STATEMENT

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In Opposition to Senate Bill 2387 (DiPalma)
March 26, 2026

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) opposes Senate Bill 2387 (SB 2387), 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 their 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 a purported "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. However, neither the "certification" nor the Federal Final Rule provided any proof that importation programs would 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 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 the United 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."[1] Therefore, the financial and practical burden would fall to U.S. authorities and local law enforcement. Kirsten Hillman, who recently served as the Ambassador of Canada to the United States until February 15, 2026, 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 … for Canadians."[2]

Responding to the threat posed by U.S. importation, 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

[1] Letter to the Washington Post, Leona Aglukkaq, Former Minister (2008-2013), Health Canada, May 12, 2017.
[2] Statement from Canada's Acting Ambassador to the United States on U.S. Importation of Pharmaceutical Drugs from Canada, December 18, 2019.

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 most recent former Minister of Health, 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 "[w]e'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."[3]

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 up 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 criminal organizations to increase the flow of substandard, adulterated, and counterfeit drugs—including pills laced with deadly fentanyl—into the U.S. FDA's review is the gold standard in ensuring the safety and effectiveness of medicines for the U.S. market, and importation would undermine FDA regulations and consumer protections codified in federal law.

The legislation fails to acknowledge the complexities of setting up a state importation program that adequately protects public health and safety, particularly because such importation programs are exempt from requirements under the Drug Supply Chain Security Act (DSCSA). In 2013, Congress enacted the bipartisan DSCSA to address concerns of unsafe and counterfeit drugs entering the U.S. pharmaceutical supply chain. Among other requirements, the DSCSA requires trading partners, including manufacturers, wholesale distributors, and dispensers, to capture, store, and share information (i.e., "track and trace") with each transaction of a product and to have procedures to handle, investigate, and report suspect and illegitimate product. Under the Federal Final Rule, drugs imported under state importation programs are exempt from key provisions of the DSCSA. State drug importation programs like the one contemplated in Rhode Island's legislation would severely undercut the protections of the DSCSA, compromising patient safety.

Additionally, 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% of the drugs sold by supposedly Canadian pharmacies come from 27 countries other than Canada.[4]

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

[3] Tasker, John Paul. "Federal health minister says he won't allow Florida to 'pillage' the drug supply," CBC News, January 10, 2024. https://www.cbc.ca/news/politics/canada-health-minister-florida-pillage-drugs-1.7079641.
[4] FDA. "FDA Operation Reveals Many Drugs Promoted as 'Canadian' Products Really Originate From Other Countries." December 2005.
[5] https://www.hhs.gov/sites/default/files/importation-final-rule.pdf.

- ***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; development of a prescription drug importation list; and ongoing administrative costs associated with registering, licensing, and auditing program participants.

- ***Compliance with Federal Law:*** Both the Foreign Seller and the Importer, under supervision of the state, will be subject to the supply chain security and other requirements set forth in the Federal Final Rule, including costs associated with inspecting imported prescription drugs; reliably recording and sharing adverse events; recalls and disposal of recalled drugs; development of IT systems and reporting infrastructure; and new capital expenditures to support the Importer's relabeling and repackaging obligations.

- ***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."[6] 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."[7]

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) sued HHS and FDA in the U.S. District Court for the District of Columbia, challenging the Federal Final Rule and former HHS Secretary Azar's "certification" on grounds including, but not limited to:

- ***FD&C Act Violations:*** Section 804 of the FD&C Act authorizes HHS to permit certain wholesale Canadian drug importation in certain circumstances if the Secretary certifies to Congress that doing so will "pose no additional risk to the public's health and safety" and "result in a significant reduction in the cost of covered products to the American consumer." However, there is no indication that the Federal Final Rule will reduce patient costs. In the preamble to the Federal Final Rule (and the preceding proposed rule), HHS acknowledged that it cannot quantify the savings, if any, from the rule. In a budget document, HHS left a cost savings chart completely blank, and it even classified the rule as "not economically significant" for purposes of Office of Management and Budget review. Moreover, drugs imported under the Federal Final Rule would necessarily be unapproved new drugs and misbranded drugs.

- ***Administrative Procedure Act (APA) Violations:*** For nearly 20 years, no Secretary was willing to certify that importation would significantly reduce costs and pose no added health or safety risk. The "certification" and Federal Final Rule did not acknowledge or explain HHS's departure from long-held

[6] NSA Opposes Drug Importation Legislation (undated; viewed on Mar. 7, 2025), https://www.sheriffs.org/nsa-opposes-drug-importation-legislation-0.

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

positions and factual findings, thereby violating APA procedural requirements. The "certification" also is contrary to federal law, since it is conditioned on assumptions that states will submit SIPs in the future that will meet the safety and cost criteria—even though the statute requires the Secretary to certify "that the implementation of [section 804] *will*" produce significant savings for American consumers at no additional risk to public health and safety, leaving no room for the Secretary to defer this determination until sometime into the future.

- ***Constitutional Concerns:*** Aspects of the Federal Final Rule violate manufacturers' First Amendment speech rights and raise serious questions under the Fifth Amendment Takings Clause.

The Court dismissed the case solely on standing grounds, noting that FDA may never approve a Section 804 Importation Program Proposal. On January 5, 2024, however, FDA purported to authorize Florida's importation proposal ("Florida Proposal") pursuant to the legally flawed Federal Final Rule and "certification." The authorization is similarly legally insufficient, unexplained, and unreasoned. It simply concludes, without support, that the Florida Proposal satisfies the statutory requirements relating to cost reduction and health and safety risk.

PhRMA, PSM, and CAHC have submitted citizen petitions asking FDA not to authorize Section 804 Importation Program Proposals submitted by three states, including Florida.[8] However, FDA rejected the petitions related to Florida, and it has not responded substantively to the petitions concerning the other two states.

Rhode Island residents prefer policy solutions that focus on reducing patient out-of-pocket spending over policy solutions that would import prescription drugs from foreign countries.

PhRMA is increasingly concerned that the substantial rebates and discounts paid by pharmaceutical manufacturers, approximately $356 billion in 2024,[9] do not make their way to offsetting patient costs at the pharmacy counter. Patients need concrete reforms that will help lower the price they pay for medicines at the pharmacy, such as making monthly costs more predictable, making cost-sharing assistance count toward a plan's out-of-pocket spending requirements, and sharing negotiated savings on medicines with patients.

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. PhRMA respectfully urges the Committee to oppose SB 2387.

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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 $850 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.

[8] Florida (proposal submitted November 23, 2020); New Mexico (proposal submitted December 2020); Colorado (proposal submitted December 5, 2022).

[9] Fein, A. "The 2025 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers," Drug Channels Institute. March 2025.