

OPTIONS

Revolutionary Ideas in the War on Cancer



THE NEWSLETTER OF PEOPLE AGAINST CANCER

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Medical Mistakes An Insult To American Citizens

Editorial

Above all—Do No Harm

—The Hippocratic Oath

This week the Institute of Medicine issued a shocking report.

Hundreds of thousands of US Citizens are killed by medical mistakes every year.

Researchers report over 140,000 other deaths are caused by prescription medicine.

What is going on here?

This is shocking!

Modern medicine may be the 3rd leading cause of death in America.

Every man, woman and child in this country should be outraged.

At the turn of the century, the allopathic physicians, who use "drug based medicine," forced homeopaths and naturopaths who use natural and non-toxic medicines out of medical schools and the marketplace.

They have now become a deadly medical monopoly—answerable to no one.

Monopolies do what monopolies do—they seek to eliminate competition and gain market share.

Instead of cleaning up their own deadly "war on diseases," the medical establishment is staging a "war on alternatives."

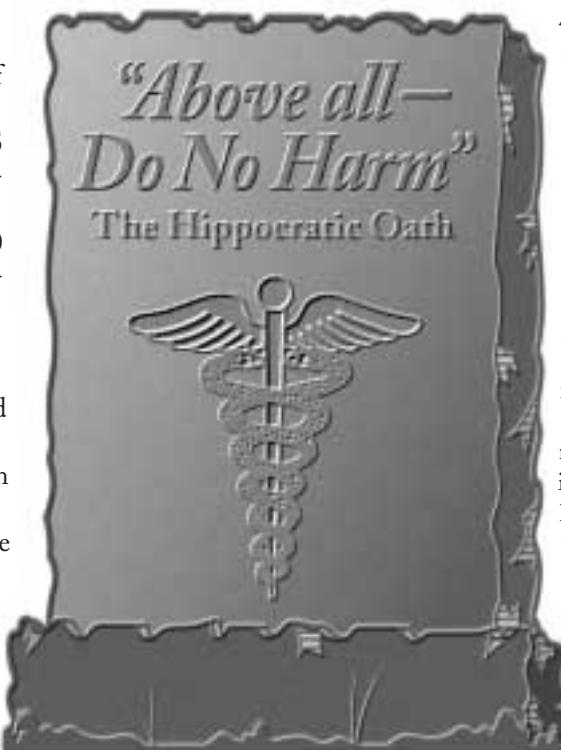
Medical licensure boards across the country are taking the licenses of alternative practitioners and plotting further investigations. Physicians and people with cancer live in fear.

This is a medical monopoly war.

And in the end—the casualties are American citizens.

OPTIONS

Options: Revolutionary Ideas in the War on Cancer is published quarterly as the Newsletter of People Against Cancer. We hope you find it both provocative and informative.



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PEOPLE
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Deadly Medical Mistakes

The most dangerous places in the world are the hospital, the doctors office and the dentist office wrote Ivan Illich in *Medical Nemesis*.

Medical mistakes kill anywhere from 44,000 to 98,000 hospitalized Americans a year, says a new report that calls the errors stunning and demands major changes in the nation's health care system to protect patients.

140,000 die from conventional medicines and 2 million suffer serious side effects.

The groundbreaking report by the *Institute of Medicine* says there are ways to prevent many of the mistakes and sets as a minimum goal a 50 percent reduction in medical errors within five years.

The problem is less a case of recklessness by individual doctors or nurses than it is the result of basic flaws in the way hospitals, clinics and pharmacies operate, the report says. The institute cited two studies that estimate hospital errors cost at least 44,000, and perhaps as many as 98,000, lives, but research on the topic is unable to pinpoint fatalities more precisely.

Doctors' notoriously poor handwriting too often leaves pharmacists squinting at tiny paper prescriptions. Did the doctor order 10 milligrams or 10 micrograms? Does the prescription call for the hormone replacement Premarin or the antibiotic Primaxin?

Too many drug names sound alike, causing confusion for doctor, nurse, pharmacist and patient alike. Consider the painkiller Celebrex and the anti-seizure drug Cerebyx, or Narcan, which treats morphine overdoses, and Norcuron, which can paralyze breathing muscles.

