



1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

June 30, 2021

The Honorable Christi A. Grimm
Principal Deputy Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue SW
Washington, DC 20201

RE: Follow-up Request for an Office of Inspector General investigation of the Food and Drug Administration’s inappropriate close collaboration with Biogen before and after the submission of the biologics license application for aducanumab for treatment of Alzheimer’s disease

Dear Principal Deputy Inspector General Grimm:

Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide, is writing in follow-up to its December 9, 2020, letter requesting that your office immediately launch a formal investigation to scrutinize the unprecedented and inappropriately close collaboration between the Food and Drug Administration (FDA) and Biogen that occurred before and after the submission of Biogen’s biologics license application (BLA) for the new biologic drug aducanumab for treatment of Alzheimer’s disease.

Stunning new disclosures in a detailed exposé published yesterday by STAT¹ appear to provide further evidence that starting more than two years ago, key FDA staff in the Center for Drug Evaluation and Research’s (CDER’s) Office of Neuroscience (ON) who were responsible for the review of Biogen’s 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 of aducanumab after a prespecified interim futility analysis and to end development of the drug — Biogen Chief Scientist, Al Sandrock, reached out to CDER’s ON Director, Dr. Billy 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

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.

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.”

- “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 FDA 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 your office to immediately investigate the collaboration between the FDA and Biogen, including the disturbing circumstances detailed in the STAT article.

Public Citizen hopes that you share our concern regarding this troubling matter, and we look forward to an appropriate, favorable response to our urgent request. Please contact me at 202-588-7781 if you have any questions or need additional information.

Sincerely,



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

cc: The Honorable Xavier Becerra, Secretary of Health and Human Services