March 9, 2020

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Re: Importation of Prescription Drugs Proposed Rule.

Dear Sir or Madam:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) on its *Importation of Prescription Drugs Proposed Rule*. NCPA represents America's community pharmacists, including 21,000 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care settings.[1] Together, our members represent a $76 billion healthcare marketplace, employ approximately 250,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA submits these comments on behalf of both community and long-term care independent pharmacies.

Today's debate over the rising cost of prescription medications has led some policymakers to consider proposals that would allow for the importation of drugs from foreign countries by either consumers, pharmacies, or other stakeholders. As we thoughtfully consider this proposal to lower prescription drug costs and impacts on community pharmacies and the patients we serve, we have concerns about unintended consequences that could rise from importation such as insufficient supply in Canada; patient safety; the possibility of standards lower than those established by the *Drug Supply Chain Security Act*; disappointing cost savings that fail to deliver on the hope for better patient access; and the lost opportunity for patient counseling to enhance medication adherence. **NCPA urges FDA to not approve any state importation program (SIP) that cannot offer meaningful evidence to back up importation cost savings estimates and demonstrate its SIP would not pose additional risks to health and safety. NCPA asks that FDA withdraw the Importation Proposed Rule, or at the very least, ensure several minimum requirements for independent community pharmacies are met.** Please find *NCPA's Minimum Requirements Regarding Importation Policy Proposals* listed in the attachment to our comments.

[1] *2019 NCPA Digest*.

100 Daingerfield Road
Alexandria, VA 22314-2888
(703) 683-8200 PHONE
(703) 683-3619 FAX

Canada does not have sufficient drug supply to fill America's needs.

Canada has expressed that it fears drug shortages and higher prices of its own, and its supply is wholly insufficient to provide drugs for the U.S. market. The Alliance for Safe Online Pharmacies (ASOP) Canada stated the following, "Canadians are sympathetic to the struggles that our American neighbors face in accessing affordable medicine but importing prescription drugs from Canada is not a safe solution. Our drug supply is meant for Canadian citizens, not a country with a population 10 times our size. Canada already faces shortages for a range of life-saving diabetes, cancer and other medicines."[2] Canada has a population of 36 million people, while just four states in the U.S. that have passed importation legislation (Florida, Vermont, Maine, and Colorado) combined have 29 million people. Even if Canada did decide to accommodate U.S. demand, it would likely incentivize manufacturers to increase prices to offset the decreased demand in the U.S. market. Because Canadian pharmacists have openly objected to engaging in an importation plan with the U.S. due to its own risk of drug shortages and patient safety, this proposal is not practically workable.

Importation poses unacceptable safety risks to our supply chain and our patients.

1. Drug Supply Chain Security Act (DSCSA) track and trace safeguards do not exist in Canada.

Importation poses heightened risks to our drug supply chain and our patients. Pharmacists and other healthcare practitioners have spent considerable time and resources ensuring compliance with 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 standards do not exist in Canada. Intertwining our supply chain with another country's without adequate safeguards, such as those presented in the DSCSA, presents serious risks. In addition, the proposed rule would effectively nullify much of the investment pharmacies, wholesalers, distributors, and manufacturers have made to implement DSCSA-compliant systems, and place patients at risk.

NCPA recommends, at the very least, that any importation program require such product that is acquired from a foreign wholesaler or manufacturer to comply with U.S. federal labeling and quality requirements. For example, the product must comply with the DSCSA in that the product must have the unique product identifier and trading partners must provide traceability data.

2. It is questionable whether wholesalers will participate in SIPs.

FDA's proposed rule creates gaps in the supply chain as drugs are distributed from Canada into the U.S. market. For example, it is questionable whether the largest wholesalers will participate in SIPs. In that case, SIPs would need to depend on comparatively unknown or new wholesaler entrants that may not have the essential resources or experience to safely implement an importation program.

[2] ASOP Canada Statement on Proposed Regulations to Import Prescription Medicines from Canada (Dec. 18, 2019), *available at* https://buysaferx.pharmacy/canada-statement-importation/.

3. 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.

Because drugs imported from Canada will not have full transaction histories like those in the U.S., there is a higher risk for counterfeit drugs to be introduced into our supply chain. Under the DSCSA, pharmacists have the duty to identify suspect and illegitimate products. Imported products that may have incomplete transaction histories could likely fall into this category of suspect or illegitimate products. Not only does this create additional burdens for pharmacies, it could slow the availability of drugs to patients.

4. Assignment of multiple National Drug Codes (NDCs) for the same product for the purposes for importation as proposed by the FDA is concerning.