Medical knowledge grows so rapidly that it is difficult for health care workers to keep up with the latest treatment or newly discovered danger. Technology poses a hazard when device models change from year to year or model to model, leaving

Deadly Medical Mistakes cont'd on page 2

Deadly Medical Mistakes (cont'd from page 1)

doctors fumbling for the right switch.

And most health professionals do not have their competence regularly retested after they are licensed to practice, the report said.

Indeed, health care is a decade or more behind other high-risk industries in improving safety, the report said. It pointed to the transportation industry as a model: Just as engineers designed cars so they cannot start in reverse and airlines limit pilots' flying time so they're rested and alert, so can health care be improved.

"These stunningly high rates of medical errors...are simply unacceptable in a medical system that promises first to 'do no harm,'" wrote William Richardson, president of the W.K. Kellogg Foundation and chairman of the institute panel that compiled the report.

As the report's title—"To err is human"—implies, no one will ever eradicate medical mistakes.

But "errors can be prevented by designing systems that make it hard for people to do the wrong thing and easy for people to do the right thing," Richardson concluded. Unfortunately, he continued, medical mistakes usually are "discussed only behind closed doors."

In recent years, however, researchers have begun coming up with ways to avert medical mistakes. Some hospitals now use computerized prescriptions, avoiding the handwriting problem and using software that warns if a particular patient should not use the prescribed drug. Many hospitals now mark patients' arms or legs—while they're awake and watching—to prevent removal of the wrong limb. Anesthesiologists made their field safer by getting manufacturers to standardize anesthesia equipment from one model to the next. The Food and Drug Administration is trying to prevent new drugs from hitting the market with sound-alike names.

But the Institute of Medicine concluded that reducing medical mistakes requires a bigger commitment, and recommended some immediate steps:

Establish a federal Center for Patient Safety in the Department of Health and Human Services. Congress would have to spend some \$35 million to set it up, and it should eventually spend \$100 million a year in safety research, even building prototypes of safety systems. Still, that represents just a fraction of the esti-



"...the tremendous safety risks... will remain a fundamental problem with high tech medicine and drugs—even without mistakes."

"Alternative medicine is the answer to the health care crisis in America. It is safer, often more effective and certainly more cost effective."

—Frank D Wiewel

mated \$8.8 billion spent each year as a result of medical mistakes, the report calculated.

¶ The government should require that hospitals, and eventually other health organizations, report all serious mistakes to state agencies so experts can detect patterns of problems and take action. About 20 states now require such reports, but how much information they require and what penalties they impose for errors varies widely, the report said.

¶ State licensing boards and medical accreditors should periodically re-examine health practitioners for competence and knowledge of safety practices.

"Any error that causes harm to a patient is one error too many," said Dr. Nancy Dickey, past president of the AMA, which already has started a National Patient Safety Foundation designed to address some of these issues.

But she cautioned that some of the changes will be difficult because doctors do face large liability for any mistake. "We may know to talk about a culture of safety, but we still live in an environment of blame," she said.

The Institute of Medicine is part of the National Academy of Sciences, an organization chartered by Congress to advise the government on scientific matters.

The White House and Congress has taken notice. Early in 2000 they return to Washington they plan to implement mea-

sures to address this appalling problem.

"But the larger issue," says consumer advocate, Frank Wiewel, "is the tremendous safety risks which will remain a fundamental problem with high tech medicine and drugs—even without mistakes. Alternative medicine is the answer to the health care crisis in America. It is safer, often *more* effective and certainly more cost effective."

But many in the medical establishment would disagree saying that most alternative medicines have not been tested for safety and efficacy in the same way that pharmaceutical drugs are tested.

"While this may be true," admits Wiewel, "No one can spend \$500 million to do large scale, double blind clinical trials on a natural product which will never have any kind of patent protection. They could never recoup their investment. And the pharmaceutical industry knows this. They like this."

And for millions of Americans, prescription drugs are a way of life—approximately 2 billion are dispensed each year—for anxiety and allergies to diabetes and depression. But in a study published in the *Journal of the American Medical Association (JAMA)*, researchers found that each year prescription drugs rank between the 4th and 6th leading cause of death in the United States.

Researchers at the University of Toronto analyzed 39 studies conducted in American hospitals over four decades. The Toronto team found, for example, that 106,000 patients died in 1994 from reactions to medications administered properly. And more than 2 million other patients suffered serious side effects. The University of Toronto study didn't count patients who misread or disregarded warning labels, otherwise the number of deaths jumps to over 140,000.

