PhRMA
RESEARCH • PROGRESS • HOPE
950 F STREET, NW, SUITE 300 • WASHINGTON, DC 20004 • 202-835-3400 • PhRMA.org

# Memorandum

**Date:** November 4, 2019
**To:** The Honorable Hank Vaupel, House Health Policy Committee Chair
**From:** Saiza Elayda, JD, State Policy, The Pharmaceutical Research and Manufacturers of America
**Subject:** In Opposition to House Bills 4978 and 4979
**CC:** The Honorable Tommy Brann and The Honorable Steven Johnson

The Pharmaceutical Research and Manufacturers of America (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 oppose House Bills 4978 and 4979, which would seek to establish Canadian and international drug importation programs 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 implementation of this section will –
>
> **(A)** pose no additional risk to the public's health and safety; and
>
> **(B)** results 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. Further, federal law only allows for wholesale importation from Canada; wholesale importation from other foreign countries is not contemplate by 21 U.S.C. § 384. Additionally, the requirements of the federal law, HB 4978, and HB 4979 make it highly unlikely that any eligible importer (and therefore the state) could successfully craft a program that guarantees both no additional risk to public health and a significant cost savings to Michigan consumers.

Due to the U.S. Food and Drug Administration's (FDA) comprehensive drug approval process, medicines on the U.S. market are widely regarded as the safest in the world. The U.S.'s closed distribution system plays a critical role in helping to keep the global proliferation of counterfeit medicines from infiltrating the U.S. prescription medicine system. Importation programs jeopardize the integrity of our current distribution system and, as a result, the safety of Michigan consumers.

**Additional Risk to Public Health and Safety**

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.

Both HB 4978 and HB 4979 require that the importation program, established in each bill, "[does] not put a consumer at a higher health and safety risk than if the program did not exist." To date, no HHS

Secretary, who is charged with making the certification required in 21 U.S.C. § 384 to Congress before authorizing importation from Canada, has not been able to make the certification. Because the federal law only contemplates Canadian wholesale importation, the HHS Secretary would not be able to certify wholesale importation from other foreign countries.

Even if the HHS Secretary makes the required certification to Congress for a Canadian importation program, it is the FDA who is charged with promulgating rules to implement the 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.[1]

**Foreign Nations Do Not Have the Ability or Resources to Accommodate Michigan's Program**

It is unlikely Canada or any foreign nation would be able or willing to supply Michigan with medicines they regulate. For example, the population of Canada is approximately 37 million, and the population of Michigan, alone, is approximately 10 million. 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 Michigan residents over the needs of Canadians and renegotiate their contracts to accommodate Michigan'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.[2]

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[3]."

**Health and Safety Impact Must Assume Transshipment**

If the state truly intends to limit imported medicines to those originally regulated and approved by a foreign nation that can certify adherence to good manufacturing regulations for pharmaceutical products, it would need among other things to require interested eligible imports to show evidence of an international supplier's willingness to certify that they will only export such drugs to Michigan's program. Any importer applicant would need assurances from the foreign nation's 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 importer candidates are

---

[1] 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

[2] https://www.drugshortagescanada.ca/

[3] Letter to the Washington Post, Leona Aglukkaq, Former Minister (2008-2013), Health Canada, May 12, 2017.

unlikely to be able to produce, MDHHS would have to assess a health and safety impact based on the drugs shipped from a foreign nation, which would mean imported medicines that are transshipped or regulated by countries.

**Transshipment and Counterfeit Medicines**

Drugs entering Michigan through any foreign nation 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. For example, 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[4]." As such, importer candidates would need to provide the state with an assessment comparing the safety and security of foreign regulatory systems to 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 Michiganders is worse off than it would be absent an importation program.

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[5]." The proposed importation programs are 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 also 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.

**Law Enforcement's Ability to Protect Public Health Jeopardized**

Law enforcement officials have expressed concern regarding the adequacy of current resources to respond to the opioid crisis, and importation schemes would undermine their ability to keep Americans safe. In July 2017, the National Sheriffs Association approved a resolution in opposition of state importation legislation because such programs would "jeopardize law enforcement's ability to protect the public health, threaten the safety of our (U.S.) drug supply, and endanger law enforcement officers, their canines, and other first responders[6]."

Importation would overburden law enforcement, making it easier to smuggle illicit drugs into the U.S., as the volume of prescription drug packages sent through the mail or parcel services would vastly

---

[4] HHS Task Force on Drug Importation, Report on Prescription Drug Importation, at 60 (Dec. 2004).

[5] 3https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html

[6] 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).

expand. As former Federal Bureau of Investigation 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[7]."

HB 4978 and HB 4979 would severely undermine Michigan's efforts to combat the opioid epidemic. While this legislation excludes controlled substances from the list of drugs that can be imported, the high financial rewards to drug trafficking organizations are still likely to result in an increase of fentanyl entering the U.S. should the program be implemented. The Drug Enforcement Administration recently testified, "The illicit market for prescription drugs is considerable in size, which significantly increases the risk that fentanyl or fentanyl derivative-laced counterfeit pills will cause more overdoses across the nation as they are more readily produced by drug trafficking organizations." Because of its low dosage range and potency, one kilogram of fentanyl purchased in China for $3,000 to $5,000 can generate upwards of $1.5 million in revenue on the illicit market.

