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Report to Chairman, Special Committee on Aging, U.S. Senate

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HEALTH PRODUCTS FOR SENIORS

"Anti-Aging" Products Pose Potential for Physical and Economic Harm

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Abbreviations

AG	Attorney General
CDC	Centers for Disease Control and Prevention
DHEA	dehydroepiandrosterone
DSHEA	Dietary Supplement Health and Education Act
FDA	Food and Drug Administration
FTC	Federal Trade Commission
GMP	good manufacturing practice
HHS	Department of Health and Human Services
NCCAM	National Center for Complementary and Alternative Medicine
NIH	National Institutes of Health

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United States General Accounting Office
Washington, D.C. 20548

September 7, 2001

The Honorable John Breaux
Chairman, Special Committee on Aging
United States Senate

Dear Mr. Chairman:

The risk to consumers from potentially harmful health products is a perennial concern for consumer protection groups, health authorities, federal and state regulators, and law enforcement officials. Many alternative medicine products, including dietary supplements,[1] have widespread popular appeal among consumers, and some have yielded promising results in studies that focus on chronic health conditions that affect many older adults, such as depression, dementia, and arthritis. For example, some studies have suggested that St. John's wort may counteract feelings of mild to moderate depression and that ginkgo biloba may improve cognitive performance in dementia. At the same time, regulators and medical experts are concerned that some products have health risks or are marketed with misleading and unsubstantiated claims.

Some companies promote their products to senior citizens by using "anti-aging" or "cure-all" claims for which there is little or no supporting scientific evidence of either safety or efficacy.[2] In addition, there are concerns that some of these products may cause physical or economic harm. Seniors are thought to be at particular risk of physical harm because they often take multiple prescription pharmaceuticals, increasing their risk of possibly dangerous supplement-drug interactions. Seniors can also be harmed indirectly if they decide to follow an unsubstantiated alternative regimen and forgo needed conventional medical treatment. There is also concern that seniors may be wasting money on products that have little or no therapeutic value.

[1]Alternative medicine products are those remedies, supplements, and devices that are not currently considered an integral part of conventional medicine. These include dietary supplements such as vitamins, minerals, herbal and botanical supplements, and specialty supplements.

[2]Efficacy is the ability of a medication to produce the intended or desired effect under ideal conditions of use.

Since 1994, when the Dietary Supplement Health and Education Act (DSHEA) was enacted, sales of dietary supplements have soared. A significant number of these products are herbal supplements, and others are nonherbal specialty supplements.[3] DSHEA permits dietary supplements to feature so-called structure/function label claims, which are statements that an ingredient in the product will benefit a body's structure (such as "builds strong bones") or function (such as "promotes restful sleep"). As we reported last year, consumers may incorrectly view such statements as claims to reduce the risk of or to treat a disease.[4]

In light of these concerns, you asked us to examine (1) whether there is evidence that anti-aging and alternative medicine products, particularly dietary supplements aimed at conditions of aging, cause physical harm to senior citizens; (2) whether there is evidence that questionable anti-aging and alternative medicine products cause economic harm to senior citizens; and (3) federal and state oversight efforts to protect consumers from questionable anti-aging and alternative medicine products.

To address these questions, we obtained documents from and interviewed officials with the Food and Drug Administration (FDA), the Federal Trade Commission (FTC), the National Institutes of Health (NIH), state Attorneys General (AG) offices, and state health departments, as well as representatives of the dietary supplement industry and other interested organizations and experts. We also reviewed the scientific literature on dietary supplements and other products marketed as anti-aging therapies. Our work focused primarily on those products that purport to have anti-aging properties or which claim to address chronic diseases and conditions common among senior citizens, such as cancer, memory loss, and arthritis. We conducted our review from April through August 2001 in accordance with generally accepted government auditing standards. (See app. I for further information on our scope and methodology, including a list of the organizations we contacted.)

[3]Specialty supplements are generally those that are not herbs, botanicals, vitamins, or minerals, and may include amino acids, animal products, concentrates, metabolites, constituents, or proteins.

[4]*Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and "Functional Foods"* (GAO/RCED-00-156, July 11, 2000).

Results in Brief

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 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. FDA and the Centers for Disease Control and Prevention (CDC) have received reports of adverse events for persons taking dietary supplements in recent years, including some for senior citizens. FDA has issued warnings to consumers and industry about the health risks of several dietary supplement products. The dietary supplement trade associations and medical experts we talked with generally agreed that some products may pose a potential for harm to seniors under certain conditions.

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 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 on the Internet and in other media. NIH has an evolving and 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 administrative rulemaking authority. 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 to combat health fraud against seniors and other vulnerable consumer populations 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

Dietary supplements and other alternative medicine products are widely used by seniors. For example, as many as 4 out of 10 senior citizens have reported using herbal dietary supplements. In 2000, total U.S. sales for the herbal and specialty supplement industry reached $5.8 billion.[5] Research suggests that some of these products show promise for mitigating symptoms associated with certain health conditions. FDA, FTC, and state agencies all have oversight responsibility for alternative medicine products.

[5]Estimates of 1997 out-of-pocket expenditures by Americans of all ages for alternative therapies–including herbal products, high-dose vitamins, therapy-specific books and classes, diet products, and professional services–range from $27 billion to $34.4 billion nationally.

Use of Alternative Medicine Products by Older Americans

A number of surveys have been conducted to determine the proportion of the population that uses alternative medicine products. One national survey of more than 2,000 adults conducted in 1997 found that 42 percent of Americans of all ages used at least one type of alternative therapy in the prior year for conditions such as back problems, fatigue, arthritis, high blood pressure, insomnia, depression, and anxiety.[6] The survey found that 12 percent used herbal remedies. Other studies have found that 16 to 18 percent of Americans used dietary supplements, including amino acids and over-the-counter hormones.[7]

When considering only senior citizens, surveys have generally found that as many as 40 percent of seniors used herbal and specialty supplements at some time in the previous year, with a smaller percentage reporting regular use. For example, a survey conducted in 1999 for *Prevention Magazine* found that 43 percent of seniors used herbal supplements and 23 percent used specialty supplements in the previous year. This study also found that one-quarter of older Americans often use herbal and specialty supplements in combination with prescription medications. A recent unpublished Harris Poll survey conducted for the Dietary Supplement Education Alliance (June and July 2001) found that 12 percent of those aged 65 or older used herbal supplements and 9 percent used specialty supplements on a regular basis. 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 app. II for details regarding these substances).

[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.

[7]R.J. Blendon and others, "Americans' Views on the Use and Regulation of Dietary Supplements," *Archives of Internal Medicine*, Vol. 161(2000), pp. 805-10.

Research on Alternative Medicine Products

NIH's National Center for Complementary and Alternative Medicine (NCCAM) has noted that preliminary evidence-based reviews suggest that some alternative therapies may have beneficial effects. These include St. John's wort for depression, ginkgo biloba for dementia, and glucosamine and chondroitin sulfate for osteoarthritis. For example, one source stated that increased memory performance and learning capacity have been established experimentally for ginkgo biloba.[8] One controlled study has shown positive results for ginkgo biloba in tests of cognitive performance in dementia.[9] Similarly, some reviews have suggested that studies of glucosamine in the treatment of osteoarthritis found positive results,[10] as did studies of St. John's wort for depression.[11] A systematic review of studies of St. John's wort for depression found evidence of effectiveness in the treatment of mild to moderately severe depression,[12] although it has also been associated with potentially dangerous interactions with prescription drugs.

