The staggering price of survival

SPECIAL REPORT: Patients wondering why the cancer drug thalidomide costs so much

BY LISA PRIEST

MONDAY, AUGUST 15, 2005 PAGE A1

A 75-year-old cancer patient from Prince Edward Island is depleting her life savings to pay $4,500 a month for thalidomide.

An Albertan, living on a small pension, cashed in some RRSPs to pay for the drug to treat his multiple myeloma, a cancer of the plasma cells in the bone marrow.

And an Ottawa-area father has paid thousands so his teenage son with brain cancer could get the drug.

All of these people are wondering how a drug, almost a half-century old, which can be made for less than a dime in a Brazilian government laboratory, can cost as much as $37.50 a capsule in Canada.

They are not alone. The BC Cancer Agency, the only publicly funded provincial cancer organization to fund thalidomide, is also disturbed by the high cost of the medication, noting it has increased nine-fold over the past five years.

"This drug which costs hardly anything to make, they have jacked up the price on it year after year," Susan O'Reilly, head of medical oncology for the BC Cancer Agency, said. ". . . It's disgraceful."

For a drug that gained worldwide notoriety for causing horrific birth defects more than 40 years ago, thalidomide has made a spectacular comeback as a cancer drug.

It has done so, in part, because the very mechanism that caused those birth defects -- the damaging of blood vessel growth -- has been found to help starve some tumours. Thalidomide also helps stimulate cells of the immune system to attack cancer cells.

The way this small, white capsule has come into its own is a story of opportunity, scientific research and how, when it comes to cancer medications, no price appears too high -- even in Canada, which prides itself on lower drug costs thanks to price controls.

Celgene Corp., the U.S.-manufacturer of the drug, which is sold under the trade name Thalomid, said it provides the drug free to 15 per cent of its cancer patients in the United States. In Canada, that figure is believed to be much higher. And 40 per cent of the company's revenue is used to fund research and development of other medicines.

Brian Gill, Celgene's director of corporate communications, said Thalomid is priced relatively low when compared with other drugs used to treat multiple myeloma, adding that "it truly reflects its therapeutic value in the marketplace." It is considered a last-ditch treatment for the illness.

Still, many are baffled at how thalidomide has managed to command such dramatic price increases, particularly since the patent on the drug's composition expired in 1976.

Currently, the only way the drug can be obtained in Canada is through Celgene under the federal government's special-access program, Health Canada spokesman Paul Duchesne said. Under this program, an unapproved drug can be given to patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable or unavailable.

Given its special status here, a generic company could not even attempt to replicate it at a cheaper cost to patients because Thalomid has not gone through the Canadian drug approval process.

While there are at least two patents attached to Thalomid, neither falls under the jurisdiction of Canada's Patented Medicine Prices Review Board, which ensures the cost of patented medicines is not excessive.

In 2000, the BC Cancer Agency paid about $120 for a bottle containing 30 50-milligram capsules of the drug. The cost to that cancer agency today is roughly $1,100 according to spokeswoman Nicole Adams.

Those not fortunate enough to get the drug free, either through the BC Cancer Agency or through Celgene's assistance program, are often left to pay for it themselves.

One such patient is 75-year-old Dorothy Ingraham, of Kensington, PEI, who has been taking the drug for four months. A year's supply, she estimates, will cost her $54,000 and exhaust her savings.

"It's terrible, but we have no choice," said Mrs. Ingraham, who is paying $4,500.34 a month for the drug after other treatments for her multiple myeloma failed.

She said she tried every possible route to get the drug subsidized, but to no avail. Now, she and her retired clergyman husband, Eric Ingraham, are anxious at the thought of the money running out.

"We're not happy, but all we can say is that I'm a firm believer that the Lord will provide," Mr. Ingraham said.

Vic Audy, a 70-year-old Albertan, was prescribed the drug two months ago for his multiple myeloma after other drugs failed to halt the disease. He describes thalidomide as "probably the last survival technique I can use."

The only way he is able to afford the drug, which has so far cost him $4,000 for little more than a two-month supply, was to cash in some of his RRSPs.

Mr. Audy said he read through the lengthy application for Celgene's free-drug program, but he didn't fill it out. Being a homeowner, he said, automatically disqualified him.

"It was completely silly to bombard me with such a big application form," said the retired carpenter, who lives in Whitecourt, Alta., 180 kilometres northwest of Edmonton. "You have to be completely broke [to qualify]."

Despite its price, more than 11,000 requests under Health Canada's special-access program have been made for thalidomide from 2002 to 2004 for use in multiple myeloma, other cancers and autoimmune diseases.

However, it is not known how many of these were repeat requests or how many requests were denied, according to Health Canada spokeswoman Nathalie Lalonde. Introduced in West Germany in 1957 by another company, thalidomide was prescribed to pregnant women as a way to combat morning sickness and insomnia. It caused severe birth defects, such as missing or deformed limbs, in more than 10,000 babies worldwide. According to the Thalidomide Victims Association of Canada, there are 125 Canadians who were born disabled as a consequence of the drug. It was on the market in Canada for 11 months before it was withdrawn.

