Response to Colorado RFI#: UHAA 2020*13

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RFI RESPONSE 1. Would you be interested in contracting with Colorado to provide wholesale importation services from Canada? Why or why not?

Not applicable.

RFI RESPONSE 2. What factors would encourage your participation?

Not applicable.

RFI RESPONSE 3. What factors would prohibit your participation or decrease your interest in participating?

Not applicable.

RFI RESPONSE 4. Do you have locations in Canada?

Not applicable.

RFI RESPONSE 5. Do you already purchase medications from Canadian or other foreign sources?

Not applicable.

RFI RESPONSE 6. What is the breakdown by percent of your existing volume of maintenance vs specialty medications over the past 12 months?

Not applicable.

RFI RESPONSE 7. What parts of electronic track and trace requirements in the DSCSA to be required in the future have you already implemented?

Not applicable.

RFI RESPONSE 8. Do you have direct relationships with manufacturers? All manufacturers? No manufacturers? Mix of some manufacturers and other wholesalers?

Not applicable.

RFI RESPONSE 9. How would the following potential requirements influence your decision to sign up for a state program? (Please state why you are supportive or opposed to each idea)

- **Separate warehouse space for Canadian stock?**
- **Creating a separate invoice/file for Canadian drugs?**
- **Requirement to obtain a separate license from the state for importation?**
- **Equal fee schedule for all pharmacies participating in the importation program**
- **Audit of financial records to ensure "substantial cost savings" to the consumer**
- **Additional inspections by the state and potentially federal level**
- **What other requirements not listed above could be a barrier?**

Not applicable.

RFI RESPONSE 10. What payment models would work for you?

Not applicable.

RFI RESPONSE 11. Would you be reluctant to participate in a wholesale importation program from Canada out of concern that it could impact your existing contracts with drug manufacturers or expose you to risks of retaliation from opposing market actors?

Not applicable.

RFI RESPONSE 12. What other support would you need from the State of Colorado?

Not applicable.

RFI RESPONSE 13. What other information do you want to share with the State of Colorado?

PhRMA represents 35 of the world's leading biopharmaceutical companies and has 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 Senate Bill 19-005, which establishes a Canadian drug importation program pending approval by the U.S Secretary of Health and Human Services (HHS) under 21 U.S.C. § 384.

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 the federal law. Additionally, the requirements of both the federal law and Senate Bill 19-005 make it highly unlikely that any vendor (and therefore the state) could successfully craft a program that guarantees both no additional risk to public health and a significant cost-savings to Colorado consumers.

The following comments highlight some, but not all of the challenges that would likely prevent successful implementation of a Colorado program.

<u>Additional Risk to Public Health and Safety</u>

A drug importation program will create vulnerabilities in the U.S. pharmaceutical supply chain and significantly weaken the progress achieved with the enactment and implementation of the federal Drug Supply Chain and Security Act (DSCSA), creating a serious risk to public health and safety.

Canada Does Not Have the Ability or Resources to Accommodate Colorado's Program

It is unlikely Canada would be able or willing to supply Colorado with medicines they regulate. The population of Canada is approximately 37 million, and the population of Colorado, alone, is approximately 6 million. It is impossible for the Canadian supply chain to accommodate Colorado'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 Colorado residents over the needs of Canadians and renegotiate their contracts to accommodate Colorado'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 that 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[ii]."

Health and Safety Impact Must Assume Transshipment

If the state truly intends to limit imported medicines to those originally regulated and approved by Health Canada, and indeed the HHS Safe Importation Action Plan seemingly envisions "demonstration projects" for Health Canada approved drugs, it would need among other things to require interested vendors to show evidence of a Canadian supplier's willingness to certify that they will only export such drugs to Colorado's program. Any vendor applicant would need assurances 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. Such assurances are unlikely to be given as evidenced by the statements from Canadian officials cited above. Absent this evidence, which vendor candidates are unlikely to be able to produce, the Department of Health Care Policy and Financing would have to assess a health and safety impact based on the drugs shipped from Canada that are not regulated or approved by Health Canada, which would mean imported medicines that are transshipped or regulated by countries other than Canada.