Government Oversight of Anti-Aging Products and Dietary Supplements

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 Health and Human Services Secretary may declare the existence of an imminent hazard from a dietary supplement,

[8]M. Blumental (ed.), *The Complete German Commission E Monographs: Therapeutic Guide to Herbal Medicines* (Boston, Mass.: American Botanical Council, 1998).

[9]P.L. Le Bars and others, "A Placebo-Controlled, Double-Blind, Randomized Trial of an Extract of Ginkgo Biloba for Dementia," *Journal of the American Medical Association*, Vol. 278, No. 16 (1997), pp. 1327-32.

[10]T.E. Towheed and others, "Glucosamine Therapy for Treating Osteoarthritis," *The Cochrane Library*, No. 3 (2001).

[11]L.K. Mulrow, "St. John's Wort for Depression," *The Cochrane Library*, No. 2 (2001).

[12]K. Linde and others, "St. John's Wort for Depression—an Overview and Meta-Analysis of Randomised Clinical Trials," *British Medical Journal*, Vol. 313 (1996), pp. 253-58.

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 that 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 Have Been Associated With Potentially Serious Health Consequences for Senior Citizens

Some dietary supplements can have potentially serious health consequences for seniors. Although precise estimates of the physical harm caused to senior citizens by questionable anti-aging and alternative products are not available, there is evidence in the medical literature that seniors are at risk for adverse effects, that dietary supplements are contraindicated for individuals with some underlying health problems, and that a variety of frequently used dietary supplements can have dangerous interactions with drugs that are being taken concurrently. Although documented adverse effects from most herbal and specialty supplements are generally mild, potential complications from supplements that might be contraindicated under certain circumstances and from interactions with certain prescription medications may be serious. In addition, there is evidence that 1 in 10 herbal products may be contaminated with pesticides and heavy metals, which can have serious health consequences. Adverse event reports received by FDA and others give an indication of some possible risks. FDA has issued warnings to consumers and industry about the health risks of several dietary supplement products. Recognizing these health risks, the American Medical Association has recommended that dietary supplements and herbal remedies include specific warnings on their labels, and several trade associations representing manufacturers, suppliers, and distributors of dietary supplements have instituted voluntary programs to reduce the risk of potentially harmful products.

Scientific Evidence Shows Potential Adverse Effects, Contraindications, and Drug Interactions for Some Popular Supplements

Our review of the medical literature identified several areas where individuals, particularly seniors, may be at risk of physical harm due to adverse effects--especially if dietary supplements are used when they are contraindicated--or interactions between these dietary supplement products and prescription or over-the-counter drugs.[13]

The literature suggests that among healthy adults, most supplements when taken alone have been associated with only rare and minor adverse effects. These include stomach distress, headache, breast tenderness, restlessness, skin reactions, and hypersensitivity to sunlight. However, others are associated with more serious adverse effects. For example, the literature suggests that DHEA may increase the risk of breast, prostate, and endometrial cancer, and shark cartilage has been associated with thyroid hormone toxicity.

Contraindications have been identified in the literature for several supplements. 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. Other potential complications cited were an increase in the sedative effect of anesthetics and increased metabolism of many drugs.[14]

The literature also identifies a number of possible interactions with prescription medications. Since seniors take more prescription medicines on average than do younger adults, the risk of interactions among seniors may be higher. For example, evening primrose oil, garlic, 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

[13]A summary of some of the principal known adverse effects, contraindications, and interactions for leading supplement products is provided in appendix II.

[14]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.

suggesting that ginkgo biloba may reduce the effects of seizure medications and glucosamine may have a harmful effect on insulin resistance.

An additional concern is that individuals with potentially serious health conditions may seek alternative therapies, some of which are unproven, in lieu of conventional medical therapies, and may do so without consulting their physician. For example, the *Prevention Magazine* survey we described earlier found that 39 percent of the respondents aged 65 or older who used a herbal supplement to prevent or treat a disease used the herbal remedy instead of an over-the-counter medication and 34 percent had tried a herbal remedy instead of a prescription medication. Surveys have also found that individuals who use alternative therapies (either in conjunction with or instead of traditional therapies) often do not discuss this fact with their physicians. For example, one survey found that only 39 percent of adults who used an alternative therapy said they informed their doctor,[15] and a Harris poll survey found that 49 percent of respondents who used a dietary supplement informed their doctor. In addition, many respondents in that survey were found to have misperceptions about the responsible use of supplements. For example, one-third said they did not think it was necessary to follow recommended dosage guidelines. Nearly 40 percent thought they would benefit from having more information about avoiding potential adverse reactions.

Some Dietary Supplements Contain Harmful Contaminants or Too Much Active Ingredient

Commercial and scientific studies of selected dietary supplements have repeatedly found that contaminants may be present and that the amount of active ingredient present does not always match that indicated on the product label.

[15]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.

Contaminants can pose significant health risks to consumers. Some pesticides and heavy metals, for example, are probable carcinogens and can 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 tested were contaminated in some way. Three percent of the specialty supplement products showed signs of contamination.

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. Amounts of active ingredients that exceed what is indicated on a product label may increase the risk of overdose for some patients. For pharmaceuticals, the tolerable range of product content is between 90 and 110 percent of the amount of active ingredient stated on the label. For example, one study of DHEA found that only 44 percent of the products sampled were within this range and one brand contained 150 percent of the amount indicated on the label.[16] In a study of ephedra, one product was shown to have as much as 154 percent of the active ingredient indicated on the label.[17] A study of feverfew (promoted as a migraine prophylaxis) found that 22 percent of the products tested contained more than 110 percent of what the authors considered to be the therapeutic dose of its active ingredient, in two cases doubling that amount.[18] Studies of ginseng have found that product concentrations varied nearly fivefold across different products[19] and that 38 percent of the products tested had more than 110 percent of the amount of active ingredient on the label, four of them containing more than twice as much.[20] Studies of SAM-e (promoted as an antidepressant and in the treatment of the joint pain, stiffness, and inflammation associated with osteoarthritis) and St. John's wort also found

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

[17]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.

[18]S. Hepinstall and others, "Parthenolide Content and Bioactivity of Feverfew (*Tanacetum parthenium* (L.) Schultz-Bip.). Estimation of Commercial and Authenticated Feverfew Products," *The Journal of Pharmacy and Pharmacology*, Vol. 44, No. 5 (1992), pp. 391-95.

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

that products frequently contained more of the active ingredient than indicated on the label. This was true for 42 percent and 20 percent of the products tested, respectively.

Reports of Adverse Events Associated With the Use of Dietary Supplements Signal Possible Risks

Although FDA does not determine causality in the adverse event reports it receives, it does use these reports to signal possible risks to consumers from dietary supplements. The agency also consults other sources, such as reports in the medical literature, to identify dietary supplements that may be hazardous to consumers.

