



March 3, 2020

Stephen Hahn, MD  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

Re: Importation of Prescription Drugs [FDA-2019-N-5711]

Dear Commissioner Hahn,

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Food and Drug Administration's (FDA) proposed rule to allow for the importation of prescription drugs. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 159,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

The College appreciates the Administration's interest in addressing rapidly increasing prescription drug costs and making drug pricing an agency priority. This issue is particularly important to physicians because prescription drugs are a key part of a physician's comprehensive toolkit and have been crucial in improving the health and lives of millions of our patients. Research has shown that rising costs make prescription drugs less accessible for patients, making them more likely to forego their medications and posing a barrier to the adherence of recommended treatment plans. ACP is concerned that under the status quo, barriers to obtaining necessary medications will result in the development of more serious health issues and, in turn, lead to diminished quality of life, poorer outcomes, and additional financial burden to the health care system. Medication non-adherence causes roughly 125,000

deaths, 10 percent of hospitalizations, increased morbidity and mortality rates, and costs the health care system anywhere from \$100-\$300 billion a year in the United States.<sup>1</sup>

We are pleased the Administration is expressing a willingness to consider novel approaches, like a drug importation program, in order to more immediately lower costs for our patients. As outlined in our 2016 policy paper [“Stemming the Escalating Cost of Prescription Drugs.”](#) ACP supports the importation of drugs, especially sole-source generic drugs, as part of larger efforts to control the cost of prescription drugs. The U.S. spends more per capita and as a percentage of gross domestic product on prescription drugs than any other country in the world, with Americans paying higher prices for many of the same exact drugs that are sold elsewhere around the world for much less.<sup>2</sup> For example, Canada’s Patented Medicine Prices Review Board found that the average price ratio for drugs sold in the U.S. compared to drugs sold in Canada was over 3:1 in 2017.<sup>3</sup> **While it is clear that action is needed to reduce the high cost of prescription drugs in the U.S., including consideration of drug importation, it is critical to center such efforts on assuring high quality and prioritizing patient safety.**

The Medicare Prescription Drug, Improvement, and Modernization Act, which amended the Federal Food, Drug, and Cosmetic (FD&C) Act to pave the way for the establishment of a prescription drug importation program, was signed into law in 2003. Specifically, it amended section 804 of the FD&C to allow for the Department of Health and Human Services (HHS) to issue rules to permit pharmacists and wholesalers to import certain drugs under certain conditions, so long as the Secretary of HHS certifies that the rules will “pose no additional risk to the public’s health and safety” and “result in a significant reduction in the cost of covered products to the American consumer.” Despite interest from various stakeholders in importing less expensive drugs from Canada, including the establishment of numerous state programs seeking to utilize the law, no administration has ever made the required certification and issue regulations.

## **FDA Proposal**

Under the proposed rule, the FDA would create a process to allow the importation of certain prescription drugs from Canada through section 804 Importation Programs (SIPs). These SIPs, which would be authorized for two years and be eligible for two-year extensions, must be managed by a non-federal governmental entity sponsor, like a state, territorial, or tribal governmental entity. The SIP could be co-sponsored by other relevant parties, including a pharmacist, wholesaler, or other non-federal government entity. As part of the materials that

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<sup>1</sup> Viswanathan, Meera, Carol E. Golin, Christine D. Jones, Mahima Ashok, Susan J. Blalock, Roberta CM Wines, Emmanuel JL Coker-Schwimmer, David L. Rosen, Priyanka Sista, and Kathleen N. Lohr. "Interventions to improve adherence to self-administered medications for chronic diseases in the United States: a systematic review." *Annals of internal medicine* 157, no. 11 (2012): 785-795.

<sup>2</sup> Sarnak, Dana O. "Prescription Drug Spending Why Is the U.S. an Outlier?" Prescription Drug Spending: Why Is the U.S. an Outlier?, October 5, 2017. <https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier>.

<sup>3</sup> Patented Medicine Prices Review Board (PMPRB), 2017, “Annual Report 2017: Regulating Prices of Patented Medicines: Continued Vigilance Necessary, Bilateral Price Comparisons, Average Foreign-to-Canadian Price Ratios, Bilateral Comparisons,” <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1380&lang=en>.

must be submitted to FDA for approval, the SIP sponsor must demonstrate that importing the drug would not pose a risk to public health and safety and how doing so would result in a reduction of costs. The proposal must also address manufacturing, storage, and transportation concerns pertaining to controlling contamination, preserving sterility, and ensuring stability. Origins of the active ingredients of the drugs that are imported must be disclosed in the proposal.

