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HEALTH PRODUCTS FOR SENIORS

Potential Harm From "Anti-Aging" Products

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Mr. Chairman and Members of the Committee:

I am pleased to have the opportunity to testify as the Committee considers "anti-aging" and alternative medicine products marketed to America's senior citizens. Today we are releasing a report that summarizes the risks associated with such products and reviews federal and state oversight activities in this area.[1]

Anti-aging and alternative medicine products are popular among consumers. Surveys have found that as many as 40 percent of senior citizens have used dietary supplements in the past year and that approximately 10 percent of seniors use them regularly. These supplements include herbal or botanical dietary supplements, such as ginkgo biloba, ginseng, and St. John's wort, as well as specialty supplements, such as glucosamine, fish oil, and melatonin. Some of these products show potential health benefits. For example, some studies have suggested that St. John's wort may counteract feelings of mild to moderate depression and that gingko biloba may improve cognitive performance in dementia. However, regulators and medical experts are concerned that some products have health risks and some are marketed to seniors with anti-aging and "cure-all" claims for which there is little scientific evidence of either safety or effectiveness. There is also concern that seniors may be wasting money on products that have little or no therapeutic value.

Because of these concerns, you asked us to look at dietary supplements and devices that are marketed for health conditions that affect older adults. I will summarize the key findings of our report, in which we (1) describe the potential physical harm associated with some anti-aging and alternative medicine products, (2) describe the economic harm associated with questionable anti-aging and alternative medicine products, and (3) examine federal and state oversight efforts designed to protect consumers from questionable anti-aging and alternative medicine products.

In summary, dietary supplements marketed as anti-aging therapies may pose a potential for physical harm to senior citizens. Evidence from the medical literature shows that a variety of frequently used dietary supplements can have serious health consequences for seniors. Particularly risky are products that may be used by seniors who have

[1] *Health Products for Seniors: "Anti-Aging" Products Pose Potential for Physical and Economic Harm* (GAO-01-1129, Sept. 7, 2001).

underlying diseases or health conditions that make the use of the product medically inadvisable or supplements that interact with medications that are being taken concurrently. Further, studies have found that products sometimes contain harmful contaminants or much more of an active ingredient than is indicated on the label. The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have received reports of adverse events experienced by seniors taking dietary supplements in recent years. FDA has issued warnings to consumers and industry about the health risks of several dietary supplement products.

Unproven anti-aging and alternative medicine products also pose a risk of economic harm to seniors. Although we were unable to find any recent, reliable estimates of the overall economic harm to seniors from these products, we did uncover several examples that illustrate the risk of economic harm. FDA and the Federal Trade Commission (FTC) have identified a number of products that make advertising or labeling claims with insufficient substantiation, some costing consumers hundreds or thousands of dollars apiece. A recent review of cases prepared for us by FTC estimated that, for 20 companies marketing products to seniors that have been the subject of law enforcement activities, the average economic harm to consumers as a whole was about $1.8 million per company. In addition, tests of selected dietary supplements have found that some contain little or none of the active ingredient claimed on the label, rendering these products virtually worthless.

The potential for harm to senior citizens from health products making questionable claims has been a concern for public health and law enforcement officials, and federal and state agencies have activities under way to protect consumers of these products. FDA and FTC sponsor programs and provide educational materials for senior citizens to help them avoid health fraud. The National Institutes of Health (NIH) has an expanding research agenda to evaluate popular alternative therapies. FDA has taken various enforcement actions against firms that have violated laws regarding the marketing and sales of anti-aging and alternative products, including products that were being marketed as dietary supplements but which are drugs. However, FDA has not prohibited the marketing of any specific substances using its rulemaking authority. Further, FDA's voluntary adverse event reporting system for dietary supplements has shortcomings, and proposed regulations to establish standards for good manufacturing practices, which could provide FDA with additional authority to regulate facilities that manufacture, distribute, and store dietary supplement products, have not yet been issued. Recently,

FTC and FDA have combined efforts in an ongoing Internet-based initiative known as "Operation Cure.All," which targets companies that make unsubstantiated advertising and labeling claims for dietary supplements and other health products. At the state level, agencies are working to protect consumers of health products by enforcing state consumer protection and public health laws, although anti-aging and alternative products are receiving limited attention.

