

Why We Pay So Much For Drugs

How the clamor for cheap Canadian imports is heating up the 2004 campaign and giving Washington a headache

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Helen Clark of Kennebunk, Maine, is a smuggler of sorts. At 77, the retired registered nurse doesn't look the part. She still does volunteer work—administering flu shots, cutting toenails and organizing blood drives—at the Southern Maine Medical Center, where she worked for more than four decades, first in the maternity ward and later in the operating room. Clark is a model of frugality as well. She and her husband Dorrance raised 10 children on modest salaries. When he developed lung cancer in 1991, she stopped working to care for him until he died. She has lived in the same house since she was 1 year old. She seldom buys anything for herself, reuses already reused sewing material and carefully budgets her food money. "You plan out what you can afford," she says.

What has turned Clark into a renegade bargain hunter is the price of her medications. Like many other elderly people, she takes multiple prescription drugs for several conditions, including high blood pressure, elevated cholesterol and glaucoma. To make the money stretch, she joins other seniors in her state on overnight bus trips to St. Stephen, N.B., just across the border from Calais, Maine. On average, name-brand prescription drugs in Canada cost an estimated 40% less than they do in the U.S. On a trip last November, Clark did even better than that, buying a six-month supply of medications for a little more than \$1,000, a cache that she estimates would have cost about \$3,000 in Maine for the same drugs.

One of them is Lipitor, the expensive, heavily marketed cholesterol-lowering drug developed by Pfizer. "Lipitor is my biggest savings," Clark says. "For a six-month supply, it's \$1,900 in the U.S. I paid \$500 [in Canada]." At U.S. prices, she couldn't afford her total drug bill and would have to pick and choose which conditions to treat. Yet what Clark and others are doing is technically illegal, since the U.S. forbids the import of prescription drugs by anyone other than the original U.S. manufacturer, and even then only when the drugs meet all the approval requirements of the U.S. Food and Drug Administration (FDA). The FDA contends it is looking out for consumer safety, but in fact a growing volume of prescription drugs sold in the U.S. is made overseas

and brought in by domestic manufacturers.

What's really being protected, critics say, is the pharmaceutical industry. It has a powerful partner in the FDA, which over the past year has conducted widely publicized seizures of prescription drugs shipped into the U.S. from Canada, Mexico and elsewhere that it maintains could be harmful to consumers. The most recent disclosure came last week, when the FDA revealed a blitz inspection of medicine being imported from Canada that turned up five packages of an asthma medication, Serevent, that had been recalled in Canada because of a manufacturing defect. While there is no doubt that counterfeit and adulterated medicines—some potentially injurious, possibly even lethal—are sold over the Internet by unscrupulous vendors, a TIME investigation suggests the FDA's actions against Canadian imports have been part of a concerted campaign to simultaneously discredit its counterpart agency in Canada, provoke fear among American consumers who buy their drugs there, blunt an exploding political movement among local and state governments to begin wholesale drug buys in Canada and ultimately preserve the inflated prices charged U.S. consumers and taxpayers.

The price of drugs has already emerged as a hot issue in this year's elections, cropping up everywhere on the campaign trail, along with jobs and national security. In his State of the Union address last week, President Bush hailed the passage of the Medicare bill that will give seniors "the modern medicine they deserve" and touted the new drug-discount card that the Administration says will save them 10% to 25% on pharmaceuticals. The even larger Canadian discounts, meanwhile, have attracted a popular passion that is shared by politicians on both sides of the aisle. G.O.P. Congressman Dan Burton—who represents Indiana, where drug giant Eli Lilly employs thousands of voters—has accused the industry of "raping the American people." In the Democratic presidential debate last week, Senator Joe Lieberman described the trend toward buying drugs from Canada as "a kind of Boston Tea Party of the 21st century ... There's only [one] way that this is going to begin to turn around, and it is if we begin to allow the legal importation of drugs from Canada. That's the way we can speak with our money to the drug companies to treat us more fairly." Senator John Edwards of North Carolina said, "Here's a perfect example of what goes on in Washington every day ... These powerful lobbies for the drug [companies], they're taking the democracy away from the American people."

