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February 23, 2021

S. Andrew Josephson, M.D.
Editor, *JAMA Neurology*
Professor of Neurology and Chair of the Department of Neurology
505 Parnassus Ave, Box 0114
University of California, San Francisco
San Francisco, CA 94143

Sent via email to jamaneuro@jamanetwork.org

RE: Musiek ES, Morris JC. Possible Consequences of the Approval of a Disease-Modifying Therapy for Alzheimer Disease. *JAMA Neurol*. 2021 Feb 1;78(2):141-142.

Dear Dr. Josephson:

Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide, is writing to express its concern about the apparent lack of clarity regarding the financial conflicts of interest disclosed by one of the authors of the above-referenced Viewpoint article that was published in the February 2021 issue of *JAMA Neurology*.

The Viewpoint article opened with a generally positive assessment of the investigational drug aducanumab for treatment of Alzheimer's disease dementia, as reflected in the following excerpt:

> Biogen submitted an application to the US Food and Drug Administration (FDA) for approval of aducanumab for the treatment of Alzheimer disease (AD) dementia. Aducanumab, a monoclonal antibody targeting aggregated amyloid-β, showed in a phase 3 clinical trial (but apparently not in another phase 3 trial) success in clearing amyloid plaques from the brain and slowing the rate of cognitive decline in some patients with mild AD dementia. While the aducanumab clinical trial data are complicated and the path to approval far from clear, approval is certainly possible, and other promising antibodies (such as Biogen's BAN-2401 and Genentech's gantenerumab) are just steps behind. Thus, the long-awaited advent of disease-modifying therapy for AD may be soon upon us, representing a major advance in the battle against AD and a beacon of much needed hope for patients.

The conflict-of-interest disclosures at the end of the Viewpoint article noted the following regarding Dr. Eric Musiek's conflicts of interest:

> Dr Musiek reports grants from Eisai Pharmaceuticals, the National Institutes of Health, and Cure Alzheimer's Fund outside of this work and consulting for Eisai Pharmaceuticals.

What is not made clear to readers of this Viewpoint article is the potential significance of Dr. Musiek's stated conflicts of interest related to his receipt of grants from, and consulting for, Eisai Pharmaceuticals given the fact that since October 2017, Biogen and Eisai have collaborated on the development and commercialization of aducanumab globally.[1]

It is critically important that opinion pieces, like *JAMA Neurology*'s Viewpoint articles, provide adequate clarity regarding the conflicts of interest that may influence the opinions expressed by the authors. To weigh the opinions expressed in Dr. Musiek's Viewpoint article, it is essential for readers to know both Eisai's role in developing and commercializing aducanumab and whether the grant(s) that Dr. Musiek received from Eisai or his consulting for the company were related in any way to the development of aducanumab.

Public Citizen therefore urges you to consider publishing in *JAMA Neurology* a clarification of reporting of potential conflicts of interest regarding the above-referenced Viewpoint article.

More broadly, scientific journals, like those published by the JAMA Network, must ensure that their conflict-of-interest policies function properly.

Thank you for your consideration of these issues.

Sincerely,

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

cc: Erik S. Musiek, M.D., Ph.D., Department of Neurology, Washington University School of Medicine, St. Louis, Missouri
Howard Bauchner, M.D., Editor in Chief, *JAMA*

[1] Eisai U.S. Biogen and Eisai announce FDA's 3-month extension of review period for the biologics license application for aducanumab. January 29, 2021. https://eisai.mediaroom.com/pressreleases?item=122804. Accessed February 20, 2021.