AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

S. HRG. 111–651

DIETARY SUPPLEMENTS: WHAT SENIORS NEED TO KNOW

HEARING

BEFORE THE

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

SECOND SESSION

WASHINGTON, DC

MAY 26, 2010

Serial No. 111–18

Printed for the use of the Special Committee on Aging

Available via the World Wide Web: http://www.gpoaccess.gov/congress/index.html

U.S. GOVERNMENT PRINTING OFFICE

57–983 PDF WASHINGTON : 2010

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2250 Mail: Stop SSOP, Washington, DC 20402–0001

SPECIAL COMMITTEE ON AGING

HERB KOHL, Wisconsin, *Chairman*

RON WYDEN, Oregon
BLANCHE L. LINCOLN, Arkansas
EVAN BAYH, Indiana
BILL NELSON, Florida
ROBERT P. CASEY, Jr., Pennsylvania
CLAIRE McCASKILL, Missouri
SHELDON WHITEHOUSE, Rhode Island
MARK UDALL, Colorado
KIRSTEN GILLIBRAND, New York
MICHAEL BENNET, Colorado
ARLEN SPECTER, Pennsylvania
AL FRANKEN, Minnesota

BOB CORKER, Tennessee
RICHARD SHELBY, Alabama
SUSAN COLLINS, Maine
GEORGE LeMIEUX, FLORIDA
ORRIN HATCH, Utah
SAM BROWNBACK, Kansas
LINDSEY GRAHAM, South Carolina
SAXBY CHAMBLISS, Georgia

DEBRA WHITMAN, *Majority Staff Director*
MICHAEL BASSETT, *Ranking Member Staff Director*

CONTENTS

	Page
Opening Statement of Senator Herb Kohl	1
Opening Statement of Senator Bob Corker	3
Opening Statement of Senator Al Franken	3
Opening Statement of Senator Orrin Hatch	3

PANEL I

Statement of Greg Kutz, Forensic Audits and Special Investigations, Government Accountability Office, Washington, DC	6
Statement of Tod Cooperman, President, Consumerlab.com, White Plains, NY	36
Statement of Charles Bell, Program Director, Consumers Union, Yonkers, NY	43
Statement of Steven Mister, President and CEO, Council for Responsible Nutrition, Washington, DC	61

PANEL II

Joshua Sharfstein, Deputy Commissioner, Food and Drug Administration, Silver Spring, MD	98

APPENDIX

Prepared Statement of Senator Al Franken	127
Mr. Mister's Response to Senator Al Franken's Question	127
Testimony submitted by The Coalition for Dietary Supplements, Washington, DC	128

HEARING ON DIETARY SUPPLEMENTS: WHAT SENIORS NEED TO KNOW

WEDNESDAY, MAY 26, 2010

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The committee met, pursuant to notice, at 2:05 p.m. in room SD–562, Dirksen Senate Office Building, Hon. Herb Kohl (chairman of the committee) presiding.

Present: Senators Kohl [presiding], Franken, Corker, and Hatch.

OPENING STATEMENT OF SENATOR HERB KOHL, CHAIRMAN

The CHAIRMAN. Good afternoon. We'd like to thank our witnesses for participating in today's hearings on dietary supplements.

The use of dietary supplements, which can take the form of vitamins, minerals, fiber, or other nutritional products, has grown substantially over the past few decades. Recent surveys indicate that at least 40 percent of American adults consume these products, many of which can serve as a valuable addition to daily diets.

Today, we'll address concerns that have arisen over whether the marketing and manufacturing of these products meet the standards that American consumers deserve.

Dietary supplements have become a multibillion-dollar industry. In 2006, Americans reportedly spent $23 billion on herbal and specialty supplements, which is almost half the amount that they spent on prescription drugs. However, several consumer safety issues arise with these products. Because dietary supplements are available over the counter, consumers sometimes take them in addition to, or even as a replacement for, other prescription medication or drugs, without consulting their doctors or receiving notification of potentially harmful interactions. In fact, the accurate information is not always easily accessible to the average consumer.

The number of scientific studies conducted on the safety or efficacy of herbal supplements is limited, and unlike pharmaceutical drugs, these supplements are not subject to FDA approval before being marketed and sold. In addition, claims about these products and advertisements are subject to only limited regulation.

In 2007, the FDA released Good Manufacturing Practices, or GMPs, that began to address some of these concerns. Though it took 13 years to complete them, these guidelines are intended to improve the safety and production of dietary supplements.

The industry itself has stepped up oversight efforts and has taken on an active role in monitoring its own practices and helping both the FDA and the Federal Trade Commission identify and ef-

fectively deal with misleading ads and unfair marketing. Despite these positive developments, we'll hear today that legitimate concerns remain about the industry.

A Government Accountability Office investigation uncovered both improper advertising and marketing of dietary supplements, as well as the existence of contaminants, such as mercury, lead, and pesticides, in certain products.

While the levels of contaminants have not set off alarms with Federal regulatory officials or scientists, some exceed allowable limits. As part of their investigation, GAO referred marketing and contaminant samples to FDA and FTC for further review and possible action. Given these findings, it's obvious that more must be done.

We look forward to working with colleagues in the Senate, including Senators Harkin and Hatch, and Senators McCain and Dorgan, who have long taken an interest in dietary supplement issues, in order to ensure that meaningful provisions addressing these issues are included in the Food Safety Act, soon to come about.

We need to be sure companies are properly registered, including their product lists, so that FDA has the ability to identify and act on safety concerns. Since two-thirds of consumers believe the government requires supplement labels to contain warnings about potential side effects or dangers, we must ensure consumers receive comprehensive information about the safety of these products, by requiring warning labels on products that contain ingredients known to have adverse effects or harmful interactions with prescription drugs. We should also encourage vigorous oversight to reduce and eliminate dangerous contaminants even in small amounts. We need to ensure that FDA has the authority to recall products that are found to harm those who take them.

Finally, as FDA authority expands, we need to continue to provide them with the resources to do these things. Last year, we were successful in securing a $152-million increase for FDA's food safety oversight, and we'll continue to advocate for additional funding in the future.

Now, let's be clear, no one is suggesting that consumers should not be able to take vitamins or other dietary supplements. Our concern is that be able—that they be able to do so safely. American consumers should have access to comprehensive, accurate information about these products so that they are empowered to make the best decisions about their own health.

We thank you once again for being here, one and all.

We turn, now, to the ranking member, Senator Corker, for his comments.

OPENING STATEMENT OF SENATOR BOB CORKER, RANKING MEMBER

Senator CORKER. Mr. Chairman, thank you. I thank you for having this hearing, and certainly welcome the witnesses.

I wake up every morning, drink a cup of coffee, and take some dietary supplements. Certainly I care about the safety of those. I know today we going to hear about some of the practices of vendors and others relating to dietary supplements.

I do want to point out that, back in 1994, we passed a law, DSHEA, that in implementation, would have overseen the safety of many of these dietary supplements. Sixteen years later, we still haven't fully implemented a portion of that law, which is Good Manufacturing Practices.

I think one of the things that we should do here in Congress, before we look at passing new laws, is try to make sure the laws that are on the books are actually implemented appropriately.

So, today I look forward to hearing from our witnesses. As I've said, I thank you for coming, and certainly look forward to being educated, in the process.

Thank you very much.

The CHAIRMAN. Thanks, Senator Corker.

Senator Franken.

OPENING STATEMENT OF SENATOR AL FRANKEN

Senator FRANKEN. I really have no opening comments.

I'm eager to hear the witnesses and thank them for coming.

Thank you, Mr. Chairman, for having this hearing.

The CHAIRMAN. Thank you, Senator Franken.

Senator Hatch.

OPENING STATEMENT OF SENATOR ORRIN HATCH

Senator HATCH. Well, thank you, Mr. Chairman.

As the author, along with Senator Harkin, of the DSHEA—of the Dietary Supplemental Health and Education Act—if you don't mind, I would like to make a formal statement.

The CHAIRMAN. Sure.

Senator HATCH. I appreciate you, Mr. Chairman, for allowing me to.

This issue before the committee today is extremely important to my home State of Utah, and my fellow Utahans, and, I think, every citizen in America. I want all Americans, including senior citizens, to have the best and most accurate information about the dietary supplements that they use.

False health claims about these products, on the Internet and newspaper ads or on product labels, are illegal today. So is selling contaminated dietary supplements. Companies engaging in these types of activities are breaking the law, and therefore, should be taken off the market immediately. That power is granted through current law. So, amending that law is not necessary. What is necessary is providing the Food and Drug Administration the funding it needs to properly enforce and implement current law.

As an original author of the 1994 Dietary Supplement Health Education—Health and Education Act, and the Nonprescription

Drug Consumer Protection Act of 2006, it is important for committee members to understand the history behind these laws.

Senator Tom Harkin and I were the lead sponsors of both bills, which enjoyed strong bipartisan support. In fact, DSHEA passed the Senate twice, by unanimous consent; in the House of Representatives, once, by unanimous consent. DSHEA established a statutory framework for the FDA so that dietary supplements are regulated as foods. The law grandfathered U.S. dietary supplements already on the market at the time of its enactment, because these products had a history of safe use. DSHEA also includes a strong safety standard so that potentially harmful products could be removed from the market.

Through DSHEA, the FDA has an imminent hazard authority it may use to immediately remove any unsafe product from the market. The law also requires manufacturers to submit marketing safety information to the FDA about any new agreements not previously marketed. This information must be submitted to the FDA 75 days prior to putting a product on the market.

Another key provision authorized issuance of Good Manufacturing Practice, or GMP, standards so that FDA inspectors could ensure products are being manufactured in compliance with the law. One of my biggest frustrations was that, once the DSHEA was signed into law, it took the FDA many years to implement any GMP standards. Today, these GMP standards apply to large- and medium-sized manufacturers, and, in a few weeks, will apply to small manufacturers.

Finally, DSHEA required that all ingredients on dietary supplements be listed on the label, and that any claims made must be truthful and not misleading. Misleading claims or labels are a violation of the law, and the FDA should take products with misleading claims and labels off the market, period.

Some have argued that dietary supplements should be subject to premarket approval. But, let me explain why this is not done. Most dietary supplements have been used safely for years and raised no concerns warranting the time and resources necessary for premarket approval, or even review. The entire time Senator Harkin and I were writing this legislation, not one Member of Congress raised any concerns about the Grandfather Clause.

In addition, the FDA has not been able to find the necessary resources to even enforce the current law. As chairman of the Appropriations Subcommittee which funds the FDA—you are aware of this issue. Therefore, it is clear to me that FDA has much higher priorities than dietary supplements. Moreover, the FDA has not asked for additional funding for supplement enforcement, which I believe is an indicator these products are not the safety concerns some would argue from the cases highlighted at this hearing.

The Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006 mandated a system to provide the government with information about serious adverse events associated with the use of the two FDA-regulated products: dietary supplements and over-the-counter drugs. This law requires manufacturers, packers, or distributors of these products to provide to the FDA, within 15 business days, any reports of serious AERs. It also is important to note that previous FDA commissioners—Dr. Jane

Henney, Dr. Mark McClellan, Dr. Lester Crawford, and Dr. Andy von Eshenbach—have all stated, in Senate hearings and in meetings—in my meetings with them—that through DSHEA they had the power necessary to regulate dietary supplements. Moreover, current FDA commissioner, Dr. Margaret Hamburger—Hamburg, excuse me—has assured me that she will work with me to ensure that these laws are enforced.

To ensure that these laws are properly enforced, Senator Harkin and I introduced a Dietary Supplement Full Implementation and Enforcement Act of 2010. This legislation requires the Secretary of Health and Human Services to submit annual reports to Congress regarding HHS activities on dietary supplements. It directs the FDA to issue its "new dietary ingredient," or NDI, guidance, as recommended by the General Accountability Office, within 180 days, and requires the FDA to notify the Drug Enforcement Agency if it finds that a new dietary ingredient being evaluated contains an anabolic steroid. Now, I'm also the author of the Anabolic Steroid law, along with now-Vice President Biden. We've worked hard to make sure that the consumers are protected.

This bill, S. 3414, is supported by the Major League Baseball Players Association, the NFL Players Association, the Natural Products Association, the United Natural Products Alliance Council for Responsible Nutrition, American Herbal Products Association, and the Consumer Healthcare Products Association. So, I urge the members of the committee to seriously consider supporting our bill.

Now, Mr. Chairman, before I close, I want to emphasize that a vast majority of the dietary supplement industry are providing consumers not only with safe products, but also accurate information about their use. They, too, want bad-actor companies—and certainly I do, as well—off the market.

So, as chairman of the Agricultural Appropriations Subcommittee, please work with me, Mr. Chairman, to ensure that the FDA has the money to enforce existing laws. That should be this committee's first goal. We should not be talking about changing current law; and, instead, focus on enforcing current law. Hopefully, today's hearing will begin such discussions.

Thank you, Mr. Chairman, sorry it took so long.

The CHAIRMAN. Thank you very much, Senator Hatch, for your statement.

We'll now introduce the first panel.

The first witness today will be Greg Kutz. Mr. Kutz is the Managing Director of the Government Accountability's Office of Forensic Audits and Special Investigations Unit. The unit is charged with providing Congress with the results of these forensic audits and investigations.

Our second witness today will be Tod Cooperman. Dr. Cooperman is the President and Founder of ConsumerLab.com and PharmacyChecker.com, which publish consumer reports and independent evaluations of popular products and online pharmacies. He's a graduate of Boston University's School of Medicine.

Third today will be Charles Bell. Mr. Bell is a Programs Director for Consumers Union, the nonprofit publisher of Consumer Reports Magazine. He oversees grant-funded projects that provide compara-

tive information on health insurance and other consumer healthcare issues.

Next, we'll be hearing from Steve Mister. Mr. Mister is the President and CEO of the Council for Responsible Nutrition, a trade association that represents product manufacturers and raw ingredient suppliers of dietary supplements. Mr. Mister is speaking here today on behalf of the five major trade organizations. He's a former Vice President and Associate General Counsel for the Consumer Healthcare Products Association.

We welcome you all here today, and we're looking forward to your statements, hopefully at about 5 minutes.

Mr. Kutz.

STATEMENT OF GREG KUTZ, FORENSIC AUDITS AND SPECIAL INVESTIGATIONS, GOVERNMENT ACCOUNTABILITY OFFICE, WASHINGTON, DC

Mr. KUTZ. Mr. Chairman and members of the committee, thank you for the opportunity to discuss dietary supplements.

Today's testimony highlights the results of our investigation into allegations of deceptive marketing practices. My testimony has two parts. First, I will discuss the marketing of supplements; and second, I will discuss our testing of supplements for harmful substances.

First, posing as fictitious elderly consumers, we tested the marketing practices of numerous storefront and mail-order retailers. This included telephone calls across the country and in-store visits here in the Washington, D.C., area and in Florida. We also evaluated claims made on Web sites and in other written materials. What we found was deceptive marketing practices related to supplements frequently used by the elderly.

Perhaps more alarming was the dangerous medical advice provided to our fictitious consumers. Key claims made include: first, supplements can prevent and cure serious disease; second, supplements can replace prescription medications; and, third, supplements can safely be combined with aspirin or other medications.

I have in my hand a bottle of garlic capsules that cost us about $11 for a 30-day supply. Mr. Chairman, you'll be amazed to know that this product, according to its marketing materials, "prevents and cures cancer." As an added bonus, it "prevents the common cold, obesity, and diabetes." If these claims were true, imagine how this product could reduce healthcare costs in this country.

Next, I have in my hand a bottle of ginseng capsules that cost us about $10 for a 50-day supply. In another amazing claim, this product "reduces brain damage from a stroke." As an added bonus, it's supposed to "treat Lou Gehrig's disease, and improve digestion, endurance, and sexual performance." There are numerous supplements claiming to treat and cure things like cancer and Alzheimer's disease. You can see these products for sale on eBay, Amazon.com, and craigslist.

So, what's the problem with this? These products should not be marketed as a treatment or cure for specific disease without FDA approval as a drug. None of these products has that FDA approval.

In addition to these deceptive claims, we found other dangerous information provided to our fictitious consumers. For example, we

were told that we could stop taking our prescription medication for high blood pressure, and instead, take garlic. In another case, we were told that we could take ginkgo with our daily prescription of aspirin. According to FDA, combining ginkgo with aspirin can increase the risk of bleeding. As the Chairman mentioned, we have referred several of these cases to FDA and FTC for further investigation. In a moment, I will play for you excerpts from some of our undercover visits and phone calls to sellers of supplements.

Moving on to my second point, we found trace amounts of harmful substances in 37 of the 40 herbal supplements that we tested. All 37 had trace amounts of lead, while others had trace amounts of items such as mercury, arsenic, and pesticides. However, FDA and EPA do not consider these trace amounts to be an immediate health risk.

In conclusion, the deceptive marketing and dangerous advice identified pose a risk to the health of the elderly and perhaps other consumers. Aggressive marketers are providing consumers with unsubstantiated claims that their products can treat incurable disease. My advice to consumers across the country is to consult with your doctor before taking any dietary supplements.

I will now play the audio excerpts I mentioned, Mr. Chairman, of our marketing tests. You will see the transcription of the conversations on the monitors as you listen.

[Video presentation.]

Mr. KUTZ. Mr. Chairman, I applaud you and the other members of the committee for your efforts today to protect elderly and other consumers from the deceptive marketing of dietary supplements.

That ends my statement, and I look forward to your questions.

[The prepared statement of Mr. Kutz follows:]

United States Government Accountability Office

GAO

Testimony
Before the Special Committee on Aging, U.S. Senate

For Release on Delivery
Expected at 2:00 p.m. EDT
Wednesday, May 26, 2010

HERBAL DIETARY SUPPLEMENTS

Examples of Deceptive or Questionable Marketing Practices and Potentially Dangerous Advice

Statement of Gregory D. Kutz, Managing Director
Forensic Audits and Special Investigations

GAO
Accountability * Integrity * Reliability

GAO-10-662T

May 26, 2010

GAO
Accountability·Integrity·Reliability

Highlights

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

HERBAL DIETARY SUPPLEMENTS

Examples of Deceptive or Questionable Marketing Practices and Potentially Dangerous Advice

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)*	Analyte	Detection limit (ppm)*
(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)*	Analyte	Detection limit (ppm)*
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.

This is a work of the U.S. government and is not subject to copyright protection in the United States. The published product may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.

GAO's Mission

The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's Web site (www.gao.gov). Each weekday afternoon, GAO posts on its Web site newly released reports, testimony, and correspondence. To have GAO e-mail you a list of newly posted products, go to www.gao.gov and select "E-mail Updates."

Order by Phone

The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's Web site, http://www.gao.gov/ordering.htm.

Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.

Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Web site: www.gao.gov/fraudnet/fraudnet.htm
E-mail: fraudnet@gao.gov
Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Ralph Dawn, Managing Director, dawnr@gao.gov, (202) 512-4400
U.S. Government Accountability Office, 441 G Street NW, Room 7125
Washington, DC 20548

Public Affairs

Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800
U.S. Government Accountability Office, 441 G Street NW, Room 7149
Washington, DC 20548

Please Print on Recycled Paper

The CHAIRMAN. Thank you very much, Mr. Kutz.

Dr. Cooperman.

STATEMENT OF TOD COOPERMAN, PRESIDENT, CONSUMERLAB.COM, WHITE PLAINS, NY

Dr. COOPERMAN. OK. Senators Kohl, Senator Corker——

Can you hear me? OK.

Senators Kohl and Corker, members of the committee, I'm Dr. Tod Cooperman, President of ConsumerLab.com, a company that I founded 11 years ago to help consumers better identify high-quality health and nutrition products based on independent testing.

I'm accompanied by Dr. William Obermeyer, our Vice President for research, who spent 9 years at the FDA, testing foods and dietary supplements within the Center for Food Safety and Applied Nutrition.

We appreciate this opportunity to present findings that are particularly relevant to the aging population.

ConsumerLab's testing is funded by over 40,000 individual and institutional subscriptions to our Web site. We also provide a voluntary certification program, and test products for clinical researchers, particularly those funded by the NIH. Our recent survey of people who receive our free e-newsletter revealed that, among those aged 65 and older, 32 percent use 10 or more supplements daily.

A senior citizen in a vitamin store is a bit like a kid in a candy store. However, while the FDA recommends a strict limit on lead contamination in candy, it has not set a limit in supplements. Our tests show that this policy has created a buyer-beware situation. Based on tests of over 2,000 dietary supplements, representing over 300 different brands, we find that one out of four has a quality problem. Problems have been found in products from every-size manufacturer and are most common in herbal supplements, multivitamins, and products with ingredients that are newer to the market.

The most common problem is a lack of ingredient or substandard ingredient. Our most recent tests of herbal supplements show that 46 percent contained less than their expected amounts of key compounds. For example, an extra-strength ginseng product provided less than 10 percent of the claimed amount of expected ginsenoside compounds. We reported a similar problem with the same product 3 years earlier.

A major cause of these problems is the reliance by some manufacturers on cheap, nonspecific tests which overstate the amount of actual ingredient in raw materials and supplements. More specific tests show the actual amounts to be lower.

The next most common problem is contamination with lead and other heavy metals. The FDA professes a policy of reducing lead levels to the lowest amount that can be practicably obtained in manufacturing, yet the FDA has neither set, nor suggested, limits on heavy metals in supplements.

The only limit for lead in supplements in the United States is in the State of California. That limit, which is half of a microgram per daily serving, typically works out to be just slightly higher than the FDA candy limit. But, it is still very conservative and meaningful.

Products sold in California exceeding this limit must carry a warning label. ConsumerLab has found that 11 percent of herbal supplements exceed the California limit for lead.

