Canada: the Prescription for Lower Drug Prices?

An Analysis of Prescription Drug Importation Policy

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Introduction

Sixty-four year-old nun and part-time Spanish teacher Sister Mary Kay Kottenstette takes three medications to treat her high cholesterol, gout, and thyroid problems: Lipitor, allopurinol, and Synthroid. Sister Kottenstette estimates that in 2002, she spent $1,068 of her $15,000 salary on her medications. Far from the border of Canada and thus unable to cross into the country herself, Sister Kottenstette began utilizing www.canadianmedsusa.com, which provides her with her exact same American-manufactured, name-brand drugs—at much lower Canadian prices. This year, instead of spending $1,068 on medications, Sister Kottenstette estimates that she will spend $640. (Redeker 2004).

Health spending in the United States rose 9.3% in 2002—the largest increase in 11 years (Barlett 2004). At 15% a year the cost of drugs is rising far faster than any other health costs in the United States (Phillips 2000); prescription drug prices increase at four to five times the rate of inflation (United States a 2003). 2001 United States pharmaceutical sales were the highest of any developed country at $654 per capita; the United States leads Japan, France, Switzerland, Germany, Italy, Britain, and Spain in pharmaceutical spending, yet boasts the lowest life expectancy of these countries. With price controls in most other countries, in 2002 the pharmaceutical industry made nearly half its sales—$200 billion—in the United States (Harris 2003). And while seniors such as Sister Mary Kay Kottenstette struggle to pay for expensive, essential medications, the two largest pharmaceutical companies in the U. S., Pfizer Inc. and Eli Lilly & Co., have the highest returns on revenue of all U. S. companies, at 28.4% and 24.4%, respectively. (Bartlett 2004)

A survey of ten popular drugs in the U.S. and Canada conducted by the Associated Press in November 2003 found that pharmaceutical drugs sold in Canada were 33 to 80 percent cheaper than the same pharmaceuticals sold in the United States (Sherman). Individuals who import Canadian drugs also enjoy substantial savings; Shirely Johnson, 68, of Cedar Falls, Iowa claims she saves over $1500 out of the $8,375 her family normally spends on medical expenses by purchasing through online Canadian pharmacies (Drug Week c 2003).

Aside from pharmaceutical companies the FDA has been the strongest opponent of prescription drug importation, pointing out that pharmaceutical importation is illegal under the Federal Food Drug and Cosmetic
Act, primarily due to the FDA’s safety concerns; the FDA warns that buying Canadian drugs “presents significant, potential health and safety risks” (Health & Medicine Week 2003) caused by improper drug labeling, the questionable country of origin of Canadian drugs, and insufficient and/or improper inspection by Canadian authorities. However, a study conducted in 2003 by the Congressional Research Service found that the Canadian and United States systems of prescription drug distribution were virtually identical (Sarasota Herald-Tribune 2003), that drug-safety regulation is often stricter in Canada and overseas than in the United States, and that there have been no reported adverse effects from Canadian imported pharmaceuticals in the United States, according to the FDA (Barlett 2004). The FDA claims that it would cost “hundreds of millions of dollars to set up a legal, safe program to import drugs from Canada” (Baldor 2003); however, the Congressional Budget Office calculated that the importation of FDA-approved drugs would reduce federal expenditures for Medicaid by $2.9 billion between 2004 and 2013, and state Medicaid expenditures by $240 million between 2004 and 2008 (Flanagan 2004). According to authors of a Time Magazine report published in February 2004, the FDA is a “powerful partner” to the “pharmaceutical industry… the FDA’s actions against Canadian imports has been part of a concerted campaign to simultaneously discredit its counterpart agency in Canada, provoke fear among American consumers who buy there drugs there… [and to] ultimately preserve the inflated prices charged [to] U.S. consumers and taxpayers” (Barlett 2004).

In June of 2003 the Senate voted 62 to 28 in favor of prescription drug importation under H. R. 2427, the Pharmaceutical Market Access Act; in July, the House of Representatives voted 243 to 186 in favor of the bill (Pear 2003). Both Houses cited the need for an alternative to high prescription drug prices in the United States. The proposed legislation authorized United States pharmacies to import prescription drugs made in Canada and other industrialized counties, if the drugs were approved for sale in the U. S. by the FDA and if manufacturers use counterfeit-resistant technologies (Barlett 2004). After passage in both houses, the bill was deleted from the Medicare Bill in a secret joint House-Senate conference—a modification no one is taking credit for (Barlett 2004); the approved 2003 Medicare Prescription Drug, Improvement and Modernization Act allows for the Secretary of the Department of Health and Human Services to implement a system of prescription drug importation from Canada only if the Secretary is able to prove to Congress that the system is safe and cost-effective (Food and Drug Administration Docket No. 2004N-0115, 2004).
Public support for prescription drug importation remains high; a Kaiser Health Poll report conducted in September of 2003 revealed overwhelming support for prescription drug importation, with 68 percent of respondents claiming to “favor the federal government making it easier to buy prescription drugs from Canada” (Kaiser 2003). Today, Canadian online pharmacies supply a growing number of Americans—approximately one million—with drugs estimated to cost nearly 700 million United States dollars per year (Simon 2003); United States House estimates, however, place American spending on the Canadian pharmaceutical system at a mere $20 million, yet concede that this number is rapidly growing (Carey 2003).

“The current debate over Canadian prescription drug sales to Americans is the perfect example of the fact that many of the best solutions...trickle up from leaders in places like Springfield, Massachusetts, and the states of Illinois and Minnesota, where grassroots problem solvers of both political parties have focused on Canadian re-importation as the practical solution that is the best answer to their problem...these leaders [Charlie Ryan of Springfield, Massachusetts; Rod Blagojevich of Illinois; Tim Pawlenty of Minnesota] have forced a national debate on an important question” (Managed Care 2003). National drug importation policy in the United States has been shaped primarily at the state level by legislators and interest-groups, yet has gained momentum due to wide-spread public popularity resulting from national media coverage. While states advocating prescription drug importation concede that the practice is certainly not a viable long-term solution to rising drug costs, the importation of Canadian drugs as an alternative to traditional state plans utilizing expensive American drugs may impress adequate pressure on the federal government to lower prescription drugs costs in the United States. The evolution of drug importation as a policy issue can be explained through an examination of the relevant actors involved, an assessment of the history of pharmaceuticals in the United States, and an understanding of the events involved in the battle for drug importation from Canada.

Actors in the Policy Process

The concept of federalism has impacted drug importation policy in that states and the federal government disagree on where the power to regulate prescription drug importation should lie; while states hold that importing drugs is a state issue which should not be subject to control by the federal government, federal actors such as those in the FDA advocate the supremacy of federal law.
Article 1, Section 8 of the United States Constitution, or the Commerce Clause, states “Congress shall have the power...to regulate Commerce with foreign nations, and among the several states, and with Indian Tribes” (United States Constitution). Historically, the Supreme Court has interpreted the Commerce Clause very differently, granting supremacy to both federal and state governments in the regulation of interstate commerce. In *US v. E. C. Knight Co.* (1895) the Supreme Court made federal regulation very difficult by setting up the Stream of Commerce Doctrine which was subsequently applied in *Swift & Co. v. US* (1905) and *Stafford v. Wallace* (1922). In *National Labor Relations Board v. Jones & Laughlin Steel Corporation* (1937) the court reversed earlier decisions, returning power of regulation to the federal government; in holding that manufacturing was “interdependent” (Epstein 418) and subsequently an interstate issue, the Court broadened the scope of federal power in enforcing the Commerce Clause. Chief Justice Hughes asserted that “although activities may be intrastate in character when separately considered, if they have such a close and substantial relation to interstate commerce that their control is essential or appropriate to protect that commerce from burdens and obstructions, Congress cannot be denied the power to exercise that control” (Epstein 418). Further, in the majority opinion written by Justice Jackson in *Wickard v. Filburn* (1942), the Court reinforced the supremacy of the federal government, holding that “even if an appellee’s activity may be local and though it may not be regarded as commerce, it may still, whatever its nature, be reached by Congress if it exerts a substantial economic effect on interstate commerce, and this irrespective of whether such effect is what might at some earlier time have been defined as ‘direct’ or ‘indirect’” (Epstein 424). Thus, under *Wickard* precedent, very little activity can be defined as purely intrastate, consequently significantly broadening the scope of the Commerce Clause. However, in *United States v. Lopez* (1995) and in *United States v. Morrison* (2000) the Supreme Court ruled that federal legislation which “does not regulate an economic activity that, in the aggregate, substantially affects interstate commerce” would be “constitutionally suspect” (Epstein 437); despite these cautionary rulings the Court has yet to strike down any federal programs under the Commerce Clause (Epstein 436).

