OPTIONS
Revolutionary Ideas in the War on Cancer

PEOPLE AGAINST CANCER THE NEWSLETTER OF PEOPLE AGAINST CANCER Volume 1, Number 1, September **1994**

From Russia With Love

Editorial

For a brief moment in July, I escaped the tyranny of the medical monopoly in the land where I was born. I traveled to Moscow.

Medical historian, Dr. Harris Coulter, my wife, Denise, and I traveled to Russia to oversee a small clinical trial of American and Canadian cancer patients who were treated by Russian Immunologist Dr. Valentin I. Govallo.

20 years ago, Govallo discovered substances contained in the human placenta that fight cancer. Our journey actually began months earlier, when former Iowa Congressman Berkley Bedell (D-IA) told me about Dr. Govallo's book *The Immunology of Pregnancy and Cancer*.

Sitting in the Immunology Laboratory in Moscow how different everything seemed. Despite old world surroundings, Govallo's ideas were revolutionary and new. Rather than treating all patients the same, Govallo labored long hours over the assessment and treatment of each individual, agonizing over the most effective approach that was safe for the patient, saying, "I am a physician, above all, I must do no harm."

At the end of our visit I asked Govallo if he was going to weekend in his dacha in the country like his orthodox colleagues, Govallo replied, "I have no dacha, I have no car, all I have is my patients and my work." Humility, innovation and compassion. Revolutionary ideas in the war on cancer.

From Russia with love.

OPTIONS PREMIERE ISSUE

This month we publish the premiere issue of our new bi-monthly newsletter OPTIONS: *Revolutionary Ideas in the War on Cancer*. We hope you find it provocative and informative.

Dr. Harris Coulter and Frank Wiewel, founder of People Against Cancer, in Moscow to oversee Clinical Trials of Russian Immunologist Valentin I. Govallo.

ALSO IN THIS ISSUE

PEOPLE AGAINST CANCER

Govallo Trials Begin in Moscow

For three weeks in July a group of 13 people with cancer from the U.S. and Canada went to Moscow to be treated by Dr. Valentin Govallo at his Immunology Laboratory. Most were people with stages 3 & 4 cancer of the breast, bone, lung, colon and lymph system. Most had exhausted their orthodox remedies and felt Govallo may be their only hope.

With guidance from researchers at the Office of Alternative Medicine (OAM), Frank Wiewel, founder of People Against Cancer and Dr. Harris Coulter of the Center for Empirical Medicine in Washington, DC, provided oversight for the trial. Coulter, translator for Gorbachev and Yeltsin, provided Russian translation.

The historic three week trial went remarkably well considering this was the first ever attempt by people with cancer from the West to be treated with an alternative cancer therapy in Russia.

Govallo's non-toxic biological treatment is called Immune Embryonic Therapy (IET). He uses specific isolated extracts of placental tissue, from healthy live births, to undermine the immune system of the tumor thus rendering it vulnerable to the immune system of the person with cancer. In the initial visit, Govallo would assess the individual's immune system by a unique blood test which measures the activity of large and small cell lymphocytes. The patients were assessed then

Govallo Trials continued on page 2

Govallo Trials (continued)

given one or more injections of the biological therapy.

Reactions were vigorous and included mild fever, mild headaches and sleepiness. Most reactions were mild, subsided quickly and none required medical treatment. Patients were urged to remain quiet for 48 hours after treatment. Interestingly, patients often reported tactile sensations and some reported pain at the tumor site. Generally four visits for alternating treatment and assessment were required. Some participants showed immediate objective tumor response and most showed subjective improvement, including alleviation of pain and improved immune status. Participants will be closely followed and scientific evaluations of their responses performed.

Moscow is magnificent yet maddening. Still struggling to immerge from the decades of Communist rule, the simplest task can be daunting. Though Moscow has one of the world's best subway systems, organized travel and translation support was necessary. Support was provided by Harris Coulter, Frank and Denise Wiewel, and Russian translators. Travel was through a system of bus and van routes. Most people stayed at centrally located hotels, but a few enjoyed Russian hospitality while staying with Russian families. In afternoons and evenings transportation was available for sightseeing, culture and dining. Some spent a Sunday at the famous walled monastery at Zagorsk. Others found the sightseeing boat rides on the Moskva River, which runs through the center of Moscow, interesting. The Kremlin, St. Basil's Cathedral, Red Square and the Moscow Symphony were highlights.

