

# **ALZHEIMER'S GERM QUEST**

**4301 Gulfshore Blvd., Suite 1404**

**Naples, FL 34103**

**ALZgerm.org**

RE: Aducanumab

February 15, 2021

Patrizia Cavazzoni, MD  
Director (Acting)  
Center for Drug Evaluation and Research

Peter Stein, MD  
Director, Office of New Drugs

Billy Dunn, MD Director (Acting)  
Office of Neuroscience  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Drs. Cavazzoni, Stein, and Dunn,

How much weight should FDA give recommendations from advocacy groups tainted by apparent financial conflict of interest?

I refer, of course, to the October 23, 2020 letter from the Alzheimer's Association and the January 19, 2021 one from UsAgainstAlzheimer's, both asking you to approve the proposed drug aducanumab, sponsored by Biogen and Esai.

Neither letter provided a scintilla of additional data, nor did either offer a re-analysis of existing results. The Alzheimer's Association merely said they believe the data submitted by the drug companies, but they have refused to reveal how their conclusion was reached, or by whom.

UsAgainstAlzheimer's letter recited yet again the well-known seriousness of Alzheimer's disease, which nobody doubts. They then offered the results of a survey they conducted, which they claim indicates the present drug candidate is desired by many citizens. However, on reading the actual survey questions, one sees there is no accurate description of drug side effects, nor length of treatment, nor accurate efficacy.

Given this artificially affirmative slant of the questionnaire, only a simpleton would not agree such a theoretical drug would be nice. But they fail to show the drug you are considering would have these wonderful attributes.

Most disturbing of all is that neither advocacy group revealed in its letter to you its cozy financial relation with Biogen and Esai, which certainly creates the potential for a conflict of interest. If there was nothing to be ashamed of, why not disclose that immediately in their letters to you?

For example, the Alzheimer's Association has received millions of dollars from these firms. And just recently, UsAgainstAlzheimer's at its 2020 Virtual Summit, lauded Biogen and Esai as "Premier Sponsors", a payment category they created higher than Gold and Platinum.

The hypocrisy of this behavior is seen when one reviews the strict requirements (See Addendum) the two leading Alzheimer's journals place upon scientists submitting research papers. In such submittal letters, potential conflicts of interest of even a few hundred dollars must be revealed. It is not acceptable to write, "Well, it's on my lab's website somewhere; research it yourself".

Because these advocacy groups are financially entangled with the drug firm seeking approval, there must be full disclosure of monies paid them by the sponsor for the past five years. Alzheimer's patients cannot afford a drug approval tainted by financial conflict of interest.

Thank you for your consideration.

Sincerely,

Leslie

Leslie C. Norins, MD, PhD, FIDSA (Emeritus)  
Founder and CEO  
[leslie.norins@ALZgerm.org](mailto:leslie.norins@ALZgerm.org)

Enclosure: Addendum

*Alzheimer's Germ Quest is an independent organization not affiliated with or endorsed by any other group. It is self-funded, and does not sell anything nor seek or accept outside donations or grants. Its only interest is the faster understanding and cure of Alzheimer's disease, whatever its cause.*

## ADDENDUM

Dr. Leslie Norins Letter of February 15, 2021 RE: Aducanumab

---

### Potential Conflicts of Interest Must Be Disclosed Upon Submission

The two leading journals for Alzheimer's research  
(Yellow highlighting added)

#### Alzheimer's and Dementia Journal of the Alzheimer's Association

<https://alz-journals.onlinelibrary.wiley.com/hub/journal/15525279/homepage/author-guidelines>

#### Declaration of interest

All authors must disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. Examples of potential competing interests include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. Authors must disclose any interests on the title page. If there are no interests to declare then please state this: 'Declarations of interest: none'. [color sic] This summary statement will be ultimately published if the article is accepted.

---

#### Journal of Alzheimer's Disease

<https://www.j-alz.com/financial>

#### Financial Disclosure

All affiliations or financial involvement (e.g., employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, royalties) with any organization or entity with a financial interest in, or in financial competition with, the subject matter or materials discussed in the manuscript must be completely disclosed in the letter of submission.

All financial and material support for the research and work must be clearly identified in the manuscript including listing of support specified in the letter of submission that might constitute or give the appearance of influencing the findings.

All authors will be expected to complete a disclosure statement upon acceptance of any manuscript. Items included in the disclosure statement include: consulting fees or paid advisory boards (for the past two years or the known future), equity ownership/stock options (publicly or privately traded firms, excluding mutual funds), lecture fees when speaking at the invitation of a commercial sponsor (for the past two years or the known future), employment by the commercial entity that sponsored the study, grant support from industry, patents and/or royalties, expert witness, and other activities performed for a commercial sponsor.###