In 1993, FDA published a list of dietary supplements for which evidence of harm existed.[21] In 1998, the agency also published a guide to dietary supplements, which included a list of supplements associated with illnesses and injuries.[22] FDA has also issued warnings and alerts for dietary supplements and posted those to its Web site.[23] The most recent alert reiterated the agency's concern, first noted in 1993, that the herbal product comfrey represents a serious safety risk to consumers from liver toxicity. In addition, the agency has issued warnings for products including, among others, chapparal, which is promoted as an antioxidant and cancer cure and is associated with nonviral hepatitis; aristolochic acid, which is sold as "traditional medicine" and has been associated with permanent kidney damage and some cancers; and L-tryptophan, which is promoted for insomnia and depression but has been associated with an autoimmune disorder and deaths. CDC has also identified reports of adverse events associated with dietary supplements and reported them in Morbidity and Mortality Weekly Report. CDC's report about L-tryptophan also noted that the substance has led to at least 27 deaths.

[20]M.R. Harkey and others, "Variability in Commercial Ginseng Products: An Analysis of 25 Preparations," *American Journal of Clinical Nutrition*, Vol. 73 (2001), pp. 1101-06.

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

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

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

Medical Organizations and Trade Associations Have Taken Steps to Address Health Risks

Medical organizations and trade associations that represent manufacturers, suppliers, and distributors of dietary supplements recognize that some health risks are associated with these products and have made recommendations and adopted voluntary programs to address some of the concerns. For example, the American Medical Association has issued a policy statement recommending that dietary supplements and herbal remedies include the following information on the product label: "This product may have significant adverse side effects and/or interactions with medications and other dietary supplements; therefore it is important that you inform your doctor that you are using this product." The policy statement also recommends that manufacturers be required to label products with data on adverse effects, contraindications, and possible drug interactions.

Trade associations that represent various manufacturers, suppliers, and distributors of dietary supplements have adopted voluntary programs to reduce the risks of potentially harmful products. Thus, the Consumer Healthcare Products Association has established eight voluntary programs focusing on either product manufacturing or labeling of specific products. For example, the association urges manufacturers to put quality control procedures in place to ensure that ginseng is free of quintozene (a potentially carcinogenic pesticide) and related compounds. For kava kava products, member companies are asked to include specific dosage limits and cautionary statements, and for comfrey and St. John's wort products, members are asked to include general label warnings about the advisability of consulting a physician. The American Herbal Products Association has incorporated labeling and warning recommendations in its code of ethics for members. These include, among others, labeling recommendations for ephedra (with both warnings and serving limits), warnings for chaparral and pyrrolizidine alkaloids (which are found in comfrey and can cause fatal liver failure), and dosage limits and warnings for kava kava. The association has also suggested warning labels for both saw palmetto and St. John's wort.

The National Nutritional Foods Association requires all members who manufacture dietary supplements and herbs under their own label to participate in a quality assurance program. The program was established, in part, to increase confidence that products are accurately labeled. Products are registered, with random testing for content every 2 to 3 years. Association officials reported that approximately 25,000 product labels are currently registered under this program, estimating that this accounts for more than half of the dietary supplements on the market. The association

also sponsors its own good manufacturing practices program, and 23 manufacturers are currently certified.

Senior Citizens May Spend Millions of Dollars on Unproven or Poorly Manufactured Products

Senior citizens who buy anti-aging and alternative medicine products may spend millions of dollars on products that either make unsubstantiated claims or contain less of the active ingredient than is indicated on the label. There are no overall estimates of economic harm attributable to questionable anti-aging products; however, federal officials have identified a number of expensive products making unsubstantiated claims. In an analysis of 20 of its cases for products targeted to senior citizens, FTC estimated that consumers as a whole spent an average of nearly $1.8 million annually per company. In addition, because some dietary supplement products contain little or none of the active ingredient listed on the product label, consumers may be spending millions of dollars per year on products that are virtually worthless.

Expensive Products With Unsubstantiated Claims Cost Consumers Millions of Dollars

FTC and FDA have identified a number of anti-aging and alternative medicine companies making unsubstantiated advertising or labeling claims for their products. FTC does not have an estimate of economic harm attributable to these products, but some of these unproven products can cost hundreds or thousands of dollars apiece. For example, rife machines,[24] which are frequently advertised on the Internet, can cost up to $5,000, and some herbal product packages for cancer cures can cost nearly $1,000. PC-SPES, an herbal supplement being studied for prostate cancer, costs more than $400 per month.

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 at $1,759,000 per company.

[24]Rife machines are designed to emit light-only or electrical frequencies that manufacturers claim kill viruses and parasites and mitigate a wide variety of diseases and health conditions.

Consumers May Waste Money on Products Containing Less Active Ingredient Than Indicated on Product Labels

Consumers may purchase anti-aging and alternative medicine products that contain much less active ingredient than is indicated on the product label, thereby wasting their money on worthless products. Results of commercial laboratory tests and scientific studies that analyzed product contents for active ingredient levels have shown that some dietary supplement products contain far less of that active ingredient than labeled. For some products, analyses have found no active ingredient.

A series of commercial laboratory analyses of herbal products showed that 22 percent of herbal supplements, and 19 percent of specialty supplements, contained substantially less active ingredient than the amount indicated on the label.[25] Tests on echinacea products found that two had no detectable levels, and for valerian, four products were found to have none of the active ingredient. Six SAM-e products tested had less than half of the labeled amount of active ingredient.

Studies published in the medical literature have shown similar results. In an analysis of DHEA products, nearly one-fifth contained only trace amounts or no active ingredient.[26] In analyses of garlic products, most were found to release less than 20 percent of their active ingredient.[27] One study of ginseng found that 35 percent of the products tested contained no detectable levels of an active ingredient,[28] and another found no detectable levels in 12 percent of the tested products.[29] 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.

[25]More detailed test results for all products tested can be found at www.consumerslab.com.

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

[27]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.

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

[29]J. Cui, "What Do Commercial Ginseng Preparations Contain?"

Federal and State Education, Research, and Enforcement Activities Aim to Protect Senior Citizens

The potential for harm to senior citizens from health products making questionable claims has long been a concern for public health and law enforcement officials, and federal and state agencies have activities under way to protect consumers from these products. FDA and FTC sponsor programs and provide educational materials for senior citizens to help them avoid health fraud on the Internet and in other media. NIH is funding research and research centers to evaluate popular anti-aging and alternative therapies. FDA has taken various enforcement actions against firms that have violated legal requirements regarding the marketing and sales of anti-aging and alternative products, including dietary supplements, but it has not prohibited the marketing of any specific substances using its administrative rulemaking authority. FDA's voluntary adverse event reporting system for dietary supplements has shortcomings, and proposed regulations to establish good manufacturing practices for dietary supplements are still under review by the Office of Management and Budget. Through "Operation Cure.All," FTC is trying to stop companies from making unqualified health claims that are not supported by credible scientific evidence, and it has been joined in these efforts by FDA and other agencies. 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.

Some Federal Consumer Education Activities Target Health Fraud Against Senior Citizens

Both FDA and FTC sponsor education 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. In addition, officials in some districts made drug safety presentations that highlighted ongoing FDA programs, including the MedWatch adverse event reporting system that consumers are encouraged to use and which encompasses drugs, biological products such as vaccines, medical devices, dietary supplements, and food products.