Dr. Govallo is eager to teach his therapy and share his ideas with all interested. Govallo is currently accepting patients in Moscow. Those interested in research or treatment should call or write People Against Cancer.

Senator Daschle Introduces The Access to Medical Treatments Act—Senate Bill-2140

On May 13, Senator Thomas Daschle (D-SD), introduced the Access To Medical Treatments Act (S-2140). This revolutionary act would allow physicians and patients free access to therapies not yet approved by FDA, in the hope of saving lives and alleviating suffering. Leaders of the alternative health world have called it "the most important bill of our lifetime."

At a time when Congress seems hopelessly mired by partisan infighting with Health Care Reform, this bill represents a revolutionary new direction in health care reform. Despite the current climate in Washington, the bill has garnered wide bi-partisan support. "Both Democrats and Republicans are supporting this bill," says former Iowa Congressman Berkley Bedell who was instrumental in the drafting of the legislation. In Congressional testimony, Bedell cited serious problems with health care in our country saying, "It is illegal for anyone to use a medicine without spending millions of dollars for FDA approval."

Bedell was himself a victim of the current system when he was forced to go outside of the medical profession, outside of the law and outside of the country for treatment of his lymes disease and prostate cancer, which failed to respond to conventional therapy. He went on to say "It breaks my heart to tell people these therapies are not available in America because of government regulation."

FDA regulations, now under fire from orthodox and alternative physicians alike, now require 10–15 years of research and $100 to $500 million for the approval of a therapy. Experts argue that this virtually guarantees high cost medicine, which is often too little and too late.

Cancer and AIDS activists have long argued that the system fails to provide the basic freedoms now enjoyed by citizens of other countries such as Europe and China and now even Russia. "I saw more medical freedom in Moscow than we have in America. I was ashamed," said cancer activist Frank Wiewel, "All throughout Europe, I saw innovative medicine saving lives—and it was paid for by the governments which provide universal health care for all citizens."

Nearly a decade ago, in 1986, People Against Cancer, together with many of the leaders of the alternative health world, convinced Congress to look into the issue. As a result, over 40 members of Congress demanded a study of alternative cancer therapies by the Office of Technology Assessment (OTA). The study, called by *Science Magazine,* "the most controversial study in the history of OTA," found positive evidence in nearly 200 published reports and recommended serious scientific study by the National Cancer Institute (NCI). One member of the National Cancer Advisory Board told OTA head Dr. Roger Herdman, "you're telling us we have an illness, but we don't feel sick." NCI countered by giving a $500,000 grant for a database on alternatives to Emprise, Inc., an organization of self proclaimed "quack-busters." After a massive outcry from the alternative health world, the Emprise database became mired in controversy. NCI relented and denied funding to implement the database.

Convinced that the National Institutes of Health had obviously failed to properly evaluate alternative medicine, Senator Tom Harkin (D-IA) established the Office of Alternative Medicine (OAM) to evaluate and validate alternative medicine.

Still not satisfied, Harkin Co-sponsored S-2140 saying, "Medical science has always been skeptical of the unknown, but Americans want more choices." S-2140 Co-sponsors include Senators Orin Hatch, Dennis DeConcini, Charles Grassley, Paul Simon, Claiborne Pell and Mark Hatfield. *(See Action Alert Page 5.)*

Stanislaw Burzynski, MD, PhD, Put on Probation By Texas State Board of Medical Examiners—Told to "Obey the Law."

It was high noon in Austin, Saturday, August 20th, and the Texas State Board of Medical Examiners was once again gunning for legendary cancer researcher Dr. Stanislaw Burzynski.

Burzynski, long the target of the cancer establishment, was facing license suspension action which began back in 1988. The Texas State Board of Medical Examiners (TSBME) suspended his license for 10 years, then stayed the entire suspension and put him on probation, telling him he must "obey the law."

But what was the law?

Texas law, section 5.09, says a physician is free to use any medicine to administer to the needs of his patients. But the TSBME said no! They contended that section 5.09 doesn't really mean that–saying everyone has to follow the law–you can't give illegal drugs. The Texas Board had found another law which they interpreted to say that "any medicine" meant only those medicines approved by the Food and Drug Administration. They ruled that Burzynski was violating the law and had been doing so since 1977.

