

October 21, 2020

The Honorable Alex M. Azar II  
Secretary for Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

Dear Secretary Azar:

The Campaign for Personal Prescription Importation (CPPI) writes to express concern that the millions of Americans who currently rely on personal importation from licensed online Canadian pharmacies for access to affordable life-saving prescription drugs will be denied their medication due to the Department of Health and Human Services (HHS) September 24 "[Final Importation Rule](#)"<sup>1</sup> and "[Request for Proposals Regarding Waivers for Individual Prescription Drug Importation Programs](#)."<sup>2</sup> We urge you to exercise your authority to continue to permit Americans to import from licensed Canadian pharmacies.

While the Administration's intention of reducing Americans' prescription drug costs by expanding importation is clear, the September 24th Final Importation Rule and RFP would have the unintended consequence of cutting Americans off from the licensed pharmacies on which they depend. The RFP ignores [Food and Drug Administration \(FDA\)](#) guidance that for more than a decade has allowed millions of Americans to safely personally import prescriptions when using certified, trusted, and legitimate Canadian pharmacies.<sup>3</sup> The National Federation of Independent Business (NFIB) flagged a similar concern over the prohibition on personal importation. In a January 2020 letter, the NFIB requested that the FDA, "proceed promptly to implement personal importation under section 804(j) of the Food, Drug, and Cosmetic Act."<sup>4</sup>

The September 24th Request for Proposal offers that, "a pathway would not authorize individuals in the United States to purchase prescription drugs through the Internet, directly from a foreign pharmacy, or from any other foreign seller." The September 24th RFP would restrict importation of prescription drugs only to authorized State-licensed pharmacies, effectively blocking the CPPI community and millions of Americans from accessing their medications.

Instead of lowering American prescription drug costs, the Final Rule and RFP could actually increase costs as it installs middlemen between American patients and Canadian medication providers. The Final Rule calls for the following new middlemen: an importer, statutory tester, relabeler or repackager, a wholesaler and a pharmacist. Each of these new middlemen would eat into the savings that Americans who personally import currently benefit from. In this manner the Final Rule would actually increase

---

<sup>1</sup> FDA, Final Rule on Section 804(b) through (h) of the FD&C Act (21 U.S.C. 384(b) through (h)), "<https://www.hhs.gov/sites/default/files/importation-final-rule.pdf>

<sup>2</sup> FDA, "REQUEST FOR PROPOSALS REGARDING WAIVERS FOR INDIVIDUAL PRESCRIPTION DRUG IMPORTATION PROGRAMS," September 24, 2020, <https://www.hhs.gov/sites/default/files/individual-prescription-drug-importation-programs.pdf>

<sup>3</sup> FDA, "Is It Legal for Me to Personally Import Drugs," <https://www.fda.gov/about-fda/fda-basics/it-legal-me-personally-import-drugs>

<sup>4</sup> Comment from the National Federation of Independent Business

costs on Americans who currently rely on prescription importation, and would eliminate Americans' greatest savings on imported prescription medications.

There are [real savings](#) for Americans through personal prescription importation that President Trump and you have worked to advance and heralded in the [Executive Order](#) issued in July.<sup>5</sup> The average monthly savings for Americans purchasing prescriptions for importation from licensed online Canadian pharmacies is \$245 a month. For Americans spending more than \$300 a month on prescriptions, as is the case for many American seniors, the average monthly savings is \$648. [CPPI cost comparisons](#) of ten of the most commonly ordered brand name prescription drugs have consistently found that, even with coupon discounts, prescription drugs that Americans struggle to pay for are 50% to 90% cheaper from licensed online Canadian pharmacies.

Prescription importation from licensed online Canadian pharmacies is safe, and the extensive work that this administration has undertaken to expand importation speaks to its safety.

American Enterprise Institute economist Roger Bate has studied importation and the role of the Internet extensively. While rightly identifying the “whack a mole” problem of unscrupulous rogue actors online, Bate conducted investigations in 2012 and 2019 that found all samples from the Canadian International Pharmacy Association (CIPA) and PharmacyChecker credentialed pharmacies were authentic. Bate argues it is safe to use licensed Canadian pharmacy websites: “the reason importation remains illegal without explicit authorization from the FDA is due to economics and politics, not safety.”<sup>6</sup>

Organizations such as CIPA are able to identify licensed retail pharmacies that meet trusted standards including: requiring a valid prescription, obtaining patient medical information and maintaining health profile with medication history to avoid adverse drug interactions, having a licensed pharmacist on staff to supervise dispensing of medications and available for consultation, and not selling controlled substances, narcotics, opioids, highly temperature sensitive products, or any product containing pseudoephedrine. CPPI [research](#) shows that Americans who order prescriptions from abroad know how to identify “rogue” pharmacies and are savvy in their search to find trusted online pharmacies. More than half of our community selected an online pharmacy because it was a certified site.

