Congressional report: U.S. FDA broke own protocols in approving Biogen Alzheimer’s drug

WASHINGTON, Dec 29 (Reuters) – The U.S. Food and Drug Administration failed to adhere to its own guidance and internal practices during the approval process for Biogen’s (BIIB.O) Alzheimer’s drug Aduhelm, which was “rife with irregularities,” a congressional report showed on Thursday.

The FDA’s interactions with Biogen were “atypical” and did not follow the agency’s documentation protocol, according to a staff report on the findings of an 18-month investigation conducted by two House of Representatives committees into the drug’s regulatory review, approval, pricing, and marketing.

The FDA approved Aduhelm in June 2021 under an accelerated approval pathway over the objections of its panel of outside advisers, who did not believe data definitively proved the drug’s benefit to patients.

It was authorized based on evidence that it could reduce brain plaques, a likely contributor to Alzheimer’s, rather than proof that it slowed progression of the lethal mind-wasting disease.

The Medicare program restricted its coverage, which has led to severely limited use of the Biogen drug.

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