

PHYS 320: Science and Public Policy
Professor Bonnie Fleming

By submitting this essay, I attest that it is my own work, completed in accordance with University regulations. —Stephanie Heung

Importing Prescription Drugs from Canada: A Public Health Solution

by Stephanie Heung

Importing Prescription Drugs from Canada: A Public Health Solution

**Addressed to: The Health Subcommittee of the U.S. House
of Representatives Energy & Commerce Committee**

**From: Stephanie Heung, Policy Director of the American
Association of Retired Persons**

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I. Executive Summary

American prescription drug prices are the highest in the world. Numerous studies have shown that American consumers often pay much more than their international counterparts for the exact same drug. As a result, millions of citizens struggle to afford the burdensome prices of their prescription drugs, to the point where 48 million Americans fail to take their medication because they cannot afford it.¹ We believe that high prescription drug prices have led to a public health crisis.

The American Association of Retired Persons therefore urges the members of the U.S. House Subcommittee on Health to introduce a measure to legalize importation of prescription drugs from Canada. The benefits to this policy are as follows: (1) Help your constituents save significant amounts of money on their prescription drugs, (2) Resolve a public health crisis in which millions of Americans fail to take their medication because they cannot afford it, (3) Exert a downward pressure on inflated American drug prices. Furthermore, we demonstrate that Canadian prescription drugs do not pose a health risk to American patients, and outline an accreditation and licensing system to further guarantee the safety of online Canadian pharmacies. Finally, we examine alternate policy recommendations and demonstrate that our proposed policy is the most effective, politically viable option.

II. Organization Experience

The American Association of Retired Persons (AARP), is a nonprofit, nonpartisan association that helps people 50 and older improve the quality of their lives. With a membership of over 37 million, the AARP is one of the largest membership organizations in the United States.²

The AARP has historically fought for the rights of seniors, especially in the area of health policy. We have conducted extensive legal advocacy – for instance, influencing the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the largest overhaul of Medicare in the program’s history.³ Furthermore, we educate seniors on navigating the health care system through our website, mailing list, and blog posts.⁴

The AARP is deeply invested in the availability of safe and affordable prescription drugs for seniors. More than any other age group, seniors are prone to chronic health conditions that require a long-term supply of medications. **In fact, 9 out of every 10 seniors use at least one prescription drug a month, and 76 percent of seniors use two or more prescription drugs a month.**¹ Given that many seniors are prescribed multiple medications for their condition and medications must be refilled throughout the year, seniors often accumulate staggering prescription drug bills that they struggle to afford.

On the specific issue of importing drugs from Canada, the AARP has historically supported seniors purchasing their drugs from licensed Canadian pharmacies given the excellent safety track record of Canadian drugs.⁵

III. Background

(1) Issue: U.S. pharmaceutical prices are the highest in the world

U.S. pharmaceutical prices consistently rank as the highest in the world. **Americans almost always pay the higher prices for the exact same prescription drug than every other country worldwide.**

Per capita drug spending in the U.S. is 40 percent higher than in Canada, 75 percent higher than in Japan, and nearly 300 percent higher than in Denmark.⁶ A 2012 study by the International Federation of Health Plans found that U.S. prices were the highest in all 21 categories of medical costs studied, including in all six commonly prescribed medications that were analyzed.⁷ Figures 1 and 2 in the Appendix illustrate worldwide prices for Celebrex and Nasonex, two of these six common medications.

This disparity in prescription drug prices is directly due to government policy. **In almost all other developed countries, government health plans use their bulk purchasing power to negotiate with pharmaceutical companies and decrease prescription drug prices for their citizens.** Other strategies to rein in prescription drug prices are also used: the Japanese government insists that the price of a given prescription drug must decrease every two years, and European countries refuse to pay any more than their neighbors for a specific drug.⁸

In contrast, the U.S. government does not negotiate prices with pharmaceutical companies, therefore allowing pharmaceutical companies to price their drugs as high as the market will bear – a price that is usually the highest in the world. Though American

pharmaceuticals supposedly operate under competitive pricing, this free market is frequently an illusion, as many life-saving drugs are manufactured by a single company.⁸

(2) The FDA bans importation of prescription drugs from other countries

Though American drug prices are higher than anywhere else in the world, the FDA currently bans importation of prescription drugs from other countries for personal use.

