



VIA ELECTRONIC SUBMISSION

March 6, 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 (Docket No. FDA-2019-N-5711)

The Council of State Bioscience Associations (“CSBA”) appreciates the opportunity to submit the following comments regarding FDA’s recent proposal to implement aspects of the Canadian importation provisions of Section 804 of the Food Drug & Cosmetics Act (“FD&C Act”).¹

CSBA represents state and regional life science organizations across the country, and our members are dedicated to supporting the development and delivery of innovative life-enhancing and life-saving products. Our organizations represent the backbone of America’s biopharmaceutical sector, including companies researching and developing the next generation of life saving cures. We are committed to ensuring that Patients have access to the treatments they need when they need them, and we support policies aimed at improving access to those groundbreaking therapies and treatments. We also firmly believe that lowering the costs Patients pay at the pharmacy counter should be a central tenet of any measure aimed at addressing the cost of prescription treatments.

As outlined in comments submitted by both the Pharmaceutical Researchers and Manufacturers Association (PhRMA) and the Biotechnology Innovation Organization (BIO), this program is unlikely to achieve any savings and thus run afoul of the statute’s mandate that programs operate in a manner that delivers significant savings to the US consumer.

The proposed rule seeks to enable pharmaceutical importation from Canada by defining a regulatory process for certain entities (e.g., states) to submit importation plans for certain treatments to the Department of Health and Human Services (HHS) for approval. Section 804 of the Food, Drug and Cosmetics Act has long permitted HHS to allow for prescription treatment importation – provided that the Secretary can establish that importation will “(a) pose no additional risk to the

¹ 21 U.S.C. § 384.

public's health and safety; and (b) result in a significant reduction in the cost of covered products to the American consumer."

The United States has long been the global gold standard in ensuring the safety of prescription treatments. Importation from other countries – even Canada – does not guarantee that the same safety and efficacy standards would apply to imported drugs. For example, Canada imports 80 percent of its prescription medicines from other countries, and while its regulators rightfully oversee the safety of the supply of medicines intended for and used in Canada, they do not apply those standards to drugs intended only for export.² Further, a 2017 report conducted by former law enforcement officials concluded that "drug importation proposals would deplete and overburden already limited resources... [and would] force law enforcement agencies to make tough prioritization decisions that leave the safety of the U.S. prescription drug supply vulnerable to criminals seeking to harm patients."³ Moreover, no current or former Food and Drug Administration Commissioner – Republican or Democrat – has ever certified the safety of importation, despite having the authority to do so, and multiple former Commissioners have made public statements to this effect⁴. Given existing concerns with counterfeit prescription medications in the domestic supply chain as well as abroad, it is unfathomable to move forward with an importation proposal in which counterfeiters may thrive, further putting Patient health and safety in jeopardy.

Most importantly, the rule as proposed will not result in lower costs for American consumers – in fact, the proposed rule states that the Department is "unable to estimate how Section 804 Importation Programs (SIPs) may affect U.S. markets for prescription drugs" and "we are unable to estimate the volume or value of drugs that may be imported under the SIPs or the savings to U.S. consumers who may participate in such programs." The drug supply system is highly regulated and works to ensure that American Patients receive the treatment they were prescribed and not a counterfeit, adulterated, misbranded or tampered product. Providing for large scale Canadian importation will lead to significant supply chain cost increases and additional burden on Federal and State law enforcement agencies tasked with interdiction of counterfeit drugs. Moreover, many products offered in the United States – where 95 percent of all new treatments are launched – are not available in Canada or many other industrialized nations. In short, the logistical complications of safely importing prescription treatments as outlined in the proposed rule would lead to additional system costs rather than providing for savings to Patients or payors.

As written, the proposed rule will likely do little to lower consumer costs at the pharmacy counter and will almost certainly compromise the underlying safety of the American drug supply chain. As such, CSBA respectfully and strongly urges the

² CRS Memorandum, *Drug Regulation in Canada*, January 24, 2017.

³ Freeh, Louis, "Report On The Potential Impact Of Drug Importation Proposals On U.S. Law Enforcement", June 2017. Accessible at: http://fightthefakes.org/wp-content/uploads/2017/07/20170605_Report-on-Counterfeit-Drugs.pdf

⁴ <https://www.washingtonpost.com/news/to-your-health/wp/2017/03/17/four-former-fda-commissioners-denounce-drug-importation-citing-dangers-to-consumers/> accessed 20FEB2020 18:14

Administration to withdraw this proposal. Alternatively, CSBA urges the Administration to provide statutorily required analysis in order to support the assertion that patients could actually realize cost savings under an SIP in any re-published version of the proposed rule. CSBA welcomes the opportunity to work collaboratively with the Administration to implement workable solutions that lower Patient out-of-pocket prescription costs and protect Patient health and safety.

Respectfully submitted,

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