STATEMENT

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In Opposition to House Bill 5853 (Tanzi)
March 5, 2025

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) opposes House Bill 5853 (HB 5853), which directs the Executive Office of Health and Human Services (EOHHS) 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 its final rule (the Federal 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 Federal 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.

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

This legislation would open our closed distribution system to importation, which 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 Final 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 enacted bipartisan legislation to address concerns of unsafe and counterfeit

drugs entering the U.S. pharmaceutical supply chain. The DSCSA requires trading partners, including manufacturers, wholesale distributors, and dispensers, to capture, store, and pass along information (i.e., "track and trace") with each transaction of a product and have procedures to investigate and verify suspect or illegitimate product. Through the DSCSA and prior actions, the U.S. has established one of the most secure supply chains in the world and ensures proper protection of patients. Drug importation programs would 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.

It is also notable that Canadian law does not prohibit the transshipment of drugs from any country—including those in developing countries—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.[i]

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

The Federal 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."[ii] Extensive state resources are required for the implementation and administration of an importation program, including but not limited to:

- ***Start-up and Ongoing Costs:*** A state importation program would ultimately assign numerous new responsibilities to Rhode Island, including: the design of the importation program; compliance with existing federal laws, including Drug Supply Chain Security Act (DSCSA) requirements; development of a wholesale prescription drug importation list; and ongoing administrative costs.

- ***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 Federal Final Rule and under the Federal Food, Drug & Cosmetic Act (FD&C Act).

- ***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 (U.S.) drug supply, and endanger law enforcement officers, their canines, and other first responders."[iii] As former FBI director Louis J. Freeh 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."[iv]

- ***Public and Stakeholder Education:*** Any statewide prescription drug program requiring

voluntary participation from supply chain entities and consumers will require training and education.

This legislation fails to recognize the challenges of the Canadian prescription drug market, and Canada has been clear that it will not put its prescription drug supply in jeopardy to send medicines to U.S. states.

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."[v] Therefore, the financial and practical burden would fall to U.S. authorities and local law enforcement. Kirsten Hillman, acting Ambassador to the U.S., 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 "Canada's priority is to ensure a steady and solid supply of medications at affordable prices for Canadians."[vi]

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. Subsequently, Canada's food and drug regulations were amended to prohibit establishment license holders from distributing a drug outside Canada absent reasonable grounds to believe that the distribution will not cause or exacerbate a shortage of the drug.

Mark Holland, Canada's current Minister of Health, has stated, "There is no way we will allow any jurisdiction, be it a state or another foreign jurisdiction, to endanger the Canadian drug supply," and "We're going to do everything in our power to make sure that another country cannot be given the ability to pillage our health system for its own benefit."[vii]

The Federal Final Rule and FDA's approval of Florida's Importation Program Proposal raise significant legal concerns.

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 HHS and FDA. The litigation challenged the Federal Final Rule and the associated "certification" made by former HHS 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. As such, PhRMA, PSM, and CAHC asked the Court to hold unlawful, set aside, and permanently enjoin implementation of the Certification and Federal Final Rule. The Court dismissed the case solely on standing grounds, observing that FDA might never approve a Section 804 Importation Program Proposal. On January 5, 2024, however, FDA purported to authorize the State of Florida's Section 804 Importation Program. That same day, FDA denied PhRMA, PSM, and CAHC's citizen petitions requesting that the Agency reject Florida's proposal.

The Federal Final Rule and associated "certification" remain invalid:

- The Certification was contrary to law, did not satisfy the Administrative Procedure Act's requirement of reasoned decision-making, and was procedurally improper. Section 804 of the FD&C Act 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 had been willing to make this certification due to inability to ensure both public safety and cost reduction. Former Secretary Azar's "certification" letter applies only to commercial distribution, contains conclusory statements as to safety and cost savings without supporting evidence, and punts the responsibility for safety and cost savings to state governments (which, in turn, punt that responsibility to third parties). The former Secretary also failed to consider important aspects of the problem before him and failed to acknowledge or adequately explain HHS and FDA's departure from long-held prior positions and factual findings related to importation.
- The Federal Final Rule disregards key patient safety protections of the FD&C Act. For example, drugs imported under the Federal Final Rule would necessarily be unapproved new drugs and misbranded drugs.
- There is no indication that the Federal Final Rule will reduce costs to actual American patients. In the preamble to both the proposed and Federal 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.
- Aspects of the Federal Final Rule violate manufacturers' First Amendment rights and raise serious questions under the Fifth Amendment Takings Clause.

In addition to undertaking litigation, PhRMA, PSM, and CAHC have also submitted citizen petitions to FDA requesting that the agency refrain from authorizing Section 804 Importation Program Proposals submitted by the states of Florida (originally submitted on November 23, 2020), New Mexico (originally submitted in December 2020), and Colorado (originally submitted on December 5, 2022). In addition to being issued pursuant to an invalid and legally deficient certification and Federal Final Rule, all three Proposals fail to adequately demonstrate that importation will pose no additional risk to public health and safety and fail to show that importation will lead to any reduction—let alone a significant reduction—in the cost of prescription drugs for American consumers. Moreover, the entire negotiation process between FDA and applying states has been conducted outside the public view, impeding the ability for stakeholders to submit public comment. FDA has not responded substantively to the citizen petitions concerning the New Mexico and Colorado proposals.

As with the Federal Final Rule and the associated "certification," both FDA's approval of Florida's Section 804 Importation Program Proposal and the Agency's denial of PhRMA, PSM, and CAHC's citizen petitions challenging that proposal are legally insufficient. FDA's approval of

Florida's proposal and its denial of the citizen petitions are almost wholly unexplained and unreasoned. Neither explains how Florida's Section 804 Importation Program Proposal will satisfy the statutory requirement of a significant reduction in costs to the American consumer. They simply declare that requirement satisfied without analysis. There also remains no showing that the approval will not create additional risk to public health and safety.

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

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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are laser focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. Over the last decade, PhRMA member companies have invested more than $800 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.

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

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

[iii] 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).

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

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

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

[vii] Tasker, John Paul. "Federal health minister says he won't allow Florida to 'pillage' the drug supply," CBC News, January 10, 2024. Access: https://www.cbc.ca/news/politics/canada-health-minister-florida-pillage-drugs-1.7079641.