

Dietary Supplements: What Is Safe?

What you need to know first about dietary supplements

Dietary supplements include things like vitamins, minerals, herbs, or products made from plants. They can also be made from animal parts, algae, seafood, yeasts, fungus, and many other food substances or extracts. They include powdered amino acids, enzymes, energy bars, and liquid food supplements.

Some dietary supplements are formulated under careful conditions in clean, controlled laboratories and labeled accurately. Others are made less carefully, and have been found to contain none of the substances listed on their labels. And some supplements contain other substances that are not listed on their labels – fillers, different herbs, or actual drugs that are known to be able to cause harm.

If you are thinking about using dietary supplements as part of your cancer treatment, you'll want to know more before you decide what to do. The information here will help you learn more about dietary supplements so you can make a more informed decision about using them safely.

Risks and side effects of dietary supplements

Like drugs, dietary supplements have risks and side effects. But sellers aren't required to do research studies in people to prove that a dietary supplement is safe. And unlike drugs, dietary supplements are mostly self-prescribed with no input from informed medical sources like doctors, nurses, or pharmacists.

There's a lot of wrong information out there. Even for those who are usually well informed, it can be hard to find reliable information about the safe use and potential risks of dietary supplements.

As part of its function to monitor supplement safety, the US Food and Drug Administration (FDA) tracks reports of illness, injury, or reactions from supplements. And supplement makers are required to report serious harmful effects to the FDA. Early numbers are reported on the FDA website. Recent FDA information shows that the number of reports has continued to climb each calendar year:

2010: 1,009 reports of dietary supplement adverse events

2011: 2,047 reports of dietary supplement adverse events

2012: 2,844 reports of dietary supplement adverse events

Exposures to supplements (such as vitamins, herbs, protein powders, and botanicals) accounted for more than 35,000 calls to US poison control centers in 2011. Of these calls, more than 4,000 people were reportedly treated in health care facilities. More than 800 cases were described as having moderate to severe outcomes, with 4 deaths reported to poison control centers.

Most people who suffer unexpected side effects, illnesses, or drug interactions from dietary supplements don't call a poison control center or the supplement manufacturer. This means that the numbers we have are likely very low estimates of actual events.

Used properly, certain dietary supplements may help reduce the risk of some diseases, reduce discomfort caused by certain drugs or conditions, or simply make you feel better (improve your quality of life). And most people can use dietary supplements safely within certain dosage guidelines. But taking dietary supplements can be risky, especially for people who are getting cancer treatment.

Special problems for people getting cancer treatment

There are several ways that supplements can cause problems for people during cancer treatment. For example, some dietary supplements can cause skin sensitivity and severe reactions when taken during radiation treatment. People who are getting radiation treatments should talk to their doctors before taking any supplement.

People getting chemotherapy may be at higher risk for drug interactions if they take dietary supplements. There is also concern that antioxidants might interfere with cancer cell-killing treatments. Cancer experts often recommend that patients avoid dietary supplements altogether until their cancer treatment is over. But if you decide to take supplements anyway, be sure to let your doctor know exactly what you are taking.

Dietary supplement advertising and promotion

Keep in mind that a great deal of what you hear or read about dietary supplements is based on *anecdotal* evidence. Anecdotal evidence is based on people's (even doctors') personal experiences or opinions rather than objective, controlled research studies.

Be skeptical of sources that make grand claims based on a few people's testimonials or vague references to "scientific proof." The rule "if it sounds too good to be true, it probably is" usually applies to such claims. Keep in mind that the makers and sellers of supplements have a financial interest in promoting their products.

Supplement makers do not have to get FDA (US Food and Drug Administration) approval to market their products. The FDA does look at potentially illegal products (that is, products that may be unsafe or make false or misleading claims). But they can only do this after the product is on the market. As its resources permit, the FDA also looks at supplement labels and other information, such as package inserts, claims, and Internet ads. But it cannot review all of the many products on the market today.

