New pathways for U.S. importation threaten Canadian prescription drug supply.

ABSTRACT
Within recent months, the U.S. has opened up the possibility for Americans to import prescription pharmaceuticals from Canada. The U.S. FDA is now accepting proposals for both personal and commercial drug importation from Canada. Importers can be individuals, wholesalers, pharmacies, and governments. This research examines the impact U.S. drug importation will have on the Canadian prescription drug supply. Using the total number of prescriptions dispensed in 2018 for Canada and the U.S., models were developed to estimate the number of days before the Canadian drug supply would be exhausted. The model included variations in the demand for prescriptions from the U.S. and included a safety stock of 10%. Models were developed for both total drugs and for just brand name pharmaceuticals. The results showed that the 2018 Canadian prescription drug supply will last approximately 165 days if 20% of U.S. prescriptions were sourced from Canada. When a 10% safety inventory was added, it was estimated that the Canadian pharmaceutical supply will be exhausted in 182 days or approximately six months. A 40% demand from the U.S. shows a prescription drug supply of 118 days before Canadian drug stores are exhausted of their 2018 pharmaceutical supply. For the brand name drugs model, if 20% of the U.S. brand name drugs were sourced from Canada, the brand name drug supply will be exhausted in 281 days. If 40% of U.S. brand name prescriptions were sourced from Canada, the Canadian brand name drug supply would be exhausted in 216 days or seven months. The above analysis is an overview of all brand name drugs. Some drugs will be exhausted sooner than others, depending on the demand. The study shows that Canada would have exhausted its 2018 pharmaceutical supply in three months, with just 40% of U.S. prescription demand. It needs to be emphasized that U.S. commercial importation will enhance the risk to the Canadian health care system. Serious drug shortages are predicted unless Canada puts a halt to exporting drugs to the U.S.
INTRODUCTION

In the last six months, requests were received to update my previous studies which examined the impact U.S. drug importation will have on the pharmaceutical supply in Canada. The requests came from individuals from both Canada and the U.S. It was believed that few changes occurred since my 2018 study or my earlier 2010 study. The 2018 study used 2015 data, whereas the 2010 study used 2007 data. However, with the recent drug importation position changes by the Trump Administration and the Department of Health and Human Services (HHS), plus with four states, Florida, Vermont, Maine, and Colorado, having passed legislation to establish drug importation programs from Canada, it was decided to have another look at the issue.

The continuing increase in the cost of drugs for U.S. patients has fueled the U.S. public’s demand to obtain prescription drugs from Canada. In 2017, select Canadian prescription drug prices ran on average about 65% lower when compared to the U.S. This is because Canada’s Patented Medicine Prices Review Board (PMPRB) controls the price of pharmaceuticals.

As mentioned, four states have passed legislation for drug importation. However, all four require HHS’s approval before enactment. This year President Trump has voiced support for drug importation. He asked HHS to reexamine if it was possible for states to have Canadian drug importation programs without jeopardizing the safety and quality of pharmaceuticals for U.S. residents. In July of 2019, HHS released an Action Plan for drug importation with two “pathway approaches.” The first pathway will allow for the importation of drugs from Canada which are approved for sale in Canada and are versions of U.S. approved drugs with the “conditions to ensure the importation poses no additional risk to the public’s health and safety and will result in significant reduction in the cost of covered products to the American consumer.” This pathway allows commercial drug importation for wholesalers, pharmacies, and states. Entities need to submit a plan to HHS for approval. The difference in this “pathway” and the rhetoric of ten to fifteen years ago is that there is an emphasis on commercial drug importation instead of personal importation.

The other HHS pathway is to have U.S. pharmaceutical manufacturers submit a proposal which will allow foreign versions of their FDA-approved drugs to be imported. It is unclear why a U.S. company would import a foreign version of their patented product to compete in the U.S. market for less money, but it is an option for companies.

The HHS call for “pathway” proposals is a major change in U.S. policy. For the past seventeen years, all HHS Secretaries and U.S. Food and Drug Administration Commissioners have not supported drug importation, mainly because of the problems of assuring quality and safety of the imported products. Even the current HHS Secretary Azar had not been a supporter of drug importation; on May 14, 2018, he delivered a speech saying drug importation was a “gimmick.” Now, HHS is soliciting proposals for importation of pharmaceuticals.