Cadmium, a toxin and carcinogen, also occurs in certain herbal supplements, but the FDA has not set a limit on cadmium in supplements. ConsumerLab has found that 40 percent of St. John's wort supplements and 14 percent of valerian supplements exceed World Health Organization guidelines for cadmium contamination.

While individual products with elevated levels of lead and cadmium are generally not toxic in themselves, they unnecessarily expose Americans to toxins, and the effects are cumulative. As noted earlier, many seniors take 10 or more supplements daily, and additional exposure comes from foods, beverages, and the environment. It would be dangerous to suggest that a single supplement needs to contain a toxic amount of heavy metal to be a threat to health. However, a 2007 report by the FDA on lead contamination in multivitamins made this faulty assumption, and has been criticized for doing so.

Unfortunately, the USP may soon adopt an industry proposal permitting 10 micrograms of lead per daily serving of a supplement, 20 times higher than the California limit. We think such a lax standard would be a terrible mistake, permitting an individual supplement to exceed the total amount of lead that a child can tolerate, and just a few supplements to surpass the daily threshold for adults.

Will Good Manufacturing Practices help? These practices, as mentioned, are now required of most supplement manufacturers to help ensure batch-to-batch uniformity. However, bad products can be made under Good Manufacturing Practices, because the GMPs do not include standards for purity and ingredient identity. These standards, and the selection of tests used to measure against them, are left to each manufacturer to determine for itself.

In conclusion, nearly 11 years of product reviews by ConsumerLab.com have shown consistent problems with a significant percentage of dietary supplements, particularly herbal supplements. However, in nearly every supplement category that we do test, we do find products that meet high quality standards, showing that this is achievable. If we want our supplements to be the best and safest in the world, we will need to have better guidance from the government, establishing rigorous standards and test methods, greater enforcement of current regulations, and more self-regulation from the industry.

In my written testimony, you'll find additional statistics, information, and references. Thank you for your time.

[The prepared statement of Dr. Cooperman follows:]

ConsumerLab.com, LLC
333 Mamaroneck Avenue • White Plains, NY 10605
Phone: 914-722-9149 Fax 914-721-6096
e-mail info@consumerlab.com
Web site www.consumerlab.com

Testimony of Tod Cooperman, MD, President, ConsumerLab.com to Senate Special Committee on Aging – Subcommittee on Dietary Supplements

May 26, 2010

Dear Senator Kohl and Members of the Committee,

I am Dr. Tod Cooperman, the President of ConsumerLab.com, a company that I founded eleven years ago to help consumers identify better quality health and nutrition products based on independent testing. I am accompanied by Dr. William Obermeyer, our Vice President for Research, who spent nine years at the FDA testing food and dietary supplements in the Center for Food Safety and Applied Nutrition.

We appreciate this opportunity to present findings that are particularly relevant to the aging population.

ConsumerLab.com Background:
ConsumerLab.com's testing is funded by over 40,000 individual and institutional subscribers to our website (www.consumerlab.com). We also provide a Voluntary Certification Program and test products for clinical researchers (many funded by the NIH).

Use of Supplements by Seniors:
A recent survey of people who receive our free e-newsletter revealed that that among those aged 65 and older, 32% use 10 or more supplements daily (Reference 1).

A senior citizen in a vitamin store is a bit like a kid a candy store. However, while the FDA recommends a strict limit on lead contamination in candy, it has not set a limit for supplements. Our tests show that this policy has created a "buyer beware" situation.

General Findings from Supplement Testing:
Based on tests of over 2,000 dietary supplements representing over 300 different brands, we find that one out of four has a quality problem. Problems have been found in products from every size of manufacturer and are most common in herbal supplements, multivitamins, and products with ingredients that are newer to the market.

The most common problem is a lack of ingredient or substandard ingredient.
Our most recent tests of herbal supplements show that 46% contained less than their expected amounts of key compounds. For example, an "Extra Strength" ginseng product provided less than 10% of the claimed amount of expected "ginsenoside" compounds. We reported a similar problem with the same product when purchased three years earlier (Reference 2).

Herbal supplements failing to contain claimed or expected amounts of marker compounds (among products selected in recent reviews):

- Echinacea: 5 of 6 failed to contain expected amounts of specific phenolic compounds (Reference 3).
- Garlic: 6 of 14 supplements had too little of the key compound allicin (Reference 4).
- Ginkgo: 4 of 7 supplements failed to contain the expected amounts of individual flavonol compounds, suggesting adulteration to enhance the apparent quality of the ginkgo material (Reference 5).
- Ginseng: 3 out of 13 failed to contain the expected amount of marker ginsenosides (Reference 2).
- Milk thistle: 7 of 10 failed to meet claims of silymarin standardization (Reference 6).
- St. John's wort: 3 of 10 contained only 23% to 36% of the expected amounts of hypericin or hyperforin (Reference 7).
- Turmeric: 2 of 9 were low in curcuminoids (Reference 8).
- Valerian: 8 of 14 were low in valerenic acids (Reference 9).
- A similar problem exists with certain non-herbal supplements, such as chondroitin (Reference 10).

A major cause of these problems is the reliance by some manufacturers on cheap, non-specific tests which overstate the amount of actual ingredient in raw materials and supplements. More specific tests show the actual amounts to be much lower.

The next most common problem is contamination with lead and other heavy metals.
The FDA professes a policy of reducing lead levels to the lowest amount that can be practicably obtained in manufacturing, yet the FDA has neither set nor suggested limits on heavy metals in supplements. The only official limit on lead in supplements is in the State of California. That limit, 0.5 mcg per daily serving typically works out to be slightly higher than the FDA candy limit, but is still very conservative and meaningful. Products sold in California exceeding this limit must carry a warning label (Reference 11). ConsumerLab.com has found that 11% of herbal supplements exceed the California limit for lead.

Cadmium, a toxin and carcinogen, also occurs in certain herbal supplements, but the FDA has not set a limit on cadmium in supplements. ConsumerLab.com has found 40% of St. John's wort supplements and 14% of valerian supplements to exceed World Health Organization guidelines for cadmium contamination.

Herbal supplements found to exceed California Prop 65 lead limit or the WHO cadmium guidelines:

- Echinacea: 1 of 6 failed for lead (Reference 3).
- Garlic: 2 of 14 failed for lead (Reference 4).
- Ginkgo: 1 of 7 failed for lead (Reference 5).

- Ginseng: 1 out of 13 failed for lead (Reference 2).
- Milk thistle: None of 10 failed for lead (Reference 6).
- St. John's wort: Out of 10 products, 1 failed for lead and 4 failed for cadmium (including the product contaminated with lead) (Reference 7).
- Turmeric: 2 of 9 failed for lead (Reference 8).
- Valerian: Out of 14 products, 1 failed for lead and 2 for cadmium (Reference 9).
- The highest levels found by ConsumerLab.com are 16 mcg and 19 mcg of lead, respectively, in daily servings of ginkgo and turmeric supplements (References 5, 8).
- Some chromium supplements are contaminated with a carcinogenic form of chromium, known at hexavalent chromium. The FDA has not established limits for hexavalent chromium in supplements. California has proposed a limit on hexavalent chromium in its water supplies, which equates to 0.12 mcg in a normal daily intake of water. We recently found much higher amounts (1.6 to 26.4 mcg of hexavalent chromium) in three chromium supplements (Reference 12).

While individual products with elevated levels of lead and cadmium are generally not toxic in themselves, they unnecessarily expose Americans to toxins and the effects are cumulative. As noted earlier, many seniors take ten or more supplements daily and additional exposure comes from foods, beverages, and the environment. It would be dangerous to suggest that a single supplement needs to contain a toxic amount of heavy metal to be a threat to health. However, a 2007 report by the FDA on lead contamination in multivitamins made this faulty assumption and has been criticized for doing so (Reference 13).

Unfortunately, the USP may soon adopt an industry proposal permitting 10 micrograms of lead per daily serving of a supplement – twenty times higher than the California limit. We think such a lax standard would be a terrible mistake, permitting an individual supplement to exceed the total amount of lead that a child can tolerate (6 mcg), and just a few supplements to surpass the daily threshold for adults (Reference 11).

Other problems:

- Tablets that won't break apart properly to release all of their ingredients (References 5, 10, 14, 15, 16).
- A lack of proper labeling to indicate the parts of the plants used (References 5, 8) and deceptive labeling suggesting more ingredients than actually provided (References 10, 17).
- A lack of voluntary warnings which could help consumers avoid potential problems, such ingredients in excess of known tolerable intake levels (References 18, 19).
- Faulty products left on the market due to inaction by manufacturers or "quiet" recalls announced to retailers but not to the public. (Reference 2)
- Spiking of supplements with prescription drugs, particularly those for erectile dysfunction. (Reference 20)
- Lack of public access to adverse event reports filed by manufacturers with the FDA.

Will Good Manufacturing Practices (GMPs) Help?
Good Manufacturing Practices (GMPs) are now required of most supplement manufacturers to help ensure batch-to-batch uniformity. However, "bad" products can, and are, being made under these "good" practices because the GMPs do not include standards for purity and ingredient identity. These standards, and the selection of tests used to measure against them, are left to each manufacturer to determine for itself.

Conclusion
Nearly eleven years of product reviews by ConsumerLab.com have shown consistent problems with a significant percentage of dietary supplements, particularly herbal supplements. However, in nearly every supplement category that we test, we do find products that meet high quality standards, showing that this is achievable. If we want our supplements to be the best and safest in the world, we will need better guidance from government establishing rigorous standards and test methods, greater enforcement of current regulations, and more self-regulation from the industry.

In my written testimony, you will find additional statistics, information, and references.

