

Congress of the United States
Washington, DC 20515

April 4, 2017

President Donald J. Trump
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

Re: Use Existing Taxpayer Protection Rights Law to Lower Prescription Drug Prices Now

Dear President Trump,

We write regarding your oft-stated commitment to bring down pharmaceutical prices. You have said that the pharmaceutical industry is “getting away with murder” and called drug prices “astronomical.” We urge you to use your existing statutory authority to respond to soaring drug costs harming so many American families.

Currently, the federal government grants companies (including foreign companies) monopoly pricing power to overcharge American taxpayers for life-saving medications developed through taxpayer-financed research. The government prevents competitors from entering the market, thus removing any market forces that might keep drugs affordable. Your Administration already has legal authority to prevent pricing excesses by promoting competition, while protecting taxpayer investments and addressing the failures of government-approved monopolies. This health and taxpayer protection issue is one that the prior Administration declined to address.

When taxpayer-funded federal research results in a new drug patent, the National Institutes of Health (NIH) is permitted to require the patent holder to license the federally-funded intellectual property to third parties, under certain circumstances. This power, granted in 1980 through the Bayh-Dole Act, authorizes federal agencies that fund private research to retain certain rights in patented inventions.

Under 35 U.S.C. §203(a)(2), when “action is necessary to alleviate health and safety needs which are not being reasonably satisfied” or, as noted in 35 U.S.C. §201(f), when the benefits of the patented product are not “available to the public on reasonable terms,” the government can assert what are sometimes called “march-in rights,” but would be better described as “taxpayer protection rights.” By exercising these rights, the government can encourage competition and lower prices by allowing other manufacturers to produce and sell the taxpayer-funded drug. Unfortunately, NIH has never utilized this taxpayer protection law.

Drug manufacturers and patients need clarity. We urge you to direct NIH to issue public guidelines on the circumstances that will likely require it to invoke taxpayer protection rights. Reasonable and transparent guidelines would discourage drug price gouging and create a more competitive market for drugs developed using tax dollars. American taxpayers should be able to access publicly-funded medications on reasonable terms, instead of being burdened with unreasonable prices.

Last year, NIH also refused to hold a hearing on whether to exercise its statutory rights on Xtandi, a prostate cancer drug developed at the University of California, Los Angeles (UCLA) through taxpayer-supported research grants, but licensed to a Japanese company. As a result, Americans are still paying two to four times more than consumers in other high-income countries for a life-saving medication developed with our tax dollars—without even the benefit of a public hearing to determine why NIH refused to protect taxpayers.

We are confident that reasonable guidance can be developed to address price gouging with transparency and fairness. We want pharmaceutical manufacturers to have the certainty of clear guidelines that indicate when taxpayer protection rights would apply, so that they can perform in a constructive way that avoids ever necessitating use of this extraordinary remedy. Since companies that do not engage in price gouging would not be affected, innovation and industry partnerships with public research institutions would not be threatened.

With adequate guidance, pharmaceutical companies should make better-informed pricing decisions that reflect the value of the taxpayer investment. High prescription drug prices are not limited to one treatment or one disease. Rising prices are reflected in ballooning Medicare and Medicaid drug budgets, and hit consumers through rising premiums, greater cost-sharing, and the higher prevalence of high-deductible plans. With drug prices continuing to soar and Americans continuing to struggle to access life-saving medications, your quick use of this taxpayer protection law will provide significant help to American families.

We look forward to your prompt response on this strategy to promote competition, target bad actors, and protect taxpayer investments.

Sincerely,

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