

# The Prepared Patient®



**CFAH** CENTER FOR  
ADVANCING  
HEALTH  
*Evidence. Engagement. Equity.*

## Vitamins & Supplements: Before You Dive In

### What Are Dietary Supplements and How Are They Regulated?

**V**itamins, herbs and other dietary supplements are sold as natural alternatives to pharmaceuticals and many people turn to them in an attempt to improve their health. Others seek supplements to lose weight or after hearing that they can help with serious medical conditions. These products are now used at least monthly by more than half of all Americans—and their production, marketing and sales have become a \$23.7 billion industry, according to the Nutrition Business Journal.

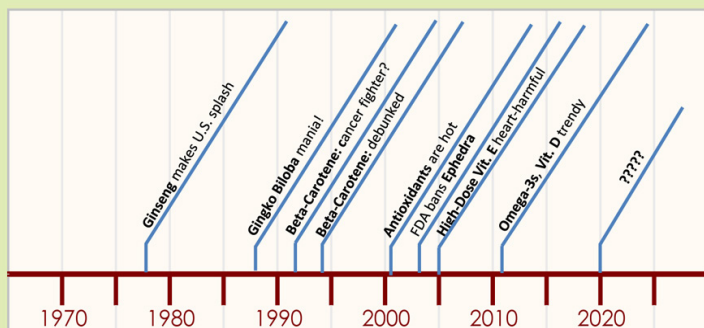
98-year-old Bob Stewart, a retired podiatrist and senior Olympian, credits his use of supplements for his healthy aging. Writer Betsy McMillan, a mother of two now adult children, however, nearly suffered permanent liver damage

due to a supplement that contained potentially fatal levels of niacin.

Unlike pharmaceuticals—which must be FDA-approved as safe and effective before they can be marketed—supplements are considered as foods by regulators and assumed to be safe until proven otherwise. Although pharmaceutical manufacturers face inspections to ensure that the right dose is in the right pill without dangerous contaminants, supplements do not undergo such intense government scrutiny.

Despite many reports of health problems, only one supplement has ever been pulled from the market: the stimulant ephedra, which was banned in 2004 following reports of deaths. With such little regulation and oversight, safe supplement use requires that consumers be cautious and savvy.

### Vitamins and Supplements in Vogue



Source: Center for Advancing Health/Health Behavior News Service

“Supplement is a broad term that includes vitamins, minerals, herbs and botanicals,” says Carol Haggans, a registered dietician and science and health communication consultant for the Office of Dietary Supplements of the National Institutes of Health. Herbs and botanicals are derived from plants, while other supplements may include animal sources. Vitamins are essential nutrients made up of organic compounds, while minerals is an imprecise term for certain chemical elements necessary to life, like calcium.

“They’re regulated under the umbrella of foods and are not intended to treat, diagnose, mitigate, cure or prevent disease. If something claims to do that, then it becomes a drug under FDA regulation,” Haggans says.

She adds, “The FDA has instituted ‘good manufacturing practices’ (GMP) that manufacturers must follow to ensure the identity and quality of supplements and they can take enforcement action if it’s unsafe or unfit for human consumption, but they do not routinely test products.” Once manufacturers implement these practices, they can display a seal on their packaging, noting their compliance.

But Dr. Bob Linden, a general practitioner and author who has used supplements but also has seen problems with them in patients, says he’s rarely seen the GMP seal in stores where he lives in Connecticut, despite the agency’s plan to complete most of the implementation by last year.

### Looking for Safer Products

So how can consumers protect themselves and find high-quality products? Haggans says that several independent organizations test products and offer their seal of approval only to those that pass. “Those can give some assurance that the product is properly manufactured, contains the ingredients listed on the label and doesn’t contain harmful levels of contaminants,” she says. Consumer Reports Health also regularly reviews supplements but may require a subscription for full access to information. (See “Finding Safe Supplements.”)

“I think people use them primarily because they think they’re natural [and from] plants,” Linden says. “They also think they’re safe because you don’t need a prescription.” He has taken supplements himself for arthritis. But he also had one patient who suffered liver damage after taking a supplement containing Chinese skullcap, which is known to be dangerous to the liver but is still on the market.

“They can’t label them as treating disease, on the bottle, they say it’s ‘promoting health,’” Linden says. “But people do take them specifically for [diseases], such as St. John’s wort for depression.”

### Managing Interactions and Dosing

Like drugs, supplements can combine with other medications in unhealthy ways. “Dietary supplements can interact with both over-the-counter and prescription medication,” Haggans says. “That’s one reason we tell people to talk with their doctors about all the supplements that they’re taking.” For example, the anticoagulant medicine warfarin (Coumadin) can interact with ginkgo biloba and with garlic and cause bleeding. St. John’s wort, which is often used to treat depression, can weaken the effects of birth control pills and other medications. Vitamins C and E can also potentially interfere with chemotherapy used to treat cancer.