Thus, the Commerce Clause, Article 1, Section 8 of the United States Constitution covers prescription drug importation policy due to the Constitutional authority granted to the federal government to regulate interstate commerce. While Canadian drugs are currently only being imported on a state and local level, Supreme Court precedent has repeatedly allowed the federal government authority to regulate any commerce
which may have an affect on interstate commerce; the pharmaceutical industry’s reaction to the importation of Canadian prescription drugs is likely to effect localities, states, the nation—and Canada. The federal mechanism for monitoring and regulating drugs is the Food and Drug Administration, or the FDA, which has emerged as the principle actor at the federal level in prescription drug importation policy.

The Department of Health and Human Services

The FDA

Drug regulation as a public policy issue dates back to 1848 with the passage of the Drug Importation Act, which required the U. S. Customs Service to inspect and prevent the entry of foreign adulterated drugs from overseas. The ability to regulate drugs now falls under the Food and Drug Administration, which has evolved in scope and purpose since 1906 with the passage of the Federal Food and Drugs Act, which created an agency responsible for regulating food and drugs. Prior to 1906 the regulation and inspection of food and drugs was primarily a state function. Due to vastly inconsistent control of drugs state-by-state, the growing incidence of the adulteration and misbranding of foods and drugs, the increasing ability of science to detect fraud in food and drugs, and public support, the Federal Food and Drugs Act became instrumental in regulating interstate commerce of food and drugs; Constitutional basis for the regulation falls under Article 1, Section 8.

Amid a widely-publicized toxic drug scandal, Franklin Roosevelt signed the Food, Drug, and Cosmetic Act on June 25, 1938. The new law brought cosmetics and medical devices under federal control, required that drugs be labeled with adequate directions for safe use, and mandated pre-market approval of all new drugs by requiring drug manufacturers to prove to the FDA that a drug was safe before its public sale and marketing. In addition, the law formally authorized factory inspections and added injunctions to the FDA’s enforcement mechanisms. While many amendments have been made to the Food Drug and Cosmetic Act, the law remains in place today. (FDA Online 2004) On April 11, 1953, the Cabinet-level Department of Health, Education and Welfare (HEW) was created under President Eisenhower; in 1979 the Department of Education Organization Act, which provided for a separate Department of Education, resulted in the replacement of HEW with the Department of Health and Human Services on May 4, 1980. The Food and Drug Administration is an agency of the Department of Health and Human Services. (Department of Health and Human Services 2004)
The Department of Health and Human Services, a cabinet-level department, is managed by Secretary Tommy Thompson, who was appointed by President George W. Bush and confirmed by the Senate. Within the Food and Drug Administration officials have considerable authority to shape public policy; these officials work closely with Presidential appointees who head both the FDA and the Department of Health and Human Services, who in turn work closely with the White House to ensure that department and agency policy decisions are consistent with presidential policies. (Kraft 2004) Thus, the Department of Health and Human Services and the FDA will make prescription drug importation policy recommendations in accordance with the White House position on prescription drug importation policy. HHIS Secretary Tommy Thompson's promised in his confirmation hearing before the Senate to "revisit [former Secretary Donna] Shalala's determination" to not adopt a policy of prescription drug importation from Canada (Kouzoukas 2002); at the time his statement was consistent with President Bush's support of prescription drug importation.

FDA Laws and Regulations under the Food and Drug Act of 1938 prohibit the importation of prescription drugs into the United States by anyone other than the drug's United States manufacturer (Hassel 2003); drugs produced in the United States and shipped to Canada cannot be "reimported" back to the U.S. by anyone other than the manufacturer; additionally, drugs produced in FDA-approved manufacturing facilities in Canada and abroad cannot be imported to the U.S. by anyone other than the drug's manufacturer. Section 331 of the Food, Drug, and Cosmetic Act states that:

Congress has the power to determine which articles may be permitted importation into the United States from a foreign source and the terms upon which the importation will occur. An article subject to the Federal Food, Drug, and Cosmetic Act is still in "interstate commerce" even if it is purchased before being shipped across state lines. This is true even if the article is intended solely for personal consumption. Therefore, the Act properly regulates personal articles imported into the United States for personal consumption. The Act also prohibits the importation into the United States of any unapproved new drug. (FDA 2004)

Thus, the regulation of prescription drug importation falls under federal jurisdiction.

Essentially, the FDA is a public health agency, and derives its power from Congressional legislation dating back to 1906. As stated on their website, applicable to drug regulation, the FDA's mission is to "protect the public health by assuring the safety, efficacy, and security of human...drugs...and help the public get the accurate, science-based information they need to use medicines...to improve their health" (FDA 2004).

The Drug and Food Act of 1938 (21 U.S.C.), Sections 331(d) and 355(a) states that federal law:
prohibits the interstate shipment (which includes importation) of unapproved new drugs. Unapproved new drugs are any drugs, including foreign-made versions of U.S. approved drugs, that have not received FDA approval to demonstrate they meet the federal requirements for safety and effectiveness. (FDA 2004).

However, the Food and Drug Act of 1938 does allow for the importation of small quantities of prescription drugs for personal use in the event that:

1) the intended use [of the drug] is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; 2) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue; 3) the product is considered not to represent an unreasonable risk; and 4) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than 3 month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product or provides evidence that the product is for the continuation of a treatment begun in a foreign country (FDA 2004).

This clause, commonly referred to as "personal importation policy" is intended to allow treatments not available in the United States, and thus cannot be applied to drugs available in the United States and manufactured elsewhere. (FDA 2004) In addition, drugs sold in the United States must meet FDA labeling requirements and bear FDA-approved labeling; drugs must be dispensed by a pharmacist pursuant to a valid prescription (Hassel 2003).

The Department of Health and Human Services and the FDA have both been outspoken opponents of prescription drug importation. Citing safety concerns including counterfeit drugs and improper labeling, William K. Hubbard, Associate Commissioner for Policy and Planning for the HHS, testified to Congress on behalf of both the HHS and FDA in June 2003 that "despite continued efforts to identify ways to assure the safety of imported drugs, FDA for many years has consistently stated that it cannot assure the safety of prescription drugs that are obtained outside its comprehensive regulatory system" (Department of Health and Human Services c 2004). Under direction of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), the Department of Health and Human Services announced plans on February 26, 2004 to create a task force to advise and assist the agency in determining how drug importation might be conducted safely and the potential impact of pharmaceutical importation on the health of American patients, medical costs, and the development of new medicines. "The importation of drugs remains a long-standing safety concern for the Department of Health and Human Services, as we currently cannot guarantee the safety of these medicines,"

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Secretary Tommy Thompson stated, "This task force will study what it would take in terms of oversight and resources to safely import drugs...I'm confident that it will produce a balanced picture of the costs and benefits of drug importation" (Department of Health and Human Services b 2004). The deadline for the task force decision is December.

Other Agencies of the Department of Health and Human Services

Other agencies of the Department of Health and Human Services, such as the Center for Disease Control and Prevention and the Agency for Healthcare Research and Quality, have deferred authority regarding prescription drug importation to its parent department, the HHS, and the Food and Drug Administration. As agencies of the Department of Health and Human Services, a national department headed by a member of the Bush cabinet, it is likely that the agencies would not support prescription drug importation.

The National Institutes of Health has not made their position on prescription drug importation public. As the primary agency for the funding of medical and biomedical research, the NIH is responsible for the $28 billion federal investment in research and development (National Institutes of Health Summary of the FY 2005 President’s Budget 2004). Within the NIH the National Institute of Biomedical Imaging and Bioengineering (NIBIB) frequently works closely with the pharmaceutical industry in the development of new drugs; $289 million will be allotted to the NIBIB alone for the development of new drugs, among other drug research programs (National Institutes of Health Summary of the FY 2005 President’s Budget 2004). As Congress continues to debate whether the government's financial, scientific, and clinical support of health-related research and development entitles the public to lower prices for pharmaceuticals resulting from a collaboration with the NIH, the NIH continues to invest substantially in drug development with the pharmaceutical industry (CRS Report for Congress 2000). Thus, it is probable that the NIH would not support a policy of prescription drug importation in light of the pharmaceutical industry’s prediction of declining pharmaceutical research in the United States. In addition, as an agency of the Department of Health and Human Services, it is unlikely that the department would take a stance contrary to that of its Secretary and President.

The President
During his campaign President George W. Bush claimed that prescription drug importation “makes sense” as a way to provide “an immediate helping hand” to the elderly. However, following his election, President Bush became non-committal on the issue; not until mid-2001 with the release of his health care budget proposals did the President make his opposition to drug importation policy apparent (Kouzoukas 2002). While President Bush opposes to prescription drug importation from Canada, citing safety concerns, his 2003 Medicare Budget did allow for paltry financial support for the study of the viability of prescription drug importation. Rather than taking a concrete stand on prescription drug importation himself, President Bush has continually referred the issue to the FDA; because the FDA cannot guarantee the safety of imported drugs, the President remains opposed to the practice. While White House Press Secretary Ari Fleischer claimed that “The President is very troubled about the price of prescription drugs and the lack of access that senior citizens have to prescription drugs” (Los Angeles Times 2001), arguably, the Medicare Budget does little to relieve high pharmaceutical prices. On April 9, 2001 President Bush included the study of drug importation in his budget proposals, yet undermined the practice by cutting research funding by 20 million dollars—nearly 90 percent of the 23 million-dollar budget required to fund the initiative (Kaiser Network 2001); Bush’s failure to financially back the proposal was viewed as a calculated effort to discredit drug importation policy.

