STATEMENT

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In Opposition to Rhode Island House Bill 5249

March 1, 2021

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) strongly opposes HB 5249, which directs the Rhode Island Executive Office of Health and Human Services, in consultation with other entities, to design a wholesale prescription drug importation program for the importation of drugs from Canada. This legislation mischaracterizes importation as a tool to lower drug costs and disregards the inherent threats to patient safety associated with drug importation.

In September 2020, the U.S. Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) issued a final rule (the Final Rule) implementing a provision of federal law allowing the commercial importation of certain prescription drugs from Canada through FDA-authorized, time-limited programs sponsored by states or Indian tribes. The Secretary concurrently offered "certification" that the program would pose no additional risk to the public's health and safety and would result in a significant reduction in the cost to the American consumer as required by law. The Final Rule provided no proof that importation programs will not provide additional risk to public health and safety or result in significant cost savings. Instead, the federal government placed the responsibility of ensuring public safety and proving significant cost savings on the states.

HB 5249 is unlikely to produce significant cost savings and fails to recognize the additional resources needed to implement and maintain an importation program.

Given the known challenges from the start, the ongoing requirements and the unforeseeable variables ahead, the Rhode Island Executive Office of Health and Human Services (the "Executive Office"), would likely arrive at the same conclusion as the Final Rule - "unable to estimate the cost savings."[i] 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."[ii] 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.[iii]

It is also important for a state to consider the numerous other costs associated with establishing and administering an importation program. The Final Rule places the onus on states to prove "significant cost savings" from a state importation program (SIP) and acknowledges that "SIP Sponsors will face costs to prepare proposals, implement authorized programs, and produce records and program reports."[iv] Extensive state resources are required for the implementation and administration of an importation program including but not limited to:

- *Start-up and Ongoing Costs:* HB5249 assigns numerous new responsibilities on the Rhode Island Executive Office including: the design of the Program, compliance with existing federal laws, including track and trace and development of a wholesale prescription drug importation list.

- *Compliance with Federal Law:* Both the Foreign Seller and the Importer, under supervision of the state, will be subject to the supply chain security requirements set forth in the Final Rule and under the federal Food, Drug & Cosmetic Act (FD&C Act).

- *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.[v]

- *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."[vi] 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."[vii]

- *Public and Stakeholder Education:* Any statewide prescription drug program requiring voluntary participation from supply chain entities and consumers will require training and education. In addition to the program, there must be a hotline to answer questions and address needs of consumers, employers, health insurance carriers, pharmacies, health care providers and others affected by the program. Both the NPRM and HB 5249 require establishment and upkeep of an educational website.

In public comments to the FDA during the rulemaking process, several states that passed importation laws expressed concern with the ability to recoup state costs, prove significant savings, achieve appropriate levels of access, and operate efficiently under the parameters outlined in the proposed rule. The Final Rule failed to address these concerns. The Colorado Joint Budget Committee approved their state's Department of Health Care Policy and Financing's FY 2020-21 recommendation to delay of the implementation of Colorado's Canadian importation program in light of budget concerns. After conducting a study on the feasibility of importation, the state of Wyoming determined in September 2020 that a state drug importation program would likely not create significant savings and would be unsustainable in the long-term.

HB5249 could increase the risk to consumer health and safety by weakening the closed supply chain and opening the State to increased criminal activity.

Opening our closed distribution system to importation would gravely compromise the integrity and safety of the U.S. prescription drug supply. Importation presents a huge opportunity for unscrupulous suppliers and/or criminal organizations to increase the flow of substandard, adulterated or counterfeit drugs – including pills laced with deadly fentanyl – into the U.S. FDA is the gold standard in ensuring the safety and effectiveness of medicines for the U.S. market and importation would have the same effect as repealing current FDA and consumer protections.

The legislation fails to acknowledge the complexities of setting up a state importation program that adequately protects public health and safety. Specifically, it fails to acknowledge the challenges associated with adherence to 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 the draft legislation and the federal Rule 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 Rhode Island pursues an importation program, it will assume significant risk and potential cost in an effort to ensure public safety.

Canadian law does not prohibit the transshipment of drugs from any country—including those in the third world—into Canada and then into the United States, heightening concerns about the safety and reliability of these medicines. The FDA determined that 85 percent of the drugs sold by supposedly Canadian pharmacies come from 27 countries other than Canada.[viii]

The Importation Final Rule raises significant legal concerns and is the subject of ongoing litigation.