No matter what they claim, dietary supplements are not intended to treat, diagnose, cure, or relieve the effects of diseases. They cannot completely prevent diseases, as some vaccines can. But some supplements are useful in reducing the risk of certain diseases. They are allowed to make label claims about these uses. For example, folic acid supplements may make a claim about reducing the risk of birth defects of the brain and spinal cord when taken by pregnant women.

If a supplement claims to do the same thing as a prescription drug, you are right to be doubtful. The claim may be false, or the product may contain an illegal drug. (See "What kinds of problems have there been with supplements and herbs?" in the section "FDA regulation of drugs versus dietary supplements.")

Look past the advertising for evidence or research on the supplement from objective, third-party sources. See our document called Complementary and Alternative Methods and Cancer to learn how to do this. You can read it on our website or call us for a free copy. We also have information on many different types of herbs and supplements in the "Complementary and Alternative Medicine" section of our website.

Talking with your doctor about dietary supplements

No matter what kind of treatment you are getting, it's always safest to talk with your doctor about the type and amount of each supplement you want to try. Do this before you spend any money or start taking anything new. If you have been taking supplements and want to keep taking them, it's important that your doctor knows this, too.

Many doctors are just starting to learn about the uses, risks, and potential benefits of dietary supplements. In some cases, it can cause problems between patient and doctor when it comes to using supplements along with standard cancer treatment. This is getting better as more studies are done and better information is becoming available.

Gather as much information as you can on the dietary supplement you are thinking about using. Then, approach your doctor with the information you have, and ask for an open conversation about it. Ask for his or her professional opinion as to whether the treatment is safe and medically sound. Also ask how it might be safely used along with your cancer treatment. Remember to make sure that your doctor knows about other medicines, vitamins, and supplements that you're already taking.

Common misconceptions about dietary supplements

Megadosing: The "More is better" myth

Many people wonder why dietary supplements like vitamins, herbs, and botanicals are sold without a prescription from a doctor, while medicines (or drugs) are closely regulated and controlled. People often make the mistake of assuming that because supplements are sold over the counter, they are completely safe to take, even in high doses.

In the 1990s there was a trend of "megadosing" antioxidants like vitamin C, beta carotene, and vitamin E. Even though no scientific studies have ever proven that large doses of vitamin C can prevent or cure colds, many people still think this is true. Even now, you may hear claims about other benefits of taking large doses of certain vitamins. But using large doses of vitamins to fight disease in humans is not supported by scientific evidence so far.

In fact, large doses of some vitamins or minerals have been shown to be dangerous and even toxic. For example, too much vitamin C can interfere with the body's ability to absorb copper, a metal that's needed by the body. Too much phosphorous can inhibit the body's absorption of calcium. The body cannot get rid of large doses of vitamins A, D, and K and these can reach toxic levels when too much is taken.

Talk with your doctor before taking large doses of any vitamin, mineral, or other supplement. Your nurse or pharmacist may also be able to give you more information on safe dosages. Even when vitamin doses are not high enough to cause toxic effects, they can have a bad impact on overall health. For instance, several large studies have found that, on average, people taking vitamin E supplements lived no longer than those who didn't. Some even died sooner, particularly of heart failure.

The "Natural is safe" and "Natural is better" myths

In today's world, you won't find much support for the idea that a man-made or refined substance is better or safer than one sold in its unrefined, natural state. But supplements that claim to be "all natural" are not always better or safer than refined or manufactured substances.

Keep in mind that some of the most toxic substances in the world occur naturally. Poison mushrooms, for example, are completely natural but not safe or helpful to humans. Many plants in nature are toxic or deadly if taken internally.

Botanical supplements (such as garlic, ginger, ginkgo biloba, echinacea, and others) are made of plant material, so many of them are sold as "natural" products. But plants are made up of many chemicals. Some of these chemicals can be helpful while others are poisonous or can cause allergies in humans. Botanicals that are marketed as "all natural" are not always the most helpful ones, since they may not be refined to remove potentially harmful chemicals.

