Negative Brief: Drugs Imports from Canada

By “Coach Vance” Trefethen

***Resolved: The United States Federal Government should significantly reform its import and/or export policy within the bounds of international trade***

The AFF plan allows / encourages US pharmacies and drug wholesalers, as well as individuals going online, to order prescription drugs from Canada (and possibly other countries, depending on the wording of the plan).

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Negative: Drug Imports

MINOR REPAIRS

Colorado Study: Using generics would solve

Shabbir Imber Safdar 2021 (Executive Director, Partnership for Safe Medicines, a not-for-profit that accepts no corporate members or donations; members are other nonprofits and trade associations that represent manufacturers, wholesalers, pharmacists, and patients) 18 Jan 2021 Executive Director, Partnership for Safe Medicines, <https://www.ndlegis.gov/assembly/67-2021/testimony/HIBL-1250-20210118-972-A-SAFDAR_SHABBIR.pdf> (accessed 29 May 2022)

Colorado is one of the states currently pursuing a Canadian drug importation program. In March 2020, the state released a draft of its plan that included a list of potential drugs to import. PSM did an analysis and found that nearly one-third of the drugs on the list already had a generic version on the U.S. market and that the state could save over $43 million just by switching to the generic versions of those drugs.

State experiments have found several workable alternatives

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There isn’t an elected official today who doesn’t hear from their constituents that health care costs are an issue, and pharmaceutical spending, which is less than 20% of overall healthcare spending, is certainly a piece of the problem. But states are finding other, safer ways to address these costs. California is aggregating its spending across different healthcare programs to achieve volume discounts. Louisiana has negotiated a “Netflix” subscription model, which will allow the state to treat hepatitis C at a fixed cost. West Virginia kicked their PBM out of their Medicaid program to use a pass thru entity and saved $52 million in their first year.

HARMS / SIGNIFICANCE

1. Generics

No cost crisis: 90% of prescriptions in the US are low-cost generics

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Ninety percent of prescriptions are filled in the U.S. are filled with generic drugs, the vast majority of which costs less than $20.24 Seventy-seven percent of the money that U.S. patients spend is on the ten percent of prescriptions that are filled with brand-name drugs. So North Dakota’s potential pool for citizens that would benefit from drug importation would be limited to people for whom there is not an FDA-approved generic option.

2. Pharmaceutical costs are not excessive

Considering all the factors - prescription drug spending burden in the US is declining, not rising

Dr. Joe Kennedy 2019 (law degree and a master’s degree in agricultural and applied economics from the University of Minnesota and a Ph.D. in economics) 9 Sept 2019 " The Link Between Drug Prices and Research on the Next Generation of Cures" <https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures> (accessed 5 June 2022)

It should be no surprise that total health care spending is increasing, since the nation is getting richer and its population has grown. Nevertheless, total retail spending on drugs has increased almost sixfold, even after correcting for the Bureau of Labor Statistics’ consumer price index for prescription drugs (see figure 4). However, so has gross domestic product (GDP). Figure 5 shows that, as a percentage of GDP, the rise was far less dramatic—with 2017 levels below 2009 levels—and only a small portion of total income. Much of the increase has been driven by increased demand, in part as drugs have become more effective medical treatments. And much of the demand has been driven by those over the age of 65. Between 2002 and 2014, total retail spending on prescription drugs rose by $140 billion. Spending on those over the age of 65 accounted for $54 billion, or 38 percent of this rise. Yet the proportion of those over 65 in the population only rose from 12.3 percent to 14.3 percent of the total population. Figure 6 again shows total spending on retail prescription drugs, adjusted for inflation. It then adjusts this spending by the growth in the number of people ages 65 or older, revealing that when controlling for the growth of the elderly, real spending has declined 10.4 percent since 2007.

Incorrect calculations create exaggerated estimates of drug price inflation

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Even when a common price definition is used, price indexes of the real cost of pharmaceuticals tend to overestimate the amount of inflation. First, The U.S. Bureau of Labor Statistics (BLS) infrequently changes the market basket of drugs whose prices it monitors, so new generics are often not included in the sample for several years even though their entrance into the market quickly lowers prices. And when they are included, they are measured as new products, not as cheaper versions of the branded drugs. According to an estimate from 1993, this resulted in an upward bias in the measured price of drugs of 1.2 percentage points a year. Making this adjustment would mean actual prices fell in 3 of the last 9 years (see figure 1).

