



March 9, 2020

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Importation of Prescription Drugs (FDA-2019-N-5711)

Submitted electronically

Dear Sir/Madam,

Biocom appreciates the opportunity to submit the following comments in response to the Food and Drug Administration's (FDA) [notice of proposed rulemaking](#) (NRPM) to amend its regulations to implement provisions of the Food, Drug, and Cosmetic Act (FD&C Act)¹ to allow the importation of certain prescription drugs from Canada.

Biocom is the largest, most experienced leader and advocate for California's life science sector, which includes biotechnology, pharmaceutical, medical device, genomics and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors and service providers. With more than 1,300 members dedicated to improving health and quality of life, Biocom drives public policy initiatives to positively influence the state's life science community in the research, development, and delivery of innovative products. California's life sciences industry generates nearly \$346 billion in annual economic output, boosts the state's total gross product by \$195.8 billion, supports almost 1.3 million jobs, and increases labor income by more than \$104 billion per year².

Biocom strongly opposes permitting the importation of Canadian drugs into the United States. While we support efforts to ensure patients have access to medicines they need, we believe that importation proposals pose serious threats to Americans' health and safety and have failed to demonstrate a significant reduction in costs to patients.

¹ 21 U.S.C § 384

² See Biocom 2019 Economic Impact Report Databook <https://www.biocom.org/eir/>



Importation undermines the track-and system

Under the guidance of the Food and Drug Administration (FDA), the United States operates the most comprehensive approval and regulatory framework for medicines in the world. The rigorous drug review process at FDA is recognized worldwide as the gold standard and ensures patients that their medicines are safe and effective. The safety of those medicines was furthered strengthened in 2013 by the Drug Supply Chain Security Act³ (DSCSA), which provides for an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.

Imported products designated for foreign markets would not meet the standards of safety and security established by the DSCSA necessary to ensure the integrity of the supply chain. The DSCSA mandates several technical standards aimed at preventing counterfeit drugs from entering the U.S. supply chain. Drug manufacturers and repackagers are required to add DSCSA-specified product identifiers to their packages, which include a unique standardized numerical identifier that comprises of the FDA-registered National Drug Code and unique serial number. Additionally, every drug must have a complete transaction history from the initial sale by the original manufacturer or by a repackager that purchased it directly from the original manufacturer. Every subsequent seller must provide the buyer with the complete transaction history and a transaction statement asserting compliance with various DSCSA requirements.

Drugs imported from Canada cannot be tracked and traced throughout the supply chain. Canadian drugs are not required to be serialized. Health Canada assigns a Drug Identification Number to all prescription and over-the-counter drugs as opposed to a DSCSA-compliant identifier with an FDA-registered National Drug Code. Canada's drug numbers are distinct from the FDA-assigned drug numbers. There is currently no legal or operational means of converting a drug packaged for the Canadian market into a drug that meets the requirements of the DSCSA's track and trace system.

Importation enables counterfeits

Today, more than one million patients die annually due to the global threat caused by counterfeit drugs⁴. A 2017 study found that counterfeit pharmaceuticals constitute the biggest segment of the global counterfeit trade, with sales ranging from \$163 billion to \$217 billion annually⁵. 1 in 10 medicines worldwide and up to 50 percent of drugs consumed in developing nations are substandard or falsified⁶.

The threat of counterfeit drugs is on the rise in Canada. In 2019, the agency seized \$2.5 million worth of counterfeit drugs at the border and companies controlled by Canada Drugs, an online pharmacy, pleaded

³ Pub.L. 113-54

⁴ Behner, Peter, Hecht, Dr. Marie-Lyn, Wahl, Dr. Fabian, *Fighting Counterfeit Pharmaceuticals: New Defenses for an Underestimated – and Growing – Menace*, PwC, June 29, 2017 <https://www.strategyand.pwc.com/gx/en/reports/fighting-counterfeit-pharmaceuticals.pdf>

⁵ See *Fighting Counterfeit Pharmaceuticals*

⁶ World Health Organization. (2018, January 31). Substandard and falsified medical products. Retrieved from <https://www.who.int/en/news-room/fact-sheets/detail/substandard-and-falsified-medical-products>

guilty in U.S. federal court to selling counterfeit and misbranded pharmaceuticals in the U.S.⁷. The firms agreed to forfeit \$29 million which was equal to their sales of illegal drug proceeds from 2009-2012⁸.

In another anti-counterfeiting operation in 2018, Canadian officials inspected nearly 3,600 packages and found that 87 percent contained counterfeit or unlicensed health products and that a striking number of "Canadian" drugs were not actually from Canada⁹.

Canadian drugs that enter the U.S. through importation will not be subject to the standards established by the DSCSA and, as a result, counterfeit, substandard or diverted, repackaged and adulterated drugs could be introduced into our closed and secure drug supply chain. Canadian regulators have warned Americans that importation could be risky. Health Canada has stated that it 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 future¹⁰. If the DSCSA requirements are relaxed to allow for importation, it would be extremely difficult to separate illicit drugs from legitimate drugs because imported products cannot be traced back to the original manufacturers.

