

Alzheimer's and aducanumab: Unjust profits and false hopes

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The U.S. Food and Drug Administration's controversial decision to approve aducanumab for the treatment of Alzheimer's disease raises at least three major ethical issues that need to be addressed, states a new



article in the Hastings Center Report:

- Billions of dollars in Medicare resources (which is to say, taxpayer dollars) are at risk of being unjustly squandered.
- Physicians must choose between facilitating this unjust squandering and denying desperate patients and families access to this drug.
- Patients and families are having false hopes legitimated and encouraged when physicians prescribe aducanumab.

The drug's approval was contrary to the nearly unanimous judgment of an FDA advisory committee that there was little reliable evidence of significant benefit. And given the drug's \$56,000 annual price and the 3.1 million people who are candidates for the drug, the total cost to Medicare or a private insurer would be \$174 billion per year. An additional \$93 billion in health care costs would be needed to cover infusion costs and the brain scans needed to monitor the risk of drug side effects, which include brain swelling or small-vessel brain bleeds.

"If the drug reversed and cured Alzheimer's, it would make ethical and economic sense to fully fund access to it, in my view," writes Leonard Fleck, a professor in the Center for Bioethics and Social Justice at Michigan State University. "But it does not do that."

Fleck concludes with a proposal to minimize the <u>ethical issues</u> cited above and set an important precedent for similar drugs in the pipeline. Medicare should require Biogen, the manufacturer, to provide aducanumab at cost—between \$2,500 and \$5,000 per year—(plus a modest profit) while it conducts further research to establish whether the drug is safe and effective.

Fleck suggests that "this is the best nonideal resolution we can achieve, given competing pressures form intense patient demands and the need



for the just and prudent allocation of limited health care resources."

He adds, "Other pharmaceutical companies could expect the same crimped profits . . . if they could not prove decisively that their <u>drug</u> yielded substantial clinical benefits at a reasonable cost. This would be unforgettable tough love."

More information: Leonard M. Fleck, Alzheimer's and Aducanumab: Unjust Profits and False Hopes, *Hastings Center Report* (2021). DOI: 10.1002/hast.1264

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