"Take the case of Chinese herbs," says Wiewel, "they have been used for over 3000 years in a safe and effective manner. People aren't stupid. Physicians and researchers won't continue to prescribe a useless product and the people who are sick won't take medicines if they don't work."

As long as we clearly establish the issue of safety, consumers, physicians and the marketplace will determine what is effective and cost effective." ¶



FDA Seeks Injunction Against Shark Cartilage and MGN-3



WASHINGTON December 14, The Federal Food and Drug Administration (FDA) asked a federal judge Friday to stop sales of a popular brand of shark cartilage called Benefin, MGN-3 and SkinAnswer, saying they illegally claim to treat cancer.

Benefin

Benefin, shark cartilage, has not been proven to treat cancer, the Food and Drug Administration said in seeking a permanent injunction against New Jersey-based Lane Labs-USA's sales of the product.

The FDA complaint also names a Lane skin cream called SkinAnswer that claims to treat skin cancer. Additionally, FDA has moved against a rice-bran extract called MGN-3 that is used to treat both cancer and AIDS.

FDA officials also warned cancer patients Friday to beware of the products' claims. "People should not be misled into thinking bogus remedies are going to be effective," said Dr. Janet Woodcock, the FDA's drug chief. "We have a very vulnerable population of cancer patients and their families out there that are really looking for hope. We are not going to let companies promote products that have not been adequately tested and are not shown to be effective."

"We are not making any claims about Benefin, SkinAnswer or MGN-3," said Andrew Lane, executive officer of Lane Laboratories, a New Jersey based company. "We are doing the science. We have a signed contract to study Benefin with the National Institutes of Health (NIH). NIH has committed \$6,000,000 to study the effects of Benefin on terminal cancer patients at the Mayo Clinic. The plan was to have 300 patients, with advanced breast cancer and colon cancer, who have failed to respond to conventional therapy, treated with Benefin and another 300 who would receive a placebo. We planned to invest nearly \$1,000,000 to supply the Benefin, for this Mayo trial—now we will be forced to spend the money defending ourselves against our own government. The people with cancer will suffer," Lane said.

Doctors have estimated that 50,000 U.S. cancer patients have tried some form of shark cartilage, a product whose popularity resulted in part from William Lane's books *Sharks Don't Get Cancer* and *Sharks Still Don't Get Cancer*. CBS 60 Minutes ran a

story on Shark Cartilage in which a noted radiologist identified tumor response in individuals who had received large doses of shark cartilage.

Shark cartilage has been shown to inhibit blood vessel formation in tumors. This process is called antiangiogenesis. Researchers say shark cartilage has antiangiogenic properties similar to a new drug called Angiostatin. Angiogenesis is the formation of blood vessels which supply tumors so they can grow. The search for drugs which have an effect against blood vessel formation in tumors has been the subject of massive research in the scientific community.

Angiostatin is a drug, which has received special priority handling under FDA's fast tract approval for the treatment of cancer. Angiostatin received worldwide notoriety when a front-page story in the *New York Times* (NYT) quoted, Nobel laureate Watson, as saying, "Judah Folkman, the developer of Angiostatin, will be curing cancer in 2 years" and suggesting that it was the most important development since Darwin, the *Times* reported. Watson charged that the *NYT* misquoted him and claimed that he never made the statements. The entire fiasco regarding Angiostatin, the Watson comments and the issues of wild unsupported claims for new drugs in the media, was also the subject of a front-page *Time Magazine* article.

"This is another disgusting chapter in the great medical monopoly wars—and the American citizens will be the losers," said Frank Wiel, founder of a non-profit public interest group, People Against Cancer. "The Federal Trade Commission (FTC) and FDA are acting in an illegal restraint of trade and in direct violation of the 1st Amendment which protects free speech. Their injunction will have the effect of preventing important research into non-toxic natural therapies and protecting the medical monopoly of drugs."

"Companies cannot claim their experimental drugs treat disease until the studies actually prove it," Woodcock said.

Both FTC and FDA said they had warned Lane Labs about illegally touting its products as cancer treatments in articles and on the Internet. One Internet search for Benefin turned up a Web page listing that said, "If you are a cancer patient, this could save your life."

