ASHP and State Affiliates Joint Comments on Importation of Prescription Drugs

Food and Drug Administration

March 9, 2020

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[Submitted electronically to www.regulations.gov (www.regulations.gov)]
Dr. Stephen Hahn, Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20903

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

Dear Commissioner Hahn: A

SHP (American Society of Health-System Pharmacists) and the undersigned state pharmacy organizations are pleased to submit comments to the Food and Drug Administration (FDA) regarding the proposed rule, "Importation of Prescription Drugs", which sets forth a framework for the wholesale importation of prescription drugs from Canada. Collectively, we represent over 55,000 pharmacists, student pharmacists, and pharmacy technicians practicing across the country in acute and ambulatory care settings.

We are committed to working with policymakers to find solutions to high drug prices. However, FDA's wholesale importation proposal would create undue risks to our drug supply chain and patients, with no guarantee of a meaningful reduction in drug costs. There is scant evidence that importation will meaningfully impact the price of prescription drugs available to U.S. consumers, but ample evidence that it presents a clear threat to the security of our nation's drug supply. Under the law, importation cannot proceed unless the Secretary certifies to Congress that importation will "pose no additional risk to the public's health and safety" and will "result in a significant reduction in the cost of covered products to the consumer." Thus, we respectfully request that FDA either withdraw the proposed rule or, barring withdrawal, refuse to approve any state importation program (SIP) that does not fully validate its cost savings estimates and demonstrate that there is will be no additional risk to public health and safety.

I. Importation is not a Viable Solution to High Drug Prices.

Importation is not a viable solution to high drug prices for two reasons – insufficient drug supply and the lack of a willing partner country. Canada's drug supply is wholly inadequate to supply the U.S. market. The U.S. demand dwarfs Canada's supply. The numbers do not add up - Canada has 37.59 million people, the United States has 327.2 million people. Florida alone has 21.3 million people. Canada's drug supply could not possibly stretch to cover excess demand from Americans, unless Canada decided to substantially increase its purchases. Should Canada decide to increase its purchases to meet new U.S. demand, it would likely only incentivize

manufacturers to increase prices to offset the reduced demand in the United States. Second, the importation proposal assumes that Canada would be a willing partner to such an arrangement. In reality, Canadian pharmacists have objected to the FDA's plan, concerned that siphoning Canadian drugs into the U.S. market would result in shortages for their own patients. Thus, it appears likely that some of the foundational requirements for a workable Canadian importation proposal – sufficient supply and a willing partner country – are not guaranteed.

II. Importation Poses Significant Safety Risks to Our Drug Supply.

Importation also poses unacceptable safety risks to our supply chain and our patients. Pharmacists and other drug supply chain stakeholders have been working for years to implement the Drug Supply Chain Security Act (DSCSA), which creates a closed supply chain to track and trace prescription drugs as they move from manufacturer to distributor to pharmacist. These same safeguards do not exist in Canada.

FDA's proposed rule creates a patchwork of interim supply chain measures that introduce gaps and loopholes in the supply chain as drugs are distributed from Canada into the U.S. For example, the largest wholesalers have indicated that they do not intend to participate in SIPs. As a result, SIPs would need to rely on relatively unknown, inexperienced, or new wholesaler market entrants that may not have the requisite resources to safely implement an importation program. The emergence of new players could also complicate U.S. efforts to identify and crack down on any attempts to fraudulently import counterfeit or adulterated drugs. In particular, unlike domestic drugs with full transaction histories, drugs imported from Canada will have only a partial transaction history, potentially making it easier for counterfeit drugs to be introduced into our system. Under DSCSA, pharmacists are charged with identifying suspect and illegitimate product, and imported products, which may have incomplete transaction histories, are likely to fall into this category. Not only does this create additional burden for pharmacies, it could create bottlenecks in the supply chain and slow the availability of drugs to patients.

Further, intertwining our supply chain with another country's without adequate safeguards presents serious risks. The recent spate of nitrosamine-related recalls vividly illustrates the complexity of the global supply chain and the potential downstream risks to U.S. consumers. Other risks include things Americans take for granted, such as child-resistant packaging – Canada's standards are markedly lower than the U.S. requirements, potentially increasing the risks of accidental poisoning. Every member of the U.S. supply chain – pharmacies, wholesalers, distributors, and manufacturers - has invested millions of dollars as well as time and effort to implementing DSCSA-compliant systems, but the proposed rule would effectively nullify much of that investment and place patients at risk.

Finally, importation may create the mistaken impression amongst patients that purchasing drugs from Canada is always safe. As a result, it may validate consumers' impulse to save money or increase convenience by purchasing drugs directly from websites purporting to sell Canadian drugs. Research indicates that the vast majority of these pharmacies claiming to offer "Canadian drugs" are selling drugs that have never actually entered the Canadian supply chain. Thus, the drugs sold are not subject to oversight by Health Canada nor will they be vetted by the FDA, making it much more likely that they are counterfeit, adulterated, or otherwise unsafe for patients. Drugs purchased online create yet another new hazard to our supply chain – unlike drugs imported through SIPs, drugs purchased by individuals are not subject to DSCSA, making them almost impossible to trace.