Botanicals can contain any or all parts of the plant, including roots, stems, flowers, leaves, pollen, and juices. Different parts of plants can have very different effects on humans. For instance, dandelion root is a laxative (it causes bowel movements), while dandelion leaves contain a diuretic (a chemical that increases urination). If you decide to use a botanical supplement, make sure you know what parts of the plant were put into it. If you're unsure, contact the company and ask them how they make their supplement.

Remember, too, that safety and dose are related. The leaves or roots of many plants can be safely taken in small amounts as an herb. But concentrated extracts sold as liquids or pills may contain the plant's chemicals in far greater amounts and may not be safe.

The "It's been used for thousands of years, so it must work" myth

Knowing that a botanical has been used in folk or traditional medicine for thousands of years is helpful, but is not convincing proof that it works or that it's safe. If small amounts of a plant caused painful or life-threatening side effects right away, it probably wouldn't have been used in

folk medicine or traditional medical systems. But traditional medical systems thousands or even hundreds of years ago did not have the scientific methods to detect long-term side effects. So, if a plant seemed useful over the short term but actually increased the risk of chronic disease (like cancer, heart failure, or kidney failure) after years of use, those side effects would not have been noticed. Also, if a patient's problem got worse after using an herb, the worsening may not have ever been linked to the treatment itself. Deaths weren't unusual; unlike today, people of all ages died of illnesses that can now be prevented, treated, or cured. Finally, in some traditional systems, herbs were given to cause vomiting or diarrhea. These effects may have been considered helpful at the time, even if the final, long-term outcome wasn't good.

It also helps to find out whether a plant used today is being used like it was traditionally. For example, tea prepared from a certain plant might have been safely used in traditional Chinese medicine to treat occasional bouts of asthma when given by an experienced practitioner. On the other hand, daily use of much higher doses taken in a concentrated pill form with no expert supervision might be quite unsafe.

As you consider ancient treatments, remember that most herbs, plants, and other methods were used in traditional medicine systems to reduce symptoms or make the person feel better. This was helpful to people who were likely to recover anyway. Still, it was understood that death was a possible outcome of most serious illnesses. It's safe to say that science and technology have helped us better understand the causes of illness today than anyone did centuries ago. Now, most people whose families once used these traditional healing methods prefer to be treated with modern medicine, if there's a proven treatment available.

The "It can't hurt to take supplements along with my regular medicines" myth

Many people assume that dietary supplements are always safe to take along with prescription drugs. This is not true. For example, certain botanicals can block or speed up the body's absorption of some prescription drugs. This can cause the person to have too much or too little of the prescribed drug in their bloodstream. Most drug companies and producers of herbal supplements do not research possible drug interactions, so the risks of taking supplements with other drugs are largely unknown.

Talk with your health care team about any supplements you are taking or wish to take. Your doctor or pharmacist can tell you about any known interactions with medicines you may be taking. Keep in mind that with new drugs and supplements, interactions may not be known.

"The FDA wouldn't let them make that claim if it wasn't true" myth, and the "If it could hurt you they wouldn't be allowed to sell it" myth

Because of the way dietary supplements are regulated, the FDA (US Food and Drug Administration) cannot check every claim made about a supplement. And, safety is up to the manufacturer. The FDA is allowed to step in only if they are aware of a problem. This is discussed in more detail below.

FDA regulation of drugs versus dietary supplements

All prescription and non-prescription drugs are regulated in the United States by the Food and Drug Administration (FDA). But dietary supplements are treated more like special foods.

Because supplements aren't considered drugs, they aren't put through the same strict safety and effectiveness requirements that drugs are. So all the drugs you can buy, even without a prescription, must be proven safe and effective – but dietary supplements do not.

