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Canadian drug reimportation debate goes on

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The raging debate of Canadian drug reimportation to the US could soon spell bad news for US consumers and Canadian internet pharmacies, as Canadian Health officials currently weigh a decision to restrict or put an end to the practice. It's a sentiment that puzzles many who wonder why the Canadian government would oppose a \$1 billion dollar a year industry that employs nearly 4,000 Canadians and has so far has not harmed a single US consumer. In the US, some state representatives vocally support the trade, evidenced by five pro-importation bills currently pending in both the US House and Senate. A decision could be announced anytime and is expected before summer.

Critics

Critics level that this shift in attitude on the part of the Canadian government comes on the heels of US president George W. Bush's visit to Canada in November to meet with Canadian Prime Minister Paul Martin. The current US administration sides with the pharmaceutical industry in seeking a ban on drug reimportation, with critics crying foul on account of campaign contributions from the pharmaceutical industry. The FDA is now seizing prescription drug shipments from Canada intended for US consumers, with expectant consumers receiving seizure notices in lieu of filled prescriptions.

Prescription drugs from Canada can save US consumers as much as 60% for the identical product sold in US pharmacies. The price discrepancy is the result of controls imposed by the Canadian government in exchange for patent protection extensions for drug manufacturers. Currently, nearly 1.8 million Americans turn to Canada for affordable medicines. The US is the only country in the developed world that does not have pharmaceutical price controls.

Jeff Trewhitt, spokesman for the Pharmaceutical Research and Manufacturers of America (PhRMA), an advocacy group for the country's pharmaceutical and biotechnology companies, acknowledges that the US is facing a crisis. '25% of the US population doesn't have coverage or has inadequate coverage,' he says, 'and we agree that it's a crisis.' But he says the industry is working to offset this problem through patient assistance programs that have provided 40 million free prescriptions over the last two years (www.helpingpatients.org).

Transshipment

Rather, he says that the threats posed to US consumer safety and pharmaceutical innovation are the reasons why PhRMA is so opposed to drug reimportation from Canada. 'One third of internet drug sellers aren't really Canadian and aren't coming from Canada,' he says, but are based in countries like South Africa, Romania, India and Thailand. 'Evidence

is compelling that products are transshipped from these countries [via Canada]. He says that the South African health minister has stated that one in five drugs from his country is counterfeit.

But David MacKay, executive director of the Canadian International Pharmacy Association (CIPA), representing Canada's mail order pharmacies, says that the drugs filled by their Canadian pharmacies are from Canadian or G8 western European suppliers and manufacturers, and are not from third world countries. US consumers can verify the legitimacy of a mail order pharmacy through CIPA.

MacKay says that Canadian mail-order pharmacies attempt to fill the prescription in Canada first, but have had to resort to European countries of late since Canadian pharmacies suspected of supplying US consumers have found themselves blacklisted by seven major pharmaceutical companies, effectively choking off their wholesale supply. As a result, some drugs must be obtained from Europe and the US consumer is notified in writing prior to the prescription being filled, he says.

He says that no health threat is posed by legitimate Canadian mail order pharmacies considering that the big drug companies have manufacturing sites in countries around the world, distributing products in tamper-proof, bubble packs. Even drugs sold in US pharmacies can be manufactured in western European countries such as Ireland and the UK.

Death knell

While mail-order companies are feeling the squeeze imposed by big pharma, the Canadian government itself may sound the

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death knell for the Canadian drug import industry. Canada's health minister, Ujjal Dosanjh, has announced three options: (1) prohibiting Canadian doctors from counter-signing prescriptions from US physicians after reviewing patient charts; (2) prohibiting any non-Canadian from acquiring a Canadian drug unless they are physically examined by a Canadian physician; and (3) devising a protected drug list of any drug deemed in short supply and not permitted for resale to the US. He is expected to announce his decision soon.

If the trade is not stopped, says Trewitt, the very foundation of research and development is threatened, he says. 'The US pharmaceutical and biotech industry provides 60–70% of the world's new medicines – we think one of the major reasons is that we have competitive pricing.'

But MacKay argues that the notion of drug reimportation posing a threat to R&D funding is faulty logic. He says Canadian sourcing creates customers where they otherwise would not exist. Patients who cannot afford US prices simply won't buy the drug. 'You can't get profit out of a no-sale,' says MacKay. They will buy it, however, if they can find it affordably priced in Canada. The Canadian purchase 'is a new business sale and market for the pharmaceutical company,' he says.

'It's not as if they're losing money,' counters Trewitt, 'but that profit is much more modest – too modest to sustain the current level of innovation.' It's a trend that he says has been

seen many times among drug companies based in Europe and Canada wherever there has been a history of price control. 'You still have a number of cutting edge [companies] in Europe, but what they've done is opened up very large US subsidiaries,' he explains. 'When it comes time to open up a \$400 million center, they're opening it up in the US, they don't do it in their home countries.'

Fears

But MacKay argues that the reason the drug companies are fighting this issue tooth and nail – despite reaping profits regardless of whether the drugs are sold in Canada or the US – is because of another unspoken threat. 'Why they want us [Canadian mail order pharmacies] gone is because of the public relations nightmare we create for them,' he says. 'They fear this importation issue will create a huge demand for price controls in the US domestically and eliminate their worldwide cash cow – and we're raising attention to how they're [American consumers] are being gouged,' he says.

Furthermore, he argues, banning the trade will only fuel the illegitimate market that opponents, including PhRMA, cite as the chief threat posed by reimportation. 'They would be creating a Pandora's box,' he says. 'If you kill the only legitimate channel of trade, you have a system where counterfeiters and unregulated products will fill the void of demand. These people will fall into the hands of unscrupulous vendors.'

THD1

We listen

Getting inside the bug: new targets for TB drugs

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Few of us probably noted the passing of World TB day on March 24 (www.niaid.nih.gov/director/worldtbdays_05.htm). But for hundreds of scientists and clinicians working to combat the disease, TB is the focus of every day. Among them are Harvey Rubin and his colleagues at the University of Pennsylvania, who have identified a new drug target in the organism [1].

Global public health crisis

Mycobacterium tuberculosis claims over two million lives worldwide each year – and dwells, hidden, in as many as two billion people. Development of new therapeutics has been stymied for 40 years, and strains of *M. tuberculosis* are gaining resistance to available drugs – a difficult six-month treatment course. The worsening situation has prompted the World Health Organization to declare TB a global public health crisis.