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## Promoting Drug Importation Is Risky Politics

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With cases of the H1N1 virus on the rise, the Food and Drug Administration recently issued a warning to people buying purported flu treatments over the Internet. In several instances, the agency bought what was marketed as Tamiflu, one of two leading treatments for H1N1, only to find that the products were not what they appeared to be.



Food and Drug Administration Commissioner Margaret Hamburg made the warning plain: “Medicines purchased from Web sites operating outside the law put consumers at increased risk due to a higher potential that the products will be counterfeit, impure, contaminated, or have too little or too much of the active ingredient.” When you buy drugs online you are opening up the risk of fake or contaminated shipments. During my time in Congress, I was the chief advocate for federal regulation of Internet prescription sales, ensuring that each online pharmacy had to note its physical location, as well as the state and local jurisdictions where it was licensed. But here we are, 10 years later, and patients are still seeing the frightening and, in some cases fatal, results of buying unsafe drugs when they thought it was simply a convenience.

Despite these very real and recent safety concerns, a movement afoot in Congress would change U.S. law to allow American patients, pharmacies and health insurance companies to import drugs from foreign countries. While advocates claim drug importation would lower costs for patients, the reality is that cost savings would be negligible while the risk of importing contaminated or counterfeit drugs would skyrocket.

Importing drugs from abroad is potentially dangerous because it short-circuits the FDA drug safety process. The FDA upholds the highest standards of safety throughout the drug manufacturing and distribution chain < from clinical trials, to sterilization and safe shipping procedures, to oversight that ensures the drug you think you’re taking actually contains the labeled ingredients.

But what if the bottle comes from China? Or Mexico? Or France? Are the standards maintained in those countries as rigorous as our own? If you buy a cheap pair of imported sneakers that turn out to be poorly made, it’s apparent by the look and feel of the shoes. If you buy an imported drug labeled as a cholesterol medication, you won’t know whether it’s the real deal until you can measure the effect it has on your blood. Are we ready to take that risk?

Some drug importation measures claim to uphold safety standards by only allowing importation from certain trusted countries. But while drugs coming from Canada, Europe, Australia or Japan may sound safe, it’s important to remember that just because a drug may ship from a trusted country doesn’t mean it originated there.

This is particularly true of Europe, where the common market means that drugs coming from a country with weaker regulatory standards can be easily transported to and shipped through countries with tougher standards.

Similarly, a sting operation conducted by the FDA at three U.S. airports in 2005 found that 85 percent of the

drugs labeled as coming from a Canadian pharmacy were actually shipped from countries such as India, Costa Rica and Vanuatu.

Trans-shipment of drugs increases the risk that a drug being delivered across borders will be counterfeit. Over a two-month period last year, the European Commission seized 34 million counterfeit drugs, including antibiotics and cancer and cholesterol medication. The sheer number of drug manufacturing operations around the world means the FDA can't inspect most of them. Foreign drug manufacturers that import drugs to America may go a decade without being checked by the FDA. Domestic U.S. plants get checked at least every other year.

With the FDA ill-equipped to police the global pharmaceutical market, Americans can have no confidence that foreign-sourced drugs are safe. Making matters worse, some legislation specifically avoids requiring the secretary of Health and Human Services to certify that importing drugs wouldn't imperil the safety of Americans, calling such a provision a "poison pill." It's an odd choice of words considering that safety certification is designed to prevent Americans from being exposed to pills that are actually poisonous.

Congressional efforts to allow importation of drugs from abroad not only threaten patient safety, but also undermine the progress made on passing genuine health care reform. It's time for Congress to end the sideshows and focus on the main event < passing reform that increases access to affordable health insurance, emphasizes disease prevention and comprehensive care, and promotes innovation so that Americans can access the most advanced treatments and pharmaceuticals safely.

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