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June 30, 2021

The Honorable Xavier Becerra
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington, D.C. 20201

RE: The FDA’s reckless decision to approve aducanumab for treating Alzheimer’s disease

Dear Secretary Becerra:

Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide, is writing in follow-up to its June 15 letter calling on you to immediately request the resignation or seek the removal of Acting Food and Drug Administration (FDA) Commissioner Janet Woodcock, Center for Drug Evaluation and Research (CDER) Director Patrizia Cavazzoni, and CDER’s Office of Neuroscience (ON) Director Billy Dunn because of the FDA’s indefensible decision to approve Biogen’s aducanumab (Aduhelm) for treatment of Alzheimer’s disease despite the lack of evidence that the drug provides any meaningful clinical benefit, plus the fact that the drug has a well-documented risk of potentially serious brain injury.

Stunning new disclosures in a detailed exposé published yesterday by STAT¹ appear to provide further evidence that starting more than two years ago, key staff in CDER’s ON who were responsible for the review of Biogen’s biologics license application (BLA) for aducanumab for treatment of Alzheimer’s disease engaged in an unprecedented and inappropriately close collaboration with the company in the analysis of data from the key clinical trials of the drug that dangerously compromised the independence and objectivity of the agency’s review and approval of the drug. Among the most troubling disclosures in the STAT article were the following:

- In early May 2019 — shortly after Biogen and its partner Eisai had announced the decisions to terminate the two pivotal phase 3 clinical trials testing aducanumab after a prespecified interim futility analysis and to end development of the drug — Biogen Chief Scientist Al Sandrock reached out to Dr. Dunn, with whom he “already had a longstanding professional relationship,” and sat down with him for an “off-the-books” meeting while the two were attending a neurology conference in Philadelphia. “Sandrock wanted to let Dunn know that Aduhelm — publicly declared ineffective — might actually be slowing the progression of Alzheimer’s... And wanted to know if Dunn would be open to helping find a way to get the drug approved.”

¹ Feuerstein A, Herper M, Garde D. Inside ‘Project Onyx’: How Biogen used an FDA back channel to win approval of its polarizing Alzheimer’s drug. June 29, 2021. STAT. <https://www.statnews.com/2021/06/29/biogen-fda-alzheimers-drug-approval-aduhelm-project-onyx/>. Accessed June 29, 2021.

- “It was clear that Billy Dunn was an ally, so the job for Biogen became figuring out how to support his efforts within the FDA,’ a former Biogen employee told STAT.”
- Following Sandrock’s meeting with Dunn, Biogen “mounted a secret campaign, code-named ‘Project Onyx,’ to resurrect the drug and convince the FDA to give it the green light. Central to their mission was an inside ally: Billy Dunn, the agency’s top regulator of Alzheimer’s drugs.”
- “The FDA’s support grew quickly. By June 2019, only a month after the crucial meeting with Dunn, agency officials in his Office of Neuroscience were so willing to advance Aduhelm that they proposed as one option a regulatory shortcut called ‘accelerated approval,’ according to meeting minutes read to STAT. The move stunned even Biogen’s top executives, who had considered that out of the question for a host of reasons, including the fact that the FDA had never used the [accelerated approval] pathway for an Alzheimer’s treatment.

“This disclosure contradicts what the FDA has said publicly in recent weeks about how it came to consider the use of accelerated approval for Aduhelm. An internal review document made public by the FDA last week claimed officials inside the agency first raised the possibility of an accelerated approval of Aduhelm during a meeting held this past March 31.”

- “To some inside Biogen, the FDA’s tone made approval seem inevitable.”
- “The signal of support provided by the FDA’s Dunn to Sandrock during their off-the-books meeting in early May 2019 triggered Project Onyx and the revival of Aduhelm. By mid-May, Biogen was sharing clinical data and other information with FDA officials.”
- “All of the investment that Biogen put into courting Dunn appeared to be paying off. Dunn’s Office of Neuroscience offered Biogen a road map to Aduhelm’s approval, suggesting five different scenarios or options for ways the drug could be reviewed by the agency to allow it to reach the market. Only one of those five options even contemplated Biogen having to conduct another clinical trial before approval. Three would result in the drug’s immediate approval.”
- “After the June 14, 2019, meeting [between Biogen and the FDA], Biogen and the FDA established a ‘working group collaboration’ consisting of company employees and agency review staff. The group met or communicated almost daily in June, July, and August of 2019, working to collect and analyze Aduhelm data for inclusion in the planned marketing submission. The group decided to pursue a standard FDA approval based on data on how patients had fared on cognitive surveys.”

- “I knew from the interest levels within FDA that the agency was always going to find a way to approve Aduhelm,” said a former Biogen employee with knowledge of its interactions with Dunn and other FDA officials during this time period.”

The circumstances described in the STAT exposé, if confirmed, provide overwhelming additional unequivocal evidence of the unprecedented and inappropriately close collaboration between the FDA and Biogen before the submission of the company's BLA for aducanumab for treatment of Alzheimer's disease. They also paint a damning picture of drug regulators who surrendered their independence and objectivity, essentially began working on behalf of Biogen, and fostered regulatory capture at the agency.

Moreover, the disclosures appear to reveal that Dr. Dunn deliberately misled members of the agency's Peripheral and Central Nervous System Drugs Advisory Committee at their November 6, 2020, meeting regarding aducanumab when he explicitly indicated that FDA was not considering approval of the drug based on a surrogate endpoint (i.e., reduction of amyloid-beta in the brain) under the agency's Accelerated Approval pathway.

Public Citizen therefore renews its previous call for you to immediately request the resignation or seek the removal of the three officials most responsible for the agency's aducanumab approval decision: Acting FDA Commissioner Janet Woodcock, CDER Director Patrizia Cavazzoni, and CDER's ON Director Billy Dunn. It is also imperative that you urge the Department of Health and Human Services' Office of Inspector General to immediately initiate a thorough investigation of the collaboration between the FDA and Biogen, including the circumstances detailed in the STAT article.

Thank you for your attention to these urgent public health issues.

Sincerely,



Michael A. Carome, M.D.
Director
Public Citizen's Health Research Group

cc: The Honorable Rachel Levine, Assistant Secretary for Health, HHS