MGN-3

Another, perhaps more important product, named in the FDA court filing is MGN-3. MGN-3 (modified arabinoxylan), is a rice bran extract, which enzymatically integrates rice bran with polysaccharides from medicinal mushrooms, Lentanin from Shitake, Krestin from Kawaratake, and Sizofiran from Suehirotake, which raises Natural Killer Cell activity in cancer patients. Researchers at Drew University and UCLA have documented unprecedented increases in Natural Killer cell activity.

Dr M. Ghoneum has treated over 100 people with cancer and has published scientific studies in peer-reviewed medical journals, which document increases in Natural Killer cell activity of up to 500% in people receiving about 3000 mg of MGN-3 per day. Ghoneum documented a 400% increase in the binding capacity of Natural Killer cells to tumor cells. He has concluded, "MGN-3 seems to act as a potent immunomodulator causing augmentation of natural killer cell activity and with the absence of notable side-effects. MGN-3 could be used as a new biological response modifier having possible therapeutic effects against cancer."

Ghoneum has published 7 scientific publications. He reported that in the treatment of 27 cancer patients: "People with cancer had a low level of basal NK activity (10-40%) and treatment with MGN-3 caused a remarkable increase in NK activity at 2 weeks. The percentages of induction were as follows: breast cancer 154-332%, prostatic 174-384%, leukemia 100-240%, Multiple Myeloma 100-537% and cervical 100-275%. Enhancement of NK activity continues to rise at 3 and 6 months after treatment."

Further efficacy studies have been performed in Japan at the Department of Urology of Nippon Medical School, Kobe Women College, Jichi Medical School, Kyorin University, Hokkaido University and Teikyo University.

"Natural Killer cells kill cancer. This is a clear example of FDA ignoring good scientific studies published in peer-reviewed medical publications. MGN-3 is an important non-toxic therapy for cancer and FDA wants to take it away from people who have cancer," says Wiel.

Benefin and MGN-3 are still available at Innovative Therapeutics: 888-688-9922.



By Bill Asenjo, PhD(c), CRC

Bob Karjala never smoked, but at 55 he was diagnosed with stage IV lung cancer. A career as a biochemist and lab manager for over 30 years exposed Bob to low levels of iodine-125 radiation.

In telling his story, Bob stressed that he wanted to be as objective as possible in relating the facts of his case, that way those who read his story will make their own decisions. He added that he felt it was important to pass along some of the reasons to support the alternative choices he'd made.

How It Happened

In March 1998 Bob was diagnosed with a 2.5cm adenocarcinoma of the lung with metastases to the lymph nodes and spine. He also had a 3cm mass in his liver. As a result, he underwent 14 radiation treatments to his spine to alleviate pain and simultaneously began carboplatin/taxol chemotherapy.

Bob made a decision not to use any alternative therapies at first, because he wanted to give the chemo a chance to work, affording him an opportunity to evaluate its effectiveness.

A bone scan on April 22, 1998 revealed a second spine metastasis, but it remained asymptomatic and did not show up on X-rays. During May, Bob began taking 2-3 ounces of essiac tea daily.

When chest X-rays in the middle of June—after four chemo treatments—showed no change in the size of the lung tumor, and a slight reduction in size of the lymph nodules, Bob decided to add

Bob Karjala: The C

several alternative therapies to his treatment regimen (see Bob's Therapy later in this article). Six weeks later his primary tumor had shrunk by 50%.

After reading an advertisement, Bob began taking Dr. Julian Whitaker's "Forward Plus" vitamin and mineral supplements. He also increased his essiac tea consumption to twice daily (2-3 ounces morning and evening).

In addition, he began taking 400 mgs. of Coenzyme-Q10 daily along with a daily capsule of Cat's Claw bark (Una de Gato) and a daily capsule of grape seed extract with methyl sulfonyl methane (MSM).

By July—after six chemo treatments and six weeks on the alternative regimen—a CT scan showed that Bob's liver tumor had disappeared, his lung tumor had shrunk to 50% of its original size, his spine was healing and showed evidence of healthy new tissue, and the enlarged lymph nodes were smaller and fewer in number. After chemo #6, Bob began taking a daily capsule of astragalus root.

As Bob said, "I assume that the dramatic change in my lung tumor, during the 6 weeks between chemo #4 and chemo #6, was mainly due to the alternative therapies which I started in June!"