According to the FDA website: “Under the FD&C Act, the interstate shipment of any prescription drug that lacks required FDA approval is illegal. Interstate shipment includes importation — bringing drugs from a foreign country into the United States.”⁹

FDA guidelines encourage its staff to avoid prosecuting violators of the law if all of the following circumstances apply:

- If the intended use is for a serious condition for which effective treatment may not be available domestically
- If the product is not considered to represent an unreasonable risk
- If the individual seeking to import the drug affirms in writing that it is for the patient's own use and provides the name and address of the U.S.-licensed doctor responsible for his or her treatment with the drug or provides evidence that the drug is for continuation of a treatment begun in a foreign country
- If the product is for personal use and is a three-month supply or less and not for resale, since larger amounts would lend themselves to commercialization
- If there is no known commercialization or promotion to U.S. residents by those involved in distribution of the product.⁹

However, these are merely guidelines rather than a regulation or law. Furthermore, the fairly stringent rules sometimes discourage consumers for importing medications, and the requirement that imported prescription drugs “not be available domestically” is failed by consumers seeking to purchase cheaper but otherwise identical versions of their medications abroad.

(3) The FDA’s ban on importing prescription drugs is ineffective

Due to high prices for American prescription drugs, many consumers break the law and obtain cheaper medications abroad. According to the Canadian International Pharmacy Association, over 1 million Americans now illegally buy their medications from Canada each year.¹⁰ Furthermore, a 2011 survey by the Centers for Disease Control and Prevention found that 2% of adults and 5% of the uninsured admitted to purchasing prescription drugs from other countries.¹¹ The CDC figures are likely underestimates because many people are reluctant to admit to illegal activity in a government survey. These people are very rarely prosecuted, despite breaking the law.¹²

(4) Statewide legislation has already been passed to legalize importation of Canadian drugs

State legislation has previously been enacted that legalizes importation of prescription drugs from abroad. On October 9, 2013, Maine passed the Act to Facilitate the Personal Importation of Prescription Drugs from International Mail-Order Pharmacies. It became the first state to legalize importing prescription drugs, specifically from licensed mail-order pharmacies

based in Canada, the United Kingdom, New Zealand, and Australia.¹³ Pressure in favor of the legislation was spearheaded by seniors and small businesses seeking to reduce their employee health care costs. Because the legislation was passed just two months ago, it is too early to fully examine its impact.

The lessons from the Maine legislation are twofold: (1) There is significant political pressure in support of legalizing drug importation, making national legislation potentially politically viable, and (2) Inconsistent policy from the FDA and the federal government has led to a “regulatory limbo,” so we are at an ideal time to reform national policy on this issue.

IV. Recommendations

The American Association of Retired Persons recommends introducing a measure to permit drug importation from licensed Canadian pharmacies for personal use. This can be accomplished by introducing it within existing legislation being currently being debated by the U.S. House Subcommittee on Health, such as the Medicare Prescription Drug Savings and Choice Act of 2013. Alternatively, it can be accomplished by introducing a separate bill solely devoted to this issue. The specifics of the legislation would be as follows:

- Purchase of prescription drugs from a brick-and-mortar Canadian pharmacy is legalized.
- An accreditation and licensing system for online, mail-order pharmacies should be developed as a collaboration between the FDA and Health Canada. This will ensure that online pharmacies purporting to be Canadian are actually selling drugs of Canadian origin.

- Purchase of prescription drugs from an online, mail-order Canadian pharmacy is legalized for those businesses accredited and licensed by the FDA and Health Canada (the equivalent of the FDA in Canada). This will take effect three years after the accreditation system is first created to ensure that the system is fully functional before consumers purchase their drugs online.
- The drugs that can be legally imported are those whose average retail prices are 150% more expensive in the U.S. than Canada. This determination will be made by the U.S. Government Accountability Office, which regularly prepares financial reports upon the request of congressmen, including on the topic of health care.¹⁴

V. Reasoning for Recommendation

(1) Legalizing prescription drug importation will help consumers save money

American prescription drugs are the most expensive in the world. Permitting importation of prescription drugs is an opportunity to help your constituents save significantly on their medical bills.