To help consumers discriminate between legitimate and fraudulent claims, FTC publishes consumer education materials on certain frequently promoted products and services, including hearing aids and varicose vein treatments. The agency also publishes guidelines on how to spot false claims and how to differentiate television shows from "infomercials."

NIH Supports Research on Alternative Therapies

Federal support of research on alternative therapies is provided by NIH's NCCAM, which has developed research programs to fund clinical trials to evaluate the safety and efficacy of some popular products and therapies. The trials are studying alternative products and therapies for conditions such as arthritis, cardiovascular disease, and neurological disorders. There are also studies, either ongoing or planned, to examine the effects of glucosamine/chondroitin, St. John's wort, ginkgo biloba, and others. (A list of NCCAM studies on alternative therapies relevant to seniors is provided in app. III.) In addition, the agency funds specialized, multidisciplinary research centers on alternative medicine in such areas as cardiovascular disease, neurological disorders, aging, and arthritis.

FDA Has Taken Enforcement Actions

FDA has taken enforcement actions against firms selling anti-aging products alleged to be dangerous or illegally marketed. It has taken actions to remove from the market anti-aging products that the agency found were actually unapproved new drugs or medical devices and actions against firms that promoted their dietary supplements for the treatment or cure of a disease. Although DSHEA allows FDA to remove from the market dietary supplements that the agency can prove are dangerous, the agency has not prohibited the marketing of any specific substances using its administrative rulemaking authority. However, the agency has taken steps to identify for consumers and industry ingredients it deems to be unsafe and unlawful. The agency has then pursued cases against specific manufacturers and products when the ingredients continued to be marketed in dietary supplements despite the agency's warnings. FDA's efforts in this regard have been unsuccessful, and many of these products remain on the market and are still available to consumers. A description of some of FDA's recent enforcement activities is provided in appendix IV.

FDA enforcement actions taken against products that it judged to be unapproved drugs or medical devices include court cases filed to halt 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. The devices have been purchased by many senior citizens, according to FDA officials. An estimated 800,000 of these devices were sold between 1994 and 1997.

FDA has notified some dietary supplement manufacturers that their promotional materials have illegally claimed that their products cure disease, but some of these products are still available. 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 disease claims used in marketing the products, 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 sent several dozen "cyber-letters" by electronic mail to Internet-based companies making such claims stating 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." This letter also advised the industry that FDA had concluded that any dietary supplement that contained aristolochic acids was adulterated under the law and that it was unlawful to market such a product. At the same time, the agency issued an import bulletin (later converted to an import alert) that prohibited the importation of bulk and finished products that may contain aristolochic acids until the importer could provide direct analytical evidence that the product was free of these substances. In April 2001, the agency issued a new industry letter and consumer warning after its analysis of marketed products found that many contained aristolochic acids. This letter reiterated the agency's conclusion that the marketing of such products was unlawful and that manufacturers needed to take steps to ensure that aristolochic-acid-containing products do not find their way into the marketplace.

FDA pointed to another safety risk for consumers using herbal medicines in July 2001, when the agency 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 that contain 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's Voluntary Adverse Event Reporting System Has Shortcomings

As we reported in 1999,[30] FDA's adverse event reporting system for dietary supplements receives reports for only a small proportion of all adverse events, and the reports it receives are often incomplete. FDA's adverse event reporting system for dietary supplements is a voluntary postmarketing surveillance system. There is no statutory requirement that dietary supplement manufacturers provide adverse event reports they receive to FDA. For example, we found that documents disclosed in a recent court case showed that a manufacturer of a product containing ephedra had received more than 1,200 complaints of adverse events related to its product; FDA told us that it was aware of few, if any, of these reports before the lawsuit was filed. Similarly, a 2001 report by the HHS Office of Inspector General noted that FDA's reporting system fails to capture sufficient data on medical information, product information, and manufacturer information.[31] For example, FDA told us that 12 percent of the dietary supplement adverse event reports that included consumer age that it has received since 1994 were for senior citizens, but that many of the reports did not contain information about the age of the consumer.

[30]*Dietary Supplements: Uncertainties in Analyses Underlying FDA's Proposed Rule on Ephedrine Alkaloids* (GAO/HEHS/GGD-99-90, July 2, 1999).

[31]Department of Health and Human Services (HHS), Office of Inspector General, *Adverse Event Reporting for Dietary Supplements*, OEI-01-00-00180 (Washington, D.C.: HHS, April 2001).

FDA Currently Inspects Relatively Few Dietary Supplement Manufacturers and Related Facilities

FDA inspects relatively few dietary supplement manufacturers and related facilities.[32] FDA told us that the agency inspected 61 manufacturers and repackers of dietary supplements in 1999, and 53 in 2000. In 2001, 80 inspections are planned. The agency does not know precisely how many facilities are operating, because there is no registration requirement. However, FDA estimates that there are more than 1,500 facilities, suggesting that FDA inspects less than 5 percent of facilities annually. FDA officials told us that its inspectors look at sanitation, buildings and facilities, equipment, production, and process controls.

Regulations to Establish Good Manufacturing Practices for Dietary Supplements Have Not Yet Been Issued

In 1997, FDA published an advance notice of proposed rulemaking regarding good manufacturing practice (GMP) in manufacturing, packing, and holding of dietary supplements. In publishing the draft for comment, FDA noted that much of the dietary supplement industry believes GMP regulations are important in establishing standards to ensure that dietary supplements are "safe and properly labeled." FDA officials have stated that a proposed GMP rule has now been developed and is still under review by the Office of Management and Budget. Publication of final GMP regulations will improve FDA's enforcement capabilities, since DSHEA provides that dietary supplements not manufactured under conditions that meet GMPs would be considered adulterated and unlawful.

Recent FTC and Joint-Agency Enforcement Efforts Focus on the Internet

As part of its consumer protection activities, FTC enforces federal statutes that prohibit misleading and unsubstantiated advertising. In recent years, FTC has joined with other organizations to focus attention on the fraudulent marketing of some anti-aging and other alternative medicine products.

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

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, which later became known as "Operation Cure.All," primarily involved conducting Internet-based searches to identify Internet sites making unsubstantiated claims that use of their products would prevent, treat, or cure serious diseases and conditions. The searches were conducted with the participation of FDA, CDC, and some state attorneys general and other organizations.[33]

Evaluations of "Operation Cure.All" have found that some companies have made changes in their Internet 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 notified 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. In addition, FTC identified for us 15 "Operation Cure.All" cases brought by the FTC against companies and individuals making claims for products or services that were not backed by "competent and reliable" scientific evidence. In total, FTC has brought over 30 dietary supplement cases since the agency released guidelines on its approach to substantiation of advertised claims in 1998. A list of relevant cases from FTC enforcement efforts is provided in appendix V.