After continued daily alternative nutritional therapies and eight chemotherapy treatments, X-rays taken on September 11th indicated that the primary lung tumor had shrunk to less than 1 cm and that the lymph nodes were almost totally clear.

Following the 10th and final chemotherapy treatment, X-rays on October 20, 1998 revealed the remarkable—Bob's lung was essentially normal!

A week later, a CT scan verified that there was no detectable tumor in Bob's lung and that the largest of the lymph nodes had shrunk to less than 3mm, which is normal size. As a result of this CT scan, the doctors said that instead of an initially diagnosed liver tumor, Bob probably never had cancer in the liver.

On November 3, 1998 Bob heard the words that every cancer patient longs to

hear from an oncologist—"you're cured." But the oncologist cautioned there might still be undetectable cancer cells. He added that it would take years before any more cancer was detectable. Bob said, "Of course that assumes no further treatment. You know I'll be taking my vitamins, CoQ-10, and essiac as a preventative for the rest of my life."

Bob's Therapy

1. He took the Whitaker "Forward Plus" vitamin program (the vitamin ingredients and amounts are now listed on his website).
2. He took 400 mg of CoQ-10 per day.
3. He drank 2-3 ounces of essiac tea, twice a day (morning and evening) on an empty stomach.
4. He took 1 Cat's Claw (500mg) capsule per day.
5. He took 1 grape seed extract (100mg/MSM 400mg) capsule per day
6. He did NOT take vitamins, grape seed extract, or CoQ-10 on chemo day or the evening before.

Why Bob Takes What He Takes

Bob told *Options*, "During my first round of chemo and simultaneous radiation therapy, I had severe pain in my back and had to increase my daily dose of oxycontin painkiller to 120mg per day. I think the oxycontin and possibly the radiation were responsible for the nausea and mild vomiting which occurred during the first three weeks of therapy. On the last day of radiation and just prior to the second chemo, I was pre-treated with steroids which must have reduced swelling around my spine, because the pain was totally absent and never returned. About five days after my second chemo I had some mild nausea and a queasy stomach. It was around this time that I began taking essiac once a day, and a few weeks later that I began the full alternative program.

"During the time I've followed this program I haven't had any nausea, vomiting, nor any fatigue from the chemo. I feel fine and have continued to work full

Cancer Survivors Program

time. I had hair loss, and 11-12 days after each chemo my neutrophil counts were low enough that I required 2 days of neupogen shots to boost my white blood cell count. A numbness in my toes became evident after my final chemo on 10/3/98, but this has improved as of January 1999—it's very mild and causes no problems," he said.

"Until this experience I had never taken vitamin supplements, but I read many reports about the effectiveness of higher levels of antioxidant vitamins and minerals in reducing cancer risk. The Whitaker program contained much higher levels of many vitamins and minerals than an ordinary multivitamin. It seemed like a convenient solution. Assuming that a full spectrum of vitamins and minerals might have beneficial effects for the immune system, I began taking Whitaker's "Forward Plus" vitamins in June after chemo #4.

"During this experience, I read about a patient with incurable cancer who was being treated for a heart problem with CoenzymeQ-10—and his tumor disappeared! Subsequent studies showed that high doses of CoQ-10 were even more effective in shrinking tumors, so I began taking 400mg/day of CoQ-10 after chemo #4."

Bob continues, "I learned about essiac tea from a friend at work whose mother lived next to a cancer patient with a remarkable story. I called him and he explained that he had colon cancer which had been treated with surgery and chemo, but had spread to his lung and liver." When surgeons at Los Angeles' City of Hope hospital attempted to implant tubes in order to deliver chemo directly to his tumors, they discovered that his liver was so riddled with tumors that they could not proceed with the operation. They closed him up and told him to get his affairs in order because he had only a few months to live.

"He began taking essiac tea. Now, almost four years later, he feels fine and jogs every day. He said that the tumors are still there but they are not growing or spreading," Karjala told *Options*.

President John F. Kennedy's personal physician Dr. Charles A. Brusch signed a notarized statement in 1990 stating he had cured his own colon cancer through the use of essiac tea alone.

