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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.”

Our organizations are pleased to submit these comments regarding the Food and Drug Administration’s (“FDA”) proposed rule regarding wholesale importation of prescription drugs from Canada. Collectively, we represent over 200,000 pharmacists, student pharmacists, residents and pharmacy technicians in all settings.

Each of our organizations is 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 the public’s health and safety” and will “result in a significant reduction in the cost of covered products to the consumer.”<sup>1</sup> 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.

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<sup>1</sup>21 U.S.C. § 384l(1)(A)-(B).

Importation is not a viable solution to high drug prices for several reasons. First, 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. 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.<sup>2</sup> 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 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.

Additionally, 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.<sup>3</sup> 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.

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

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<sup>2</sup> See, e.g., A. Martell, "Canada Warn U.S. Against Drug Import Plans, Citing Shortage Concerns", Reuters (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>.

<sup>3</sup> See e.g., <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine>

studies that indicate importation is unlikely to generate significant savings.<sup>4</sup> 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.<sup>5</sup> 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 approximately \$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, repackaging, testing, etc.<sup>6</sup> 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.

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

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<sup>4</sup> 84 Fed. Reg. 70798 (Dec. 23, 2013) (Stating that “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.”).

<sup>5</sup> See “Vermont’s Canadian Wholesale Importation Program for Prescription Drugs,” October 2019, available at <https://nashp.org/wp-content/uploads/2019/12/vt-submittal-to-omb-12-3-2019.pdf>.

<sup>6</sup> See “Florida’s Canadian Prescription Drug Importation Concept Paper” (Aug. 20, 2019), available at [https://ahca.myflorida.com/executive/communications/requested\\_documents/Florida\\_Canadian\\_Prescription\\_Drug\\_Importation\\_Concept\\_Paper.pdf](https://ahca.myflorida.com/executive/communications/requested_documents/Florida_Canadian_Prescription_Drug_Importation_Concept_Paper.pdf).

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,

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