

In Depth 12.5

The Safety and Effectiveness of Dietary Supplements



Learning Outcomes

After studying this In Depth, you should be able to:

- 12.1 Discuss the limitations in current regulation of dietary supplements sold in the United States.

- 12.2 Explain what constitutes an herbal supplement and what special precautions are indicated for its use.
- 12.3 Identify groups of people who might benefit from taking a dietary supplement as well as situations in which dietary supplements are not advised.

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In April of 2015, 14 U.S. Attorneys General signed a letter to the congressional subcommittee responsible for consumer product safety requesting that Congress launch an investigation into the dietary supplements industry. The action came after DNA testing of several supplements found that they did not contain the ingredients listed on the labels; some were contaminated with high levels of heavy metals including lead and mercury; and some contained allergens such as wheat and grass not identified on the label. Some supplements were labeled as containing natural plant extracts when they actually contained synthetic stimulants. In November 2015, the U.S. Justice Department brought criminal and civil suits against 117 individuals and companies marketing these supplements, some of which had caused illnesses and even deaths.

The Office of Dietary Supplements (ODS) at the National Institutes of Health (NIH) reports that, in 2014, sales of dietary supplements reached nearly \$37 billion.¹ A recent survey of students at five U.S. universities found that 66% use a dietary supplement and 12% consume five or more.² Is this smart? Dangerous? Who, if anyone, *should* be taking supplements?

How are dietary supplements regulated?

LO 1 Discuss the limitations in current regulation of dietary supplements sold in the United States.

According to the U.S. Food and Drug Administration (FDA), a **dietary supplement** is a product containing ingredients such as vitamins, minerals, herbs, amino acids, or enzymes. They are intended to supplement the diet, not to treat, diagnose, prevent, or cure disease.³ Supplements come in many forms, including tablets, capsules, softgels, liquids, and powders.



Dietary supplements can be pills, capsules, powders, or liquids and contain micronutrients, amino acids, herbs, or other substances.

Figure 1 shows a label from a multivitamin and mineral (MVM) supplement. There are specific requirements for the information that must be included on the supplement label. Labels bearing a claim must also include the disclaimer "This statement has not been evaluated by the FDA. This product is not intended to diagnose, cure, or prevent any disease." Any products not meeting these guidelines can be removed from the market.

Figure 1

A multivitamin and mineral supplement label highlighting the dietary supplement labeling guidelines.





100 Tablets

*"Helps promote optimal energy."
This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Directions: Adults: One tablet daily, with food.

Supplement Facts
Serving Size: One tablet

	Amount Per serving	% Daily Value
Vitamin A	2500 IU	50%
Vitamin C	60 mg	100%
Vitamin D	400 IU	100%
Vitamin E	30 IU	100%
Thiamin	1.5 mg	100%
Riboflavin	1.7 mg	100%
Niacin	10 mg	50%
Vitamin B ₆	2 mg	100%
Magnesium	50 mg	12%
Iron	18 mg	100%
Zinc	15 mg	100%
American Ginseng Standardized Extract	200 mg	++

++No Daily Value established for Ginseng.

Other ingredients: Cellulose, Dextrin, Gelatin, Starch, Dextrose, FD&C Yellow #6, FD&C Blue #2

Made in U.S.A.
Distributed by:
Supervitamin Corporation
P.O. Box XYZ
Energized, CA 00000

2 Net quantity of contents

3 Directions

4 Supplement facts panel

5 Other ingredients in descending order by weight and using common name

6 Name and place of business, manufacturer, packer, or distributor; the address for more information

The Dietary Supplement Health and Education Act (DSHEA) of 1994 classified dietary supplements within the general group of foods, not drugs. This means that the regulation of supplements is much less rigorous than the regulation of drugs. Currently, the FDA is reconsidering how it regulates foods and supplements that are marketed with health claims, but no changes have been finalized at this time. As an informed consumer, you should know that:³

- The FDA does not have the authority to review the safety and effectiveness of dietary supplements before they are marketed.
- The company that manufactures a supplement is responsible for determining that the supplement is safe; the FDA does not test any supplement for safety prior to marketing.
- Supplement companies have to notify the FDA if their supplement contains a new dietary ingredient; however, the FDA only reviews such notifications—it does not approve them—and only for safety, not for effectiveness.
- The FDA requires supplements manufacturers to produce products of quality and free of contamination; however, it does not regulate practices to ensure the purity, quality, safety, and composition of dietary supplements.
- Once a supplement is marketed, the FDA can take steps to remove it from the market if it is found to be unsafe or if the claims on the label are false and misleading. Supplements advertisers must be able to substantiate all label claims.