On November 23, 2020, PhRMA, the Partnership for Safe Medicines (PSM), and the Council for Affordable Health Coverage (CAHC) filed a complaint in the U.S. District Court for the District of Columbia against the U.S. Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA). The litigation challenges the final rule on Importation of Prescription Drugs (Final Rule) and an associated "certification" made by Secretary Azar on the grounds that they suffer from fatal flaws, including failing to demonstrate that importation will pose no additional risk to public health and safety or will result in significant cost savings.

The complaint alleges that the Final Rule disregards key patient safety protections of the Federal Food, Drug, and Cosmetic Act (FDCA). Section 804 of the FDCA authorizes HHS in certain circumstances to permit both the importation of drugs by pharmacists and wholesalers for commercial distribution and the importation of drugs by individual patients. **Section 804 is effective, however, only if the HHS Secretary certifies to 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." Although this law was enacted nearly twenty years ago, no previous HHS Secretary has been willing to make this certification due to inability to ensure both public safety and cost reduction. The Final Rule and Secretary Azar's "certification" letter, which apply only to commercial distribution, contain conclusory statements as to safety and cost savings without supporting evidence and punt the responsibility for safety and cost savings to state governments.

In addition, there is no indication that the Final Rule will reduce costs to actual American patients. In the preamble to both the proposed and Final Rule, HHS has acknowledged that it cannot quantify the savings, if any, that would result from its rule, even classifying it as "not economically significant" for purposes of review by the Office of Management and Budget. Indeed, in the budget document released with the rule, the cost savings chart was left completely blank, suggesting cost savings could not be calculated.

Furthermore, aspects of the Final Rule are contrary to the FDCA, violate manufacturers' First Amendment rights and raise serious questions under the Fifth Amendment Takings Clause. As such, PhRMA, PSM and CAHC are asking the Court to hold unlawful, set aside and permanently enjoin implementation of the Certification and Final Rule.

In addition to the ongoing federal litigation, PhRMA, PSM, and CAHC submitted a Citizen Petition to FDA requesting that the agency refrain from authorizing Florida's Section 804 Importation Program Proposal for the Importation of Prescription Drugs from Canada (Proposal), which Florida submitted to FDA on November 23, 2020. In addition to being issued pursuant to an invalid and legally deficient certification and Final Rule, the Proposal does not adequately demonstrate that importation will pose no additional risk to public health and safety, and it fails to show that importation will lead to any reduction—let alone a significant reduction—in the cost of prescription drugs for American consumers.

State importation programs fail to recognize the challenges of the Canadian prescription drug market.

The Canadian government is not in a position to monitor and regulate medicines that are intended for the U.S. market. Canada's former Health Minister Leona Aglukkaq said, "Canada inspects drugs for its own citizens; Canadian authorities wouldn't have the ability or resources to inspect medicines destined for the United States."[ix] Therefore, the financial and practical burden would fall to U.S. authorities and local law enforcement. Kirsten Hillman, acting Ambassador to the United States, stated that "the Canadian market is too small to have a real impact on U.S. drug prices. The U.S. consumes 44% of the global prescription drug supply, compared to Canada's 2%," and that "Canada's priority is to ensure a steady and solid supply of medications at affordable prices for Canadians."[x]

In November 2020, Health Canada issued an Interim Order stating that the distribution of certain medicines intended for the Canadian market outside of Canada is prohibited if the distribution would cause or exacerbate a shortage of the medicines in Canada. To date, no state that has submitted an application to FDA to sponsor a state importation program has secured the required foreign seller from Canada to facilitate importation.

PhRMA shares a desire to address patient affordability within the health care system and reduce consumer costs in the State of Rhode Island. 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.

<u>For these reasons, we urge legislators to vote no on HB 5249.</u>

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 $1Trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone.

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[i] FDA Final –Importation of Prescription Drugs. November 30, 2020. https://www.fda.gov/media/142408/download

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

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

[iv] https://www.hhs.gov/sites/default/files/importation-final-rule.pdf

[v] CBO. "CBO Cost Estimate: The Pharmaceutical Market Access Act of 2003." 2003

[vi] 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.

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

[viii] FDA. "FDA Operation Reveals Many Drugs Promoted as "Canadian" Products Really Originate From Other Countries." December 2005

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

[x] Statement from Canada's Acting Ambassador to the United States on U.S. Importation of Pharmaceutical Drugs from Canada, December 18, 2019