Numerous studies have demonstrated that Americans pay far more than their Canadian counterparts for the exact same drug. A 2012 study by the International Federation of Health Plans analyzed six commonly prescribed medications and found that the U.S. prices were consistently the highest worldwide, significantly exceeding the price for the exact same medication in Canada.⁷ Figures 1 and 2 in the Appendix demonstrate this point for Celebrex and Nasonex, two of the medications analyzed.

This price differential is not merely a recent economic blip; it has historically held true and will likely remain true for the foreseeable future. For example, eight different studies dating from 1992-2003 examined the price differential between American and Canadian drugs in three categories: the prices charged by the drug manufacturer, wholesale drug prices, and retail drug prices. The studies were variously conducted by the U.S. government, academics, and third-party organizations, and all eight studies found that the majority of medications were significantly more expensive in the U.S. than in Canada.¹⁵

This issue is very important to your constituents. A large fraction of your constituents would be impacted: 48% of Americans have at least one prescription, 21% have at least three prescriptions, and 11% have five or more prescriptions.¹ Given that many consumers are prescribed multiple medications and medications must be refilled throughout the year, consumers often accumulate staggering prescription drug bills that they struggle to afford. In fact, this financial burden of prescription drugs is skyrocketing: In 2009, the average American spent \$956 on prescription drugs, a 97% increase compared to 1999.¹ **Permitting importation of prescription drugs is an opportunity to help your constituents save significantly on their medical bills.**

(2) Legalizing prescription drug importation will fulfill a public health need

The high costs of prescription drugs in America has led to a public health crisis. **In 2010, over 48 million Americans failed to take their medicine because they cannot afford it, a number that has risen 66% since 2001.**¹ By not taking their medication, they are not only harming their own health, but also decreasing workplace productivity and driving up health care

costs in the long term due to their deteriorating medical condition. **A sensible public health measure, therefore, is to permit importation of drugs from Canada so that millions of patients can finally afford to take the medications that they need.**

(3) The policy will create a downward pressure on American prices

The proposed legislation states that the drugs that can be legally imported are those whose average retail prices are 150% more expensive in the U.S. than Canada. This determination will be made by the U.S. Government Accountability Office, which regularly prepares financial reports upon the request of congressmen, including on the topic of health care.

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We included this measure because it will create downward pressure on American pharmaceutical prices. **In an effort to avoid losing consumers to the Canadian market, pharmaceutical companies will likely decrease their American prices to less than 150% of the Canadian prices.** This will allow pharmaceutical companies to retain their business while offering Americans fairer prices on their medications.

Given that pharmaceutical companies are willing to sell the exact same medications to other countries for a fraction of the U.S. price, they would evidently still be making a profit if they sell prescription drugs to Americans at Canadian prices. We therefore believe that pharmaceutical companies would therefore be willing to decrease the price if offered the proper incentives.

VI. Opposition to Recommendation

(1) Canadian drugs are safe

Historically, the principal argument against permitting drug importation from Canada is that the FDA cannot guarantee the safety of foreign pharmaceuticals. This is the argument that the FDA itself uses to justify the ban. We would like to tackle this argument on two fronts: the safety of brick-and-mortar pharmacies physically located in Canada, and the safety of online mail-order pharmacies claiming to be Canadian.

Brick-and-mortar Canadian pharmacies, which sell medications approved by Health Canada, have a very strong safety record, comparable to their American counterparts. Reports from the Congressional Research Service concluded that prescription drugs manufactured in Canada meet or surpass the FDA quality control guidelines, and that “the statutory requirements for approving and marketing pharmaceutical products in the United States and Canada are, in general, quite similar.”¹⁶ Tom McGinnis, the FDA’s director of pharmacy affairs, has himself stated that, “I can’t think of one thing off the top of my head where somebody died or somebody got put in the hospital because of these medications. I just don’t know if there’s anything like that.”¹⁷ Health Canada has too reported that it “does not have any information that would indicate that any Americans have become ill or have died as a result of taking prescription medications purchased from Canada.”¹⁸ Even Peter Rost, Pfizer’s vice president for marketing, admits that regarding Canadian drugs, “the safety issue is a made-up story.”¹⁸ It is clear that Canadian medications do not pose a safety risk to American patients.

