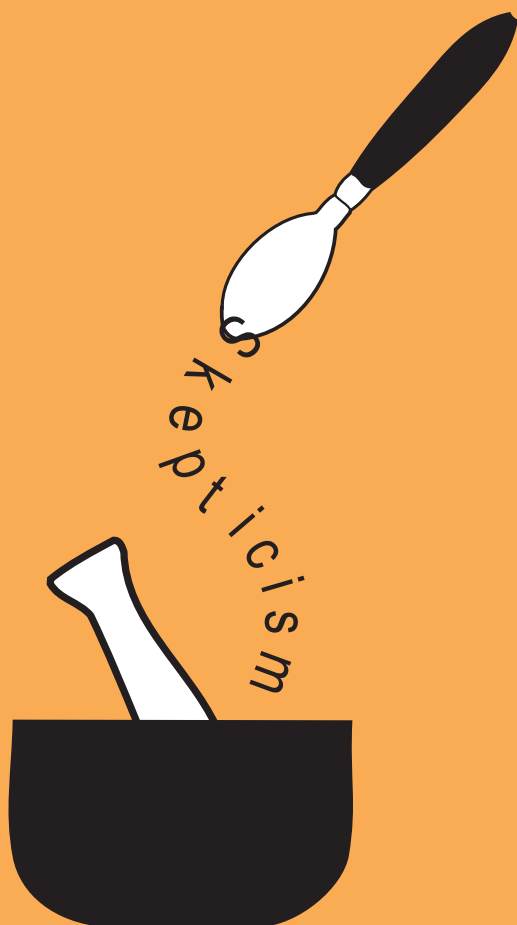


FTC FACTS for Consumers

ftc.gov
FOR THE CONSUMER

FEDERAL TRADE COMMISSION
1-877-FTC-HELP

‘Miracle’ Health Claims: Add a Dose of Skepticism



Produced in cooperation with the Food and Drug Administration

Whether they're looking for a short cut to losing weight or a cure for a serious ailment, consumers may be spending billions of dollars a year on unproven, fraudulently marketed, often useless health-related products, devices and treatments. Why? Because health fraud trades on false hope. It promises quick cures and easy solutions to a variety of problems, from obesity to cancer and AIDS. But consumers who fall for fraudulent "cure-all" products don't find help or better health. Instead, they find themselves cheated out of their money, their time, and maybe even their health. Fraudulently marketed health products can keep people from seeking and getting treatment from their own healthcare professional. Some products can cause serious harm, and many are expensive because health insurance rarely covers unapproved treatments.

To avoid becoming victims of health fraud, it's important for consumers to learn how to assess health claims and seek the advice of a health professional.



Common Health Fraud Targets

Officials at the Federal Trade Commission (FTC) and the Food and Drug Administration (FDA) say health fraud promoters often target people who are overweight or have serious conditions for which there are no cures, including multiple sclerosis, diabetes, Alzheimer's disease, cancer, HIV and AIDS, and arthritis.

Cancer

A diagnosis of cancer can bring feelings of fear and hopelessness. Many people may be tempted to turn to unproven remedies promoted as cancer cures. But they and their loved ones should be skeptical of "miracle" claims because no single device, remedy or treatment can treat all types of cancer. Cancer is a name given to a wide range of diseases; each requires different forms of treatment that are best determined with the advice of a health professional.

Cancer patients who want to try an experimental treatment should enroll in a legitimate clinical study. The FDA reviews clinical study designs to help ensure that patients are not subjected to unreasonable risks.

For more information about cancer treatments, contact the American Cancer Society; the nearest local chapter will be listed in the yellow pages of your phone book. For free publications on cancer research and treatment, call the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) or log on to <http://cancernet.nci.nih.gov>.

HIV and AIDS

Although legitimate treatments can extend life and improve the quality of life for people with AIDS, there is, so far, no cure for the disease. People diagnosed with HIV, the virus that causes AIDS, may want to try untested drugs or treatments. But trying unproven products or treatments, such as electrical and magnetic devices and so-called herbal cures, can be dangerous and may cause HIV-positive individuals to delay seeking medical care.

An example is the herb St. John's Wort, which has been promoted as a safe treatment for HIV. There is no evidence that this herb is effective in treating HIV, and in fact, studies have shown that it interferes with medicines prescribed for HIV.

People who think they may be HIV-positive may turn to home test kits. But claims for these products may be misleading and possibly harmful. Safe, reliable HIV testing can be done only through a medical professional or a clinic, or through the Home Access Express HIV-1 Test System; it is the only system approved for home use by the FDA.

The U.S. government has a toll-free HIV-AIDS Treatment Information Service, 1-800-HIV-0440 (1-800-448-0440), which is staffed by English- and Spanish-speaking health information specialists. Information also is available at www.hivatis.org.

