The Affordable and Safe Prescription Drug Importation Act

BACKGROUND:

Americans pay – by far – the highest prices in the world for prescription drugs. For three consecutive years, retail prescription drugs have experienced double-digit price increases in the U.S. well above inflation. Americans have seen the price of some drugs skyrocket by as much as 5,000 percent literally overnight.

In 2017, the U.S. spent about 40 percent more on prescriptions per person than Canada, twice as much as the average major industrialized country, and more than three times as much as Denmark. According to surveys by both the Commonwealth Fund and the Robert Wood Johnson Foundation, nearly 1 in 5 U.S. adults did not fill a prescription in the last year because they could not afford it, which can lead to unnecessary pain, suffering, and premature death.

In order to get the medicine they need, millions of people are buying their prescription drugs from other countries. According to the Kaiser Family Foundation, 8 percent of American adults – 19 million people – say they or someone in their household had imported a drug at some point to get a lower price.

Safety standards regulated by Health Canada and the European Union are as tough as FDA standards, according to a December 2016 bipartisan report from the Senate Special Committee on Aging: "While some countries' pharmaceutical manufacturing standards are lax, others, particularly in Canada and the European Union, are stringent and comparable to U.S. standards."

Canadian officials say U.S. drug prices are so high that they are skewing the cost of those medicines in Canada. Drug prices in Canada are informed by prices in seven other countries, including the United States. Canada's Minister of Health Jane Philpott recently said she wants to strike the U.S. from that list and replace it with a country like New Zealand, where drug prices are much lower.

Allowing the importation of safe and affordable prescription drugs is overwhelmingly supported by the American people. According to an April 2017 poll by the Kaiser Family Foundation, 72 percent favor allowing Americans to buy prescription drugs imported from Canada.

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SUMMARY OF LEGISLATION:

The Affordable and Safe Prescription Drug Importation Act would instruct the Secretary of Health and Human Services, within 180 days after enactment of this Act, to issue regulations allowing wholesalers, licensed U.S. pharmacies, and individuals to import qualifying prescription drugs manufactured at FDA-inspected facilities from licensed Canadian sellers. After two years, the Secretary would have the authority to permit importation from countries in the Organisation for Economic Co-operation and Development (OECD) that meet specified statutory or regulatory standards that are comparable to U.S. standards.

The bill would not permit importation of controlled substances, anesthetic drugs inhaled during surgery, or compounded drugs. Legally imported drugs under this Act must be purchased from an FDA-certified foreign seller and have the same active ingredient(s), route of administration, and strength as drugs approved in the U.S. Certain types of drugs, such as certain biologics, could only be imported by wholesalers or pharmacies.

In order to be a "certified foreign seller," the entity must be a wholesale distributor or licensed foreign pharmacy, be current with any applicable registration fees, and sell only qualifying prescription drugs. Certification criteria include that the establishment: (1) is located in Canada; (2) is engaged in the distribution of prescription drugs offered for importation under this bill; (3) has been in existence for at least five years and has a purpose for existing other than for this program; (4) if selling to an individual, does so only after receiving a valid prescription; (5) can certify that the physical premises and data reporting procedures and licenses are in compliance with all applicable laws and regulations in Canada, and has implemented policies to monitor compliance; (6) conducts ongoing and comprehensive quality assurance programs, including blind testing; (7) agrees that laboratories approved by the Secretary shall be used to test product samples; (8) agrees to notify the Secretary, importers, and individuals of product recalls; (9) has a process for resolving grievances and will be held accountable for violations of established rules; (10) does not sell products to customers in the United States that the seller could not otherwise legally sell in Canada; (11) meets any other criteria established by the Secretary. The bill would require recertification every two years or until there is a material change in circumstances.

Certified foreign sellers shall pay a fee, as determined by the Secretary, to fund the administration and enforcement of the program.

Additionally, the bill specifies that individuals importing a prescription drug under this Act shall do so only from pharmacies licensed to practice pharmacy and dispense drugs in Canada, shall purchase only for personal use in quantities that do not exceed a 90-day supply, and must have a valid prescription issued by a health care practitioner licensed to practice in the U.S.

Importers under this bill are required to submit biannual reports to the Secretary containing information on the drugs they are purchasing from certified foreign sellers, including the name, strength and dosage form, number of containers and container size, lot number, date of the transaction and shipment, business names and addresses of seller and purchaser, and the unique facility identifier where the drug was manufactured.

The bill grants the Secretary authority to approve one or more laboratories to conduct random testing of prescription drugs to assess their chemical authenticity.

The bill grants the Secretary authority to suspend the importation of a product or suspend all products from a certified foreign seller or importer if there is an importation involving counterfeit drugs, drugs that have been recalled or withdrawn, or drugs in violation of any requirement of this section until an investigation is completed and the Secretary determines that the drug, seller, or importer does not endanger the public health. The Secretary must suspend a product or all products from a seller or importer if there is a pattern of such violations.
Except in the case of a drug shortage, the bill prohibits drug manufacturers from directly or indirectly engaging in actions to restrict, prohibit, or delay the importation of qualifying drugs under this program.

Under this bill, persons selling adulterated or counterfeit products with the intent to defraud or mislead, with reckless disregard for safety of the public, or knowingly dispensing drugs without a valid prescription, shall face a penalty of not more than 10 years imprisonment or a fine of not more than $250,000.

The bill clarifies that nothing under this Act preempts or changes remedies available under state, federal, or common law for civil relief.

Certified foreign sellers may only purchase drugs intended for importation into the U.S. from FDA-registered manufacturers and entities or other certified foreign sellers, and shall provide to the importer information including the unique facility identifier associated with the manufacturer, the transaction history, transaction information (including the name of the product, the strength and dosage form, the container size, the number of containers, the lot number, the date of the transaction, the date of the shipment, and the business names and addresses of the entities selling and receiving the drug), and a statement that the certified foreign seller did not knowingly ship a suspect or illegitimate product, provide false transaction information or alter the transaction history of the drug. The Secretary shall seek to enter into a memorandum of understanding (MOU) or cooperative agreement with Canada or another permitted country to ensure compliance with Subchapter H of chapter V of the FDCA (track and trace); such MOU or cooperative agreement may supersede these requirements.

The Secretary of Health and Human Services shall issue a report to Congress and the public not later than one year after the date the rules are final. GAO shall also conduct a study within 18 months following the final rule to analyze the implementation of the Act, including a review of drug safety and cost-savings and expenses, including cost-savings to consumers in the United States and trans-shipment and importation tracing processes.