Drugs are considered unsafe until proven safe

In general, the FDA considers new drugs to be unsafe until they are proven safe through clinical trials. And the FDA must approve any new drug before it can be legally sold in the US. Clinical trials are studies done under well-controlled conditions on human volunteers. These tests must be done on all drugs – even those that are sold over the counter (without a prescription). The FDA approval process requires that the drug be proven in a series of clinical trials. These studies must show "substantial evidence" that the drug is both safe and effective for each of its intended uses. (See our document *Clinical Trials: What You Need to Know* for more on this process.)

Once the FDA approves the drug, it must be manufactured under carefully monitored conditions and packaged with complete information on the best dose, route, and schedule. The package information must also include:

- Conditions the drug has been proven to treat
- Known side effects
- Contraindications (special conditions under which using the drug should not be used because it would cause too much risk)
- Unsafe interactions with other drugs

Once the general public is using a new drug, the FDA follows up on any ill effects patients and their doctors report (see "How to report adverse reactions" in the section "Guidelines for choosing dietary supplements safely"). The drug company is required to file information they get about side effects as well. This data helps ensure that any side effects not seen in the clinical trials will eventually be found and tracked for the safety of other people.

While counterfeit medicines are sometimes made and circulated, they don't usually get into wide circulation unless they're being distributed outside of the usual channels (such as from undocumented internet pharmacies). This is because drugs are typically seen by doctors, pharmacists, and nurses. When counterfeit drugs do make it into the system, health professionals often notice the differences in response between the real and fake drugs so that they are caught quickly. The FDA takes quick action when these problems are found.

Dietary supplements are considered safe until proven unsafe

In 1994, the Dietary Supplement Health and Education Act (DSHEA) defined dietary supplements as a category of food, which put them under different regulations than drugs. They are considered safe until proven otherwise. The DSHEA says that dietary supplements cannot contain anything

that may have "a significant or unreasonable risk of illness or injury" when the supplement is used as directed on the label, or with normal use if there are no directions on the label.

A dietary supplement is considered "new" if it contains an ingredient not recognized as a food substance, unless it was sold as a supplement before October 1994. If it is new, the manufacturer must provide the FDA with reasonable evidence that the new ingredient is safe before the supplement is marketed to the public.

But manufacturers are not required to test new ingredients or supplements in clinical trials, which would help find risks and potential interactions with drugs or other substances. The DSHEA gives the FDA permission to stop a company from making a dietary supplement, but only when the FDA proves that the product poses a significant risk to the health of Americans. This means they are found unsafe only *after* they cause harm. This is the reverse of the way prescription and non-prescription drugs are handled.

Dietary supplements are usually self-prescribed, so there's no controlled system for reporting bad reactions and side effects. Doctors and patients can report problems, but are not required to do so. If a supplement has unknown side effects or interactions with other drugs, foods, or supplements, they are not likely to be discovered as quickly as those of new drugs on the market.

What kinds of problems have there been with supplements and herbs?

Many dietary supplements have clean safety histories. For instance, millions of people take multivitamins safely and have no ill effects. Many manufacturers are very careful with their claims, labeling, and the ingredients they use in their products.

But since they became widely available in 1994, the FDA and some independent researchers have found problems with some dietary supplements. Products like herbs were sometimes tainted with germs, pesticides, or toxic heavy metals. Other supplements did not contain what was listed on the label. Still others contained more or less than the amount listed on the label.

This problem extends beyond the supplement makers and sellers. Some herbal suppliers (those who grow, harvest, or sell the crops) may mix or even substitute their crops with less expensive or more readily available plants. There's also the problem of accidental contamination, when one plant grows in with others, as well as cases of mistaken identity (when one plant looks like another). Given the global market, all of these problems can make it harder for a company to be sure that what they thought they were buying to make supplements is actually the herb they wanted.

In 2013 researchers in Toronto published a report in which they sampled and analyzed 44 supplements. The supplements were sold in both the US and Canada, and labeled as containing single herbs. Using DNA bar coding analysis, less than half the supplements (48%) contained any of the herb listed on the label. More than half of the supplements contained something that wasn't on the label (substitutions or fillers). Only 2 of the 44 samples contained only the herb listed on the label, without fillers or contaminants.