Bob also learned about a neighbor who had undergone 6 rounds of chemo for his lung cancer, but the chemo didn't work. The tumor had grown to the size of a baseball, spreading to his liver and prostate. He too was told he had only a few months to live. He began taking essiac tea only a few weeks after Bob began, and he decided that if 2-3 ounces was recommended, he'd use 10-12 ounces at a time. Within a few weeks his tumor shrank to the size of a marble. Bob was told, that in October of 1998, his doctors declared that his neighbor was in complete remission. Bob had read about many other compelling cases which convinced him to add the essiac tea to his arsenal against cancer.

Similarly, he read or heard about cancer recoveries involving Cat's Claw bark and grape seed extract, so he decided it wouldn't hurt to add them to his regimen.

"Did something in the alternatives play an important part in my recovery?" asks Bob. The medical literature tells us that patients with stage IV lung cancer undergoing similar chemo have only a 35-40% response rate and most of those responses only stabilize the disease.

"There are very few (2-3%) complete remissions. I may have been in the lucky 2-3%, but the fact that my response coincided with the beginning of alternative therapy strongly suggests that something in the alternatives played an important part in my recovery," Bob told *Options*.

In March of 1998 his oncologist explained that, at that time, stage IV lung cancer was an incurable disease. Yet he was the same oncologist who told him on November 3, 1998 that he was cured. Since he actually used the word "cured," Bob feels comfortable stating the facts of his case. He has copies of most of his radiology reports and test results and would gladly submit them to

a qualified medical researcher for evaluation.

"Since a cure for stage IV lung cancer is rare," Bob says, "I may have been an exceptional case, or as I would like to believe, I may have stumbled on a combination of therapies that is effective. Without controlled studies, there is no way of knowing which components are, or are not, important."

"Repeating everything exactly as I did could be viewed as a controlled study. In my opinion, it would be easy to add this non-toxic program to patients currently on carboplatin/taxol therapy to see if my results can be duplicated. If so, perhaps a medical professional or researcher would be interested in determining the active ingredients," Karjala suggested.

Bob told *Options*, "I'm so excited about this second lease on life that I feel obligated to pass this information on so that others may benefit from what I've learned.

"I have learned about 'miracle recoveries' from people using essiac tea. If you have any positive or negative results with the tea, I would like to hear the details, so I can pass the information along to my doctors at Cedars Sinai Comprehensive Cancer Center or to the alternative therapies section of the National Cancer Institute."

"Although this regimen worked for me, it may or may not work for others, just as traditional therapy does not work the same for everyone. Because of its non-toxic nature and relatively inexpensive cost, it certainly seems worthwhile to see if my results can be duplicated," Bob said.

Bob has had no treatment since his final chemo on 10/3/98. A complete physical exam with chest and spine x-rays on 8/3/99 was all clear. He continues to be in excellent health as of 12/4/99. ☺

You can find more details on Bob's therapy at: <http://www.essiac-info.org/Bob.html>

For specific information about combining different therapies, join People Against Cancer and access the Alternative Therapy Program: 515-972-4444.

Congress and the White House Take Action on Medical Mistakes

WASHINGTON (AP) — Propelled by a report that medical mistakes kill thousands of Americans, lawmakers and the White House are rushing to put together plans to quickly cut down on the numbers.

Their recommendations will take the form of legislation next year and "guidelines" from the White House to be released immediately, which will track suggestions made last week by the Institute of Medicine, Sen. Edward Kennedy, D-Mass., said Monday.

"I believe we can have a strong bipartisan bill in the next session," Kennedy, the senior Democrat on the Senate Health, Education, Labor and Pension Committee, told reporters. He said he would base the legislation on guidelines he expected President Clinton to release.

For example, Kennedy said, his legislation would create a national center for patient safety that would set safety goals, track progress in achieving them and serve as a clearinghouse for organizations seeking tips on improving medical safety.

The Institute of Medicine said such a center would cost \$35 million to set up. Eventually, the report said, Congress should spend \$100 million a year in safety research, even building prototypes of safety systems.

Still, that would be just a fraction of the estimated \$8.8 billion spent each year as a result of medical mistakes, the report calculated.

The legislation also would provide grants and contracts for research on preventing medical errors and on creating error-reporting systems.

Kennedy said that Republican senators, including committee chairman James Jeffords of Vermont and Bill Frist, a Tennessee doctor, have expressed interest in such a bill.

Both the legislation and the White House action would be based, Kennedy said, on the Institute of Medicine report and recommendations last week.