Transshipment and Counterfeit Medicines

Drugs entering Colorado 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."[iii] As such, vendor candidates would need to provide the state with an assessment comparing the safety and security of foreign regulatory systems to the U.S. Food and Drug Administration's (FDA's) regulatory system to protect medicines intended for the United States. Even with such an assessment, the Department likely would not be able to determine whether the health and safety of Coloradans 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 that the FDA lacks the resources needed to oversee an importation program.[iv]

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."[v] 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 those and other 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.

Compliance with Federal Law and State Law

Colorado's law 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 manufacturer to the dispenser to create a closed drug distribution system, partly in response to an influx of counterfeit cancer medications.[vi] For each transaction of product, trading partners are required to exchange, and maintain, detailed information about the product. Moreover, the DSCSA requires that manufacturers affix a product identifier to each package and homogenous case of product intended for sale in the U.S. Downstream trading partners are required to transact in only product with a product identifier. The product identifier plays a key element in verifying "suspect product" and ensuring the supply of legitimate prescription medicines. Taken as a whole, the requirements of the DSCSA establish a closed pharmaceutical supply chain that helps ensure patient safety. SB 19-005 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."[vii] 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 must be addressed in any vendor's response.

Supply Chain Vulnerable to Criminal Element

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."[viii] Any vendor or program participant would need to conduct an analysis, including input from law enforcement, on the potential impact an importation program may have on Colorado's illicit drug trade and ways to guard against or address those impact. Even with such an analysis, there is no guarantee of safety or certainty that the program will meet federal safety standards.

Senate Bill 19-005 requires the state and the vendor to ensure the safety and authenticity of drugs imported through the program. Accordingly, any vendor must be able to demonstrate 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 Colorado supply. Further, the state would need to impose a requirement on vendors 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.

No Significant Reduction in the Cost of Covered Products to the American Consumer.

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 due to participation in a government program, as they personally pay little or nothing for their prescription drugs. It is unclear if the State itself will experience any significant savings because it currently benefits from Medicaid Best Price, statutory Medicaid rebates, supplemental Medicaid rebates, Medicaid inflation rebates, FMAP, 340B discounts, and numerous other discounts. Pharmaceutical manufacturers rebate $569M to Colorado and the federal government each year, and only 4.6% of the Medicaid budget is spent on retail brand and generic prescription drugs.[ix] 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."[x] Vermont estimated 0.3 to 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.[xi]

In the commercial market, it is important to note that savings must be seen by consumers, not payers, according to federal law. Participating commercial payers will have to determine if the costs associated with participation in the program are worthwhile considering there is limited financial incentive and a potential for significant increased administrative costs. To prove that individuals are receiving significant savings, plans will need to track many factors including prescribing patterns, changes to the drug lists, fluctuations in currency exchange rates, and change in federal, state, and Canadian and provincial laws.

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. That 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.

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 the Department, 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 the Department, must factor into overall administrative and operating costs for the Program.

Start-up and Ongoing Costs

SB 19-005 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 the state. 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 the Department can estimate where its drug spend could potentially be impacted.

Repackaging and Relabeling

SB 19-005 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 Colorado 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.[xii] 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.

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

Any statewide prescription drug program requiring voluntary participation from supply chain entities and consumers will 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, SB 19-005 requires the list of drugs eligible for 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.

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.

[i] https://www.drugshortagescanada.ca/
[ii] Letter to the Washington Post, Leona Aglukkaq, Former Minister (2008-2013), Health Canada, May 12, 2017.
[iii] HHS Task Force on Drug Importation, Report on Prescription Drug Importation, at 60 (Dec. 2004).
[iv] 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.
[v] 3https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html
[vi] 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/.
[vii] Healthcare Distribution Alliance Opposition Letter to the Utah House Business and Labor Committee. February 21, 2019
[viii] 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.
[ix] The Menges Group analysis of FY2018 CMS Financial Management Reports (FMR) and State Drug Utilization (SDU) data files.
[x] Vermont Agency of Human Services, Report to the Vermont Legislature, "Wholesale Importation Program for Prescription Drug Legislative Report," December 31, 2018.
[xi] Congressional Budget Office, "Cost Estimate: S.1392 FTC Reauthorization Act of 2005," September 8, 2005.
[xii] CBO. "CBO Cost Estimate: The Pharmaceutical Market Access Act of 2003." 2003
[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.