

Feasibility of Canadian Drug Importation to lower prescriptions costs for Utahns

A Report for the Utah State Legislature/Health Reform Task Force

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**Background:** The cost of prescription medications has been a concern for patients, health care institutions, and health insurance companies for many years. Over the past ten years, we have seen double-digit inflation in the cost of prescription drugs. The drivers for these cost increases are multiple and include the development of new, usually expensive, drugs for treating conditions that were not treatable in the past (e.g., Hepatitis C, certain cancers) and may impact a large number of patients, as well as unexplained major price increases for both brand name and generic drugs by their manufacturers.

For many years, US consumers have been concerned by the fact that US pharmaceutical companies (Pharma) sell their products to other countries at markedly reduced prices compare to their US prices. As most industrialized nations have some form of “single-payer” health insurance for their citizens, it has provided them with significant negotiating power when purchasing medications for their health care systems.

During the 2018 legislative session, Representative Norm Thurston offered House Bill 163, co-sponsored by Senator Deidra Henderson, to address these concerns about high US prices compared with much lower prices in Canada for identical medications. This bill was drafted based upon input that Representative Thurston received from multiple stakeholders (e.g., health systems, health insurance companies, state Medicaid program) and specifically proposed that Utah pursue the feasibility of establishing a Canadian Drug Importation. The bill would have required the Utah Department of Health to seek a waiver from the federal government to allow Canadian drug importation, and if successful, to design and implement a program to accomplish that. A key requirement of this program would be that it “generate substantial savings for Utah consumers.”

**Applicable Federal Law:** Section 804 of the Federal Food, Drug and Cosmetic Act permits a program of wholesale or personal importation of prescription drugs from Canada provided that the Secretary of HHS certifies to Congress that implementation of such a program will: pose no additional risk to the public’s health and safety beyond the current US prescription drug supply chain; and, result in a *significant reduction* (emphasis added) in the cost of prescription drugs to

the American consumer. To date, the Secretary of HHS has only received proposals for personal importation that have been denied. Federal law does prohibit the importation of narcotics, biologics, intravenous drugs and inhaled drugs used in surgery

This year, Vermont enacted a law similar to Rep. Thurston's HB 163, so they will become the first state to seek the Secretary's permission for an importation program. It is important to note that the Trump administration has stated their desire to reduce the consumer cost of prescription drugs. In July of this year, FDA Commissioner Scott Gottlieb announced that they are exploring how to import costly off-patent and generic drugs as well as biologics to improve price competition in the US market. In addition, Intermountain Healthcare has announced their membership in a collaborative effort of several large health systems to establish their own pharmaceutical manufacturing for generic drugs in order to lower medication costs.

### **Pertinent Information Regarding Current Drug Production:**

- 40% of the US prescription drug supply is currently imported.
- 80% of pharmaceutical ingredients are imported for US manufacturing of medications.
- Over 30 Canadian drug manufacturers are currently FDA approved.
- US Pharmaceutical firms have numerous manufacturing plants outside of the US.

### **Utah Responsibilities for Establishing a Canadian Drug Importation program:**

(Note: there are issues with each of these steps that will be discussed in a later section.)

1. The State of Utah will need to create and administer a Drug Importation Program.
2. Obtain approval from the Secretary of HHS (which requires assurance of *significant savings to Utah consumers* [emphasis added]).
3. Establish, administer and oversee the drug importation program.
4. Identify those drugs to be imported based upon their likelihood of providing significant savings based upon high utilization or large cost savings or both.
5. Verify that a Utah market exists for the purchase of imported drugs (e.g., pharmacies, clinics, hospitals, health care providers, nursing homes, others) as participation would be voluntary.
6. Identify one or more Canadian suppliers willing to sell the desired quantities for US importation.
7. Identify one, or more, US wholesalers who are willing to purchase the Canadian drugs with the following requirements:
  - a. assure that the drugs came from FDA-approved facilities,
  - b. only import drugs that are safe and have approved FDA labeling,
  - c. be able to repackage the Canadian drugs with US National Drug Codes (NDC) for accurate tracking and billing,
  - d. re-label the Canadian drugs consistent with FDA requirements, and
  - e. comply with US rules on electronic tracking of drugs through the entire supply chain.
8. Identify a wholesale distributor who will purchase these imported drugs from the wholesaler and sell them to the various entities noted in #5.
9. There must be verification of the safety, purity and contents of imported drugs. This could be done through a contract with a private lab (see #11, Issues of Concern, below).

