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June 25, 2019

Ms. Crystal Demott
Procurement Director
Agency for Health Care Administration
2727 Mahan Drive
Tallahassee, FL 32308

Submitted via email: Solicitation.questions@ahca.myflorida.com

RE: Request for Information – Canadian Drug Importation Program

Dear Ms. Demott:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on the Agency for Health Care Administration (AHCA) Request for Information 003-18/19. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.

Statement of Interest in the Services Outlined in RFI

As the trade association representing 35 of the world's leading biopharmaceutical companies, we have a unique understanding of the pharmaceutical supply chain and threats to its security. As

an organization dedicated to patient safety, we have serious concerns with the implementation of House Bill 19, which requires the state to submit a request for certification of a Canadian importation program, to the U.S Secretary of Health and Human Services. Federal law (21 U.S.C. § 384) states:

> **(1) Commencement of program** This section [regarding importation of prescription drugs] shall become effective only if the Secretary certifies to the Congress that the implementation of this section will—
>
> **(A)** pose no additional risk to the public's health and safety; and
>
> **(B)** result in a significant reduction in the cost of covered products to the American consumer.

There is no authority for certification of a state importation program under 21 USC 384. Additionally, the requirements of both the federal law and HB 19 make it highly unlikely that any vendor (and therefore AHCA and the state) will successfully craft a program that guarantees both no additional risk to public health and a significant cost savings to Floridian consumers. The following comments summarize items that must be considered to accurately assess program impact on health and safety, as well as program net costs.

Risk to Public Health and Safety

It is unlikely Canada would be able or willing to supply Florida with medicines they regulate for a number of reasons. The population of Canada is approximately 37 million, and the population of Florida alone is approximately 21 million. It is impossible for the Canadian supply chain to accommodate Florida's prescription drug needs. Canada negotiates its drug prices with manufacturers at a national and provincial level for drugs dispensed to Canadians. There is no reason to believe that Canada will place the needs of Florida residents over the needs of Canadians and renegotiate their contracts to accommodate Florida's request. In addition, Canada has suffered from drug shortages in recent years and is unlikely to place its citizens at further shortage risk by assuming responsibility for a portion of the U.S. market as well.[i]

Notably, Canadian officials have long stated they do not have the resources to regulate medicines diverted to the United States market. Former Health Canada Secretary Leona Aglukkaq stated in 2017, "Absent a major policy shift here in Canada, if bulk Canada-U.S. drug shipments were to become a reality, Americans could receive uncertified, uninspected, third-party drugs. Canada inspects drugs for its own citizens; Canadian authorities wouldn't have the ability or resources to inspect medicines destined for the United States."

If Florida's intent is to limit imported medicines to those originally regulated by Health Canada, all interested vendors should be required to show evidence of a Canadian supplier's willingness to certify they will only export such drugs to Florida's program. If vendor candidates are unable to make this certification, AHCA will have to assess a health and safety impact based on the assumption that imported medicines will be transshipped or regulated by countries other than Canada. Moreover, HB 19 requires that wholesale importation of drugs from Canada be limited to FDA-approved drugs. All interested venders should be required to additionally establish that such drugs are also FDA-approved.

It is also important for any vendor applicant to detail the assurances received from Canadian authorities regarding exports of their drug supply and what, if any, responsibility the country assumes for the prescription drugs exported through the program.

Transshipment and Counterfeit Medicines

Drugs entering Florida through Canada could be transshipped from almost any country, which increases the likelihood of not only the mishandling of drugs (e.g., through temperature/humidity variations and contamination), but also counterfeiting, mistakes in repackaging, and deceptive packaging and relabeling practices. Canadian law does not prohibit the transshipment of drugs from any country – including those in the developing world – into Canada and then into the U.S. As the U.S. Health and Human Services Task Force on Prescription Drug Importation found, "most countries impose a lesser level of regulation on products that are merely transshipped through their country."[ii] As such, vendor candidates should be required to include an assessment comparing the safety and security of foreign regulatory systems to the United States Food and Drug Administration's (FDA's) regulatory system to protect medicines manufactured for the United States. Absent such an assessment, AHCA will not be able to determine whether the health and safety of Floridians is worse off than it would be absent an importation program.