Background

Since 1994, when the Dietary Supplement Health and Education Act (DSHEA) was enacted, sales of dietary supplements have soared. In 2000, total U.S. sales for herbal and specialty supplements reached $5.8 billion. Surveys have found that many older Americans use these supplements to maintain overall health, increase energy, improve memory, and prevent and treat serious illness, as well as to slow the aging process, among other purposes. Products frequently used by seniors to address aging concerns include herbal supplements such as evening primrose, ginkgo biloba, ginseng, kava kava, saw palmetto, St. John's wort, and valerian, and specialty supplements such as chondroitin, coenzyme Q10, dehydroepiandrosterone (DHEA), glucosamine, melatonin, omega-3 fatty acids (fish oil), shark cartilage, and soy proteins. (See the appendix for details regarding these substances.)

FDA, FTC, and state government agencies all have oversight responsibility for products marketed as anti-aging therapies. In general, the law permits FDA to remove from the market products under its regulatory authority that are deemed dangerous or illegally marketed. FDA's regulation of dietary supplements is governed by the Federal Food, Drug, and Cosmetic Act as amended by DSHEA in 1994. DSHEA does not require manufacturers of dietary supplements to demonstrate either safety or efficacy to FDA prior to marketing them. However, if FDA subsequently determines that a dietary supplement is unsafe, the agency can ask a court to halt its sale. For dietary supplements, the Secretary of the Department of Health and Human Services may declare the existence of an imminent hazard from a dietary supplement, after which the Secretary must initiate an administrative hearing to determine the matter, which may then be reviewed in court. DSHEA does not require dietary supplement manufacturers to register with FDA, or to identify to FDA the products they manufacture, and dietary supplement manufacturers are not required to provide the adverse event reports they receive to FDA. However, FDA does regulate nutritional and health claims made in conjunction with dietary supplements.

FTC has responsibility for ensuring that advertising for anti-aging health products and dietary supplements is truthful and can be substantiated. FTC can ask companies to remove misleading or unsubstantiated claims from their advertising, and it can seek monetary redress for conduct injurious to consumers in appropriate cases. FTC published an advertising guide for the dietary supplements industry in November 1998, which reminded the industry that advertising must be truthful and that objective product claims must be substantiated. State agencies can take action against firms that fraudulently market anti-aging and other health products.

Some Dietary Supplements May Be Risky for Senior Citizens

Health risks associated with dietary supplements come in a number of forms. First, some dietary supplements have been associated with adverse effects, some of which can be serious. Second, individuals with certain underlying medical conditions should avoid some dietary supplements. Third, some frequently used dietary supplements can have dangerous interactions with prescription or over-the-counter drugs that are being taken concurrently. Fourth, dietary supplements may contain harmful contaminants. Finally, dietary supplements may contain more active ingredient than indicated on the product label.

Research suggests that among healthy adults, most dietary supplements, when taken alone, have been associated with only rare and minor adverse effects. Other supplements are associated with more serious adverse effects. For example, research suggests that DHEA may increase the risk of breast, prostate, and endometrial cancer, and shark cartilage has been associated with thyroid hormone toxicity. Adverse event reports can also signal possible risks from dietary supplements. FDA publishes lists of dietary supplements for which evidence of harm exists.[2] In 1998, the agency published a guide to dietary supplements, which included a list of supplements associated with illnesses and injuries.[3] FDA has also issued warnings and alerts for dietary supplements and posted them to its Web site.[4] For example, the most recent alert reiterated the agency's concern,

[2]http://www.cfsan.fda.gov/~dms/ds-ill.html.

[3]P. Kurtzweil, "An FDA Guide to Dietary Supplements," *FDA Consumer* (Sept.-Oct. 1998, FDA 99-2323).

[4]http://www.cfsan.fda.gov/~dms/ds-warn.html and http://www.cfsan.fda.gov/~dms/ds-osupp.html.

first noted in 1993, that the herbal product comfrey represents a serious safety risk to consumers from liver toxicity.