The prices Americans pay for prescription drugs, which are far higher than those paid by citizens of any other developed country, help explain why the pharmaceutical industry is—and has been for years—the most profitable of all businesses in the U.S. In the annual Fortune 500 survey, the pharmaceutical industry topped the list of the most profitable industries, with a return of 17% on revenue. The FDA drive within the U.S. to shut down the Canadian pipeline has coincided with a campaign by drugmakers to pressure the Canadian government to cut off drug sales to the U.S. At the same time, the big U.S. drug companies have warned Canadian pharmacies that their supplies of all prescription drugs

will be halted if they sell to U.S. citizens, thereby threatening to deprive Canadian citizens of access to drugs. Explaining the industry's opposition to American purchases of Canadian drugs, a spokesman for the Pharmaceutical Research and Manufacturers of America (PhRMA) told TIME, "The FDA has said consistently and repeatedly over the years, through both the Clinton and Bush administrations, that there are safety risks and this shouldn't happen and in fact it's illegal."

The main battlefield over the Canadian conduit has been in Congress, where the drug industry has developed a close working relationship with powerful legislators to hold the line against cheap foreign imports. Just before Congress passed the \$400 billion Medicare bill providing prescription drug coverage to seniors in November, friendly lawmakers deleted from the legislation a provision that would have legalized the importation of Canadian drugs with appropriate safeguards. While the passage of the new Medicare law was sold by supporters as a major step toward reducing the burden of drug costs on Americans, the controversy is boiling over again. In fact, the Medicare bill does comparatively little for Clark and millions of seniors like her who fall within an income and spending range that offers fewer benefits.

Nor does it help the millions of working people not eligible for Medicare coverage. As health-care spending keeps rising, (9.3% in 2002, according to the trade journal Health Affairs, the largest increase in 11 years) and employers tighten their coverage to cut costs, consumers have grown more resentful of what they are paying at the drugstore. While prescriptions represented only 10.5% of total health-care costs in the U.S. in 2002, they amounted to 23% of out-of-pocket costs for the consumer. Americans spent \$162.4 billion on prescription drugs in 2002, up from less than \$100 billion a decade ago.

The reasons for the boom are many. Prices on individual drugs have climbed sharply. More people are also taking what might be termed lifestyle drugs. And physicians are increasingly prescribing drugs for children and multiple drugs for an aging population. Yet the disparity between U.S. and other countries' drug prices is becoming a major sore point. The reason drug companies charge more in the U.S. is that, until lately, the market would bear it. Most countries in the world are too poor to pay top dollar for name-brand drugs, and in almost every other developed country, governments regulate lower prices with suppliers.

That's the case in Canada. The U.S. government has largely avoided doing so, mainly because of drug-industry lobbying and political resistance to anything like price controls, but rifts have begun to develop. State and local governments from New Hampshire to California, tired of waiting for the border to open, have started considering ways to skirt federal laws to get Canadian drugs to their citizens. What makes drugs cost so much? Are those prices fair to the American consumer? To find out, TIME investigated how drugs are made and sold in the U.S.—and why Washington has missed so many opportunities to rein in their costs.

HOW DISCOUNT DRUGS FELL OUT OF THE MEDICARE LAW

Whenever Congress goes about the legislative process, it takes care of some people and denies protection to others. The Medicare bill was no different, as can be seen in the fate of three provisions with direct influence on drug prices. Those that would have reduced prices disappeared from the law, while one that protected high prices remained. As the legislation worked its way through Congress, lawmakers edged closer to legalizing the purchase of prescription drugs from Canada. An amendment sanctioning sales to U.S. pharmacies was sponsored by Representative Gil Gutknecht, a Minnesota Republican, and approved in July by a vote of 243 to 186. Notably, Gutknecht's language provided ample protection for consumers—long the argument cited by the FDA and the pharmaceutical industry for prohibiting Canadian drug purchases.

The provision authorized U.S. pharmacies to import prescription drugs made in Canada and other industrialized countries as long as manufacturers used counterfeit-resistant technologies and the drugs were approved by the FDA. Even while addressing the issue of safety, Gutknecht pointed to what he believed to be the main motivation for resistance to such legislation: "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. We ask ourselves, Why are Americans, the world's best customers, paying the world's highest prices? ... I am a Republican. There is nothing wrong with the word profit, but there is something wrong with the word profiteer."

Gutknecht's amendment made it all the way to the secret joint House-Senate conference, where it was deleted by members of his own party. But as so often is the case in the congressional editing process, no one is claiming credit. Another provision in the bill, related to pricing but with the opposite goal, managed to stay in the law. "Subpart 2, Prescription Drug Plans" contained three paragraphs that will have an enduring effect on how much America's elderly pay for prescription drugs: "(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." In layman's terms, the bill bars the Department of Health and Human Services (HHS), which purchases drugs for some seniors under Medicare, from negotiating with drug companies to get better prices, a practice the Federal Government employs routinely in negotiations with other contractors, such as defense suppliers.