As expected, Canada has been very vocal against the U.S. taking their pharmaceuticals. Health Canada, the agency which regulates pharmaceuticals in Canada, has not changed its position. “The ministry said officials have ‘made Canada’s position clear’ to both federal and state

officials in the United States and it stood ready to ‘take action’ to ensure Canadians have uninterrupted access to the prescription drugs they need.’” Reuters News Agency used Freedom of Information and discovered a Canadian government document of a briefing on U.S. drug importation plans. Parts of the document were reported by CBC News. The document stated: "Canada does not support actions that could adversely affect the supply of their prescription drugs and potentially raise costs of prescription drugs for Canadians.”

This research will take a third look at the impact U.S. drug importation will have on the Canadian pharmaceutical supply. The question is: Can Canada be the drugstore of America? Both my previous publications stated that Canada’s drug supplies are too limited to support U.S. personal and commercial drug importation and will have to acquire more pharmaceuticals to avoid a drug shortage. Does this still hold true today?

**METHODOLOGY**

The research methods employed are very similar to the ones I used in my previous studies. Dollars expressions will be in U.S. dollars and designated as US$; Canadian dollars, when used, will be designated as CNS. Since the demographic and drug use statistical data are from 2018, the dollar exchange rate employed will be 1.295, which was the average rate for 2018 from the Bank of Canada. To convert Canadian dollars to U.S. dollars, divide Canadian dollars by the exchange rate (1.295).

To determine the financial impact on Canada, drug exports and imports and drug manufacturing production needs to be examined. Two classification systems were employed. The international commodity classification coding system known as the Harmonization System (HS), for import and export commodities and the North American Industry Classification System (NAICS) was used for manufacturing.

The HS system uses a six-digit numbering system to classify goods for international imports and exports, although some countries add digits to expand beyond the six digits. The HS Schedule B provides export information on 8,000 commodities; the import system provides data on 14,000 classification commodities. The U.S. uses a ten-digit coding system for Schedule B exports with the first six digits being the HS codes. The World Customs Organization administers the HS schedule codes. HS codes are recognized in 98% of the world trade.

Due to the proprietary nature of the import and export information, HS codes are used for product groups, not individual products such as cardiovascular or antidepressant drugs. The four-digit HS code most frequently used in this report is HS 3004, which represents pharmaceuticals dispensed in community and hospital pharmacies. The code definition follows medicaments, put up in measured doses (incl. those in the form of transdermal admin. systems) or packed for retail. This designation was used because it was believed that it best reflects drug products for consumer use, rather than using bulk pharmaceuticals and medicines product codes primarily used in manufacturing. The HS 3004 code is the same code used in the earlier studies.

The second product classification system used is the North American Industry Classification System (NAICS). Products are grouped into industries according to the process used to produce the product or service. This system is used by Canada, the U.S., and Mexico. The NAICS code used in this study 3254, which is for pharmaceutical preparation manufacturing.

**RESULTS**

The latest prescription drug use data found for both countries was for 2018; thus, the research is an update of three years from the 2015 study. Canada’s population in 2018 was approximately one-ninth the size of the U.S. (Canada 37,058,856 versus U.S. 327,127,434). The


total number of prescriptions dispensed in Canada in 2018 was 699.2 million or 1.916 million prescriptions per day.\textsuperscript{18} The total number of U.S. prescriptions dispensed in 2018 was 4.214 billion or 11.55 million prescriptions per day.\textsuperscript{19} The number of prescriptions dispensed in the U.S. is six times higher than in Canada.

The number of prescriptions dispensed per capita in the U.S. was 12.88 (4.214 billion/327.127 million). If just 20% of the U.S. population (65.42 million) were to purchase the average per capita number of prescriptions from Canada, the total would be 842.6 million prescriptions. This number exceeds the total number of prescriptions dispensed by Canada during 2018 by 143.4 million. If you add this new demand to the already existing Canadian market (842.6 million + 699.2 million), Canada will need to provide pharmaceutical supplies for 1.541 billion prescriptions. This total is more than double the 2018 demand, and this is with only 20% of the Americans sourcing their drugs from Canada.

The National Center for Health Statistics reported that nearly 50% of Americans had a prescription filled within the last 30 days.\textsuperscript{20} Other studies have shown that between 60% and 70% of Americans have at least one prescription filled annually.\textsuperscript{21,22} Using 70%, a total of 228,989,204 (327,127,434 people x 0.70) had at least one prescription filled in 2018. There were 4.214 billion prescriptions dispensed in 2018. Thus the number of prescriptions filled per person per year who had at least one prescription filled was 18.0 (4.124 billion prescriptions/228,989,204 people). If 20% of Americans who had at least one prescription dispensed were to purchase their prescriptions from Canada, the total number of people would be 45.797 million (228,989,204 x 0.20). The approximate number of prescriptions demanded from Canada from this group would be 824.346 million prescriptions (45.797million people x 18 prescriptions per year/person).