Consumption of some substances has been shown to be inadvisable, or contraindicated, for persons with some preexisting medical conditions. For example, ginseng is not recommended for persons with hypoglycemia. Kava kava may worsen symptoms of Parkinson's disease. Saw palmetto is contraindicated for patients with breast cancer, and valerian should not be used by those with liver or kidney disease without first consulting a physician. A recent study also suggested that echinacea (promoted to help fight colds and flu), ephedra (promoted as an energy booster and diet aid), garlic, ginkgo biloba, ginseng, kava kava, St. John's wort, and valerian may pose particular risks to people during surgery, with complications including bleeding, cardiovascular instability, and hypoglycemia.[5]

According to a recent survey,[6] about half of seniors who use a dietary supplement do not inform their doctor. Another survey found that seniors often used dietary supplements with a prescription medication. Since seniors take more prescription medicines on average than do younger adults, the risk of drug-supplement interactions may be higher. For example, evening primrose, ginkgo biloba, ginseng, glucosamine, and St. John's wort magnify the effect of blood-thinning drugs such as warfarin or coumadin. We also identified reports suggesting that ginkgo biloba may reduce the effects of seizure medications and glucosamine may have a harmful effect on insulin resistance.

Contaminanted products can also pose significant health risks to consumers. For example, supplements have been found to be contaminated with pesticides or heavy metals, some of which are probable carcinogens and may be toxic to the liver and kidney or impair oxygen transport in the blood. One commercial laboratory found contamination in samples from echinacea, ginseng, and St. John's wort products. As much as 20 times the level of pesticides allowable by the U.S. Pharmacopeia was found in two samples of ginseng. Overall, 11 percent of the herbal products and 3 percent of the specialty supplements tested were contaminated in some way.

[5]M.K. Ang-Lee and others, "Herbal Medicines and Preoperative Care," *Journal of the American Medical Association*, Vol. 286, No. 2 (2001), pp. 208-16.

[6]D.M. Eisenberg and others, "Trends in Alternative Medicine Use in the United States, 1990-1997," *Journal of the American Medical Association*, Vol. 280, No. 18 (1998), pp. 1569-74.

Amounts of active ingredients that exceed what is indicated on a product label may increase the risk of overdose for some patients. Some scientific studies have found that there may be significantly more active ingredient in some herbal and specialty supplement products than is indicated on the label. Studies of DHEA, ephedra, feverfew (promoted as a migraine prophylaxis), ginseng, SAM-e (promoted as an antidepressant and in the treatment of symptoms associated with osteoarthritis), and St. John's wort have found that a number of products have substantially more active ingredient than indicated on the label. One study of DHEA found one brand contained 150 percent of the amount of active ingredient indicated on the label.[7] In a study of ephedra, one product was shown to have as much as 154 percent of the active ingredient indicated on the label.[8] Studies of ginseng have found some products contained more than twice as much active ingredient as indicated on the product label.

Recognizing that there are some safety risks, trade associations that represent manufacturers, suppliers, and distributors of dietary supplements have created and adopted voluntary programs to reduce the risks of potentially harmful products by standardizing manufacturing practices.

Seniors May Spend Millions of Dollars on Unproven or Poorly Manufactured Products

Some unproven anti-aging products can cost hundreds or thousands of dollars apiece. For example, rife machines, which emit light or electrical frequencies and claim to kill viruses and parasites, are frequently advertised on the Internet and can cost up to $5,000. Some herbal product packages for cancer cures can cost nearly $1,000. FTC provided us with a partial estimate of economic harm based on 20 cases involving companies that fraudulently marketed unproven health care products commonly used by seniors and for which national sales data were available. FTC estimated the average annual sales for those products at nearly $1.8 million per company.

Consumers may be purchasing products that contain much less active ingredient than indicated on the label. Results of commercial laboratory

[7]J. Parasrampuria and others, "Quality Control of Dehydroepiandrosterone Dietary Supplement Products," *Journal of the American Medical Association*, Vol. 280, No. 18 (1998), p. 1565.

[8]B.J. Gurley and others, "Content Versus Label Claims in Ephedra-Containing Dietary Supplements," *American Journal of Health-System Pharmacists*, Vol. 57 (2000), pp. 963-69.

tests and scientific studies that analyzed product contents for active ingredient levels have shown that some dietary supplement products contain far less active ingredient than labeled. For some products, analyses have found no active ingredient. Academic studies have shown similar results. In an analysis of DHEA products, nearly one-fifth contained only trace amounts or no active ingredient.[9] In analyses of garlic products, most were found to release less than 20 percent of their active ingredient.[10] One study of ginseng found that 35 percent of the products tested contained no detectable levels of an active ingredient,[11] and another found no detectable levels in 12 percent of the tested products.[12] Studies of SAM-e and St. John's wort products also found that tested samples often contained less active ingredient than indicated on the label.