Although many dietary supplements contain the ingredients listed and are safe, the recent investigations mentioned earlier show that many others are dangerous. Because the liver is responsible for clearing toxins from the blood, it is often the organ damaged by use of contaminated supplements. For example, a 2014 study found that, over a 10-year period, eight U.S. medical centers reported more than 100 cases of liver damage caused by dietary supplements. Many of these cases resulted in the need for a liver transplant, and 13% were fatal.⁴ How can you avoid purchasing such supplements? The FDA suggests that you keep in mind the nearby **Quick Tips** when evaluating dietary supplements.⁵

Quick Tips

Staying Safe with Supplements

- ✓ Check with your healthcare provider or an RDN about any nutrients you may need in addition to your regular diet.
- ✓ Look for the Pharmacopeia (USP) Verified Mark on the label (Figure 2 ). Though it doesn't indicate that the supplement is effective in treating any condition, the mark does indicate that the manufacturer followed the standards that the USP has established for features such as purity, quality, and labeling.
- ✓ Choose recognized brands of supplements. Although not guaranteed, products made by nationally recognized companies more likely have well-established manufacturing standards.
- ✓ Do not assume that the word *natural* on the label means that the product is safe. Arsenic, lead, and many other natural substances can kill you if consumed in large enough quantities.
- ✓ Be skeptical of anecdotal information or personal “testimonials.”
- ✓ Ask yourself if the claims for the supplement sound too good to be true; for example, promising that the supplement will enable you to lose a large amount of weight in a short amount of time, or that it is a “miracle cure,” or can be used to treat a wide variety of diseases.
- ✓ Do not hesitate to question a company about how it makes its products. Reputable companies have nothing to hide and are more than happy to inform their customers about the safety and quality of their products.

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Source: U.S. Food and Drug Administration (FDA). Center for Food Safety and Applied Nutrition. 2015, September 4. Six tip-offs to rip-offs: Don't fall for health fraud scams. www.fda.gov/forconsumers/consumerupdates/ucm341344.htm

Figure 2

The USP Verified Mark indicates that the manufacturer has followed certain standards for features such as purity, strength, and quality. Registered Trademark of U.S. Pharmacopeial Convention (USP). Used with Permission.



Are there special precautions for herbs?

LO 2 Explain what constitutes an herbal supplement and what special precautions are indicated for its use.

A common saying in India cautions that “A house without ginger is a sick house.” Indeed, ginger, echinacea, lavender, and many other herbs (also called *botanicals*) have been used for centuries by different cultures throughout the world to promote health and treat discomfort and disease. Many prescription and over-the-counter drugs are based on botanicals.

The National Center for Complementary and Integrative Health (NCCIH) defines an herb as “a plant or plant part (such as leaves, flowers, or seeds) that is used for its flavor, scent, and/or potential health-related properties.”⁶ As you would suspect, with a definition this broad there are hundreds of different herbs on the market. Which of these may be effective, and for what disorders, in what forms, and at what dosages? And are some ineffective or even dangerous? To help consumers answer these questions, NCCIH evaluates the most commonly used herbs in “Herbs at a Glance” fact sheets, available at its website (see the [Web Links](#) at the end of this chapter).



Echinacea, commonly known as purple coneflower, has been used for centuries to prevent colds, flu, and other infections.

The use of herbal supplements requires special precautions. In addition to the **QuickTips** for all types of dietary supplements, practice the following strategies offered by the NCCIH specifically for consumers considering the use of herbs.⁶

- Consult a healthcare provider before using any herbal supplement. Herbs can act the same way as drugs; therefore, they can cause medical problems if not prescribed.
- Never take herbal supplements if you have a serious illness, regularly take any prescription or over-the-counter medication, or are pregnant or breastfeeding, unless your physician has approved their use.
- Do not treat children with herbal supplements unless your physician has approved their use.
- Be aware that the active ingredients in many herbal supplements are not known. They may contain dozens, even hundreds, of unknown compounds. Analyses of herbal supplements, like those noted earlier, have routinely found differences between what is listed on the label and what is in the bottle. This means you may be taking less—or more—of the supplement than what the label indicates or ingesting potentially harmful substances such as grasses, metals, unlabeled prescription drugs, and microorganisms.
- Be aware that the words *standardized*, *certified*, or *natural* on a label is no guarantee of product quality; in the United States, these terms have no legal definition for supplements.
- Finally, certain herbs are associated with severe—even life-threatening—adverse effects. These should be avoided entirely (Table 1).