III. Importation Is Unlikely to Deliver Promised Cost Savings.

Importation is also unlikely to deliver cost savings that justify the inherent risk it poses to the U.S. supply chain. FDA does not provide an estimate of potential savings in the proposed rule, instead citing older studies that indicate importation is unlikely to generate significant savings. Similarly, two recent state analyses of potential savings - Vermont and Florida - do not project cost savings in amounts sufficient to justify risking the security of our national supply chain.

- The Vermont analysis suggests that, at best, an importation program would result in savings for $1 – 5 million annually. The analysis was completed well before FDA's proposal was published, so it may not have included high-cost drugs that would be excluded from SIPs. However, even if the full savings were realized, when extrapolated across Vermont's population, the savings would amount to about $4 per person – about the price of a cup of coffee. This amount seems insufficient to meet the "significant reduction" test laid out in 21 U.S.C. § 384l(1)(B) and certainly does not rise to a level that justifies compromising patient safety.
- Florida's "concept paper" makes its estimates of a $150 million cost savings based on a 45% markup to the Canadian drug price to cover the costs of relabeling, repacking, testing, etc. However, they acknowledge that the given the "uncertainty of negotiations" the importation costs could deviate substantially. Florida's concept paper is also very data light – while there is a table showing savings for a sample of drugs, there are no numbers to back up the 45% markup figure or to justify their extrapolation of $150 million in annual cost savings. This type of back-of-a-napkin cost analysis lacks the rigor necessary to validate meaningful cost savings that would support importation. We urge the agency not to approve any SIP without a thorough cost analysis, including hard data supporting markup estimates and cost savings estimates. Florida does provide savings estimate for a subset of HIV/AIDS drugs, but that table indicates savings (using the 45% markup for importation costs) of approximately $20 million – less than $1 per Florida resident. Again, despite our desire to see reduced drug costs, we do not believe that such minimal amounts justify short-circuiting the safety requirements that protect the American drug supply.

At present, wholesale importation is only appropriate to mitigate drug shortages. In shortage situations, FDA oversees importation from start to finish. Even though importation to mitigate shortages is time-limited and involves one drug at a time, the process is extremely resource-intensive for the agency. We struggle to understand how the SIPs, which would be magnitudes larger than FDA's shortage importation program, but with less intensive agency oversight, would be safer or more cost-effective.

IV. Policymakers Should Pursue Solutions That Do Not Pose Safety Risks.

Rather than waste time and resources on a policy proposal that may create more problems than it solves, we urge policymakers to focus on meaningful drug pricing solutions such as increasing the availability of low-cost generic medications and ending the perverse system of manufacturer rebates to insurers that keep drug prices high at the expense of patients. Although we recognize that FDA has limited control over drug pricing, we would urge policymakers generally to shift away from flashy policies with limited efficacy, such as importation, to focus more substantive policy options, including drug pricing solutions focused on the following areas:

- *Risk Evaluation and Mitigation Strategies (REMS):* We oppose the manipulation of the regulatory process to artificially inflate drug prices and/or interfere with the professional practice of pharmacists, physicians, nurses, and other providers. Some manufacturers use REMS programs to impose unnecessary restricted distribution networks in order to reduce competition rather than to protect patient health and safety. Specifically, manufacturers have used unnecessary REMS restricted distribution programs to prevent competitors from acquiring sufficient drug product to conduct the testing required to bring new generics to

market. REMS restricted distribution networks have also been a means to cut down on competition between providers by steering patients to certain providers. Keeping competitors out of the market keeps prices high. We have requested that Congress require the Food and Drug Administration (FDA) to investigate the use of REMS restricted distribution programs to artificially increase drug prices and limit access to critical medications.

- *Strengthening the Supply Chain:* We urge adoption and implementation of policies that strengthen the overall generic supply chain in order to prevent shortages and related price spikes. In 2017 and 2018, healthcare providers faced shortages of basic generic products such as sterile water, small-volume parenterals, injectable opioids, and sodium bicarbonate. Shortages jeopardize patient safety and siphon clinician resources away from direct patient care to shortage management, resulting in significant systemic costs, including increased prices. We request that policymakers consider means to incentivize generic competition and manufacturing upgrades to reduce and eventually eliminate shortages.
- *Generic and Biosimilar Competition:* We support efforts to enhance generic and biosimilar development and access. ASHP supports efforts to combat manufacturer tactics such as "pay-for-delay" and "evergreening" that stifle generic and biosimilar entry into the market.

Given the risks presented by the proposed rule and likelihood that it will not meaningfully reduce drug prices, we urge FDA to withdraw the proposed rule. Barring that, the agency should not approve any SIP that cannot produce hard data to back up its importation cost and cost savings estimates and demonstrate that its SIP poses no additional risk to public health and safety. All SIP proposals, including cost savings data and estimates, should be made publicly available to ensure full scrutiny of their potential impact on public health and safety. We remain committed to working with the agency and policymakers to identify and implement solutions that reduce prescription drug costs without threatening the safety and security of the U.S. drug supply chain. Please do not hesitate to let us know if we can assist the agency in any way with these efforts.

Sincerely,

American Society of Health-System Pharmacists
Alabama Society of Health-System Pharmacists
Alaska Pharmacists Association
Arizona Pharmacy Association
Arkansas Association of Health-System Pharmacists
Avera Health
California Society of Health-System Pharmacists
Colorado Pharmacists Society
Connecticut Society of Health-System Pharmacists
Florida Society of Health-System Pharmacists
Georgia Society of Health-System Pharmacists
Illinois Council of Health-System Pharmacists
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