A more recent trend is extra ingredients in supplements. Some "herbal" supplements have been found to contain prescription drugs or other compounds that are not listed on their labels. For example, some supplement ads are targeted to men as "enhancers" or muscle builders. Certain of these so-called "supplements" have been found to contain substances much like Viagra[®] or

Cialis[®], and have been recalled. "Prostate health" supplements have been found to contain terazosin, a prescription drug used to treat the symptoms of an enlarged prostate. Other ads target women and tout the supplement as an aid to weight loss. Some of these "weight loss supplements" contained the weight loss drug sibutramine, which was banned in the United States because of the risk of heart attack and stroke. The supplement makers recall these only after they have been found to have these illegal additives. Then the FDA can seize these drugs and prosecute the companies who make them.

There are also times that new ingredients with little-known effects are slipped into supplements. In one situation, supplements were labeled as being made from geranium but turned out to contain the stimulant drug dimethylamylamine (DMAA). This type of supplement was sold as a "natural stimulant," but it contained DMAA, a man-made drug. The DMAA-containing supplements were exposed after some serious events, including several deaths, leading the FDA to send warning letters to US manufacturers in 2013.

These kinds of extras can cause serious health issues for people who take the supplement. There are also risks of mystery drug interactions because the person doesn't know that he or she is taking a drug.

Despite all these issues, the FDA is not legally responsible for the safety of dietary supplements; the manufacturers are. The manufacturers are also responsible for what's in them, and being sure the contents are the same from one pill or package to another. The FDA only looks into reported problems or safety hazards. To find out more about what's in a supplement, the manufacturer is your first contact.

To avoid tainted supplements, **don't** buy any of these:

- Products that claim to work like prescription drugs
- Products that are advertised through mass e-mails
- Products marketed mainly in a foreign language
- Products that promise weight loss, body-building, or enhanced sexual performance
- Products that say they are a legal alternative to anabolic steroids

Manufacturing guidelines for dietary supplements

It is the manufacturer's responsibility to see that the supplements they prepare are standardized, quality products that match the descriptions on their labels. Many manufacturers have always followed careful, consistent standards and sell only high-quality, correctly labeled supplements. But less honest manufacturers, or those who are less careful, make supplements that contain little or none of the products listed on the label. Some supplements even contain a larger dose than the label lists, possibly due to poor quality controls. There have been reported cases of toxic products, too.

Guidelines put out by the Department of Health and Human Services cover all supplement makers as of 2010. With these rules, it's more likely that supplements from careful manufacturers contain what the label says they do. But it's important to know that, even though these rules are in effect, many supplements are still found to be tainted with real drugs or dangerous substances – not all manufacturers follow the rules.

How the rules affect herbs and supplements

The DHHS guidelines require that dietary supplements follow standards called *Good Manufacturing Practices*, or GMPs. This means that dietary supplements must:

- Be produced in a quality manner
- Not contain any contaminants or impurities
- Be labeled with the ingredients that are actually in the product

The companies still sell their products the same way they did before. But if companies are following the 2010 guidelines, the supplements will be more likely to contain what's listed on the label. These guidelines also address the quality of manufacturing processes for dietary supplements and the accurate listing of their ingredients on the label.

It's also important to know what the guidelines do **not** do:

- They do not limit consumers' access to dietary supplements.
- They do not address the safety of the supplements' ingredients.
- They do not address the supplements' effects on the body as long as good manufacturing processes are used.

Even so, the improvements in quality and label accuracy should make supplements less likely to cause harm when companies follow these rules.

Also remember that, like all laws, the DHHS guidelines will not stop dishonest or criminal sellers from selling supplements with false labels. You'll still hear about products that are sold as herbs or "all natural" compounds, but are tainted with drugs or other harmful substances. While it's up to the FDA (US Food and Drug Administration) and other law enforcement groups to stop criminal manufacturers once they have been discovered, it falls to the consumer to gather truthful information about these products.