Online, mail-order pharmacies are a separate issue from their brick-and-mortar counterparts. **There is little question that online pharmacies actually based in Canada are safe.** A 2012 analysis by the U.S.-based National Bureau of Economic Research found no difference in drug safety between U.S.-certified online pharmacies based in the U.S. and Canadian-certified online pharmacies based in Canada. ¹⁹

However, there are numerous online pharmacies purporting to be Canadian, but in reality selling drugs of dubious quality from Third World countries such as India and Thailand. A 2005 FDA sting operation, “Operation Bait and Switch” intercepted medication packages at airports and found that 85% of drugs promoted as being “Canadian” actually came from 27 countries across the world. Of the 4,000 parcels examined, 32 were determined to be counterfeit. ²⁰

We argue that in order to protect consumers from fraudulent online pharmacies, we must implement an accreditation and licensing system as a collaboration by the FDA and Health Canada. Under our proposed legislation, purchase of medications from these government-certified Canadian online pharmacies would be legalized. There are existing accreditation systems from the National Association of Boards of Pharmacy, the Canadian International Pharmacy Association, LegitScript.com, and PharmacyChecker.com. However, we believe that it is the government’s responsibility to develop its own accreditation system and ensure the safety of the drug supply chain for its citizens. Furthermore, third-party pharmacy organizations – especially those based in the United States – have a vested interest in Americans purchasing their medications from the U.S. rather than Canada, and therefore may be biased in their evaluation of Canadian pharmacies. A government-based accreditation and licensing system is therefore the most impartial option.

We believe that it is important to ensure access to safe Canadian drugs via the Internet. While we are certain of the safety of brick-and-mortar Canadian pharmacies, access to these pharmacies primarily benefits only the citizens of U.S. states that border Canada. Accrediting and licensing high-quality online Canadian pharmacies will allow the entire country to benefit from decreased prescription drug prices, not just the border states.

Finally, the argument that Canadian drugs pose a public health risk ignores the fact that over 48 million Americans did not take their medication in 2010 because they could not afford it, a number that has risen 66% since 2001.¹ We argue that this failure to take medications prescribed by their doctors is the true public health crisis, not Canadian prescription drugs, which are proven to be safe.

(2) Adverse impact on the American pharmaceutical industry will be limited

Another important opponent of our proposed legislation is the American pharmaceutical industry, which argues that permitting consumers to import drugs from Canada will detract from their business. They argue that high drug prices are necessary to cover their R&D costs, which in turn develops innovative new drugs to benefit Americans.

However, we believe that the pharmaceutical industry is so profitable that it will not be adversely impacted by our proposed policy. Over the last decade, the top 11 drug companies earned \$711 billion in profits, with profit margins at about 30%.^{21 22} These are some of the highest profits among all Fortune 500 companies.²³ It is important to note that these statistics are profits, not revenue, therefore invalidating pharmaceutical companies' argument that high drug prices are justified by their R&D costs. In fact, though pharmaceutical companies

reported that their R&D costs rose by \$34 billion between 1995 and 2010, this is far outpaced by their self-reported \$200 billion increase in revenue over the same time period.²⁴

There are other flaws to the pharmaceutical companies' argument that high prices are necessary to support the R&D that goes into creating innovative new drugs. Pharmaceutical companies spend 19 times as much on marketing and advertising than they do on R&D, according to a recent study in the British Medical Journal.²⁵ **Furthermore, the R&D that the industry does undertake is often not innovative at all: many new drugs are minor molecular modifications of existing drugs on the market (known as "me too" drugs), guaranteeing additional profits from a new patent without actually improving upon existing medications.**²⁵ A number of studies dating from the past decade have found that about 85-90% of new drugs have no added clinical benefit for patients compared to existing drugs.²⁶^{27,28} We therefore believe that pharmaceutical companies cannot justify their high drug prices as necessary for the creation of innovative new drugs, and therefore ultimately benefiting America.