Kennedy called the institute's goal of reducing medical errors by 50 percent "optimistic," but he also said any legislation would adopt similar goals.



"It is high time for Congressional action," said consumer activist Frank Wiewel. "We see horror stories like this everyday. It is outrageous that fundamental flaws exist in hospitals, clinics and pharmacies which endanger the lives of over nearly 100,000 American citizens each year—and I think it is much worse. I think these numbers are very conservative estimates. There is simply no excuse for this outrage. We will work with Congress and the White House to mandate that physicians, hospitals and clinics clean up their acts immediately."

The institute said it found fatal flaws in the way hospitals, clinics and pharmacies operate. It cited two studies that estimate hospital errors cost at least 44,000, and perhaps as many as 98,000, lives a year.

Some problems are familiar, it suggested: Doctors' famously poor handwriting too often leaves pharmacists squinting at tiny paper prescriptions, and too many drug names sound alike.

Also, medical science advances so rapidly that it is difficult for health care workers to keep up with the latest treatments and new dangers. Technology poses a hazard when device models change from year to year.

And most health professionals do not have their competence regularly retested after they are licensed to practice, the report said.

Indeed, health care is a decade or more behind other high-risk industries in

improving safety, the report said.

Kennedy's other proposals include requirements for reporting errors. Only about 20 states now require such reports, but how much information they require and what penalties they impose for errors varies widely, the report said.

President Clinton on Tuesday ordered the government to take steps to prevent medical errors that kill hundreds of thousands of Americans a year.

One week after a study showed up to 98,000 people die every year due to medical errors, Clinton said the federal government must "lead by example." He ordered plans providing health care for federal employees to implement safety standards and the latest error reduction techniques.

He also gave a federal government task force 60 days to produce recommendations on how to prevent medical errors and improve health care quality and patient safety.

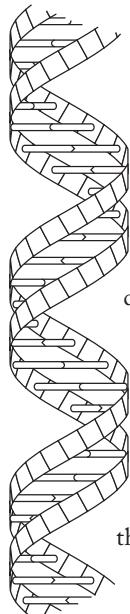
The cost of all the errors is up to \$29 billion in lost income, disability and health care costs.

"But this is about far more [than] dollars or statistics, it's about the toll that such errors take on people's lives and on their faith in our health care system," Clinton said in the Rose Garden after meeting health care representatives.

"The *Institute of Medicine's* report makes clear a systematic approach to reducing medical errors gives us the best chance for success," he said.

"I am committed to working with all these people in partnership to do our part to save lives in needless medical errors and make the best health care system in the world even better in the next century." Clinton reauthorized the Agency for Health Care Quality and Research and earmarked \$25 million for research to improve health care quality and prevent medical errors.

He said he wanted quality and patient safety initiatives in next year's budget. "I want next year's budget to provide the largest investment to eliminate medical errors, improve quality and enhance patient safety we've ever offered." ☐



Six Die in Gene Therapy Experiments

Hearings Held In Washington

Scientists and drug companies did not notify the National Institutes of Health about six people who died during gene therapy experiments in the past 19 months, in the latest sign of a possibly finance-driven shift toward secrecy in the research area, the *Washington Post* reports.

The deaths are the first in gene therapy to come to light that were purposely withheld from the NIH, said one of two federal agencies charged

with overseeing the safety of the controversial field of medical research that seeks to cure diseases by giving patients new genes.

Federal regulations have long held genetic treatments to a higher level of public scrutiny than conventional new therapies because of public discomfort with the idea of manipulating people's genetic makeup.

But as the field has become increasingly dominated by private industry, drug companies and scientists with a financial stake in their research are challenging the broad interpretation of that rule. They are filing reports with demands for confidentiality, or maintaining that they do not have to file them with the NIH at all.

Confirmation of the six deaths follows revelations earlier of a death and two serious illnesses in gene therapy patients

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—Frank D Wiewel

that were reported to the NIH with the unprecedented insistence that they be kept confidential, defying a long-standing agency policy of public disclosure.

In the case of the six deaths, all of the people died during heart studies headed by two leading gene researchers—Ronald Crystal of the New York Hospital-Cornell Medical Center in Manhattan and Jeffrey Isner of Tufts University in Boston, the *Post* said.

The two founded competing gene therapy companies—Isner's Vascular Genetics and Crystal's GenVec—are racing to be the first to grow new blood vessels around blocked ones as an alternative to heart bypass surgery.