In March 2017, a bipartisan group of four former FDA Commissioners sent a letter to Congress opposing importation from Canada. Among their reasons for opposition, the Commissioners cited serious risks to patients and consumers and an increased likelihood that drugs purchased from foreign countries may be substandard, unsafe, adulterated, or fake. The letter further stated the FDA lacks the resources needed to oversee an importation program.[iii]

In 2018, HHS Secretary Azar stated, "the last four FDA commissioners have said there is no effective way to ensure drugs coming from Canada really are coming from Canada, rather than being routed from, say, a counterfeit factory in China. The United States has the safest regulatory system in the world. The last thing we need is open borders for unsafe drugs in search of savings that cannot be safely achieved. You can't improve competition and choice in our drug markets with gimmicks like these."[iv] The proposed importation program is targeted at lowering the state's costs for covering many vulnerable populations. The inherent dangers of an open supply chain not only put individuals at risk but could have the unintended consequences of exacerbating the costs of treatment due to increased hospitalizations, emergency room visits, and other health conditions associated with consumption of an adulterated medicine.

Importation also enables criminals to profit through transshipment. A report by former FBI Director Louis Freeh found that "drug importation would increase financial incentives for individuals and criminal organizations to transship products through Canada that are likely to be counterfeit, diverted, adulterated, sub-standard and/or other non-FDA-approved products."[v] Respondents to the RFI should be required to include an analysis, including input from law enforcement, on the potential impact an importation program may have on Florida's illicit drug trade. Such an analysis is critical when determining whether a program will meet federal safety standards for certification.

HB 19 requires the state and the vendor to ensure the safety and authenticity of drugs imported through the program. As such, vendor RFI responses should include a description of how the state or entities with whom the vendor contracts will be able to identify where unsafe drugs entered a foreign regulatory system before being transshipped through Canada to the Florida supply. Further, the vendor should be required to provide an explanation of how it will certify that imported drugs are not adulterated or misbranded, and an attestation that there will be no increase in the number of suspect shipments in need of inspection, should an importation program be implemented.

Significant Cost Savings to American Consumers Unlikely

The importation program must also show significant cost savings to consumers, and the vendor is required by law to identify the list of drugs that will achieve a significant cost savings for the state. In accordance with HB 19, those eligible to receive medications through the proposed Florida Canadian Importation Program are residents who receive their health benefit through one of the following government-funded entities:

- County health department or free clinic
- Medicaid
- Department of Corrections
- State-owned and operated developmental disabilities center
- State-owned and operated treatment facility

As such, the state will be hard-pressed to argue any significant reduction in costs to the individuals who are eligible to participate in the proposed program, as they personally pay little or nothing for their prescription drugs. It is unclear if the State will experience any significant savings as it currently benefits from Medicaid Best Price, statutory Medicaid rebates, supplemental Medicaid rebates, Medicaid inflation rebates, Federal Medical Assistance Percentages (FMAP), 340B discounts, and numerous other negotiated discounts. Florida is well-recognized for highly-effective purchasing and negotiating power. Pharmaceutical manufacturers rebate $1.7 billion to Florida and the federal government each year, and only 5.7% of the Medicaid budget is spent on retail brand and generic prescription drugs.[vi] Moreover, drug-specific Medicaid rebate information is confidential under federal law and thus unavailable to any vendor applicant.

In the much smaller state of Vermont, with a population just over 623,000, the Department of Vermont Health Access determined that, "drug importation from Canada would not provide net savings to the state or individuals because Medicaid's existing prescription drug rebate program already yields substantial savings."[vii] Vermont estimated 0.3 – 1.3% savings in the private market, which comports with a Congressional Budget Office estimate that a national importation scheme would reduce prescription drug expenditures in the U.S. by just one percent.[viii]

Vermont estimated a 45% markup on the Canadian price of a drug just to cover extra costs to the supply chain as well as a profit margin for supply chain entities. The Vermont estimate is conservative, as it only estimates a 25% markup for additional costs borne by voluntary participants in the program's supply chain. As we detail in the comments below, this estimate may not consider substantial additional costs that could be required to implement the program.

In addition, the 45% markup on the Canadian list price assumes a 20% profit along the supply chain. There is no provision in HB 19 to limit vendor, Canadian supplier, or importer profit margins, so it is likely the margins will reflect what the market will bear.

Vermont's 45% markup did not include additional costs associated with a state importation program such as public education and costs related to state and supply chain liability. The vendor, and therefore AHCA, must consider these and a myriad of costs when making a good-faith effort to estimate the administrative and operational costs associated with implementation of the program. Detailed knowledge of all associated costs is necessary to accurately determine the cost-effectiveness of the program and to evaluate if "significant cost savings" are achieved. In the following sections we will outline several other costs that the vendor, and therefore AHCA, must factor into overall administrative and operating costs for the Program.