3. A/T "Excess drug company profits"

Reducing drug company margins [profit percentage] would have no more than 10% impact on prices

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Finally, even a significant reduction in margins would not transform drug pricing. The Government Accountability Office estimated that pharmaceutical and biotechnology revenues were $775 billion in 2015, with an industry profit margin of 17.1 percent (not taking into account capitalization of research). Reducing this margin to 6.7 percent (the average for Fortune 500 companies) and assuming all savings were used to lower prices would have lowered prices by only 10 percent.

Total social benefit from lives improved by pharmaceuticals far exceeds drug companies' profits

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But even when companies set prices high, society can still benefit. When companies decide how much money to invest in research, they typically invest until the benefits to them stop exceeding their costs. Because companies do not benefit from the spillover benefits to society (the benefit competitors and consumers get from their innovation), they do not take them into account. In fact, research levels would be maximized by letting these companies capture all the social benefits.  A recent study by Tomas Philipson and Anupam Jena shows that drug companies typically capture only a small fraction of the total social benefit they produce. The study concentrated on therapies for HIV/AIDS introduced after the late 1980s. It estimated that these drugs increased social welfare by nearly $1.4 trillion. However, the companies that produced these drugs increased their profits by only $62.9 billion. They therefore captured less than 5 percent of the total welfare. The remainder went to the rest of society. Looking at over 200 previous studies of the cost efficiency of other drugs, the authors estimated that in 25 percent of the studies, companies captured less than 7 percent of the societal surplus. The appropriation of social welfare exceeded 25 percent in only one-quarter of the studies.

SOLVENCY

1. Canada won’t cooperate

Canadian government won’t accept export of drugs to U.S. due to fear of shortages in Canada

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Any state looking to import prescription drugs from within the Canadian drug supply chain would need Canada to be a willing participant, which it has never been. A bill proposed in 2005 would have allowed the Health Minister to ban the bulk exportation of prescription drugs from Canada to the U.S. In a March 2020 comment submitted to Health and Human Services during the proposed rulemaking comment period, the Government of Canada warned that drug importation “would not provide an effective solution to high drug prices in the U.S.” As the federal government continued pressing forward with the issue, Canada imposed an interim order in November 2020 banning the export of prescription drugs that would cause or exacerbate drug shortages in that country.

Anticipating the AFF plan, Canada has already started blocking export of prescription drugs to prevent shortages

Matthew Schwartz 2020 (journalist with National Public Radio) Canada Blocks Export Of Medications In Short Supply In Response To Trump Plan 29 Nov 2020 <https://www.npr.org/2020/11/29/939890111/canada-blocks-export-of-medications-in-short-supply-in-response-to-trump-plan> (accessed 5 June 2022)

Ahead of an expected surge in U.S. demand for prescription drugs, the Canadian government has blocked the distribution of certain medications outside Canada in order to avoid a shortage within the country.The Canadian health minister signed an [order](https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/importation-exportation/interim-order-drug-shortages-protecting-supply.html) Friday to limit bulk exports, saying it would help safeguard the country's drug supply.

Canadian government won’t participate in US drug importation programs because of drug shortages

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As of January 16, 2021, Canada has over 1,500 drugs listed as currently being in shortage. A report found that between 2017 and 2018, nearly 25 percent of medications in Canada were in shortage. A national survey released in 2018 by the Canadian Pharmacists Association found that one in four Canadians had either personally experienced or knew someone who had experienced a drug shortage in the past three years. The COVID-19 pandemic has worsened the prescription drug situation in Canada. Canada has said clearly that they will not participate in U.S. drug importation programs because it will worsen these shortages.