Federal and State Activities Aim to Protect Seniors

Federal efforts to protect seniors from health fraud include providing educational materials on avoiding health fraud, funding research to evaluate popular anti-aging therapies, and carrying out enforcement activities against companies that have violated regulations. At the state level, agencies are working to protect consumers of health products by enforcing state consumer protection and public health laws, although anti-aging and alternative products have received limited attention.

Both FDA and FTC sponsor educational activities that focus on health fraud and seniors. For example, public affairs specialists in several FDA district offices had exhibits at senior health fairs and health conferences where they distributed educational materials on how to avoid health fraud, as well as cautionary guidance on purchasing medicines and medical products online. To help seniors discriminate between legitimate and fraudulent claims, FTC publishes a range of consumer education materials on certain frequently promoted products and services, including hearing aids and varicose vein treatments. The agency also publishes guidelines on

[9]J. Parasrampuria, "Quality Control of Dehydroepiandrosterone Dietary Supplement Products."

[10]L.D. Lawson and others, "Identification and HPLC Quantification of the Sulfides and Dialk(en)yl Thiosulfinates in Commercial Garlic Products," *Planta Medica*, Vol. 57 (1991), pp. 363-70.

[11]L.E. Liberti and A.D. Marderosian, "Evaluation of Commercial Ginseng Products," *Journal of Pharmaceutical Sciences*, Vol. 67, No. 10 (1978), pp. 1487-89.

[12]J. Cui, "What Do Commercial Ginseng Preparations Contain?" *Lancet*, Vol. 344 (1994), p. 134.

how to spot false claims and how to differentiate television shows from "infomercials."

Federal support of research on alternative therapies is provided by NIH's National Center for Complementary and Alternative Medicine (NCCAM). It has developed research programs to fund clinical trials to evaluate the safety and efficacy of some popular products and therapies for conditions such as arthritis, cardiovascular diseases, and neurological disorders. There are studies, either ongoing or planned, to examine the effects of glucosamine/chondroitin, melatonin, St. John's wort, ginkgo biloba, and others. In addition, the agency funds specialized, multidisciplinary research centers on alternative medicine in such areas as cardiovascular disease, neurological disorders, aging, and arthritis.

FDA enforcement actions taken against products that it judged to be unapproved drugs or medical devices include court cases filed to halt the distribution of laetrile products that claimed to cure cancer and to halt the sale of "Cholestin," a red yeast rice product with lovastatin that was marketed with cholesterol-lowering claims. FDA also took action to halt the marketing of the "Stimulator," a device that the manufacturer claimed would relieve pain from sciatica, swollen joints, carpal tunnel syndrome, and other chronic conditions. According to FDA officials, an estimated 800,000 of these devices were sold between 1994 and 1997, with many purchased by senior citizens.

FDA has notified some dietary supplement manufacturers that their promotional materials illegally claimed that their products cure disease. For example, some manufacturers of colloidal silver products have claimed efficacy in treating HIV and other diseases and conditions. Even though FDA banned colloidal silver products as a U.S. over-the-counter drug in September 1999, after concluding that it was not aware of any substantial scientific evidence that supported the advertised disease claims, colloidal silver products may still be marketed as dietary supplements as long as they are not promoted with claims that they treat or cure disease. FDA notified several dozen Internet-based companies making such claims that their therapeutic claims may be illegal. Despite these oversight activities, colloidal silver products claiming "natural antibiotic" properties to address numerous health conditions remain available.

FDA has not initiated any administrative rulemaking activities to remove from the market certain substances that its analysis suggests pose health risks, but has sought voluntary restrictions and attempted to warn

consumers. For example, aristolochic acid, a known potent carcinogen and nephrotoxin, is believed to be present in certain traditional herbal remedies as well as a number of dietary supplement products. Following reports of aristolochic-acid-associated renal failure cases in Europe, FDA has recently taken several steps. In May 2000, FDA issued a "letter to industry" urging leading dietary supplement trade associations to alert member companies that aristolochic acid had been reported to cause "severe nephropathy in consumers consuming dietary supplements containing aristolochic acid." In this letter, FDA concluded that any dietary supplement that contained aristolochic acids was adulterated under the law and that it was unlawful to market such a product. FDA has also announced that herbal comfrey products containing pyrrolizidine alkaloids may cause liver damage. The agency's letter to eight leading dietary supplement trade associations urged them to advise their members to stop distributing comfrey products containing pyrrolizidine alkaloids. However, even though FDA has told firms that market dietary supplements that products containing comfrey are adulterated and unlawful, some firms continue to market them, and the agency is left to identify and take action to remove them on a case-by-case basis as it becomes aware of them.