See our document called *Complementary and Alternative Methods and Cancer* for more information on quackery and fraud.

USP or NF quality standards used by many companies

The US Pharmacopeia (USP) is an independent organization dedicated to quality control for the strength, quality, and purity of pharmaceuticals. The USP began publishing standards for dietary supplements in 1997. These standards focus on the strength, quality, purity, packaging, and labeling of dietary supplements. They are updated yearly. The USP also does product testing and site visits for companies who join their program.

Makers of dietary supplements are not required by law to follow USP standards, but many of them have chosen to do so. You can still look for products that use USP standards. The label may have the initials USP after the name of the product, or it may say that the product conforms to USP standards. Some companies have the initials NF (National Formulary) on their labels. NF is paired with USP, and has standards that more specifically relate to herbs and botanicals.

Supplement makers are all supposed to follow FDA rules (discussed above in the section called "Dietary supplements are considered safe until proven unsafe"), but the USP or NF initials indicate that they choose to follow even higher quality standards.

Understanding the claims on dietary supplement labels

Before you buy a supplement, read the label carefully (including label claims, packaging, ingredients, and directions for use). It's easy to misread the claims that are being made about products. The makers of dietary supplements are allowed to make 4 kinds of claims on the labels of their products. These claims are explained below.

Nutritional claims: These are statements about the general effects dietary supplements, vitamins, and minerals have on diseases known to be caused by nutrient deficiency. For example, "vitamin C prevents scurvy." These claims do not need to be approved by the FDA (US Food and Drug Administration). But the label must also state how many cases of the disease occur in the United States. In this example, consumers must weigh the risk of getting scurvy (which is fairly rare in the US) against the potential risks of the supplement itself.

Claims of well being: These are just that – statements such as "makes you feel better." These claims do not require pre-approval by the FDA. (See our documents called *Complementary and Alternative Methods and Cancer* and *Placebo Effect* for more information on these kinds of claims and the effects that supplements and other substances sometimes have.)

Health claims: These are statements about known health benefits of certain compounds. For example, risk-reduction claims such as "folate may reduce the chance of pregnant women delivering an infant with neural tube defects" fall into this category. The FDA must pre-approve all health claims, and requires that they be supported by evidence from scientific studies. Remember that risk-reduction claims are not the same as prevention claims.

Structure or function claims: These are the most confusing claims made to consumers. They are claims about the effect of the dietary supplement on the structure or function of the body. The FDA published a ruling in January 2000 that explained exactly what kinds of structure or function claims were OK for dietary supplements.

Dietary supplements may not make any claims regarding the treatment of disease. But the following descriptions and examples are considered structure or function claims that are OK for dietary supplements:

- The product's mechanism of action ("works as an antioxidant")
- The product's effects on cellular structure ("helps membrane stability")
- The product's effects on the body's physiology ("promotes normal urinary flow")
- The product's effects on chemical or lab test results ("supports normal blood glucose")
- Claims of maintenance ("helps maintain a healthy circulatory system")
- Other non-disease claims ("helps you relax")

• Claims for common conditions and symptoms related to life stages ("reduces irritability, bloating, and cramping associated with premenstrual syndrome")

Structure or function claims are not reviewed by the FDA. In fact, labels that carry them must also include the disclaimer "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."

The FDA requires this disclaimer on supplement labels because it's easy for consumers to misunderstand structure or function claims. For example, many consumers believe that a statement such as "helps maintain vision acuity" means the product has been proven to prevent vision loss, or that a statement like "helps maintain a healthy prostate gland" means the product has been proven to prevent or treat diseases like prostate cancer. This is not the case.

Don't assume that because a product claims to support or promote healthy body function that it prevents or reduces the risk of any disease, including cancer. Unlike drugs, supplements are not intended to treat, diagnose, prevent, or cure diseases. This means supplements should **not** make claims, such as "reduces arthritic pain" or "treats heart disease." Claims like these can only be made for drugs that have been proven to do what they claim.

