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Klobuchar, McCain, Grassley Urge OMB Director Mulvaney to Use Existing Executive Authority to Bring Down Prescription Drug Costs

In a letter to Office of Management and Budget (OMB) Director Mulvaney, Klobuchar, McCain, and Grassley encourage executive or administrative action to reduce the ever-increasing financial burden of prescription drugs for millions of Americans

Klobuchar, McCain, and Grassley have worked together on bipartisan legislation that would address skyrocketing prescription drug prices, including bills to allow for personal importation of medications from Canada and bills that would deter pharmaceutical companies from blocking cheaper generic alternatives from entering the marketplace

WASHINGTON, D.C. – U.S. Senators Amy Klobuchar (D-MN), John McCain (R-AZ), and Chuck Grassley (R-IA) have urged Office of Management (OMB) Director Mick Mulvaney to use existing executive authority to bring down prescription drug costs, including by certifying importation of prescription drugs from Canada. According to media reports, Mulvaney said last week that he has been actively discussing potential executive or administrative solutions with the President to address rising prescription drug costs. Additionally, Health and Human Services Secretary Tom Price has been holding "listening sessions" to discuss possible solutions.

Klobuchar, McCain, and Grassley have also worked together on bipartisan legislation that would address skyrocketing drug prices, including bills to allow for personal importation of medications from Canada, where drug prices are, on average, half the cost they are in the United States, and bills that would deter pharmaceutical companies from blocking generic alternatives from entering the marketplace. In their letter, Klobuchar, McCain, and Grassley detail how the Administration could use executive or administrative action to reduce the ever-increasing financial burden of prescription drugs for millions of Americans.

"According to media reports, you said on Thursday that you have been actively discussing potential executive or administrative solutions with the President to address rising prescription drug costs. Similarly, Secretary Price has been holding 'listening sessions' to discuss possible solutions. We write to express our support for such efforts that could provide immediate relief to Americans," the senators wrote. **"Consistent with your comments last week, the Administration has an opportunity to use existing statutory authority to quickly restore competition to the market with the introduction of cheaper, imported alternatives."**

The senators continued, **"We urge you to seriously consider this existing statutory authority as well as explore other options for executive action. We also ask that you please provide your**

recommendations as to what additional authority you would require to protect American consumers. Of course, we would welcome your support of our legislation to bring down the costs of prescription drugs as well."

Klobuchar and McCain introduced the *Safe and Affordable Drugs from Canada Act* to require the Food and Drug Administration to establish a personal importation program that would allow individuals to import a 90-day supply of prescription drugs from an approved Canadian pharmacy. The bipartisan *Preserve Access to Affordable Generics Act* Klobuchar and Grassley introduced would crack down on anti-competitive "pay-for-delay" deals in which branded companies pay their generic competitors not to compete as part of a patent settlement. These pay-for-delay agreements delay consumer access to generic drugs, which can be as much as 90 percent cheaper than brand-name drugs. The legislation would help make sure consumers have access to the cost saving generics they need by stopping these anti-competitive pay-off agreements that keep more affordable generic equivalents off the market. In addition, Klobuchar and Grassley introduced the *Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act* with Senators Patrick Leahy (D-VT), Dianne Feinstein (D-CA), and Mike Lee (R-UT). The *CREATES Act* would combat anticompetitive practices used by some brand-name pharmaceutical and biologic companies to block or delay entry of lower-cost generic drugs in the marketplace.

The full text of the senators' letter is below.

Dear Director Mulvaney:

According to media reports, you said on Thursday that you have been actively discussing potential executive or administrative solutions with the President to address rising prescription drug costs. Similarly, Secretary Price has been holding "listening sessions" to discuss possible solutions. We write to express our support for such efforts that could provide immediate relief to Americans.

We have worked together on bipartisan legislation that would address skyrocketing drug prices, including bills to allow for personal importation of medications from Canada, where drug prices are, on average, half the cost they are in the United States, and bills that would deter pharmaceutical companies from blocking cheaper generic alternatives from entering the marketplace.

While we pursue these legislative options in Congress, we strongly encourage you to take executive or administrative action to reduce the ever-increasing financial burden of prescription drugs for millions of Americans. We have previously outlined ways that the Administration could implement such strategies in a targeted manner that satisfies rigorous safety standards.

Specifically, we wrote to Secretary Price in February urging him to utilize authority the Administration already has under law. Our letter highlighted that Congress enacted legislation in 2003 that would enable importation of less costly medications from abroad. Under this law, the Food and Drug Administration (FDA) can permit pharmacists and wholesale retailers to import prescription drugs from Canada. Additionally, the FDA can issue a waiver to allow individuals to import prescription drugs for personal use. However, this law stipulates that the provisions related to importation do not become effective until the Secretary of Health and Human Services certifies that the implementation of importation would pose no additional risk to the public's health and safety and would result in a significant reduction in the cost of covered products to the American consumer.

Consistent with your comments last week, the Administration has an opportunity to use existing statutory authority to quickly restore competition to the market with the introduction of cheaper, imported alternatives. Under the statute, the Secretary has the authority to issue the certification in a targeted manner to address the current market conditions in a way that readily meets safety standards. The policy can also be expressly limited so that it does not negatively affect innovator companies that invested in the development of the drug.

We urge you to work with Secretary Price to immediately begin considering certifying importation of prescription drugs from Canada in the following circumstances:

1. The drug is off patent or no longer marketed in the United States by the innovator company that initially developed the drug;
2. In cases where there are significant and unexplained increases in price;
3. No direct competitor drug is currently in the market and introduction of a competitor drug will benefit the prices paid by taxpayers and consumers; or
4. The drug is produced in another country by the name brad manufacturer that initially developed the drug or by a well-known generic manufacturer that commonly sells pharmaceutical products in the United States.

We urge you to seriously consider this existing statutory authority as well as explore other options for executive action. We also ask that you please provide your recommendations as to what additional authority you would require to protect American consumers. Of course, we would welcome your support of our legislation to bring down the costs of prescription drugs as well.

We look forward to your timely response to this request.

Sincerely,

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