Start-up and Ongoing Costs

HB 19 delegates nearly all responsibility for developing and operating a Canadian importation program to an outside vendor. This includes developing the list of drugs that stand to produce the greatest cost savings for state programs. We believe it is crucial that any vendor submit the specific methodology it will employ to calculate cost savings and identify the threshold it would use to define "significant cost savings." Any potential vendor should provide a sample list of drugs that meets a defined savings threshold under its methodology for calculating savings so AHCA can estimate where its drug spend could potentially be impacted.

Repackaging and Relabeling

HB 19 requires that imported prescription drugs be labeled and packaged in accordance with FDA standards. In Vermont's analysis of program costs, they also assume repackaging and relabeling would meet FDA standards with one exception – the repackaging and relabeling would be done before drugs come into possession of the U.S. wholesaler. Vermont's report assumes the Canadian supplier would be responsible for repackaging and relabeling or would contract with a third-party to perform this activity. Therefore, any vendor respondent should include an attestation of its ability to fulfill this responsibility, while remaining in compliance with both U.S. and Canadian law. The vendor applicant should also include a comprehensive cost estimate of repackaging and relabeling drugs exported to Florida under an importation program and a detailed explanation of how it will ensure only FDA-approved medicines and dosages are imported and that all labeling and packaging is in English.

The Congressional Budget Office has issued estimates of the cost to comply with FDA repackaging and relabeling requirements for a national importation program and found such costs to be significant. Under the assumption used in the Vermont report, costs to repackage and relabel imported medications would be borne by the entity performing this task (Canadian supplier or third-party contractor). The FDA has estimated that this requirement could raise the cost of prescription drugs by as much as $2 billion in the first year for a US-wide importation program.[ix] For state-only importation programs, the costs would be proportionately smaller depending on the volume of drugs subject to repackaging and relabeling requirements.

Given the significant cost that could be affiliated with the repackaging and relabeling requirement, any vendor response should include a detailed analysis of costs to perform this function, in addition to any liability costs that may result from insufficiencies in the repackaging

and relabeling process. As was stated, Vermont's report assumed a 25% markup on the Canadian list price of a drug, to account for costs borne by the supply chain. It is imperative that a comprehensive analysis of repackaging and relabeling costs be included in a vendor response to ensure the overall Canadian markup estimate is accurate. In addition, per the comments below regarding the need to ensure that patients are aware that they are consuming drugs dispensed through the importation program rather that the FDA's regular closed supply system, any vendor response should account for the cost of indicating that the product has been relabeled for import into the United States.

Compliance with Federal Law and State Law

HB 19 requires the vendor to ensure the safety and quality of the drugs imported under the program by sampling and testing in a manner consistent with federal law. In 2013, the federal government passed the Drug Supply Chain and Security Act (DSCSA), which requires tracking and tracing of drugs from the pharmacy all the way back to the manufacturer to create a closed drug distribution system, partly in response to an influx of counterfeit cancer medications.[x] Specifically, the DSCSA requires that manufacturers affix a product identifier to all products intended for sale in the U.S. Downstream trading partners are similarly required to transact in only serialized product. This product identifier is then incorporated into the transaction information about the product and forms a key element of suspect product verification. Foreign entities importing drugs into the U.S. will lack the ability to transact in serialized product.[xi] HB 19 requires a vendor to contract with certain pharmacists or wholesalers to import medications under the importation program, but the Healthcare Distribution Alliance (HDA), the association for primary pharmaceutical distributors in the United States, opposes state importation programs and has stated, "Drugs that are sold or designated for sale in Canada as well as other countries do not conform with these U.S. traceability regulations, it would be a violation of federal law for any wholesaler or other trading partner to accept or distribute product within the U.S. that do not meet these standards."[xii] Given the requirements of the DSCSA, imported drugs would require proper serialization. It is unclear how transshipped medicines could be appropriately serialized, as they were not originally manufactured for the U.S. supply, at the manufacturing facility of origin. This unanswered question should be addressed in any vendor's response.

Additionally, the Vermont analysis assumes batch testing for safety and authenticity verification will be conducted by federally recognized labs and that such labs will be accredited by a nationally and internationally recognized accreditation entity. Given this assumption, vendor applicants should include the names of accredited labs willing to assume the role of spot checking drug shipments imported through the program. Vendor respondents should also include an estimate of costs for performing spot checks and a description of any reason testing protocols for drugs transshipped for Florida's program need to exceed those required for FDA approved drugs.