"We could have used Medicare's market power to negotiate lower prices for the medicines the program will be buying," said Senator Patrick

Leahy, the Vermont Democrat, last fall before he voted against the final version of the bill. "Instead, this compromise agreement actually prohibits this commonsense approach to cost containment." While Medicare doesn't currently pay for outpatient drugs, it does pay for certain medications dispensed by hospitals and doctors. Government auditors have long singled out Medicare for paying inflated prices compared with what HMOs and retail pharmacy chains pay for the same drugs. An HHS inspector general's report in 2001 said Medicare reimbursements for two dozen drugs "exceeded actual wholesale prices by \$761 million a year."

The third noteworthy drug-cost provision in the Medicare bill was one that would affect the lawmakers themselves. Last summer a provision was inserted into the Senate Medicare bill that would have slashed the prescription-drug coverage for lawmakers to whatever level they eventually gave to Medicare recipients. Written into the pending legislation by freshman Senator Mark Dayton, a Minnesota Democrat, the provision drew the support of all but seven senators. The public-spirited act of self-denial was easier to make because many Senators had been assured privately that the provision would be secretly stripped from the bill before it went to conference. It was indeed.

STOPPING SMUGGLERS: IS SAFETY THE ISSUE?

Pfizer Inc., the world's largest pharmaceutical company, wants to shut down the Canadian pipeline used by the likes of Helen Clark and her fellow border crossers. Pfizer is aggressively seeking a pharmaceutical blacklist, warning Canadian pharmacies that if they sell drugs to Americans, Pfizer will halt supplies of all its products. The company ordered Canadian wholesale distributors to prepare reports itemizing past and present sales of its products by individual drugstores. Pfizer declined to comment to TIME. Four other companies—AstraZeneca, GlaxoSmithKline, Eli Lilly and Wyeth—have taken steps to reduce Canadian sales to the U.S.

The companies are backed by some serious muscle. The FDA, charged with assuring the safety of the nation's prescription drugs, has sided with the industry, coming down hard on the Canadians. "The drug-safety laws that Congress has charged FDA to enforce require that drugs be proven to be safe and effective to be legal," says commissioner Mark McClellan. "While FDA will continue to do all it can to make safe and affordable drugs available, we are also committed to enforcing the law against those ... [who] import illegal, unapproved and potentially risky medicines." The FDA maintains that "consumers who buy prescription drugs from Canada are at risk of suffering adverse events, some of which can be life threatening. These risks include potential side effects from inappropriately prescribed medications, dangerous drug interactions or side effects due to drug contamination." Indeed. But at the same time the FDA is zealously guarding the northern border against errant pill entry, TIME's investigation suggests the real picture is quite different from the one painted by the FDA and some members of

Congress.

Influential lawmakers have given unqualified support to the FDA's anti-Canadian stance, among them Orrin Hatch, a Republican Senator from Utah. Says Hatch: "Many of my constituents have written, asking why they cannot use the lower-cost medications from Canada. The answer is easy: it is just irresponsible for Congress to jeopardize public safety by allowing the unchecked reimportation of drugs ... If we truly care about our seniors and other patients who depend upon prescription drugs, we should not expose them to what amounts to pharmaceutical Russian roulette." Actually, pharmaceutical roulette is played every day in the U.S.—with FDA-approved drugs. Each year an estimated 50,000 to 100,000 people die as a result of adverse reactions from FDA-sanctioned pharmaceutical drugs sold in America. In fact, mistakes in administering drugs, often in hospitals, are the fourth- or sixth-leading cause of death in the U.S., depending on how the cases are counted.

By comparison, the risk from defective, counterfeit or mislabeled drugs from Canada is presumed but unproved by any evidence. When TIME asked a spokesman for PhRMA, the drug-industry association, if there were any cases of Canadian drug imports harming Americans, he said, "Yes, I believe there have been some. I believe FDA has some on its website." In fact, the FDA has no such record. Over and over, congressional committees have grilled FDA officials to produce evidence of Americans who were sickened or who died as a result of buying drugs at a Canadian pharmacy. At a June 2003 hearing, members of Congress quizzed William Hubbard, the FDA's associate commissioner, on the issue: "As far as adverse events, where people have been harmed by Canadian drugs coming across the border, did you bring any of those examples for us?" asked Representative Burton of Indiana. Hubbard: "We have very little evidence." Later, Representative Gutknecht, the Minnesota Republican, pressed Hubbard along the same line: "But the bottom line is, there's no evidence of anyone who has died from taking a legal drug from Canada. Isn't that a fact?" Hubbard: "I have no evidence. That's correct."