References:

1. ConsumerLab.com Survey of Supplement Users, 2010 Report. February 1, 2010 news release.
http://www.consumerlab.com/news/Supplement_Survey_Report/1_31_2010/

2. ConsumerLab.com Product Review of Ginseng Supplements (2006)
https://www.consumerlab.com/reviews/Ginseng_Supplements/ginseng/

3. ConsumerLab.com Product Review of Echinacea Supplements (2004)
http://www.consumerlab.com/reviews/Echinacea/Echinacea/

4. ConsumerLab.com Product Review of Garlic Supplements (2006)
http://www.consumerlab.com/reviews/Garlic_Supplements/garlic/

5. ConsumerLab.com Product Review of Memory & Cognition Enhancement Supplements (Ginkgo, Huperzine-A, and Acetyl-L-Carnitine)
http://www.consumerlab.com/reviews/Memory_Supplements_Ginkgo_Huperzine_Acetyl-L-Carnitine/GinkgoBiloba/

6. ConsumerLab.com Product Review of Milk Thistle Supplements (2009)
http://www.consumerlab.com/reviews/Milk_Thistle_Supplements/milkthistle/

7. ConsumerLab.com Product Review of St. John's Wort Supplements (2010)
http://www.consumerlab.com/reviews/St_Johns_Wort/stjohnswort/

8. ConsumerLab.com Product Review of Turmeric Supplements (2008)
http://www.consumerlab.com/reviews/Turmeric_Curcumin_Supplements/turmeric/

9. ConsumerLab.com Product Review of Valerian Supplements (2006)
http://www.consumerlab.com/reviews/Valerian_Supplements/valerian/

10. ConsumerLab.com Product Review of Joint Health Supplements with Glucosamine, Chondroitin, and/or MSM (2009)
http://www.consumerlab.com/reviews/Joint_Supplements_Glucosamine_Chondroitin_and_MSM/jointsupplements/

11. ConsumerLab.com Asks USP to Adopt Safer Lead Limit for Drugs and Supplements, December 8, 2008 news release.
http://www.consumerlab.com/news/USP_Lead_Limit/12_08_2008/

12. ConsumerLab.com Product Review of Chromium Supplements (2010)
http://www.consumerlab.com/reviews/Chromium/chromium/

13. Miodovnik, et al, The U.S. Food and Drug Administration Risk Assessment on Lead in Women's and Children's Vitamins Is Based on Outdated Assumptions. Environ Health Perspect. July 2009, 117(7): 1021-1022.
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2717124/

14. ConsumerLab.com Product Review of Cholesterol-lowering Supplements (2010)
http://www.consumerlab.com/reviews/Cholesterol-Lowering_Supplements_Review_Sterols_Policosanol/cholesterol/

15. ConsumerLab.com Product Review of Supplements for Cancer Prevention (Green Tea, Lycopene and Selenium) (2009)
http://www.consumerlab.com/reviews/Supplements_for_Cancer_Prevention_Green_Tea_review_Lycopene_and_Selenium_reviews/cancerprevention/

16. ConsumerLab.com Product Review of Muscular Enhancement Supplements (Creatine, HMB, Glutamine, BCAAs) (2006)
http://www.consumerlab.com/reviews/Muscular_Enhancement_Supplements-Creatine_HMB_Gluatamine_and_BCAAs/creatine/

17. ConsumerLab.com Product Review of Resveratrol Supplements (2007)
http://www.consumerlab.com/reviews/Resveratrol_Supplements_Including_Red_Wine_Grape_and_Polygonum_Sources/Resveratrol_Red_Wine/

18. ConsumerLab.com Product Review of Multivitamin and Multimineral Supplements (2009)
http://www.consumerlab.com/reviews/Multivitamin_Multimineral_Supplements/multivitamins/

19. ConsumerLab.com Product Review of B Vitamins (2007)
http://www.consumerlab.com/reviews/B_Vitamins_B-Complexes_Thiamin_Niacin_B-6_B-12_Biotin_and_Folic_Acid/bvitamins/

20. ConsumerLab.com Archive of Recalls and Warnings
http://www.consumerlab.com/recalls.asp#Past

The CHAIRMAN. Thank you very much, Dr. Cooperman.
Mr. Bell.

STATEMENT OF CHARLES BELL, PROGRAM DIRECTOR, CONSUMERS UNION, YONKERS, NY

Mr. BELL. Chairman Kohl, Ranking Member Corker, members of the committee, I'm Charles Bell. I work for Consumers Union, the nonprofit publisher of Consumer Reports, based in Yonkers, NY.

I just wanted to point out, at the outset, that even though Dr. Cooperman and I both come from New York, we have no official relationship with ConsumerLab.com. We're separate organizations. We certainly appreciate the research work that they are doing.

If—I would—I submitted a rather long written statement. I would just summarize some of the highlights.

In terms of senior use of dietary supplements, findings from several sources indicate that dietary supplement use generally increases with age. According to a survey published in the Journal of American Medicine, 49 percent of Americans aged 57 to 85 use a dietary supplement and 52 percent of seniors reported using supplements concurrently with prescription drugs.

Many dietary supplements, including most vitamins and minerals, taken within recommended limits are generally safe and can have important benefits for consumers. However, Consumers Union is concerned that there's a significant and growing number of highly questionable products that are entering the market that would probably fail rigorous safety testing.

We would note that, since the passage of DSHEA in 1994, the marketplace has grown. This is quite a large and dynamic marketplace today, with industry sources estimating there could be between 30- to 75,000 dietary supplement products on the market, with another 1,000 new products or so entering every year. So, that's a lot of products for the FDA and other health authorities to keep an eye on. We think, at the same time, that consumers and seniors really do need to be aware that there are significant unresolved safety problems with dietary supplements.

We publish, in Consumer Reports over the last 20 years or so, several articles with lists of unsafe supplements that we think consumers should avoid. For example, in 1995 we published an article calling out five herbal supplements, including ephedra. But, the other four that were on that list—chaparral, comfrey, lobelia, and yohimbe—continue to be sold in the market today. We updated our list in 2004 and 2008.

Generally when Consumer Reports warns about product hazards, we're used to seeing some type of swift response from the marketplace, either of the product being corrected or fixed by manufacturers, or withdrawn by the governments. We are concerned that we see a lot of products that we think consumers should not be running into staying on store shelves that could be a dangerous surprise for a senior or a consumer.

But, we also have advised consumers not to use weight-loss supplements, generally speaking. We are concerned about multi-ingredient herbal supplements, often with concentrated herbal extracts spiked with stimulants, like bitter orange or high levels of caffeine. We've also been concerned about supplements marketed for sexual

enhancement purposes that also have high levels of stimulants and multiple ingredients, and sometimes also turn out to be contaminated with prescription drugs.

We are concerned that FDA does not have a program of manufacturer registration. When the HHS inspector general visited FDA in 2001, they found that the agency was unable to provide information for many, many products that it should supposedly be overseeing.

We cite, in our testimony, information about the increasing amount of imported ingredients that are used in supplement manufacturing. China now provides about one-third of global vitamin manufacturing, and many herbal and other botanical and dietary supplement products are sourced there, as well. We are concerned about whether the FDA really has sufficient resources to police the imports of products from China, or any other country, because there are many other countries that are potentially involved.

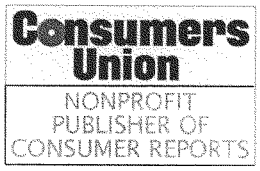
We have also expressed concern about new supplements that contain nanoparticles. There is a report that was done by the Project Emerging—on Emerging Nanotechnologies, here in DC., that there's more than 44 dietary supplements with nanoparticles that have already entered the marketplace. We don't—we're not sure the FDA has looked at the safety profile for any of these, and we do not think that they should be permitted to be sold until they are subject to premarket safety testing.

We believe that seniors really do need to be aware of interactions between—potential interactions between prescription drugs and dietary supplements. As noted, 52 percent of seniors are also taking prescription drugs. There are many, many different warnings for different types of supplements. For example, ginkgo biloba can interfere with blood clotting, and physicians generally advise consumers to cease from using herbal medicine 2 weeks prior to having surgery. In other cases, the supplement can lower the effectiveness of the prescription drugs that consumers are taking, or actually intensify it.

So, we support the Dietary Supplement Safety Act of 2010 that would strengthen public oversight of dietary supplements. It would include provisions for manufacturer registration, mandatory recall authority, and reporting of nonserious adverse events.

We thank you very much for your interest in these issues, and look forward to working with the committee, and with the industry, to address the problems that are being discussed here today.

[The prepared statement of Mr. Bell follows:]



Testimony of

Charles Bell, Programs Director

Consumers Union

before the

Senate Special Committee on Aging

Hearing on

Dietary Supplements: What Seniors Need to Know

May 26, 2010

Good afternoon, Chairman Kohl, Ranking Member Corker, and other members of the Committee. Thank you for providing me the opportunity to come before you today. I am Charles Bell, Programs Director for Consumers Union.

Consumers Union is the nonprofit publisher of *Consumer Reports* magazine. Since 1936, our mission at Consumers Union has been to test products, inform the public, and protect consumers. Today I offer this testimony on dietary supplements as part of our consumer protection function.

KEY RECOMMENDATIONS

Consumers and seniors turn to dietary supplements because they think these products will promote health and wellness. They also generally assume that such products are safe for their intended use, and would not be permitted to be sold by the federal government if they were unsafe or posed unreasonable risks to consumers. Unfortunately, in our research and reporting, we have found some very profound and troubling gaps in the system we have today to assure supplement safety. While many dietary supplements, including most vitamins and minerals taken within recommended limits, are generally safe and can have important health benefits for consumers, there is a significant and growing number of highly questionable products that would probably not be allowed on the market if they were subject to rigorous pre-market safety testing.

We believe that Congress should require more rigorous safety standards for dietary supplements. It is very important to ensure that products that are marketed and promoted to advance health are safe, and do not themselves create serious health problems. And, consumers should be assured that the products they buy followed sound manufacturing practices, and are not adulterated or contaminated with heavy metals like lead, or prescription drugs.

Consumers Union supports the Dietary Supplement Safety Act of 2010 (S 3002), that would strengthen public oversight of dietary supplements. This bill includes provisions for manufacturer registration, mandatory recall authority, and improved reporting of non-serious adverse events. We believe that the principles incorporated in this legislation would give regulators better tools for protecting the public, and help move us to a safer marketplace.

The elements of a strong, preventive safety system that we favor include the following:

- **Mandatory Manufacturer Registration Requirements**. The GAO has reported that FDA has relatively little information on the companies it is expected to regulate and oversee. All dietary supplement manufacturing, processing and holding facilities should be required to register annually with the Secretary of

Health and Human Services, so that the FDA will know who is making dietary supplements, which products the companies manufacture, and which ingredients the product contain. This will ensure better communication between manufacturers and safety officials, and facilitate swift action in the event of serious adverse events, warnings and safety recalls.

- **Mandatory Recall Authority for the FDA**. The FDA must have the necessary authority to swiftly recall unsafe products that pose risks to consumers.
- **Increased Safety Requirements for Products.** While we favor encouraging the FDA to publish new guidelines for new dietary ingredients, we also believe that the burden of proof for demonstrating that a supplement does not present a "significant or unreasonable risk" should be placed on manufacturers to establish that supplements are safe before they are sold. In that sense, we are also concerned about existing products that are "grandfathered in" that have not been rigorously tested or reviewed for safety. We support creation of a regulatory review process that would prioritize and address existing hazards in the supplements marketplace, such as the unsafe supplements we have identified that continue to be widely sold in stores and the internet. Products that pose unreasonable risks to consumers are swiftly removed by manufacturers and the FDA.
- **Better Information for Consumers and Medical Providers.** Labels of dietary supplements should clearly indicate what and how much is in the package, and provide explicit warning of possible adverse effects, including herb-drug interactions. FDA should also provide better, real-time information to consumers, medical providers and the public on emerging supplement hazards and adverse event reports, through better use of data systems like the Poison Control Centers and research by independent safety experts.
- **More Comprehensive Reporting of Adverse Events.** Since 2007, manufacturers have been required to report serious, generally life-threatening events to the FDA within 15 days. However, there is much more adverse event information and consumer complaints that are received by manufacturers that should be reported to FDA on an annual basis, or more frequently if possible. Given that our safety system is, in effect, a "post-marketing system," improving the flow of information about adverse events is critical for detecting potential safety hazards, including problems related to contamination and drug interactions.
- **Quality Assurance for Imported Ingredients.** Congress should investigate further ways to assure the safety and quality of supplements manufactured overseas, including expanding funding, oversight resources, investigation and enforcement to assure the safety of imported supplement ingredients.
- **Expanded Efforts to Reduce and Eliminate Supplement Contamination.** Efforts to implement safe manufacturing and production practices should be accelerated, with vigorous oversight by FDA. Dietary supplements should be consistently low in heavy metals and other forms of chemical or mineral contamination, and there should be zero tolerance for prescription drug contamination.
- **Expanded Resources for FDA.** FDA must be provided with sufficient funding and personnel resources to implement a preventive safety system and accomplish its critically important supplement safety mission, by increasing oversight, inspections and enforcement.

