March 9, 2020

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Md. 20993

RE: Docket No. FDA-2019-N-5711, "Importation of Prescription Drugs"

On behalf of the Small Business & Entrepreneurship Council (SBE Council) and our small business supporters and members nationwide, I am writing the Food and Drug Administration (FDA) to express concerns about the "Importation of Prescription Drugs" proposed rule, and to urge its withdrawal.

Entrepreneurs, small business owners and their employees are indeed challenged by high health care costs, including prescription drug costs. The solution, however, does not lie in importing drugs from countries that impose price controls. This will not lower drug costs, which is the stated purpose of the proposed rule. It will, however, undermine innovation, which is a big negative when it comes to patient health, specifically saving lives. U.S. competitiveness would also be damaged. Moreover, small business owners have deep concerns about the safety of these drugs and the threat of counterfeits and chancy drugs entering the supply chain, thus endangering the health (and indeed lives) of their employees and family members.

For more than 25 years, SBE Council has advocated for pro-entrepreneur and pro-market solutions in order drive innovation, investment, economic growth and entrepreneurship. Health care has remained a core issue over our 25-year history. And as we have witnessed time and again, both at home and abroad, intrusive government actions and over-regulation of health care only drive costs higher, limit access and choice, and damages innovation. Price controls as a "solution" is one of those intrusive and unwarranted actions that would lead to all of the above.

Prescription drug importation would undermine America's intellectual property, our innovative capacity and global leadership in producing the next generation of life-saving drugs. And please note, that according to 2017 Census Bureau, **small to mid-size companies dominate** the U.S. pharmaceutical industry. These small, innovative companies will be harmed in numerous ways, especially if capital investment turns cold due to market distortions and the unintended consequences of importing price-controlled drugs. Policies and proposals put forward by the Administration must focus on solutions that enable investment and competition, which in the end

would lower costs and incentivize innovation – and entrepreneurship - in this critical U.S. industry.

The pharmaceutical business involves substantial risk taking. It costs as much as $2.6 billion to bring a drug to market, according to the Tufts Center for the Study of Drug Development, and the approval rate for drugs is 12% entering clinical trials. It takes many, many years to bring a drug to market. As noted above, most pharmaceutical firms are small to medium-size companies – 57% have less than 20 workers and 79% have less than 100 workers. This critical industry is all about risk-taking entrepreneurs. They are passionate about saving lives. Again, policies should encourage this noble and critical work, not punish or impede it. Small pharmaceutical firms are working on the medicines that will improve and save lives, and drug importation of price-controlled drugs would put this important work in jeopardy.

Price controls are price controls, no matter where they are imported from. Importing price-controlled drugs from Canada will not lower costs. As noted in a February 2018 Council of Economic Advisers (CEA) report, "Reforming Biopharmaceutical Pricing at Home and Abroad," distortions caused by foreign price controls are unfair to U.S. drug consumers, therefore policies should address their "root causes" and not punish American consumers even further:

"Meaningful reforms would address the root of the problem: foreign, developed nations, that can afford to pay for novel drugs, free-ride by setting drug prices at unfairly low levels, leaving American patients to pay for the innovation that foreign patients enjoy. Since these nations benefit from the innovations regardless of the costs to Americans, they currently have no reason to raise their own prices and exploit the fact that novel drugs are already invented."

The importation of price-controlled drugs from Canada would encourage and enable this unfair policy. Policies must end this practice, not fuel it further.

As noted previously, SBE Council has concerns about the safety of the drug supply chain if importation were allowed. The February 11, 2020 comments submitted by the Partnership for Safe Medicines on the FDA's proposed importation rule summarize the significant concerns of SBE Council with respect to drug safety, which has been one of our organization's core concerns since the debate over importation began years ago. Specific to Canada, as outlined by the Partnership's comments, the country lacks a compatible system with our "trace and track system," which would "re-open a path for black market drug sellers to substitute cheaper counterfeit and unsafe drugs into the U.S. supply chain." Moreover, Canadian officials have stated that they cannot be responsible for the safety of the drugs that cross the border into the United States.

To sum up, price controls limit potential returns on entrepreneurship and investment, and given the costs and risk involved in the industry, price controls diminish innovation in medicine. By allowing for importation of drugs, the U.S. would effectively import foreign price controls. The potential negatives for consumers, patients, and entrepreneurs, businesses and employees in the pharmaceutical and medicine industry are immeasurable. Finally, there are serious safety concerns with importing drugs from Canada, or any other country.

Thank you for the opportunity to comment on the proposed rule, and SBE Council would welcome the opportunity work with the FDA on solutions that lower drug costs, incentive innovation and investment, and keep our drug supply safe.

Sincerely,

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