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# HERBAL DIETARY SUPPLEMENTS

# Examples of Deceptive or Questionable Marketing Practices and Potentially Dangerous Advice

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May 26, 2010

# HERBAL DIETARY SUPPLEMENTS

## Examples of Deceptive or Questionable Marketing Practices and Potentially Dangerous Advice

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Highlights

Highlights of GAO-10-662T, a testimony before the Special Committee on Aging, U.S. Senate

### Why GAO Did This Study

Recent studies have shown that use of herbal dietary supplements—chamomile, echinacea, garlic, ginkgo biloba, and ginseng—by the elderly within the United States has increased substantially. Sellers, such as retail stores, Web sites, and distributors, often claim these supplements help improve memory, circulation, and other bodily functions. GAO was asked to determine (1) whether sellers of herbal dietary supplements are using deceptive or questionable marketing practices and (2) whether selected herbal dietary supplements are contaminated with harmful substances.

To conduct this investigation, GAO investigated a nonrepresentative selection of 22 storefront and mail-order retailers of herbal dietary supplements. Posing as elderly consumers, GAO investigators asked sales staff (by phone and in person) at each retailer a series of questions regarding herbal dietary supplements. GAO also reviewed written marketing language used on approximately 30 retail Web sites. Claims were evaluated against recognized scientific research published by the National Institutes of Health (NIH) and the Food and Drug Administration (FDA). GAO also had an accredited lab test 40 unique popular single-ingredient herbal dietary supplements for the presence of lead, arsenic, mercury, cadmium, organichlorine pesticides, and organophosphorous pesticides.

View GAO-10-662T or key components. For more information, contact Gregory D. Kutz at (202) 512-6722 or kutzg@gao.gov.

### What GAO Found

Certain dietary supplements commonly used by the elderly were deceptively or questionably marketed. FDA statutes and regulations do not permit sellers to make claims that their products can treat, prevent, or cure specific diseases. However, in several cases, written sales materials for products sold through online retailers claimed that herbal dietary supplements could treat, prevent, or cure conditions such as diabetes, cancer, or cardiovascular disease. When GAO shared these claims with FDA and the Federal Trade Commission (FTC), both agreed that the claims were improper and likely in violation of statutes and regulations. In addition, while posing as elderly customers, GAO investigators were often told by sales staff that a given supplement would prevent or cure conditions such as high cholesterol or Alzheimer's disease. To hear clips of undercover calls, see http://www.gao.gov/products/GAO-10-662T. Perhaps more dangerously, GAO investigators were given potentially harmful medical advice. For example, a seller stated it was not a problem to take ginkgo biloba with aspirin to improve memory; however, FDA warns that combining aspirin and ginkgo biloba can increase a person's risk of bleeding. In another case, a seller stated that an herbal dietary supplement could be taken instead of a medication prescribed by a doctor. GAO referred these sellers to FDA and FTC for appropriate action. The table below includes several deceptive claims made by sellers.

**Deceptive Marketing Claims for Herbal Supplements Found by GAO Investigators**

| Claim | Comments |
|---|---|
| Garlic prevents obesity and diabetes and cures cardiovascular disease. | NIH does not recognize this herbal supplement as a treatment for obesity, diabetes, or cardiovascular disease. |
| Ginseng cures diseases, including cancer. | NIH specifically recommends that breast and uterine cancer patients avoid this product, as it may have an adverse interaction with some cancer drugs. |
| Garlic can be taken in lieu of prescribed high blood pressure medication. | Evidence that this product reduces high blood pressure is unclear, and both NIH and FDA state that no dietary supplement can take the place of prescribed medicines. |
| Ginkgo biloba can be taken with a daily aspirin prescription. | Taking this product with aspirin may increase the risk of bleeding. |
| Ginkgo biloba treats Alzheimer's disease, depression, and impotence. | No clear scientific evidence supports any of these treatment claims. |

Source: GAO.

GAO also found trace amounts of at least one potentially hazardous contaminant in 37 of the 40 herbal dietary supplement products tested, though none in amounts considered to pose an acute toxicity hazard. All 37 supplements tested positive for trace amounts of lead; of those, 32 also contained mercury, 28 cadmium, 21 arsenic, and 18 residues from at least one pesticide. The levels of heavy metals found do not exceed any FDA or Environmental Protection Agency (EPA) regulations governing dietary supplements or their raw ingredients, and FDA and EPA officials did not express concern regarding any immediate negative health consequences from consuming these 40 supplements. While the manufacturers GAO spoke with were concerned about finding any contaminants in their supplements, they noted that the levels identified were too low to raise any issues internal product testing.

Mr. Chairman and Members of the Committee:

Thank you for the opportunity to discuss findings from our investigation into the manufacture and marketing of selected herbal dietary supplements commonly used by the elderly.[1] The Dietary Supplement Health and Education Act of 1994 (DSHEA) defines dietary supplements as products that, among other things, are intended for ingestion to supplement the diet, labeled as dietary supplements, and not represented as conventional foods or as a sole items of a meal or diet.[2] Recent studies have shown that use of herbal dietary supplements, such as chamomile, echinacea, garlic, ginkgo biloba, and ginseng, by the elderly in the United States has increased substantially.[3]

In 2000, we reported that consumers did not consistently receive clear, scientifically supported information concerning products' health benefits so they could make informed dietary choices. Further, we have reported that consumers faced health risks because federal laws and agencies' efforts did not effectively and consistently ensure that dietary supplements were safe.[4] Most recently, we expressed concern that weaknesses in the regulatory system may increase the likelihood of unsafe products reaching the market, and a lack of consumer knowledge increases the potential health risks associated with uninformed consumption.[5] At your request, we determined (1) whether sellers of herbal dietary supplements are using deceptive or questionable marketing practices to encourage the use of these products and (2) whether selected herbal dietary supplements are contaminated with harmful substances.

To determine whether sellers of herbal dietary supplements are using deceptive or questionable marketing practices to encourage the use of these

[1]For purposes of this testimony, we defined elderly as people 65 years of age and older.

[2]Pub. L. No. 103-417, § 3, 108 Stat. 4325, 4327 (codified at 21 U.S.C. § 321(ff)).

[3]Herbal supplements are one type of dietary supplement. An herb is a plant or plant part (such as leaves, flowers, or seeds) that is used for its flavor, scent, therapeutic properties, or a combination of these. "Botanical" is often used as a synonym for "herb." An herbal supplement may contain a single herb or mixtures of herbs.