Arthritis

Consumers spend an estimated \$2 billion a year on unproven arthritis remedies — thousands of dietary and so-called natural cures, like mussel extract, desiccated liver pills, shark cartilage, CMO (cetylmyristoleate),

honey and vinegar mixtures, and magnets and copper bracelets. But these remedies are not backed by adequate science to show that they offer long-term relief. For current, accurate information on arthritis treatments and alternative therapies, call the Arthritis Foundation at 1-800-283-7000 or visit its website at www.arthritis.org.

Assessing Claims for Dietary Supplements

The array of dietary supplements — vitamins and minerals, amino acids, enzymes, herbs, animal extracts and others — has grown tremendously over the years. Although the benefits of some of these products have been documented, the advantages of others are unproven.

For example, claims that a supplement allows you to eat all you want and lose weight effortlessly are false. To lose weight, you must lower your calorie intake or burn more calories — for example, by increasing exercise. Most medical experts recommend doing both.

Similarly, no supplement can cure arthritis or cancer in five days. Such claims are false. Consumers should be wary of any claims for a dietary supplement that say it can shrink tumors, cure insomnia, cure impotency, treat Alzheimer's disease, or prevent severe memory loss. These kinds of claims deal with the treatment of diseases, and companies that want to make such claims must follow the FDA's pre-market testing and review process required for new drugs.

FDA Regulation of Health Claims

Federal law allows for certain claims to be made in the labeling of food and supplements. These include claims approved by the Food and Drug Administration that show a strong link, based on scientific evidence, between a food substance and a disease or health condition. These approved claims can state only that a food substance *reduces the risk* of certain health problems — not that it can *treat or cure* a disease. Two examples of *approved* claims are: “The vitamin folic acid may reduce the risk of neural tube defect-affected pregnancies,” and “Calcium may reduce the risk of the bone disease osteoporosis.”

Dietary supplements also may carry claims in their labeling that describe the effect of a substance in maintaining the body’s normal structure or function, as long as the claims don’t imply the product treats or cures a disease. The FDA does not review or authorize these claims. An example of such a claim is, “Product B promotes healthy joints and bones.” When a dietary supplement is promoted with a claim like this, the claim must be accompanied with 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 disease.”

To learn more about the kinds of labeling claims that can be made for foods and dietary supplements, see www.cfsan.fda.gov/~dms/hclaims.html.

Safety Concerns

Prescription drugs must undergo clinical testing and receive the FDA's full review for safety and effectiveness before they are sold. Over-the-counter medicines are subject to the OTC drug review process, which determines safety and effectiveness of the products. Dietary supplements are not required to undergo government testing or review before they are marketed. Yet, supplements may have drug-like effects that could present risks for people on certain medicines or with certain medical conditions. This is true, even if the product is marketed as "natural." For example, St. John's Wort can have potentially dangerous interactions with a number of prescription drugs, including anticoagulants, oral contraceptives, antidepressants, antiseizure medicines, drugs for HIV, and drugs to prevent transplant rejection.

If you take a prescription medicine, always consult your healthcare professional before starting a dietary supplement.

Some dietary supplement substances require further scrutiny and study before they can be considered safe for all people. Though many supplements have a history of use, that history does not necessarily guarantee safety in every circumstance.

Some substances for which safety concerns have been raised are comfrey, chaparral, lobelia, germander, aristolochia, ephedra (ma huang), L-tryptophan, germanium, magnolia-stephania and stimulant laxative ingredients, such as those found in dieter's teas. The herb comfrey, for example, contains certain alkaloids that can cause serious liver damage. Consumers should not take any product containing comfrey either orally or as

a suppository and should not apply comfrey products to broken skin.

Even some vitamins and minerals, when consumed in excessive quantities, can cause problems. For example, high intakes of vitamin A over a long period can reduce bone mineral density, cause birth defects and lead to liver damage, according to the National Academy of Sciences.

To ensure the safe use of any healthcare product, read the labels and package inserts, follow product directions and check with your healthcare professional.

How to Spot False Claims

When evaluating health-related claims, be skeptical. If something sounds too good to be true, it usually is. Here are some signs of a fraudulent claim:

- Statements that the product is a quick and effective cure-all or diagnostic tool for a wide variety of ailments. For example: “Extremely beneficial in the treatment of rheumatism, arthritis, infections, prostate problems, ulcers, cancer, heart trouble, hardening of the arteries and more.”
- Statements that suggest the product can treat or cure diseases. For example: “shrinks tumors” or “cures impotency.”
- Promotions that use words like “scientific breakthrough,” “miraculous cure,” “exclusive product,” “secret ingredient” or “ancient remedy.” For example: “A revolutionary innovation formulated by using proven principles of natural health-based medical science.”
- Text that uses impressive-sounding terms like these for a weight-loss product: “hunger stimulation point” and “thermogenesis.”