President Bush’s policy advisors have continually reinforced the importance of the FDA as the principal decision-maker in prescription drug importation. Doug Badger, the President’s Senior Health Policy Advisor, cited the FDA’s “grave concerns” over safety issues, echoing FDA Commissioner Dr. Mark McClellan statement that “there is no evidence that unapproved imported drugs are becoming any safer or more reliable... we are concerned about any measures that would increase the flow of these unapproved drugs, or provide easier channels for them to enter the U.S.” (White House 2004). Badger claimed that rather than importing Canadian prescription drugs as a means for reducing high U.S. drug prices, “the [2003 Medicare] bill relies on the pooled buying power of millions of seniors to negotiate discounts from manufacturers and pharmacists” (White House 2004). (However, President Bush’s 2003 Medicare Bill prohibits government agencies for negotiating with the pharmaceutical industry for lower prices (Barlett 2004).) Other executive Presidential agencies such as the Office of Science and Technological Policy who have not explicitly supported nor opposed prescription drug importation are habitually aligned with the President, and thus would likely not support the policy.
The 2000 Prescription Drug Act signed by former President Bill Clinton would have allowed for prescription drug importation from Canada, only if the FDA was able to certify the safety of the drug. Donna Shalala, Clinton’s Secretary of the Department of Health and Human Services, announced on December 26, 2000 that the FDA would not make the required determination that drug importation “posed no additional risk to public health and safety” or “significantly lowered the cost of prescription drugs” (Kouzoukas 2002). Because the provision’s language required the support of the HHS, prescription importation never went into effect.

State and Local Activists

Although it is clear that currently control of prescription drug importation lies with the FDA, the push to legalize prescription drug importation continues to occur primarily at the state and local level due to the individual nature of the problem and the presence of a strong pharmaceutical lobby at the national level. While the possibility of importing drugs from Canada has been discussed for years in Congress, Canadian drug importation as an important policy issue arose as state and local leaders in Springfield, Massachusetts and Montgomery, Alabama and governors in Illinois, New Hampshire, and Minnesota brought the policy to the national agenda. "We can't wait for Congress,” West Virginia Gov. Bob Wise told news sources this month. "We've got to do all we can here" (Hall 2003). Unlike many public policy issues, drug importation policy is somewhat unique in that Democrats and Republicans are working together to substantiate the validity of prescription drug importation policy.

In his testimony before the Senate, Minnesota Governor Tim Pawlenty, a Republican, quoted former President Franklin Roosevelt, saying, “It is common sense to take a method and try it; if it fails, admit it and try another. But above all, try something” (United States d 2003). While each state and locality’s plans differ in terms of the cited beneficiary, each plan is intended to save both the government and individual consumer substantial amounts of money. For example, Springfield, Massachusetts saves over four million dollars a year by utilizing a program of Canadian prescription-drug buying for the city’s 7000 municipal employees (CNN 2003).

At the state level Illinois Governor Rod Blagojevich, a Democrat, has been a forerunner in the push to
have importation legalized. He estimates that his state could save $91 million a year through importing drugs for state employees and retirees (Davey 2003). Governor of New Hampshire Craig Benson, a Republican, plans to use the program to buy medicines for prison inmates and Medicaid recipients, and Governor of West Virginia Bob Wise, a Democrat, has been the first governor to propose allowing drug stores to stock drugs purchased from Canada to be sold to anyone (Drug Week f 2003). At the local level, Springfield, Massachusetts and Montgomery, Alabama already import prescription drugs from Canada for city employees and retirees; Boston Mayor Thomas Menino plans to establish a similar program. (Washington Transcript Service 2003)

The Judiciary

While no states nor individuals have been sued in court under rules of the FDA, the agency has threatened those to plan to import Canadian drugs with lawsuits; however, two companies involved in importing prescription drugs have been shutdown pursuant the Food and Drug Act of 1938, which prohibits importation of prescription drugs into the United States by anyone other than the drug’s United States manufacturer. While the courts are the obvious appropriate choice to determine if United States laws are being violated, participants in the process have noted that “the remedy lies with Congress and the President, not in the judicial system” (Drug Week d 2003).

On February 26, 2004 a Chicago, Illinois couple filed the first federal class action lawsuit against the FDA challenging the constitutional basis of the FDA’s personal prescription drug importation policy in U.S. District Court for the District of Columbia. The lawsuit claims that federal law outlawing importation of drugs from foreign countries violates the Fifth Amendment right to privacy by denying citizens freedom to make their own medical decisions (Barclay 2004); Ray and Gaylee Andrews, who purchase drugs for diabetes, high blood pressure, arthritis, and asthma, allege they could save between 26% and 67% if they were able to purchase their drugs legally in Canada (Mercer Human Resources Consulting 2004). The Andrew’s attorney, Robert A. Clifford, criticized the FDA’s personal prescription policy, saying, "it's incongruous--with a wink and a nod from the FDA, people could mail-order drugs, but at the same time they could be subject to felony prosecution" (Barclay 2004). Illinois Governor Rod Blagojevich was quick to voice his support for the lawsuit, saying, “We are asking the court to tell the Food and Drug Administration to respect people's rights to
make their own medical decisions...if this lawsuit succeeds, the state of Illinois can go ahead and import prescription drugs from Canada" (Barclay 2004; PBS Online Newshour 2004). The FDA’s only response has been to reiterate their opposition to Canadian pharmaceutical imports due to safety concerns.

Non-Governmental Actors

While legislators and governmental actors are attempting to make policy changes, the true push is coming from constituents, who overwhelmingly support prescription drug importation policies.

Interest Groups

Many of the interest groups currently supporting prescription drug importation are seniors’ organizations, including, but not limited to, the Minnesota Senior Federation, which represents 60,000 senior citizens (Minnesota Seniors Federation 2004), The TREA Senior Citizens League, which represents 1.2 million seniors (United States c 2003), and the Alliance for Retired Americans, which represents three million members (Alliance for Retired Americans 2004). In addition, the largest senior organization, the American Association of Retired People supports prescription drug importation from Canada; CEO and Executive Director Bill Novelli issued a statement asserting that "it is a national embarrassment when Americans must [go to other countries] in search of medications they need at prices they can afford” (Barry 2003). Novelli stated “re-importation is not a panacea for the problem of soaring drug costs but it does hold the potential to place some downward pressure on the double-digit increases in costs that Americans face each year” (AARP 2004). Consumer watchdog groups such as the California-based Foundation for Taxpayer and Consumer Rights also support prescription drug importation, as does the Service Employees International Union, which represents 1.6 million health care workers and 120,000 retirees (SEIU 2004).

However, some business interest groups have spoken out against prescription drug importation; in general, these groups tend to be organizations concerned with economic and safety issues. The National Association of Boards of Pharmacy, has stated “allowing unlicensed practitioners to dispense non-FDA approved medicines without regard for patient health and safety sets a dangerous precedent that puts
Americans at risk” (FDA 2004). The Small Business Survival Committee announced its “strong opposition to proposals being put forth to authorize the reimportation of prescription drugs into this company” in July of 2002; the organization opposes the policy due to the probable loss of revenue to small pharmacies in the event of large-scale importation from Canada (Biomedical Market Newsletter 2002). The American Medical Association has also spoken out against drug importation, claiming that importation “severely undermine[s] both safety and efficacy” (American Medical Association 2003).

Pharmaceutical Industry

The largest opponent to prescription drug importation is the pharmaceutical industry, which maintains over 600 lobbyists—more than one lobbyist for every member of Congress. Between 1996 and 2003 the industry spent $435 million lobbying Congress, $57.9 million of which was in direct contributions to lawmakers (Barlett 2004). In the 2002 election cycle, the industry donated $21.9 million to candidates, 80 percent of which were Republicans (Managed Care a 2003). Specifically, the Pharmaceutical Research and Manufacturers of America spent nearly nine million dollars lobbying Congress (United States c 2003).