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

[5]GAO, *Dietary Supplements: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding*, GAO-09-250 (Washington, D.C.: Jan. 29, 2009).

products, we investigated a nonrepresentative selection of 22 storefront and mail-order retailers. We identified these retailers by searching online using search terms likely to be used by actual consumers and by observing newspaper advertisements. Posing as elderly potential consumers, we asked sales staff at each retailer a series of questions regarding the potential health benefits of herbal dietary supplements as well as potential interactions with other common over-the-counter and prescription drugs. We also reviewed written marketing language used on approximately 30 retail Web sites.[6] We evaluated the accuracy of product marketing claims against health benefit evaluations published through the National Institutes of Health (NIH) and Food and Drug Administration (FDA). While our work focused on herbal dietary supplements, we also evaluated claims made regarding nonherbal supplement products recommended to us during undercover storefront visits and telephone calls.

To determine whether selected herbal dietary supplements are contaminated with harmful substances, we purchased 40 unique single-ingredient herbal supplement products from 40 different manufacturers and submitted them to an accredited laboratory for analysis. We selected the types of herbs to purchase based on recent surveys about the supplements usage of the elderly. These surveys identified the most commonly used herbs among the elderly as chamomile, echinacea, garlic, ginkgo biloba, ginseng, peppermint, saw palmetto, and St. John's wort. We purchased these 40 unique products from a combination of retail chain storefronts and online or mail-order retailers; these retailers were selected independently from those selected for evaluation of marketing practices. For each online retailer, we selected brands based primarily on relative popularity according to the site's list of top sellers. One unopened, manufacturer-sealed bottle of each of these 40 products was submitted to an accredited laboratory where they were screened for the presence of common hazardous contaminants: lead, arsenic, mercury, cadmium, and residues from organichlorine and organophosphorous pesticides. These contaminants were selected based on prevalence and the likelihood of negative health consequences as a result of consumption. We did not independently validate the results received with another lab, or through any other mechanism. The likely negative health consequences from consumption of these contaminants were determined based on a review of relevant health standards and discussions with FDA and Environmental

[6]Our findings are limited to the individual retailers and sales staff we investigated. Our findings cannot be projected to any other retailers or sales representatives.

Protection Agency (EPA) experts. For a complete discussion of our scope and methodology, see appendix I. See appendix II for the complete list of contaminants we reviewed.

Our investigative work, conducted from September 2009 through March 2010, was performed in accordance with standards prescribed by the Council of the Inspectors General on Integrity and Efficiency.

## Background

Herbal dietary supplements are traditionally used to alleviate certain medical conditions, such as anxiety, digestive problems, and depression, and to improve general quality of life. However, for many traditional uses, there is not clear scientific evidence to show that they prevent or treat underlying diseases or conditions. Further, some herbal dietary supplements may interact in a potentially harmful manner with some prescription drugs. For example, according to NIH, St. John's wort can negatively affect the efficacy of antidepressants, HIV treatments, cancer drugs, and anticoagulants, though this is not always noted on product labels. The possibility of adverse drug interactions is one of the reasons that FDA recommends that consumers check with their health practitioners before beginning any supplement regimen. The elderly are particularly at risk from these interactions since recent studies have found that approximately 85 percent of the elderly take at least one prescription drug over the course of a year and 58 percent take three or more. Many herbal supplements have not been exhaustively tested for hazardous interactions with prescription drugs, other supplements, or foods.[7]

Under DSHEA, dietary supplements are broadly presumed safe, and FDA does not have the authority to require them to be approved for safety and efficacy before they enter the market, as it does for drugs. However, a dietary supplement manufacturer or distributor of a supplement with a "new dietary ingredient"—an ingredient that was not marketed in the United States before October 15, 1994—may be required to notify FDA at least 75 days before marketing the product, depending on the history of use of the ingredient.[8] Also, all domestic and foreign companies that manufacture, package, label, or hold dietary supplements must follow

[7]FDA does not require that herbal supplement manufacturers conduct such testing.

[8]For the products reviewed as part of this testimony, most of the dietary ingredients involved were marketed prior to October 15, 1994, and therefore were not subject to the "new dietary ingredient" approval requirement.

FDA's current good manufacturing practice regulations, which outline procedures for ensuring the quality of supplements intended for sale.[9]

## Marketing Claims

Under DSHEA, a firm, not FDA, is responsible for determining that any representation or claims made about the dietary supplements it manufactures or distributes are substantiated by adequate evidence to show that they are not false or misleading. Except in the case of a new dietary ingredient, where premarket review for safety data and other information is required by law, a firm does not have to provide FDA with the evidence it relies on to substantiate effectiveness before or after it markets its products. For the most part, FDA relies on postmarket surveillance efforts—such as monitoring adverse event reports it receives from companies, health care practitioners, and individuals; reviewing consumer complaints; and conducting facility inspections—to identify potential safety concerns related to dietary supplements.[10] Once a safety concern is identified, FDA must demonstrate that the dietary supplement presents a significant or unreasonable risk, or is otherwise adulterated, before it can be removed from the market.

A product sold as a dietary supplement cannot suggest on its label or in labeling that it treats, prevents, or cures a specific disease or condition without specific approval from FDA.[11] Under FDA regulations, a manufacturer may submit a health claim petition in order to use a claim on its product labeling that characterizes a relationship between the product and risk of a disease, and FDA may authorize it provided the claims meet certain criteria and are authorized by FDA regulations[12] (e.g., diets high in

[9]21 U.S.C. § 342(g) and 21 C.F.R. §§ 111.1 - .610

[10]As of December 22, 2007, dietary supplement companies are required to submit any report received about a serious adverse event to FDA, as mandated by the Dietary Supplement and Nonprescription Drug Consumer Protection Act. (Pub. L. No. 109-462, § 3(a),120 Stat. 3469, 3472 (codified at 21 U.S.C. § 379aa-1)). In addition, companies can voluntarily submit reports about moderate and mild adverse events. Others, such as consumers and health care practitioners, can submit reports of serious, moderate, and mild adverse events on a voluntary basis to FDA.

[11]Labeling refers to the label as well as accompanying material that is used by a manufacturer to promote and market a specific product.

[12]FDA authorizes these types of health claims under the Nutrition Labeling and Education Act of 1990 (Pub. L. No. 101-535, § 3(a), 104 Stat. 2353, 2357-60 (codified at 21 U.S.C. § 321(r))) based on extensive review of the scientific literature, generally as a result of the submission of a health claim petition, using the significant scientific agreement standard to determine that the nutrient/disease relationship is well established.

calcium may reduce the risk of osteoporosis).[13] However, manufacturers may make "qualified health claims" when there is emerging evidence for a relationship between a dietary supplement and reduced risk of a disease or condition, subject to FDA's enforcement discretion. The claim must include specific qualifying language to indicate that the supporting evidence is limited.[14,15]

Dietary supplement labeling may include other claims describing how a dietary ingredient is intended to affect the normal structure or function of the body (e.g. fiber maintains bowel regularity). The manufacturer is responsible for ensuring the accuracy and truthfulness of such claims, but must submit a claim to FDA for review no later than 30 days after marketing it.[16] Because FDA does not confirm the claim—a lack of objection allows the manufacturer to use it—the following disclaimer must be included: "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease." The manufacturer does not need to provide FDA with documentation, and FDA does not test to determine if the claim is true.