The National Council for Prescription Drug Programs (NCPDP) monitors the supply of available NDCs and has noted that the availability of unused NDCs will run out in about 8 to 10 years at the current rate. Assignment of a different US NDC number to these imported products could adversely affect the run-down rate on currently available NDCs in the US. In addition, multiple NDCs for the same product may cause patient confusion and safety at the pharmacy counter. Any SIP would need to be clear in how pharmacy systems should identify the NDC to use for dispensing and billing. The NDC is key to pharmacy systems and provides the pharmacist with access to Drug Utilization Review, adverse events, and essential product specific information that can be communicated to the patient. Due to these concerns with multiple NDCs, NCPA recommends that the FDA work more closely with NCPDP on implementing multiple NDCs for the same product if SIPs are finalized.

Importation is unlikely to deliver cost savings that justify the inherent risk it poses to the U.S. supply chain.

In the Importation Proposed Rule, FDA does not provide an estimate of potential savings, instead citing older studies that indicate importation is unlikely to generate significant savings.[3] In addition, two recent state analyses of potential savings, Vermont and Florida, do not project cost savings in amounts enough to justify risking the security of our national supply chain. The Vermont analysis suggests that an importation program could result in savings of $1 – 5 million annually. The analysis was completed before FDA's proposal was published, so it may not have included high-cost drugs that would be excluded from SIPs. 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. [4] However, they

[3] FDA Importation Proposed Rule, p. 10 – "As we lack information about the expected scale or scope of such programs, we are unable to estimate how they may affect the US markets for prescription drugs. In particular, we are unable to estimate the volume or value of drugs that may be imported under SIPs or the savings to U.S. consumers who may participate in such programs."

[4] *See* Florida's Canadian Prescription Drug Importation Concept Paper, https://ahca.myflorida.com/executive/communications/requested_documents/Florida_Canadian_Prescription_Drug_Importation_Concept_Paper.pdf (Aug. 20, 2019).

acknowledge that given the "uncertainty of negotiations" the importation costs could deviate substantially. Therefore, although we support reduced drug costs, we do not believe that minimal and uncertain savings predictions justify circumventing the safety requirements that protect the U.S. drug supply chain.

To achieve FDA's goal of reducing drug prices, instead of importation, FDA should work with other federal agencies to more closely regulate Pharmacy Benefit Managers (PBMs).

NCPA is concerned about the costs of prescription drugs and in particular, the role of pharmacy benefit managers which are ostensibly hired to manage prescription drug costs but who claim no fiduciary responsibility. PBMs contribute to the higher costs of prescription drugs by exerting undue control over prescription drug benefit designs that restrict patient access to the pharmacy of their choice, set arbitrary patient cost sharing amounts, and ultimately determine patient access to certain medications. Consumer access to affordable, safe prescription drugs and the pharmacy of their choice are vital to improved health and economic outcomes. Therefore, we recommend that FDA work with other federal healthcare agencies to better regulate PBMs in the industry wide effort to control drug pricing.

Conclusion

NCPA greatly appreciates the opportunity to share with you our comments and suggestions on FDA's Importation of Prescription Drugs Proposed Rule. NCPA urges FDA to withdraw the Importation Proposed Rule, or at the very least, ensure the attached *NCPA's Minimum Requirements Regarding Importation Policy Proposals* are met. Please find these minimum requirements attached to our comments.

Sincerely,

Ronna B. Hauser, PharmD
Vice President, Policy & Government Affairs Operations
National Community Pharmacists Association

NCPA's Minimum Requirements Regarding Importation Policy Proposals

NCPA opposes any importation proposals that do not meet the following Minimum Requirements for independent community pharmacies:

1. An importation program shall permit small business community pharmacies to acquire prescription drug product from a foreign wholesaler or manufacturer at competitive prices not currently available in today's U.S. supply chain.

2. In allowing such acquisition of prescription drug product, an importation program shall require such product that is acquired from a foreign wholesaler or manufacturer to be in compliance with U.S. federal labeling and quality requirements. For example, the product must be in compliance with the *Drug Supply Chain Security Act* (DSCSA) in that the product must have the unique product identifier and trading partners must provide traceability data.

3. Given the importance of DSCSA-compliant distribution channels, an importation program shall not permit consumers from acquiring prescription drug product from a foreign entity.

4. Given the vast benefits of brick and mortar pharmacies to promote patient's medication adherence and combat product waste, an importation program shall utilize the existing structure of the U.S. pharmaceutical supply chain to dispense prescription drug products.

5. Any importation program shall be a closed system, whereby a state (or federal government), maintains regulatory administration of such program.

6. An importation program shall not impose additional financial burden on small business community pharmacies. For example, product labeling under the DSCSA is the sole responsibility of upstream trading partners, not the dispenser.

7. An importation program shall promote wide access to prescription drug product and also promote consumer choice of where to purchase such prescription drug product at the pharmacy level.

8. An importation program shall not subject small business community pharmacies to onerous accreditation and licensing requirements outside of those requirements already currently enumerated by state and federal law.

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