A majority of "Operation Cure.All" cases have been settled administratively, with the companies agreeing to stop making unsupported disease treatment claims in advertising materials, with some calling for consumer redress. For example, FTC sued *Lane Labs-USA* for representing that its shark cartilage products could cure cancer. The company agreed in June 2000 to stop making these claims and to pay a $550,000 fine to FTC and $450,000 to be used for purchasing shark cartilage and placebo products to be tested in a clinical trial sponsored by NIH. In an ongoing "Operation Cure.All" case involving a company that markets various herbal packages as well as a device known as the "Zapper Electrical Unit," FTC's complaint

[33]On the basis of a long-standing memorandum of understanding coordinating the agencies' jurisdictional policies over product claims, FDA and FTC are working together within "Operation Cure.All" to curb the number of health products on the Internet making questionable advertising and labeling claims.

seeks consumer redress and a permanent injunction against false and misleading claims.

State Agencies Have Limited Focus on Anti-Aging and Alternative Medicine Products

The fourteen 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, and these are listed in appendix VI.

States 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.

Enforcement of Consumer Protection Laws

In the states we contacted, oversight of anti-aging product advertising has not been a priority for state consumer protection agencies. Although many representatives of state consumer protection agencies we contacted said that misleading advertising of health products targeted to seniors is a serious issue, their agencies have devoted greater resources to larger scale types of fraud such as identity theft and sweepstakes fraud.

State laws protecting consumers from false or misleading advertising may be applied to anti-aging and alternative remedies for which complaints have been filed. There is often a multi-tiered approach to resolving consumer complaints. Individual complaints may be filed with an office, usually within the Attorney General's or Governor's Office, that facilitates informal resolution between the consumer and the company. Consumers wishing to pursue legal remedies beyond this point are generally referred to a private attorney. In cases in which there are patterns or egregious cases

of deceptive advertising, the Attorney General's consumer complaint division may pursue administrative or legal remedies against the company.

Although many state consumer protection agencies are monitoring cases to see if patterns of deceptive advertising are developing that could warrant full investigation in the future, such patterns may be difficult to determine for a number of reasons. None of the consumer protection officials we contacted receives a high volume of complaints about health-related products. State consumer protection Web sites often refer consumers to a variety of resources, including the FTC, FDA, and Better Business Bureaus, and thus the agencies are not likely to have a comprehensive picture of all consumer complaints. Most of the consumer protection agencies we contacted could not search their complaint databases to obtain counts of complaints about health-related products, and none of the agencies we contacted was able to provide us with counts of complaints.

Some states consider the content of advertisements for health products to be a matter for federal authorities, whereas other states specifically regulate such advertising. For example, Ohio's consumer sales practices act covers an advertisement's claims about the sales transaction—such as price or quantity—not the content of statements about a product's effectiveness. In contrast, Iowa has a special provision in its consumer protection law for additional penalties when false advertising is targeted at seniors.

Public Health Authority

In all but one of the states we contacted, public health officials were either unable to obtain data on adverse health events resulting from anti-aging or alternative health products or have received few, if any, reports of relevant cases in the recent past. Some noted that the health department may learn of an acute event linked to a dietary supplement but that the more subtle forms of harm typically go unreported. With regard to seniors, officials are particularly concerned about supplements that make unsubstantiated claims to cure disease. Officials believe that when a product such as a dietary supplement does not achieve the promised effect, many people simply stop using it or return it to the retailer rather than notify state authorities.

Public health laws allow state and local authorities to take action against adulterated, misbranded, or dangerous products. Some states have provisions in their food and drug safety laws that incorporate federal standards.

Health authorities in the states we contacted are active to varying degrees in regulating questionable health products. In three of the states we contacted, consumer protection, law enforcement, or public health officials routinely review labels and advertising in a variety of media to determine if they are false or misleading. In several other states, authorities have ongoing investigations stemming from consumer complaints. Investigators may contact the company, review documentation that it submits in support of its claims, conduct inspections, and obtain expert analysis of products. Remedies can include restitution for consumers, fines, court orders to change or remove false claims or to prohibit the sale of misbranded products in the state, and seizure of harmful products.

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 contraindicated for consumers with certain health conditions. Other products, such as St. John's wort, hold promise as potential treatments 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.

Agency Comments

FDA, FTC, and NIH gave us technical comments on the portions of a draft of this report that addressed their respective activities. We have incorporated their suggestions where appropriate.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies to the Secretary of

Health and Human Services and others who are interested. We will also provide copies to others upon request. If you or your staff have any questions, please contact me at (202) 512-7119. Another contact and major contributors to this report are listed in appendix VII.

Sincerely yours,

Janet Heinrich
Director, Health Care—Public Health Issues

Scope and Methodology

We began our work by attempting to identify alternative medicine products marketed as anti-aging therapies that present health and economic risks to seniors. We asked experts in this area which products pose the greatest risk to seniors. Most of the responses we received concerned potential problems with dietary supplements (both herbal and specialty supplements), and occasionally some potentially harmful devices. We did not hear widespread concerns regarding alternative medical services. Therefore, our work focused principally on those herbal and specialty supplements and devices that address health conditions related to aging, such as heart disease, memory loss, fatigue, joint health, and cancer. We reviewed scientific literature and talked with medical and scientific experts, trade association representatives, consumer group representatives, individual practitioners, and researchers. Our investigation of adverse effects, contraindications, and interactions focused primarily on those supplements that were most commonly used by seniors to address issues of aging as identified in a recent survey by *Prevention Magazine*.[1] We conducted analyses of the data from this survey to focus on the use of dietary supplements by people aged 65 years or older.

We also interviewed officials and reviewed documents from the Food and Drug Administration (FDA), Federal Trade Commission (FTC), and National Institutes of Health (NIH). From FDA, we obtained all adverse event reports from 1994 through 2001 reported by people over 65 years old, as well as all reports for most of the dietary supplements mentioned in our report. We examined other FDA and FTC documents to identify warnings that the agencies have issued against certain products because of concerns about safety, labeling, or advertising. We obtained case information from FTC and FDA to determine estimates of economic harm, as well as to review the agencies' enforcement efforts. We also interviewed state attorneys general and public health officials in 14 states to examine enforcement efforts at the state level. These states were selected because they were identified by experts as being the most active in their efforts to curb the marketing and sale of health products making questionable claims. (Table 1 lists the organizations we consulted.)

[1]The herbal supplements we focused on were evening primrose oil, garlic, ginkgo biloba, ginseng, kava kava, saw palmetto, St. John's wort, and valerian. The specialty supplements we focused on were chondroitin sulfate, coenzyme Q10, dehydroepiandrosterone (DHEA), glucosamine, melatonin, omega-3 fatty acids, soy proteins, and shark cartilage.

Table 1: Organizations Consulted

Type of organization	Name of organizations
Federal agencies and organizations	National Institutes of Health (National Center for Complementary and Alternative Medicine, National Institute on Aging, Office of Dietary Supplements) Federal Trade Commission Food and Drug Administration (Center for Food Safety and Applied Nutrition, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Office of Regulatory Affairs, fraud and enforcement officers) Centers for Disease Control and Prevention White House Commission on Complementary and Alternative Medicine Policy
Consumer groups	Center for Science in the Public Interest National Poison Control Center Public Citizen Health Research Group American Council on Science and Health National Consumers League Quackwatch.com American Cancer Society AARP
Professional and trade associations	Consumer Healthcare Products Association American Academy of Anti-Aging Medicine Council for Responsible Nutrition National Nutritional Foods Association American Herbal Products Association Utah Natural Products Alliance American Medical Association representatives American Pharmaceutical Association Federation of State Medical Boards of the United States
Other	U.S. Pharmacopeia Institute of Medicine
States (attorneys general, public health officials, and/or consumer affairs officers)	Arizona California Florida Georgia Illinois Iowa Louisiana Massachusetts Michigan Montana Nebraska New York Ohio Texas

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 of those supplements, we have listed in table 2 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 2: 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.