10. The security of the supply chain must also be verified (see #12, Issues of Concern, below). This could be done as part of the contract with the wholesaler and wholesale distributor and verified through audits; or, done with a separate contract.
11. Have a method to audit the final price of these imported drugs when sold to consumers to verify a cost savings. This could be the same entity in #7, or a separate entity (state or contracted). This is an important transparency issue for consumers as well as for justification for having this program.
12. Prohibit the resale of the imported drugs to outside the State of Utah.

**Licensing Issues:**

1. Dept. of Commerce will need to determine whether Utah needs to license the wholesale importer and/or the wholesale distributor.
2. Dept. of Commerce may need to enact licensing laws for these entities and existing entities (pharmacies) that prohibit the sale of these drugs outside of Utah. DOPL can restrict sales to a 90-day maximum supply for an individual. (Note: see Issues, below for further discussion)
3. Any needed licensing requirements will have to include provisions for inspections and audits to verify compliance.

**Insurance Issues:**

1. Some insurance companies require a secondary wholesaler to have a separate certification in order for those drugs to be covered.
2. Medicaid's ability to participate remains unclear;
  - a. Would these savings be more than current savings under the rebate program?
  - b. Would participating in this program jeopardize other benefits currently provided by pharma?
3. Some state entities, such as Federally Qualified Health Centers (FQHCs, aka community health centers) are able to purchase medications for their patients through the federal 340B program. It is currently unclear whether an importation program would offer any savings over the 340B program.

**Issues of Concern:**

1. Approval from the Secretary of HHS – can we document, and commit, that there will be “significant savings?”
2. Will the Secretary of HHS approve a Vermont plan? If so, can this be a model for Utah.
3. How might this proposed program relate with the Intermountain Healthcare consortium planning to fund their own generic drug company?
4. This is clearly a very complex system that will require the state to establish its own Drug Importation Program and utilize contracted, outside expertise to assist in oversight, resulting in administrative expenses for the state.
5. Pharma is likely to exert their significant influence in a way that discourages wholesalers and wholesale distributors from participating. This may also be true for insurance companies who may currently have advantageous purchasing arrangements from Pharma.
6. Given all the steps required and the number of parties involved, each having a separate cost that would be added to the final cost of the medication, can significant cost savings be realized? Again, transparency for pricing at each step is necessary.

7. The Secretary of HHS has to determine where the re-labeling and re-packaging can occur (Canada or US, or either).
8. There are consumers living in communities that border Utah. Would they be prevented from purchasing these lower cost drugs? The major concern is preventing wholesale distribution of imported drugs outside of Utah, rather than concern with retail sales by Utah entities.
9. What actions could/should be taken if an entity is charging “excessive” costs for their service resulting in lower savings for Utah consumers?
10. Any/all licensing issues would need to be handled by DOPL, but who would be responsible for inspections and/or audits and/or any other monitoring? How will those costs be handled?
11. A contract with an independent lab will be required to assure the purity, safety and content of imported drugs.
12. Security of the supply chain may either be performed by the contracted wholesaler (with oversight audits) or through a separate contract.
13. Much more information would be required before determining if the Medicaid program could see a financial benefit from participating in this program.
14. Insurance programs may, or may not, cover the cost of these imported prescription drugs. Will this force retail sales entities (primarily pharmacies) to have duplicate stocks of some drugs (imported drugs and non-imported drugs), just as 340B pharmacies must separate those medications from the products available to sell to the general public.

#### **Final Thoughts for Legislative Consideration:**

1. Enactment of a Canadian Drug Importation program will require the establishment of a State Office to monitor and oversee this complicated program. This office will have several duties, including; a) develop, implement and monitor various contracts that will be required, b) assure transparency in these processes, especially related to costs, and be able to share that information with the legislature and the public, and c) determine future changes in the Canadian Drug Importation formulary (additions, deletions). Such a program would likely fit best within the Dept. of Commerce with the Dept. of Health as an alternative.
2. Transparency throughout all aspects of an importation system is a necessity. This relates to costs, to quality, and to the determination of which drugs to purchase.
3. A thoughtful and thorough evaluation of the potential costs to the State, both initial and ongoing, will need to be determined.
4. Fortunately, Utah will be able to observe and learn from Vermont’s experience as the first state hoping to establish a Canadian drug importation program.