In addition, these claims generally may not state that a product is intended to diagnose, mitigate, treat, cure, or prevent a disease or the adverse effects associated with a therapy for a disease, either by naming or

[13]A manufacturer may, alternately, obtain FDA approval to market its product as a drug intended for the treatment, prevention, cure, mitigation, or diagnosis of a specific disease.

[14]Dietary supplement labeling may contain nutrient content claims, which describe the level of a nutrient or dietary substance in the product using terms such as "free," "high," and "low," or compare the level of a nutrient in a food to that of another food, using terms such as "more," "reduced," and "lite."

[15]The constitutionality of some of FDA's health claim regulations for dietary supplements have been successfully challenged in court. In *Pearson v. Shalala*, 164 F.3d 650 (DC Cir. 1999), the United States Court of Appeals for the District of Columbia Circuit held that while inherently or actually misleading information could be absolutely prohibited, the First Amendment did not permit such a restriction on information that is only potentially misleading. The determination of whether regulation of potentially misleading information is permissible instead requires an analysis of the level of government interest, the potential advancement of the government interest by the regulation, and the reasonableness of the means chosen to accomplish the government's goals.

[16]FDA receives approximately 4,000 such claims submissions per year for one or more claims for one or more products.

describing a specific disease.[17] A claim also cannot suggest an effect on an abnormal condition associated with a natural state or process, such as aging.[18] Context is a consideration; a product's name and labeling cannot imply such an effect by use of pictures or scientific or lay terminology. Finally, a product cannot claim to be a substitute for a product that is a therapy for a disease, or claim to augment a therapy or drug. To make any of these claims, a manufacturer must submit and receive authorization of a health claim petition.

The Federal Trade Commission (FTC) regulates advertising for dietary supplements and other products sold to consumers. FTC receives thousands of consumer complaints each year related to dietary supplements and herbal remedies. FTC has, in the past, taken action against supplement sellers and manufacturers whose advertising was deemed to pose harm to the general public. FDA works with FTC in this area, but FTC's work is directed by different laws.

## Harmful Substance Contamination

Consuming high levels of the contaminants for which we tested the 40 products can lead to severe health consequences, such as increased risk of cancer, as noted in table 1. The negative health effects described are, unless otherwise noted, for the acute toxicity in the human body. However, the exact effects of these contaminants on an individual are based on an individual's specific characteristics. For instance, since lead can build up in the human body, the effect of consuming a potentially dangerous level of lead by a 55-year-old man depends on the amount of lead that man has consumed during his lifetime, among other factors.

[17]FDA defines a disease as "damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition."

[18]Some natural states or processes such as aging, menopause, and the menstrual cycle, are not themselves diseases but can be associated with abnormal conditions that are diseases. Two criteria determine if such a condition will be considered a disease: (1) if the condition is uncommon or (2) if the condition can cause significant or permanent harm.

**Table 1: Potential Negative Health Effects of Contaminants Tested for in Selected Herbal Dietary Supplements**

| Contaminant | Negative health effects |
|---|---|
| Arsenic | Known to increase risk of lung and skin cancer. Long-term exposure can cause skin pigment changes and a thickening of the skin of the hands and feet. |
| Cadmium | Known to cause increased risk of leukemia and testicular tumors. Long-term exposure to lower levels can lead to kidney disease, lung damage, and fragile bones. |
| Lead | May cause increased risk of lung, stomach, and bladder cancer. |
| Mercury | May cause fever, insomnia, and mood shifts. High levels may cause blindness, deafness, and long-term exposure may cause severe renal damage. |
| Carbofuran | Cholinesterase inhibitor.[a] |
| Chlorpyrifos | Light exposure may cause headaches, blurred vision, watery eyes, dizziness, confusion, diarrhea, and change in heart rate. Heavy exposure may cause seizures, coma, and death. |
| p,p-DDE[b] | May increase risk of liver and thyroid tumors. |
| gamma-HCH | May cause liver or kidney problems. |
| HCB | May cause liver, thyroid, and kidney damage; may increase risk of liver, kidney, and thyroid cancer. |

Sources: Agency for Toxic Substances and Disease Registry, EPA risk assessments, and National Toxicology Program.

Note: All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides that were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards. In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide.

[a]A cholinesterase inhibitor behaves similarly to a neurotoxin and may cause abdominal cramps, diarrhea, nausea, and vomiting.

[b]Dichlorodiphenyldichloroethylene (p,p-DDE) is a breakdown product of the pesticide dichlorodiphenyltrichloroethane (DDT).

FDA has not issued any regulations addressing safe or unsafe levels of contaminants in dietary supplements, but both FDA and EPA have set certain advisory levels for contaminants in other foods. The human body's absorption of many contaminants is governed by intake method, so advisory levels for other foods (e.g., drinking water) cannot be strictly applied to dietary supplements. In addition, EPA sets limits on how much pesticide residue can remain on food and feed products. These pesticide residue limits are known as tolerances and are enforced by FDA. If no residue tolerance has been set for a particular pesticide, any product containing that pesticide residue is considered adulterated and its sale is

prohibited by law. See table 2 for a summary of the regulations issued by FDA or EPA regarding some of the contaminants we tested for.

**Table 2: Regulatory Information for Selected Contaminants**

| Contaminant | Regulatory information |
|---|---|
| Arsenic | FDA has limited arsenic in bottled drinking water to .010 parts per million (ppm).[a] |
| Cadmium | FDA has limited cadmium in bottled drinking water to .005 ppm. |
| Lead | FDA has limited lead in bottled drinking water to .005 ppm. |
| Mercury | FDA has limited mercury in bottled drinking water to .002 ppm. |
| Carbofuran | Carbofuran's use is restricted in the United States due to ecological and health risks. FDA has limited carbofuran in bottled drinking water to .04 ppm. |
| Chlorpyrifos | EPA residue tolerances for chlorpyrifos in food commodities range from .01 to 20.0 ppm. |
| p,p-DDE | The use of the parent chemical for this breakdown product has been banned in the United States since 1972. |
| gamma-HCH | EPA National Primary Drinking Water Regulations limit the level of this pesticide in tap water to .0002 ppm. EPA residue tolerances for gamma-HCH in food commodities range from 4.0 to 7.0 ppm. |
| HCB[b] | EPA National Primary Drinking Water Regulations limit the level of this pesticide in tap water to .001 ppm. |

Source: GAO analysis of FDA and EPA regulations.

[a]Parts per million is a measure equivalent to milligrams of contaminant per kilogram of carrier material or milligrams of contaminant per liter of carrier material.

[b]Hexachlorobenzene (HCB) is subject to a voluntary usage ban by U.S. companies. It is not currently used commercially in the United States, though it was previously used to make fireworks, ammunition, and synthetic rubber.

