



## Statement Regarding Governor's Bill 5018/Raised Bill 328

March 5, 2020

Discussions about the cost and affordability of medicines are important. No patient should have to worry about whether they can afford the health care they need. In 2018, Connecticut passed first-in-the-nation legislation that takes an important step toward examining and addressing cost and affordability concerns throughout the entire supply chain and PhRMA was at the table as a partner during development of that law and has remained so during its implementation.

Likewise, PhRMA has been meaningfully engaged in discussions regarding the benchmarking provisions in this legislation since last session when they first appeared. We recognize that spending on prescription drugs is an important part of the entire health care ecosystem these provisions seek to examine, and we are happy to continue to be at the table to work toward thoughtful, balanced approaches that will have a real impact for Connecticut residents. However, we have serious concerns about provisions in both of these bills that would implement a wholesale importation program for prescription drugs.

**The Pharmaceutical Research and Manufacturers of America (PhRMA) strongly opposes provisions in this legislation which establish a Wholesale Prescription Drug Importation Program ("Program") because they mischaracterize importation as a means to lower drug costs and greatly understate the inherent threats to patient safety.**

**This legislation is unlikely to produce significant cost savings and fails to recognize the additional resources needed to implement and maintain an importation program.**

On the Medicaid side, participants pay little or nothing for their prescription drugs and the state benefits directly from Medicaid Best Price, statutory Medicaid rebates, supplemental Medicaid rebates, Medicaid inflation rebates, FMAP, and numerous other discounts. In the commercial market, 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.

Given the known challenges from the start, the ongoing requirements and the unforeseeable variables ahead, it is a challenge for the Department of Consumer Protection to estimate savings. However, looking at neighboring New England states, it is clear that meaningful alternatives to lower costs for consumers at the pharmacy counter should be pursued before expending resources into a system with a failed track record.

For example, 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."<sup>1</sup> 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.<sup>ii</sup>

It is also important for a state to consider the numerous other costs associated with establishing and administering an importation program.

- *Start-up and Ongoing Costs:* This legislation assigns numerous new responsibilities on the Department including: the design of the Program, compliance with existing federal laws, including track and trace and development of a wholesale prescription drug importation list.
- *Repackaging and Relabeling:* 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. 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.<sup>iii</sup>
- *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.”<sup>iv</sup> 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.”<sup>v</sup>
- *Public and Stakeholder Education:* Any statewide prescription drug program requiring voluntary participation from supply chain entities and consumers will require training and education. The federal NPRM requires establishment and upkeep of an educational website.

**This legislation could increase the risk to consumer health and safety by weakening the closed supply chain and opening the State to increased criminal activity.**

This legislation fails to address the complexities of the federal “track and trace” system established under the Drug Supply Chain Security Act (DSCSA) and the inherent risk to public safety if it is compromised. Both this legislation and the federal Notice of Proposed Rulemaking (NPRM) on Importation of Prescription Drugs place significant responsibility on states to adhere to federal track and trace requirements and demonstrate that any importation program would pose no additional risk to public health.

In 2013, Congress unanimously enacted bipartisan legislation to address concerns of unsafe and counterfeit drugs entering the United States pharmaceutical supply chain. The DSCSA, establishes an electronic system to uniquely identify each package of drugs and trace those packages as they are distributed. Through the DSCSA and prior actions, the United States has established one of the most secure supply chains in the world and ensures proper protection of patients. Drug importation programs severely undercut the protections of the DSCSA, compromising patient safety. If Connecticut pursues an importation program, it will assume significant risk and potential cost in an effort to ensure public safety.

An importation program will also expose Connecticut to greater risk of exposure to counterfeit medications that are transshipped through Canada and the potential for increased criminal activity. Canadian government health officials have stated that they cannot guarantee products sold to U.S. citizens are safe and effective. As Diane C. Gorman, Assistant Deputy Minister of Health Canada, stated in 2004, “Health Canada does not assure that

products being sold to U.S. citizens are safe, effective, and of high quality, and does not intend to do so in the future<sup>vi</sup>.” This concern was more recently restated by Leona Aglukkaq, Canada’s Health Minister from 2008 through 2013, in a letter to the Washington Post<sup>vii</sup>. In October, the Western Sheriffs Association approved a resolution opposing state importation legislation due to concerns that, “drug importation will likely become another loophole for criminals to exploit, importing drugs that are substandard, adulterated, misbranded and even counterfeit<sup>viii</sup>.”

PhRMA shares a desire to address patient affordability within the health care system and reduce costs in the State of Connecticut. However, for the reasons stated above, we do not believe development of a drug importation program will produce the desired results and could significantly jeopardize patient safety.

*The Pharmaceutical Research and Manufacturers of America (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. Since 2000, PhRMA member companies have invested more than \$600 billion in the search for new treatments and cures, including an estimated \$71.4 billion in 2017 alone.*

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<sup>i</sup> Vermont Agency of Human Services, Report to the Vermont Legislature, “Wholesale Importation Program for Prescription Drug Legislative Report,” December 31, 2018.

<sup>ii</sup> Congressional Budget Office, “Cost Estimate: S.1392 FTC Reauthorization Act of 2005,” September 8, 2005.

<sup>iii</sup> CBO. “CBO Cost Estimate: The Pharmaceutical Market Access Act of 2003.” 2003

<sup>iv</sup> 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*.

<sup>v</sup> Louis J. Freeh op-ed, “Cost of drug importation could unfairly shift to law enforcement,” *The Philadelphia Inquirer*, May 5, 2017.

<sup>vi</sup> HHS Task Force Report citing Letter from Diane C. Gorman, Assistant Deputy Minister, Health Canada, to Richard H. Carmona, U.S. Surgeon General, pg. 60-61. June 1, 2004.

<sup>vii</sup> Letter to the Washington Post, Leona Aglukkaq, Former Minister (2008-2013), Health Canada, May 12, 2017.

<sup>viii</sup> RESOLUTION 2019 – 08. Western States Sheriffs’ Association Opposes Drug Importation Legislation. October 2019.