When the Board announced their ruling, there was an audible gasp from the pro-Burzynski audience that included Harris County Attorney Mike Driscoll. Many in the audience were patients who said they use Burzynski's medicine to survive.

Burzynski attorney Richard Jaffe argued that Burzynski had in fact cooperated with FDA and received permission to use his medicine under six separate FDA investigational new drug permits (INDs). But the TSBME wasn't impressed.

Last year, the Board, then made up of different individuals, appealed to a Texas state administrative law judge to clarify the law. The administrative law judge ruled that at all times the Burzynski's treatment was legal because Texas law section 5.09 says a doctor may prescribe any drug to administer the needs of his patients and the Texas Department of Health had given him permission beforehand.

Ignoring the ruling of the administrative law judge, the Board conditioned his probation saying he must follow all state and federal laws applicable to new drugs.

Under the Board interpretation, for Burzynski to follow all state laws, he would not be allowed to use his therapy unless the patients are treated free of charge in clinical trials. So, under this theory Burzynski would be out of business. Many of the patients and supporters in attendance at the hearing felt this was precisely what the Board intended.

Reportedly, though always working within the law as he understood it, Burzynski will now comply with the Board interpretation of the law by setting up formal clinical trials for all patients.

Burzynski's pioneering work was independently confirmed by researchers at the NCI... [but] his name and all his scientific references were curiously wiped from the record.

Burzynski is the discoverer of antineoplastons, non-toxic peptides used in the treatment of cancer and AIDS. He says he escaped the communist tyranny of Poland and came to America in 1970 with $20 and a dream: to develop a therapy to cure cancer. For over 24 years, Burzynski has struggled to make that dream a reality, first at Baylor College of Medicine in Houston and since 1977 as an independent clinician. Since then, he has successfully treated hundreds of people with cancer and AIDS and published scores of scientific articles.

Recently, Burzynski presented his work at the prestigious International Congress of Chemotherapy in Berlin. Together with Burzynski were Japanese physicians and researchers who are now in their fourth year of conducting independent clinical trials on his treatment at a medical university in Japan.

Confounding his critics who depict him as a "quack," Burzynski has continued to publish scientific papers and present his work to scientific conferences on every possible occasion.

Historically, Burzynski has always attempted to cooperate with any researcher or institution interested in his work. Before the National Advisory Council was formed at the Office of Alternative Medicine (OAM), NIH officials deliberately gave $750,000 of the taxpayers money to Memorial Sloan-Kettering and Mayo Clinic to "scientifically" evaluate his therapy. Though cancer activists warned that these institutions were historically the enemies of alternative medicine, Burzynski nonetheless willingly cooperated by agreeing to provide $500,000 worth of the antineoplastons free of charge to the researchers.

Most recently, Burzynski's pioneering work was independently confirmed by researchers at the National Cancer Institute (NCI), including Dr. Samuel Broder, director of the Institute. Broder suggested that phenylacetate, a natural component of Burzynski's therapy, could suppress the ras-oncogene which promotes cancer. Though all of original research data came to the NCI through researchers working with Dr. Burzynski, his name and all his scientific references were curiously wiped from the record.

As the smoke cleared after this latest shootout, supporters say Burzynski was only wounded. He will live to fight another day–for his science–for his freedom and most importantly–for his patients.

Senator Daschle Holds Hearing on The Access To Medical Treatments Act

On July 22, 1994, Senator Tom Harkin (D-IA) Chaired hearings on The Access to Medical Treatments Act before the powerful Committee on Labor and Human Resources in the United States Senate with freedom of choice immerging as the clear winner.

Harkin, long a voice for medical freedom, was joined by an equally passionate Senator Thomas Daschle (D-SD) who introduced the bill in the senate earlier this year.

Harkin opened the hearing by saying, "S-2140 was developed because even though our current health care system addresses certain health problems very well, there are certain diseases for which we can offer no remedy. In fact, much of conventional medicine has not been proven. People suffering from these diseases deserve the right to receive alternative treatments." He went on to say, "Keep in mind that not too long ago antiseptic techniques were dismissed as quackery because many did not believe that germs caused disease. Clearly consumers are speaking with their feet and pocketbooks, they want more choices, they want more control over their health. In 1990, 425 million Americans visited alternative health care providers."