Furthermore, taxpayers help subsidize the pharmaceutical industry's R&D costs. An NIH study found that U.S. taxpayer-funded researchers contributed 55% of the knowledge (such as basic research, new techniques and assays, and clinical research) used in drug discovery and development.²⁹ An analysis of the top-selling drugs from 1992-1997 found that 45 out of the 50 drugs studied were created with government funding for at least one phase of development.³⁰ Because many drugs are developed with taxpayer money, it is only reasonable that the taxpayers reap the benefits by paying fair prices for their medications.

We therefore believe that allowing importation of drugs from Canada will have limited adverse impact on the pharmaceutical industry. Though profits will likely decrease due to the proposed policy, pharmaceutical profit margins are so high that it will certainly not

cripple the industry. The financial benefits reaped by millions of individual consumers far outweighs the economic inconvenience posed to an already highly profitable industry.

VII. Alternate Recommendations

(1) Permit importation of prescription drugs from all foreign countries

An inevitable question raised by the proposed policy is: Why Canada? Theoretically, importation of prescription drugs from all countries could be legalized. An advantage of this is that by opening the prescription drug market even further, Americans can purchase medications at the lowest prices offered worldwide, not just in Canada. Furthermore, legalizing drug importation from Mexico is convenient for U.S. citizens living in states that border Mexico.

However, we strongly advise against this policy option. We advocate for permitting drug importation from solely Canada due to the country's strong safety record. Numerous studies have proven that both brick-and-mortar and online pharmacies based in Canada match or surpass FDA quality standards (see Section VI, Part 1 of this memo). The same cannot be said for many countries worldwide. The World Health Organization estimates that 10-30% of medications in developing countries are counterfeit, and 50% of medications from online pharmacies that conceal their physical address are also counterfeit.³¹ The FDA cannot reasonably guarantee the safety of prescription drugs across the world, in contrast to the strong safety record of Canadian drugs.

(2) Subject American pharmaceuticals to price controls

An alternative recommendation is to subject American pharmaceuticals to price controls. In almost all other developed countries, government health plans use their bulk purchasing power to negotiate with pharmaceutical companies and decrease prescription drug prices for their citizens. In contrast, the U.S. government does not negotiate prices with pharmaceutical companies, therefore allowing pharmaceutical companies to price their drugs as high as the market will bear – a price that is usually the highest in the world.⁸ By implementing government price controls, we will follow the successful strategy of almost all other developed countries to make prescription drugs affordable for their citizens.

An advantage of this policy option is that it will effectively rein in American drug prices across the board. Our proposed policy will likely exert a downward pressure on drug prices by legalizing the importation of drugs that are 150% more expensive in the U.S. than Canada (see Section V, Part 3 of this memo), but the implementation of price controls is a more direct and comprehensive method of achieving a similar effect. Furthermore, consumers will be able to purchase affordable drugs in the U.S., and are therefore spared the hassle of traveling to Canada or finding certified online Canadian pharmacies.

However, this policy option suffers from a significant disadvantage: it is not viable in today’s political climate. With the rocky implementation of President Obama’s Affordable Care Act dominating the headlines, it is unlikely that anything resembling “socialized medicine” can be passed in the foreseeable future.^{32, 33, 34} In contrast, permitting drug importation from Canada has been successfully implemented on a state level (see Section II, Part 4 of this memo). Furthermore, it has garnered the strong backing of certain groups, e.g. seniors and small

businesses seeking to reduce their health care costs, therefore making nationwide implementation of our policy more politically viable than the alternative of government-imposed price controls.