FDA can also monitor dietary supplements by conducting inspections of manufacturing facilities,[13] during which its inspectors look at sanitation, buildings and facilities, equipment, production, and process controls. However, the agency inspects less than 5 percent of facilities annually. Publication of good manufacturing practice (GMP) regulations would improve FDA's enforcement capabilities, since DSHEA provides that dietary supplements not manufactured under conditions that meet GMPs would be considered adulterated and unlawful. A proposed GMP rule has been developed and is under review by the Office of Management and Budget.

In 1997, FTC launched an effort to find companies making questionable claims for health products on the Internet, as well as in other media. This initiative, "Operation Cure.All," primarily involved conducting Web-based searches on specified dates to identify Web sites making unsubstantiated claims that use of their products would prevent, treat, or cure serious diseases and conditions. The searches were conducted with the

[13]Inspections are authorized under 21 U.S.C. 374.

participation of FDA, CDC, and some state attorneys general and other organizations.

Evaluations of "Operation Cure.All" have found that some companies have made changes in their Web advertising as a result of receiving e-mail alerts from FTC about potentially unsupported advertising claims. In 1997, an estimated 13 percent of notified companies withdrew their claims or Web site, while 10 percent made some changes. In 1998, an estimated 28 percent of companies withdrew their claims or Web site, while 10 percent made some changes. By comparison, the percentage of companies that made no changes in both years exceeded 60 percent. FTC has brought over 30 dietary supplement cases, including those from "Operation Cure.All," against companies making unsupported claims since the agency released guidelines on its approach to substantiation of advertised claims in 1998.

The states we contacted varied in their efforts to protect consumers from fraudulent or harmful health products, but in general focused little attention on anti-aging and alternative medicine products. State agencies reported that they receive relatively few complaints regarding these products. However, many officials said that consumers are being harmed in ways that are unlikely to be reported to state agencies and that misleading advertising and questionable health products are serious problems. States have identified a number of questionable health care products, services, and advertising claims that may affect older consumers.

States can protect consumers from fraudulent or harmful health products through two approaches. The first is enforcement of state consumer protection laws against false or misleading advertising. The second is through their public health authority to ensure food, drug, and medical device safety. With some exceptions, the states we contacted take action only if there is a pattern of complaints or an acute health problem associated with a particular substance or device. Seven of the fourteen states we contacted were involved to some degree in monitoring or enforcement activity, and three have ongoing efforts to review advertising, labels, or products to enforce their health and consumer protection laws.

Conclusions

The risk of harm to seniors from anti-aging and alternative health products has not been specifically identified as a top public health priority or a leading enforcement target for federal and state regulators. However, evidence demonstrates that many senior citizens use anti-aging products

and that consumers who suffer from aging-related health conditions may be at risk of physical and economic harm from some anti-aging and alternative health products, including dietary supplements, that make misleading advertising and labeling claims. The medical literature has identified products that are safe under most conditions, but can be harmful for consumers with certain health conditions. Other products, such as St. John's wort, are promising for some conditions, but are also associated with adverse interactions with some prescription medications. Senior citizens may have a higher risk of physical harm from the use of anti-aging alternative medicine products because they have a high prevalence of chronic health conditions and consume a disproportionate share of prescription medications compared to younger adults.

This concludes my prepared statement, Mr. Chairman. I will be happy to respond to any questions that you or Members of the Committee may have.

GAO Contact and Acknowledgments

For more information regarding this testimony, please call me at (202) 512-7119. Key contributors include Martin T. Gahart, Carolyn Feis Korman, Anne Montgomery, Mark Patterson, Roseanne Price, and Suzanne Rubins.

Appendix: Known Claims, Adverse Effects, Contraindications, and Interactions of Herbal and Specialty Supplements

We focused our review on those herbal and specialty supplements that a recent survey by Prevention Magazine found were most frequently used by senior citizens for conditions associated with aging. For each supplement, we have listed in table 1 the health claims frequently associated with the products, although we have not attempted to validate the merits of any of the claims. We also list adverse effects that have been associated with the supplements, conditions for which the supplements might be contraindicated, and prescription medications with which the supplements might have dangerous interactions.

