A Primer on Drug "Reimporting"

How's it done? Is it legal? Safe? Why do drug companies object? Here are the answers to many questions swirling around the practice.

You don't have to be an accomplished cybersurfer to know that plenty of Internet operations do a brisk trade selling drugs. And it's not just Viagra, Oxycontin, and steroids that are being peddled online. Many legitimate Web pharmacies have evolved into popular money-saving options for retirees, state and city workers, and the uninsured who need prescription drugs.

One of the industry's fastest growing segments is so-called reimportation sites, which allow people to buy essential pharmaceuticals at lower prices from foreign countries. By some estimates, this year Americans will buy more than $1 billion in drugs from pharmacies in Canada alone. And sales from Canadian pharmacies account for only 20% of all reimported drugs.

The issue has become a political hot button. While federal and state regulators watch growing online pharmacy sales warily, politicians from both parties are listening to their constituents, many of whom are angry at Big Pharma over high drugs prices in the U.S., where much of the industry's revenue comes from. Instead of siding with regulators, several members of Congress have introduced bills that would ease restrictions on reimportation.

Some lawmakers are even providing lists of Web sites and other programs that will connect people to non-U.S. pharmacies. In its defense, the drug industry contends that high prices in the U.S. are necessary to pay for research into new drugs.

Here's a look at the status of cross-border buying and selling of prescription drugs, and the controversy over the issue:

What is reimportation, exactly?
The way the drug market works, big pharmaceutical companies make the bulk of their profits by selling drugs at higher prices in the U.S. to a wealthier customer base. In recent years, however, reimportation has revealed a major crack in the U.S. health-care system. Millions of Americans can't afford the out-of-pocket cost of prescription drugs (43 million have no health insurance, according to the 2000 U.S. census). So, many have resorted to buying their medicines from outfits in foreign countries, which typically charge prices that are between 30% and 70% lower than in the U.S.

How many people are doing it?
The practice has become quite widespread. Market researcher IMS Health estimates that $695 million worth of drugs were bought in Canada alone in 2003, up from $414 million in 2002. The rise of the Internet in the late 1990s made buying drugs from abroad easier. At first, people seeking painkillers and "lifestyle" drugs like Viagra were the main buyers. In the last several years, however, more and more people have flocked to sites that promise lower prices for drugs to treat chronic conditions.
How does one go about reimporting?
Today, the predominant method has become ordering through Web sites or storefronts, which often, but not always, require patients to fax a copy of a physician's prescription. Of course, it's hard to know for certain what happens once the order leaves the fax machine, but many sites promise that licensed pharmacists in their country then check that the prescription is legit. After a money-order or credit-card payment for the drug and shipping fees is received, the prescription usually arrives on your doorstep within a few days.

Even with the Internet, many people still physically travel to foreign countries to buy prescription drugs on the cheap, however.

Is reimporting safe?
That's hard to say. The FDA has been consistent in saying that people shouldn't do it. Bill Hubbard, the agency's associate commissioner for policy and planning, points out that the FDA "can't stand behind those drugs" since it can't track where they've been or how they are stored. Still, reported cases of harm caused by prescriptions filled abroad are "fairly limited," Hubbard admits. "We have no mechanism to know how many people are being harmed. We don't expect people to drop dead, but we would expect diseases are not being properly treated."

Is it legal?
It's legal for individuals to personally import a drug supply of less than three months for their own use (the "personal-use exemption" that many of the U.S. storefronts and Canadian pharmacies are exploiting).

Otherwise, it's illegal for Americans to buy drugs that are not manufactured at an FDA-approved facility. (Proponents of reimporting point out that drugs bought through pharmacies in certain countries, particularly Canada, were likely made in government-inspected facilities.) However, the FDA has done little to enforce the law. "We have never attempted to arrest or take away drugs from anyone," Hubbard says. The same is true of any packages sent through the mail.

Still, the agency has been vigorously going after commercial operators. Late last year, the FDA shut down Rx Depot, a popular Oklahoma-based Internet pharmacy that helped people get prescriptions filled from Canada. The FDA is also talking to package carriers like FedEx (FDX) and to credit-card companies about how they might help in tracking large amounts of prescription-drug imports from Canada.