Michaela Murphy Odone told the story of her son Lorenzo who was stricken with Adrenoleukodystrophy (ALD) and their discovery of "Lorenzo's Oil," the only therapy which helped him. The story, depicted in the award winning film "Lorenzo's Oil" told of their desperate struggle with the medical establishment in the search for a therapy to help their dying son. She testified that "professional scientists and physicians hold no monopoly on the scientific method. It is there for all of us to employ....as science sheds light, so too must its practitioners be open to receiving light."

Equally heart-rending testimony was given by Vernon Morin, a New Jersey man who's daughter had a neuroblastoma, a tumor of the brain. He told of his daughter Issy's harrowing experience with the side effects of chemotherapy which their oncologist had advised was "proven to be the best form of cancer treatment." He detailed the "constant nausea, vomiting and and bouts of diarrhea." He lamented that "she required three or four blood transfusions per week and suffered terribly. Then we were told that Issy had not responded at all to the treatment (which was what the oncologists expected). They said her death would be quick and painful." In excruciating pain Issy was taken to Dr. Emmanuel Revici a 98 year old NY physician. In two days, her father testified, she was out of pain completely. Mr. Morin told the packed hearing room, "Issy had a wonderful Christmas and eight months later in February her tumor had shrunk by 50%. Her oncologists called it a spontaneous remission."

Robert Carolla, of Consumers Union, testified against the bill citing "too little science and too many conflicting claims," expressing concern over practitioners who rely on anecdotal evidence. He went on to say, "Consumers need protection, however, not just from charlatans, but also from undue risks."

Also testifying against the bill was the FDA Deputy Commissioner Mary K Prendergast. She stated that the bill "could needlessly expose patients to dangerous products...we believe there will be nothing to prevent patients from being subjected to old fashioned quackery." In an interesting admission, she stated, "We are concerned that the broad access to unproven therapies permitted by this bill will significantly slow down conventional drug and device development as well."

Alexander Schauss, PhD, executive director of Citizens for Health, testified in favor of the bill indicating over 5000 deaths occur each year from FDA approved drugs, but after reviewing data from the American Association of Poison Control Centers every year since 1982, "I could not find one cause of death due to a commercial herbal product or an uncontaminated nutrient." He quoted Thomas Edison saying, "The doctor of the future will give no medicine, but will interest his patients in the care of the human frame, in diet, and in the cause and prevention of disease." He went on to say, "Medical students receive virtually no training in nutrition and absolutely no exposure to non-drug therapies."

The days star speaker was Dr. Jurgen Schurholtz, the Chairman of Commission C, which since 1972, certifies alternative medicine in Germany. He testified that in 1978, similar criticism was raised about "insupportable claims" and "that the public would suffer harm or fail to use "effective" conventional therapies. After more than 15 years of experience, these criticisms have proven to be wrong." Through the special Commissions, alternative medicine is evaluated for safety and efficacy. As a result, Germany has put alternatives on an equal footing with conventional drug based therapy. He stated, "some physicians and medical associations still resist these efforts, but as these alternatives are being repeatedly demonstrated to be safe, effective and cost-effective year after year, one has to question the motivation of these critics.

He summarized by saying, "as a result of legislation passed in 1978, pluralistic medicine has become legally available to everyone living in Germany. Those who predicted that the public would be harmed or that they would fail to seek effective conventional therapy have been proven wrong. I want to commend you Congress for taking steps to insure that Americans may have the same rights to alternative health care as Germans…we should remember that we are all part of the same healing community. *(See Action Alert page 5-6.)*

ACTION ALERT

September, 1994

Dear Friend,

On Thursday, May 19, 1994, history was made in Washington when Senator Thomas Daschle (D-SD) introduced the Access To Medical Treatment Act (Senate Bill-2140).

This Act will assure freedom of choice for people who need innovative and alternative medical care and physicians who wish to provide it.

This is landmark legislation that will change the face of American Medicine. Congressional action could end the medical monopoly.

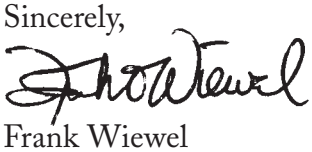
Here are some key points of the The Act (S-2140):

* It now takes years for new drug approval in America. Thousands will die waiting.
* It now costs over $250 million for new drug approval. Therefore safe, effective and economical alternatives are not available.
* It would allow American citizens access to safe alternative treatments and allow physicians the freedom to provide them.
* Safety and consumer protection are essential elements of the Bill. No advertising or marketing would be allowed before approval.
* Clinical scientific investigations would be conducted.
* It would stop the need for American citizens to outside the country for treatments shown to be safe and effective for decades.
* Americans would have the basic medical freedom enjoyed by the citizens of rest of the world.