PhRMA, the pharmaceutical industry’s trade organization, is intensely opposed to prescription drug importation, claiming that proponents of importation disregard safety concerns, and that “price controls stifle the much needed innovations that create new and better medicines. Rather than turning to foreign government price fixing, Congress should enhance access to needed medicines by completing work on a market-based Medicare prescription drug benefit” (PhRMA 2004). The trade organization has recently been charged with launching a scare campaign in Minnesota; through the Seniors Coalition, a group supported solely by PhRMA, the organization flooded the state with radio and print ads alleging that Canadian prescription drugs pose a significant risk to consumer safety and national security concerns. One flyer featured montage of newspaper headlines, including: “Rx for Death, Online-Drug Epidemic Waiting to Happen,” (a headline from the New York Post) “Illegal Drug Imports Threaten Consumers’ Health” (from the Detroit News), and “Murder by Fake Drugs” (from the British Medical Journal). The ads encouraged seniors to call their Congressional representatives to urge them to oppose prescription drug importation. (Minnesota Senior Federation b 2003).
Public Opinion

Public opinion has been very strong for prescription drug importation, mainly among senior citizens, who will spend an estimated 1.8 trillion dollars on prescription drugs over the next ten years (United States a 2003). Of the 50 drugs the elderly are most likely to use, the cost rose by an average of 7.8 percent in 2001—approximately three times the rate of inflation (Kraft 2004). According to The Big Fix by Katherine Greider, approximately 29 percent of senior citizens do not fill their prescriptions because they cannot afford to (United States c 2003), and the situation is only expected to worsen. According to a poll conducted by ABC News and the Washington Post in October of 2003, 70 percent of Americans think it should be legal for U. S. citizens to purchase drugs outside the country (USA Today 2003).

United States Health Care Policy

Background

While public health agencies designed to prevent the spread of infectious diseases, drinking water supply, sanitation, and waste have existed within states and localities since the founding of the United States, national health care policy is a relatively recent public policy issue, developing in the 1930s with the formation of health insurance. Health insurance began at the individual level, with employer-sponsored health insurance gaining popularity in the 1950’s when the Internal Revenue Service ruled that employee health insurance programs were tax-deductible business expenditures. In the early 1960s a movement to insure those without employee health insurance programs—primarily the poor and elderly—resulted in the 1965 enactment of federal Medicare and Medicaid. (Kraft 2004)

Health care in the United States continues to rely most heavily upon the private market and individuals; the U. S. has the smallest amount of public insurance or public health services of any developed nation. The hybrid health care system is a reflection of the political culture of the United States: the American emphasis on individual rights, limited governmental power, and a relatively unrestrained market system. (Kraft 2004)

Approximately 75 percent of adults in the United States under the age of sixty-five have employer-sponsored, private health insurance. While costs to consumers vary widely state-by-state, normally employer-
sponsored, private health insurance policies cover a broad range of services. The federal government specifies particular services that must be covered, yet extensive gaps in coverage exist. (Kraft 2004) Generally, the federal government legislates, funds, regulates, and delegates; the states design the administrative framework and match federal funding, then often pass authority to the local level (Hackey 2001).

In 2000 national health care expenditures totaled $1299.5 billion, $712.3 billion in the private sector and $587.2 in the public sector. Health care spending accounted for 13.2 percent of the total gross domestic product. Of the $1299.5 billion health care budget, 54 percent funded hospital care and physician and clinical services, nine percent funded prescription drugs, eight percent funded program administration and net cost, seven percent funded nursing home care, and 24 percent funded programs such as dental services, home health care, research, and public health activities. (Kraft 2004). According to the CRS Report for Congress, in 2000 health-related research and development through the National Institutes of Health accounted for $15.7 billion in federal funding (2000).

Federal Programs: Medicare and Medicaid

Federal Medicare, enacted in 1965, is intended to help people sixty-five and older meet basic health care needs. Medicare also covers those with permanent disabilities, those with diabetes, and those with end-stage renal disease. Medicare currently covers approximately forty million people in the United States.

Medicare uses a fee schedule of reasonable costs for medical services, and the government pays 80 percent of that amount, leaving individuals responsible for the remainder of the cost. However, physicians, hospitals, and nursing homes are free to charge significantly above these 'reasonable' costs. The Medicare program has two parts: one standard, Medicare Part A, and one optional, Medicare Part B. Medicare Part A, the core plan, pays partial hospital costs through Medicare trust funds, which most employees pay through payroll deductions which employers match. Under Medicare Part A, deductibles and co-payments may be substantial. Medicare Part B is supplemental insurance for non-hospital stay expenses, including physical charges and diagnostic tests. Medicare Part B is funded by individuals choosing to enroll in it and the government, which covers the majority of the cost, from general federal revenues. Approximately 95 percent of eligible recipients choose Medicare Part B. (Kraft 2004)

State Programs
During the 1990s the states emerged as the principal catalysts of health care reform; states' interest in new approaches to controlling health care costs predated the national debate over comprehensive health care reform proposals between 1992 and 1994. The 1994 policy stalemate that lead to the demise of national health care policy reform in Congress ultimately ceded responsibility for policy innovation to the states. (Hackey 2001) State health care programs include Medicaid and Children's Health Insurance Program, state hospitals, state mental hospitals, support of state medical schools, state departments of health, health education, state departments of agriculture and consumer protection, and state environmental protection programs. (Kraft 2004); thus, prescription drug costs are important to states which provide health insurance for their employees. For example, in 2002 Illinois spent $340 million on prescription drugs for employees and retirees; the state estimates that it could save $91 million a year if allowed to import drugs from Canada (Medical Letter on the CDC & FDA b 2003).

Local Programs

Local health care programs include city and county hospitals and clinics, public health departments and sanitation, emergency services, and city and county health and human services programs. (Kraft 2004) Local governments often provide health plans for employees, many of which have prescription drug benefits. For example, Boston, Massachusetts insures the city's 15,000 employees and retirees with a plan including prescription drug coverage (Washington Transcript Service 2004; Drug Week e 2004).

Health Care Costs

As previously stated, health care cost in the United States rose 9.3% in 2002 (Barlett 2004). Health care expenditures in 2000 represented 13.2 percent of the gross domestic product, and expenditures per person totaled $4,637—a record high. Medicare expenditures in 2000 reached $224 billion—38 percent of public spending on health care and 17 percent of overall health spending in the United States. Federal and state Medicaid spending in 2000 reached $202 billion—15.5 percent of overall health spending. With private health care insurance contributing 34 percent of total spending, individual spending contributed the remaining 15
percent. In 2000 total national health care expenditures were $1299.5 billion, 587.2 billion in public money. (Kraft 2004)

Popular View of Health Care

It is often argued that based on conventional indicators such as the number of physicians per capita, the number of state-of-the-art hospitals and clinics, and the number of health care specialists, the United States has one of the best health care systems in the world. Despite its strengths, other conventional indicators such as infant mortality rate, put the United States well below standards of other countries. According to the World Health Organization, the United States ranks 37th among the world’s healthiest countries, due most likely to unequal access to critical health care services; generally, the poor, elderly, minorities, and those living in rural areas experience less frequent and less adequate medical care than middle-class white residents in urban and suburban areas. (Kraft 2004)

A poll conducted in September of 2003 by ABC News and the Washington Post found that 54% of Americans are dissatisfied with the overall quality of health care in the United States; this figure is ten percent higher than in 2000. According to this same survey, a solid majority of Americans tend to be satisfied with their personal quality of health care, yet a significant number of people were concerned with the system more broadly. (USA Today 2003) In his essay “In Search of a Standard Legal and Ethical Dimensions of American Health Care Reform,” Ronald Scott Mangum, J.D., argues that popular dissatisfaction with health care in the United States is the result of consumer’s rising expectations of perfection from the health care system, the continual growth of health care costs, fraud and abuse within the system (1999).

History of Pharmaceuticals in the United States

The High Cost of Prescription Drugs

Prescription drug prices have been rising far more rapidly than the consumer price index since the early 1980s. According to economist Paul Feldstein, reasons for rising drug prices in the United States include increases in production costs, changing demand conditions, and improved drugs, yet the most important factor in increased drug prices is the ability and willingness of consumers to pay. (Feldstein 1994). However, authors
of a *Time* magazine report contend that the ability of the United States as a nation to pay for expensive prescription drugs is itself a reason for inflated domestic drug costs; still others argue that advertising and lobbying contribute to high costs (Barlett 2004).

**Increases in Production Costs: Research and Development**

According to Feldstein, an increase in production costs requires the increase of prices for producers. While Feldstein contends that it takes approximately twelve years for a drug to be developed for the marketplace at an estimated cost of over 400 million dollars, Dr. Robert Cihak from the Association of American Physicians puts the cost at 800 million (Schaffler 2003); Sean Heather, Executive Director of Congressional Public Affairs, puts the cost at close to one billion (Staneck 2004). Yet the public will never really know how much pharmaceutical money is spent during research and development; while the government publicly provides $28 billion for drug research and development through the National Institutes of Health (National Institutes of Health Summary of the FY 2005 President’s Budget 2004), the pharmaceutical industry has long refused to open its books to government auditors, and waged a nine-year battle with Congress’ investigative General Accounting Office to keep the information secret. While Congress could subpoena the issue, they have thus far refused to do so (Barlett 2004), most likely due to the strong influence of the pharmaceutical lobby at the national level.

