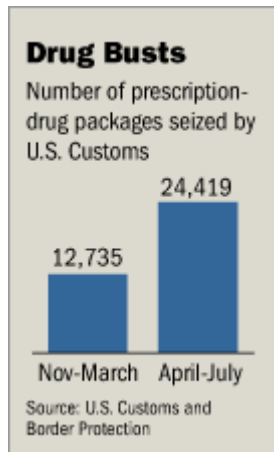


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Seizures of Canadian Drugs Rise As Congress, Customs Spar

By JOHN CARREYROU

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Eileen Bloom, a retiree who lives in the lakeside town of Sebring, Fla., has long ordered her medications from Canada, saving up to 50% on her prescription-drug bills. But twice in the past nine months, her medicine hasn't arrived.

Ms. Bloom, who suffers from diabetes, is one of tens of thousands of Americans whose drugs have been seized by U.S. Customs and Border Protection. The seizures are the result of a quiet policy change at Customs last November, which has come under fire from members of Congress who say it is intended to protect U.S. drug makers' sales at high domestic prices.

Most prescription-drug importations are illegal under current U.S. law. But Customs and the Food and Drug Administration had tended to turn a blind eye to small mail orders coming across the border from Canada, where the national health-care system negotiates cheaper prescription-drug prices than in the U.S.

On Nov. 17, that abruptly changed when Customs began systematically confiscating packages mailed to U.S. consumers by Canadian pharmacies.

The number of seized packages has now reached 37,154, angering members of Congress who have been deluged by complaints from constituents. "Some consumers have had their lives put in jeopardy. If you're on heart medication, you can't miss a day or two," says Dan McLaughlin, a spokesman for Sen. Bill Nelson, a Florida Democrat who has been rallying opposition to the new policy.

Earlier this month, the Senate voted 68-32 to approve an amendment to the Homeland Security appropriations bill that would bar Customs from using federal funds to seize prescription drugs imported by individuals from Canada. The House passed a similar amendment in May. However, it remains unclear whether the amendment will make it into law. Drug-industry lobbyists are expected to push to scrap it when the bill goes to conference in coming weeks. The Bush administration and Republican congressional leaders have supported the industry's stance against Canadian imports.

The skirmish between Customs and Congress is the latest flash point in the rising debate over high U.S. drug prices. Pharmaceutical companies earn the bulk of their profits in the U.S., one of the only markets in the world where the government doesn't exercise control over drug prices. Canadian imports, which have enabled American consumers to circumvent high U.S. prices, have been a sore point with the industry.

Last year, Canadian Internet pharmacies catering to U.S. consumers purchased \$373 million of prescription drugs from wholesalers, according to IMS Health, a pharmaceutical data-research firm. Adding in retail markups, dispensing fees and non-Internet sales to Americans who physically cross the border to buy medicine, sales by Canadian pharmacies to U.S. consumers likely exceeded \$500 million in 2005. The number is expected to be lower this year, partly because of many U.S. seniors' enrollment in Medicare Part D, a new prescription-drug benefit that provides them private-insurer coverage.

Customs says it began seizing packages late last year because of concerns that the prescription drugs coming across the border in the mail were unsafe -- an argument the drug industry has been pushing since the rise of Canadian Internet pharmacies six years ago.

A spokeswoman for Customs, Lynn Hollinger, cites a joint Customs-FDA operation in August 2005 at New York, Miami and Los Angeles airports, showing that a large percentage of drugs purportedly coming from Canadian pharmacies actually originated in India, Israel, Costa Rica and other countries, and many were counterfeit.

In a statement issued last week responding to the Senate amendment, Ken Johnson, senior vice president of the Pharmaceutical Research and Manufacturers of America, the drug industry's trade group, said: "Consumers may be risking their health by purchasing imported prescription drugs from purported Canadian Internet pharmacies -- which have been known to sell fake and potentially unsafe medicines to unknowing American consumers -- and may be run by shady dealers in countries such as India, China and North Korea."

Congressmen from both parties have cast doubt on the safety argument, noting that drugs ordered from licensed Canadian pharmacies are approved and vetted by Health Canada, Canada's equivalent of the FDA. They also criticize Customs for not making its new policy public until after the fact, leaving thousands of Americans without their medications.

Andy Troszok, president of Canada's Extended Care Pharmacy, says his sales to U.S. customers so far this year have been down about 15% from last year, but he thinks seizures are only one factor. Medicare Part D and the Canadian dollar's fluctuations against the U.S. dollar probably play a bigger role, he says. Extended Care notched about \$13 million in sales last year. Mr. Troszok says the company's shipments blend in with regular mail but they don't try to conceal what is in the packages because that would go against their effort to establish credibility with U.S. customers.

Extended Care has seen a rise in sales from Nevada: It is one of four Canadian pharmacies that the state licensed in May, flouting federal law to allow residents to order drugs from them. "I had Nevada inspectors in my pharmacy," Mr. Troszok says, "and they certified me. That has completely removed the safety argument."

Ms. Bloom, whose packages were seized without warning in November and January, says she suspects a "ploy to get seniors to sign up for Medicare Part D." Ms. Bloom doesn't qualify for the drug benefit because she is 61, and it is available only for seniors 65 and older.

Ms. Hollinger, the Customs spokeswoman, denies any connection with Medicare Part D, which went into effect Jan. 1, six weeks after the wave of seizures began. "We're an independent government agency and we are charged with enforcing the law," she says. While enrollment in Medicare Part D plans ended May 15, Customs has continued the seizures. Ms. Hollinger says the agency has no plans to stop them, unless the Congressional amendment makes it into law.

Margaret Glavin, the FDA's associate commissioner for regulatory affairs, says the agency was initially taken aback by Customs' decision to start seizing packages, but it now supports the move because it takes a strain off the FDA's limited enforcement resources.

Previously, Customs had referred a small number of packages to FDA employees deployed at mail facilities across the country. But "it wasn't even a finger in the dyke" of prescription drugs flowing in from abroad, she says. Ms. Glavin says the FDA and Customs are now working hand in hand on the issue, with FDA staffers providing Customs agents technical and scientific assistance.

For their part, drug companies didn't wait for Customs' policy change to fight the imports. Canadian pharmacies serving Americans say the big pharmaceutical companies have starved them of inventory since 2003.

Sen. Nelson has asked the Senate's Homeland Security Committee to look into allegations that British drug company GlaxoSmithKline PLC conspired with other big drug companies to put Canadian pharmacies that filled American prescriptions out of business.

The allegations stem from a civil lawsuit filed by Minnesota Attorney General Mike Hatch against Glaxo. The suit alleges that Glaxo "orchestrated a concerted pharmaceutical industry boycott of Canadian drug imports to protect drug company profits," in violation of the state's antitrust statutes. Large numbers of Minnesotans buy medicine in Canada.

Mr. Hatch has subpoenaed 45 secret documents from Glaxo that he says prove the conspiracy. According to people familiar with the case, the documents show that the boycott was first discussed by representatives from Glaxo and a half-dozen other big drug companies at a meeting in Boca Raton, Fla., in December 2002. At another meeting, representatives from the same companies met with federal officials and discussed using the threat of terrorism to dissuade seniors from buying Canadian drugs, these people say.

Glaxo has been fighting in court for two years to keep the documents confidential. The Minnesota Supreme Court is expected to rule in coming weeks on Mr. Hatch's motion to make the documents public. A spokeswoman for Glaxo, Gail Renegar, says the company's actions complied with U.S. law banning foreign drug importations and thus should exempt Glaxo from antitrust scrutiny.

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