Please write, fax and call your Senator and Representative in Congress. Ask them to Co-sponsor S-2140. On the next page, we have drafted a sample letter for guidance. Sign and send the sample letter–or better yet, write your own.

This could be the most important letter of your life.

Sincerely,



Frank Wiewel
Editor

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List of co-sponsors of S-2140:

Dennis De Concini (D-AZ)
Charles Grassley (R-IA)
Tom Harkin (D-IA)
Orin Hatch (R-UT)
Mark Hatfield (R-OR)
Claiborne Pell (D-RI)
Paul Simon (D-IL)

ACTION ALERT

September, 1994

Dear Member of Congress,

People with life threatening illness need access to medical treatments. Physicians need the freedom to treat them.

On May 19, 1994, Senator Tom Daschle introduced the Access to Medical Treatment Act (S-2140).

This act will assure freedom of choice for people who seek innovative and alternative medical care and physicians who wish to provide it. Special consumer protection and safety issues have been addressed.

It now takes decades for new drug approval in America. Thousands will die waiting. It now costs hundreds of millions of dollars for new drug approval. So safe, effective and economical alternatives are not available.

We don't have decades. We don't need millions. The Medical Treatments Act will not cost us a penny and could save thousands of lives each year. True health care reform must include alternatives.

Please help us! Please Co-sponsor The Medical Treatments Act S-2140.

Please don't send us a form letter saying, "I appreciate your interest in health care reform...I will keep your views in mind."

We really need your commitment now. Please call Pattie Mitchell C/o Senator Daschle: Phone 202-224-2321 or Fax 202-224-2047 for the Bill. And please call Teniya Jackson C/o Senator Tom Harkin: Phone 202-224-6265 or Fax 202-224-9369 for a transcript of the Hearing on S-2140.

We hope you will advise us of your co-sponsorship. If you can't co-sponsor now, please tell us why. We look forward to hearing from you.

Sincerely,

Jacobs Quits at Office of AlternativeMedicine

Joe Jacobs, MD, director of the Office of Alternative Medicine (OAM) resigned effective September 30, 1994.

The office was established by an act of congress when it became clear to certain powerful members of congress that Americans made more visits to doctors practicing alternative medicine than those using conventional medicine and that the National Institutes of Health (NIH) had failed to scientifically evaluate and validate alternative medicine practices. The Office was purposely placed within the Office of the director of NIH to shield it from historic animosity of the various institutes that had demonstrated little scientific interest in alternatives.

Jacobs, named in 1992 as the first director of the controversial new Office at the National Institutes of Health (NIH), was under fire from start. He was charged by the "quackbusters" as consorting with the quacks and promoting fraudulent medical practices. Further, cancer activists said he was moving too slowly and often bowed to pressure from within NIH. Despite pressure from both sides, Jacob viewed himself as a pioneer. He used a quote from Star Trek, saying, "My job is to go where no man has gone before." But after two years under pressure from Congress, cancer activists and orthodox critics, Jacobs changed his tune, telling the New York Times "I prefer the ticks of Connecticut to the politics of Washington."

Cancer activist Ralph Moss, PhD, editor of the Cancer Chronicles and advisor to OAM said, "Jacobs seemed very uncomfortable with the job and I wasn't happy with the direction of the office." However another OAM advisor Dr. Brian Berman from the University of Maryland said, Jacobs had "succeeded in winning over to the cause of alternative medicine the once skeptical American Medical Association and the American Cancer Society," who continue to maintain a committee on cancer quackery called the Committee on "Questionable" Cancer Therapies.

Critics charged that Jacobs, despite being sympathetic to alternative medicine, failed to understand the historic animosity of the medical establishment. OAM advisor Gar Hildenbrand said, "It is clear there is a medical monopoly in America, having been trained in orthodox medicine, I don't think Joe understood that."

Linus Pauling Remembered

Options *editor, Frank Wiewel, and Dr. Linus Pauling.*

On Saturday, August 20, there was a violent disturbance in the "force." Linus Pauling was dead at 93.