SENIOR USE OF DIETARY SUPPLEMENTS

Americans spend an estimated $20-30 billion on dietary supplements annually, and estimates of consumer use of supplements range from 10% to 52% of the overall population.[1] A national telephone survey published in JAMA in 2002 found that vitamins were taken by 40% of respondents, and that herbals and supplements were taken by 14% of those surveyed. Among prescription drug users, 16% also took a supplement.[2]

Findings from several sources suggest that dietary supplement use generally increases with age.

- An internet survey carried out by Mintel in May 2009 found that 67% of 55 to 64 year-olds, and 75% of consumers over the age of 65, report use of regular vitamin supplements, compared with 50% of 45 to 54 year-olds reporting vitamin supplement use, and reported an average use of 52% for the population as a whole.[3]

- According to a recent article published in Nutriceuticals World, consumers between the ages of 65 and 74 are the most frequent users of dietary supplements.

  "...[S]eniors are twice as likely as any other age group to take fish oil/omega 3s, vitamin E, and calcium supplements; they are also heavy users of vitamin C, B12 and B complex, and to a lesser extent antioxidants and herbals."[4]

- According to a survey published in JAMA in 2006, 49% of Americans aged 57 to 85 used a dietary supplement. 52% of seniors reported using supplements concurrently with prescription drugs.[5]

WHAT SENIORS AND CONSUMERS NEED TO KNOW ABOUT DIETARY SUPPLEMENTS

Many dietary supplements, including most vitamins and minerals taken within recommended limits, are generally safe and can have important health benefits for consumers. However, a significant and growing number of highly questionable products are entering the market that would probably would fail rigorous pre-market safety testing.

---

[1] Gardiner, P., Sarma, DN, Low Dog T, Barret ML, Chavez ML, Mahady GB, Marples RJ, Giancaspro GI. The state of dietary adverse event reporting in the United States. Pharmacoepidem Drug Safety, 2008: 17(10): 962-970. See also: Tachjian A, Maria V, Jahangir A. Use of Herbal Products and Potential Interactions in Patients with Cardiovascular Diseases. Journal of the American College of Cardiology, 2/9/10, Vol 55, No. 6 2010, 515-25.

[2] Kaufman DW, Kelly JP, Roseberg L, Andersen TE, Mitchael AA. Recent Patterns of Medication Use in the Ambulatory Adult Population of the U.S.: The Slone Survey. JAMA 1/16/02 Vol 287, No. 3, 337-344.

[3] Mintel, "Functional Foods – US," August 2009. Base: 2,000 Internet users aged 18+.

[4] "Up and coming markets: an ounce of prevention equals a pound of cure," Nutraceuticals World, September 2009.

[5] Dima M. Qato, PharmD, MPH; G. Caleb Alexander, MD, MS; Rena M. Conti, PhD; Michael Johnson, BA; Phil Schumm, MA; Stacy Tessler Lindau, MD, MAPP. Use of Prescription and Over-the-counter Medications and Dietary Supplements Among Older Adults in the United States. JAMA. 2008;300(24):2867-2878.

Consumers need to be aware that there are significant unresolved safety problems with dietary supplements. Dietary supplements may interact with other prescription drugs, over-the-counter drugs and supplements they are currently taking. We urge all consumers to discuss the use of supplements with their physicians and medical providers prior to initiating use of these products. Further we urge consumers to do their homework, and carefully consider the medical evidence that supports or advises against the use of particular products, by consulting reputable web sites, such as those operated by the National Institutes of Health Office of Dietary Supplements and the FDA.

Dietary supplement products are sold in the same stream of commerce as approved over-the-counter products, and consumers often assume that if they were not safe, the government would not permit them to be sold.

For example, in an October 2002 nationwide Harris Poll of 1,010 adults, 59 percent of respondents said they believed that supplements must be approved by a government agency before they can be sold to the public. Sixty-eight percent said the government requires warning labels on supplements' potential side effects or dangers. Fifty-five percent said supplement manufacturers can't make safety claims without solid scientific support.

Unfortunately, the respondents in this poll are incorrect. None of those widely expected protections exist for dietary supplements—they exist only for prescription and over-the-counter medicines. With respect to testing for hazards, before approval, drugs must be proved effective, with an acceptable safety profile, by means of lab research and rigorous human clinical trials involving a minimum of several thousand people, and several years. In contrast, supplement manufacturers can introduce new products without any testing for safety and efficacy. The maker's only current obligation is to send the FDA a copy of the language on the label.

Drug labels and package inserts must mention all possible adverse effects and interactions. But supplement makers do not have to put safety warnings on the labels, even for products with known serious hazards. With respect to post-surveillance monitoring, drug companies are required by law to tell the FDA about any reports of product-related adverse events that they receive from any source. Almost every year, drugs are removed from the market based on safety risks that first surfaced in those reports.

By contrast, supplement makers were only recently required to report serious adverse events to FDA, beginning at the end of 2007, and many other reports and complaints received by manufacturers are not required to be reported. As a result, FDA has only partial information about consumer safety problems arising from supplement use. In 2001, the HHS Inspector General reported that the FDA Medwatch system was an "inadequate safety valve" for detecting safety problems with dietary supplements, and many of the problems identified by the HHS, the GAO and other agencies continue to this day.

Under DSHEA, the burden of proof for removing unsafe products has been inappropriately shifted from manufacturers to government. As former FDA director David Kessler has stated, "Congress put the FDA in the position of being able to act only after the fact and after substantial harm has already occurred."

In the aftermath of DSHEA, unsafe dietary supplement products can remain on the market for many years, in the same stream of commerce as products approved by the FDA as safe and

effective for their intended use. Further, new dietary supplement products can be introduced overnight that contain novel, untested ingredients and/or novel combinations of new and/or existing supplement ingredients. Health providers and public health authorities typically receive little pre-market or post-market information about how such products may affect human health, and interact with medicines that patients are already taking.

Even where serious safety problems are documented, it is difficult for the FDA to take prompt action to protect consumers. Unless the FDA meets a high standard of proof that a dietary supplement creates "a significant or unreasonable risk," it cannot ban it. Over the last 16 years, the FDA has typically relied on warnings and voluntary compliance to address supplement hazards, allowing many dangerous products to remain on the market.

UNSAFE SUPPLEMENTS CAN REMAIN ON THE MARKET FOR MANY YEARS

Consumer Reports periodically publishes lists of unsafe supplements that we urge our readers to avoid. Unfortunately, these unsafe products do not quickly disappear from the marketplace, but continue to be widely sold through retail stores and the internet. Consumers and seniors are being put at risk by an inadequate safety system that does not move swiftly to remove dangerous products from the marketplace.

In 1995, *Consumer Reports* magazine published a list of five supplements that according to the FDA can cause serious harm to consumers--ephedra, chaparral, comfrey, lobelia, and yohimbe. Nine years later, on April 12, 2004ephedra was finally removed from the marketplace, many years after the FDA first received reports of serious consumer health problems, including deaths and disabling injuries. But the other four supplements are still being marketed and sold in retail stores and on the internet.

In May 2004, *Consumer Reports* published an updated list of 12 hazardous dietary supplements, including the four herbs named in the 1995 report, that are too dangerous to be on the market according to government warnings, adverse-event reports, and medical experts.

These "dirty dozen" unsafe supplements, which *CR* easily purchased in stores and online also included aristolochia, an herb conclusively linked to kidney failure and cancer; germander, and kava, which are known or likely causes of liver failure, and bitter orange, a herbal stimulant being marketed as a substitute for ephedra. We pointed out that the potentially dangerous effects of most of these products have been known for more than a decade, and at least five of them were banned in Asia, Europe, or Canada.

The 2004 *Consumer Reports* article described the case of Beverly Hames, who went to an acupuncturist in 1992 seeking a "safe, natural" treatment for an aching back. She obtained a selection of Chinese herbal products, at least five of which were later found to contain aristolochic acid. By mid-1994, she had symptoms of kidney failure, and in 1996 she underwent a kidney transplant. She must take anti-rejection drugs for life. The herbs' distributor said his Chinese suppliers had substituted Aristolochia for another herb without his knowledge.
"I was told that these herbs are safe, they're natural and they've been used for hundreds of years," Hames said. "I went from a perfectly healthy person to kidney failure in a very short period of time."

In January 2008, we updated our list again, and added three additional supplements that we believe pose significant hazards to consumers: cesium, which poses risks of fainting and abnormal heart rhythms; graviola, which has been linked to reports of a nerve disorder similar to Parkinson's disease; and colloidal silver, which can cause kidney damage and irreversible skin discoloration.

While we believe that all of the supplements named in our 1995, 2004 and 2008 reports should be removed from the marketplace immediately, we believe it would be a serious mistake to attempt to address the crisis in supplement safety only on an ad-hoc, substance-by-substance basis. Consumers need effective safety and quality assurance that the supplements they take are safe and effective for their intended use. The type of serious adverse reactions that we see reported for many products, such as heart arrhythmias, liver and kidney damage, strokes and even death, are not the normal sort of surprise that one would expect to find from purchasing a dietary supplement at the corner pharmacy or the internet.

The fact is, with some 30,000 or more dietary supplement products in the marketplace, and an additional 1,000 products entering every year, no one really knows the full number of hazardous products that may be out there. The consumer interest also requires establishment of an effective preventive safety system that includes manufacturer registration, pre-market safety evaluation, mandatory reporting for the full range adverse events, improved oversight of manufacturing practices, and increased FDA regulatory authority to take prompt action against known and emerging hazards.

NEW WEIGHT-LOSS PRODUCTS MARKETED AS "EPHEDRA-FREE" MAY STILL BE UNSAFE

Many companies have developed new weight-loss supplements that are being marketed as "ephedra-free," which many consumers may assume are safe for consumer use. But as Dr. Paul Coates of the National Institute of Health's Office of Dietary Supplements has warned, "The fact that a dietary supplement is ephedra-free is not a indication of its safety."[6]

Consumers spend some $17.7 billion for dietary and weight-loss supplements each year, and it has been projected that this market grows at 6-7% per year.[7] Because of safety concerns, *Consumer Reports* urges consumers to avoid all dietary supplements marketed for weight loss, because many contain dangerous stimulants and high levels of caffeine.