- Undocumented case histories or personal testimonials by consumers or doctors claiming amazing results. For example: “My husband has Alzheimer[‘s disease]. He began eating a teaspoonful of this product each day. And now in just 22 days he mowed the grass, cleaned out the garage, weeded the flower beds and we take our morning walk again.”
- Limited availability and advance payment requirements. For example: “Hurry. This offer will not last. Send us a check now to reserve your supply.”
- Promises of no-risk “money-back guarantees.” For example: “If after 30 days you have not lost at least 4 pounds each week, your uncashed check will be returned to you.”

Avoiding Unscrupulous Dealers

It’s easy to see why some people can be taken in by promoters’ promises, especially when successful treatments have been elusive. But resist pressure to decide “on the spot” about trying an untested product or treatment. Ask for more information and consult a knowledgeable doctor, pharmacist or other healthcare professional. Promoters of legitimate healthcare products do not object to your seeking additional information.

To learn whether the FDA or the FTC have taken action against the promoter of a product you may be considering, visit www.fda.gov/oc/enforcement.html or www.ftc.gov. Visit www.cfsan.fda.gov/~dms/ds-warn.html for a list of the dietary supplement ingredients for which the FDA has issued warnings.

In addition, if you’re considering a clinic that requires you to travel and stay far from home for treatment, check it out with your doctor. Although some clinics

offer effective treatments, others prescribe untested, unapproved, ineffective, and possibly dangerous “cures.” In addition, the healthcare providers who work in these clinics may be unlicensed or lack other appropriate credentials.

For information about a particular hospital, clinic or treatment center, contact the state or local health authorities where the facility is located. If the facility is in a foreign country, contact that government’s health authority to see that the facility is properly licensed and equipped to handle the procedures involved. For information about facilities in Mexico, contact the Secretary of Health (Secretaria De Salud) in the Mexican state where the facility is located.

Online Resources

Virtual Health “Treatments”

www.ftc.gov/cureall

Offers tips on avoiding health fraud online.

Dietary Supplements

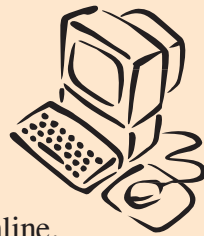
www.cfsan.fda.gov/~dms/supplmnt.html

Offers an overview of dietary supplement regulation, including safety and warning information.

Buying Medicines and Medical Products Online

www.fda.gov/oc/buyonline/default.htm

Offers tips and precautions for buying medical products online.



How to Report a Potential Problem

To report a health product that you believe is being advertised falsely, contact:

- the FTC by phone, toll-free, at 1-877-FTC-HELP (1-877-382-4357); TDD: 202-326-2502; by mail to Consumer Response Center, Federal Trade Commission, Washington, DC 20580; or online at www.ftc.gov. Click on “File a Complaint Online.”
- your state Attorney General’s office, state department of health, or local consumer protection agency. These offices are listed in the blue pages of your telephone book.

To report a product that you believe is fraudulently labeled, call your local FDA office. The number is listed in the blue pages of the telephone book.

To report an adverse reaction or illness that you think is related to the use of a supplement or other healthcare product, call a doctor or other healthcare provider immediately. You also may want to report your reaction or illness to FDA MedWatch. Call 1-800-FDA-1088 (1-800-332-1088) to request a report form, or file a complaint online at www.fda.gov/medwatch/report/hcp.htm. Patients’ names are kept confidential. For more information on how to report a problem to FDA, see www.fda.gov/opacom/backgrounders/problem.html.

Federal Trade Commission

1-877-FTC-HELP (1-877-382-4357)

www.ftc.gov

The FTC works for the consumer to prevent fraudulent, deceptive, and unfair business practices in the marketplace and to provide information to help consumers spot, stop, and avoid them. To file a complaint or to get free information on consumer issues, visit ftc.gov or call toll-free, 1-877-FTC-HELP (1-877-382-4357); TTY: 1-866-653-4261. The FTC enters Internet, telemarketing, identity theft, and other fraud-related complaints into Consumer Sentinel, a secure, online database available to hundreds of civil and criminal law enforcement agencies in the U.S. and abroad.

Food and Drug Administration

1-888-INFO-FDA (1-888-463-6332)

www.fda.gov

The FDA regulates over \$1 trillion worth of products, which account for 25 cents of every dollar spent annually by American consumers. It is part of FDA's job to see that the food we eat is safe and wholesome and that the medicines and medical devices we use are safe and effective. For more information, call toll-free, 1-888-INFO-FDA (1-888-463-6332), or visit the FDA website, www.fda.gov.



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