United States Senate
WASHINGTON, DC 20510

November 20, 2015

The Honorable Sylvia Mathews Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Burwell:

A wave of recent news reports has highlighted a troubling trend of sudden, exponential price increases for prescription drugs. These price increases have been applied to prescription drugs that have been off patent for years or lack significant generic competition. For many important drugs, the market is small enough that, when combined with high regulatory costs to enter even the generic market, there is little incentive for competition.

Many of the drugs subjected to 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 price 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 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. 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 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 impact 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 United States 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 United States.

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 and delay deter market competition. If you were to take this action, several drugs cited in the media for rapid price increases could be addressed immediately. Since these drugs are manufactured by either the original brand manufacturer that gained approval for the drug in the U.S., or a well-known generic company, there is no reason to not grant expedited approval.

While current law provides you authority to address a number of abuses, existing law may be insufficient to address every case. 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. For example, importation could be expanded to include additional countries beyond Canada with similar regulatory regimes related to drug approvals. Given the priority that voters place on addressing the high cost of prescription drugs, we believe that it is time Congress and the Administration work together to take concrete steps to address pricing abuses.

We look forward to your timely response to this request.

Sincerely,

Chuck Grassley
United States Senator

John McCain
United States Senator