Employers' Prescription for Affordable Drugs

The Honorable Nancy Pelosi
Speaker
U.S. House of Representatives
Washington, DC 20515

The Honorable Charles Schumer
Majority Leader
United States Senate
Washington, DC 20510

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
Washington, DC 20515

The Honorable Mitch McConnell
Minority Leader
United States Senate
Washington, DC 20510

June 21, 2021

Dear Speaker Pelosi and Leaders Schumer, McCarthy, and McConnell:

Earlier this month, the Food and Drug Administration (FDA) provided "accelerated approval" for the sale and distribution of Aducanumab (marketed as "Aduhelm"), a new drug to treat Alzheimer's disease. The approval of Aducanumab came despite the recommendations of FDA's own expert review panel, which concluded that the drug failed to show evidence that the drug is effective at slowing the progression of Alzheimer's. Following the approval, the drug's manufacturer, Biogen, announced that it will price Aducanumab at $56,000 per year. The approval of Aducanumab despite its questionable effectiveness, and its unjustifiable price, demonstrate the profound need for substantial reforms to how the United States approves and prices prescription drugs. **As representatives of the nation's employers who sponsor health insurance benefits, we are writing because the approval and astronomical price of Aduhelm is an urgent reminder of the need to move boldly to protect America's patients and health care purchasers by enacting comprehensive prescription drug pricing reform.**

Employers Prescription for Affordable Drugs (EmployersRx) is a coalition of national organizations representing employers and health care purchasers from across the country. EmployersRx works to mobilize large employers to drive down prescription drug costs by advocating for public policies based on increased competition, transparency and value. As a coalition focused on improving the value of prescription drugs through competition, we are deeply troubled by the approval of Aducanumab and its pricing for several reasons:

- Aducanumab drug was approved through the FDA's "accelerated approval" pathway despite having little-to-no evidence of clinical effectiveness and over the opposition of the FDA's own expert review panel. **This approval sets a dangerous new precedent for FDA's approval process.** After the approval of Aducanumab, we question how the FDA will treat future drugs which cannot reasonably demonstrate effectiveness. Further, if drug manufacturers know that the FDA will approve drugs with little-to-no value over current treatments, they will lose real incentives to develop truly innovative, lifesaving medications. We

fear the long-term consequence of this decision will be the proliferation of high-cost drugs with little clinical value.

- Second, as part of its approval, the FDA requested that Biogen perform a confirmatory trial to demonstrate effectiveness while the drug is already on the market. This confirmatory trial may last up to *nine years,* meaning **federal taxpayers and private purchasers will find themselves paying billions of dollars for a drug which has until 2030 to demonstrate that it even works.** Unlike other notoriously high-cost drugs like Sovaldi, which can cure Hepatitis C in many patients, Biogen claims only that Aducanumab may slow the progression of Alzheimer's meaning many patients will take it year-after-year.

- Third, as an injectable drug, Aducanumab will be administered in medical settings and reimbursed under Medicare Part B. **Medicare's flawed Part B payment policy provides a financial incentive to clinicians to prescribe higher cost therapeutic drugs.** Further, to safely prescribe and monitor a patient on Aducanumab, doctors will order more high-cost imaging and other tests, further driving up costs.

- Finally, unlike other industrialized countries, there is no mechanism for public payers to negotiate the price of new drugs entering the market, and no ability to mitigate the price of drugs based on their clinical effectiveness or value.

EmployersRx strongly supports market solutions to establish reasonable prices. **But where no market exists – as is the case for Aducanumab – we support allowing the federal government to enter into meaningful negotiations on the price of drugs on behalf of all payers.** Negotiated prices should align with clinical efficacy, consider the price of the drug in other industrialized countries, and protect true innovation. To ensure that these policies do not result in cost shifting to private payers, and to provide direct relief to families covered by private insurance, it is essential that any policies to directly manage drug prices extend to all payers, not just public programs.

The unprecedented approval and unjustified pricing of Aducanumab provides a cautionary tale of a broken system that is in profound need for reform. While there is little Congress can do to put the "genie back in the bottle" for Aducanumab's approval, policymakers can keep future drugs with little-to-no clinical value off the market and to ensure that the price of all future drugs take into account clinical efficacy and value. **We urge you to move boldly to protect America's patients and health care purchasers by enacting comprehensive prescription drug pricing reform.**

Sincerely,

American Benefits Council
The ERISA Industry Committee
HR Policy Association
National Alliance of Healthcare Purchaser Coalitions
Purchaser Business Group on Health
Silicon Valley Employers Forum