2. Won’t solve for drug prices

Cost of government regulatory apparatus would erase any possible savings

Liam Sigaud 2019 (*works on economic policy and research for the American Consumer Institute, a nonprofit educational and research organization*) 9 Sept 2019 " Drug Importation: High Risk, Low Reward" <https://www.realclearhealth.com/articles/2019/09/09/drug_importation_high_risk_low_reward_110943.html> (accessed 29 May 2022)

Constructing an oversight apparatus capable of closely monitoring drug imports from abroad would be so costly as to erase any economic benefits from importation. Even if we ignore safety concerns over poorly regulated imported drugs, the cost savings from importation would likely be negligible. When the nonpartisan Congressional Budget Office (CBO) [examined](https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/04-29-prescriptiondrugs.pdf) a similar proposal in 2005, it found that “permitting the importation of foreign-distributed prescription drugs would produce at most a modest reduction in prescription drug spending in the United States” -- on the order of 1 percent of total spending.

Low Canadian drug prices only available to Canadian citizens

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While Canada does have universal healthcare coverage that includes medications when administered in the hospital setting, the same is not true for any prescription drugs taken outside of a hospital. Much like in the U.S., most Canadians have prescription drug coverage through a patchwork of public and/or private insurance plans. Canada’s Patented Medicines Prices Review Board sets prices to ensure that brand-name medication is not priced excessively, but those prices are for Canadian citizens. There is nothing that can compel any Canadian wholesaler to give those same discounted prices to a U.S. state looking to import prescription drugs from Canada

3. Lack of enforcement

Not easy to enforce US laws and regulations on Canadian vendors. Example: Canada Drugs in 2014

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If a serious violation does occur, holding a Canadian vendor responsible will not be easy. Even if the case warrants the involvement of the U.S. Department of Justice, that does not mean that justice will be easy to achieve. For example, CanadaDrugs.com was indicted in November 2014 for selling $78 million worth of unapproved, mislabeled, and counterfeit cancer drugs to doctors across the U.S. including North Dakota. The Canadian defendants spent years objecting to the case until a deal was brokered. In April 2018, the CEO of CanadaDrugs.com finally stood in a U.S. courtroom and admitted to the widespread illegal sale of misbranded and counterfeit drugs. No one involved received even a one-day jail sentence. The fines and forfeiture came to just over $34 million.

FDA wouldn't be able to enforce safety standards on imported drugs

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Third, the FDA lacks the resources needed to oversee a major importation program, as recently stated by four former FDA commissioners in a March 2017 letter to Congress.  Without a large increase in resources, the FDA would not be able to certify each seller’s credentials under the act, which implies that the program would rely on self-certification. Adequate certification of sellers is crucial because, as the former commissioners highlighted, ineffective accreditation may lead to “substandard, unsafe, adulterated or false” drugs being purchased by Americans.

4. Already tried and failed

Illinois: 2006 study found costs of administration outweighed savings

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The theory that importing drugs from Canada will allow patients to see significant savings is just that: a theory. Many states looking into drug importation have applied a blanket 45% increase to the Canadian, but no state actually knows if this number is accurate. While no state has yet to operate an HHS-approved drug importation program, some have tried and there are lessons to be learned from them. Illinois operated a program called i-SaveRx in the mid-2000s. The Office of the Auditor General released a report in 2006 that showed the program was expensive for the state to run:   
● Twenty-eight agencies reported that 521 employees provided almost 5,600 hours of assistance at an estimated payroll cost of $488,000.   
● Illinois had significant expenditures on the program, including travel, contractual services, marketing, and legal services. Additionally, no state discussion importation to date has actually addressed the cost of testing outlined above. Testing alone is sufficient to make most every importation program financially unworkable.

5. Manufacturers won't cooperate

Drug manufacturers won't allocate more drugs to the Canadian market when they find out they're going to the U.S.

