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# Beta carotene found ineffective against disease

Enthusiasm for possibly harmful supplement 'ran ahead of the evidence,' MD says  
after U.S. studies

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Two large U.S. studies have found that, contrary to the beliefs or hopes of the millions of people who take it, beta carotene is ineffective in preventing cancer or heart disease.

In fact, one of the studies found that it even might be harmful to some people.

Health officials in the United States said they hope this will spell the end of the beta-carotene fad. The idea that a simple vitamin-supplement capsule might fend off cancer and other diseases, they said, simply has proved too good to be true.

"With clearly no benefit and even a hint of possible harm, I can see no reason that an individual should take beta carotene," said Dr. Richard Klausner, director of the U.S. National Cancer Institute, which financed both studies.

Beta carotene is a naturally occurring substance in fruits and vegetables that is converted to vitamin A in the body. The institute recommends that, rather than relying on supplements, people eat low-fat diets with plenty of fruits and vegetables because the hundreds of substances combined in those items might be producing the disease protection that has been sought in beta carotene.

People in the United States spend \$3.5-billion (U.S.) a year on vitamin and mineral supplements, said Dr. Annette Dickinson, director of science and regulatory affairs at the Council for Responsible Nutrition, a trade association of supplement manufacturers.

However, the health claims for many of these supplements have not been verified by rigorous scientific investigation and the U.S. Food and Drug Administration is not empowered to regulate claims that vitamin manufacturers make in advertising and promotional brochures except for those that accompany the supplements themselves on retailers' shelves.

One of the beta-carotene studies, the Physicians' Health Study, involved 22,071 doctors randomly assigned to take 50 milligrams of beta carotene or a dummy pill every other day. The study ended Dec. 31, after 12 years, with the conclusion that beta-carotene supplements did not protect against cancer or heart disease.

The other study, the Beta Carotene and Retinol Efficacy Trial (or Caret), tested both beta carotene, in a dose of 30 mg a day, and vitamin A, in a daily dose of 25,000 inter-

national units. The 18,314 participants in this study took beta carotene, vitamin A, both or a placebo. Preliminary studies had hinted that beta carotene might be especially effective in preventing lung cancer and all the subjects in the Caret study were at high risk because they smoked or had worked with asbestos.

The study was halted Jan. 10 – 21 months ahead of schedule – when investigators concluded not only that the vitamins were not helpful but also that they might be harmful. The rate of death from lung cancer was 28 per cent higher among the participants who had taken the supplements than among those who had taken the placebo and the rate of death from heart disease was 17 per cent higher. The reason for these increases is unclear and they were too small to be

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considered statistically significant. But they were nonetheless worrisome.

To underscore the importance of the findings, Dr. Klausner announced them at a news conference, without waiting for publication in a medical journal.

Dr. Klausner said that, because of the results, researchers immediately would remove beta carotene from another study involving 40,000 female health professionals taking beta carotene, vitamin E and Aspirin.

The Caret study's director, Dr. Gilbert Omenn, dean of public health at the University of Washington in Seattle, said its results were not proof that beta carotene is harmful but he still was cautionary.

"These vitamins were providing no benefit and may – with the emphasis on may – have adverse effects"

But Dr. Dickinson said the new results are not enough to indicate that people should stop taking beta carotene, especially in lower doses or in multivitamins. Although she acknowledged that heavy smokers "ought to be aware of the Caret trial and take it into consideration," she said "there is still a strong

suggestion" that beta carotene might be beneficial among the population as a whole.

Study researchers disagreed.

"There is absolutely no benefit" in beta-carotene supplements, said Dr. Charles Hennekens of Brigham and Women's Hospital in Boston, who was director of the Physicians' Health Study. And that finding, he added, is "the biggest disappointment of my career." The two studies began in the early 1980s, when researchers had high hopes that beta carotene or vitamin A might protect against cancer and heart disease.

The hypothesis was that these substances served as anti-oxidants, mopping up dangerous chemicals known as free radicals that, although a normal product of body function, can damage DNA, leading to cancer, and can convert cholesterol, usually inert, into a substance that can lead to heart disease.

In support of the hypothesis were epidemiological studies showing that people whose diets were rich in fruits and vegetables, the source of beta carotene, had less cancer and heart disease than people whose diets were not. And studies found that the more beta carotene in a person's serum, the lower their risk of cancer.

Some scientists urged caution at the time, saying that beta carotene in the serum simply might be a marker for fruit and vegetable consumption and that the complex mixture of chemicals involved in this consumption might be what promotes health.

Or it might be that people who ate fruits and vegetables were healthier to begin with: more likely to exercise, less likely to smoke and leaner than those whose idea of a vegetable is a dollop of ketchup.

One of those cautious experts, Dr. Victor Herbert, a professor of medicine at the Mount Sinai School of Medicine in New York, warned that the vitamin supplements actually could be harmful because beta carotene acts as a pro-oxidant in some circumstances.

But the anti-oxidant craze took on a life of its own.

"The enthusiasm ran ahead of the evidence," said Dr. Daniel Steinberg, a professor of medicine at the University of California at San Diego, who studies anti-oxidants and heart disease.

Now, given the new findings that beta-carotene supplements are useless or worse, some experts are saying that at least the scientific process was brought to fruition.

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"The reality is that science has worked here," Dr. Hennekens said. Despite people's willingness to accept less-than-definitive evidence, he said, scientists pushed ahead with carefully designed clinical trials.

"The major message," Dr. Klausner said, "is that no matter how compelling and exciting a hypothesis is, we don't know whether it works without clinical trials."

Some people have criticized the dietary-

supplement industry for promoting beta carotene vigorously without adequate scientific basis.

"The health-food industry is selling America a bill of goods," Dr. Herbert said.