## Deceptive or Questionable Marketing Claims May Lead to Harm for Elderly Consumers of Herbal Supplements

Our investigation found examples of deceptive or questionable marketing and sales practices for dietary supplements popular among the elderly (see table 3). The most egregious practices included suspect marketing claims that a dietary supplement prevented or cured extremely serious diseases, such as cancer and cardiovascular disease. Other dietary supplements were claimed to mitigate age-related medical conditions, such as Alzheimer's disease and diverticular disorder. We also found some claims that followed FDA's labeling regulations and guidelines, but could still be considered deceptive or questionable and provide consumers with inaccurate information. In addition, while conducting in-person and telephone conversations with dietary supplements sellers, our investigators, posing as elderly consumers, were given potentially harmful medical advice by sales staff, including that they could take supplements

in lieu of prescription medication. In making these claims, sellers put the health of consumers at risk. A link to selected audio clips from these calls is available at: http://www.gao.gov/products/GAO-10-662T.

**Table 3: Cases of Deceptive Marketing and Questionable Practices**

| Case | Product | Deceptive or questionable marketing claim/practice | Comment |
|---|---|---|---|
| 1 | Ginkgo biloba | Product labeling states it "Effectively treats Alzheimer's Disease, depression, impotence, memory … and more." | Several NIH studies have shown ginkgo to be ineffective at reducing the risk of Alzheimer's, or otherwise enhancing memory. Other studies have shown that there may be minor alleviation of depression in elderly patients taking ginkgo, but overall, there is not enough evidence to form a clear conclusion. |
| 2 | Garlic | Product labeling states that it prevents and/or cures cardiovascular disease, cancer, obesity, and diabetes. | Only a drug can claim to cure a disease, according to FDA and NIH. As a treatment for these conditions, experts typically recommend healthy eating, regular physical activity, and in some cases FDA-approved drugs, not this herbal dietary supplement. In addition, no studies suggest that this product can cure or prevent any of these conditions. |
| 3 | Ginseng | Product labeling states that it possesses a "Powerful Anti-cancer Function" and can prevent diabetes, among other questionable claims. | NIH states that there is no clear evidence to support that this supplement can prevent cancer or cardiovascular diseases, and more research is needed. While this supplement may lower blood sugar levels in patients with type 2 diabetes, the long-term effects are not clear, and NIH recommends that patients should instead use more proven therapies. |
| 4 | Garlic | Product labeling states that "it is extremely helpful in treating any form of flu or colds, from a mild head cold to pneumonia. [It] is useful for bronchial conditions such as inflammatory disease, asthma, tuberculosis …" | Some research suggests that this herb may reduce the severity of upper respiratory tract infections. However, according to NIH, better studies need to be performed to confirm this effect in humans. |
| 5 | Garlic | Product labeling states that "Hundreds of scientific studies have proven [this product] to be number one, working to enhance the body's immune function, protect cells from free radical damage, and reduce cardiovascular risk factors, including issues with blood pressure, cholesterol …" | While this herb may help with certain conditions, enhancement of the body's immune function is not a recognized benefit. Studies have shown that this herb may lower bad cholesterol and blood pressure by a small amount, but the long-term effects are not known. In addition, the effects on good cholesterol are unclear. Further, the seller does not disclose details about the "hundreds of scientific studies" cited in the product labeling. |
| 6 | Chamomile | Product labeling states that possible benefits of chamomile include the alleviation of insomnia, diverticular disorder, gum disease, and gingivitis. | Dietary supplements are not a recommended course of treatment for any of these conditions, according to FDA. While chamomile has traditionally been used as a sleep aid, there is a lack of scientific evidence supporting its effectiveness in treating insomnia, according to NIH. For the other conditions, recommended treatments often include lifestyle changes, drugs, and surgery. |
| 7 | Enzyme[a] | Publicity materials for this product include a rebuttal of an FDA disclaimer regarding the product's claim to guard against memory issues. | FDA reviewed the supplement and determined that there is little scientific evidence that it reduces the risk of dementia or cognitive dysfunction in the elderly. |

| Case | Product | Deceptive or questionable marketing claim/practice | Comment |
|---|---|---|---|
| 8 | Garlic | Sales staff informed us that this herbal dietary supplement could be taken in lieu of high blood pressure medicine. | While this herb may lower blood pressure, better studies are needed to confirm this benefit, and NIH does not recommend it as a treatment for high blood pressure. |
| 9 | Ginkgo biloba | Sales staff informed us that there are no side effects to taking the product with aspirin. | FDA warns that if this product is taken with certain drugs (including aspirin), it can increase the potential for internal bleeding. |
| 10 | Ginkgo biloba | Sales staff informed us that by using this supplement, the use of aspirin is no longer needed. | NIH advises consumers to talk to their health care providers before taking any herbal medicines or supplements and before starting or ending any drug regimen. |

Source: GAO.

[a]The product described here is not an herbal dietary supplement, but was recommended by sales staff at several retailers to help with memory issues.

Below are details on several cases in which herbal supplement marketing practices were deceptive or questionable and sometimes posed health risks to consumers. All cases of deceptive or questionable marketing and inappropriate medical advice have been referred to FDA and FTC for appropriate action.

**Case 2:** In online materials, this garlic supplement included claims that it would (1) prevent and cure cardiovascular disease, (2) prevent and cure tumors and cancer, (3) prevent obesity, and (4) reduce glycemia to prevent diabetes. According to NIH, all these claims are unproven, and garlic is not recommended for treating these conditions. In fact, for several of these conditions, garlic may interact adversely with common FDA-approved drug treatments. Nowhere in this product's marketing materials does the seller suggest that consumers should consult their health care providers prior to taking its supplement. While NIH recognizes that garlic may have some anticancer properties, the agency notes that additional clinical trials are needed to conclude whether these properties are strong enough to prevent or treat cancer. Further, studies have shown that garlic may alter the levels of some cancer drugs in the human body, lessening their effectiveness. For diabetes, there are no studies that confirm that garlic lowers blood sugar or increases the release of insulin in humans. In fact, NIH recommends caution when combining garlic with medications that lower blood sugar, and further suggests that patients taking insulin or oral drugs for diabetes be monitored closely by qualified health care professionals.

**Case 3:** According to its labeling, this ginseng supplement—which costs $500 for a 90-day supply—cures diseases, effectively prevents diabetes and cardiovascular disease, and prevents cancer or halts its progression. These

claims are unproven—no studies confirm that ginseng can prevent or cure any disease. In fact, NIH recommends that breast and uterine cancer patients avoid ginseng. In addition, ginseng may adversely interact with cancer drugs. The product labeling claims do not differentiate between type 1 and type 2 diabetes. According to NIH, ginseng's effect on patients with type 1 diabetes is not well studied. While ginseng may lower blood sugar levels in patients with type 2 diabetes, the long-term effects of such a treatment program are unclear, and it is not known what doses are safe or effective. NIH specifically recommends that consumers with type 2 diabetes use proven therapies instead of this supplement.