Table 1 Potentially Harmful Herbal Supplements

Herb	Potential Risks
Bitter orange	Increased blood pressure and heart rate; heart attack; stroke
Ephedra (also known as <i>ma huang</i> , Chinese ephedra, and epitonin)	High blood pressure, irregular heartbeat, nerve damage, insomnia, tremors, headaches, seizures, heart attack, stroke, possible death
Kava (also known as <i>kava kava</i>)	Liver damage; death
Licorice root	High blood pressure, fluid retention, hypokalemia
Noni	Liver damage
Thunder god vine	Diarrhea, nausea, skin rash, headache, hair loss, menstrual changes, male infertility; can be fatal if improperly extracted
Willow bark	Reye’s syndrome (a potentially fatal reaction that may occur when children take aspirin), allergic reaction in adults
Yohimbe	High blood pressure, increased heart rate, headache, anxiety, dizziness, nausea, vomiting, tremors, insomnia

Source: Data from National Center for Complementary and Integrative Health (NCCIH). 2016. *Herbs at a Glance*. <https://nccih.nih.gov/health/herbsataglance.htm>

Should you take a dietary supplement?

LO 3 Identify groups of people who might benefit from taking a dietary supplement as well as situations in which dietary supplements are not advised.

According to a recent survey, 67% of Americans use vitamin or mineral supplements, 35% use “specialty” supplements, 23% use botanicals, and 17% use sports supplements (some of which are ergogenic aids, discussed in more detail in [Chapter 11](#)).⁷ Many people take more than one. Among supplements users, MVM supplements are the most popular: 71% take an MVM. But contrary to popular belief, a healthful diet can usually provide an adequate level of essential nutrients. Moreover, foods contain a diverse combination of compounds that interact to maintain our health, whereas vitamin and mineral supplements contain just the micronutrients identified on the label. Thus, they’re not substitutes for a healthful diet.

However, nutritional needs do change throughout the life span, so you may benefit from taking a supplement at certain times for certain reasons. For instance, if you were to adopt a vegan diet, your healthcare provider might prescribe a supplement providing micronutrients absent or less available from plant foods, including riboflavin, vitamin B₁₂, vitamin D, calcium, iron, and zinc. Or if you joined your college soccer team, your team’s sport dietitian might review your diet and advise taking a supplement formulated to provide micronutrients that support intense physical activity.

Dietary supplements include hundreds of thousands of products sold for many purposes, so it’s impossible to discuss here all of the situations in which their use might be advisable. To simplify this discussion, [Table 2](#) identifies groups of people who might benefit from micronutrient supplementation; however, not everyone in these groups needs the supplement indicated. If you fall within one of the groups listed, check with your healthcare provider or a registered dietitian nutritionist (RDN) to find out whether or not you should take the supplement.

Table 2 Individuals Who May Benefit from Micronutrient Supplementation

Type of Individual	Specific Supplements That May Help
Newborns	Routinely given a single dose of vitamin K at birth
Infants	Depends on age and nutrition; may need iron, vitamin D, or other nutrients
Children not drinking fluoridated water	Fluoride supplements
Children with poor eating habits or overweight children on an energy-restricted diet	Multivitamin and multimineral supplement that does not exceed the RDA for the nutrients it contains
Pregnant teenagers	Iron and folic acid; other nutrients may be necessary if diet is very poor