Products that are proven to have a significant effect on any disease are considered drugs by the FDA and are strictly regulated.

Choosing and using dietary supplements safely

- Investigate before you buy or use. There are many resources in libraries and online. Look past the information that comes from the makers of the products, which can be biased or wrong. Find materials from reliable third parties, such as researchers or government agencies. (See the "To learn more" section for some places to start.)
- Check with your doctor or other health care providers before you try a supplement. While your
 doctor might not know about all the products available, he or she may be able to keep you from
 making a dangerous mistake.
- If you are shopping for a botanical (herb or other plant-based supplement), find a product that uses only the part of the plant that's thought to be helpful. Avoid botanicals that have been made using the entire plant, unless the entire plant is recommended.
- Does the label provide a way to contact the company if you have questions or concerns about their product? Reputable manufacturers will give contact information on the label or packaging of their products.
- Avoid products that claim to be "miracle cures," "breakthroughs," or "new discoveries," as well as those that claim to have benefits but no side effects, or are based on a "secret ingredient" or method. Such claims are almost always fraudulent, and the product may contain harmful substances, drugs, or contaminants.
- Try to avoid mixtures of many different supplements. The more ingredients, the greater the chances of harmful effects. Mixtures also make it harder to know which substance is causing any side effects.

- Start only one product at a time. Take note of any side effects you have while taking the product. If you have a rash, sleeplessness, restlessness, anxiety, nausea, vomiting, diarrhea, constipation, or severe headache, stop talking the supplement. Report any reaction to your doctor, and serious ones to the FDA (US Food and Drug Administration). (See the section "How to report serious reactions.")
- If you have any surgery or procedure planned, including dental surgery, talk with your surgeon about when you should stop taking supplements. Some supplements need 2 to 3 weeks to completely leave your body, and a few can cause serious problems during or after an operation.
- During pregnancy or if you are breastfeeding, take only dietary supplements prescribed or approved by your doctor. Few, if any, of these products have been studied for safety; and their effects on a growing fetus or infant are largely unknown.
- Do not take any self-prescribed remedy instead of the medicine prescribed by your doctor without talking about it with your doctor first.
- Do not depend on any non-prescription product to cure cancer or any other serious disease. No matter what the claim, if it sounds too good to be true, it probably is.
- Follow the dosage limits on the label. Overdoses can be deadly. Do not take a dietary supplement for any longer than recommended.
- Never give a supplement to a baby or a child under the age of 18 without talking to the child's doctor. A child processes nutrients and drugs differently from an adult, and the effects of many products in children are not known.
- Avoid products that claim to treat a wide variety of unrelated illnesses. If a supplement claims that it can diagnose, treat, cure, or prevent disease, such as "cures cancer," or "stops tumor growth," the product is being sold illegally as a drug.

Be aware

Know the ingredients in the herbal medicines and dietary supplements you take. To help protect consumers, the FDA recommends that people using these products consider these suggestions:

- Look for supplements with the USP or NF on the label. This indicates that the manufacturer of the product followed standards set by the US Pharmacopoeia in making the product.
- Realize that the use of the term "natural" on an herbal product is no guarantee that the product is safe. Poison mushrooms, for example, are natural but not safe.
- Take into account the name and reputation of the manufacturer or distributor. Herbal products and other dietary supplements made by nationally known food or drug manufacturers are more likely to have been made under tight quality controls because these companies have a reputation to uphold.

If you need more information about the supplement, contact the manufacturer. Ask about the company's manufacturing practices and the quality-control conditions under which the product was grown and/or made.

How to report serious reactions

If you or someone in your family suffers serious harm or illness (called an *adverse event*) due to a supplement, first call your doctor or other health care provider. The FDA considers an adverse event serious if it causes any of these:

- Death
- A life-threatening situation
- Admission to a hospital or a longer-than-expected hospital stay
- Permanent disability
- A birth defect
- The need for medical or surgical care to prevent permanent impairment or damage

After you have been treated, you or your doctor can report the adverse reaction to the FDA by calling 1-800-FDA-1088 (1-800-332-1088). Or you can go to the FDA's MedWatch website at www.fda.gov/medwatch/report/consumer/consumer.htm.