**Case 7:** While our investigators posed as consumers purchasing dietary supplements, sales staff provided them with an informational booklet regarding an enzyme that claims to "[defend] us against dementia and Alzheimer's, exhibiting a truly miraculous capacity to optimize mental performance and fight off cognitive decline." In fact, FDA reviewed the scientific evidence for the active ingredient of this supplement and found that it was not adequate to make such a claim. Because the agency considered such a health claim potentially misleading, FDA provided for the use of a qualified health claim that contains a disclaimer that must accompany the health claim in all labeling in which these claims appear. While the booklet we received does state the FDA disclaimer on the first page, the manufacturer follows it with a rejoinder: "The very cautious language of these claims, which FDA mandates can only be stated word for word, is at best a grudging concession to the extensive clinical research done with [this supplement]. Considering this agency's legendary toughness against dietary supplements, FDA's willingness to go this far with the [disclaimer] suggests that the FDA must be sure it is safe to take and also that the FDA is unable to deny [this supplement] can improve human brain function."

**Case 8:** One of our fictitious consumers visited a supplement specialty store looking for a product that would help with high blood pressure. The sales representative recommended a garlic supplement and stated that the product could be taken in lieu of prescribed blood pressure medication. According to NIH, while this herb may lower blood pressure by a small amount, the scientific evidence is unclear. NIH does not recommend this supplement as a treatment for high blood pressure and warns patients to use caution while taking this product with other drugs or supplements that can lower blood pressure. Further, it is not recommended that a consumer start or stop a course of treatment without consulting with his or her health care provider. Even if a sales representative is licensed to dispense medical advice, he or she still does not know the consumer's patient

history, including other drug programs, allergies, and medical conditions, making it potentially dangerous for the sales representative to provide medical advice.

**Case 9:** At a supplement specialty store, one of our investigators posed as an elderly consumer who was having difficulty remembering things. A sales representative recommended one of the store's ginkgo biloba supplements. The consumer told the representative that he takes aspirin everyday and asked if it was safe to take aspirin and ginkgo biloba together. The sales representative told him that it is completely safe to take the two together. However, according to FDA, if aspirin is taken with the recommended product, it can increase the potential for internal bleeding.

We spoke to FDA and FTC regarding these 10 claims, and they agreed that the statements made in product labeling for cases 1 through 6 are largely improper, as the labeling suggests that each product has an effect on a specific disease. For case 7, FDA stated that while the specific claims discussed here are allowable, depending on the context in which they were made, FDA might consider the totality of marketing materials to be improper. FDA also agreed that the claims made to our undercover investigators in cases 8 and 10 were questionable or likely constituted improper disease claims, but that to take action, additional information as to the prevalence and context of the claims would be necessary. For case 9, FDA noted that, since the statement made by sales staff was safe usage information, not a claim about the product's effects, it would not violate FDA regulations, unless the agency could develop other evidence to show that the claim was false or misleading or constituted an implied disease claim. In addition, FDA and NIH both noted that by definition, no dietary supplement can treat, prevent, or cure any disease.

## Trace Contaminants Found in Selected Herbal Dietary Supplements, but None Pose an Acute Toxicity Hazard to Humans

We found trace amounts of at least one potentially hazardous contaminant in 37 of the 40 herbal dietary supplement products we tested, though none of the contaminants were found in amounts considered to pose an acute toxicity hazard to humans.[19] Specifically, all 37 supplements tested positive for trace amounts of lead. Thirty-two also contained mercury, 28 contained cadmium, 21 contained arsenic, and 18 contained residues from at least one pesticide.[20] See appendixes III and IV for the complete results of these tests.

The levels of contaminants found do not exceed any FDA or EPA regulations governing dietary supplements or their raw ingredients, and FDA and EPA officials did not express concern regarding any immediate negative health consequences from consuming these 40 supplements. However, because EPA has not set pesticide tolerance limits for the main ingredients of the herbal dietary supplements we tested, the pesticide contaminants exceed FDA advisory levels. FDA agreed that 16 of the 40 supplements we tested would be considered in violation of U.S. pesticide tolerances if FDA, using prescribed testing procedures, confirmed our results. We note that 4 of the residues detected are from pesticides that currently have no registered use in the United States.[21] According to FDA, scientific research has not been done on the long-term health effects from consumption of such low levels of many of these specific contaminants, as current technology cannot detect these trace contaminants when they are diluted in human bloodstreams. We have referred these products to FDA for its review.

After reviewing test results with EPA and FDA officials, we also spoke with several of the manufacturers of supplements that had trace amounts

[19]Our results are limited by the tests performed. Since we only tested a single bottle of each sample, our results cannot be projected beyond the single bottle tested. Our results also cannot be projected to any other products from the same manufacturers.

[20]Different forms of mercury have distinctly different adverse effects. The tests we performed to identify mercury levels in supplements do not differentiate between these different forms of mercury.

[21]EPA cancelled all registrations of carbofuran, gamma-HCH (Lindane), and dichlorodiphenyltrichloroethane (DDT), the parent chemical of p,p-DDE. As of December 31, 2009, all related residue tolerances had been revoked. Tolclofos-methyl has never had a U.S. registration, but it is approved for use in other countries.

of contaminants.[22] The manufacturers we spoke with stated that they ensure that their products are tested for contamination, and that these tests have shown that their products do not contain contaminants in excess of regulatory standards. Manufacturers also stated that they comply with all FDA regulations and follow good manufacturing practices as defined by the agency. While the manufacturers we spoke with were concerned about finding any contaminants in their supplements, they noted that the levels identified were too low to raise any issues during their own internal product testing processes.

Mr. Chairman, this concludes my statement. I would be pleased to answer any questions that you or other members of the committee may have at this time.

## Contacts and Acknowledgments

For further information about this testimony, please contact Gregory D. Kutz at (202) 512-6722 or kutzg@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. Individuals who made major contributions to this testimony were Jonathan Meyer and Andrew O'Connell, Assistant Directors; John Ahern; Dennis Fauber; Robert Graves; Cristian Ion; Elizabeth Isom; Leslie Kirsch; Barbara Lewis; Flavio Martinez; James Murphy; Ramon Rodriguez; Tim Walker; and John Wilbur.

[22]Discussions with these manufacturers were limited to their manufacturing and quality control processes. We did not question these manufacturers regarding the marketing of their products.

