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Comment from Peter Pitts

This is a Comment on the **Food and Drug Administration (FDA)**
Proposed Rule: **Importation of Prescription Drugs**

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Comment

My name is Peter J. Pitts. I am a former FDA Associate Commissioner and now serve as President of the Center for Medicine in the Public Interest (www.cmpi.org). I have worked on the issue of drug importation for many years. It is an unsafe and unwise policy that will not lower drug costs for the citizens of the United States, but which will raise the risk of adverse medical events - which will raise the cost of healthcare in your state. Let's look at the record.

The on-the-ground reality of state and local importation schemes have been dismal and politically embarrassing. Remember Illinois' high profile "I-Save-RX" program? Over 19 months of operation, a grand total of 3,689 Illinois residents used the program which equals approximately .02 percent of the population. Program Status: Withdrawn.

And what of Minnesota's RxConnect? According to statistics, Minnesota RxConnect filled about 138 prescriptions a month. That's for the whole state. Minnesota population: 5,167,101. Program Status: Withdrawn.

Remember Springfield, Massachusetts and "the New Boston Tea Party?" Well the city of Springfield has been out of the "drugs from Canada business" since August 2006.

And, speaking of tea parties, according to a story in the Boston Globe, "Four years after Mayor Thomas M. Menino bucked federal regulators and made Boston the biggest city in the nation to offer low-cost Canadian prescription drugs to employees and retirees, the program has fizzled, never having attracted more than a few dozen participants."

The Canadian supplier for the program, Winnipeg-based Total Care Pharmacy, sent a letter to city officials saying the firm was terminating its agreement because there were so few participants. In 2006, Boston saved \$4,300 on a total of 73 prescriptions. When Total Care decided to end its relationship with the city, only 16 Boston retirees were still participating.

And such programs won't do any better on a national basis. A study by the non-partisan federal Congressional Budget Office showed that importation would reduce our nation's spending on prescription

medicines a whopping 0.1 percent and that's not including the tens of millions of dollars the FDA would need to oversee drug safety for the dozen or so nations generally mentioned in foreign drug importation schemes.

There's a good reason such programs weren't successful. For starters, Canadian drugs aren't as cheap as they're chalked up to be. Importation advocates have long exaggerated the disparity between Canadian and American drug prices. They often point to a handful of specialty drugs that cost more in America. In reality, most generic medicines (which account for roughly 80 percent of prescriptions filled in the United States) cost the same or less in the United States than they do in Canada.

The FDA can't regulate Canadian pharmacies. During a weeklong anti-counterfeiting operation last year, Canadian officials inspected nearly 3,600 packages and found that 87 percent contained counterfeit or unlicensed health products. A striking number of "Canadian" drugs aren't actually from Canada. Canadian internet pharmacies regularly import drugs from less developed and less regulated countries, like Turkey. Then they slap on their own labels and ship them elsewhere.

One FDA operation found 85 percent of "Canadian" drugs originated in 27 different countries. And more than a third of those drugs were potentially counterfeit. There is an important difference between coming into the United States from Canada and those prescription medicines that are legal for sale in Canada. "Drugs from Canada" do not always mean they are "the same medicines Canadians get."

Such concerns explain why Illinois ditched its importation program, I-SaveRX, in 2009 after failing to adequately inspect foreign pharmacies. According to a state audit, "40 percent of the required inspections of the foreign entities claiming to be pharmacies were never completed, putting patients at risk" and patients were left with "no regulator to protect them."

Canadian regulators have warned Americans that importation could be risky. One official at Health Canada, which oversees that nation's pharmaceutical supply, said the regulator "does not assure that products being sold to U.S. citizens are safe, effective and of high quality and does not intend to do so in the future."

Senior U.S. officials have issued similar warnings. Over the past 18 years, in both Democrat and Republican administrations, every FDA commissioner and secretary of Health and Human Services has failed to certify that importation is safe.

If a drug importation passes, drug costs will not decline and more counterfeit drugs could find their way into the medicine chests of the citizens of the United States. Please think twice before putting the health of Americans in jeopardy.

Sincerely,
Peter J. Pitts
President
Center for Medicine in the Public Interest