When you talk to the FDA, you will need to tell them:

- The name and telephone number of the person who got sick or had the problem. If that person cannot be reached, the FDA will need the name and number of another person who can give more information if needed
- A description of the problem and how it was addressed
- The name (including the brand or manufacturer) of the product

Along with the basic information above, you will be asked about the age, weight, and sex of the person who had the problem. The FDA staff will ask when and how much of the supplement was taken, and for how long. They will want to know where and when the product was purchased, lot number, and expiration date if available. This information is generally not needed, but if you can get it, it can help them follow up on the problem.

After you make a report to the FDA, you should notify the manufacturer of the product (listed on the label) and the store, seller, or Internet vendor where you bought the product.

To learn more

More information from your American Cancer Society

We have selected some related information that may also be helpful to you. These materials may be ordered from our toll-free number, 1-800-227-2345, or read on our website, www.cancer.org.

Complementary and Alternative Methods and Cancer

Placebo Effect

Learning About New Cancer Treatments

Learning About New Cancer Prevention Methods

American Cancer Society Operational Statement on Complementary and Alternative Methods of Cancer Management

Clinical Trials: What You Need to Know

Along with the above, information on many different types of complementary and alternative treatments are available at no cost to you from the American Cancer Society. You can find it in the "Complementary and Alternative Medicine" section of our website or request it by calling our toll-free number, 1-800-227-2345.

Your American Cancer Society also has books that you might find helpful. Call us at 1-800-227-2345 or visit our bookstore online at cancer.org/bookstore to find out about costs or to place an order.

National organizations and websites*

Along with the American Cancer Society, other sources of information and support include:

National Institutes of Health Office of Dietary Supplements

Telephone: 301-435-2920

Website: http://ods.od.nih.gov/HealthInformation/

Excellent information about wise supplement use and detailed fact sheets about individual vitamins and supplements. Also has an app you can use to keep up with supplements on your smart phone; choose My Dietary Supplements Mobile App on the left menu bar.

US Food and Drug Administration

Toll-free number: 1-888-INFO-FDA (1-888-463-6332)

Website: www.fda.gov

Information about labels, rules, regulations, and more about dietary supplements as well as tips for spotting frauds and scams

US Department of Agriculture, Food and Nutrition Information Center

Telephone: 301-504-5414 Website: http://fnic.nal.usda.gov

Choose "Dietary Supplements" from the left menu bar for info on nutrients, botanicals, herbs, and access to the International Bibliographic Information on Dietary Supplements (IBIDS) database

Memorial Sloan Kettering Cancer Center

About Herbs and Botanicals

Website: www.mskcc.org/cancer-care/integrative-medicine/about-herbs-botanicals-other-products

Provides evidence-based information about herbs, botanicals, supplements, and more, for consumers and health care professionals

MedWatch

Toll-free number: 1-800-FDA-1088 (1-800-332-1088)

Website: www.fda.gov/Safety/MedWatch/

Choose "Consumer-Friendly Reporting Form" if you wish to report an adverse event; or you can call them to report any ill effects

US Pharmacopeia (USP)

Toll-free number: 1-800-227-8772

Website: www.usp.org

More about USP and NF, and their standards

National Council Against Health Fraud

Website: www.ncahf.org

Offers information on health myths, fraud, and quackery as public health problems, using the principles of science to help consumers avoid scams

No matter who you are, we can help. Contact us anytime, day or night, for information and support. Call us at **1-800-227-2345** or visit www.cancer.org.

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^{*}Inclusion on this list does not imply endorsement by the American Cancer Society.

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Last Medical Review: 11/22/2013 Last Revised: 11/22/2013

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