In fact, drug-safety regulation is often stricter overseas than in the U.S. Through the 1990s, Bristol-Myers Squibb marketed its antidepressant, Serzone (its chemical name: nefazodone), with ever growing success. In a typical earnings announcement released in July 1996, Bristol-Myers, which had revenue of \$19.9 billion for the 12 months ended Sept. 30, 2003, declared that "sales of central-nervous-system drugs rose, particularly on the strength of *stadol ns*, an antimigraine product, and Serzone, an antidepressant treatment with a low incidence of side effects." The next year, medical studies were released claiming "Serzone to be superior to Prozac in increasing sleep efficiency and providing better sleep quality for people suffering from depression." It wasn't until a few years later that one of Serzone's rare but decidedly significant side effects began to leak out: liver damage, sometimes requiring a transplant and in extreme cases resulting in death. Bristol-Myers announced in 2002 that it would stop selling the drug in the Netherlands and Sweden,

and eventually withdrew it from all of Europe and Canada. The FDA's only response in the U.S. has been to require a black-box warning on the label, stating in part, "Cases of life-threatening hepatic failure have been reported in patients treated with Serzone." Over the past few years, the FDA has banned more than half a dozen drugs that it had earlier approved because the drugs turned out to have an unacceptable degree of fatal side effects. That was more than in the previous two decades.

WHERE LEGAL DRUGS REALLY COME FROM

While the FDA and the drug industry have talked at length about the threat posed by drugs brought in from Canada, what they neglect to mention is this: prescription drugs bought by Americans increasingly are produced in foreign countries with minimal FDA oversight and then shipped to the U.S.

In 2002 pharmaceutical imports to the U.S. totaled \$40.7 billion, a nearly fivefold increase from \$8.7 billion in 1995. Seventeen of the 20 largest drug companies worldwide now make drugs in Ireland, largely because of tax incentives. Pfizer's Lipitor for cholesterol, the largest-selling drug in the world, is made in Ireland. So too is Viagra, for erectile dysfunction. AstraZeneca's Nexium, for heartburn and acid reflux, comes from Sweden, France and other countries. TAP Pharmaceutical Products' Prevacid, another brand prescribed for heartburn and acid reflux, comes from Japan. Because of the rapid rise in drug imports, especially from Ireland, Britain and Germany, the U.S. balance of trade in pharmaceuticals has tipped sharply into deficit. During the early 1990s, according to the U.S. International Trade Commission, imports and exports of pharmaceuticals were "almost equal at just under \$10 billion each." Since then the U.S. trade deficit has spiraled from nearly \$600 million in 1995 to more than \$20 billion in 2002, the last year for which complete data are available.

The trend is continuing. Singapore is on track to be a potential Ireland. Lured by tax breaks and other incentives, American drug giants like Merck are investing heavily in the Southeast Asian country. According to the Singapore Economic Development Board, Merck has invested more than \$500 million to build two plants, which will produce the cholesterol drugs Ezetrol and Zocor. For its part, the FDA maintains that all these facilities are perfectly safe, that they have undergone inspections and that their manufacturing processes have been certified as meeting the agency's standards. But while the FDA does indeed inspect plants before opening, after that the oversight trails off. "The FDA has limited resources," an industry consultant told TIME. "The foreign drug-inspection program I don't think is very strong." Yet the industry is building more facilities abroad—both research and manufacturing complexes—placing an ever greater burden on an already overextended FDA staff.

LOOKING AT THE BOOKS: WHERE DOES THE MONEY GO?

Partly because of extraordinarily generous tax breaks but mostly because of high prices guaranteed by Congress, the U.S. pharmaceutical industry, year in and year out, ranks as the country's richest. Pfizer, which for 2002 reported profits of \$9.1 billion on revenue of \$32.4 billion, earned a return on revenue of 28%, a rate more than twice that of General Electric, nine times that of Wal-Mart and 31 times that of General Motors.

To be sure, the pharmaceutical industry insists it needs the higher prices to pay its hefty research and development tab. (The industry spends tens of millions on marketing and advertising as well but does not make an issue of that.) An academic study in 2001, partly funded by the drug industry, estimated that it costs an average of \$802 million to bring a single new drug to market, though that number is disputed by consumer advocates. Says Alan F. Holmer, president of PhRMA: "Developing new medicines requires cutting-edge science, enormous investment of time and money, and willingness to commit those resources in the face of expensive failure after failure. None of this is compatible with price controls."

