Testimony of Trish Riley, Executive Director

National Academy for State Health Policy

House Committee on Health Care

Thursday, March 22, 2018

S. 175 - An act relating to the wholesale importation of prescription drugs into Vermont, bulk purchasing, and the impact of prescription drug costs on health insurance premiums

Trish Riley
Executive Director
National Academy for State Health Policy
10 Free Street
Portland, ME 04101
TRiley@NASHP.org

Thank you for the opportunity to testify regarding Vermont's proposal to import prescription drugs from Canada. The National Academy for State Health Policy (NASHP) is a bipartisan, non-profit organization of state health policy leaders from both the executive and legislative branches of government dedicated to helping leaders lead and advancing policy solutions to the challenges states confront. NASHP often proposes options states might pursue and spotlights innovations states have developed but we recognize state policy reflects the unique situations in each state so we do not take positions on legislative proposals.

In 2016, NASHP convened a Pharmacy Costs Work Group to brainstorm and identify strategies states could consider to lower the trajectory of prescription drug costs. Our work took a broad view, recognizing states' roles as purchasers, employers and in protecting consumers. Vermont led the nation in enacting legislation to make drug prices more transparent and we were pleased that the executive director of the Green Mountain Care Board, Susan Barrett, agreed to join our work group. Through its work, we proposed eleven different options a state might consider to address both the rapid rise in prescription drug costs and the unpredictability of those increases. We believe states are the laboratories of innovation and can demonstrate and test approaches that can inform the federal debate. Indeed, many states, including Vermont, had children's health insurance programs before the Congress enacted a national program and states led on insurance reform and other matters before the federal government. We think states can again show the way by demonstrating effective strategies to reduce prescription drug costs. One of the proposals advanced by the work group was the creation of a drug importation program.

States like Vermont are familiar with initiatives to support personal importation of drugs from Canada and some of the safety concerns those mail order programs raised. NASHP's proposal – and the one included in S175 – creates instead a wholesale distribution program. Federal law allows the Secretary of the US Department of Health and Human Services to approve a program of wholesale drug importation from Canada provided that the program carries no greater safety risk for US residents than the current US system and provides significant savings to consumers. Our proposal and yours will import only selected, high cost medicines from Canada where we know prices are on average 30% lower than in the United States for the same drugs.

A state-administered program of importation can meet both savings and safety requirements and use the State's existing commercial supply chain – state licensed wholesalers, distributors and pharmacies. No new complex distribution system would be required. Vermont's bill proposes a unique and intriguing twist – to create your own non-profit wholesaler, which could assure even stronger accountability over the supply chain. Importantly, the pharmaceutical industry is already a global one, as the attached infographics demonstrate.

The U.S. drug market heavily relies on importation to supply the U.S. market. Currently:

- 80 percent of raw ingredients for drugs made in the United States are imported from other countries;
- 40 percent of finished drugs used in the United States are manufactured in other countries;
- The FDA has had a cooperative agreement addressing drug regulatory matters with Canada for years and more than 30 Canadian drug manufacturers are FDA-registered to produce drugs for U.S. markets; and
- About 20 percent of drugs licensed for the Canadian market are made in the United States.

The safety and purity of the imported prescriptions is a crucial standard in the bill. The bill complies with federal regulations governing drug importation that require guarantees of drug safety and consumer savings. In addition, the legislation requires federal approval from the Secretary of the U.S. Department of Health and Human Services.

This legislation, like NASHP's model, will safeguard the quality and safety of imported drugs by:

- Contracting with licensed, regulated drug wholesalers and distributors in Vermont and Canada;
- Importing only drugs licensed for sale in Canada;
- Testing imported products for purity on a sample basis if needed; and
- Limiting distribution of imported drugs to only Vermonters.

The legislation will deliver significant consumer savings by:

- Ensuring that consumers pay similar prices to those charged in Canada; and
- Widely publicizing the prices of the imported products so consumers know what they can expect to pay.

The state will determine which drugs would produce the most savings for the state health care system. We anticipate that a state program would import a limited number of high-cost products. This legislation will not disrupt current distribution and sales markets. We expect the Vermont program will provide a limited number of high cost drugs to all Vermonters at lower cost and deliver them through current channels. The state becomes a wholesaler, or would contract with a US wholesaler, to operate the program in Vermont. The state would select and contract with one or more licensed, regulated Canadian suppliers. The selected drugs would be shipped to Vermont and the wholesaler would use the existing commercial drug distribution system to get product to pharmacies and other provider sites.

The imports would be licensed and regulated for the Canadian market, and that is a key aspect of quality assurance. The imports would be re-labeled to meet US FDA rules and US claims payment

requirements. Drugs can be further identified as an import. The model law anticipates that all payers and providers will participate – which could simplify administration, particularly for pharmacies. Vermonters, through their health plans and as individual purchasers, can benefit as can the state budget through some lower costs for state employees and other state purchasers, as well as Medicaid.

Medicaid, of course, already enjoys the advantage of "best price" and rebates established by federal law. NASHP's model legislation does not compromise the federal rebate program. I understand that concerns have been raised regarding the cost effectiveness and efficacy of including Medicaid in this initiative. It would certainly be possible to exclude Medicaid or to phase in its participation, as concerns are addressed. Or it may be that Medicaid could benefit more from a different list of covered drugs. Canadian prices are substantially lower for high cost products. New, high-cost products typically do not come with deep discounts in the early years, so the Canadian price could be lower for Medicaid than the net price post rebates. An importation program should eliminate the need for supplemental rebate contracts and the rebate mechanism for these products.

I have seen reports in Vermont media accounts that cite three specific concerns about the bill I would like to address.

1. A state will not receive authority to conduct an importation program.

   Sec. 804 of the Food, Drug, and Cosmetic Act explicitly authorizes the Secretary of HHS to authorize programs such as you propose as long as they address safety and savings.

2. This initiative is side stepping regulations and puts the supply chain at risk and provides opportunity for counterfeit drugs to enter Vermont.

   The wholesale program envisioned in S175 would meet all FDA regulations and use the current supply chain. It does nothing different from current practice in a very global market. And Vermont's proposal to create its own wholesaler seems a "belts and suspenders" approach to double down on the accountability of the supply chain.

3. Former FDA Commissioners have warned against importation.

   The March 2017 letter referred to discusses personal importation through internet pharmacies. This is <u>not</u> the approach included in S175 or NASHP's model. Vermont's proposal creates a <u>wholesale</u> importation program that assures patient safety, meets FDA standards and uses the current supply chain.

In proposing S175, Vermont joins several other states proposing to seek Federal authority to enact a drug importation program and NASHP looks forward to bringing you all together to share approaches

and to assure success in launching this important program to lower costs of prescription drugs for Vermonters while assuring the safety of the medicines brought in from our neighbors to the north.

In Utah, a study is underway – much like that envisioned in your Legislature – to determine how to implement an importation program. NASHP is currently working with the Utah Dept. of Health to assist in that work and we hope to be joined by FDAimports, a recognized expert on the issue, whose leadership includes former FDA officials. Utah's study must be completed by October 1 and there may be ways to collaborate with that effort to drill into the logistics and develop a road map for a successful proposal to HHS. Should Vermont enact S175, NASHP stands ready to help in its implementation in anyway we can.

Thank you for this opportunity to testify.

###