

Antioxidant doses shown to interfere with drugs intended to lower cholesterol

By Alex Lyda
Associated Press

DALLAS – Extra doses of vitamins such as C and E may blunt some benefits of widely prescribed cholesterol-lowering drugs, a new study concludes.

Some research suggests that the antioxidant vitamins, intended to offset the harmful effects of oxygen, may help keep arteries healthy, while other reports have

disputed this idea.

The latest study compared patients with coronary artery disease who were taking a mix of antioxidant vitamins and drugs to those who were taking drugs alone. The drugs used were niacin and Zocor, which lowers artery-clogging LDL cholesterol while increasing beneficial HDL cholesterol.

It found that the volunteers' HDL levels failed to rise as much as expected when they mixed the vitamins with their cholesterol drugs.

"It looks like antioxidant supplements in general . . . have no value of their own" and may actually interfere with cholesterol drugs' ability to boost HDL, said Dr. B. Greg Brown of the University of Washington at Seattle, one of the researchers.

The one-year study was published in the August issue of *Atherosclerosis, Thrombosis and Vascular Biology*, a journal of the American Heart Association. It involved 153 patients ages 33 to 74 who had heart disease and low LDL levels.

The patients were randomly assigned to one of four treatment groups:

- ◆ Drug therapy with Zocor and niacin.
- ◆ A combination of the anti-

On the Net

- ◆ For more on the study, see the American Heart Association Web site:
www.americanheart.org

oxidant vitamins E, C and beta carotene plus selenium.

- ◆ Drug therapy and the antioxidant supplements.

- ◆ A placebo.

The patients receiving antioxidants and drugs had an average HDL increase of 18 percent, compared with 25 percent among those who received drugs alone. HDL remained unchanged with vitamins alone or the placebo.

A component of HDL cholesterol called HDL(2), which is thought to account for much of HDL's benefit, was especially affected. Its levels increased by 42 percent with drugs alone but remained unchanged in patients who also received antioxidants.

In an editorial, Dr. Lewis H. Kuller of University of Pittsburgh said the results, along with other disappointing findings about vitamins, make a compelling case against recommending antioxidant supplements to prevent or treat coronary artery disease.

"It will be important that physicians advise their patients that the use of antioxidants could be hazardous," he said.

But Dr. Kenny Jialal of the University of Texas Southwestern Medical Center at Dallas criticized the study's small size and disagreed with the conclusion that patients should be warned off antioxidants.

Jialal, a member of the antioxidant panel of the Institute of Medicine, noted that vitamin E has been shown in other studies to reduce the risk of heart disease.

Allergy drug makers sued by organizations that claim false ads

Associated Press

WASHINGTON — Several consumer groups filed a lawsuit Thursday against the makers of Claritin, the nation's most widely prescribed allergy drug, alleging ads for the medicine make bold claims of relief that are not true.

The plaintiffs said the drug company, Schering-Plough, has boosted its sales with TV, Internet and mailed ads, despite research they contend shows Claritin works only 50 percent of the time.

Schering-Plough denied the claims, retorting that no amount of advertising could sustain a drug that does not work.

The Prescription Access Litigation project, a Boston-based consumer group, is the lead plaintiff in the lawsuit. The group did not ask for a specific amount in damages.

"This is not a mere oversight," said Stephen Rosenfeld, a spokesman for the group. "We believe Schering-Plough has deliberately left out information about the drug's efficacy, instead serving up glowing ads to push this product in America's living rooms. The ads are misleading and designed to fool the public into paying top dollar for a drug that often as not, just doesn't work."

The lawsuit cites studies performed or requisitioned by

Schering-Plough that Rosenfeld says prove Claritin works only half the time. Yet, Schering-Plough's ads make "numerous statements of unqualified and absolute effectiveness and no mention of the limited usefulness of Claritin products," the lawsuit states.

Schering-Plough officials said any claims that the company's advertisements break the law are false, but would not comment on the research.

"All advertisements are under regulation established by the Food and Drug Administration," said Denise Foy, a spokeswoman for Schering-Plough. "Claritin remains the nation's leading allergy drug because it works. No drug could remain this popular if it did not work, nor would physicians prescribe such a drug."

Consumer groups have long accused the drug industry of making unsubstantiated claims in direct-to-consumer advertisements. Thomas Sobol, an attorney representing the consumer groups suing Schering-Plough, says the suit is not a shot against the practice of aiming advertisements at consumers.

