

# NATIONAL SECURITY IMPLICATIONS RELATED TO THE PERSONAL IMPORTATION OF PRESCRIPTION DRUGS

A White Paper presented by  
The Henry L. Stimson Center  
February 2007

A new law allowing the personal importation of prescription drugs from Canada creates a regulatory and national security loophole that could imperil the health and safety of Americans.

Given the extraordinary cost of prescription drugs in the US relative to other countries, the number of ordinary citizens seeking lower-cost medicines in Canada and elsewhere has skyrocketed. Until last fall, personal reimportation of even US made drugs was illegal, except under particular circumstances, although this did little to discourage the acquisition of affordable drugs. The only legal way to import drugs from any foreign source was for a manufacturer to do so. But the cost burden on individual consumers for their prescriptions was proving too much. After years of bills being introduced in Congress to ease restrictions on importation of pharmaceuticals from foreign countries, the FY 2007 Homeland Security Appropriations Bill, which includes a provision to lift the personal importation ban on small quantities of prescription drugs from Canada, became public law in October 2006. Another bill introduced in 2005, which would ease restrictions on drug importation from Australia, Canada, the European Union, Japan, New Zealand, Switzerland, and other countries with standards similar to the US, is still pending.

Nearly 12 million prescription drug products—tablets, capsules, inhalants, injectables, biologics, generics, brand name drugs and controlled substances—with a value of approximately \$700 million entered the US from Canada alone in 2003. They enter via internet purchases or travel to Canada by US consumers. Sales from licensed Canadian pharmacies were valued at \$43.5 million per month in early 2004.<sup>1</sup> While studies have shown that Canadian drugs have been safe, most that are imported are unapproved for the US market.<sup>2</sup> Moreover, the FDA has argued that it cannot guarantee the chain of custody or integrity of a product of foreign origin. In other words, it cannot guarantee that a drug from Canada is actually from Canada. The FDA has recently implemented a requirement that is meant to ensure the chain of custody of products manufactured and distributed in the US. While a federal standard is welcomed, not only does the requirement fail to address imported drug products, but is in conflict with the patchwork of state requirements already in existence.

Concerns about safety are on both sides of the border. A 2004 report by the Health and Human Services (HHS) Task Force on Drug Importation stated,

Some sellers of imported drugs are ‘rogue’ internet pharmacies that pretend to be legitimate and operate behind facades. Many of the drugs sold over the internet claim to be interchangeable with the approved US drug, but are not....American consumers currently purchasing drugs from overseas are generally doing so at significant risk....[Creating] an opening in the ‘closed’ [distribution] system would increase the opportunity for counterfeit and other substandard drugs to enter and be dispersed into the US drug distribution system.<sup>3</sup> (emphasis added).

In a *British Medical Journal* article in October 2006, the CEO of the Ontario Pharmacists' Association stated,

We are concerned that the legitimising of internet drug purchases by Americans encourages fraud by offshore criminals posing as Canadian pharmacists and selling counterfeit drugs. This is a health and safety threat to both American and Canadian patients who...buy drugs from what they believe are Canadian internet pharmacies, believing them to be safe and genuine.<sup>4</sup>

The new law creates a regulatory and national security loophole that could imperil the health and safety of Americans. It throws wide open an unregulated avenue of cross-border trade through which counterfeit and tampered products could easily flow, and through which bioterrorists could access or proliferate the materials needed for a small-scale biological weapon. While the barriers to employ such a scheme are significant, they are not impossible.

The growth of medical products and therapeutic countermeasures that contain or are derived from 'select agents'<sup>5</sup>, or 'select products', is expanding. At the same time, the ease of access to biological agents and weapons expertise by state and non-state actors alike has greatly increased. In the light of a rapidly advancing life sciences industry and an evolving security environment, the unlicensed acquisition, proliferation and misuse of select products which are stored and distributed globally may present new avenues through which bioterrorists could attack the United States. With the potential for a sanctioned entry-point through which unlicensed products could travel, select products demand particular attention and oversight at the national level.

To ensure the integrity of products of proliferation concern, the security of consumers and the American public, **the Henry L. Stimson Center finds that in the interest of national security, a special exception to imports should be made for products that contain or are derived from select agents.**

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<sup>1</sup> Clifford Krauss, 'Kinks in Canada drug pipeline', *The New York Times*, 6 April 2006.

<sup>2</sup> US Government Accountability Office (GAO), 'Prescription drugs: strategic framework would promote accountability and enhance efforts to enforce the prohibitions on personal importation', December 2005, GAO-05-372.

<sup>3</sup> HHS Task Force on Drug Importation, 'Report on prescription drug importation', December 2004, accessed at: [www.hhs.gov/importtaskforce/Report1220.pdf](http://www.hhs.gov/importtaskforce/Report1220.pdf).

<sup>4</sup> Barbara Kermod-Scott, 'US eases its restrictions on prescription drugs from Canada', *British Medical Journal* 2006; 333:824 (21 October).

<sup>5</sup> Defined as a category of nearly forty (40) dual-use pathogens and toxins with the potential to pose a severe threat to human health and safety and to be used as weapons by criminals or terrorists. See the CDC's Select Agent Program at: [www.cdc.gov/od/sap/](http://www.cdc.gov/od/sap/).