(Continued From Previous Page)

Product	Principal claims[a]	Principal known adverse effects	Principal known contraindications[b]	Principal known interactions
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.	
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.

(Continued From Previous Page)

Product	Principal claims[a]	Principal known adverse effects	Principal known contraindications[b]	Principal known interactions
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.
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.

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Product	Principal claims[a]	Principal known adverse effects	Principal known contraindications[b]	Principal known interactions
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.
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.

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Product	Principal claims[a]	Principal known adverse effects	Principal known contraindications[b]	Principal known interactions
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.	
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.

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Product	Principal claims[a]	Principal known adverse effects	Principal known contraindications[b]	Principal known interactions
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.
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.

NCCAM Studies on Alternative Therapies Relevant to Senior Citizens

The National Center for Complementary and Alternative Medicine (NCCAM) supports research to test the safety and efficacy of a variety of complementary and alternative medicine modalities. Some of this research focuses on health issues that are relevant to senior citizens, such as arthritis and cancer (see table 3). In fiscal year 2000, appropriations for NCCAM totaled $68.3 million. Additional expenditures by other NIH Institutes and Centers brought the agency's commitment to complementary and alternative medicine to $161 million for fiscal year 2000. In fiscal year 2001, NCCAM's appropriations increased 29 percent to approximately $89 million.

Table 3: Studies Identified in NCCAM's Fiscal Year 2001-2005 Strategic Plan Relevant to Senior Citizens

Condition	Studies
Arthritis	• Acupuncture safety/efficacy in knee osteoarthritis • Study of the efficacy of glucosamine and glucosamine/chondroitin sulfate in knee osteoarthritis
Cancer	• Control trial of ancillary nutritional support and detoxification procedures for inoperable pancreatic cancer • Self-transcendence in breast cancer support groups • Shark cartilage trial (in the treatment of patients with breast or colorectal cancer) • Shark cartilage trial (in the treatment of non-small-cell lung cancer)
Cardiovascular diseases	• Acupuncture and hypertension: efficacy and mechanisms • Effect of high-dose vitamin E on carotid atherosclerosis • Effects of medication on mechanisms of coronary heart disease
Mental health disorders	• Effects of a standardized extract of *Hypericum perforatum* (St. John's wort) in major depressive disorder • Acupuncture in the treatment of depression • Omega-3 fatty acids in bipolar disorder prophylaxis
Neurological disorders	• Ginkgo biloba depression-prevention trial in older individuals • Melatonin for sleep disorders in Parkinson's disease
Urological disorders	• Saw palmetto extract in benign prostatic hyperplasia

In addition, NCCAM funds a variety of specialized research centers that serve as focal points for initiating and maintaining state-of-the-art multidisciplinary research on complementary and alternative medicine. Some of these focus on issues specifically relevant to older Americans:

- The center for cardiovascular diseases at the University of Michigan is examining the effect of hawthorn (an herbal supplement) in the

treatment of heart failure; the effect of Reiki (a natural energy therapy) on diabetes and cardiovascular autonomic function; and the effect of Qi gong (a Chinese practice that combines movement, meditation, and regulation to enhance the flow of energy) and spirituality and psychosocial factors on wound closure, pain, medication usage, and hospital stay in postoperative cardiac patients.

- The center for neurological disorders at Oregon Health Sciences University is examining the effectiveness of three antioxidant regimens in decreasing multiple sclerosis disease activity, ginkgo biloba in the prevention or delay of cognitive decline in elderly patients, hatha yoga on cognitive and behavioral changes associated with aging and neurological disorders in multiple sclerosis, and vitamin E and ginkgo biloba in reducing oxidative end-products.
- The center on arthritis at the University of Maryland is investigating the effectiveness of acupuncture for the treatment of osteoarthritis of the knee, the effectiveness of mind-body therapies for fibromyalgia, the effects of electroacupuncture on persistent pain and inflammation, and the mechanism of an herbal combination with immunomodulatory properties.
- The center on aging at Columbia University is investigating the influence of a macrobiotic diet on endocrine, biochemical, and cardiovascular parameters; whether phytoestrogens influence bone metabolism in postmenopausal women; whether black cohosh (an herbal supplement) reduces the frequency and intensity of menopausal hot flashes and other menopausal symptoms; and the biological activities and mechanisms of a Chinese herbal formula on breast cancer cells.
- The center for the study of minority aging and cardiovascular disease at the Maharishi University of Management focuses on a form of Ayurvedic Indian medicine that incorporates herbal formulations and medication in older blacks. Specific studies focus on the basic mechanisms of meditation and cardiovascular disease in older blacks, the effect of transcendental meditation on reducing hypertension, and the effects of herbal antioxidants on cardiovascular disease in older blacks.

Recent FDA Actions

FDA identified actions it has taken in response to products making illegal claims that were targeted at least in part toward senior citizens. These are listed in table 4.

Table 4: Recent FDA Actions for Health Products Determined to Be Making Illegal Claims

Company	Products or services[a]	Claim[b]	FDA actions	Outcome
Christian Brothers Contracting Corp. (New York)	Laetrile products: "Vitamin B-17 Tablets," "Apricot Seeds," and "Amigdalina" ampuls	FDA alleged that video touted efficacy of products in curing cancer. Several Web sites featured similar claims; company sent out unsolicited e-mail notices to potential customers.	Issued warning letter to company that products being promoted were unapproved new drugs and were misbranded and that laetrile remains the subject of an import alert and had been declared to be an unapproved new drug in other matters. FDA subsequently filed a complaint for permanent injunction, based in part on an undercover investigation during which FDA agents purchased laetrile products after company allegedly said distribution had stopped.	Consent decree in November 2000 granted permanent injunction. Laetrile products ordered destroyed at company's expense. FDA given authority to make continuing unannounced inspections to check compliance.
Health Resources (Alabama)	"b-Calm'd," "Earthwise," "AloeGold," "Para 90," "Maxi-Chel," "Enhance Plus," "Super BP," "Triomin," and "Perform," among other supplement products	Among primary claims were that products could treat high blood pressure, strokes, alcoholism, flu, fevers, herpes, hepatitis, Epstein-Barr, pneumonia, and other diseases and conditions.	Issued warning letter in May 2000.	Company removed Web site and agreed to modify promotional literature and advertising to remove claims.
Hillestad Pharmaceuticals, USA (Wisconsin)	Various herbal products, including garlic, gingko biloba, and St. John's wort	Primary claims were that products could cure and treat various diseases and conditions, including anxiety, depression, coughs, asthma, and allergies.	Filed complaint arguing that products were misbranded and that labeling showed that intended use was in cure, treatment, mitigation, and prevention of disease, making products unapproved new drugs. Seized products.	Court order, July 2000, required products and catalogs featuring disease treatment claims to be destroyed or revised to remove disease treatment claims, and Web site modified to remove disease treatment claims. FDA given authority to make unannounced inspections.