Thalidomide's comeback began in 1998, when the U.S. Food and Drug Administration granted Celgene approval to market it for a leprosy-related malady under the trade name Thalomid. Once that happened, doctors could prescribe the drug for other diseases in a practice that is known as "off-label" prescribing.

But the drug really came into its own when a study, published in the New England Journal of Medicine in 1999, showed 30 per cent of the 169 patients who suffered a relapse of multiple myeloma after receiving other cancer treatments saw levels of a protein linked with that disease decrease by half or more once they received thalidomide. Donna Reece, a medical oncologist who specializes in multiple myeloma at Toronto's Princess Margaret Hospital, describes thalidomide as "one of the first breakthroughs in multiple myeloma in many years."

Not only does the drug help those who have suffered a relapse of multiple myeloma, a cancer that will develop in 1,840 Canadians this year, but she said it is also useful in earlier stages of the disease and as a form of maintenance therapy -- usually a diminished dose to try to preserve the benefit of the initial drug response.

"If the drug is paid for by the manufacturer, that's good," Dr. Reece, who has more than 50 of her multiple myeloma patients currently on the drug, said. "But if it's not, it's not an option for some people."

Lori Borsos, a 45-year-old Hamilton woman who suffers from multiple myeloma, said she qualified to receive the drug free from Celgene just before a new means test was instituted by the company in April.

"If they were to cut me off, I certainly couldn't afford to pay for it," she said.

Celgene did not provide requested information on its free-drug program in Canada. But in the United States, it is considered generous by industry standards. It helps patients who earn less than $38,000 (U.S.) and also have assets of less than $10,000 (U.S.).

Mr. Gill, the communications director, said should a patient not be able to afford the drug, Celgene would do everything it could to ensure he or she has access to it, provided that a physician says there is a clinical benefit.

On its website, Celgene describes Thalomid as "the current driver of Celgene revenue growth." Indeed, the U.S. health care system spent $279.5-million (U.S.) on the drug in 2004, according to IMS Health national sales perspectives, which supplies pharmaceutical and health-care organizations with data on disease patterns and treatment trends. No comparable figures were available in Canada.

An Ottawa-area lawyer, Jean Martel, knows firsthand the high costs of the drug.

He spent $4,348 for a 20-day supply of thalidomide for his 15-year-old son, Jean-Frédéric, who has brain cancer.

"I think it's upsetting that a company is able to charge whatever it wants without any control as to what the price is," Mr. Martel said.

He even considered going to Brazil to get the drug, where it is far cheaper. Fundacao Ezequiel Dias, a Brazilian government lab, sells 100-milligram capsules of thalidomide to its government health system for nine cents, where it is given for free to leprosy and cancer patients. A Netherlands pharmacy sells the same dose for about $3.15.

Alberta used to fund the drug for its multiple myeloma patients, but stopped about two years ago after it felt uncomfortable paying for a medicine that was not approved by Health Canada, according to Neil

Hagen, chairman of the Alberta Cancer Board's pharmacy and therapeutics committee.

The way to attain approval for such a drug, is to obtain a "notice of compliance" from Health Canada. Celgene did not say whether it has made such an application.

Health Canada spokeswoman Jirina Vlk said she was not allowed to say whether the company applied for approval to market its drug in Canada, because the information is confidential. However, she said that sometimes, when there is a small patient population, a drug manufacturer might choose not to seek such a submission.

Jeff Connell, spokesman for the Canadian Generic Pharmaceutical Association, said if a drug company does not get a notice of compliance, no generic manufacturer can even attempt to make it at a cheaper cost to patients.

That's because a generic drug maker can only make a medication if there is a reference product already on the market and approved for sale by Health Canada.

"If they don't get an NOC [notice of compliance], there may never be a generic version of it in Canada," Mr. Connell said. "And they will never have to face competition."

Chronology

1957: Thalidomide is first marketed in West Germany and touted as a wonder drug for insomnia and morning sickness.

1961: Licensed for sale in Canada under the trade name Kevadon.

1959 to 1962: More than 10,000 babies whose mothers took the drug while pregnant are born around the world with devastating birth defects, including malformed or missing limbs. An estimated 125 Canadian babies were affected.

1962: Eleven months after it went on sale in Canada, the drug is withdrawn from the market, three months after it was pulled off shelves in Britain and West Germany.

1984: Out-of-court settlement reached between 13 Canadian thalidomide victims and Merrell Dow Pharmaceuticals Inc., created by Dow Chemical Co. and which acquired Richardson-Merrell Inc. of Cincinnati, Ohio, the company that produced and sold thalidomide in Canada.

1991: Canadian government announces a $7.5-million package for about 100 surviving thalidomide victims.

1998: U.S. Food and Drug Administration approves the drug for the first time for a leprosy-related malady under the trade name Thalomid. FDA promises to make it one of the most tightly restricted medications ever marketed and insists on a strict distribution system by Celgene Corp. that keeps the drug away from pregnant women.

1999: A New England Journal of Medicine study shows the drug can benefit patients with multiple myeloma, a cancer of the plasma cells in bone marrow.

2000 to now: The drug's price climbs as it finds a new place in treating cancer.

-- Lisa Priest