American importers participating in a SIP must purchase the drug that will be imported directly from a foreign seller, which must be identified in the SIP proposal; in turn, the foreign seller must purchase the drug directly from the manufacturer. The foreign seller must be licensed by Health Canada and registered with FDA, while the importer must be a licensed wholesaler/pharmacist in the United States. To meet the requirements of being an eligible drug, they must both be approved by Health Canada's Health Products and Food Branch (HPFB) and meet the conditions stipulated in an FDA-approved New Drug Application (NDA) or Abbreviated NDA (ANDA). Biologics, infused drugs, drugs subject to risk evaluation and mitigation strategies, and intravenous/intrathecal/intraocularly injected drugs are excluded from this rule and are not permitted to be imported under a SIP.

Once imported drugs have arrived in the United States, the manufacturer or importer must test the drugs for authenticity, degradation, and standards compliance at a qualified U.S. lab. Importers are responsible for relabeling to meet U.S. labeling standards, to be serialized and identifiable at the package level, and meet other Drug Supply Chain Security Act (DSCSA) obligations. The SIP sponsor must also provide FDA with certain records, including adverse event, medication error, and other data. Serious and unexpected adverse events must be reported within 15 calendar days while all adverse events must be reported within 90 days. A plan to communicate and implement recall procedures must be established.

### **ACP Comments**

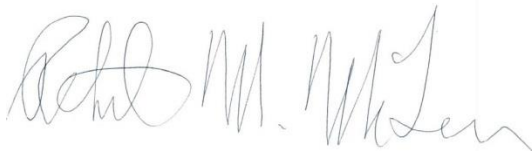
The College has [longstanding policy on drug importation](#), including a policy paper establishing the principles upon which any proposed drug importation plan should be evaluated. While ACP is generally supportive of drug importation as laid out in this proposed rule as a means to control the cost of prescription drugs, the FDA must guarantee that the design and implementation of the rule includes numerous measures and safeguards to ensure patient safety. By limiting the origin of imported drugs to Canadian-certified and FDA-approved and registered drugs and entities, we believe the proposed rule meets the required U.S. standards to assure high-quality drugs and patient safety. Any final drug importation system must also be one that is a closed system and have a tightly controlled and documented supply chain to assure authenticity and avoid degradation of the drug. We are pleased the FDA has excluded biologics, infused/injected drugs, and controlled substances from allowed prescription drugs due to their unique risks and further urge the Agency to explicitly exclude products that are photoreactive or have strict temperature requirements. **Additionally, given concerns of the quality and safety of prescription drugs manufactured abroad, we believe it is important that any effort to import foreign drugs ensures sufficient resources for the FDA to inspect facilities**

**abroad and for the FDA, U.S. Customs Service, law enforcement agencies, and other agencies to prevent products that are illegal, counterfeit, or do not meet U.S. safety and quality standards are not allowed into the country.**

We appreciate the opportunity to provide comments on this proposed rule. Past research has shown that brand name drugs cost 24 percent less at Canadian pharmacies compared to American pharmacies.<sup>4</sup> A drug importation program should be considered as a more immediate option to provide relief for the millions of patients unable to afford lifesaving therapies, so long as patient safety and drug quality are forefront. **That said, prescription drug importation is not a long-term solution to the high cost of prescription drugs.** It is important to simultaneously explore other options, especially since this proposed rule excludes insulin and other drugs that are necessary for survival, yet cost prohibitive.

Although manufacturers are solely responsible for setting their price, it is important to keep in mind that other factors (i.e. PBMs, payers, physicians, regulations, patents, etc.) play a role in how manufacturers set them, regardless of other motivations. Any solution addressing the many issues surrounding prescription drug pricing cannot be as straightforward as unilateral action by a single actor—it will require commitment by all stakeholders. In addition to pursuing drug importation, the federal government must consider other avenues such as improving price and cost transparency for health plans, pharmaceutical benefit managers, and manufacturers; allowing Medicare and other federal programs to directly negotiate drug prices; and measures to increase competition. Please contact Josh Serchen, Senior Analyst, Health Policy at [jserchen@acponline.org](mailto:jserchen@acponline.org) if you have any questions or need any additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert M. McLean". The signature is fluid and cursive, with the first name being the most prominent.

Robert M. McLean, MD, FACP  
President

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<sup>4</sup> Quon, Bradley S., Rafael Firszt, and Mark J. Eisenberg. "A comparison of brand-name drug prices between Canadian-based Internet pharmacies and major US drug chain pharmacies." *Annals of internal medicine* 143, no. 6 (2005): 397-403.