Table 1: Principal Claims and Principal Known Adverse Effects, Contraindications, and Interactions of Leading Dietary Supplements Used by Seniors to Address Issues of Aging

Product	Principal claims[a]	Principal known adverse effects	Principal known contraindications[b]	Principal known interactions
Chondroitin sulfate	Alleviates joint pain associated with osteoarthritis and reduces inflammation.	Mild gastrointestinal complaints such as heartburn and nausea.		
Coenzyme Q10	Slows aging; increases energy; enhances endurance and aerobic performance; strengthens heart; lowers blood pressure; improves immune function; promotes weight loss; treats cancer, stroke, and gum diseases.	Rare, but include heartburn, nausea, stomachache, diarrhea, headache, fatigue, and skin reactions.		May interact with blood thinners.
Dehydroepi-androsterone (DHEA)	Slows aging; improves memory; stimulates libido and increases sex drive; eases symptoms of depression; boosts energy; promotes weight loss; builds muscle mass and increases strength; prevents growth and recurrence of some cancers; protects against heart disease; reduces the risk of osteoporosis; prevents diseases such as diabetes, Parkinson's, and Alzheimer's.	Increased facial hair; acne; scalp hair loss; oily skin; mood swings; aggressiveness; altered hormone profiles; liver abnormalities; menstrual cycle irregularities; increased risk of heart disease, diabetes, stroke, prostate cancer in men, and breast and endometrial cancer in women; insomnia; fatigue; low energy; headache; nervousness; deepening of the voice; irritiability; decreased levels of high-density lipoprotein (HDL) cholesterol; heart rhythm disturbances; hepatitis.	People with a hormone-related cancer (prostate, ovarian, endometrial, breast) should consult physician. Should be avoided by men with enlarged prostate.	

Product	Principal claims[a]	Principal known adverse effects	Principal known contraindications[b]	Principal known interactions
Evening primrose oil	Beneficial for victims of coronary artery disease; improves rheumatoid arthritis and other inflammatory conditions; alleviates hot flashes, pre-menstral syndrome, and breast pain associated with the menstrual cycle; improves eczema and dermatitis; aids in weight loss; prevents diabetic neuropathy; eases symptoms of schizophrenia and attention deficit/hyperactivity disorder; benefits chronic viral infections such as chronic fatigue syndrome; reduces effects of multiple sclerosis; aids high cholesterol, asthmatic cough, and upset stomach; has anticancer properties.	Gastrointestinal upset, nausea, loose stools, headache, seizure.		May increase the anticoagulant effect of drugs such as warfarin. Should not be used with anticonvulsant medication.
Garlic	Reduces serum cholesterol; thins blood; lowers blood pressure; may prevent heart disease, atherosclerosis, stroke, and hypertension; acts as antimicrobial for mild respiratory and digestive tract infections; relieves nausea.	Rare, but include mild gastrointestinal symptoms such as heartburn and nausea, body and breath odor, headache, and vertigo.	May decrease blood glucose.	May potentiate the blood- thinning effects of anti- inflammatory medications such as aspirin and supplements such as vitamin E and fish oil; may interact with the blood- thinning drug warfarin (Coumadin); may potentiate antihypertensives.
Ginkgo biloba	Improves memory and mental sharpness; alleviates symptoms of Alzheimer's disease; eases symptoms of depression; improves circulation; thins blood; improves cardiovascular health; acts as antioxidant; improves vertigo, headache, and tinnitus; relieves intermittent lower leg cramps, diabetic retinopathy, wheezing, dizziness, motion sickness, and Raynaud's.	Very rarely associated with gastrointestinal upset, allergic skin reaction, and headache.	Not for people with seizure disorders because it may reduce the effects of seizure medication. Not to be taken by people hypersensitive to poison ivy, cashews, or mangoes.	Could pose a concern to people with blood clotting problems or those taking anticoagulant medications. Not recommended for people using aspirin, or nonsteroidal antiinflammatory drugs.