Law Enforcement Costs

In July 2017, the National Sheriffs Association approved a resolution opposing state importation legislation because such programs would "jeopardize law enforcement's ability to protect the public health, threaten the safety of our (US) drug supply, and endanger law enforcement

officers, their canines, and other first responders."[xiii] As former FBI director Louis J. Freeh recently wrote, "the sheer strain that legalized drug importation would have on law enforcement agencies cannot go unappreciated… [W]e've also been faced with resource and budget challenges that force us to do more with less. Rolling the dice on a drug importation law would undoubtedly take resources away from other important law enforcement efforts."[xiv]

Aside from the additional costs associated with potential increased illegal activity, a vendor applicant must also factor in costs associated with ensuring that any medicines in the program are not sold across state lines.

Public and Stakeholder Education

While not explicitly required in HB 19, it is likely that a statewide program requiring voluntary participation from supply chain entities and consumers would require training and education. Given the potential for significant costs to perform necessary education and training related to an importation program, vendor applicants should include cost estimates of such efforts and examples of the type of initial and ongoing training that may be required for supply chain entities. For example, HB 19 requires the list of drugs eligible or importation to be updated every three months. As such, there may be ongoing training required for participating pharmacies that have to manage "left over" inventory of an imported drug that is no longer eligible to be dispensed under the program.

Consumers should also have transparency related to drugs they are dispensed through the program, and any risks affiliated with taking an imported drug, as opposed to a drug intended for U.S. domestic supply. Additionally, consumers will need to know if the imported drug they are taking is being pulled from the list of drugs under the program and whether that will impact their access to a non-imported drug. Potential vendors should include a detailed plan for a state-wide consumer education and the initial and ongoing costs for implementation of that plan.

These are just a few of the factors that must be considered when determining total costs and savings. There are additional factors beyond a state's control relating to legal, international, and federal policies that could impact the calculation of costs.

In closing, we urge AHCA to contemplate any vendor application with utmost thoroughness due to the high stakes involved in the importation of prescription drugs. We also strongly encourage AHCA to make public the criteria it intends to use to judge an applicant's ability to create and implement the program, protect public safety, provide significant cost savings, prove solvency, promote transparency, and assume liability.

We appreciate the department's consideration of our comments. Please do not hesitate to contact me at 202-835-3400 with questions or concerns.

Sincerely,

Kristin Parde

Kristin Parde

[i] https://www.drugshortagescanada.ca/
[ii] HHS Task Force on Drug Importation, Report on Prescription Drug Importation, at 60 (Dec. 2004).
[iii] McGinley, L. Four former FDA commissioners denounce drug importation, citing dangers to consumers. Washington Post. March 17, 2017. https://www.washingtonpost.com/news/to-your-health/wp/2017/03/17/four-former-fda-commissioners-denounce-drug-importation-citing-dangers-to-consumers/?utm_term=.7be381f7d329.
[iv] 3https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html
[v] Freeh, Sporkin, and Sullivan, LLP, and Freeh Group International Solutions, LLC, "Report on the Potential Impact of Drug Importation Proposals on U.S. Law Enforcement," June 2017.
[vi] The Menges Group analysis of FY2016 CMS 64 reports and State Drug Utilization data files.
[vii] Vermont Agency of Human Services, Report to the Vermont Legislature, "Wholesale Importation Program for Prescription Drug Legislative Report," December 31, 2018.
[viii] Congressional Budget Office, "Cost Estimate: S.1392 FTC Reauthorization Act of 2005," September 8, 2005.
[ix] CBO. "CBO Cost Estimate: The Pharmaceutical Market Access Act of 2003." 2003
[x] Hamburg, M. Former FDA Commissioner. Improving the Integrity of the Drug Supply in a Global Marketplace. April 2012. https://blogs.fda.gov/fdavoice/index.php/2012/04/improving-the-integrity-of-the-drug-supply-in-a-global-marketplace/.
[xi] https://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/drugsupplychainsecurityact/ucm376829.htm
[xii] Healthcare Distribution Alliance Opposition Letter to the Utah House Business and Labor Committee. February 21, 2019
[xiii]Drug Enforcement Administration (undated; viewed on July 25, 2017), DEA Warning to Police and Public: Fentanyl Exposure Kills, https://ndews.umd.edu/sites/ndews.umd.edu/files/DEA%20Fentanyl.pdf. Also, Drug Enforcement Administration (July 2016), supra.
[xiv] Louis J. Freeh op-ed, "Cost of drug importation could unfairly shift to law enforcement," The Philadelphia Inquirer, May 5, 2017.