Drug Administration	Centers for Medicare & Medicaid Services
• Helped assemble a 2018 consortium that led to a biomarker-based definition of Alzheimer's. This definition is controversial because most neurological diseases are still diagnosed through symptoms. • Lobbied the FDA to approve Aduhelm, even though the trials did not reliably show that the drug reduced cognitive impairment. • Called the CMS decision discriminatory against minorities because it limits access for marginalized groups. Critics say this feels contradictory, considering the organization lobbied for Aduhelm's approval despite that its clinical trials lacked racial diversity.	• Has not included a diverse population in Aduhelm clinical trials even though Hispanic and African American populations have higher Alzheimer's risk. Thus, the drug's effects in these populations is unclear. • Started Project Onyx to lobby the FDA for Aduhelm's approval despite ambiguous efficacy data. • Had back-channel meetings with the FDA that have triggered a congressional investigation. • Initially marketed Adulem at $56,000, much higher than the fair price estimated by an independent third party. • Slashed the price in half amid poor sales and rejections from regulators in Japan and Europe. • Internal strife at the company following Aduhelm's approval.	• Originally approved Aduhelm as a broad-label treatment even though it had only been tested in mild Alzheimer's. The FDA later walked back the broad-label. • Had back-channel meetings with Biogen that have triggered a congressional investigation. • Approved Aduhelm on an accelerated track despite a lack of consensus about beta-amyloid as an Alzheimer's biomarker. Biostatisticians and members of the FDA advisory panel objected; some even resigned. • Contradicted in its Aduhelm approval decision by subsequent rejections from European and Japanese regulators.	• Initially waffled about whether it would cover Aduhelm, leaving patients and families in limbo. • Increased the price of Medicare premiums for all subscribers, blaming Aduhelm costs, despite very low Aduhelm sales, all before announcing its decision to limit coverage. • Announced plans to only cover Aduhelm for people enrolled in a CMS-approved clinical trial of the drug's efficacy, despite that Biogen is already running such a trial. • Undermined the authority of the FDA in announcing its own make-or-break vetting process for Aduhelm and all other Alzheimer's monoclonal anti-amyloid therapies to follow.