It is true that government price controls, despite their lack of political viability, are the most effective solution in reining in U.S. pharmaceutical prices. It has been successfully implemented in almost all other developed countries around the world. Yet a systemic overhaul of the American pharmaceutical industry – which is badly needed – is not politically viable in the near future. **We therefore see our proposed policy of permitting drug importation from Canada as a temporary solution to limit prescription drug expenditures in the short term. Eventually, in future years with a more favorable political climate, we hope for a more systematic reform of the pharmaceutical industry, including government price controls to match those of other developed nations.**

VIII. Conclusion

It is clear that the prices of American pharmaceuticals, the highest in the world, pose an unacceptable economic and medical burden on the country. **The American Association of Retired Persons therefore urges the members of the U.S. House Subcommittee on Health to introduce a measure to legalize importation of prescription drugs from Canada.** This is a safe, cost-effective, and politically viable option to protect our country's public health.

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X. Appendix

Figure 1: Comparison of worldwide prices for Celebrex. U.S. and Canadian prices highlighted in red. Source: International Federation of Health Plans.

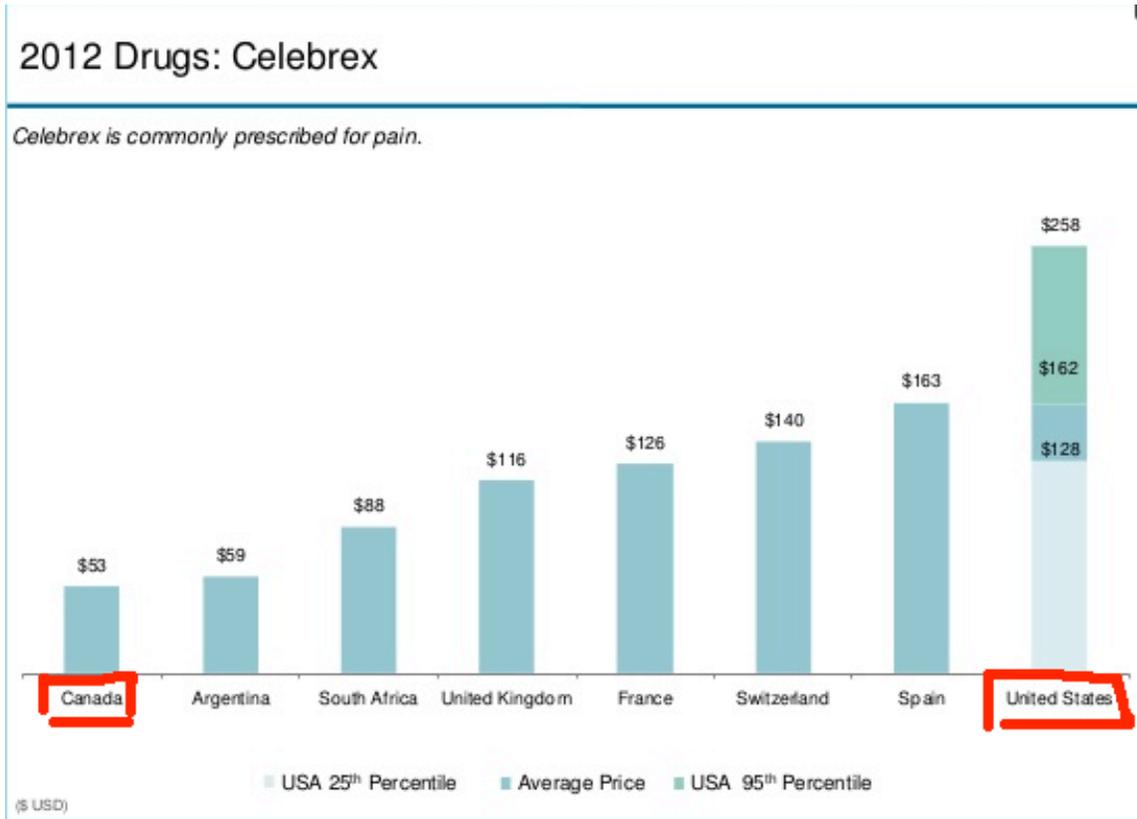


Figure 2: Comparison of worldwide prices for Nasonex. U.S. and Canadian prices highlighted in red. Source: International Federation of Health Plans.

