March 4, 2020

By electronic submission via www.regulations.gov

The Honorable Stephen Hahn, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Docket No. FDA-2019-N-5711 for "Importation of Prescription Drugs"

Dear Commissioner Hahn:

The Healthcare Leadership Council (HLC) welcomes the opportunity to provide comments on the Food and Drug Administration's (FDA) proposed rule on "Importation of Prescription Drugs." HLC appreciates the Administration's efforts to address the affordability and accessibility of medicines for American patients and consumers. However, the evidence is compelling that allowing the wholesale importation of drugs into our nation's closed drug supply system will undermine nearly two decades of drug safety policy and place American patients and consumers at unnecessary risk. Furthermore, importation will not have the kind of significant impact on drug affordability to make this risk worthwhile.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century health system that makes affordable, high quality care accessible to all Americans. Members of HLC—hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, biotech firms, health product distributors, pharmacies, post-acute care providers, and information technology companies—are committed to advancing a consumer-centered healthcare system that values innovation, affordability, and accessibility.

HLC has provided an informed perspective on this issue throughout the sustained period in which we have seen political pressure to allow wholesale importation of prescription drugs from outside U.S. borders. Our position is shaped by a membership that includes both pharmaceutical manufacturers and healthcare payers, but also the healthcare product distributors that would be charged with facilitating movement of these imported drugs into the United States.

We have found that the promised cost savings from importation cannot be realized. When shipping, relabeling, storage, liability coverage, and other costs are factored into the economics of importation, the cost differential between medicines in this country and those that employ government price controls are largely erased. Further, as multiple Canadian authorities have pointed out, Canada is frequently faced with drug shortage challenges and simply does not have the capacity to meet its own citizens' needs as well as demand from the United States.

In Republican and Democratic presidential administrations, Health and Human Services Secretaries and FDA Commissioners have consistently attested that wholesale drug importation cannot be

implemented without unacceptable risks to the American public. Today, those risks are more acute than ever before. Policymakers should consider the following when making any final decisions regarding drug importation:

- **We already have a drug crisis in this country**, much of it fueled by the proliferation of lethal fentanyl that is originating in other countries and finding its way here through our ports and via the international mail service. Law enforcement authorities have said their resources are being stretched to the breaking point by the influx of illegal drugs. Government-authorized wholesale importation will only make law enforcement's task far more difficult.

- **It is a fallacy that drugs coming in from Canada can be assumed safe.** Today, according to the National Association of Boards of Pharmacy, there are over 35,000 online drug sellers, many of them based in Canada. More than 95 percent of these operations are in violation of applicable laws. There is no way for the FDA to guarantee that prescription drugs coming here from Canada did not originate in another country where they could have been counterfeited or adulterated.

- **We are in the midst of a global counterfeit drug crisis.** The World Health Organization has estimated that one in every 10 pharmaceutical products in low- and middle-income countries is falsified or substandard. Americans have benefited from a closed drug supply system in which manufacturing and distribution of prescription medications is approved and overseen by the FDA. Opening our borders to imported pharmaceuticals will only place Americans at greater danger from those of ill intent who see the United States as a lucrative market.

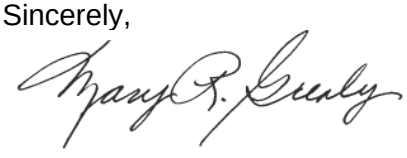
We also believe policymakers must consider the ramifications for future medical innovation should other governments' price controls be imported into the United States economy. Today, we are the world's leading developer of new treatments and therapies. Americans are living healthier, longer lives because of an environment that encourages investment in pharmaceutical research and development. Even if wholesale importation was workable, the tradeoff in reduced R&D resources and investment would be unacceptable.

As a diverse coalition of healthcare stakeholders across the U.S. healthcare system, we believe there are numerous policy actions that can have an impact on drug affordability without endangering the health and safety of the American people, including FDA reforms to bring generic medications to the market at a faster pace; modernization of federal fraud and abuse laws to enable pro-patient, value-focused collaboration among payers, providers, and manufacturers; and creating a cap on out-of-pocket drug costs in Medicare.

HLC members from all health sectors agree that treatment affordability and accessibility must continue to be health policy priorities. Opening our borders, however, to drugs of unverifiable origin at a time of increased global drug counterfeiting and trafficking of illicit substances is not an acceptable solution to achieve this goal. Allowing the importation of prescription drugs will create more problems than it solves. It is clear that this proposed rule will not lead to any significant reduction in drug costs and could, in fact, lead to additional regulatory burdens because of the complexities of trying to safely import medicines from beyond our borders.

As always, we look forward to working with the administration on measures to improve the accessibility and quality of care for all Americans.

Sincerely,



Mary R. Grealy
President