

March 9, 2020

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Importation of Prescription Drugs (Docket No. FDA-2019-N-5711)

Dear Secretary Azar:

On behalf of Life Sciences Pennsylvania and our 860 member organizations, I'm writing to express serious concerns regarding the Food and Drug Administration's (FDA) recent proposal to implement aspects of the Canadian importation provisions of Section 804 of the Food Drug and Cosmetics Act¹. I appreciate the opportunity to submit comments on this proposal

Life Sciences Pennsylvania is the statewide trade association for the Commonwealth's life sciences community. Our membership is comprised of pharmaceutical manufacturers, biotechnology companies, medical device and diagnostic makers, academic research institutions, patient advocacy groups, and myriad service providers that support the industry. As an organization we are committed to ensuring patients have access to the novel treatments, cures and technologies our members are developing. We are supportive of policies that lower the out-of-pocket costs patients pay at the pharmacy counter. Unfortunately, this proposal is unlikely to achieve savings for patients and, more concerning, introduce unsafe, unreliable and counterfeit medicines to the United States closed supply chain.

The rule is being put forth as a way to lower the cost of prescription medicines; however, the proposed rule explicitly states that the U.S. Department of Health 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." Significant resources are required to ensure the authenticity and safety of new medicines entering the U.S. supply chain, and Canadian officials have previously stated they do not have the resources to undertake such comprehensive searches.² As it stands, neither do the FDA or law enforcement agencies whose limited resources are already stretched thin. The costs required to ensure the safety of imported medicines would almost certainly outweigh any savings, as a prior Congressional Budget Office (CBO) report found importation would only lower drug costs by 1 percent over a 10-year period.³

¹ 21 U.S.C. § 384

² Leona Aglukkaq, "Dear Bernie Sanders: Canada is not the United States drugstore," *Washington Post*, May 12, 2017, https://www.washingtonpost.com/news/global-opinions/wp/2017/05/12/dear-bernie-sanders-canada-is-not-americas-drug-store/?utm_term=.6158c21355dd (accessed March 4, 2020)

³ Congressional Budget Office, *Cost Estimate on S. 1392 FTC Reauthorization Act of 2005*, September 8, 2005, Washington, D.C.

More important, though, is the safety risk importation would pose to U.S. patients. The U.S. is home to the worldwide gold standard for supplying safe prescription medicines to patients. As previously noted, Canada does not have the resources and cannot guarantee the same safety and efficacy standards for drugs intended for export. Further, a 2017 report conducted by former law enforcement officials concluded “drug importation proposals would increase the threat of illegitimate products entering the United States...[and] law enforcement and regulatory capacity would be unable to ensure a safe prescription drug supply chain under importation.”⁴ The U.S. drug supply chain is highly regulated and structured to ensure patients receive the medicines prescribed by their doctor, and not adulterated, counterfeit, misbranded or tampered products.

For these reasons, Life Sciences Pennsylvania respectfully requests the Administration withdraw this proposed rule and examine other opportunities to lower the costs patients pay for prescription medicines. Life Sciences Pennsylvania welcomes the opportunity to work with the Administration to identify solutions to the rising cost of health care that do not put patients in harm’s way. I will close with a reference to a letter written by four previous FDA Commissioners (from Republican and Democrat administrations) to Congress in March 2017 where they argued importation “will not achieve the aim [of lower costs], and...is likely to harm patients and consumers.”⁵

Sincerely,



Christopher P. Molineaux
President and CEO

⁴ Freeh, Sporkin, and Sullivan LLP and Freeh Group International Solutions, LLC, “Report on the Potential Impact of Drug Importation Proposals on U.S. Law Enforcement,” June 2017, <https://safedr.org/FreehReport>.

⁵ Former FDA Commissioners, Drs. Robert Califf, Margaret B. Hamburg, Mark B. McClellan, and Andrew Von Eschenbach, Letter to Congress, March 16, 2017, http://www.safemedicines.org/wp-content/uploads/2017_03_16_commissioners_letter_final.pdf