Eli Lilly, the President, Chairman, and C.E.O. of Eli Lilly, one of the nation’s leading drug manufacturers, argues that medical innovation is responsible for high costs of prescription drugs. According to Lilly, scholars at Tufts University examined all 284 new medicines approved in the United States during the 1990s and found that 93 percent “originated” from the pharmaceutical industry, with the remaining seven percent split between the government and academic institutions. Lilly argues that research and development requires “staggering investments” with “daunting” odds of success, and contends that “an extraordinarily small number of drug candidates ultimately recoup the cost of development” (Taurel 2003). However, as one of the two pharmaceutical companies to boast the highest returns on revenue of *all* U.S. companies at 24.4% (Barlett 2004), it does not appear that Eli Lilly is having trouble “recoup[ing]” any costs; the company is certainly not suffering financially.
According to a report by the Joint Economic Committee of Congress in 2000, the Federal Government, through the National Institutes of Health, “funds about 36 percent of all U.S. medical research...of the 21 most important drugs introduced between 1965 and 1992, fifteen were developed using knowledge and techniques from federally-funded research” (Barlett 2004). In addition, new drugs produced by the pharmaceutical industry often receive government funding; the General Accounting Office reported in 2003 that Taxol, a company with world-wide sales over six billion dollars between 1998 and 2002, benefited “through a collaboration with NIH [which provided] substantial investments in research.” (Barlett 2004).

**Increases in Production Cost: FDA Approval and Regulation**

Approval of new drugs in the United States is a stringent, immense process due to 1962 amendments to the Food, Drug, and Cosmetic Act which require extensive testing designed to ensure the safety of pharmaceuticals. Dr. Cihak of the Association of American Physicians blames the FDA for increased prices in drugs, saying, “the FDA is part of the reason [prescription drugs]...cost so much. Maybe if we could bring those costs down, it would help consumers in this country” (Schaffler 2003).

**Demand Conditions**

As defined by Feldstein “demand for drugs” is “how much consumers are willing to pay.” Feldstein argues that with private prescription drug insurance, patients have become less price sensitive and thus producers can raise prices and reap greater profits, and any loss in sales would thus be offset by higher prices. The two markets for drugs--the retail market, which consists of individual patients, and the large purchasers, which consist of HMO’s, hospital purchasing groups, and state and local governments--are charged disparate prices. While large groups are generally more price sensitive and knowledgeable, the retail market is generally more willing to pay high prices for brand-name, heavily advertised drugs. Thus, drug prices in the retail market greatly exceed those paid by large purchasers. (Feldstein 1994).

In the United States Medicare pays for certain medications dispensed by hospitals and doctors; while it appears that as a large purchaser, the government could save substantial amounts of money, government auditors have long criticized Medicare for paying inflated prices for prescription drugs compared to prices paid by HMOs and retail pharmacy chains. In 2001 a Department of Health and Human Services Inspector...
General's Report found that 2001 Medicare reimbursements for two dozen drugs "exceeded actual wholesale prices by $761 million dollars." The report stated that the average prices that "Medicare carriers currently use to establish reimbursement amounts bear little or no resemblance to actual wholesale prices that are available to physicians, suppliers, and other large government purchasers" (Barlett 2004).

One government agency purchaser, the Department of Veterans Affairs, is able to save significant amounts of money through aggressive negotiations for its Pharmacy Benefits Management Program, which provides veterans with drugs at deep discounts. The VA program operates under a 1992 law mandating lower prescription drug prices for the nation's veterans and the Defense Department personnel; last year, the VA filed 108 million prescriptions at a cost of 2.8 billion dollars, with savings estimated to be in the hundreds of millions of dollars. According to the 2001 Inspector General's Report, the VA paid an average of 52 percent less for the same list of two dozen drugs than Medicare did (Barlett 2004) based on the agency's willingness and ability to negotiate with the pharmaceutical industry.

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**Improved Drugs**

According to Feldstein, a new drug for which there is no substitute and that is clearly therapeutically superior to existing drugs will be higher priced. The price of new drugs are thus determined by consumers' willingness to pay for its greater therapeutic benefits; accordingly, rising drug prices are an indication that new drugs are more effective than existing drugs. (Feldstein 1994)

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**Willingness and Ability of Consumers to Pay**

While Feldstein admits that while research and development costs are important in price setting, he maintains that the willingness and ability of consumers to pay is the most important factor in drug pricing. (Feldstein 1994) In 2002 Americans spent $162.4 billion on prescription drugs; in 1992 Americans spent less than $100 billion. More people are now taking "lifestyle drugs," and doctors are prescribing more drugs for children and the elderly than in previous years. The United States is a wealthy country, and while most countries in the world are too poor to buy name-brand drugs, or operate on systems where governments negotiate for lower prices with suppliers or impose price ceilings, such as in Canada, the United States can afford to pay for expensive drugs. Wayne Critchley, Executive Director of Canada's Patented Medicine Prices
Review Board stated, "The United States is probably the only country that I know of in the developed countries that does not have the same degree of oversight over the pricing of drugs" (Massingale b 2003). Simply put, drugs are more expensive in the United States than in poorer countries because, until recently, the market would bear high prices. (Barlett 2004).

Advertising and Lobbying

A study conducted by Families USA found that marketing, advertising, and administrative costs are much higher than current research and development costs (United States c 2003). As previously cited, the industry spends large amounts of money on lobbying expenses: $435 million between 1996 and 2003, $57.9 million in direct contributions to lawmakers (Barlett 2004).

The United States Health Care System and the Canadian Health Care System: A Comparison

Universal health care in Canada can be attributed to a number of factors, both political and ideological. Politically, the allocation of power between the national government and provincial governments, the relationship between the legislative bodies and the executive, the system of political parties and their objectives, and the influence of interest groups impact the Canadian health care system; ideologically, the public’s views on the role of government in society and the collective social attitudes regarding responsibility for the poor are health care policy determinants. (Taylor 1990)

Whereas in the United States health care policy is driven by the American ideals of individual rights, limited governmental power, and a relatively unrestrained market system, Canadian health policy is driven by a feeling of collective responsibility. Ideologically, Canada is a socially conscious country in which citizens share a feeling of responsibility for all members of society: low-income earners, the unemployed, the elderly, and the sick and disabled are able to utilize a variety of social programs, including a comprehensive unemployment program, a vocational rehabilitation of disabled persons program, and a universal old-age security program which provides monthly payments to the elderly. (Taylor 1990) In Canada, the “clearly articulated public and political support for the principles of universality, accessibility, and comprehensiveness”
(Raffel 1997) that underlie the system may be based on the fact that Canadians may be more aware of the plight of the impoverished due to the relatively small size of the country—twenty-nine million people in contrast to over 290 million in the United States—but are also constantly reminded of human needs and the obligation of citizens to provide a secure and equitable society for all by strong voices in political parties and special-interest groups. (Taylor 1990; U.S. Census Bureau 2004)

**Evolution of the Canadian Health System**

While universal government health insurance was first proposed in 1919, it was not only the 1940s when many provinces began establishing health insurance programs that universal health care gained widespread acceptance. In 1966 the federal government enacted the Medical Care Act, which created Canadian Medicare—a system in which physician payments were guaranteed for every service. Controversy over finance-sharing between the federal and provincial governments, conflict between medical professionals and the government, and growing public concerns over escalating health costs lead to the Federal Royal Commission of 1979. The Commission examined the existing system and aided in the enactment of the Canada Health Act of 1984, which required that provinces set up insurance plans which covered all residents, be publicly administered and non-profit, cover all medically necessary services, and cover residents regardless of where they received service in Canada; further, the Act stated that Canadians must have “reasonable access to health services without financial or other barriers” to those services deemed “medically necessary” (Raffel 1997).

**Pharmaceuticals in Canada**

Pharmaceutical prices are usually much lower in Canada than in the United States even for American-made drugs due to the Canadian socialized health-care system wherein the government imposes price ceilings and negotiates prices with pharmaceutical companies (Barry 2004; Calfee 2003; Cavuto 2003). The Patented Medicine Prices Review Board dictates the maximum price that can be charged for a new drug upon its Canadian introduction, and provinces are responsible for keeping prices for regulating drug prices in accordance with inflation; the board also links price ceilings to European controls (Calfee 2003). Additionally, in Canada drug companies agreed to price controls in the early 1990s in exchange for the end to
the Canadian compulsory licensing system, which allowed generic versions of drugs to be produced before the expiration of the drug's patent (Rubins 2004).

In addition, often lower-cost, generic versions of brand name drugs come to market more quickly in Canada because of different patent laws. For example, the Canadian generic version of the breast cancer drug Tamoxifen was originally priced at one-tenth of the brand-name version available in the United States. Today, even after the generic version of the drug is available in the U.S., it still costs less in Canada. (Barry 2004) (Currently, the Free Trade Area of the Americas proposal is seeking to change U.S. patent laws; the proposal, sponsored by Brazil, some Latin American pharmaceutical groups, humanitarian groups such as Doctors Without Borders, and the U.S.-based Generic Pharmaceutical Association, is meeting strong opposition from major U.S. corporations and trade groups, including the National Association of Manufacturers, and is thus unlikely to be successful (Miami Herald 2003)). Furthermore, the American dollar, which is frequently much stronger than the Canadian dollar, has high buying power in Canada; the Canadian dollar historically trades at 30 to 35 percent less than the American dollar (Canadian Pharmacy Source 2004). However, Michael Weissman, President of Canadian Pharmacy Discount Rx, claims that “the real reason and the biggest reason” that Canadians pay less for prescription drugs is that the government “pays significantly less…[to] the drug companies” (Cavuto 2003).

