



LIFELINES

of the National Association of Cancer Patients

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"Magic bullet" therapies nearing approval, availability may be problem

by Marlene Oliver, Northwest NACP Chapter

There is good news in the fight against cancer: It appears likely that the FDA will soon approve a kinder, gentler breed of cancer treatment that is very effective and generally does not inflict the debilitating side-effects of older, traditional treatments such as chemotherapy. The success of this family of new radiopharmaceutical drugs is based on scientists' improved ability to target cancer cells, allowing the radioisotope being used to kill the cancer without harming healthy tissue nearby.

Designer molecules

How does it work? Each type of cell in our body is chemically shaped differently from every other type of cell. The same is true of cancer cells. Scientists can design a small biological molecule in a brief period of time that will "latch on" to a receptor site unique to that cancer cell's surface—and not to any other type of cell,

just like a singular key fits a singular lock. Further chemical wizardry creates a "linker" molecule that piggybacks a medical radioisotope to the biological carrier molecule.

As the radioisotope emits its energy and decays, disappearing completely in a very short time, cancer cells continue to be destroyed. Side effects are greatly reduced, often transitory, and may be nonexistent for many patients. Some patients lucky enough to have received this treatment in clinical trials, even after other treatments such as chemotherapy and external beam radiation have failed to stop their cancer, call them "magic bullets."

Several new drugs are in the pipeline nearing FDA approval. They include Bexxar, which could be approved before the end of this year. Bexxar uses the isotope iodine-131 with

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Curing the disease—but not the misconceptions

Abstracted from an article by William H. Rastetter, chairman, CEO and president of IDEC Pharmaceuticals

Although cancer is the second leading cause of death in the United States with over a half million estimated to die this year, only about 2 to 3 percent of adult cancer patients ever participate in one of approximately 600 cancer trials underway in the United States.

When you consider that clinical trials may result in new treatments and therapies for fatal or debilitating diseases, the overall lack of clinical trial participation is deeply regrettable.

So why the dearth of adult cancer candidates in clinical trials? In May, a survey released at the American Society of Clinical Oncologists annual meeting reveals an appalling lack of knowledge among patients about clinical trials.

Eight-four percent of cancer patients polled are unaware of opportunities to participate in clinical trials. And, while the remaining 16 percent

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"Magic bullet" therapies *(continued from p. 1)*

an antibody (tositumomab) that is specific to non-Hodgkins lymphoma cells. Although designed specifically to fight lymphoma, its developer believes it will also be successful in treating a wide variety of advanced breast, blood, lung, colon and ovarian cancers.

A huge bonus is that Bexxar can be administered on an outpatient basis via an injection or intravenous infusion.

One patient involved in clinical trials of Bexxar testified that after suffering through three rounds of debilitating chemotherapy that did not work, a single, thirty-second injection of Bexxar put her Non-Hodgkins' lymphoma into remission.

Clinical trials involved patients with advanced stage III and stage IV lymphoma. Over 70% saw their cancer go into complete remission. Ninety-seven percent saw a favorable response, with a reduction of at least 75% of the tumor's bulk. At the end of three years, 91% were still alive, and 71% of these patients remained free of progressive disease.

And there's more to come

Similar successes are occurring in trials of other radiopharmaceutical drugs. For instance, when a drug containing radioactive vitamin B-12 is administered to a breast cancer patient, it allows the physician to determine

where the cancer is, and just as importantly, where it *isn't*, because the radioisotope concentrates only in breast cancer tissue. The benefit to the patient is tremendous: It clearly identifies what tissue needs to be removed and spares healthy breast tissue.

This in turn minimizes the occurrence of a common complication from breast surgery, lymphedema, since it is possible to remove only lymph nodes associated with the cancer, leaving behind those where no breast cancer cells are found. The healthy nodes remaining minimize or eliminate arm fluid buildup.

Another example is the treatment of ovarian cancer patients with a drug based on the radioisotope yttrium-90. In the past, only 14% of U.S. ovarian cancer patients have lived five years after diagnosis. A recent study showed that six years after "magic bullet" treatment with Y-90, eighty percent of these women were still alive. Half of the remaining twenty percent who died succumbed to other factors such as heart disease and complications from diabetes.

Nearly half of all men and about one-third of all women in the U.S. will be diagnosed with cancer at some time in their lives. These promising new therapies can make a huge difference, if they are available. But that's the problem:

- Federal funding for medi-

cal isotope therapy research is currently only about \$10 per cancer patient, a totally inadequate sum. That must be increased ten-fold.

- Physicians frequently can't obtain the medical isotopes they need because the U.S. lacks the infrastructure to produce them.
- And approval of new cancer drugs still takes far too long. The FDA should place medical isotope therapies on a fast track for approval. These medicines could then be approved in as little as eighteen months, instead of the current five years.

What needs to be done?