### Supply Days for Pharmaceuticals

Another approach is to examine the number of supply days the 2018 annual pharmaceutical inventory for Canada will last if 20% of Americans purchased pharmaceuticals from Canada. The mathematical calculation for determining the number of supply days is as follows:

$$\text{Days Supply} = \frac{\text{Annual Number of 2015 Canadian prescriptions} (699,200,000)}{[\text{Number of U.S. Prescriptions dispensed daily} (4,214,000,000/365) \times \text{Proportion of Number Prescription Purchased in Canada (20%)}] + \text{Number of Canadian Prescriptions Dispensed Daily} (1,916,000)}$$

Using the above model, the 2018 Canadian prescription drug supply will last approximately 165.46 days if 20% of U.S. prescriptions were sourced from Canada (699,200,000 annual prescriptions dispensed in 2018 divided by the daily demand of 2.31 million additional prescriptions from the U.S. combined with the Canadian daily demand of 1,916,000 prescriptions). The results show that the 2018 Canadian drug supply would be exhausted in approximately five and one-half months if just 20% of U.S. prescriptions were added and no additional drugs were imported or were manufactured to meet the added demand.

### Adjustment for Pharmacy Inventory

The inventory in retail pharmacies is greater than just the number of prescriptions dispensed. Pharmacies keep a reserve or safety inventory for possible fluctuations in the market. To determine the reserve supply, the average pharmacy inventory turnover rate for prescription drugs was examined. Turnover rate is the average number of times the inventory is sold and replaced per year.

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The National Association of Community reported that in 2015 the prescription drug inventory turnover rate was 11.9. In other words, independent pharmacies turn the inventory approximately every 30 days. It is expected that the prescription drug turnover rate for chain drug stores will be the same or higher. Based on this number, it was decided to add a 10% safety stock to protect from fluctuations in the market to the total number of Canadian prescriptions dispensed in 2018. Thus, the base number for 2018 Canadian prescriptions is increased to 769.12 million.

Using an annual supply of 769.12 million prescriptions, and assuming that 20% of Americans will get drugs from Canada the total number of prescriptions demanded per day will be 4.225 million and the days supply for Canada will increase from 165 to 182.04. Thus, with the addition of the 10% safety stock, Canada’s 2018 drug supply will last approximately six months with a demand of 20% from the U.S. without any additional supplies for Canada. A 40% demand from the U.S. shows a prescription drug supply of 118 days before the Canadian drug stores will be exhausted in 2018 without any additional pharmaceutical supplies. CHART 1 depicts the trend in the number of days supply of prescriptions controlling for the proportion of drugs demanded from the U.S.

**Model for Brand Name Drugs**

As mentioned, the U.S. demand for prescription drug will be primarily for brand name prescription drugs, not generic drugs. Generic drugs are more expensive in Canada and have been for years when compared to the U.S. However, Canada has made progress in reducing their generic drug prices since 2010. When compared to other countries, Canadian generic drug prices remain higher. In 2018, 71.8% of the Canadian prescriptions dispensed were for generic drugs; whereas for the U.S., 90% of the prescription drugs dispensed were

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Using these proportions, the number of brand name drugs dispensed was calculated. Canada dispensed a total of 197.174 million brand name prescriptions (699.2 million prescriptions x 28.2%) in 2018. The number of brand name prescriptions dispensed daily in Canada was 540,204. For the U.S., in 2018, 421.4 million brand name prescriptions were dispensed (4.214 billion x 10%). The number of brand name prescriptions dispensed daily in the U.S. was 1,154,521.

As with the previous day supply calculations, a 10% safety stock was added to the total number of brand name drugs dispensed in Canada. Thus, the total number of Canadian brand name prescriptions is 216.891 million brand name prescriptions (197.174 million x 110%). This number was used for calculating the number of days it will take to exhaust the 2018 brand name drug supply in Canada if U.S. residents purchased brand name drugs in Canada and no additional pharmaceuticals were acquired.

If 20% of U.S. brand name prescriptions were sourced from Canada, the daily demand is 230,904 prescriptions (1,154,521 brand name daily demand x 20%). This daily demand was added to Canada’s daily demand to get a total daily demand of 771,106 brand name prescriptions per day (540,202 from Canada + 230,904 from the U.S.).

The number of days supply for brand name products if 20% of U.S. prescriptions were sourced from Canada is 281.2 days (216.891 million per year capacity/771,106 daily demand). If 40% of U.S. brand name prescriptions were sourced from Canada, Canada’s drug supply would be exhausted in 216 days or seven months.