Product	Principal claims[a]	Principal known adverse effects	Principal known contraindications[b]	Principal known interactions
Ginseng	Relieves stress, eases symtoms of anxiety, delays or reduces the effects of aging used as a tonic for well-being, enhances immune function, reduces blood sugar, improves cognitive function, relieves menopausal symptoms, acts as an antioxidant, hypocholesterolemia, enhances athletic performance, boosts energy, increases sexual stamina, helps with impotence and infertility, prevents and fights diseases such as cancer, increases energy, protects the heart, strengthens stomach functions, prevents arteriosclerosis, stabilizes blood pressure and insulin levels.	Generally considered quite safe although it is recommended that a course of treatment not exceed 3 months; may cause breast tenderness, swollen breasts, vaginal bleeding in women, nervousness, excitation, hypertension, headaches, insomnia, restlessness, vomiting, and may cause breast cancer to reoccur in women who have had the disease previously.	Caution recommended for individuals with hypertension and those prone to hypoglycemia. High doses may inhibit immune function in early stages of infection. People with cancer should consult their physician. People with cardiovascular disease or diabetes exercise caution.	May interfere with digoxin activity or monitoring. If used with warfarin or other anticoagulant, can alter bleeding times. If used with phenelzine sulfate (an antidepressant) or a monoamine ozidase inhibitor (MAOI), can cause headaches, tremors, and manic episodes. Caution with insulin.
Glucosamine	Reverses osteoarthritis, protects joints and tendons from injury, decreases inflammation.	Occasional symptoms of gastrointestinal discomfort; reduced insulin secretion noted in animal studies.		Concern about interactions for people on blood-thinning medications and about harmful effects on insulin resistance.
Kava kava	Eases symtoms of anxiety, restlessness and nervous tension; promotes relaxation; aids sleep; balances mood; restores vigor; eases symptoms of depression and menopause (hot flashes); acts as an analgesic, headache remedy, and mild sedative; eases uterine inflammation, colds, rheumatism; promotes urination; soothes upset stomachs; eases symptoms of asthma and tuberculosis; cures fungal infections; inhibits gonorrhea; soothes stings and skin inflammations.	Can result in temporary skin and liver problems, allergic reactions, gastrointestinal discomfort, absence of urination, numbness of the mouth, painful twisting movements of the trunk, disturbances of the oculomotor equilibrium, and can disturb motor reflexes and judgment when driving.	Not appropriate for individuals with major anxiety conditions. Should not be used while driving. May worsen symptoms of Parkinson's. Use in endogenous depression should be avoided. Should not be used for more than 3 months. Should not be used if gall bladder or liver problems, including cirrhosis and hepatitis.	Should not be taken with alcohol or antianxiety drugs such as valium. May have additive effects with other muscle relaxants, sedatives, antianxiety agents, and antidepressants. Should not be taken with antidepressants or antipsychotics.

Product	Principal claims[a]	Principal known adverse effects	Principal known contraindications[b]	Principal known interactions
Melatonin	Promotes sleep, reduces symptoms of jet-lag, slows aging process, increases sex hormone secretion, acts as antioxidant, relieves tinnitus, may inhibit growth of breast cancer cells.	May cause infertility, hypothermia, and retinal damage; reduces sex drive in males; leads to high blood pressure, diabetes, and cancer.	Can induce or deepen depression in susceptible individuals. May be dangerous for people with cardiovascular risk factors. Should not be taken by people with immune-system disorders (including severe allergies), autoimmune diseases (such as rheumatoid arthritis), immune-system cancers (e.g., lymphoma), severe mental illness, or those taking steroids.	May interfere with hormone replacement therapy. May enhance the effectiveness of certain chemotherapy drugs.
Omega-3 fatty acids (fish oil)	Provides heart protection; dilates blood vessels; reduces blood pressure; reduces blood clotting; suppresses inflammation; relieves pain of rheumatoid arthritis; eases symptoms of depression and attention deficit/hyperactivity disorder; increases growth hormone levels; relieves symptoms of allergies, asthma, and skin disorders; can help prevent breast, prostate, and colon cancers; inhibits growth of pancreatic cancer, protects against kidney failure.	Encourages bleeding and hemorrhage, causes fishy breath odor, belching, abdominal bloating, increases total blood cholesterol.		
Saw palmetto	Aids in the treatment of benign prostate hyperplasia (BPH), increases libido, increases sperm production, increases breast size of women, useful as a urinary antiseptic and diuretic, prevents hair loss (men only), treats low thyroid function and irritable bladder.	Rare but include headaches, gastrointestinal disturbances, diarrhea, vomiting, upset stomach, constipation, nausea, dizziness, erectile dysfunction, difficulty sleeping, fatigue, and heart pain.	People with enlarged prostate should consult physician on a regular basis. Use should be avoided in patients with breast cancer.	

