

Canadians smuggle in cheaper Thalidomide

Cancer Treatment

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Faced with massive costs here for a life-extending drug with a dark history, many desperately ill Canadian cancer patients are turning to Mexico, Brazil and other developing countries for far-cheaper supplies of Thalidomide.

One Mexican company says it has 100 Canadian customers who buy the drug over the Internet, in person in Mexico or even through vacationing relatives toting their loved ones' prescriptions.

The price is less than a 20th of that charged for the version available in Canada, but patients who import Thalidomide from overseas are breaking the law, and running the risk of consuming sub-standard or dangerous pills, some experts and regulators warn.



Thalidomide -- banned in the 1960s as a morning-sickness medication after a slew of birth defects -- has recently become one of the leading treatments for multiple myeloma, a blood cancer that afflicts about 6,000 Canadians and kills 1,350 a year.

"I've had patients try to get it through physicians they know in Brazil or from India," said Dr. Donna Reece, a hematologist at Toronto's Princess Margaret Hospital specializing in myeloma. "It's not a desirable mechanism.... I tell them it's not the legitimate way to get it."

Thalidomide -- banned in the 1960s as a morning-sickness medication after a slew of birth defects -- has recently become one of the leading treatments for multiple myeloma, a blood cancer that afflicts about 6,000 Canadians and kills 1,350 a year.

It and two other drugs are adding years to the lives of myeloma patients who until recently faced a particularly grim prognosis.

Costs can top \$40,000 annually, however, and most provincial drug plans and private insurers do not reimburse the expense.

While the manufacturer that is patented in Canada, Celgene Corp. of New Jersey, offers it free to lower-income patients, many do not qualify for the program.

"When you're faced with a disease like myeloma, like I am, it is a death sentence without these drugs," said Lori Borsos, a myeloma patient in Hamilton who takes Thalidomide.

"I don't think there are too many people who wouldn't go to any length to get the drug. I know it's a big risk, but you've got to take the risk. Who cares where it comes from if it's going to keep you alive?"

Dr. Tom Kouroukis, a hematologist in the same city, said he has a handful of patients who have obtained Thalidomide from Mexico, and would have no problem recommending others try the same route if they could not afford the Celgene version. The Mexican pills seem to work just as well, he said.

A spokesman for Health Canada, however, said it is illegal for individual Canadian patients to import such drugs

by mail or courier, though officials can permit a patient to bring up to a 90-day supply with them into the country.

Observers agree that only a minority of myeloma patients are seeking the drug from offshore sources so far, but the practice is a dramatic illustration of the financial barriers faced by many cancer patients prescribed potentially life-saving -- and exorbitantly priced -- new medications.

"The health care system is built on equity of access," Dr. Kouroukis said.

"[But] you know some people are getting the drug and some people are not. It creates this uncomfortable feeling about different tiers of ability to provide medical care to people."

Two other promising drugs for treating multiple myeloma -- Revlimid and Velcade -- have been approved by Health Canada, but most provinces have yet to agree to pick up the costs, which can be as high as \$100,000 annually, noted John Lemieux, president of the Myeloma Canada advocacy group.

The Thalidomide story has some unique features, however. It became perhaps the most infamous prescription drug ever after many children of women who took it for morning sickness in the 1950s and 1960s were born with missing limbs and other defects.

Researchers later discovered Thalidomide was useful for other conditions, though, including leprosy and, most recently, myeloma.

The cancer is incurable, but studies suggest that Thalidomide can stretch the average survival time from four or five years to as much as 10, said Dr. Pierre Laneuville, past president of the Canadian Hematology Society. Ms. Borsos said she was given three years to live when she was diagnosed and has already survived twice that long on the drug.

Velcade and Revlimid, which act in a similar fashion as Thalidomide but is more potent, have also brought new hope to myeloma patients, but Thalidomide is likely to continue to play an important role, Dr. Reece said.

Celgene, which also makes Revlimid, has never applied to have Thalidomide approved for marketing in Canada, but it is available under Health Canada's special access program.

The manufacturer will cover the costs of some patients. Celgene estimates that 60% qualify but some doctors say most of their patients fail to meet the means test.

That leaves them with an unenviable choice: pay the tens of thousands of dollars annually out of their own pockets or go without.

Or they can buy from overseas. Getting the 50-year-old drug through official channels in Canada means a price tag of \$900 for about 30 tablets of 50 milligrams, though patients sometimes need four times that dose per day, bringing the bill to as much as \$43,000 annually. The Patented Medicines Price Review Board -- a federal watchdog -- has launched a review of the drug's cost.

In contrast, the Mexican company Laboratorios Serral, which makes Thalidomide under the locally patented brand name of Talizer, charges \$90 for 50 pills of 100 milligrams each, said Ariadne Nunez Lugo, the firm's self-export manager.

She estimated that about 100 Canadians have bought Thalidomide from Serral, online and in person.

Close family members can also pick up the drug from an authorized pharmacy chain in Mexico, as long as they have the patient's prescription and some identification, Ms. Lugo said.

Studies have confirmed that Talizer is a high-quality version of Thalidomide, she said. Serral has asked Health Canada about getting its pill approved here, but was told the government was not interested in licensing the drug, Ms. Lugo said.

Some doctors here cautioned, however, that patients are taking their chances with imported drugs that are not under any kind of Health Canada oversight.

The molecule is in the public domain and chemists can duplicate it relatively easily, but minor slip-ups in manufacturing can significantly undermine a drug's efficacy or safety, Dr. Laneville said.

As for why Thalidomide is so expensive, the manufacturer says it has incurred major costs for clinical trials, dealing with regulators in various countries and "risk management" -- expenses that are spread over the relatively small group of myeloma patients, said Brian Gill, a spokesman for the firm.

"Our therapies are priced based on their value to society," he said.

"Our therapies are probably the least costly solution and option that patients have right now in improving the quantity and quality of their lives."