The legendary researcher, and two time Nobel laureate, had discovered the chemical bond and led the struggle for peace in a troubled world.

Pauling, the chairman of the scientific advisory board of People Against Cancer, was the most respected voice in the history of alternative medicine. As a champion of Vitamin C, he spent the last 20 years in a controversial fight for the scientific evaluation of vitamins in prevention and treatment of disease. Pauling, who ran afoul of the medical establishment, recently told Options, "I always had the support of the scientists, I only had trouble when I got involved with organized medicine."

Though the man is gone, his wisdom, and his vision of peace and healing, will live on forever.

MEMBERSHIP FORM

Yes! I would like to support the important work of *People Against Cancer.*

- ❑ $35 .....**Regular Annual Membership** — Includes our newsletter, *Options.*
- ❑ $50 .....**Foreign Regular Annual Membership** — Includes our newsletter, *Options.*
- ❑ $100 .....**Supporting Annual Membership** — Includes our newsletter, *Options,* plus a free book.
- ❑ $450 .....**Sustaining Annual Membership** — Includes the Alternative Therapy Program with: a comprehensive search for the best treatment options worldwide, a detailed written report, an extensive personal telephone consultation, unlimited one year follow-up. Also includes our newsletter *Options* and the book *Repression and Reform.*

PEOPLE AGAINST CANCER

- ❑ $500 .....**Benefactor Annual Membership** — Includes all the benefits of Sustaining membership plus a free book.
- ❑ $1,000 .....**Founding Annual Membership** — Includes all the benefits of Benefactor membership plus special select reports and publications.
- ❑ $5,000 .....**Patron Annual Membership** — Includes all the benefits of Founding Membership and all select reports and publications.
- ❑ $10,000 .....**Golden Circle Patron Membership** — Special Membership with all select reports and Golden Circle publications.

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COMING IN THE NEXT ISSUE

- NIH Gives $1.8 Million to University Centers; OAM Advisory Board "Shocked"
- New Questions About the War in Cancer "Prevention vs. Cure"
- Will OAM Board Members Lose First Amendment Rights?
- People Against Cancer Announces "Alternative Therapy Program"

Vitamin Bill Passes Senate

August 18th the Senate passed the dietary supplement bill by unanimous consent. Senator Orin Hatch (R-OR), sponsor of the bill applauded the move saying, "Today we honor the wishes of a 100 million people, consumers of dietary supplements, people who simply want the ability to lead healthy lifestyles without the constant intervention of one tiny agency [FDA] which is possessed by a regulatory zeal equally none."

Under the new bill awaiting House approval, consumers will be legally allowed to receive balanced, truthful, and non-misleading literature on nutritional supplement as long as it does not promote any specific brand. Additionally, manufacturers will be allowed to make statements about how the nutrient affects the structure or function of the body. Because of controversy over labeling, historically a major problem between physicians, supplement companies and the FDA, the Act establishes an Office of Dietary Supplements at NIH and an Executive branch Commission on Labels. Hopefully they will have the wisdom to use a plan similar to Germany, where commissions are staffed by individuals knowledgeable of nutritional supplements.

LK200 Trials Begin in Freeport

In a new program of patient funded research, clinical trials on a non-toxic lymphokine therapy called LK200 will begin in Freeport Bahamas in September. Researchers from Tuft's University, the University of Colorado, the Northwest Oncology Group and physicians throughout North America joined representatives of People Against Cancer and the Office of Alternative Medicine in Monterey, Mexico in August to evaluate the promising early results.

Researchers will focus on prostate, breast and non-hodgkins lymphoma but positive responses have been achieved in many kinds of cancer and trials will be open to people with a wide variety of cancer.

The innovative non-toxic therapy is a mixture of natural biological substances found to be deficient in people with cancer. Like a diabetic augments their supply of insulin, LK200 augments the immune system. Early results demonstrate improvements in quality of life, enhanced functional status, reduction of pain together with partial and complete tumor responses in people with advanced cancers which were not treatable by conventional therapy. Readers interested in the trials should call People Against Cancer.

PEOPLE AGAINST CANCER

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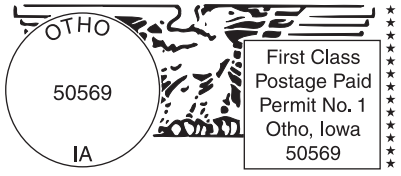

New Directions in the War on Cancer