According to Canadian law, only licensed pharmacists can dispense prescription drugs; some provinces require that physicians have a relationship with a patient before prescribing drugs. Generally, Manitoba and Alberta, provinces with looser prescription drug regulations, supply the majority of pharmaceuticals to the United States. (Medical Letter 2003)

Safety Concerns

With the influx of attention regarding prescription drug importation from Canada, the FDA has the following statement posted on their website:

FDA is very concerned about the importation of prescription drugs from Canada. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U.S.- approved prescription drugs have been of unknown quality. We cannot provide adequate
assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA. (FDA 2004)

However, TSCL Chairman George Smith stated, “seniors especially ask to be treated like the responsible men and women they are...seniors should have the right to assume the miniscule risk of using a drug obtained from Canada, rather than suffer the risk of not having the prescription drug to take at all” (United States c 2003). Minnesota Republican Representative Gil Gutknecht echoed Smith’s opposition to the FDA, saying, "Now, when we talk about safety, I think the real question is, Who are we protecting from whom? Who is really being protected by our FDA? More and more of us are coming to the conclusion that the only people really being protected are the big executives of the large pharmaceutical companies” (Barlett 2004).

**Quality of Drugs and Drug Inspections**

FDA Pharmacy Affairs Director Tom McGinnis claimed that the United States would “never rely on Canada’s assurances that drugs sold in Canada are safe” (Baldor 2003), claiming that Canada relies on inspections conducted by the drug maker’s host company. Health Canada spokesman Emmanuel Chabot, however, defends the safety of Canadian drugs and inspections, saying, “we conduct regulatory reviews of drugs to ensure there is sufficient evidence of safety, efficacy, and quality before [drugs] receive authorization to be sold in Canada. We also do surveillance and enforcement once the drug is on the market” (Baldor 2003).

Drug safety regulations, inspections, and monitoring are, in fact, considered far more stringent overseas and in Canada than in the United States. Mary Gates of the Minnesota Senior Federation claimed that “In Canada, the track record of the drug supply...is undoubtedly safer than the current drug supply in the United States” (Minnesota Seniors Federation 2004). In the United States the FDA has banned over half a dozen previously approved drugs because the drugs were found to cause an unacceptable degree of fatal side effects over the past few years. For example, Serzone, Bristol-Myers’ anti-depressant, was heavily marketed throughout the world in the 1990s. In 1996 Bristol-Myers credited strong sales of Serzone for high company revenues. By the late 1990s however, significant side effects from Serzone began to emerge: liver damage resulted in the need for liver transplants and deaths in patients taking the drugs. In 2002 Serzone was withdrawn from markets in Europe and Canada. So far, the FDA’s only response has been to require a warning
label on the drug stating “causes of life-threatening hepatic failure have been reported in patients treated with Serzone” (Barlett 2004).

In addition, state and local plans provide additional inspections for safeguarding public health. Under Minnesota’s importation program, “only reputable Canadian pharmacies licensed by a Canadian province willing…to have their safety protocols reviewed by the Minnesota Department of Human Services” are utilized. Further safety and security protocols are in place: (1) pharmacies associated with the importation program must be accredited by an organization such as the Internet Mail-Order Pharmacy Accreditation Commission, which uses 92 standards in their accreditation process; (2) medications will only be dispensed in the manufacturer’s unopened, safety-sealed containers in dose-appropriate amounts; (3) medications shipped from Canada must be produced in an FDA-approved manufacturing facility. (United States d 2003)

**Questionable Origin of Drugs**

In testimony before Congress, Director of the National Association of Boards of Pharmacy Carmen Catizone claimed that the FDA identified “drugs shipped from Canada that were actually distributed from India” (United States b 2003). However, Catizone was unable to cite any health problems resulting from the use of these drugs. Catizone further claimed that the National Association of Boards of Pharmacy were told first-hand by a Canadian internet pharmacy corporation that drugs shipped into the United States may have originated in New Zealand or Vietnam; he also stated that “several newspapers have interviewed Canadian Internet pharmacies who admit freely to purchasing and exporting to the US medications from Pakistan, Bulgaria, and Latin America” (United States b 2003).

What the FDA neglects to inform consumers, however, is that prescription drugs purchased in the United States are frequently produced in foreign countries with minimal FDA oversight. In 1995 pharmaceutical imports into the United States were 8.7 billion dollars; in 2002 pharmaceutical imports into the United States were 40.7 billion. While in the early 1990s the balance of trade in the pharmaceutical industry was roughly equal, United States pharmaceutical trade is now in the deficit due to the increasing trend of pharmaceutical companies to produce drugs overseas. Of the twenty largest drug United States-based companies, seventeen now produce drugs abroad, primarily in Ireland but also in Sweden, France, Japan,
Britain, and Germany because of the tax incentives provided to these companies abroad. While the FDA inspects foreign plants upon their opening, the oversight then stops. (Barlett 2004).

**Adverse Effects from Drugs**

Catizone cited two examples of customers shipped incorrect drugs:

A patient in Illinois ordered an inhaler to treat her child’s asthmatic condition from a Canadian pharmacy. After using the inhaler, the child told her mother that the medicine "seemed different." Shortly after using the inhaler, the child suffered an asthmatic episode, the first in a considerable time. The mother only learned that the drug sent to her by the Canadian pharmacy was wrong when she asked the pharmacist at her local pharmacy to identify the medication.

An Oregon patient being treated for breast cancer received the wrong medication for a Canadian pharmacy. She continued to take the wrong drug for three months as her condition worsened. 
(United States b 2003)

In June of 2003 however, Associate Commissioner of the FDA William Hubbard stated that the FDA had “no evidence” of patients suffering adverse effects from Canadian pharmaceuticals; yet approximately 50,000 to 100,000 people in the United States die every year as a result of adverse reactions to FDA-sanctioned pharmaceuticals (Barlett 2004). David Funderburk, President of the TREA Senior Citizens League, claimed that “an American has a greater risk of getting sick by eating imported food than he or she does getting sick from a drug purchased in Canada” (United States c 2003). Even Catizone’s sole examples of adverse effects from drugs appear to be the result of the incorrect shipment of drugs rather than the result of “bad” drugs.

**Dispensing of Drugs Without Prescriptions**

Catizone claimed that a “staggering” number of websites offer controlled substances without valid prescriptions. He stated that a “never before witnessed preponderance of spam emails offering unrestricted and illegal access to controlled substances have flooded the computers of US citizens” (United States b 2003), which he blames on “the advocacy for the purchase and import of drugs from other companies by public officials in certain cities and states” (United States b 2003). However, these statements were not backed with specifics; further, all implemented and proposed state and local plans include regulations requiring prescriptions from both American and Canadian physicians.
Counterfeit Drugs

While the FDA has insisted that the counterfeiting of drugs would be a major issue, H. R. 2427 included safety measures intended to protect against counterfeiting. The bill would have required that all prescription drugs manufactured both in the United States and abroad use counterfeit-resistant packaging similar to the technology used by the Department of the Treasury (United States a 2003).

The Evolution of Drug Importation from Canada as Public Policy

Conception

In 2002 Daniel Bozarth of Denver, Colorado was searching for cheaper prescription drug prices for his mother-in-law online and discovered a Winnipeg, Manitoba website where he could save nearly thousand dollars per year on his mother-in-law’s prescriptions. Today, Bozarth runs Canadian Meds USA, a company which serves as an intermediary between clients in the United States and Canadian pharmacies. (Kraft 2004) Today, Canadian Meds serves 15,000 customers. (Canadian Meds USA 2004)

How FDA Regulations are Circumvented

State and private programs share a similar method of evading FDA regulations. First, plans enter into agreements with a pharmacy benefit manager in the United States, who gives plan participants access to mail-order drugs imported from Canada. Plan participants send their prescriptions to a company within the United States, which will forward the prescriptions to a pharmacy in Canada. In Canada a Canadian pharmacist re-writes and fills the prescription, then sends the prescription directly to the plan participant in the United States. (Hassel 2003)

Localities:

The Implementation of Canadian Drug Importation

Springfield, Massachusetts is a forerunner in prescription drug importation from Canada, and thus the first city to blatantly violate FDA regulations prohibiting prescription drug importation. The city, which is self-
insured, imports medications from Windsor, Ontario for the city’s 7,000 municipal employees, retirees, and their dependents. Michael Albano, Mayor of Springfield, claims that the city saves “anywhere from $4 million to $9 million by using the Canadian prescription medication program;” his son uses U.S.-manufactured insulin and paraphernalia to treat his Type 2 diabetes from Canada, and estimates that he saves 500 dollars a year. Roger Landry of the Springfield Police Department, calls the savings “phenomenal,” saying that he receives the same drugs from Canada at a “20 to 80 percent discount.” (CNN 2003)

Montgomery, Alabama has become the second major city in the United States to employ an importation program. Montgomery’s program, which imports medication for employees and retirees, is small in scope, serving only 300. (Institute for Policy Innovation 2004).

