



May 9, 2017

Dear Senator,

The Partnership for Safe Medicines has dutifully studied the problem of counterfeit drugs in America for over a decade. We have examined court transcripts of prosecutions of counterfeiters, watched scientists test counterfeits in their labs that looked like the real thing and wept with families who have lost siblings, parents, and children to counterfeit drugs.

Our work has taught us that whenever you break the closed, secure drug supply chain, such as every importation proposal does, American patients are endangered. Earlier this year, we joined a coalition of nearly 170 healthcare groups around the country to speak up about the dangers of importing unregulated medicine from foreign countries. That letter is attached.

Here are some of the reasons these proposals are unwise:

Unregulated foreign entities cannot be trusted to comply with U.S. law: Four former heads of the very agency entrusted with securing our drug supply, the U.S. Food and Drug Administration (FDA), wrote an unprecedented letter explaining the reality that “Americans who currently use the internet to purchase drugs from outside the U.S. are likely receiving medicines that are either of substandard quality, adulterated, or fake.” They explicitly addressed the impossible task of securing such a scheme stating that “none of us, acting in our roles as former FDA Commissioners, were able to conclude that a wider policy of routine importation would increase access to safe and effective drugs for the American public.”¹

Undermines Congress’ Track and Trace law: In 2013, Congress passed the Drug Supply Chain Security Act and set in motion framework to protect American patients. In a recent letter, healthcare and track and trace expert Allan Coukell from the Pew Charitable Trust wrote, “This poses a safety risk with respect to imported product, but also undermines the entire system, which depends on being able to flag non-compliant product as being potentially counterfeit or otherwise illegal.”²

Worsens the fentanyl crisis currently killing Americans: Alongside the current opioid crisis killing Americans, there is a lesser known plague of counterfeits made with fentanyl. Unsuspecting Americans are dying after taking a single, counterfeit pill made with fentanyl.

¹ <http://www.safemedicines.org/2017/03/former-fda-commissioners-warn-about-drug-importation.html>

² <http://www.safemedicines.org/2017/03/pew-trust-warns-senator-sanders-that-drug-import-bill-could-compromise-the-safety-of-the-u-s-drug-supply.html>

Former law enforcement officer Charlie Cichon recently wrote in an editorial that “counterfeit and illegal medicines already kill Americans by the hundreds each year. Existing penalties are not enough to stop them, and that's even before we open the door to importation. The existing problem of counterfeits laced with substances like fentanyl (a powerful and widely abused synthetic opioid) could be scaled up one hundred-fold if we let down our guard.”³

Opens the U.S. to the global criminal counterfeit industry: In just the last five years, federal investigators have brought four different rings of counterfeit criminals to justice. Counterfeiters sold fake cancer medications, osteoporosis medications, and many others. Seized documents show that the criminal rings were doing business with over 2,000 U.S. doctors and medical clinics.

Based upon erroneous belief that all drugs are cheaper in Canada: Proponents of importation frequently claim that most medication is cheaper in Canada. But our researchers have looked up several of the top 50 medications prescribed in the U.S. and found that several of them are cheaper in the US⁴⁵. The U.S. Food and Drug Administration has looked at some of the top selling medications in America and found this on a broader scale⁶. On top of that, Consumer Reports repeatedly finds a large disparity in medicine prices in different U.S. pharmacies, finding medication price differences of 1000% between retailers in the same zip code.⁷

Opposed by patients and regulators in Canada: Not surprisingly, the people least excited about Americans importing drugs from Canada are Canadians themselves. The only researcher to study this, PSM Board President Dr. Marv Shepherd, estimated that the Canadian drug supply would be depleted within a year if just 10% of Americans ordered their medications from Canada⁸. A broad coalition of Canadian patient groups have said they are adamantly opposed to American proposals to buy Canadian medicines⁹, and several of Canada’s regulators have stated they are opposed to the practice.^{10,11}

³ <http://www.washingtonexaminer.com/importing-drugs-from-canada-is-a-dangerous-game/article/2620047>

⁴ <http://www.safemedicines.org/2017/05/safe-savings-tip-atorvastatin.html>

⁵ <http://www.safemedicines.org/2017/03/you-can-lower-your-cholesterol-and-healthcare-cost-with-generic-crestor.html>

⁶ <https://www.fda.gov/Drugs/ResourcesForYou/ucm134441.htm>

⁷ <http://www.consumerreports.org/drugs/6-tips-for-finding-the-best-prescription-drug-prices/>

⁸ <http://www.safemedicines.org/wp-content/uploads/Shepherd-US-pharmaceutical-drug-importation-2010.pdf>

⁹ <http://www.safemedicines.org/2016/03/exportation-of-pharmaceuticals-from-canada-to-the-united-states.html>

¹⁰ <http://www.safemedicines.org/2017/04/canadian-pharmacy-board-of-newfoundland-labrador-opposes-potential-u-s-drug-importation-legislation.html>



In closing, whether offered broadly or for a narrow set of medications, there's never a good time to sacrifice safety. No patient is served well by a drug from an unknown source, stored under unknown conditions, and which contains unknown ingredients because it passed through unlicensed, foreign middlemen who operate beyond U.S. law.

As the four former FDA Commissioners stated so well, we urge Congress “not to place false hope in measures that will place patients who need treatment at risk and jeopardize public health.”

With very best regards,

The Board of the Partnership for Safe Medicines

Marv Shepherd, Ph.D.
President, Partnership for Safe Medicines, Professor Emeritus
College of Pharmacy, University of Texas-Austin

Samuel J. Louis, JD
Vice President, Partnership for Safe Medicines
Partner Strasburger & Price
Former Deputy Criminal Chief of the Program Fraud Group, Department of Justice

Kenneth L. McCall, Pharm.D
Associate Professor and Residency Director
University of New England College of Pharmacy

Kimberly New, JD, BSN
Principal Consultant, Diversion Specialists
International Health Facility Diversion Association Executive Board Member

Robert John West
Former Special Agent in Charge,
U.S. Food and Drug Administration Office of Criminal Investigation

Susan Winckler, JD
Managing Partner Leavitt Partners
Former Chief of Staff for the U.S. Food and Drug Administration

¹¹ <http://www.safemedicines.org/2017/04/canadian-pharmacists-oppose-drug-importation-bill-in-congress-suggest-looking-at-long-term-reforms.html>