

DRUG IMPORTATION IS ABOUT POLITICS, NOT SAFETY

by Merrill Matthews, Ph.D.

After a 15-year hiatus, the effort to legalize, even encourage, the importation of prescription drugs has moved back to the public policy front-burner—with bipartisan support.

President Donald Trump, Health and Human Services Secretary Alex Azar, numerous politicians at all levels, and mostly left-leaning advocacy groups are backing the change.

But importing prescription drugs from Canada or other countries is no safer today than it was more than a decade ago when several states created illegal importation schemes—virtually all of which eventually shut down due to lack of interest.

FLORIDA TAKES THE LEAP

Nonetheless, the state of Florida recently took the leap by creating a state importation plan.

Governor Ron DeSantis, with zero prescription drug-handling experience, assured Floridians that prescription drugs imported from Canada would be safe, effective and, most importantly from a political standpoint, cheaper.

A TRAGIC EXAMPLE

Betty Hunter of Arizona would likely disagree with DeSantis and other importation advocates—if she were still alive.

She died in 2011 because her doctor gave her a fake prescription drug imported from Canada.

Hunter's family told Arizona's ABC 15: "They [the U.S. Food and Drug Administration] came out and told us that the oncologist had purchased counterfeit drugs and administered them to our mom."

Hunter had lung cancer and was supposed to be receiving Avastin, a biologic administered by infusion. Instead, the FDA said Hunter's oncologist gave her "a mix of mold and water."

FDA investigators determined the provider, CanadaDrugs.com, sold fake drugs to Hunter and others. After reaching a plea deal with the FDA, CanadaDrugs.com shut down last year.

The oncologist was never charged, but the family thinks as a medical professional she should have known better. So should politicians, but apparently many don't.

DEATH FROM GOOD INTENTIONS

To be sure, DeSantis had a worthy goal: to increase Floridians' access to affordable prescription drugs.

Back in the mid-2000s, seven states and two cities tried a similar approach by creating or joining some type of importation program, often by setting up websites linked to alleged Canadian pharmacies. They abandoned that effort within a few years because of high costs and the lack of consumer interest—especially after Medicare's prescription drug program (Part D) went into effect in 2006.

Some local governments continue helping their employees buy from Canada, Great Britain and Australia. And both Vermont and Colorado have passed importation legislation and are awaiting HHS approval. At least 10 states reportedly are considering similar legislation. Without HHS approval, such state programs would be illegal. But whether legal or not, they would still be unsafe.

THE FDA'S ROLE IN ENSURING DRUG SAFETY

The FDA regulates all U.S. prescription drug approvals, manufacturing and sales. No drug shipped into the U.S. is legal apart from an FDA-approved "chain of custody," which includes FDA-approved facilities in other countries. Drugs imported from Canada or other countries bypass those channels and are thus illegal.

But there's a caveat to current law: Drugs can be imported if the Secretary of HHS certifies that they would impose "no additional risk" to patients. Not Donna Shalala under

President Bill Clinton, nor Tommy Thompson or Mike Leavitt under President George W. Bush, nor Kathleen Sebelius or Sylvia Burrell under President Barack Obama were willing to make that guarantee. Nor has any FDA commissioner.

WHAT ABOUT TRAVELING TO CANADA?

While it is illegal to bring any prescription drugs into the U.S., government officials generally overlook it when people living in the U.S. travel to Canada—or Mexico—to buy a small amount of prescription drugs for personal use.

Buying from a brick-and-mortar pharmacy in Canada is very safe. Buying from an online pharmacy that claims to be located in Canada is a different matter—Hunter’s fake drugs came from CanadaDrugs.com.

FAKE VS. COMPROMISED DRUGS

Hunter received a fake drug, but compromised drugs are also a threat. Those are drugs that have been mishandled—e.g., not refrigerated as needed, possibly diluted or have already expired.

Avastin is a biologic and needs refrigeration. Improper refrigeration could compromise the drug, reducing or eliminating its effectiveness. Compromised and mishandled drugs can be as deadly as fake ones. Apart from that chain of custody, no one can guarantee a drug has been properly handled.

CAN GOVERNMENT GUARANTEE A DRUG IS FROM CANADA?

Florida’s importation scheme requires drugs to come from Canada. However, the Canadian government contracts with drug manufacturers to supply the country with the prescription drugs its citizens need. Since Canada has one-tenth the U.S. population, 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. And that opens a door to fake and compromised drugs entering both Canada and the U.S.

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.”

Importation strains Canadian supplies, as the Canadian government is now acknowledging, and has led Canadian officials to oppose U.S. importation schemes.

CAN STATES GUARANTEE WHAT THE FDA CAN’T?

While states can claim they will monitor the Canadian suppliers, states cannot do what the FDA, with staff, funding and expertise says it cannot do: ensure the safety of imported drugs. Neither the FDA nor state law can force Canadian internet pharmacies to do anything.

And yet state programs, even limited ones, reinforce the general impression among the public that importation is safe.

THE NEW TRACK-AND-TRACE SYSTEM

Past importation schemes led to the U.S. being overrun with diverted drugs—i.e., drugs destined for another country but ending up in the U.S. In response, Congress passed, and President Obama signed, the Drug Quality and Security Act of 2013 to identify and trace prescription drugs in the U.S.

This process, which is currently being implemented, establishes unique identifiers for every legal prescription in the U.S. Imported drugs will bypass this system thus making them impossible to trace, and it often leaves their vendors unaccountable when things go wrong.

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Democrats have made importing prescription drugs a key campaign promise. Sen. Bernie Sanders says on his first day as president he would sign an executive order allowing importation. But don’t expect Democrats to take the blame if and when patients are harmed or die because of importation—any more than they have been willing to take the blame for Obamacare’s numerous problems.

The Trump administration also wants to open the door to importation, though it plans to move slowly, beginning with demonstration projects. But these too are ill-advised.

CONCLUSION

Counterfeiting drugs is already big business, and it would be even bigger if importation proponents get their way, leading to many more Betty Hunter stories than there already are.

Importation proponents used to say “show us the bodies” of people harmed by importation. Sadly, today we can.

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