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Company	Products or services[a]	Claim[b]	FDA actions	Outcome
Jewell Hall (Arkansas)	"Black Pills for Arthritis" and "Joint Factors"	Primary claims were that "Black Pills" could relieve pain due to rheumatism, paralysis, bone pain, and acute and chronic neuralgia. "Joint Factors" claimed to address pain, rheumatoid arthritis. FDA analysis also revealed "Black Pills" contained four prescription drugs not on the label.	Filed seizure complaint, arguing that "Black Pills" were misbranded, labeling was inadequate, and products were unapproved new drugs. Destroyed drugs and labeling after court condemnation.	Following no reply to complaint, products ordered destroyed in court order issued November 2000.
Lane Labs-USA, Inc. (New Jersey)	"BeneFin" (produced from shark cartilage), "SkinAnswer" (a glycoalkaloid skin cream), and "MGN-3" (rice bran extract)	FDA alleges that the products are intended for use in the treatment of cancer, skin cancer, and HIV/AIDS, among other diseases.	Issued warning letter in September 1997 notifying the company that "BeneFin" and "SkinAnswer" were misbranded and unapproved new drugs. Through an undercover investigation in 1998-99, FDA determined that the company was continuing to distribute unapproved and misbranded drugs. A complaint for permanent injunction was filed in December 1999.	In December 1999, FDA filed a complaint for permanent injunction alleging violations in warning letter.
NutriSOY International (Indiana)	Soy protein products, including "California Joe Drink"; other products included "Essential ProPLUS," and "Essential Protein"	Primary claims were for lowering cholesterol; treatment of numerous diseases, including cancer, diabetes, and heart disease; to "help the liver recover from the effects of alcohol, viruses, and other toxic agents;" and to treat kidney stones, stroke, and other serious illnesses and conditions.	Issued warning letter in March 2000 that products were making disease treatment claims and were unapproved new drugs.	Company agreed to redesign Web site and other promotional materials to remove disease treatment claims.
Pharmanex (California,Delaware, and Utah)	"Cholestin," a red yeast rice product containing lovastatin	Primary claims were that "Cholestin" lowers serum total cholesterol, lowers serum triglycerides, lowers LDL cholesterol, and raises HDL cholesterol.	Issued an administrative ruling that "Cholestin" was not a dietary supplement but an unapproved new drug.	Court upheld FDA decision.

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Company	Products or services[a]	Claim[b]	FDA actions	Outcome
Scientific Health Products doing business as Natural Wonders (Utah)	"Prevent," "AloeWonder," "Inflam-mation-B," "Herb-A-Derm," "S-E-T Free," "Kleen-Sweep-I," "Me Again," and "Depression," among other products.	Primary claims were various disease treatment claims, including "prevents degenerative disease and age-related health problems," most commonly, heart disease and cancer.	Issued warning letter in August 1999, with follow-up inspection in July 2000.	Company modified claims for some, but not all, products, and destroyed some catalogs. In May 2001, company agreed to cease operation.
Universal Manage-ment Services, and Natural Choice Products (Ohio)	"Stimulator" device (similar to gas grill igniters outfitted with finger grips)	Primary claims were for relief of many kinds of pain, including migraine headaches, sciatica, swollen joints, and carpal tunnel syndrome.	At FDA's request, U.S. Marshals seized about 16,000 "Stimulators" from company's offices. Company continued to distribute the unapproved devices.	Court order required companies to pay refunds of about $82 each on request; refund program administered externally.
Worldtech Research Group; World Without Cancer, Corp.; Health Genesis Corp.; The Health World Inter-national (Florida)	"Vitamin B17" (commonly known as laetrile or amygdalin).	Primary claim was that laetrile products cured cancer and inhibited tumor growth.	Issued warning letter to Worldtech Research Group that laetrile is an unapproved new drug, and that claims for other products were disease treatment claims.	Permanent injunction granted against sale and distribution of laetrile products or any other "new drugs." FDA given authority to make continuing unannounced inspections to check compliance. Decree required defendants to modify Web sites so as to cease using the Web sites to promote for sale laetrile products or any other drug product that is a new drug.

[a]Specific product names are listed in quotation marks.

[b]List does not necessarily include all claims for products.

Recent FTC Actions

FTC identified examples of actions it has taken in response to products with illegal advertisements and that were targeted at least in part to senior citizens. These are listed in table 5.

Table 5: FTC Cases of Illegal Advertising for Products Targeted to Senior Citizens

Company	Products or services[a]	Claims challenged	Outcome
Aaron Company (Florida)	Colloidal silver, chitosan with vitamin C, and "Ultimate Energizer"	Colloidal silver product can cure or treat more than 650 diseases (including HIV/AIDS, multiple sclerosis, and cancer); chitosan product made weight loss claims; and "Ultimate Energizer" is safe and has no side effects.	July 2001, company ordered not to make unsubstantiated disease treatment claims and ordered that products containing ephedra or ephedrine carry a label warning that such products can have dangerous effects on the central nervous system and should not be taken with MAO inhibitors or allergy medications. No consumer redress ordered.
Arthritis Pain Care Center (Texas)	"CMO" (cetylmyristoleate)	"CMO" treats most forms of arthritis and is beneficial in treating numerous other diseases.	September 1999, company ordered not to make future unsubstantiated disease treatment claims and to monitor distributors' advertising and promotional activities, and to notify distributors about the order. No consumer redress ordered.
Christopher Enterprises (Utah)	Various comfrey products	Comfrey products for internal consumption are effective in treating and/or curing asthma, colds, coughs, lung congestion, sore throats, emphysema, bronchitis, tuberculosis, broken bones, polio, multiple sclerosis, spinal curvature, and spinal cancer. Suppository products are effective for prolapsed bowel and uterus, yeast infections, and herpes simplex. Comfrey antiseptic is effective for thrush, infection, pyorrhea, sore throat, and toothaches.	July 2001, company agreed to preliminary injunction to stop marketing comfrey products for internal uses or use on open wounds, to include a warning on products, and to cease making safety and health benefit claims in the absence of supporting scientific evidence.
CMO Distribution Centers of America (Michigan and Florida)	"CMO" (cetylmyristoleate)	"CMO" "normalizes" immune system; cures arthritis; and treats asthma, emphysema, and certain cancers.	May 2000, company ordered not to make future unsubstantiated disease treatment claims and required to monitor product advertising by distributors, and to notify distributors about order. Full refund (about $100 per bottle) ordered for individuals requesting one within 120 days of order.