Crystal was the first to request confidentiality from the NIH for a patient death report in May 1998, just two weeks after his company GenVec announced its initial stock offering, reported the *Post*.

The report disclosed that NIH staff said, at the time, Crystal cited concerns about the impact on his business if the death were

made public. But Crystal has denied this.

Crystal and Isner said they believe the fatalities in their studies were not directly caused by the gene therapy but by complications stemming from the patients' underlying illnesses.

Because they decided the deaths were not caused by gene therapy, they argued, federal regulations do not require them to notify the NIH—a new interpretation of those regulations that stands in sharp contrast to the one held by NIH officials and a decade of practice, according to the *Post* report.

The researchers told the *Post* they reported the deaths to the Food and Drug Administration, which keeps such information secret.

But NIH officials in the federal office that oversees gene therapy were adamant that even deaths not initially believed to have been caused by the therapy must be reported to the NIH and made public.

Hearings were held on December 8th where FDA officials said that Jesse Gelsinger, 18 an Arizona teenager who died in a University of Pennsylvania gene therapy experiment should never have been part of the study and that researchers violated at least two rules of the testing.

Frank Wiewel, a former advisor to NIH said, "This shocking story is another sad chapter in the book of Dangerous Medicine. We must demand that Alternative Medicine, which is far safer, be given a significant portion of our research budget!"

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*.



\$500 **Benefactor Annual Membership** — Includes all the benefits of Sustaining membership plus a free book.
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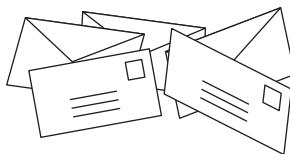
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Options is for educational purposes only. It does not advocate any treatment modality. Each reader is strongly urged to consult a qualified health professional for medical problems.



Cancer Treatment Options— A Patients Right To Know

Day after day the obituary column of the Ames, Iowa *Tribune* dutifully announces a loved one taken by cancer; someone's father, mother, sister or brother or even a child. How untimely you think—how unfair. But what if a member or you received the dreadful diagnosis?

My mother died at 35 when I was 10 and my daughter was stricken at 13 (and is surviving, thankfully).

When you or a loved one receive such news, you are gripped with fear, paralyzed beyond belief, overwhelmed and weakened physically and emotionally. You are broken—defeated. Your only option you believe is to submit to your doctors advice.

I need to say that our family was very grateful for the kind, caring, concerned medical personnel with us in the time of extreme stress and worry when our teenage daughter was ill. We all need to be reminded, however, that there are limits in medical training. Doctors in training who will eventually treat cancer are trained primarily, if not exclusively, in the treatment areas of surgery, chemotherapy and radiation. Some have had courses in complementary, supplemental or alternative therapies as well as nutrition and strengthening the immune system but this is the exception and not the norm.

With no disrespect intended to those who have taken the Hippocratic oath and truly strive to extend life, the patient knows

that there are other good therapies for treating cancer with a good outcome.

A doctor who values your life as much as you do will not be offended if you get another opinion or elect to try a non-toxic treatment option before undergoing chemotherapy or radiation or even surgery.

Questions to ask your doctor include:

- What is your protocol for treating the specific type of cancer?
- What is the outcome in most cases?
- Are there survivors you can talk to about their treatment experience?

If the outcome looks bleak you have everything to gain (at least time) by trying another type of treatment option.

In many cases, aggressive toxic treatments used in an attempt to knock out the cancer also wipes out the patient's resistance and in many cases hastens death though that wasn't the intention.

For those of you who value research and find it enlightening to pursue the full range of information on a topic—like cancer treatment—I would suggest contacting People Against Cancer, based right here in Iowa.

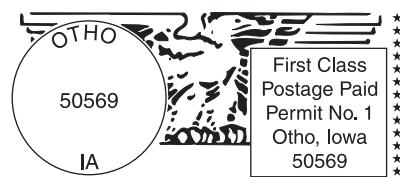
People Against Cancer will distribute educational materials about non-toxic, innovative forms of cancer prevention, diagnosis and therapy. It can be worth your time and life to pursue this information for yourself or a loved one. ☺

Jean Harty
 Ames, Iowa



P.O. Box 10
 Otho, Iowa 50569

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in the War on Cancer*