Aren't some states and cities trying to help people buy drugs through Canadian pharmacies?
Yes. Budget-strapped states and cities say they can save money if employees and retirees use pharmacies in Canada or elsewhere. The Canadian drug-purchasing program set up in Springfield, Mass., for example, could save the city as much as $4 million depending on how many of its 900,000 workers and former workers use the program.

Four states -- Minnesota, Wisconsin, North Dakota, and New Hampshire -- have set up Web sites or other programs to encourage and help its state workers buy drugs through non-U.S. pharmacies. Cities with similar efforts to Springfield's include Burlington, Vt., and Montgomery, Ala. North Carolina's Caldwell County has a site, and Boston and the state of West Virginia may set up programs by this summer.

If it's illegal to reimport drugs, why do local and state governments enable people to do it?
The increase of elderly and uninsured people resorting to illegal and potentially unsafe drugs to save money on medicines is a heart-tugger for politicians. "Obviously there's lots of political appeal to make drugs less expensive," says lawyer Al Lorman, a partner at Mayer, Brown, Rowe & Maw LLP, in Washington, D.C. In February, with public encouragement from the mayor of Chicago, an elderly Illinois couple filed a suit against the federal government for "limiting their access to medical choices."

In situations where states and cities are enabling reimportation, "we have warned them that it is illegal and urged them not to do it," says the FDA's Hubbard. So far, the agency hasn't prosecuted the states and cities, though down the road it "may have to ask a federal judge to mediate."

Could reimportation become legal this year?
Not likely, although the issue will certainly get a lot of attention on Capitol Hill. As part of the Medicare bill that was passed last December, the Health & Human Services Dept. must present a report to Congress by yearend that looks at whether and how reimportation could be done safely.

Several bills are in the works. In early April, Senator Charles Grassley (R-Iowa) unveiled legislation that would legalize importing of drugs from Canada and create a 90-day deadline for the FDA to set up a system to register and inspect Canadian suppliers. After two years, the bill would allow Australia, Japan, and European Union countries to participate.

Senators Byron Dorgan (D-N.D.), Judd Gregg (R-N.H.), John McCain (R-Ariz.), and Olympia Snowe (R-Me.) are all working on various reimportation bills.

What would the impact be of making imports legal? Would it ultimately drive down drug costs?
Increased competition could certainly cause a dramatic fall in prices in the short run, says Joshua Cohen, senior research fellow at Tufts Center for the Study of Drug Development Research. But critics point out that allowing regulated drug imports in Europe was no panacea. A study by Panos Kanavos and other economists at the London School of Economics provided evidence that savings to insurers and patients were modest. And supply shortages became common in countries where the cheapest drugs were available.

"Reimporting is skirmishing around the edges of the problem," says Alan Sager, professor at Boston University's School of Public Health and co-director of the school's health-reform program. "The real problem is getting affordable medications for all Americans while enhancing research for breakthrough drugs."

How are the drug companies reacting to this?
This much is certain: The drug industry won't give up its fight to keep reimportation from becoming legal. Drugmakers contend that lower prices (and lower profits) would limit the incentive to invest in their new-product pipelines.

Given that the drug industry has been built on constant innovation, however, reimportation isn't likely to seriously crimp companies' incentive to come up with new, lifesaving drugs. Boston University's Sager argues that lower prices resulting from reimportation would be more than offset by the sharp rise in volume of new prescriptions for people who couldn't previously afford the drugs at all.

What about the bigger issue of making drugs more affordable? How might that get fixed?
Unlike most developed countries around the world, Washington doesn't set price caps on drugs. However, the U.S. market could see an effect similar to having price caps in the next couple of years. In 2006, when the Medicare drug benefit kicks in, the country's largest insurer "could use its sheer-volume clout to reduce the price of drugs," Cohen says. That will likely create a powerful -- and lasting -- downward push on U.S. drug prices.

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