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Company	Products or services[a]	Claims challenged	Outcome
EHP Products (Kentucky)	"CMO" product, "Myristin" capsules	"CMO"/Myristin relieves arthritis and prevents rheumatoid arthritis and osteoarthritis.	May 2000, company ordered not to make unsubstantiated treatment claims, and required to notify distributors of order and to monitor product advertising by distributors. Ordered full consumer refund (about $100 per bottle), plus shipping fee of $3.50, for consumers requesting one within 120 days.
ForMor (Arkansas)	"St. John's Kava Kava," colloidal silver, and "Ultimate II Shark Cartilage Concen-trate"	"St. John's Kava Kava" is effective in treatment of HIV/AIDS, colds, syphilis, tuberculosis, dysentery, and other conditions; colloidal silver was effective for more than 650 infectious diseases; and shark cartilage product was effective in treatment of arthritis and brain cancer.	August 2001, company ordered not to make unsubstantiated disease treatment claims and to include warning label on "St. John's Kava Kava" product alerting consumers to potential risks of interactions with prescription drugs, including anticoagulants, oral contraceptives, antiseizure medications, HIV drugs; and not to make unsubstantiated disease treatment claims for colloidal silver and shark cartilage. Ordered full consumer refunds for customers requesting refund within 90 days for colloidal silver and shark cartilage products purchased between January 1999 and August 2001.
Jaguar Enterprises (Florida, North Carolina, Texas)	Electronic devices, including the "Black Box," the "Magnetic Pulser," the "Magnetic Multi-Pulser," the "Beck-Rife Unit," and the "Portable Rife Frequency Generator"; also, a "Miracle Herbs" product.	Electronic devices cure and prevent serious diseases such as cancer, AIDS, arthritis, Gulf War syndrome, and chronic fatigue syndrome, and "Miracle Herbs" treats cancer of all types, AIDS, and various bacterial and viral infections.	August 2001, company ordered not to make unsubstantiated disease treatment claims. Ordered full consumer refund, including shipping and handling fees, for individuals requesting refund within 90 days of required notice.
Lane Labs-USA, Inc. and Cartilage Consultants (New Jersey)	"BeneFin" and "Skin-Answer"	"BeneFin" and "SkinAnswer" effectively treat cancer.	June 2000, company ordered not to make unsubstantiated therapeutic claims. Judgment of $1 million required, including $450,000 to be used for purchase of shark cartilage and placebo products to be tested in NIH clinical trial.
Maxcell Bioscience, Inc., and Oasis Wellness Network (Colorado)	"Longevity Signal Formula with DHEA (LSF)," and "Anabolic/ Catabolic Index Test" (an at-home urine test).	"LSF" reverses the aging process and prevents, treats, or cures numerous age-related diseases and conditions, including atherosclerosis, arthritis, high blood pressure, elevated cholesterol levels, weight gain, and poor liver function. "Anabolic/Catabolic Index" measures youthfulness and healthiness.	August 2001, company ordered not to make unsubstantiated disease treatment and "anti-aging" claims for LSF or claims that device test results provide a clinical gauge of overall healthiness and youthfulness; and company required to notify distributors of order and to monitor product advertising and promotion by distributors. Ordered $150,000 in consumer redress.

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Company	Products or services[a]	Claims challenged	Outcome
Natural Heritage Enterprises (Colorado)	Essiac tea	Essiac tea treats cancer, diabetes, HIV/AIDS, and feline leukemia.	May 2000, company ordered not to make unsubstantiated disease treatment claims and required company to notify consumers that there is no scientific evidence that Essiac tea cures cancer or other diseases. Ordered payment of $17,500 for consumer redress.
Pain Stops Here! (New York)	Magnets and magnetic products, including magnetic sleep pads and magnetized water	Magnets and magnetic products can treat cancer, cure liver disease, reduce cholesterol, prevent and reverse heart disease, and relieve pain associated with arthritis, bursitis, and sciatica.	September 1999, company ordered not to make unsubstantiated disease treatment claims and to notify distributors of order and to monitor product advertising by distributors. No consumer redress ordered.
Panda Herbal International, Inc. (Pennsylvania)	"Herbal Outlook" and "Herb Veil 8"	"Herbal Outlook" is an effective treatment for HIV/AIDS, tuberculosis, influenza, and hepatitis B; "Herb Veil 8" is an effective treatment for carcinomas, and melanoma.	August 2001, company ordered not to make unsubstantiated disease treatment claims; required warning label for "Herbal Outlook" alerting consumers to potential risks of interactions with prescription drugs, including anticoagulants, oral contraceptives, antiseizure medications, HIV/AIDS drugs; and required company to monitor advertising and promotional materials distributed by purchasers who are resellers. Ordered to pay full refunds within 90 days to consumers who purchased "Herb Veil 8" and requested a refund.
Rose Creek Health Products and Staff of Life (Washington)	"Vitamin O"	"Vitamin O" allows oxygen molecules to be absorbed through the gastrointestinal system and prevents or treats life-threatening diseases.	April 2000, companies ordered not to make unsubstantiated therapeutic claims and to notify distributors of order. Payment of $375,000 ordered for consumer redress and consumer education.
SmartScience Laboratories (Florida)	"JointFlex"	"JointFlex," a topical skin cream, eliminates pain due to disabling joint conditions, crushed vertebrae, herniated disks, and other conditions.	November 2000, company ordered not to make unsubstantiated disease treatment claims for its products. No consumer redress ordered.
Western Dietary Products Co. (Washington)	Various herbal formulas, "cure" packages, and "Zapper Electrical Unit" device	Herb formulas and cure packages can treat and cure cancer, diabetes, and arthritis. "Zapper Electrical Unit" can treat and cure Alzheimer's and HIV/AIDS.	Company agreed to preliminary injunction in June 2001, involving its products and activities. FTC has requested consumer refund. Outcome is pending.

[a]Specific product names are listed in quotation marks.

Examples of Questionable Health Care Products Used by Senior Citizens, as Reported by State Officials

State officials we talked with described a number of products used by seniors that were questionable or had questionable advertising and where state action was taken, including the following:

- Companies marketing therapeutic magnets with unsubstantiated claims that they can cure a variety of diseases, including diabetes and osteoporosis. One state health department official noted that some magnet companies are aware that they can only be sold for general well-being, but in other states they continue to be marketed with health claims.
- A national mail-order company selling a variety of health products with unsubstantiated promises to cure prostate disease, bladder problems, hair loss, skin discoloration, sexual impotence, and cancer. Authorities in one state have obtained restitution for consumers, civil fines, and court orders to keep this and similar companies from selling fraudulently advertised products, including anti-aging formulas, to its residents. However, the authorities have no means to prevent the company from publishing misleading material and selling questionable products in the rest of the country.
- A Web-based company advertising a breast-enhancement product to women who have had mastectomies with the claim that it can regenerate lost breast tissue. The company removed its claim after being contacted by a state attorney general's office.
- Herbal remedies contaminated with toxic substances such as heavy metals. Authorities in one state have analyzed products and found cases of adulteration in imported ingredients used in traditional Chinese medicine.
- Herbal supplements "spiked" with prescription drugs or synthetic ingredients. In one case a diabetic had to seek medical treatment after taking an herbal product that contained a prescription diabetes drug. Another product marketed as an "all-herbal" weight-loss formula using ephedra was found to contain ephedrine, a synthetic substance not listed on the label. Concerns about the potential health hazards associated with ephedra have prompted several states to issue regulations restricting its dosage or sale.
- Testing blood and hair samples to diagnose nutritional deficiencies or illnesses to induce people to buy a particular dietary supplement as treatment. In one state, there is an ownership link between the out-of-state laboratories doing the analyses and the manufacturer of the dietary supplements.

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