Many weight loss supplements that are being marketed as "ephedra-free" contain bitter orange. Bitter orange is derived from the Seville orange and has the botanical name citrus aurantium. It appears in some foods, including orange marmalades. In dietary supplements, it appears in a concentrated form, and its active ingredient—synephrine—mimics the effects of ephedra. Synephrine stimulates the cardiovascular system, raises the heart rate, raises blood pressure, and stimulates the central nervous system. While its use has been studied in animals, there have been few studies involving human subjects.

---

[6] Jill Burcum, "Your Health: Ephedra-free products loaded with new herbs of concern," Minneapolis Star Tribune, April 29, 2003.

[7] Tachjian A, Maria V, Jahangir A. Use of Herbal Products and Potential Interactions in Patients with Cardiovascular Diseases. Journal of the American College of Cardiology, 2/9/10, Vol 55, No. 6 2010, 515-25.

In its May 2004 article, *Consumer Reports* profiled a 21-year-old college student studying for finals who took weight loss supplements containing bitter orange, believing they were safe because they were labeled as "ephedra-free." After three weeks of taking the product, she experienced a seizure. Her neurologist told her that the bitter orange in the supplement product was a likely cause. Since discontinuing use of the supplement, she has not experienced any more seizures.

MULTI-INGREDIENT DIETARY SUPPLEMENTS MAY POSE SIGNIFICANT HAZARDS

Many weight-loss and body-building supplements, and also supplements marketed for enhancing sexual capacity, contain multiple herbal ingredients, extracts, caffeine, green tea and other ingredients. Many of these ingredients are also marketed as "proprietary blends" so the consumer does not necessarily know how much of each ingredient the product contains, and potential hazards it poses.

In general, little is known about how multiple herbal ingredients, extracts and compounds interact together. Further, these products often contain ingredients that *Consumer Reports* has singled out for concern, including bitter orange, yohimbe, and high levels of caffeine. In a pilot project carried out in California, researchers found that nearly half of reports to local poison control centers involved multi-component supplements containing caffeine.[8] Again, *Consumer Reports* urges consumers to avoid such multi-component weight-loss supplements, both because they may contain high levels of caffeine and other untested ingredients, and there is a lack of medical research to substantiate either their safety or efficacy for the marketed use.

POST-MARKETING SURVEILLANCE OF DIETARY SUPPLEMENTS IS "AN INADEQUATE SAFETY VALVE"

In April 2001, the Office of Inspector General at the Department of Health and Human Services concluded that the FDA's adverse event reporting system was "an inadequate safety valve" because of inadequate authority and organizational capacity to collect and take action on adverse event reports. The report noted that in contrast to requirements for monograph drugs and new drug application (NDA) drugs, manufacturers of dietary supplements are not required to register their companies or their products with the FDA. As a result, the FDA does not have a list of supplement products and ingredients when it receives an adverse event report. The Inspector General found that FDA was unable to determine the ingredients for 32 percent of products mentioned in adverse event reports (AERs). It also lacked product labels for 77 percent of the products mentioned in the AERs, and product samples for 69 percent of products that it requested. For products referenced in the AERs, the FDA was unable to determine the manufacturer for 32 percent of the products, and the city and state for 71 percent of manufacturers.

As discussed above, many consumers are surprised to learn the government does not currently evaluate the safety of dietary supplements before they are sold. This situation poses a serious risk to public health, and amounts to a vast, uncontrolled clinical trial on an unsuspecting public. Mr. Joseph Levitt, Esq., Director of the FDA's Center for Food Safety and Applied Nutrition,

---

[8] Haller C, Kearney T, Bent S, Ko R, Benowitz, N, Olson, K. Dietary Supplement Adverse Events: Report of a One-Year Poison Center Surveillance Project. Journal of Medical Toxicology, June 2008, Vol 4., No. 2.

testified in Congress in March 2001 that the current "regulation of dietary supplements is, for the most part, a post-marketing program."

MANUFACTURERS SUPPRESSED INFORMATION REGARDING DIETARY SUPPLEMENT ADVERSE EVENTS

The safety problems that consumers experienced with ephedra also demonstrated that manufacturers may conceal substantial numbers of consumer complaints regarding their products. Many customer complaints were received by manufacturers that were not forwarded in a timely way to the FDA.

- On August 15, 2002, the Justice Department disclosed that it was investigating whether Metabolife, a major manufacturer and distributor of ephedra products, had made false statements to the FDA regarding the existence of consumer complaints about its products. On the same day, Metabolife announced that it would turn over 13,000 consumer health complaints or "adverse event reports" to the FDA.[11] After analyzing the Metabolife adverse events reports, the special investigations division of the House Committee on Government Reform concluded that 2,000 of the 13,000 reports were "significant" effects, including three deaths, 20 heart attacks, 24 strokes, 40 seizures, 465 episodes of chest pains and 966 reports of heart rhythm disturbances.

- Depositions in a lawsuit in San Francisco against E'ola (a Utah-based multilevel-marketing firm) regarding a death allegedly linked to ephedra revealed that the company had received 3,500 customer complaints about one of its ephedra weight-loss products. According to the San Francisco Chronicle, none of the complaints were ever disclosed to the FDA.

On December 22, 2007, mandatory manufacturer reporting of serious adverse events related to dietary supplements went into effect, as a result of provisions included in the Dietary Supplement and Nonprescription Drug Consumer Protection Act, passed in 2006. Manufacturers were directed to report serious events such as serious cardiac, respiratory and gastrointestinal disorders.

However, many so-called non-serious adverse events are not covered by the law that Congress passed, even though this information would help FDA develop a better safety profile for many supplements. But these prominent examples from the past do not inspire confidence that important and significant health impacts arising from the use of herbal supplements will be promptly reported to responsible health authorities under a voluntary reporting system. We remain concerned that the flow of information to FDA needs to be improved to generate better, timely signals of emerging hazards.

CONSUMERS NEED PROMPT FDA ACTION AND EARLY WARNING ABOUT EMERGING HAZARDS

At a minimum, we believe that dietary supplement manufacturers should be required to forward all adverse event reports to FDA on a regular basis. While reporting of non-serious events has been required since the end of 2007, we do not think that the current reporting system gives FDA enough information to trigger timely action against products that pose unreasonable risks to consumers. We are also concerned that consumers do not receive warning about products that pose emerging hazards. Delays in reporting hazards increases potential risks to consumers.

For example, in the case of Hydroxycut, a top-selling weight-loss supplement recalled by FDA on May 1, 2009, the FDA's Medwatch system did not report reported hazards until the product's recall, even though the agency had received six dozen reports of adverse events, including 23 cases of liver toxicity and at least one death.

According to researcher Ano Lobb, a public health consultant who has worked in the past on the Consumer Reports Health Letter, the only warning about Hydroxycut were growing case reports in the medical literature. Lobb also points out that the nation's Poison Control Centers may be detecting 10 times more adverse events related to supplements. The FDA could potentially increase its postmarket surveillance capacity by incorporating the Poison Control Center data, and coordinating with independent researchers who could help provide earlier warning of supplement hazards.[9]

SENIORS NEED TO BE AWARE OF THE SERIOUS POTENTIAL RISKS OF INTERACTIONS BETWEEN PRESCRIPTION DRUGS AND DIETARY SUPPLEMENTS

Consumers may also experience safety problems with dietary supplements because of potential interactions with existing health conditions, such as diabetes, coronary problems or hypertension, and with other prescription or over-the counter medications they are currently taking.

As noted above, according to a survey published in JAMA in 2006, 49% of Americans aged 57 to 85 used a dietary supplement. 52% of seniors reported using supplements concurrently with prescription drugs.[10] It is very important for seniors to understand that prescription drugs may interact in many complex ways with other prescription drugs, over-the-counter drugs and dietary supplements. The bottom line is that patients and physicians need to discuss the specific products that the consumer is taking, to avoid adverse interactions and ensure that prescribed treatments will be effective.

Few clinical studies have systematically assessed potential interactions between supplements and medications, and many potential concerns have been reported. Depending on the combination of prescription drugs, OTC drugs and supplements the consumer may be taking, the effectiveness of intended treatments may be reduced, and the patient may be put at minor or serious risk in a wide range of other ways.

In particular, herbal remedies can interact dangerously with medications. In the January 2007 issue of Consumer Reports Health, we published an article on "Risky herb-drug combos" that listed potential interactions with nine top selling herbal supplements and common prescription drugs. Potential effects fall into four categories:

1) reduced drug efficacy
2) increased chance of drug side effects

---

[9] Lobb A. Enhancing FDA's Post-Market Surveillance of Dietary Supplements: Two Simple Steps to Build Capacity. Journal of Dietary Supplements, 9/21/09, Vol 6(3), 204-210.

[10] Dima M. Qato, PharmD, MPH; G. Caleb Alexander, MD, MS; Rena M. Conti, PhD; Michael Johnson, BA; Phil Schumm, MA; Stacy Tessler Lindau, MD, MAPP. Use of Prescription and Over-the-counter Medications and Dietary Supplements Among Older Adults in the United States. JAMA. 2008;300(24):2867-2878.

3) potentially dangerous increases in drug efficacy
4) and potentially dangerous rise in drug efficacy AND increased chance of side effects.

As an example, ginkgo biloba, a popular supplement taken to enhance memory taken by as many as 11 million Americans, may reduce platelets in the blood, and make it more difficult for the blood to clot. This can cause excessive bleeding, and in some cases strokes. Because of the potential complications with surgical procedures, Dr. John Neeld, the president of the American Society of Anesthesiologists, advises consumers to discontinue the use of herbal medicine at least 2 to 3 weeks prior to surgery.

A recent article published in the Journal of the American College of Cardiology provides a detailed description of potential interactions for herbal interactions for patients who have cardiovascular diseases. The article lists 27 commonly sold herbal products that patients with such diseases may need to avoid, and points out that the evidence for safety and efficacy for many of these products is scant. The article advises physicians to carefully question patients about supplement use, especially elderly patients who may be at higher risk.[11]

According to Dr. Arthur Grollman, professor of medicine and pharmacological sciences at the State University of New York at Stony Brook:

> Interactions between herbal products and prescription or over-the-counter drugs constitutes one of the greatest risks posed by the used of botanical medicines. Botanical medicines can act through a variety of mechanisms to alter the actions and metabolism of prescription and OTC drugs.... In fact, serious adverse effects have been reported in patients taking cyclosporine or antiretroviral agents when they added St. John's wort, which caused blood levels of their life-saving drug to fall to amounts that were no longer therapeutic.
>
> The extent of herb-drug interactions is unclear, but its potential magnitude can be judged by a recent survey of medication use in the U.S. A recent survey found that among individuals over 18 years of age, 50% took at least one prescription drug during the preceding week. Among women over 65 years or older, 23% took at least five prescription drugs. 16% of those taking prescription drugs also took an herbal supplement. Thus, many Americans unknowingly risk therapeutic failures or adverse effects due to herb-drug interactions, especially older individuals who take multiple medications for chronic diseases.[12]

For these reasons, *Consumer Reports* recommends that consumers discuss the use of all dietary supplements with their physicians or health providers prior to taking them, to guard against the possibility of adverse health effects or drug reactions. The American Society of Anesthesiologists reported several years ago that as many as seven in 10 consumers do not discuss the use of supplements with their doctor. Ensuring open channels of communication between physicians and patients about supplement use and potential drug-supplement interactions is critical for promoting and maintaining good health.

