

**Woman's last hope tied up in red tape**

*By Lisa Priest*

Catherine Pytel has a drug that would act as a smart bomb on her cancer cells, and even though it could save her life, she can't find a doctor who will administer it.

Catherine Pytel's last shot at life rests in a vial of liquid, given to her for free by a drug company to treat her non-Hodgkin's lymphoma. But she has not been able to crack it open because no hospital is willing to administer it.

Instead of receiving the 10-minute infusion of Zevalin that could beat back a stubborn cancer, the 54-year-old spends much of her day in bed, wearing a morphine patch to fight off the pain, trying to hang on to a life that is all but slipping away.

"She is dying without this drug," Stephen Reingold, physician leader of medical oncology at William Osler Health Centre in Brampton, Ont., said in an interview. "If she doesn't get this drug shortly, she is going to die from this disease."

Unlike most cancer patients who are faced with new and expensive therapies they cannot afford, Ms. Pytel's problem is the opposite: She obtained the \$25,000 drug as a compassionate sample via her doctor from Berlex Canada, which licenses and distributes Zevalin. With no hospital willing to administer it, it is useless to her.

"It's getting to the point where I can't take this any more," she said in a telephone interview from her home in Georgetown, west of Toronto. "The whole situation, I just can't understand. It's beyond my comprehension. You've got the drug and nobody's going to give it to you . . . I'm only 54 years old. If there's a drug that's going to help, then let's get on it."

Although Zevalin was approved by Health Canada in May of 2005, only British Columbia and Quebec currently fund it for cancer patients such as Ms. Pytel; namely those with large-cell non-Hodgkin's lymphoma who have exhausted all other therapies. The drug has been recommended for funding in Alberta.

Ontario decided to not fund Zevalin, acting on a recommendation from the Drug Quality and Therapeutics Committee, an expert advisory committee, Tanya Wymer, spokeswoman for Cancer Care Ontario, confirmed.

Consequently, many hospitals in Ontario are not set up to administer the drug. Princess Margaret Hospital and Sunnybrook and Women's College Health Sciences Centre, both in Toronto, have run clinical trials on radio-immunotherapy, but Dr. Reingold said Ms. Pytel didn't fit the criteria for either trial. Hospitals in Montreal and Ottawa were contacted and he is awaiting a reply.

Zevalin works like a smart bomb, delivering radiation directly to tumour cells, uniting the monoclonal antibody search agent "ibritumomab tiuxetan" with the cancer-killing radioisotope "yttrium-90."

Under this cruise-missile-type therapy, the monoclonal antibody searches for a specific type of protein called CD20, found on the surfaces of cancer cells. There, it fastens itself to the cancer and the isotope showers radiation on the lymphoma cell.

"Theoretically, it could get her well enough so she could go on to have stem-cell transplant," Dr. Reingold said. "If you have a successful stem-cell transplant, you get cured. This [drug] has wide impact on patients."

Numerous small studies have shown that patients who have low-grade non-Hodgkin's lymphoma B cells and who have stopped responding to previous therapies, responded to a single dose of Zevalin -- all that is required.

A study of 143 patients assigned to two groups -- patients who received either Zevalin or Rituxan, a similar drug that fastens to the cancer cells and tags them for removal by the immune system -- found 80 per cent of those who received Zevalin had a positive response, compared with 56 per cent of patients receiving Rituxan.

A positive response meant the drug killed off cancer cells to varying degrees. In addition, about twice as many Zevalin patients (30 per cent) went into complete remission as did Rituxan patients, according to the study published in the Journal of Clinical Oncology in 2002.

As with all drugs, there are side effects with Zevalin, which include nausea and, in a very small minority of patients, severe skin reactions; one patient died as a result of that reaction, according to the Health Canada website.

Kong Khoo, a Kelowna-based medical oncologist, who is on the board of directors of the Cancer Advocacy Coalition of Canada, said he has seen enough patients who have had meaningful remissions with Zevalin that he thinks it should be the standard of care.

"This drug has been approved in Canada and is based on sound evidence, but it's expensive," he said in a telephone interview. "It's really not fair to cancer patients when you have this huge disparity."

Dr. Khoo said there needs to be a federal and provincial plan to deal with new and expensive cancer drugs for those patients with advanced forms of the disease after standard treatments have been exhausted.

Last year, an estimated 6,400 patients were diagnosed with non-Hodgkin's lymphoma in Canada, a disease where the white blood cells behave like cancerous cells, growing uncontrollably. The tumours can show up in the lymph nodes, bone marrow, intestines or spinal cord.

Treatment ranges from watchful waiting, to radiation and chemotherapy, depending on the type and stage of the disease. Zevalin is one of several drugs that offer new hope, but for many patients, when it is not funded by provincial governments, the cost can be prohibitive.

"Drug costs are the greatest threat to my field," Dr. Reingold said. "In years past, when I had a great drug, I would just pay for it through my own budget."

But Dr. Reingold can no longer do that, particularly with these new targeted cancer drugs, which cost tens of thousands of dollars. According to BC Cancer Agency spokeswoman Nicole Adams, a province where the drug is funded for patients like Ms. Pytel, one dose of Zevalin costs \$25,000.

A spokesperson for Berlex Canada could not be reached for comment.

Graham Vincent, chief operating officer at the Toronto-based Provis Infusion Clinic Inc., said that the clinic may be able to provide Zevalin to patients as early as four to six weeks from now, after having received its nuclear medicine licence on Friday.

"We have a team in place. And now it's just a matter of training staff, making sure all the protocols are in place," Mr. Vincent said.

However, because Zevalin must be given with another drug, Rituxan, he estimated the cost could run to \$30,000 to \$40,000, which would include two doses of Rituxan and one dose of Zevalin -- all that is required.

"If it's a non-funded medication, a hospital won't go to the trouble of getting their licence changed and going through the training," Mr. Vincent said. "Patients are kind of stuck, they can't get a hospital to try and infuse it."

That's certainly how Ms. Pytel, a mother of three, feels.

"They're saying this drug, it's taken people from palliative care and made them feel better," she said. "This situation doesn't make any sense to me. They have these laws where you can't commit suicide and then they turn around and do this to me. They might as well be handing me a gun."