**Localities: Proposed Programs**

Boston, Massachusetts mayor Thomas Menino has promised to implement a prescription drug importation program for Boston by July 1, 2004 for the city’s 15,000 employees and retirees (Washington Transcript Service 2004; Drug Week e 2004). Massachusetts Senator Edward Kennedy claimed that prescription drug importation “is not a safety issue...this is another...Boston Tea Party, but the revolution isn’t against the government, its against the prescription drug industry” (Washington Transcript Service 2003). Tentative safety measures include only utilizing licensed Canadian dealers and the establishment of Boston public health officials system of independent inspections (Washington Transcript Service 2003). The city estimates the importing drugs from Canada would save the city a million dollars a year (Drug Week e 2004).

Burlington, Vermont plans to start importing prescription drugs for city employees starting on March 1, 2004 (Drug Week e 2004); the city is currently served by Discount Prescription Services, which links customers with Canadian pharmacies. The service has “several hundred” customers, primarily senior citizens. The President of Discount Prescription Services claims his company is supported by Representative Bernard Sanders and Patrick Leahy. (Managed Care Weekly Digest b 2003)

On January 30, 2004 Seattle City Councilmember Tom Rasmussen announced his plans to add the City of Seattle to the growing number of local and state governments allowing city employees to purchase prescription drugs from Canada. Rasmussen cited the predicted 12.3% rise in health care costs in Seattle in 2004; he further stated that since 2001, prescription drug costs have soared more than 17% in the city. “We
need to be proactive about dealing with the effect of rising prescription drug costs on the City budget,” said Rasmussen. “Taxpayer dollars are going towards expensive drug coverage when they could be otherwise used for city services, public safety, transportation improvements or human services.” In designing Seattle’s program, Rasmussen plans to review the importation programs of Springfield and Boston. (City of Seattle News Advisory 2004)

States: Established Plans

Minnesota

Minnesota Governor Tim Pawlenty testified as to the specifics of his state’s importation plans before Congress in late November 2003. The governor, who claimed that “there is a difference between paying a premium and being a chump” (Sturdevant 2003) explained that the goal of the Minnesota plan is simply “to get a better deal for Minnesotans” (United States d 2003). While the Governor allowed that importing drugs is not the ideal, “It will provide some near-term relief, but, more importantly...[will] pressure the federal government to change” (Cavuto 2003).

Under the Minnesota Plan, www.minnesotaxconnection.com allows individuals to determine if their prescriptions are available at a lower cost through two Canadian pharmacies: Total Care Pharmacy and Granville Pharmacy (Rubin 2004). In the even that the drug is cheaper, the individual will be given instructions as to how to order the drugs. Both Total Care Pharmacy and Granville Pharmacy are reputable pharmacies licensed by a Canadian province and reviewed for safety by the Minnesota Department of Human Services under Human Services Coordinator Kevin Goodno. To utilize the system individuals must obtain a prescription and a medical history from their physician to be forwarded to a physician in Canada, who review and cosign the prescription. Approved orders are mailed to individuals in the manufacturer’s original, sealed container. (United States d 2003; Rubins 2004)

States: Proposed Importation Plans

Illinois

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The state of Illinois spent 340 million dollars on prescription drugs for its employees and retirees in 2002—a 15 percent increase from 2001 (Medical Letter b 2003). On December 22, 2003 Governor Rod Blagojevich asked for federal permission to set up a program to import medications from Canada for the state’s 230,000 employees and retirees. As part of Illinois’ plan, the state would develop a list of drugs, all approved by the FDA, that could be imported; all prescriptions would be filled by an Illinois pharmacist first, and only refills would be imported (Drug Week b 2003).

To support his proposal, Blagojevich cited a report conducted by special advocates on prescription drugs, state officials, and the departments of public health and safety; according to a summary of the report, the governor’s importation plan would save the state $90.7 million a year. On the individual level the report estimates that state employees and retirees using three prescriptions a month could save as much as $1008 a year if they filled prescriptions through a Canadian mail-order plan. (Health & Medicine Week b 2003).

On November 7 the FDA refuted Illinois’ study, claiming that the report “inflates the savings and wrongly assumes Canadian health authorities can guarantee the safety of drugs sent into the United States” (Medical Letter b 2003). In a letter signed by FDA Associate Commissioner for Policy and Planning William Hubbard, the FDA alleged that the report inflated savings because not all state employees and retirees are expected to participate; Hubbard also claimed that shipping costs were not included, and that the report did not address liability concerns. However, Blagojevich administration spokeswoman Abby Ottenhoff said that those harmed by Canadian drugs would have legal recourse in Canada or Illinois, and report author Scott McKibbin, said that shipping costs were factored into the study. (Medical Letter b 2003)

Although Governor Blagojevich asked the FDA for a response within 30 days of his request, the FDA has yet to formally comment on his request, saying only “against...relatively modest savings are important health risks...these risks indicate that there are far better ways to get savings in medical costs for Illinois residents than by turning to a questionable importation scheme” (Department of Health and Human Services, 2003). The FDA has yet to offer any other suggestion as to how to lower medical costs in Illinois. However, according to a poll conducted by the Illinois State Journal Register, 73% of registered voters support the Governor’s proposal for drug importation (Massingale 2004).

New Hampshire
The day after President Bush signed the Medicare Prescription Drug Bill, New Hampshire Governor Craig Benson announced that the state would begin importing Canadian pharmaceuticals for prison inmates and Medicaid recipients as soon as possible. Governor Benson claims that the state will save money on 90 percent of the drugs most commonly prescribed to inmates, and will buy Medicaid drugs when Canadian prices are lower than United States prices. *(Drug Week e 2004)*

Lawsuits Resulting from Drug Importation

**Rx Depot**

In February of 2003 FDA Associate Commissioner Hubbard sent a letter to Rx Depot, a Tulsa, Oklahoma based company which facilitates mail-order prescriptions from Canada, stating that “any party participating in the hands-off import agreement does so at its own legal risk…those who can be found civilly and criminally liable include all who cause a prohibited act under the Food and Drug Act” *(Hassel 2003)*. On March 21, 2003, a formal warning letter was issued to Rx Depot, instructing the company to “cease…unlawful conduct” *(Hassel 2003)*. The letter claimed that the company “present[s] a significant risk to public health [and]…mislead[s] the public about the safety of drugs obtained through Rx Depot” *(Department of Health and Human Services b 2003)*. Again, no evidence of a “significant risk” was presented.

On November 6 U. S. District Judge Claire Eagan issued a shutdown order of Rx Depot at the request of the FDA and the Justice Department. The ruling held that Rx Depot “openly and notoriously violated the law,” claimed that the quality of drugs from Canada were “less predictable” than those in the United States, and that Canadian drugs were commonly dispensed in high quantities than requested *(Medical Letter b 2003)*. Rx Depot denied wrong-doing, claiming “we weren’t a pharmacy…we weren’t handling any drugs” *(Drug Week a 2003)*.

On November 18, 2003 Rx Depot asked the 10th U. S. Circuit Court of Appeals in Denver, Colorado to allow the company to reopen in twenty-five states while the court decides if its operations are legal, claiming “if a stay of the preliminary injunction is not granted, numerous U. S. citizens with the resources to obtain prescription drugs at U. S. prices will be forced to go without their medication” *(Drug Week a 2003)*. Currently, no further action has been taken and Rx Depot remains shutdown.
**CanaRx Services**

On September 16, 2003 the FDA issued a warning letter to CanaRx Services, Inc., of Detroit, Michigan, notifying the company that its operations are illegal and a risk to public health. The letter stated that CanaRx’s illegal Internet website and mail operation result in subjecting Americans to risky imported drug products and making misleading assurances to consumers about the safety of its drugs. "Firms like this should not continue to profit through illegal actions that put the health of the American public at risk," said Mark B. McClellan, M.D., Commissioner of Food and Drugs (FDA News 2003). The FDA held that because the medications obtained and shipped by CanaRx are not subject to FDA’s safety oversight, they could be outdated, contaminated, counterfeit or contain too much or too little of the active ingredient. In the case of CanaRx, these risks are heightened by the fact that many of the products sold to U.S. consumers are produced to treat serious medical problems. (FDA News 2003)

**Expedite-Rx**

In January of 2004, the FDA sent a warning letter to Temple, Texas-based Expedite-Rx, the program which facilitates buying drugs from Canada to citizens of Montgomery, Alabama; the Food and Drug Administration informed the company that it was required to explain how it would begin complying with laws outlawing the importation of foreign drugs, or face legal action. (Wallstreet City 2004)

Tom McGinnis, Pharmacy Affairs Director of the FDA, claimed that “documents from Montgomery and Expedite-Rx's Web site clearly showed they were in violation of federal law...the [FDA is] going to move aggressively against anybody breaking federal law and putting public health at risk.” Expedite-Rx spokesman Tom Curb refuted the charges, declaring that the company is not “handling any drugs and we're not actually intermediating;” the company functions like a pharmacy benefits manager by processing copay information for prescriptions handled by Montgomery's chosen Canadian pharmacy and providing computer records to help assure that patients do not buy drugs in Canada that would interact dangerously with pharmaceuticals purchased in the U.S. (Wallstreet City 2004)

**Congressional Legislation**

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On October 28, 2000, despite his own qualms about safety issues, former President Clinton signed the Medicine Equity and Drug Safety Act of 2000, which was intended to amend Section 801(d) of the Federal Food Drug and Cosmetic Act. The new act allowed the reimportation of American-made prescription drugs by the manufacturer of the product only if the FDA was able to verify the safety and cost-effectiveness of the program (Arent Fox 2000). However, in December of 2000, former Health and Human Services Secretary Donna Shalala refused to implement the law, calling it “unworkable” due to safety concerns and claiming it would not lower costs. In a letter to then President Clinton, Shalala said she would not request the $23-million appropriated to begin the program due to “flaws and loopholes…making it impossible…to demonstrate that it is safe and cost effective” (Fritz 2001). The law never went into effect.