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To avoid recreating the unregulated circumstances that occurred in the early 2000s, the Affordable and Safe Prescription Drug Importation Act includes conditions that would only allow products with the same active ingredient, route of administration and strength as drugs approved in the US to be purchased from a Canadian seller certified by the US Food and Drug Administration (FDA).Certified sellers would be Canadian wholesale distributors or licensed pharmacies engaged in the distribution of prescription drugs for importation under the legislation, have been in business for at least five years and have a purpose other than the export program. Sellers would need to receive a valid prescription before supplying drugs to individuals. They would also have to certify that their physical premises, data-reporting procedures and licences are in compliance with all applicable Canadian laws and regulations, and have policies to monitor compliance. Sellers would have to pay a fee to fund the administration and enforcement of the program. Access to lower-price drugs would improve the well-being of Americans without health insurance. However, the act is an impractical way to address the drug-pricing problem in the US for several reasons. First and foremost, drug manufacturers allot sales to a country by assessing the number of people who will take the drug each year based on past practice and a reasonable estimate of likely increases. Manufacturers are unlikely to increase manufacturing capacity in Canada or to allocate more drugs to Canada from other countries when they know that the drugs will be redistributed to another market, especially a much larger and more lucrative one.

DISADVANTAGES

1. Dangerous drugs

Link: Importation = more counterfeit drugs

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And foreign countries like Canada have [made it clear](https://www.safemedicines.org/2019/03/drug-importation-claim-vs-fact-at-florida-senate-subcommittee-hearing.html) that Americans shouldn’t expect them to monitor the safety of drugs being shipped to the U.S. “There’s no question that a drug importation scheme will increase the flow of counterfeits in the U.S. supply chain,” [wrote](https://www.forbes.com/sites/scottgottlieb/2016/03/04/why-trump-is-wrong-on-drug-prices/#4decbe892e74) former FDA Commissioner Scott Gottlieb in 2016.

Example: Maine tried drug imports from Canada in 2013 and got counterfeits and hazardous drugs

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While Maine is currently attempting to run a state-sponsored drug importation program, the state did allow a personal drug importation program beginning in 2013. Long before a federal judge ruled that the law was in violation of federal law, counterfeit and substandard medicine was being illegally shipped into the state. The former head of the Maine Pharmacy Association filed a lawsuit after testing of drugs he purchased showed that all of the drugs did not have enough active pharmaceutical ingredients and one of them had an unknown, potentially hazardous contaminate. While Maine’s law required the medications to be sourced from a limited set of countries, the medications received came from unapproved countries anyway (India, Mauritius, and Turkey.)

Impact: Sickness and death

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Opening the door to counterfeit drugs from abroad would not only endanger the health of those who took the drugs but also anyone taking a similar drug. Just a few unsafe capsules could trigger massive nationwide recalls, creating shortages and discontinuities of care for millions of patients. In 1982, for example, 31 million bottles of Tylenol were [removed](https://www.pbs.org/newshour/health/tylenol-murders-1982) from circulation after seven people died from pills laced with potassium cyanide. Imagine the effects of a similar recall of insulin or other life-saving medicine triggered by a tainted shipment of foreign products.

No way to track the origin or genuineness of drugs from Canada

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Given that Canada has not implemented a track-and-trace system for any medical products, any drug importation plan would automatically be breaking track-and-trace. Simply slapping an identifier onto a bottle when it enters the country only gives you information as far back as that. The state would just need to trust everyone else earlier in the supply chain that the medication is what they say it is, it has been handled properly. The proposed law requires track-and-trace compliance for any medical products before the medicine enters the state. However, there is no Track-and-Trace system in Canada to rely upon, and Canadian entities cannot be categorized as Trusted Trading Partners under the DSCSA because they do not possess state-issued wholesaler or pharmacy licenses.

No, Canada and the US do not have the same drug safety standards

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Second, although Health Canada and the FDA have relatively similar processes for drug approvals, apply the same standards and sometimes accept each other’s data, their processes are not identical. Drugs can be approved for different indications or dosages. For example, olaparib received FDA approval in patients with BRCA-mutated advanced ovarian cancer who have had three or more previous lines of chemotherapy, whereas Health Canada approved the drug for patients with platinum-sensitive relapsed BRCA-mutated high-grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer that responds to platinum-based chemotherapy. The differences frequently reflect varying views on the risks of specific products. Drugs are also commonly submitted for and receive regulatory approval later in Canada than in the US; olaparib was approved by Health Canada more than 16 months after receiving FDA approval.