# Appendix I: Scope and Methodology

To determine whether sellers of herbal dietary supplements are using deceptive or questionable marketing practices to encourage the use of these products, we investigated a nonrepresentative selection of 22 storefront and mail-order retailers selling herbal dietary supplements. We identified these retailers by searching online using search terms likely to be used by actual consumers and by observing newspaper advertisements. Posing as elderly customers, we asked sales staff at each company a series of questions regarding the potential health benefits of herbal dietary supplements as well as potential interactions with other common over-the-counter and prescription drugs.[1] While our work focused on herbal dietary supplements, we also evaluated claims made regarding nonherbal supplement products during undercover storefront visits and telephone calls. We also reviewed written marketing language used on approximately 30 retail Web sites. We evaluated the accuracy of product marketing claims against health benefit evaluations published through the National Institutes of Health and Food and Drug Administration (FDA).

To determine whether selected herbal dietary supplements were contaminated with harmful substances, we purchased 40 unique single-ingredient herbal supplement products from 40 different manufacturers and submitted them to an accredited laboratory for analysis. We selected the types of herbs to purchase based on recent surveys about the supplements usage of the elderly, defined for this report as individuals over the age of 65. These surveys identified the most commonly used herbs among the elderly as chamomile, echinacea, garlic, ginkgo biloba, ginseng, peppermint, saw palmetto, and St. John's wort.

We purchased these 40 unique products from a combination of retail chain storefronts and online or mail-order retailers. For each online retailer, we selected products based primarily on relative popularity according to the site's list of top sellers. At each retail chain storefront, because of limited selection, we selected only items that would be expected to be sold at all chain locations. All 40 products were submitted to an accredited laboratory where they were screened for the presence of lead, arsenic, mercury, cadmium, and residues from organichlorine and organophosphorous pesticides. These contaminants were selected based on prevalence and the likelihood of negative health consequences due to consumption. The recommended daily intake levels of these contaminants

[1]Our findings are limited to the individual retailers and sales staff we investigated. Our findings cannot be projected to any other retailers or sales representatives.

and the likely negative health consequences because of consumption were determined based on a review of relevant health standards and discussions with FDA and Environmental Protection Agency experts.

For each herbal dietary supplement product, we submitted one unopened, manufacturer-sealed bottle to the laboratory for analysis. To identify levels of arsenic, cadmium, lead, and mercury, products were analyzed using inductively coupled plasma mass spectrometry according to method AOAC 993.14. Detection limits for these contaminants were .075 milligrams/kilogram, .010 milligrams/kilogram, .005 milligrams/kilogram, and .050 nanograms/gram, respectively. To identify levels of pesticide residues, products were analyzed using a variety of residue-specific methods, including those methods published in the FDA *Pesticide Analytical Manual*. We did not independently validate the results received with another lab or through any other mechanism. See appendix II for a complete list of analytes and their related detection levels.

# Appendix II: Full List of Analytes and Detection Limits

| Analyte | Detection limit (ppm)[a] | Analyte | Detection limit (ppm)[a] |
|---|---|---|---|
| (2-Ethylhexyl)-Diphenylphosphate | 0.01 | cis-Chlordane | 0.01 |
| Acrinathrin | 0.01 | Clomazone | 0.01 |
| Aldrin | 0.01 | Coumaphos | 0.01 |
| Allethrin | 0.01 | Cyanazine | 0.01 |
| alpha-BHC | 0.01 | Cyanophos | 0.01 |
| Ametryn | 0.01 | Cycloate/Ro Neet | 0.01 |
| Aminocarb | 0.01 | Cycluron | 0.01 |
| Amitraz | 0.05 | Cyhalothrin lambda | 0.01 |
| Aniten/Flurecol Butyl Ester | 0.05 | Cymiazole | 0.01 |
| Arsenic | 0.075 | Cypermethrin | 0.02 |
| Atrazine | 0.01 | Cyproconazole | 0.01 |
| Azinphos-methyl | 0.01 | Cyprodinil | 0.01 |
| Azoxystrobin | 0.01 | Dacthal (DCPA) | 0.01 |
| Benalaxyl | 0.01 | DEF | 0.02 |
| Bendiocarb | 0.01 | delta-BHC | 0.01 |
| Benfluralin | 0.01 | Deltamethrin | 0.01 |
| beta-BHC | 0.01 | Desmedipham | 0.01 |
| Bifenthrin | 0.01 | Desmetryn | 0.01 |
| Biphenyl | 0.02 | Di-allate | 0.01 |
| Bromopropylate | 0.01 | Diazinon | 0.01 |
| Bufencarb | 0.01 | Diazinon (O Analog) | 0.01 |
| Bupirimate | 0.01 | Dichlobenil | 0.05 |
| Buprofezin | 0.01 | Dicloran | 0.02 |
| Butylate | 0.01 | Dieldrin | 0.01 |
| Cadmium | 0.01 | Diethofencarb | 0.01 |
| Carbaryl | 0.01 | Difenoconazole | 0.01 |
| Carbofuran | 0.01 | Dimethachlor | 0.01 |
| Carbofuran 3-OH | 0.01 | Dimethoate | 0.01 |
| Carbosulfan | 0.02 | Diniconazole | 0.01 |
| Carboxin | 0.01 | Dioxacarb | 0.01 |
| Chlordene, beta | 0.02 | Dioxathion | 0.05 |
| Chlordene, gamma | 0.02 | Diphenamid | 0.01 |
| Chlordimeform (CDF) | 0.01 | Disulfoton | 0.01 |
| Chlorfenvinphos (Total Isomers E, Z) | 0.01 | d-Phenothrin | 0.01 |
| Chlorobenzilate | 0.01 | Edifenphos | 0.01 |
| Chloroneb | 0.01 | Endosulfan I (alpha-endosulfan) | 0.01 |

