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Reimportation of Prescription Drugs

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Spending on prescription drugs in America has increased faster than any other category of health care expenditure. Yet in Canada and many other industrialized nations, prescription drug prices are either partly or entirely kept in line by government negotiation and policy – leading to significantly lower prices for consumers.

This price difference attracts many Americans to cross the border to Canada in search of life-saving, affordable prescription drugs. Canadian medications can cost 40 to 70 percent less than the same product in the United States.

Even though importing prescription drugs for personal use is generally illegal, about 2 million Americans buy drugs from Canada. The Food and Drug Administration has adopted a policy that people importing prescriptions for their own use will not be prosecuted as long as the drug is in small quantities, not a controlled substance, treats a serious health condition and is not available in the United States. Yet most of the reimported drugs are available here, which means the bulk of Americans who are trying to save money on their prescriptions through reimportation are breaking the law.

Drug companies argue that allowing reimportation threatens their ability to recover their research investment in new drugs. Yet recent studies have challenged that premise, showing drug companies invest relatively little in new drugs compared to the money spent on "me-too" drugs – those chemically similar to existing drugs with minor improvements such as a long-acting feature – and the marketing of these drugs as "new and improved."

Reimportation opponents also say the FDA cannot guarantee the safety of drugs brought in by individuals from other countries. Congress has twice passed reimportation legislation, but it cannot be implemented because it requires the FDA to "certify" that imports would not pose any additional health risks – facts that are simply impossible for the agency to confirm with certainty.

New, bi-partisan legislation is pending in Congress that would address safety concerns. The Pharmaceutical Market Access and Drug Safety Act (S. 2328), sponsored by Senators Dorgan and Snowe, would help ensure reimported drugs are safe by:

- Allowing in only drugs approved by the FDA and made in FDA-inspected plants.
- Requiring importers and resellers to provide full tracking of the drug, from point of manufacture to point of sale.
- Requiring Canadian exporters who sell to individuals to register with the FDA and post a bond they will lose if they send unsafe drugs.

- Requiring American wholesalers and pharmacists who reimport commercially to register with the FDA and be subject to criminal penalties if they import unsafe drugs.
- Requiring frequent FDA inspections of facilities, to be paid for by user fees on registered reimporters and Canadian exporters.

The bill would allow reimportation of prescription drugs from Canada within nine months of enactment, and from 19 major industrialized nations that have drug approval and distribution systems similar to ours within a year (the European Union countries and Australia, New Zealand, Japan and Switzerland).

Safety of prescription drugs is as critical to consumers as is price. This legislation will increase the FDA's authority to inspect for safety and ensure compliance, while decriminalizing efforts by Americans to access more affordable prescription drugs. The danger to consumers from drugs reimported from countries with similar systems as ours is minimal, and allowing in only those drugs from FDA-inspected facilities will increase consumer confidence.

While reimportation will provide some immediate financial relief to consumers, it is not the long-term solution to spiraling drug and Medicare costs. Congress must enact laws and policies that ensure Americans can purchase at home the safest and most affordable drugs available, eliminating the need to reimport medicines at all.