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COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

June 7, 2023

The Honorable Xavier Becerra Secretary U.S. Department of Health & Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201

Dear Secretary Becerra:

The United States pays, by far, the highest prices in the world for prescription drugs. This is not only a disaster for millions of ordinary Americans who cannot afford the medicine their doctors prescribe, but it is a disaster for the financial solvency of Medicare and for our national debt.

In that regard, I am writing to urge you to use the full extent of your authority to ensure that taxpayers and Medicare recipients are not forced to pay the outrageously high price being asked for the new Alzheimer's drug, Leqembi, if it receives full approval by the Food and Drug Administration (FDA).

Despite concerns among the scientific community about the clinical benefit of Leqembi, its manufacturers, Eisai and Biogen, plan to charge \$26,500 per year for this drug even though the Institute for Clinical and Economic Review, an independent non-profit organization, has estimated that this drug should be sold for as little as \$8,900 per year based on its effectiveness.

Alzheimer's is a horrible disease. We must do everything possible to find a cure for the millions of people who suffer from it. But we cannot allow pharmaceutical companies to bankrupt Medicare and our federal government in the process. If we are serious about reducing the national debt, we must substantially lower the price that Medicare pays for prescription drugs like Leqembi.

If just 10 percent of the 6.7 million older adults with Alzheimer's disease take Leqembi, the Kaiser Family Foundation has estimated that it would cost \$17.8 billion—or nearly *half* of what Medicare Part B spent on all drugs in 2021. And this is just for one drug. As you know, many of the new drugs coming onto the market are even more expensive. This is not sustainable.

Further, the introduction of Leqembi at this unconscionable price would be grossly unfair to seniors suffering from Alzheimer's disease who simply could not afford to pay the 20 percent copayment of more than \$5,000 a year for this drug. With a median income of about \$30,000 a year for seniors on Medicare the purchase of this one drug would amount to over one-sixth of their

limited income. That would clearly not just be unaffordable to many seniors it would be an absurd and unfair government policy.

This week, the FDA will convene an advisory committee meeting on Leqembi. As it considers whether to grant full approval of this drug, FDA has a special responsibility to restore the public trust after its inappropriate relationship with Biogen during the agency's review of a prior Alzheimer's drug, Aduhelm.

If the FDA does grant full approval of Leqembi, the United States Department of Health and Human Services (HHS) must protect patients and substantially reduce the price of Leqembi.

Under current law, Medicare has the responsibility to determine whether Leqembi is "reasonable and necessary" for the treatment of Alzheimer's. In my view, charging an outrageously high price for this drug is not reasonable. It will prevent seniors who need this drug from receiving treatment. It will undermine the finances of Medicare. And it will increase the premiums of over 60 million seniors who receive Medicare whether they need to take this drug or not.

If Biogen and Eisai refuse to lower the price of this drug, HHS has the authority (under 28 U.S.C. Section 1498) to break the patent monopoly on Leqembi. Further, HHS can direct the Center for Medicare and Medicaid Innovation to launch a new demonstration project that would limit payment for Leqembi to reflect the drug's actual benefit.

People with Alzheimer's disease deserve a drug that is safe, effective, and affordable.

Mr. Secretary: As you well know, a prescription drug is not effective if a patient who needs that drug cannot afford to take it.

As Chairman of the Senate Committee on Health, Education, Labor, and Pensions, I look forward to discussing this important issue with you as soon as possible. I, and other committee members, would like to know how Biogen and Eisai came up with a cost of \$26,500 and what the cost of this drug will mean to the finances of Medicare. I would also like your estimate as to how much Medicare premiums will go up for all seniors if Biogen and Eisai are allowed to charge \$26,500 for Leqembi, as well as how many seniors who need this drug would not be able to afford to pay a 20 percent co-payment for it.

Sincerely,

Bernard Sanders

Buf Sanders

Chair

U.S. Senate Committee on Health, Education, Labor, and Pensions