| Analyte | Detection limit (ppm)[a] | Analyte | Detection limit (ppm)[a] |
|---|---|---|---|
| Chloropropylate | 0.01 | Endosulfan II (beta-Endosulfan) | 0.01 |
| Chlorothalonil | 0.01 | Endosulfan sulphate | 0.01 |
| Chlorpyrifos (Dursban) | 0.01 | Endrin | 0.01 |
| Chlorpyrifos-methyl | 0.01 | EPN | 0.01 |
| Chlorpyrifos-O-analogue | 0.01 | Epoxiconazole | 0.01 |
| EPTC/Eptam | 0.01 | Isocarbamid | 0.01 |
| Esfenvalerate-2 | 0.01 | Isofenphos | 0.01 |
| Etaconazole | 0.01 | Isoprocarb | 0.01 |
| Ethafluralin | 0.03 | Isopropalin | 0.01 |
| Ethiofencarb | 0.01 | Isoprothiolane | 0.01 |
| Ethiolate | 0.01 | Isoproturon | 0.01 |
| Ethion | 0.01 | Kresoxim-methyl | 0.01 |
| Ethofumesate | 0.01 | Lead | 0.005 |
| Ethoprop (Ethoprophos) | 0.01 | Lenacil | 0.01 |
| Ethoxyquin | 0.01 | Linuron | 0.01 |
| Etobenzanid | 0.01 | Malathion | 0.01 |
| Etofenprox | 0.01 | Malathion OA (Malaoxon) | 0.01 |
| Etridiazole | 0.01 | Mercury | 0.05[b] |
| Fenamiphos | 0.01 | Metalaxyl | 0.01 |
| Fenarimol | 0.01 | Methidathion | 0.01 |
| Fenazaquin | 0.01 | Methiocarb | 0.01 |
| Fenbuconazole | 0.01 | Methoprotryne | 0.01 |
| Fenchlorphos | 0.01 | Methoxychlor, o,o' | 0.01 |
| Fenitrothion | 0.02 | Methoxychlor, p,p' | 0.01 |
| Fenobucarb | 0.01 | Methyl Parathion | 0.02 |
| Fenoxycarb | 0.01 | Metolachlor | 0.01 |
| Fenpropimorph | 0.01 | Metolcarb | 0.01 |
| Fenthion | 0.01 | Metribuzin | 0.01 |
| Fenvalerate | 0.01 | Mevinphos | 0.01 |
| flopet | 0.01 | Mexacarbate | 0.01 |
| Fluchloralin | 0.04 | MGK-264 | 0.01 |
| Flucythrinate (Total Isomers) | 0.01 | Mirex | 0.01 |
| Fludioxonil | 0.01 | Molinate | 0.01 |
| Flusilazole | 0.01 | Monocrotophos | 0.01 |
| Flutolanil | 0.01 | Monolinuron | 0.01 |
| Fluvalinate | 0.02 | Myclobutanil | 0.01 |
| Fonofos | 0.01 | Naphthalene Acetamide | 0.01 |

| Analyte | Detection limit (ppm)[a] | Analyte | Detection limit (ppm)[a] |
|---|---|---|---|
| Gamma-cyhalothrin | 0.01 | Napropamide | 0.01 |
| gamma-HCH (Lindane) | 0.01 | Nitralin | 0.01 |
| Heptachlor | 0.01 | Nitrofen | 0.01 |
| Heptachlor Epoxide (cis, trans) | 0.01 | Nitrothal-isopropyl | 0.02 |
| Heptenophos | 0.01 | nonachlor cis- | 0.01 |
| Hexachlorobenzene (HCB) | 0.01 | Nonachlor trans- | 0.01 |
| Hexaconazole | 0.01 | Norea | 0.02 |
| Hexazinone | 0.01 | Nuarimol | 0.01 |
| Iprodione | 0.02 | o,p-DDE | 0.01 |
| o,p-DDT | 0.01 | Quintozene (PCNB) | 0.02 |
| Oxydemeton Methyl Sulfone | 0.05 | Resmethrin | 0.01 |
| p,p-DDE | 0.01 | S 421 (Octachlordipropylether) | 0.02 |
| p,p-DDT | 0.01 | Sethoxydim | 0.02 |
| Parathion-ethyl | 0.01 | Simazine | 0.01 |
| Penconazole | 0.01 | Simetryn | 0.01 |
| Pendimethalin | 0.01 | Sulfotep | 0.01 |
| Pentachloroaniline | 0.01 | Sulprofos | 0.01 |
| Pentachlorobenzene | 0.01 | Tebuconazole | 0.01 |
| Pentachlorobenzonitrile | 0.01 | Tebufenpyrad | 0.01 |
| Pentachlorothioanisole | 0.01 | Tebutam | 0.01 |
| Permethrin-cis | 0.01 | Tebuthiuron | 0.01 |
| Permethrin-trans | 0.01 | Tecnazene | 0.01 |
| Phenmedipham | 0.01 | Terbufos | 0.01 |
| Phorate | 0.01 | Terbumeton | 0.01 |
| Phorate-sulfone | 0.02 | Terbuthylazine | 0.01 |
| Phorate-sulfoxide | 0.01 | Terbutryn | 0.01 |
| Phosalone | 0.01 | Tetrachloroaniline, 2,3,4,6- | 0.01 |
| Phosmet | 0.01 | Tetrachlorvinphos | 0.01 |
| Pirimicarb | 0.01 | Tetraconazole | 0.01 |
| Pirimifos-methyl | 0.01 | Tetradifon | 0.01 |
| Prochloraz | 0.01 | Tetramethrin | 0.01 |
| Procymidon | 0.01 | Thiabendazole | 0.01 |
| Profenofos | 0.01 | Tolclofos-methyl | 0.01 |
| Profluralin | 0.01 | Tolylfluanid | 0.01 |
| Promecarb | 0.01 | Tralkoxydim | 0.05 |
| Prometon | 0.01 | trans-Chlordane | 0.01 |
| Prometryn | 0.01 | Triadimefon | 0.01 |

| Analyte | Detection limit (ppm)[a] | Analyte | Detection limit (ppm)[a] |
|---|---|---|---|
| Propachlor | 0.01 | Triadimenol | 0.01 |
| Propanil | 0.01 | Triallate | 0.01 |
| Propargite | 0.01 | Triazophos | 0.01 |
| Propham | 0.01 | Tricyclazol | 0.01 |
| Propiconazole | 0.01 | Trifloxystrobin | 0.01 |
| Prothiofos | 0.01 | Triflumizole | 0.01 |
| Pyracarbolid | 0.01 | Trifluralin | 0.01 |
| Pyrazophos | 0.01 | Trimethacarb 2.3.5- | 0.01 |
| Pyridaphenthion | 0.01 | Trimethacarb 3.4.5- | 0.01 |
| Pyrimethanil | 0.01 | Triticonazole | 0.01 |
| Pyriproxyfen | 0.01 | Vinclozolin | 0.02 |
| Quinalphos | 0.01 | | |
| Quinoxyfen | 0.01 | | |

Source: GAO, based on laboratory methodology.

[a]Parts per million is a measure equivalent to milligrams per kilogram or milligrams per liter.

[b]Mercury results appear as parts per billion.