Product	Principal claims[a]	Principal known adverse effects	Principal known contraindications[b]	Principal known interactions
Shark cartilage	Cures or prevents cancer, promotes wound healing, relieves arthritis pain and stiffness.	Could lead to thyroid hormone toxicity, may cause nausea, indigestion, fatigue, fever, and dizziness.	May slow down the healing process for people recovering from surgery. Shark cartilage enemas should be avoided by people with a low white blood cell count. Relying on this type of treatment alone and avoiding conventional medical care may have serious health consequences.	
Soy proteins and isoflavones	Reduces cholesterol and triglyceride levels, reduces risk of heart disease, suppresses menopausal symptoms (hot flashes), reduces bone breakdown (osteoporosis), prevents cancer.	Mild gastrointestinal complaints such as bloating and flatulence.		May interfere with the absorption of supplemental thyroid hormones. May interact with ipriflavone, a synthetic isoflavone.
St. John's wort	Eases symptoms of mild to moderate depression; stabilizes mood; improves tolerance to stress; improves sleep patterns in older people; eases symptoms of anxiety; increases energy levels; controls appetite and promotes weight loss; eases bronchial inflammation, stomach problems, hemorrhoids, hypothyroidism, migraines, kidney disorders; aides insect bites and stings, skin diseases, scabies, skin inflammation, burns and wounds, and blunt injuries bedwetting; aids in wound healing and in resistance to viral infection when applied topically.	Mild gastrointestinal upset, skin rashes, tiredness, insomnia, restlessness, dizziness, confusion, photosensitivity, (especially in fair-skinned individuals) serotonin syndrome, dry mouth, fast or irregular breathing.	Can be toxic to sperm; not for the treatment of severe depression.	No longer believed that it magnifies effect of MAOI, but users should consult physician. May decrease effectiveness of HIV drugs, immunosuppressants, digoxin, blood thinners, chemotherapy drugs, and asthma medications. Abrupt withdrawal can increase blood levels of various medications. Should not be used with alcohol, narcotics, amphetamines, anticoagulants, antibiotics, or cold and flu medicines such as pseudo-ephedrine. Should not be used with other antidepressants or with certain cheeses. May interfere with action of certain oral contraceptives.

Product	Principal claims[a]	Principal known adverse effects	Principal known contraindications[b]	Principal known interactions
Valerian	Promotes relaxation, induces sleep, ease symptoms of anxiety, calms nerves, helps people quit smoking, eases congestion, and relieves muscle spasms.	Headaches, mild nausea, upset stomach, heart palpitations, restlessness, excitability, hypersensitivity reactions, insomnia, blurred vision, and very high doses may weaken the heartbeat and cause paralysis.	People taking sedatives or antidepressants should consult physician. Should not be consumed for more than 2 weeks. People with liver or kidney disease should consult physician.	Should not be taken with alcohol, certain antihistimines, muscle relaxants, psychotropic drugs, sedatives, barbiturates, or narcotics. Should not be taken with alcohol or other tranquilizers.

[a]Principal claims are manufacturing claims and uses that have been reported. However, we have not substantiated any of these claims.

[b]We do not include any contraindications for children or pregnant or nursing women.

Sources: *Physicians' Desk Reference for Herbal Medicines*, 2nd ed. (Montvale, N.J.: Medical Economics, 2000); Blumental, M. (ed.) *The Complete German Commission E monographs: Therapeutic Guide to Herbal Medicines*, (Boston, Mass.: American Botanical Council, 1998); J. H. McDermott, "Herbal Chart for Health Care Professionals" (chart) (Washington, DC: American Pharmaceutical Association. 1999); Bruss, Katherine (ed.), *American Cancer Society's Guide to Complementary and Alternative Cancer Methods* (Atlanta, Ga.: American Cancer Society, 2000); M. McGuffin and others (eds.), *American Herbal Products Association's Botanical Safety Handbook*, (Boca Raton, Fla.: CRC Press, 1997); Center for Science in the Public Interest, "Supplements: Latest research on vitamins, minerals and herbs" (reprinted selections from *Nutrition Action Healthletter*) (Washington, D.C.: Center for Science in the Public Interest, 1999); www.supplementwatch.com; and www.supplementinfo.org.