

March 17, 2017

Dear Member of Congress:

As the regulatory authority in Kentucky tasked with overseeing the public's access to safe prescription medications, I write today to share the Kentucky Board of Pharmacy's concern with proposed federal legislation that would allow the distribution of non-United States Food and Drug Administration (FDA)-approved medicines to patients in the US. As explained below, importation of foreign medicines puts patient safety at risk, as there is no way for US federal and state authorities to ensure the safety and efficacy of those products.

The Kentucky Board of Pharmacy is the authority that protects the public health in Kentucky by regulating the pharmaceutical supply chain through the licensure of pharmacists, pharmacies, drug wholesalers, and other parties handling prescription medicines. The Kentucky Board of Pharmacy also investigates complaints dealing with controlled substance thefts and abuse; dispensing adulterated, counterfeit, and unapproved drugs; misfilled prescriptions; and other violations.

It is our understanding that Congress is contemplating legislation that would amend the US Food, Drug, and Cosmetic Act to allow US consumers to buy Health Canada-approved medicines through authorized wholesalers and Canadian online pharmacies that have been determined to be safe. As the state regulatory authority responsible for protecting your constituents, we urge you to oppose this legislation for the following reasons:

1. **Proposals allowing importation undermine nearly two decades of drug safety policy.** No Department of Health & Human Services (HHS) or FDA official in recent times has been willing to certify that drug importation would pose no significant risk to the public health or that any potential cost savings would outweigh the resources that would be required to ensure the safety and efficacy of any imported products.
2. **Even if *claiming* to be from Canada, there is no way for us to be sure the medicines sold to US patients from foreign sources will be safe and effective.** Canadian law does not prohibit the transshipment of drugs from any country – including from countries with low manufacturing standards – into Canada and then on to the US. In fact, Canadian law explicitly states that the Canadian equivalent to FDA does not have to inspect drugs for export.
3. **In our experience, US consumers buying medications from Canadian online pharmacies rarely, if ever, receive the Health Canada-approved products afforded to Canadian customers.** Instead, these Canadian pharmacy websites sell US patients medicines manufactured in places where they would not even drink the water, eg, India, Turkey, or Southeast Asia. Too often, we take for granted that the medicines in the US are safe and effective, but the same is not true in most parts of the world. Outside the closed and tightly regulated drug supply chain, the safeguards put in place to ensure the identity, efficacy, and safety of prescription medications no longer apply. **Sending consumers online to look for Health Canada-approved medicines is reckless, as US patients are likely to receive unapproved, substandard, and counterfeit drugs from unknown foreign sources, posing a serious risk to patient safety.**
4. **Even if the law required consumers to only buy from HHS-certified Canadian pharmacy websites, the reality is:**
 - **Lists of certified online pharmacies do not work.** We have tried for nearly two decades to direct consumers to the National Association of Boards of Pharmacy® Verified Internet Pharmacy Practice Sites® list with minimal success. Consumers either do not learn or do not remember how to find the safe online pharmacy list, or do not care to try, preferring to do a quick search instead.

- Your constituents will do a search for “Canada medicine online” and find **tens of thousands of sites that look legitimate but do not actually provide Health Canada-approved medicines to US consumers**. The nature of the internet makes this bait and switch so easy to do and is basically invisible to regulators and law enforcement. Please see the attached infographic that visualizes what actually happens to constituents in our state.
5. **Passing a law that encourages US consumers to find a safe Canadian online pharmacy will lead to a proliferation of fake Canadian pharmacy sites, exacerbating the patient safety threat.** Already there are roughly 35,000 active online drug sellers, 96% of which are operating illegally, and 600 new fake pharmacy sites are launched each month. Fake pharmacy sites are easy to set up and highly profitable, and there is a very low risk of being caught or prosecuted.
 6. **Encouraging consumers to buy medicine from foreign online pharmacies enables prescription drug abuse.** In violation of US law, already there are more than 3,400 online pharmacies that sell controlled substances to US patients, typically without a prescription. Further, foreign online sellers do not connect to state-based prescription drug monitoring programs. During this time of a national prescription drug abuse epidemic, it is both irresponsible and inconsistent with previous recent Congressional actions to pass laws that bypass existing, proven-effective systems for reducing prescription drug abuse.
 7. **Proscriptive statutes, enhanced penalties, and additional enforcement resources do nothing to protect your constituents from illegal foreign actors who blatantly disregard US laws, operate anonymously, and/or hide in jurisdictions that will not extradite criminals.** Even with the full force of US law enforcement going after illegal sites that claim to be Canadian, thousands of illegal online pharmacy websites based offshore would continue to dupe your constituents into believing they are buying from a “real” Canadian online pharmacy.

Given what we know about the ineffectiveness of lists, the realities of consumer web search behavior, and the dangers posed by illegal online pharmacies, we urge you to oppose any legislation that would have the effect – even if not the intent – of sending Kentucky consumers online to buy “Canadian” medicine. As explained, they will not get Health Canada-approved medicine and could instead be seriously harmed.

Additionally, for more than three years the Kentucky Board of Pharmacy, state-licensed pharmacies and wholesalers, and pharmaceutical manufacturers have been working to further secure the US drug supply chain by implementing the Drug Supply Chain Security Act (DSCSA). The DSCSA enables the tracing of prescription pharmaceuticals in the US in an effort to prevent counterfeit and unapproved medicines from hurting US patients. **Authorizing importation of Canadian medicine seriously complicates – if not completely frustrates – the implementation of this important federal drug safety law, as Canada does not have similar drug packaging and tracing requirements.** We urge you not to unravel the patient safety benefits accomplished by this law or throw away the years of time and billions of dollars invested in its implementation and the decades of policy debate that went into making it a reality in the US.

This is an issue that threatens patients across our nation, including your constituents in Kentucky. We appreciate your consideration of our comments and offer any assistance that we can provide. Please do not hesitate to contact us at pharmacy.board@ky.gov or via phone at 502/564-7910 with feedback or questions.

Sincerely,



Executive Director, KENTUCKY BOARD OF PHARMACY

Attachment: US vs Canada Internet Supply Chain Infographic