But no one really knows how the money is spent. Indeed, the industry has refused to open its books to government auditors and once waged a nine-year legal battle with the General Accounting Office (GAO), Congress's investigative arm, to keep the information secret. Congress could subpoena the information but has refused to do so, in no small part because of the power of the pharmaceutical industry lobby.

While the industry is quick to claim how much it must spend to come up with new drugs, it is slow to acknowledge the contributions of the Federal Government and American taxpayers. Universities, foundations, researchers and congressional committees have concluded for years that many major drugs owe their origins to research funded by the National Institutes of Health (NIH), the National Cancer Institute and other public agencies. A report by the Joint Economic Committee of Congress in 2000, then headed by Republican Senator Connie Mack of Florida, summed it up: "The Federal Government, mainly through the NIH, funds about 36% of all U.S. medical research ... Of the 21 most important drugs introduced between 1965 and 1992, 15 were developed using knowledge and techniques from federally funded research." A GAO report last year on Taxol, which had worldwide sales of \$6.2 billion from 1998 to 2002, noted, "Through a collaboration with NIH, [Bristol-Myers Squibb] benefitted from substantial investments in research conducted or funded by NIH." The collaboration "provided the company with research results that enabled [Taxol] to be quickly commercialized ..."

WASHINGTON AND THE STATES: GOING SEPARATE WAYS

One reason the industry does so well in the capital is its potent lobby. It maintains more than 600 lobbyists—more than one for every member of Congress. It spent \$435 million to influence Washington from 1996 to

2003 and handed out \$57.9 million in contributions from 1991 to 2002, according to Common Cause. Says Representative Pete Stark, a California Democrat who has waged a decade-long war for lower Medicare drug prices, a move that government auditors say could save taxpayers nearly \$1 billion a year: "These guys are awfully good. I only wish they were on the right side of the issues. They don't care about curing people. They only care about profits. They are very effective. My only hope is that sooner or later they are going to overreach."

The lobbying is about to reach critical mass with states and cities squeezed by runaway health-care expenditures in general and the unchecked increase in drug prices in particular. Both have grown irritated with Congress's failure to consider pricing alternatives and have become especially annoyed lately with the FDA's threats to initiate legal actions against any government that seeks to enter into buying arrangements with the Canadians to slash their prescription drugs costs for employees, prisoners and Medicaid recipients. The latter group represents a significant financial burden for the states. Although the feds kick in some Medicaid money, overall spending on drugs topped \$23 billion in 2002, with New York accounting for \$3 billion and California for \$2.6 billion. The Democratic leader of the California state senate said last week that he would introduce a bill to require California to consider buying Canadian drugs under state programs. Although no state has yet begun to do that, two local governments—Springfield, Mass., and Montgomery, Ala.—are buying drugs and saving millions. Some two dozen other cities and states have begun efforts to link up with Canadian suppliers. "Cash-strapped state and local governments are looking for relief in a logical place," says Representative Jo Ann Emerson, a Missouri Republican. Further fueling the states' animosity toward the feds, the FDA has threatened legal action against state and local governments that pursue the Canadian option, thereby increasing the likelihood of another congressional showdown.

NEEDED: A BETTER WAY TO CUT PRICES

While it may provide some short-term relief, buying drugs in Canada is indeed a roundabout way for the U.S. to address the high cost. And selling drugs over the Internet, with the FDA's refusal to even consider a regulatory framework, isn't the answer either. No one disputes that while there are many legitimate online pharmacies, the Internet at the moment also has its share of charlatans and hucksters offering dubious and possibly dangerous products. When TIME asked a PhRMA spokesman why the industry simply did not designate one or more Internet pharmacies as approved sites, he replied, "We really—we actually really don't have a position on that. It's the FDA that is investigating the Internet pharmacies and has some concerns about it." And what's the FDA's position? Says Dr. Janet Woodcock, director of the Center for Drug Evaluation and Research: "There's no structure set up for regulating a pharmacy."


For its part, the pharmaceutical industry would like to direct attention

away from Canada and the debate in Washington. Says the PhRMA representative: "There are safer, better ways to resolve the access problem, to help patients who are having difficulty. You've got the patient-assistance and -discount programs. You've got, as a third option, the fact that as part of competitive marketing, our companies provide free samples of medicines, all types of medicines, to hundreds of thousands of doctors all over the country. And quite often those doctors give those free samples to patients who are having difficulty. And so there's that option: ask for a free sample."

— With reporting by Laura Karmatz and Barbara Kiviat and research by Joan Levinstein

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