In addition, the Canadian medicine supply is not large enough to support both Canadian and U.S. consumers. With a population of 37.5 million, Canadian pharmacies serve a population that is one-tenth the size of the U.S. population. Studies have estimated that Canada's drug supply would be exhausted in less than eight months if just 10 percent of U.S. prescriptions were filled with Canadian drugs¹¹.

Canada has expressed opposition to the United States' importation plan, arguing that it could adversely affect the supply of prescription drugs in Canada and potentially raise costs of prescription drugs for its citizens¹². The Canadian Pharmacist Association has stated that the plan could exacerbate some of the drug shortages that they are already seeing¹³. This would lead to increased prices for legitimate drugs and augment the opportunity and ability for counterfeit drugs to enter the market¹⁴.

Importation is unlikely to produce significant cost savings to American consumers

Importation isn't likely to provide meaningful reductions in the cost of prescription drugs for American consumers. A study issued by the Congressional Budget Office found that importing drugs from Canada

⁷Whalen, J. (2017, December 16). Guilty Pleas in Canada Drugs Counterfeit-Medicines Cases. Retrieved from <https://www.wsj.com/articles/guilty-pleas-in-canada-drugs-counterfeit-medicines-cases-1513383756>

⁸Acri, K. (2018, March 2). They cost us billions and they can kill: Counterfeit drugs are invading Canada. Retrieved from <https://business.financialpost.com/opinion/they-cost-us-billions-and-they-can-kill-counterfeit-drugs-are-invading-canada>

⁹Partnership for Safe Medicines. (2019, January 8). Raid In British Columbia, Canada Turns Up A Pill Press And Over 100 Different Pill Dyes. Retrieved from <https://www.safemedicines.org/2019/01/raid-in-british-columbia-canada-turns-up-a-pill-press-and-over-100-different-pill-dyes.html>

¹⁰HHS Task Force Report citing Letter from Diane C. Gorman, Assistant Deputy Minister, Health Canada, to Richard H. Carmona, U.S. Surgeon General, pg. 60-61. June 1, 2004.

¹¹Shepherd, M. (2010). The Effect of US Pharmaceutical Drug Importation on the Canadian Pharmaceutical Supply. Canadian Pharmacists Journal / Revue Des Pharmaciens Du Canada, 143(5), 226–233. <https://doi.org/10.3821/1913-701X-143.5.226>

¹²Martell, A. (2019, July 19). Exclusive: Canada warns U.S. against drug import plans, citing shortage concerns. Retrieved from <https://www.reuters.com/article/us-canada-pharmaceuticals-exports-exclus/exclusive-canada-warns-us-against-drug-import-plans-citing-shortage-concerns-idUSKCN1UD2LN>

¹³Coletta, A. (2019, August 1). Trump and Sanders want to ease imports of drugs from Canada. Canada says not so fast. Retrieved from https://www.washingtonpost.com/world/the_americas/trump-and-sanders-want-to-ease-imports-of-drugs-from-canada-canada-says-not-so-fast/2019/08/01/1f0f91a6-b463-11e9-acc8-1d847bacca73_story.html

¹⁴Blackstone, E. A., Fuhr, J. P., Jr, & Pociask, S. (2014). The health and economic effects of counterfeit drugs. American health & drug benefits, 7(4), 216–224.

would only reduce U.S. pharmaceutical spending by 1 percent¹⁵.

Generics make up a majority of the drugs Americans take, accounting for roughly 80 percent of prescriptions filled¹⁶, and Canadian generic drug prices are generally not lower than U.S. generic drug prices. One study indicated that of the 27 leading generic drug products examined, 21 had higher prices in Canada than in the U.S.¹⁷. The proposed importation plan excludes most of the highest-cost drugs including insulin and other biologics.

The additional cost associated with the proposed plan would most likely outweigh any cost savings realized from importing Canadian drugs. The drugs that are included in the proposal would indeed have costs related to relabeling, testing, complying with the DSCSA workaround, and developing recall and adverse event reporting systems.

Biocom urges the agency to withdraw the proposed rule. Congress has taken significant actions to enhance the drug supply chain through the enactment of the Drug Supply Chain Security Act. Allowing for the importation of prescription drug products would expose the domestic supply and patients to unnecessary risk. Health Canada nor the Food and Drug Administration can guarantee the safety of imported drugs. The proposed plan also does not ensure meaningful reductions in the cost of prescription drugs to American consumers.

Thank you again for the opportunity to provide these comments. We look forward to a continued dialogue with the FDA on the implications of the proposed importation plan. If you have any questions about these comments, please contact Brittany Blocker, Manager of Regulatory Affairs at bblocker@biocom.org.

Sincerely,



Joe Panetta
President and CEO
Biocom

¹⁵ Congressional Budget Office. (2004, April 29). Would Prescription Drug Importation Reduce U.S. Drug Spending? Retrieved from <https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/04-29-prescriptiondrugs.pdf>

¹⁶ See Congressional Budget Office

¹⁷ World Health Organization. (2018, January 31). Substandard and falsified medical products. Retrieved from <https://www.who.int/en/news-room/fact-sheets/detail/substandard-and-falsified-medical-products>