Addressing these three problems—funding, isotope production capacity, and FDA approval time—will make these "magic bullet" therapies broadly available to cancer patients who desperately need them.

It's up to Congress to find solutions, so NACP urges you to contact your local representative, write letters and make phone calls to your state's Senators, and tell them cancer patients are looking for their leadership to remove these roadblocks to better cancer treatments.

**" . . . a kinder,
gentler breed of
cancer treatment"**

Surprise research results offer hope to leukemia patients

Researchers at Memorial Sloan-Kettering Cancer Center in New York have come up with a promising new therapy for cancer patients. It is a new technology that can kill leukemia cells without harming healthy tissue, and uses a radioisotope that up until now was considered waste.

Initial human trials of what is being called “alpha particle immunotherapy” were completed last year at Sloan-Kettering, with surprising results.

Scientists believed that the isotope bismuth-213, an alpha particle emitter, could kill cancer cells, but thought the treatment might also damage

so much healthy tissue that it would not be useful in treating cancer.

To find out for sure, they attached the isotope to an antibody designed to carry it directly to the cancer. According to an Associated Press report published in the *New York Times*, the results were surprising.

Not only was the therapy safe, but leukemia cells were eliminated in the blood stream and reduced in the bone marrow of 13 of the 18 acute myeloid leukemia patients taking part in the test, according to Dr. Joseph Jurcic, one of the researchers.

“We really think it has broad implications for the whole field of oncology, not just for leukemia,” he said.

Bismuth therapy would not replace chemotherapy or surgery, but would be used to kill residual cancer cells that remain after those primary treatments.

“The majority of these patients go into remission with chemotherapy, but they relapse because of these residual cells,” Dr. Jurcic said. “That’s where we think the bismuth is going to be particularly useful.”

Second phase testing to measure the therapy’s effectiveness will begin at Sloan-Kettering this fall and will involve 35 - 40 patients.

The problem was obtaining enough of bismuth-213 to

conduct the trial—in fact, the researchers struggled to get enough for the first phase now completed. A somewhat exotic isotope with a 46-minute half-life, bismuth-213 is a product of the decay chain from uranium-233—and that led researchers to the national weapons program at Oak Ridge, Tennessee, which has a large stockpile of uranium-233 waiting to be disposed of.

Obtaining the bismuth required special permission from Energy Secretary Bill Richardson, who has agreed to double the supply by 2002 for the Sloan-Kettering research.

Internet addresses worth visiting:

Drkoop.com oncolink.com
onhealth.com WebMD.com
Achoo.com noah.cuny.edu
Intelihealth.com
HealthAtoZ.com
Healthcentral.com
mayohealth.org
Healthfinder.com
www.4women.org

A needed boost for medical isotope production

The Department of Energy is currently considering reopening the Fast Flux Test Facility located on the Hanford, WA federal reservation. The FFTF is uniquely capable of producing many of the medical isotopes needed for research and treatment of cancer patients. Please write to your congressional representatives and Secretary Bill Richardson, urging favorable consideration of restarting FFTF.

Lifelines is published by the National Association of Cancer Patients. Comments on its content and suggestions for future articles are welcome.

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Clinical trials *(continued from p. 1)*

surveyed are aware of clinical trials, only about one in four would take part. Why?

Reasons vary: some believe they might receive a placebo instead of the experimental drug; others think the current standard drugs or treatments are better than experimental ones; still others believe that clinical trials are inherently dangerous; and finally, some worry their insurance will leave them footing the bill.

Of course, none of these may be true. First, cancer patients in Phase I and Phase II clinical trials never receive placebo. Withholding therapy from patients who have few remaining alternatives for treatment is unethical and strictly forbidden.

Second, cancer patients in a Phase III clinical trial usually are randomized into one of two treatment "arms:" one

arm will receive the experimental drug and the other will receive the best standard drug or treatment. No one in a Phase III trial goes untreated and, again, no one receives placebo.

Third, patients typically receive first-rate medical attention in clinical trials.

Normally, there are two major safeguards to protect the health and safety of patients in clinical trials: (1) Food and Drug Administration oversight and (2) Institutional Review Board evaluation of clinical trials and informed consent of patients. These two firewalls have worked in the vast majority of cases.

Finally, insurance reimbursement for Medicare patients is no longer a problem. In June, President Clinton announced a new federal initiative to cover the clinical trial costs for new

drugs and medical treatments under medicare.

Of course, these remedies address concerns of cancer patients aware of clinical trials but reluctant to participate in them. What about the 84 percent who are completely in the dark?

I propose that representatives of the National Cancer Institute, the Biotechnology Industry Organization, the Pharmaceutical Research and Manufacturers of America and the American Cancer Society come together to launch a national educational campaign in 2001 highlighting the benefits as well as the risks of participating in cancer clinical trials.

Remember, a clinical trial may help us develop a cure for a disease but it can't cure misconceptions fed by misinformation.