Safe prescription drugs - and the ingredients that comprise them – originate from diverse, international supply chains. A 2019 Senate Homeland Security and Government Affairs Committee minority staff report found that in 2015, the U.S. imported \$86 billion in pharmaceutical products.<sup>7</sup> The Food and Drug Administration (FDA) estimates that 40 percent of finished dose prescription drugs are foreign made.<sup>8</sup> FDA's Center for Drug Evaluation and Research Director testified at an October 2019 House Energy and Commerce Committee hearing that only 28 percent of active pharmaceutical ingredient facilities are

---

<sup>5</sup> U.S. White House, “Executive Order on Increasing Drug Importation to Lower Prices for American Patients,” July 2020;

<https://www.whitehouse.gov/presidential-actions/executive-order-increasing-drug-importation-lower-prices-american-patients/>

<sup>6</sup> Roger Bate, “Personal Medicine Importation: What Are the Risks, and How Can They Be Mitigated?” American Enterprise Institute, September 2019

<sup>7</sup> “A Price Too High: Cost, Supply, and Security Threats to Affordable Prescription Drugs;” December 2019

<sup>8</sup> [www.gao.gov/assets/690/681689.pdf](http://www.gao.gov/assets/690/681689.pdf)

domestic.<sup>9</sup> Drug importation is the current industry norm and cost-savings from importation should be permitted for consumers.

American's need for access to safe affordable prescription drugs through personal importation has been highlighted by the economic impacts of the Coronavirus. As people have lost health insurance coverage and been forced to seek more socially distanced access to medications during the pandemic, personal importation from licensed online Canadian pharmacies has offered a safe affordable option. More American patients are turning online for healthcare access, and a growing number are looking for their medications delivered by mail.<sup>10</sup> In the current pandemic environment, Americans need access to life-saving medicines more than ever. The Department of Homeland Security has restricted movement between the U.S. and Canada to essential travel since March. This means border state Americans are no longer able to fill their prescriptions at reduced costs in Canada. Pandemic-related travel limitations make cross border travel for the purpose of obtaining affordable prescription drugs impossible.

Now is the time to make personal prescription importation easier, not harder, for Americans so that they can take advantage of safe and affordable prescription medication from Canada. Eighty percent of Americans support expanding access to prescription importation from countries like Canada to reduce prescription drug prices according to polling from the [Kaiser Family Foundation](#).<sup>11</sup> We commend the Administration's support for prescription importation and success in recognizing that safe medications from abroad offer an affordable option for Americans.

We strongly urge that any importation regulations, guidance, or requests for proposals allow continued access to safe and affordable medicines for the millions of Americans that are currently importing medicines for personal use.

Sincerely,

A handwritten signature in black ink, appearing to read "John Pfeiffer", is written over a horizontal line.

John Pfeiffer  
Executive Director  
Campaign for Personal Prescription Importation

[About the Campaign for Personal Prescription Importation](#)

<sup>9</sup> Testimony, Janet Woodcock, M.D. October 30, 2019.

[www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019](http://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019)

<sup>10</sup> Jared Hopkins, "Mail Order Drug Delivery Rises During Coronavirus Lockdowns," Wall Street Journal, May 2020. <https://www.wsj.com/articles/mail-order-drug-delivery-rises-during-coronavirus-lockdowns-11589281203>

<sup>11</sup> Ashley Kirzinger, Lunna Lopes, Bryan Wu, and Mollyann Brodie, "KFF Health Tracking Poll – February 2019: Prescription Drugs."

<https://www.kff.org/health-reform/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>

The Campaign for Personal Prescription Importation (CPPI) is a national nonprofit patient advocacy organization that fights for Americans' access to safe, affordable prescription medications from Canada for personal use. Tens of millions of Americans – especially the elderly and others on fixed incomes – struggle to pay the extremely high price of prescription medications in the U.S. We are here to be their voice.

Millions of Americans use licensed Canadian pharmacies annually, to purchase their daily prescription medications at an affordable price. We believe that all Americans have a right to affordable medications. It is time to change the current U.S. policy on this issue to provide immediate access to life-saving medications, taken daily for chronic health conditions, at affordable prices.