CHART 2 depicts the number of supply days of Canada’s brand name prescriptions controlling for the proportion of U.S. brand name prescriptions demanded. It needs to be pointed out that the above analysis is an overview of all brand name drugs. Some drugs will be exhausted sooner than others, depending on the demand. For example, the price of insulin in Canada is much, much lower than in the U.S. ($30 per vial in Canada versus over $300 in the U.S.). The demand for Canadian insulin from U.S. residents will be very aggressive and could be a threat to Canada’s diabetic community. Because of the differences in demand by product type, some brand name products will be exhausted much sooner than depicted by CHART 2.

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DISCUSSION

The results of this study are very similar to the previous studies. This study found that Canada would exhaust its total drug supply in 118 days if 40% of U.S. prescriptions were sourced from Canada without additional pharmaceutical supplies; the 2015 study found 117 days. For brand name prescription drugs, the Canadian brand name prescription supply would be exhausted in 216 days if 40% of U.S. patented prescription drugs were sourced from Canada. In 2015, it was 182 days.

The results show that the risk to Canada health care system is very high if U.S. residents, wholesalers, state governments, and pharmacies imported drugs from Canada. In the first two studies, the emphasis was on personal importation, but with FDA’s announcement of “pathways for drug importation,” commercial importation appears to have a high probability.

Canada’s Drug Trade Trends

An understanding of Canada’s importation and manufacturing trends provides a better understanding of the complexities of this issue. In 2018, Canada imported a total of US$ 7.597 billion of HS 3004 pharmaceutical products, pharmaceuticals “put up in measured doses or packed for retail sales.” U.S. was the largest supplier of drugs to Canada, 26.6% (US$ 2.023 billion) in 2018.

Canada’s Pharmaceutical Manufacturing

In addition to the US$ 7.597 billion in Canada’s pharmaceutical imports, Canada manufactured CA$ 27.0 billion (US$ 20.85 billion) in pharmaceuticals (CA$ 16.8 brand name and CA$ 10.2 generic products). However, from this CA$ 27.0 billion, Canada exported CA$ 11.0 billion (US$ 8.49 billion) with about half going to the U.S. Thus, CA$ 16.0 billion (US$ 12.3 billion) of Canada’s manufactured drugs in 2018 was used domestically. Thus, the total domestic supply of pharmaceuticals for 2018 is the sum of drug imports and manufacturing production minus exports. The total comes to US$ 19.957 billion (US$ 7.597 billion + US$ 20.85 billion - US$ 8.49 billion).

Since Canada’s prescription drug supply would be exhausted in three months with an added demand of 40% from Americans, Canada will need to increase their manufacturing and imports by 300% to have the additional nine months’ supply needed to meet this demand. In other words, the Canadian drug supply will need to increase from US$19.957 billion to US$59.871 billion with the added demand from 40% of U.S. prescriptions.

Options for Canada

The options for Canada are limited. Increased domestic production or increased imports are not feasible options. Nearly all of the American demand from importation will be for branded drugs, therefore Canada’s generic production is irrelevant, and brand multinationals will not boost their Canadian production to meet American importation demand, nor will they increase exports to Canada.

In regard to halting or limiting drug exportation, the following is a list of the possibilities:

- Canada can charge a tax or tariff on exported drugs. Depending on the extent of tax/tariff, this has the potential of reducing the price differential between countries to the point that there is limited or no savings in purchasing drugs from Canada.

- Another approach is for Canada to add specific prescription medications to their “export control list.” The Canadian government does have an export control list which lists products which cannot be exported. Each drug will have to be approved by the Canadian government before it is exported. The Canadian government can add items to this list at any time.

- The last option for Canada is to ban personal and commercial exportation of drugs which were intended for Canadians. This option has a strong following in Canada, including many in the Canadian

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health industry. In August 2018, the Canadian Health Ministry Spokesman Alexander Cohen was quoted as saying: “Our top priority is ensuring Canada’s prescription drug supply and we will take all necessary measures to safeguard the medications Canadians rely on.”

CONCLUSION

The results for this study are unchanged from my 2017 and 2010 studies. The study shows that Canada will exhaust their 2018 pharmaceutical supply in three months, with just 40% of U.S. prescription demand. It needs to be emphasized that U.S. commercial importation will enhance the risk to the Canadian health care system. Serious drug shortages are predicted unless Canada puts a halt to exporting drugs to the U.S.

Making Canada the drugstore of America is short-sighted. The U.S. has the potential of swallowing every Canadian pill and capsule without solving the U.S. problem.

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