



North Carolina Association of Pharmacists
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Dockets Management Staff (HFA-305)
Food and Drug Administration\
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA- 2019-N-5711 for “Importation of Prescription Drugs.”
[Submitted electronically to www.regulations.gov]

The North Carolina Association of Pharmacists (NCAP) respectfully submits these comments on the Food and Drug Administration’s (“FDA”) proposed rule regarding wholesale importation of prescription drugs from Canada.

Improving medication affordability is key priority for NCAP. We support policy solutions that reduce drug costs without imposing new health or safety risks. Unfortunately, the 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 little evidence that importation will meaningfully impact the price of prescription drugs available to U.S. consumers, but there is much evidence demonstrating that importation 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.”¹ 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.

Importation is not a viable solution to high drug prices for two reasons:

- Insufficient Drug Supply: Canada’s drug supply is wholly insufficient 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. North Carolina, alone, has 10.5 million citizens and many of our communities are some of the fastest growing retirement areas, which is important since, older adults use a disproportionate amount of prescription medications. 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.
- Lack of Partner Country Buy-In: FDA’s 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.² 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.

Furthermore, importation 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 Section 804 Importation Programs (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.

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.³ Similarly, two recent state analyses of potential savings - Vermont⁴ and Florida⁵ - do not project cost savings in amounts sufficient to justify risking the security of our national supply chain.

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.

² See, e.g., Alison Martell, “Canada Warns U.S. Against Drug Import Plans, Citing Shortage Concerns” (July 18, 2019), available at <https://www.reuters.com/article/us-canada-pharmaceuticals-exports-exclus/exclusive-canada-warns-us-against-drug-import-plans-citing-shortage-concerns-idUSKCN1UD2LN>.

³ FDA, *Importation of Prescription Drugs*, 84 Fed. Reg. 70798 (Dec. 23, 2019) (“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 Vermont’s Canadian Wholesale Importation Program for Prescription Drugs (Oct. 2019), available at https://crain-platform-cmh-assets.s3.amazonaws.com/assets/graphics/2019/Vermont_concept_paper_imports.pdf. The Vermont analysis suggests that, at best, an importation program would result in savings for \$1 – 5 million annually. 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.

⁵ Florida’s Canadian Prescription Drug Importation Concept Paper, available at https://ahca.myflorida.com/executive/communications/requested_documents/Florida_Canadian_Prescription_Drug_Importation_Concept_Paper.pdf (Aug. 20, 2019). 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, repackaging, testing, etc. However, the analysis is data light and it’s unclear how the state arrived at its numbers. It does provide data 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, so it remains unclear how they arrived at the \$150 in total savings.

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, quelling the unfair business practices of pharmacy benefit managers, which generate absurd profits at the expense of patients and small businesses, creating measures which end price gouging by manufacturers following drug shortage events, and ending the perverse system of manufacturer rebates to insurers that keep drug prices high at the expense of patients.

Thank you for the opportunity to provide feedback to FDA regarding the importation proposal. Please do not hesitate to reach out, at the contact information provided below, with questions or if we can provide any additional information. We look forward to continuing to work with FDA and other policymakers to identify and implement safe and effective drug pricing solutions.

Respectfully,



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