2. Harmful to Canada

Link: Importation from Canada would create drug shortages and substantial distress to Canadians

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The actions of Bernie Sanders, who has led the proposal, President Trump and others may simply be a way of putting pressure on the US to introduce controls for drug pricing or for pharmaceutical companies to make their products more affordable. However, if it is enacted and Canadian wholesalers and pharmacies attempt to supply even a small number of Americans who are currently unable to pay for their drugs, shortages would increase in Canada and cause substantial distress to Canadians. Canada’s drug supply is not a long-term solution to America’s homegrown drug-pricing problem.

Impact: Cross-apply AFF's harm about lack of access to prescription drugs

If the AFF's problem is that people are sick and dying in the US because they lack access to prescription drugs, those impacts simply shift to Canada post-plan.

3. Loss of pharmaceutical R&D

Artificially reducing drug prices means reduction in future research that could have made new drug discoveries

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For the issue of pharmaceutical drugs, an overwhelming body of academic research shows that price controls will significantly restrict the number of new drugs in the future. The pharmaceutical industry is the epitome of a dynamic high-tech industry, wherein the profits from one generation of products go to pay the high development costs for the next generation. Artificially reducing drug revenues today will not only cause companies to cut back on their future research—meaning the next generation will benefit less from new drug discoveries—it will jeopardize U.S. leadership in an industry that punches above its weight in funding research and employing scientists.

OECD Study finds almost 1:1 (actually 1 to 0.97) relationship between R&D spending and drug company revenues

**[This means if revenues go up 1%, R&D research spending goes up almost 1%, or 0.97%]**

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The Organization for Economic Cooperation and Development (OECD) conducted a detailed study of this issue in the pharmaceutical industry. It found that “[p]harmaceutical pricing and reimbursement policies stand to affect innovation through multiple channels, influencing both the incentives to invest in private R&D and the costs of investment. The main channel of prospective influence is the impact of pricing and reimbursement policies on the expected return on investment in R&D.” In fact the generation of large revenues is closely related to the amount of research an individual company does. Figure 9 shows R&D expenditures and sales of the 151 largest pharmaceutical firms in the world in 2006. There was clearly a very strong correlation (0.97).

Drug company revenues aren't just "free money" - It's reinvested for future drug discovery efforts

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In order to maximize social welfare with limited resources, policymakers need to appreciate the costs and benefits of each decision they make. In the context of drug prices, they need to clearly understand the strong link between current revenues (which may or may not be the same as consumer prices) and the generation of future drugs. Put simply, drug companies must make significant profits on their best-selling drugs in one generation in order to reinvest in the next generation. A large portion of these “profits” goes to three sources before they are available for distribution to shareholders. First, the revenues must cover the costs of the high number of failed research efforts, most of which generate no revenues. Second, they must pay for the long delays between initial research and product sales. These capital expenditures account for roughly half of the total costs of developing new drugs. Finally, a large portion of the remainder goes into new research on the next generation of drugs.

Impact: Negative net benefits. Lost opportunity of new drugs outweighs present benefit of lower prices

Dr. Joe Kennedy 2019 (law degree and a master’s degree in agricultural and applied economics from the University of Minnesota and a Ph.D. in economics) 9 Sept 2019 " The Link Between Drug Prices and Research on the Next Generation of Cures" <https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures> (accessed 5 June 2022)

The creation of net benefits also extends to future drugs. Reduced biomedical innovation would increase future health care costs and slow improvements in health and longevity. The Alzheimer’s Association recently evaluated the current cost of treating the disease.  By 2050, 16 percent of Americans 65 or older will suffer from some stage of Alzheimer’s, with 6.5 million individuals in the severe stage of needing round-the-clock care. The cost of treating Alzheimer’s that year will be $1.2 trillion in 2019 dollars. The report estimates that discovering a drug in 2025 that would delay the onset of Alzheimer’s by 5 years would reduce the cost of treatment in 2050 by one-third. Savings in the first 10 years alone would total $935 billion.

Impact: Net benefits. Long-term benefit justifies higher prices

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The granting of a monopoly through patents and other intellectual property protection has a positive effect on product development—which in the case of drug companies, is on research, development, and testing. While market power from intellectual property protection may reduce short-term welfare, it increases long-term welfare by encouraging more investment and innovation. This is why the Founding Fathers included patent protection in the Constitution.