Women who may become pregnant	Multivitamin or multivitamin and multimineral supplement that contains 0.4 mg of folic acid
Pregnant or lactating women	Multivitamin and multimineral supplement that contains iron, folic acid, zinc, copper, calcium, vitamin B ₆ , vitamin C, and vitamin D
People on prolonged or highly calorically restrictive weight-reduction diets	Multivitamin and multimineral supplement
People recovering from serious illness or surgery	Multivitamin and multimineral supplement
People with HIV/AIDS or other wasting diseases; people addicted to drugs or alcohol	Multivitamin and multimineral supplement or single-nutrient supplements
People who do not consume adequate calcium	Calcium should be consumed in whole foods and beverages; however, for some populations, supplements may be prescribed
People with low exposure to sunlight	Vitamin D
People eating a vegan diet	Vitamin B ₁₂ , riboflavin, calcium, vitamin D, iron, and zinc
People who have had portions of their intestinal tract removed; people who have a malabsorptive disease	Depends on the exact condition; may include various fat-soluble and/or water-soluble vitamins and other nutrients
Elderly people	Multivitamin and multimineral supplement, vitamin B ₁₂

The following are instances in which taking supplements is unnecessary or may be harmful:

- Providing fluoride supplements to children who already drink fluoridated water.
- Taking supplements in the belief that they will cure a disease, such as cancer, diabetes, arthritis, or heart disease.
- Taking nonprescribed supplements if you have a serious illness or are taking any prescription medications. For instance, physicians may prescribe micronutrient supplements for their patients with liver or kidney disease to replace nutrients lost during treatment for these diseases. However, these patients should not take any unprescribed supplements because their disease impairs their metabolism, putting them at high risk for toxicity. Similarly, people who take the blood-thinning drug Coumadin should not take any dietary supplements unless their physician has approved them. Vitamin E or K, licorice, St. John's wort, and willow bark are just a few of many supplements that can dangerously alter the effects of Coumadin. People who take aspirin daily should check with their physician before taking any supplements because aspirin also thins the blood.⁸
- Taking beta-carotene supplements if you are a smoker. There is evidence that beta-carotene supplementation increases the risk for lung and other cancers in smokers.
- Taking supplements to increase your energy level. Although many vitamins and minerals assist in energy metabolism, they do not provide energy because they do not contain fat, carbohydrate, or protein (sources of Calories). Moreover, many stimulant supplements that are taken to increase energy levels have been associated with altered heart rhythms, central nervous system disturbances, and even death.⁹
- Taking single-nutrient supplements, unless prescribed by your physician for a diagnosed medical condition (e.g., prescribing iron supplements for someone with anemia). These supplements contain high amounts of the given nutrient, and taking them can quickly lead to toxicity. Especially harmful in high doses are vitamin A, which can cause liver damage; vitamin B₆, which can injure nerves; niacin, which can cause vomiting, diarrhea, and damage

to muscles, liver, and heart; and the mineral selenium, which can cause tissue damage.



One of the best strategies for maintaining good health is to eat a diet that provides a variety of whole foods. If you do that, you probably won't need supplements.

MVM supplements are unlikely to cause harm, so should you take one, just for “insurance”? A recent editorial in the *Annals of Internal Medicine* advised most Americans to stop wasting their money on MVM supplements.¹⁰ It cited other articles published in the same issue of the journal that illustrated no clear evidence of a beneficial effect of dietary supplementation on all-cause mortality, CVD, cancer,¹¹ or cognitive decline.^{12,13} The U.S. Preventive Services Taskforce finds that current evidence is insufficient to support the use of MVMs or single- or paired-nutrient supplements.¹¹ If you do decide to take an MVM, select one that contains no more than 100% of the recommended levels for the nutrients it contains, but be aware: you might be wasting your money.

THEO



“You know, I never thought I needed to take a multivitamin and mineral supplement because I’m healthy and I eat all different kinds of foods. But now I’ve learned in my nutrition course about what these vitamins and minerals do in the body, and I’m thinking, heck, maybe I should take one just for insurance. I mean, I use up a lot of fuel playing basketball and working out. Maybe if I popped a pill every day, I’d have an easier time keeping my weight up!”

Do you think Theo should take a multivitamin and mineral supplement “just for insurance”? Why or why not? Would taking one be likely to have any effect on Theo’s weight?

Web Links

<https://ods.od.nih.gov/>

Office of Dietary Supplements

Search this website to find reports evaluating individual supplements you might be considering as well as general information about the health benefits, safety, and regulation of dietary supplements.

www.cfsan.fda.gov

U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition

This site provides information on how to make informed decisions and evaluate information related to dietary supplements.

<https://nccih.nih.gov>

National Center for Complementary and Integrative Health

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From the menu on the left side of the home page, click on “Herbs at a Glance” to find information about an herb you might be considering using.

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