---

[11] Tachjian A, Maria V, Jahangir A. Use of Herbal Products and Potential Interactions in Patients with Cardiovascular Diseases. Journal of the American College of Cardiology, 2/9/10, Vol 55, No. 6 2010, 515-25.

[12] Grollman, Arthur, MD. Testimony before Senate Commerce Committee hearing on dietary supplements, October 28, 2003.

CONTAMINATION OF DIETARY SUPPLEMENTS WITH PRESCRIPTION DRUGS AND HEAVY METALS

From January through September 2007, the FDA issued nine "safety alerts" warning consumers to stop using 13 brands marketed as supplements, because FDA testing found that they contained prescription medications. Nine concealed erectile-dysfunction drugs such as sildenafil (Viagra) or tadalafil (Cialis), three harbored lovastatin (Mevacor), a prescription drug for high chloresterol; and one, sibutramine (Meridia), a weight loss drug. These products unknowingly put consumers at risk of pharmaceutical side effects and potential drug interactions.

In August 2009, the FDA discovered more than 140 products, most of them labeled as dietary supplements, that were contaminated with prescription drugs. In some cases, the level of the prescription weight loss drug sibutramine was up to three times the maximum recommended daily drug dose.

On May 3, 2010, the Food and Drug Administration warned consumers against using Vita Breath, after a patient with lead poisoning reported using the supplement plus two other herbal products. The New York City Department of Health and Mental Hygiene alerted the FDA to the case of lead poisoning. When that agency tested Vita Breath, it found the drug contained 1,100 parts per million of lead, that's 10,000 times higher than the FDA's maximum allowable lead levels for candy.

Vita Breath, which is manufactured by American Herbal Lab in California, is sold at health fairs and on the internet. People who have taken Vita Breath should talk to their health care provider about getting their lead levels tested. The FDA is currently analyzing samples of the dietary supplement, and working with New York and California officials to further investigate the product.

Acute lead poisoning symptoms can include abdominal pain, muscle weakness, nausea, vomiting, diarrhea, weight loss and bloody or decreased urinary output. Children are particularly vulnerable to lead poisoning. Also note that people with high levels of lead in their blood may show no symptoms, but the condition can still damage the nervous system and internal organs.

According to an article by Dr. Peter Cohen in the New England Journal of Medicine, such reports represent only the fraction of the contaminated supplements that are probably present in the marketplace. Dr. Cohen points out the unscrupulous manufacturers have made it more difficult for the FDA to detect the contamination by modifying the original chemical structure of the drug to elude testing. According to the article, many of the contaminated products found to date were made in China, Brazil and other countries.[13]

Consumers Union is concerned that FDA is not providing adequate oversight of supplement contamination problems. We need to assure consumers that dietary supplements are consistently low in heavy metals and other forms of chemical or mineral contamination, and we should have zero tolerance for prescription drug contamination. At a minimum, we believe that products should not exceed U.S. Pharmacopeia limits for lead and other heavy metals. Because consumers do not expect to encounter heavy metal contamination in supplements, and many

---

[13] Cohen P. American Roulette: Contaminated Dietary Supplements, NEJM, 10/7/09, NEJM.org.

consumers may take multiple supplements or multiple doses of supplements, additional oversight may be needed to reduce hazards and warn consumers about unexpected health risks.

NEW UNTESTED NANO-INGREDIENTS IN SUPPLEMENTS

In 2009, the Project on Emerging Nanotechnologies reported that 44 dietary supplement products that claim to contain nano-particles were on the market. Yet the FDA has little information about such products, and there are serious questions about whether such products are safe for consumers to use.[14]

"It is not clear that the supplement industry is conducting the rigorous testing needed either to understand the effects of nanoscale ingredients in its products or to back up the product claims. This means that consumers are potentially exposed to unknown risks that should be balanced with the possible benefits of taking these supplements," says David Rejeski, PEN's director.

The Project has issued a report entitled "A Hard Pill to Swallow: Barriers to Effective Regulation of Dietary Supplements Containing Nanoparticles."

According to the Report's Executive Summary:

> The FDA's ability to regulate the safety of dietary supplements using nanomaterials is severely limited by lack of information, lack of resources and the agency's lack of statutory authority in certain critical areas. Three main problems need to be addressed:
>
> > 1. FDA does not have the capacity to identify nano-based dietary supplements that are being developed and marketed, unless manufacturers submit to the pre-market notification process for new dietary ingredients.
> >
> > 2. To the extent that FDA is aware of nano-based dietary supplements, it has little regulatory authority over them.
> >
> > 3. Even if it were granted increased regulatory authority, FDA lacks the scientific expertise and resources to effectively regulate nanomaterials in supplements.

The report recommends that Congress adopt legislation granting FDA the authority to collect additional information about those supplement products containing nano-particles, and ensure that they are tested for their effects on human health.

"Such legislation should prohibit the sale of new dietary supplements made with nanotechnology until they have been demonstrated to be safe, and it should provide FDA with sufficient resources to regulate these products," according to the report. "...Until Congress acts, consumers who take dietary supplements containing engineered nanoparticles will be at additional, unknowable and potentially serious risk."[15]

---

[14] Erickson, Britt. "Nanoceuticals?" Chemical and Engineering News, 2/9/09, available at: http://pubs.acs.org/cen/government/87/8706gov3.html

[15] Shultz, William, and Barclay, Lisa. "A Hard Pill to Swallow: Barriers to Effective FDA Regulation of Nanotechnology-Based Dietary Supplements," Project on Emerging Nanotechnologies, January 2009.

QUALITY ASSURANCE FOR IMPORTED INGREDIENTS

Another important concern for seniors and consumers is assuring the quality of imported ingredients that are used in dietary supplements. These concerns were recently highlighted by a report issued by the U.S.-China Economic and Security Review Commission. NSD Bio Group LLC, a research group under contract to the Commission, reported in April that there are a variety of potential concerns regarding the expanded sourcing of pharmaceutical and dietary supplement products and ingredients from China.[16]

The report comes in the wake of health concerns raised by unsafe raw materials discovered in imported products from China. There have been numerous recalls and warning issued by US firms in the last several years in relation due to health and safety concerns about products and ingredients imported from China. These have included heparin (a blood thinner widely used by kidney-dialysis and post-surgical patients to prevent blood clots), and wheat gluten (corrupted with the chemical melamine). Melamine was found in animal feed and pet food in the US 2007, and dairy products and infant formula in China in 2008.

The Commission report examines the potential health and safety impacts of Chinese-sourced ingredients used in the production and supply of pharmaceutical products, dietary and nutritional supplements. China is now the largest bulk drug manufacturing and exporter in the world, and has emerged as America's number one pharmaceutical trade partner. China is also the number one producer of Acetominophen and many other commonly used over-the-counter cold and allergy medications.

The report also notes the huge and growing size of the US market for dietary and nutritional supplements, and points out that many US nutrition supply companies are either based in China or do extensive sourcing there.

"China has come to dominate the vitamin raw material market over the last decade, controlling approximately one third of the world's vitamin production," according to the report. For example, China now supplies 92% of the vitamin C, 65% of vitamin B, and 40% of vitamin E raw materials imported into the U.S.

Obviously, these concerns are not just limited to China. US health and safety officials must assure the safety of all imported products that are used in the US, particularly food, drugs and supplements, regardless of the country of origin. As foreign trading partners play a larger role in supplying nutritional supplements and materials for their production, there is an urgent need for greater public oversight to assure the quality of imported products and ingredients.

While the FDA has recently launched new initiatives to expand its Foreign Drug Inspection Program and has stationed a handful of inspectors in China, we are concerned that current oversight capacity and process is grossly inadequate for the task of policing such a diverse array and large volume of imported products and ingredients. Even if we were to just take the sourcing and manufacture of herbal products alone, it does not appear that FDA has either the funding or the staff resources to adequately assure the safe sourcing and supply of such ingredients. As an example, we would cite continuing reports of contamination of herbal

---

[16] NSD Bio Group LLC, "Potential Health and Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced Ingredients," prepared for the US China Economic and Security Review Commission, April 2010.

supplements with prescription drugs and heavy metals, and also the problems related to the Chinese herb aristolochia, which we reported about in our May 2004 Consumer Reports article.

Consumers and seniors need to be assured that the oversight processes we have in place will prevent serious safety problems, and enable swift regulatory action and effective recalls when problems are detected and found. Because of the recent surge in product warnings and recalls, this is an urgent issue that must be addressed swiftly. We urge Congress to investigate problems and issues related to sourcing of dietary supplement ingredients from China and other exporting nations, and work rapidly to modernize the regulatory infrastructure to address this new challenge.

RECOMMENDATIONS

As a nation, we stand at a crossroads regarding dietary supplement safety. Consumers turn to dietary supplements because they think these products will promote health and wellness. It is very important to ensure that these products are safe and do not themselves create serious health problems. Consumers who take supplements should not be test animals for highly questionable products that have not been sufficiently tested by their manufacturers prior to coming to market.

For the last sixteen years, consumers have borne the unacceptable risks and consequences of system that allows untested supplements to be aggressively marketed and sold, with no prior safety testing and evaluation. This situation unfairly shifts the burden of proof to demonstrate supplements are safe before they can be sold from manufacturers to the government, and externalizes the costs and risks of that policy onto consumers and the health system.

We believe that Congress should make steady and sure progress toward developing a sensible preventive safety system that ensures that dietary supplement products are reviewed for safety prior to marketing and sale.

Consumers Union supports the Dietary Supplement Safety Act of 2010 (S 3002), that would strengthen public oversight of dietary supplements. This bill includes provisions for manufacturer registration, mandatory recall authority, improved reporting of non-serious adverse events. We believe that the principles incorporated in this legislation would give regulators better tools for protecting the public, and help move us to a safer marketplace

The elements of a strong, preventive safety system that we favor include the following:

- **Mandatory Manufacturer Registration Requirements**. The GAO has reported that FDA has relatively little information on the companies it is expected to regulate and oversee. All dietary supplement manufacturing, processing and holding facilities should be required to register annually with the Secretary of Health and Human Services, so that the FDA will know who is making dietary supplements, which products the companies manufacture, and which ingredients the product contain. This will ensure better communication between manufacturers and safety officials, and facilitate swift action in the event of serious adverse events, warnings and safety recalls.
- **Mandatory Recall Authority for the FDA**. The FDA must have the necessary authority to swiftly recall unsafe products that pose risks to consumers.

