

PRESCRIPTION DRUG IMPORTATION: UNSAFE, UNNECESSARY AND UNWISE

by Merrill Matthews, Ph.D.

Vermont Senator Bernie Sanders has introduced S-934, an amendment to the Prescription Drug User Fee Act (PDUFA), which is up for reauthorization in 2017.

The stated purpose of the Sanders amendment is, "To allow the importation from Canada of safe and affordable drugs by wholesale distributors, pharmacies and individuals."

The problem with this amendment is that it assumes what is virtually impossible to guarantee: that imported drugs would be safe, much less effective.

CAN THE SECRETARY OF HHS VERIFY IMPORTED DRUGS' SAFETY?

The Sanders amendment lays out a list of things the secretary of the Department of Health and Human Services (HHS) is empowered to do to "certify" the safety of prescription drugs coming from Canada. That list includes ensuring that the foreign sellers' "physical premises and data reporting procedures and licenses are in compliance with all applicable laws and regulations of Canada and has implemented policies designed to monitor ongoing compliance with such laws and regulations."

In other words, the secretary of HHS is supposed to police and enforce Canadian law on Canadian pharmacies located in Canada.

Perhaps Sanders is unaware that federal law already gives the HHS secretary the power to approve the importation of prescription drugs from foreign sources—*as long as the secretary certifies that the imported drugs are safe.*

To date, no secretary, Republican or Democrat, has exercised that power. Indeed, several took a public stance against such actions. U.S. Food and Drug Administration (FDA) commissioners have been just as vocal—and critical. (See box)

Even former FBI Director Louis J. Freeh (1993-2001) has recently weighed in: "The largest Canadian online pharmacy and related entities were indicted for selling \$78 million

worth of unapproved and counterfeit medicines that ultimately were administered to cancer patients."

And he warns: "Candidly speaking, this move [legalizing importation] will vastly increase the incentive for criminal organizations to counterfeit drugs. The result would be that U.S. and international law enforcement would be overwhelmed as they lose a major tool in fighting the proliferation of counterfeit drugs."

Counterfeiting drugs is already big business, and it would be even bigger if the Sanders amendment passes.

Sanders assumes that the HHS secretary can ensure that drugs imported from Canadian pharmacies will be safe. But the senator has zero expertise in that area, and the people who do have the expertise have zero confidence in Sanders's assurances.

HHS SECRETARIES AND FDA COMMISSIONERS VOICE OPPOSITION TO DRUG IMPORTATION

- Sec. Donna Shalala (1993-2000) claimed, "flaws and loopholes make it impossible for me to demonstrate that it [importation] is safe and cost effective."
- Sec. Tommy Thompson (2001-5) observed, "It's impossible for us to certify that these drugs are safe."
- Commissioner Andrew C. von Eschenbach (2006-9) stated, "The product [drug] itself ... is often coming from places other than Canada that we have absolutely have no control or confidence in ..."
- Commissioner Margaret A. Hamburg (2009-15) added, "Many US consumers are being misled in the hopes of saving money by purchasing prescription drugs over the Internet from illegal pharmacies. Unfortunately, these drugs are often counterfeit, contaminated, unapproved products or contain an inconsistent amount of active ingredient."

UNDERMINING THE CANADIAN AND U.S. PRESCRIPTION DRUG MARKET

The Canadian government contracts with drug manufacturers to supply the country with the prescription drugs its citizens need. But Canada has one-tenth the U.S. population, so the quantities of drugs are very limited.

If Canadian pharmacies began exporting prescription drugs to the U.S. in large quantities, they would quickly run out of inventory and would have to buy more from foreign sources—undermining Sanders’s notion that the drugs would be from Canada.

In 2007, when an earlier importation push was winding down, Acting FDA Deputy Commissioner for Policy Randall W. Lutter testified before Congress: “An FDA operation in 2005, called ‘Bait and Switch,’ found that nearly half of the imported drugs that FDA intercepted from four selected countries (India, Israel, Costa Rica, and Vanuatu) were shipped to fill orders that consumers believed were placed with ‘Canadian’ pharmacies. Of the drugs being promoted as ‘Canadian,’ 85 percent appeared to come from 27 countries around the globe. Many of these drugs were not adequately labeled to help assure safe and effective use and some were found to be counterfeit.”

Canada has a safe pharmacy system, and patients going to a Canadian brick-and-mortar pharmacy—and their affiliated online systems—can trust that they are getting genuine, uncompromised products.

But legalizing importation doesn’t just create a threat to U.S. citizens, it threatens Canadians as well if Canadian pharmacies must replenish their limited supplies from foreign sources.

OTHER IMPORTATION SCHEMES FAILED

Speaking of failed importation schemes, in the mid-2000s seven states, including Sanders’s home state of Vermont, and two cities created or joined some type of importation program. They all abandoned the effort within a few years because of high costs and the lack of consumer interest.

THERE IS NO NEED FOR IMPORTATION

Importation proponents used to claim that too many Americans did not have access to prescription drug coverage and importation would meet their needs.

However, Congress passed the Medicare Prescription Drug Act in 2003, creating a taxpayer-subsidized prescription drug benefit for seniors.

In addition, the Affordable Care Act (ACA) provides those under age 65 with subsidized health insurance, including prescription drug coverage.

Between Medicare Part D and the ACA, millions of Americans have access to prescription drug coverage that did not have it in the past.

Ironically, legalizing importation could discourage people from accessing currently available prescription drug coverage options, thinking they could buy their needed prescription drug(s) from Canada, so why bother?

However, uninsured patients may discover the most expensive drugs weren’t available through Canada. Seniors who delayed signing on to Medicare’s drug coverage would have to pay a higher premium—the penalty for delaying

enrollment. Others would have to wait, perhaps nearly a year, before being able to obtain coverage during the ACA’s annual open enrollment period.

IMPORTATION IS FAKE TRADE, NOT FREE TRADE

Some proponents argue that importation is simply free trade, even though most importation proponents, especially Sanders, are longtime, vocal opponents of free trade.

The vast majority of Americans have prescription drug coverage, which means their out-of-pocket costs would almost certainly be lower when buying through legal, FDA-approved channels.

Thus the primary customers for Sanders’s imported drugs would likely be people seeking to bypass the normal process, looking to obtain restricted drugs, such as opioids, without a prescription.

The Centers for Disease Control estimates that in 2014 some 2 million Americans abused or were dependent on prescription opioids. If Sanders is successful in legalizing importation, they will be his primary beneficiaries.

Free trade negates barriers to competition, not health and safety regulations. Even free trade countries may impose restrictions on products—e.g., tainted meat—when serious problems arise. That is all the FDA is doing, as several HHS secretaries and FDA commissioners have explained.

CONCLUSION

The Sanders amendment creates economic incentives for even more bad actors to engage in smuggling counterfeit, diluted or compromised prescription drugs and selling them to Americans as the genuine article.

The FDA struggles now to meet its obligations to ensure the safety and efficacy of prescription drugs being manufactured and sold to Americans without having to become the guarantor of Canada’s pharmacies also.

Counterfeiting prescription drugs is already big business, and the Sanders amendment opens the door even wider, giving the criminals, organized crime and terrorists who are involved in counterfeiting drugs a legitimate opening to the U.S. market.

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