"We understand that the law allows these types of ads," Sobol said. "But when these ads blatantly trick the public into spending money on something that is no more effective than a sugar pill, that is unfair."

Psoriasis drug a success in tests

Same approach may be used for MS, arthritis

Associated Press

BOSTON — An exquisitely targeted drug has been found to kill renegade immune cells and clear up stubborn psoriasis, suggesting a promising new approach to other diseases that occur when the body's defenses run amok.

Those diseases include arthritis, multiple sclerosis and inflammatory bowel disease.

"I think it's really exciting," said Cornell University dermatologist Dr. Richard D. Granstein. He said it is one of several psoriasis drugs in testing that are "opening up a whole new approach to treatment" of autoimmune diseases.

The research was paid for in part by the drug's manufacturer, Biogen, which expects to seek federal approval for the medication later this year.

Findings on the new drug, a fusion of two proteins known as alefacept, were published today in *The New England Journal of Medicine*.

Later testing, which is still unpublished, reinforces evidence that the drug is generally safe and effective for some patients, said New York University dermatologist Dr. Mark Lebwohl, who took part in those experiments.

About 2 percent of people suffer from red patches, silvery scales or

Leukemia drug shows early promise in study

Associated Press

BOSTON — A genetically engineered drug shows great early promise in tracking down and killing a rare leukemia, raising doctors' hopes in the long quest for a magic bullet against cancer.

Eleven of the 16 patients treated in a study of the drug were left with no readily detectable trace of the disease.

The experimental drug relies on a piece of antibody from a mouse's immune system to latch tightly onto the cancer cells, while shunning normal cells. A bacterial poison fused to the antibody is then carried inside the cancer cells and kills them.

Doctors have long tested mouse antibodies as drugs. Researchers said this drug — and similar ones under study — may eventually prove useful for some other types of cancer, too.

"People thought this kind of thing was going to happen 25 years ago, and it just didn't happen," said immunologist Dr. Terry Strom of Beth Israel Deaconess Hospital in Boston. "Something's happening now."

He co-wrote an accompany-

ing editorial on the leukemia study, which was published today in *The New England Journal of Medicine*.

The researchers at the National Cancer Institute in Bethesda, Md., developed and tested the drug, an immunotoxin known as BL22, on 16 patients with hairy cell leukemia untreatable by the usual chemotherapy.

The blood and bone marrow cancer, named for the hairy look of the cells under a microscope, accounts for about 2 percent of all leukemia cases. Many cases are easily controlled, but the disease can sometimes be fatal.

The early experiment was designed largely to find out whether the drug can be taken safely. The researchers said three patients were clearly given too little or were immune to the bacterial toxin.

Of the 13 others, 11 were left completely free of the disease, judged by standard techniques, after an initial cycle of treatment. During two years of follow-up, only three of those 11 needed more treatment. Two patients developed serious blood clotting in their kidneys.

other symptoms of psoriasis. It is usually mild but persists for a long time. In severe cases, it can cover

large expanses of skin and lead to a form of arthritis.

There is no outright cure but

there are many treatments, including ointments, sunlight or ultraviolet treatments, and stronger drugs that can damage the liver or kidneys.

The disease is suspected to stem from an immune reaction to an unknown irritant made by the body. Immune fighters known as memory effector T cells marshal an attack and prompt skin inflammation.

The new drug targets the overactive T cells while leaving the rest of the immune system largely intact. Existing treatments launch more broad-based attacks on immune cells, which can weaken the body's defenses against disease and cause other side effects.

"We're just going after the specific cells that we're most interested in stopping," said Dr. Charles Ellis, a University of Michigan dermatologist who co-wrote the *New England Journal* report on the drug.

His team tested it on 229 psoriasis patients, at 22 health centers, who had failed to respond to standard drugs. Those given the biggest injections improved an average of about 50 percent in their symptoms. The psoriasis vanished or nearly did so in a quarter of the patients.

People did not need more treatment for an average of 10 months, a longer time than with other therapies. The researchers found no serious side effects.

The later tests on more than 1,000 patients arrived at similar findings, Lebwohl said. Almost three quarters of the patients improved by 50 percent or more, and many were left with little or no psoriasis, he said.

He predicted that the drug will replace other treatment for some patients.