**Importation of prescription drugs erodes the economic and innovative impact of free trade in the U.S. pharmaceutical marketplace.**

Drug importation is contrary to the free market principles that drive America's economy and our leadership in medical innovation. Importation cedes U.S. sovereignty to the prescription drug policies of foreign governments, including government price controls effective in Canada, weakening of intellectual property protections and opaque and discriminatory pricing policies that limit patient access to the newest medicines. Michigan should not allow importation to become a back-door mechanism for incorporating such policies from Canada's or other countries' systems, which could devastate R&D investments in the discovery of new treatment and cures and threaten the 15,982 direct sector biopharmaceutical jobs in Michigan.[8]

**No Significant Reduction in Cost of Covered Products to Michiganders**

The state will be hard-pressed to argue any significant reduction in costs to the individuals who are eligible to participate in the proposed programs 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 $1.3 billion to Michigan and the federal government each year, and only 3% of the Medicaid budget is spent on retail brand and generic prescription drugs.[9] Moreover, drug-specific Medicaid rebate information is confidential under federal law and thus unavailable to any importer applicant.

---

[7] Louis J. Freeh op-ed, "Cost of drug importation could unfairly shift to law enforcement," The Philadelphia Inquirer, May 5, 2017.

[8] TEConomy Partners, The Economic Impact of the Biopharmaceutical Industry: U.S. and State Estimates. Report prepared for PhRMA in September 2019 and reflects 2017 data. https://www.phrma.org/state-map/michigan. Accessed November 2019.

[9] The Menges Group analysis of FY2018 CMS Financial Management Reports (FMR) and State Drug Utilization (SDU) data files.

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[10]." 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.[11]

In the commercial market, it is important to note that savings must be seen by consumers 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 importer, 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 importer, and therefore the Department, must factor into overall administrative and operating costs for the Program.

**Start-up and Ongoing Costs**

HB 4978 and HB 4979 require the state to develop and implement a Canadian or international importation program. This includes developing the list of drugs that stand to produce the greatest cost savings for state programs. We believe it is crucial that MDHHS should be transparent about the specific methodology it will employ to calculate cost savings and identify the threshold it would use to define "cost savings."

**Public and Stakeholder Education**

While not explicitly required in either HB 4978 or HB 4979, it is likely that a statewide program requiring voluntary participation from supply chain entities and consumers would require training and education.

---

[10] Vermont Agency of Human Services, Report to the Vermont Legislature, "Wholesale Importation Program for Prescription Drug Legislative Report," December 31, 2018.

[11] Congressional Budget Office, "Cost Estimate: S.1392 FTC Reauthorization Act of 2005," September 8, 2005.

Setting these programs up has the potential to be a significant cost to the State to perform the necessary education and training related to an importation program. For example, HB 4978 requires the list of drugs eligible or importation to be updated every three months, and HB 4979 requires the list of drugs eligible or importation to be updated every six 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.

Neither HB 4978 nor HB 4979 provide transparency to consumers 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, neither bill discloses to consumers 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.

**Label Certification and Product Testing**

HB 4978 and HB 4979 require that imported prescription drugs be labeled in accordance with FDA standards. The bills require that any eligible importer should provide to the state a "certification that the prescription drug is approved for marketing in the United States, is not unadulterated or misbranded, and meets all of the labeling requirements of 21 U.S.C. 352." Further, these bills require that an eligible importer "shall ensure that each test required [by the provision of the bill regarding authenticity and degradation] is performed at a laboratory [that the department has determined to meet the standards applicable under federal and state law governing laboratory qualifications for drug testing."

HB 4978 requires the vendor conduct the necessary tests on the products being shipped into the United States. HB 4979 requires MDHHS to ensure each batch of every shipment of a prescription drug being imported by an eligible imported is sampled and tested and allows MDHHS to enter into contractual agreements to administer this process. The cost of the ensuring the laboratories doing to testing meet applicable federal and state laws governing laboratory qualifications, the testing of the product, and contracting with eligible vendors could be a significant cost to the state, which in turn could raise the cost of prescription drugs and possibly negate any savings by the State.

These are just a few 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, the biopharmaceutical industry is committed to working with Michigan lawmakers, patients, health care providers, and other health care stakeholders to pursue policies that promote innovation and help ensure consumers have access to new medicines. We can keep consumers safe and make medicines more affordable by moving toward a health care system that focuses on results, measures value through the eyes of the patient, and enables the private sector to develop new and better ways to pay for medicines. Conversely, HB 4978 and HB 4979 put consumer safety at risk, jeopardize law enforcement's ability to protect the public, and ignores other policy options that lower patient drug costs without introducing vulnerabilities into the U.S. pharmaceutical supply chain. Therefore, PhRMA respectfully urges lawmakers to oppose HB 4978 and HB 4979.