In 2003 Minnesota Republican Congressman Gil Gutknecht sponsored H.R. 2427, the Pharmaceutical Market Access Act, which was intended to sanction sales of Canadian drugs to pharmacies in the United States. The bill would strike language from Section 804 of the Federal Food, Drug, and Cosmetic Act and instead require the FDA to design and implement a system to grant individuals, pharmacists, and wholesalers in America legal access to FDA-approved drugs from FDA-approved facilities abroad. The bill would allow importation only from the European Union, Australia, Canada, Iceland, Israel, Japan, Lichtenstein, New Zealand, Norway, Switzerland, and South Africa. In addition, safety measures in the bill included mandatory counterfeit-resistant packaging for drugs produced in the U.S. and abroad; the importation of pharmaceutical narcotics is prohibited.

In June 2003 the Senate voted 62 to 28 in favor of prescription drug importation; in July, the House of Representatives voted 243 to 186 in favor of prescription drug importation (Pear 2003). “The will of Congress spoke. The American people want relief,” said Representative Jo Ann Emerson (Carey 2003). However, immediately prior to the passage of the Medicare Bill in December 2003, H. R. 2427 was deleted from the bill in a secret joint House-Senate conference by Republicans (Barlett 2004); no one is taking credit for the deletion.

However, Section 1121 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 grants the Secretary of the Department of Health and Human Affairs authority to implement a system of prescription drug importation in the United States only if he is able to certify the safety and cost-effectiveness of the policy to Congress; the Secretary is instructed to conduct a study designed to determine if and under what circumstances importation could be conducted safely, the likely consequences for health, medical costs, and
development of new medications. The newly created Task Force on Drug Importation is currently researching prescription drug importation; the deadline for the study is December of this year (Food and Drug Administration Docket No. 2004N-0115 2004).

Though completely opposite the relief intended by H. R. 2427, the Medicare Bill does contain a provision regarding pricing of prescription drugs. “Subpart 2, Prescription Drug Plans” says:

(i) noninterference. In order to promote competition under this part and in carrying out this part, the Secretary—
(1) may not interfere with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] sponsors; and
(2) may not require a particular formulary or institute a price structure for the reimbursement of covered...drugs
(Barlett 2004).

Essentially, the new legislation prevents the Department of Health and Human Services, which is responsible for purchasing drugs for some seniors under Medicare, from negotiating with drug manufactures for lower prices. Democrats blame Republicans for this “noninterference” clause, but the Service Employees International Union, which claims to be the largest health care union, blames “the army of nearly 700 lobbyists that the pharmaceutical industry dispatched to Congress to make sure that their massive profits weren't touched” (Health Care Profile 2004). “We could have used Medicare’s market power to negotiate lower prices for the medicines the program will be buying. Instead, this compromise agreement actually prohibits the commonsense approach to cost containment,” said Vermont Senator Patrick Leahy (Barlett 2004).

Possible Results of Drug Importation

According to John E. Calfee of the conservative think tank the American Enterprise Institute, drug importation will have little effect on pharmaceutical prices in the United States unless foreign drugs can be imported in large volumes. Calfee argues that the Canadian market, which only represents five percent of the United States market in revenues, is not a large enough drug market to supply the growing number of American programs seeking to utilize it. Calfee theorizes that as Canadian companies increasingly ship drugs into the United States, the pharmaceutical companies will begin limiting shipments of drugs into Canada, creating shortages for Canadians themselves. Calfee also argues that other countries would be forced to raise price
ceilings on drugs, and that the international demand for price controls in the United States would become the centerpiece of national diplomacy. (Calfee 2003)

As predicted, in January 2004 Pfizer Inc. added new restrictions on Canadian retailers, requiring that, in order to stock Pfizer drugs, retailers must promise not to ship drugs back into the United States. (Rubin 2004) However, University of Toronto political scientist Jillian Cohen points to legal protections against the limiting of drug supply for Canadians; Cohen points to mandatory Canadian licensing agreements, where generic companies would be given permission to manufacture drugs that were not provided by the companies holding the patents to name-brand drugs (Edwards 2003).

Roger Philon of the CATO Institute advocates opening up the domestic drug market to importation. Philon contends that to deal with foreign importation, drug makers will raise prices enough abroad or lower prices enough in the United States to reduce the incentive to import into the United States. In terms of safety, Philon argues that drug makers will have a strong incentive to make sure all drugs sold under their name, including imported ones, are safe, because the risks of counterfeiting would destroy the company’s sales and reputation. (Carnahan 2003)

In response to the argument that research and development funding would be virtually decimated by lower pharmaceutical prices in the United States, Wharton School health economist Mark Pauly argues that there is no way to predict the outcome because there is so much government distortion of the market (i.e., government investment in research and development compared to pharmaceutical investment in research and development) that it is essentially impossible to determine how much money is spent now on research and development within the pharmaceutical industry. (Carnahan 2003)

However, the most important result of drug importation policy is the pressure placed on the government and the pharmaceutical company to lower domestic drug prices. John Auerbach, Executive Director of the Boston Public Health Commission, stated, “the more states and cities that buy Canadian drugs, the more pressure on the Food and Drug Administration to address the problem of the high cost of medication in this country” (Drug Week g 2004). As stated by Illinois governor Rod Blagievich, “we’re not going to violate the law, we’re going to urge a changing of the law” (Rubin 2004).
Conclusions

Thus, national drug importation policy in the United States has been shaped primarily at the state level by legislators and interest-groups, yet has gained momentum due to widespread public popularity resulting from national media coverage. While states advocating prescription drug importation concede that the practice is certainly not a viable long-term solution to rising drug costs, the system may impress adequate pressure on the federal government to lower prescription drugs costs. The evolution of drug importation as a policy issue can be explained through an examination of the relevant actors involved, an assessment of the history of pharmaceuticals in the United States, and an understanding of the events involved in the battle for drug importation from Canada.

The model of public policy applicable to prescription drug importation policy is the Elite Theory, which stresses the superiority of the values and preferences of the governing elites rather than the public in the development of public policy. The elite theory assumes that the elites, either economic, cultural, or elected officials, have the most influence on the development of public policy. (Kraft 2004)

In the case of prescription drug importation, the elites are the pharmaceutical industry. It is clear that the seemingly limitless financial capabilities of pharmaceutical companies control the policy-making process, especially at the national level; the influence of the industry is reflected in the omission of H. R. 2427 from the 2004 Medicare Bill, the reluctance of the government to impose price ceilings or engage in strenuous negotiations for bulk purchasing. Elite theory holds that “the U. S. policymaking process may not be as democratic as many believe it to be” (Kraft 2004); clearly, when 70% of the public supports a measure which continually fails to be government-approved, democracy is not the dominating force.

Importing drugs from Canada is clearly not the answer to lowering pharmaceutical costs in the United States, yet may prove to be a valuable tool in public policy. With 29% of seniors unable to afford to fill their prescriptions, a crisis is obviously taking place. In the event that President Bush is defeated in November and democratic candidate John Kerry elected, reforms in the health care industry may eliminate the need for Canadian pharmaceutical importation; Kerry has stated his opposition to the inability of government agencies to
negotiate for lower prices with the pharmaceutical industry (Koevery 2004). If government continues its seeming refusal to reduce the cost of pharmaceuticals in the United States, consumers will likely continue to purchase drugs outside the FDA-sanctioned marketplace; clearly, this presents more safety concerns than FDA-controlled importation. As stated by Representative Rahm Emanuel of Illinois, “the FDA can try to lip-sync the pharmaceutical industry’s line, but people are going to continue to go over the border to buy the drugs they need at prices they can afford…that…is a problem no amount of enforcement may correct” (Medical Letter a 2003).
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