# Appendix III: Contaminants Found in Selected Herbal Dietary Supplements (in Parts per Million)

| Sample | Herb | Arsenic[a,b] | Cadmium[a,b] | Lead[a,b] | Mercury[b,c] | Number of pesticides[d] |
|---|---|---|---|---|---|---|
| 1 | Saw palmetto | nd | 0.011 | 0.024 | 1.210 | 0 |
| 2 | Echinacea | 0.090 | 0.348 | 0.106 | 1.170 | 0 |
| 3 | Echinacea | 0.093 | 0.030 | 0.043 | nd | 0 |
| 4 | Echinacea | 0.226 | 0.069 | 1.290 | 6.960 | 1 |
| 5 | St. John's wort | 0.391 | 0.090 | 0.353 | 0.980 | 2 |
| 6 | St. John's wort | 0.153 | 0.033 | 0.587 | 2.330 | 0 |
| 7 | Ginkgo biloba | nd | nd | 0.564 | 1.340 | 1 |
| 8 | Garlic | nd | nd | 0.046 | 0.810 | 1 |
| 9 | Ginkgo biloba | 0.151 | nd | 0.036 | 1.480 | 2 |
| 10 | Ginkgo biloba | 0.162 | 0.017 | 0.037 | 3.420 | 1 |
| 11 | Garlic | nd | 0.026 | 0.026 | 0.620 | 2 |
| 12 | Ginseng | 0.123 | 0.057 | 0.126 | 10.700 | 5 |
| 13 | Peppermint | nd | nd | 0.007 | 2.170 | 1 |
| 14 | Saw palmetto | nd | nd | 0.011 | nd | 0 |
| 15 | Echinacea | 0.116 | 0.016 | 0.109 | 4.110 | 0 |
| 16 | Ginkgo biloba | 0.222 | 0.030 | 0.112 | 6.090 | 0 |
| 17 | Garlic | nd | 0.040 | 0.029 | 1.090 | 0 |
| 18 | Saw palmetto | nd | nd | 0.026 | nd | 0 |
| 19 | St. John's wort | nd | 0.011 | 0.026 | 0.860 | 3 |
| 20 | Ginseng | 0.078 | 0.127 | 0.439 | 1.510 | 0 |
| 21 | Garlic | nd | 0.062 | 0.030 | 0.640 | 0 |
| 22 | Chamomile | nd | 0.375 | 0.049 | 2.900 | 0 |
| 23 | Chamomile | 0.094 | 0.146 | 0.375 | 2.420 | 4 |
| 24 | Peppermint | nd | nd | nd | nd | 0 |
| 25 | Chamomile | nd | nd | nd | nd | 0 |
| 26 | Chamomile | nd | nd | nd | nd | 0 |
| 27 | St. John's wort | 0.155 | 0.054 | 0.111 | 0.530 | 0 |
| 28 | Garlic | nd | 0.050 | 0.305 | 0.780 | 0 |
| 29 | St. John's wort | 0.180 | 0.062 | 0.148 | 0.760 | 2 |
| 30 | Peppermint | nd | nd | 0.023 | nd | 1 |
| 31 | Chamomile | 0.286 | 0.058 | 0.802 | 4.260 | 0 |
| 32 | Ginkgo biloba | 0.524 | 0.054 | 0.487 | 77.800 | 2 |
| 33 | Ginseng | 0.229 | 0.105 | 1.290 | 32.900 | 6 |
| 34 | Ginseng | 0.172 | nd | 0.032 | 2.110 | 2 |
| 35 | Ginseng | 0.154 | 0.156 | 0.408 | 5.990 | 3 |

| Sample | Herb | Arsenic[a,b] | Cadmium[a,b] | Lead[a,b] | Mercury[b,c] | Number of pesticides[d] |
|---|---|---|---|---|---|---|
| 36 | Saw palmetto | nd | nd | 0.008 | 1.100 | 0 |
| 37 | Saw palmetto | nd | 0.012 | 0.125 | 1.710 | 0 |
| 38 | St. John's wort | nd | 1.150 | 0.138 | 3.000 | 0 |
| 39 | Echinacea | 0.152 | 0.032 | 0.649 | 6.930 | 0 |
| 40 | Ginkgo biloba | 0.115 | 0.025 | 0.061 | nd | 2 |

Source: GAO, based on laboratory analysis.

[a]Parts per million is a measure equivalent to milligrams per kilogram or milligrams per liter.

[b]Results marked as "nd" indicate that the contaminant was not detected in excess of the underlying tests' detection limit (.075 mg/kg for arsenic, .010 mg/kg for cadmium, .005 mg/kg for lead, and .050 ng/g for mercury). A result of "nd" does not mean that a contaminant does not exist in a sample. It means that if a contaminant is in the product, it appears at a level below the detection limit for that particular test method.

[c]Mercury results appear as parts per billion, a measure equivalent to nanograms per gram or nanograms per milliliter.

[d]For additional details on pesticide residues found, see appendix IV.

# Appendix IV: Pesticide Residues Identified in Selected Herbal Dietary Supplements (in Parts per Million)

| Sample no. | Herb | Pesticide residue | Detected level |
|---|---|---|---|
| 4[a] | Echinacea | Chlorpyrifos (Dursban) | 0.01 |
| 5[a] | St. John's wort | Amitraz | 0.05 |
| | | Propargite | 0.04 |
| 7[a] | Ginkgo biloba | Phorate-sulfoxide | 0.06 |
| 8[a] | Garlic | Triadimenol | 0.03 |
| 9[a] | Ginkgo biloba | Phorate-sulfoxide | 0.10 |
| | | Triadimenol | 0.26 |
| 10[a] | Ginkgo biloba | Phorate-sulfoxide | 0.06 |
| 11[a] | Garlic | Carbofuran | 0.04 |
| | | gamma-HCH (Lindane) | 0.08 |
| 12[a] | Ginseng | Azoxystrobin[b] | 0.02 |
| | | Difenoconazole | 0.02 |
| | | Flutolanil | 0.03 |
| | | Tebuconazole | 0.02 |
| | | Tolclofos-methyl | 0.05 |
| 13 | Peppermint | Propargite[b] | 0.16 |
| 19[a] | St. John's wort | Azoxystrobin | 0.01 |
| | | Chlorpyrifos (Dursban) | 0.01 |
| | | Hexazinone | 0.06 |
| 23[a] | Chamomile | Flusilazole | 0.01 |
| | | Metolachlor | 0.02 |
| | | Tebuconazole | 0.04 |
| | | Trifloxystrobin | 0.01 |
| 29[a] | St. John's wort | Amitraz | 0.06 |
| | | Triadimefon | 0.02 |
| 30 | Peppermint | Propargite[b] | 0.62 |
| 32[a] | Ginkgo biloba | Phorate-sulfoxide | 0.01 |
| | | Triadimenol | 0.06 |
| 33[a] | Ginseng | Hexachlorobenzene (HCB) | 0.02 |
| | | Metalaxyl[b] | 0.01 |
| | | p,p-DDE | 0.02 |
| | | Pentachloroaniline | 0.28 |
| | | Pentachlorothioanisole | 0.05 |
| | | Pyrimethanil | 0.03 |
| 34[a] | Ginseng | Metalaxyl[b] | 0.03 |
| | | Propiconazole | 0.02 |

| Sample no. | Herb | Pesticide residue | Detected level |
|---|---|---|---|
| 35[a] | Ginseng | Azoxystrobin[b] | 0.03 |
| | | Dacthal (DCPA)[b] | 0.07 |
| | | Pyrimethanil | 0.11 |
| 40[a] | Ginkgo biloba | Phorate-sulfoxide | 0.01 |
| | | Triadimenol | 0.10 |

Source: GAO, based on laboratory analysis.

[a]Product would be considered in violation of U.S. pesticide tolerances, should these results be confirmed.

[b]Pesticide residue detected is not considered, by the Food and Drug Administration, to be of regulatory significance.

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