

# United States Senate

WASHINGTON, DC 20510

February 14, 2017

The Honorable Tom Price  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Price:

Many of the drugs subjected to recent, drastic price increases are available in other countries for a fraction of the cost, and are often still produced by either the original brand manufacturer or a reputable generic manufacturer. A pattern has emerged in which the original manufacturer of a drug will sell the rights to market or manufacture a drug to a buyer in the U.S. while retaining the rights to the drug in other countries. The purchaser then has exclusive rights over the distribution, supply, and pricing. This pattern is true of many other drugs that have been targeted for dramatic price increases. As this trend continues, these increases are passed on to taxpayers in the form of higher spending for Medicare and Medicaid, or to employers and other insured Americans through higher insurance premiums.

As public concern over rising costs of prescription drugs continues, there is a need to reduce the financial burden that prescription drugs are placing on Americans. In 2003, in response to high drug costs, Congress enacted legislation that would enable importation of less costly medications from abroad. Specifically, under the Medicare Prescription Drug Improvement and Modernization Act of 2003, 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 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. Current circumstances present you with an opportunity to use existing statutory authority to quickly restore competition to the market with the introduction of cheaper, imported alternatives.

Understandably, certifying that importation will not pose additional risks to the public and will result in a significant cost reduction to Americans may be a difficult standard for the importation of all drugs from Canada.

However, 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.

The Secretary should consider immediately certifying importation of prescription drugs from Canada in the following circumstances:

1. The drug is off patent or no longer marketed in the U.S. by the innovator company that initially developed the drug;
2. 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 brand manufacturer that initially developed the drug or by a well-known generic manufacturer that commonly sells pharmaceutical products in the U.S.

Where these conditions are met, the Secretary should permit importation from Canada with a fast track approval process for the competitor. Fast track approval is key because regulatory costs can deter market competition. We urge you to carefully consider the recommendations outlined in this letter, which, if enacted, would provide immediate relief to millions of Americans struggling to afford the increasing cost of prescription drugs.

If you believe additional authority is required to address this situation more comprehensively, please provide your recommendations as to what additional authority related to importation you would require to protect American consumers.

We look forward to your timely response to this request.

Sincerely,



Chuck Grassley  
United States Senator



John McCain  
United States Senator



Amy Klobuchar  
United States Senator