## Finding Safe Supplements

Check out these sources of vitamin/supplement information before plunging in:

- These three organizations all keep regularly updated fact sheets on the most commonly used herbs, supplements and vitamins.
  - **The Office of Dietary Supplements** (<http://ods.od.nih.gov/factsheets/list-all>)
  - **National Center for Complementary and Alternative Medicine** (<http://nccam.nih.gov/health/herbsataglance.htm>)
  - **Memorial Sloan-Kettering Cancer Center** (<http://www.mskcc.org/mskcc/html/11570.cfm>)
- **U.S. Pharmacopeia** aims to help ensure the quality, safety and benefit of medicines and foods. (<http://www.usp.org/>)
- **Consumer Reports Health** regularly reviews supplements but may require a subscription for full access to information. (<http://www.consumerreports.org/health/natural-health/dietary-supplements/overview/index.htm>)
- **NSF International**, a non-profit NGO, also is involved in testing and certification efforts. ([http://www.nsf.org/consumer/dietary\\_supplements/index.asp?program=DietarySup](http://www.nsf.org/consumer/dietary_supplements/index.asp?program=DietarySup))
- **ConsumerLab.com** tests and reports on health and nutritional products. (<http://www.consumerlab.com/>)

Doctors might not know about interactions between supplements and prescriptions and since supplement labels don’t list warnings, patients need to do their own research: look for guidance from the sites listed in the resource section and talk to a nutritionist or check with reliable sources at “health food” stores or reputable “wellness” centers. This is a situation where watching carefully for side effects is especially important and consumers are mostly on their own to be vigilant.

Some supplements can be monitored by testing blood

levels. This can be expensive but it might also reduce problems related to potential toxicity or unusual individual reactions. Check with your doctor to see if blood tests might be suitable for you.

## Researching Appropriate Supplements

The scientific evidence supporting the use of supplements is often weaker than that available for drugs because of the lack of legal requirements to prove safety and efficacy. “You can get a lot of conflicting evidence depending on where you look,” Haggans says.

The Office of Dietary Supplements, the National Center for Complementary and Alternative Medicine, and the Memorial Sloan-Kettering Cancer Center all keep regularly updated fact sheets on the most commonly used herbs, supplements and vitamins. (See sidebar.)

Beyond that, there are several important principles to keep in mind if you take supplements. First, “Natural is not always safe,” Haggans says. Both arsenic and poisonous mushrooms are completely natural but deadly to eat. Second, never rely on a single study or personal story to provide definitive evidence.

In contrast, review articles—particularly those done under the rigorous standards of the Cochrane Collaboration—can be a high quality source of evidence. “Review articles like Cochrane Reviews look at the totality of the evidence in different populations,” Haggans says, which is especially important since studies of nutrition often have conflicting results.

For example, beta-carotene was once thought to be a universal cancer fighter—but long-term studies found that smokers and other people at high risk for lung cancer who took it actually increased their risk of contracting the disease and their risk of early death from other causes.

## Avoiding Overdose

Dose is also a critical consideration. “Many nutrients have an upper limit,” Haggans says. “More is not better and above certain amounts, they can be toxic.” She notes that iron is one mineral that is dangerous in high doses. Niacin—as McMillan unfortunately found out—is another.

The use of supplements—like much of American life—is highly susceptible to fashion. The “in” supplements of the 1980s and 90s like ginkgo biloba and ginseng were followed by an antioxidant fad for vitamins A, C and E in the 2000s. The 1994 study on beta-carotene and smoking and a 2005 finding that high-dose vitamin E may do harm took some steam out of those trends. Currently, omega-3 fatty acids and vitamin D are the headline makers. Overall, the supplement industry has grown dramatically, continuing to increase sales despite the recession.

Given this—and given the fact that some risky supplements like the Chinese skullcap that harmed Dr. Linden’s patient remain on the market—it’s important that people considering them “do their homework,” as Haggans puts it. “Go to a trusted source like your doctor for information.” At the least, your doctor can help you weigh the evidence.

## Narrowing Your Choices

Linden suggests closely following directions on products’ bottles. He adds, “Stay away from supplements [advertised for] weight loss—you don’t know what you’re getting and it’s looking for trouble.” Some weight-loss supplements and some sold as sexual aids have been found to contain prescription medications that were illegally manufactured.

Stewart’s advice is to stick to supplements that are essentially unaltered whole foods, like flaxseed and vinegar. “The type of food we have now in grocery stores is terrible,” he says, echoing the complaints of nutrition experts about over-processed and chemical-laden foods.

Supplements can be helpful in some cases but they are less well regulated than drugs and have many of the same side effects, drug interactions and toxicities at high doses seen with pharmaceuticals. Consequently, they should be used with care and with guidance from a doctor.

### Terms of Use

This *Prepared Patient* feature is protected by copyright. When reproducing any material, including the abridged “key points” version, attribution to the “Health Behavior News Service, part of the Center for Advancing Health,” is required.

© Copyright 2011

The  
Prepared  
Patient

Published by  
**HEALTH BEHAVIOR NEWS SERVICE**  
Lisa Esposito, Editor  
Written by Maia Szalavitz, Contributing Writer  
Design by Brandon Moore, Dir. of New Media

For information and resources, visit us online at  
<http://www.preparedpatient.org>