- **Increased Safety Requirements for Products.** While we favor encouraging the FDA to publish new guidelines for new dietary ingredients, we also believe that the burden of proof for demonstrating that a supplement does not present a "significant or unreasonable risk" should be placed on manufacturers to establish that supplements are safe before they are sold. In that sense, we are also concerned about existing products that are "grandfathered in" that have not been rigorously tested or reviewed for safety. We support creation of a regulatory review process that would prioritize and address existing hazards in the supplements marketplace, such as the unsafe supplements we have identified that continue to be widely sold in stores and the internet. Products that pose unreasonable risks to consumers are swiftly removed by manufacturers and the FDA.
- **Better Information for Consumers and Medical Providers.** Labels of dietary supplements should clearly indicate what and how much is in the package, and provide explicit warning of possible adverse effects, including herb-drug interactions. FDA should also provide better, real-time information to consumers, medical providers and the public on emerging supplement hazards and adverse event reports, through better use of data systems like the Poison Control Centers and research by independent safety experts.
- **More Comprehensive Reporting of Adverse Events.** Since 2007, manufacturers have been required to report serious, generally life-threatening events to the FDA within 15 days. However, there is much more adverse event information and consumer complaints that are received by manufacturers that should be reported to FDA on an annual basis, or more frequently if possible. Given that our safety system is, in effect, a "post-marketing system," improving the flow of information about adverse events is critical for detecting potential safety hazards, including problems related to contamination and drug interactions.
- **Quality Assurance for Imported Ingredients.** Congress should investigate further ways to assure the safety and quality of supplements manufactured overseas, including expanding funding, oversight resources, investigation and enforcement to assure the safety of imported supplement ingredients.
- **Expanded Efforts to Reduce and Eliminate Supplement Contamination.** Efforts to implement safe manufacturing and production practices should be accelerated, with vigorous oversight by FDA. Dietary supplements should be consistently low in heavy metals and other forms of chemical or mineral contamination, and there should be zero tolerance for prescription drug contamination.
- **Expanded Resources for FDA.** FDA must be provided with sufficient funding and personnel resources to implement a preventive safety system and accomplish its critically important supplement safety mission, by increasing oversight, inspections and enforcement.

CONCLUSION

Mr. Chairman, Members of the Committee, thank you very much for the opportunity to testify here today about this critically important consumer protection issue. We thank you for your efforts to protect consumers in these tough economic times, and look forward to working with you as you move forward in addressing these issues.

The CHAIRMAN. Thank you, Mr. Bell.

Now we'll hear from Mr. Mister.

STATEMENT OF STEVEN MISTER, PRESIDENT AND CEO, COUNCIL FOR RESPONSIBLE NUTRITION, WASHINGTON, DC

Mr. MISTER. Good afternoon. My name is Steve Mister. I'm the President of the Council for Responsible Nutrition.

More than 150 million Americans take dietary supplements each year, including many who are extremely passionate about their rights to purchase supplements and to have access to information about their health choices.

The dietary supplement industry is committed to manufacturing and marketing high quality, safe, and beneficial products that have a valuable role in a wellness regimen. This industry is likewise committed to ensuring that consumers receive truthful, accurate, and nonmisleading information on dietary supplements.

We also share the committee's concerns about bad actors in the industry, whether they are unaware of the extensive regulatory framework governing dietary supplements or they are willfully breaking the law. We condemn adulterated or misbranded products, and we denounce false, misleading, or deceptive marketing practices, activities that are engaged in by a very small minority, who damage the reputation of the responsible industry.

The supplement industry, as a whole, has a demonstrated track record of providing high quality products to its consumers, as well as a reputation on Capitol Hill for active lobbying for stronger enforcement of the law under which our industry operates. Our industry has gone even further; through its five industry associations, we have developed a variety of voluntary self-regulatory programs that address the issues that have the potential to tarnish our industry and hurt our consumers.

So, let's put some perspective on the committee's concerns:

First, the notion that supplement users will forsake conventional medicine or other healthy behaviors is a myth. To the contrary, supplement users are more likely than nonusers to engage in other healthy habits, such as eating a healthy diet, exercising regularly, and visiting their doctors.

Second, among our passionate supplement users are a high percentage of healthcare professionals—doctors, nurse practitioners, pharmacists, and registered dietitians.

Third, there are literally millions of dietary supplements sold in this country each year, and very, very few serious adverse events. The strong safety profile for the overwhelming majority of these products defies the examples that were raised before the committee.

Let's also be clear here that the FDA and the FTC have ample authority under existing law to address the concerns that are being raised. The Dietary Supplement Health and Education Act authorized FDA to prescribe comprehensive regulations for the manufacturing of supplements, called "Good Manufacturing Practices." When it comes to the safety of ingredients, DSHEA provides the agency with the ability to remove products from the market if they present an unreasonable or significant risk of injury or illness to consumers. It likewise requires companies to notify FDA before

they bring a new dietary ingredient to the market, and to provide evidence that demonstrates a reasonable expectation of the safety of the ingredient. The law prohibits labeling claims that purport to treat or cure a disease, and it demands that all label claims be truthful, not misleading, and substantiated with adequate evidence.

Separately, the FTC Act gives the Federal Trade Commission similar authority over supplement advertising and marketing claims, whether made by manufacturers or retailers.

The problem is that FDA has suffered from a lack of funding, resources, and, until recently, perhaps the political will, to consistently and aggressively enforce and implement this law. The industry calls on Congress today to provide sufficient resources to FDA to fully implement the provisions of DSHEA that were enacted 16 years ago. The Dietary Supplement Full Implementation and Enforcement Act of 2010, introduced recently by Senators Harkin and Hatch, will go a long way toward providing adequate funding and accountability for FDA.

The industry recognizes that it, too, must foster a climate of compliance, and all five industry associations have ambitious programs to do just that. Individual companies also maintain their own rigorous programs. For instance, all three major vitamin supplement retail chains require initial training for all of their entry-level employees, and ongoing continuing education for their retail staffs, to remind their employees over and over about the limits on what they can and cannot say to consumers.

However, based on the testimony and the video today, the industry associations recognize that we need to do more. So, today the five associations pledge to the committee to increase our efforts to educate retailers and their clerks who sell dietary supplements about what is permitted under the law.

We are confident in the role that dietary supplements can play in the health and wellness of this Nation, particularly senior citizens. Dietary supplements help to preserve good health and independence for our senior citizens, and they can help to reduce the risk of certain chronic diseases. Vitamins fill in nutritional gaps, especially when seniors fail to get a nutritious diet, or when aging itself reduces their bodies' natural ability to absorb nutrients from conventional food.

I'm confident this industry and robust government agencies, working together, can address the concerns raised today under the existing law. We look forward to working with Congress, the FDA, and the FTC to provide senior citizens, as well as all consumers, with even more confidence in the safety, quality, and benefits of dietary supplements.

Thank you.

[The prepared statement of Mr. Mister follows:]

Written Testimony
by Steve Mister, President and CEO
Council for Responsible Nutrition
1828 L Street, NW, Suite 510
Washington, DC 20036

Submitted to the United States Senate Special Committee on Aging

on behalf of the American Herbal Products Association (AHPA), Consumer Healthcare Products Association (CHPA), Council for Responsible Nutrition (CRN), Natural Products Association (NPA), and United Natural Products Alliance (UNPA)

"Dietary Supplements: What Seniors Need To Know"
May 26, 2010

The Council for Responsible Nutrition (CRN) appreciates this opportunity to provide testimony to the Senate Special Committee on Aging on behalf of the dietary supplement industry to reassure you and your colleagues, your constituents, and our customers that the dietary supplement industry is committed to manufacturing and marketing high quality, safe and beneficial products that have a valuable and appropriate role in a wellness regimen. This industry is likewise committed to ensuring that consumers receive truthful, accurate and non-misleading information on dietary supplements.

This testimony is submitted on behalf of the five trade associations who collectively represent all segments of the dietary supplement supply chain: ingredient growers, suppliers and processors, manufacturers and retailers. They are: the American Herbal Products Association (AHPA); the Consumer Healthcare Products Association (CHPA); the Council for Responsible Nutrition (CRN); the Natural Products Association (NPA); and the United Natural Products Alliance (UNPA).

These associations share the concerns of the Committee about any bad actors in the industry—those companies, whether they are manufacturers or retailers, that are either unaware of the extensive regulatory framework governing dietary supplements or are willfully breaking

the law. At the outset, we want to assure you that our industry condemns adulterated products and false, misleading or deceptive marketing practices—activities engaged in by a very small minority who have damaged the reputation of the responsible industry that comprises the vast majority of supplements sold in this country. The responsible supplement industry has a demonstrated track record of providing high-quality products to its consumers and of active lobbying for stronger regulatory guidelines, for broader implementation of the laws under which our industry operates, and for increased enforcement activity, as well as for adequate funding for the Food and Drug Administration (FDA). Our industry has gone even further—developing educational initiatives for consumers designed to make supplement shoppers more savvy and voluntary self-regulatory programs that address the issues that tarnish our industry and potentially hurt our consumers. The latter include a variety of training programs to inform manufacturers and retailers of the legal requirements and their compliance obligations.

Our industry, like all industries, has its outliers, and we applaud this committee's efforts to shine the spotlight on those activities that break the law. But we would be remiss if we did not put some perspective around these concerns. The great majority of American consumers who take dietary supplements are using safe, high-quality supplements to maintain and improve their healthy lifestyles. Adulterated dietary supplement products remain a small minority of supplement products sold in our country today.

More than 150 million Americans—including many who are extremely passionate about their right to purchase supplements—take dietary supplements each year. We know from market research that a high percentage of our consumers are highly proactive in managing their health, engaging by large measure in other healthy habits such as trying to eat a healthy diet, exercising regularly, visiting their doctors. The data defies the myth that supplement users will forsake other healthy behaviors and put their health solely in the hands of a supplement pill. To the contrary, dietary supplement users are more likely than nonusers to engage in the healthy habits noted above[1]. We also know that among the more than 150 million Americans who use dietary supplements are a high percentage of nine healthcare populations (including physician specialties such as orthopedists, cardiologists, dermatologists and OBGYNs, as well as nurses, nurse practitioners, pharmacists, and registered dietitians) who both personally take and professionally

---

[1] *See* Addendum #1.

recommend dietary supplements[2]. There are literally millions of shelf units of supplements sold in this country each year—and very few serious adverse events associated with their usage. In 2008 (the last year for which complete data is available), the agency received only 1,025 reports of serious adverse events associated with dietary supplements though it should be noted that these "signals" are not considered by FDA to be evidence that a dietary supplement actually caused the reported event. At the same time, the scientific support continues to grow for the important health benefits of many of our products—products like multivitamins, calcium, fish oil, vitamin D, and more—taken by our core consumers, including the aging and elderly populations.

Every regulated consumer products industry faces the kinds of challenges that the dietary supplement industry faces. By simply enforcing the current law, if the agencies devoted greater focus and had greater resources to fully implement it, these incidents could be further reduced. And when the pending Food Safety legislation (S. 510) is enacted (legislation which our industry supports), there will be additional laws in place—including mandatory recall authority for FDA—to continue to strengthen the regulation of this industry and conventional foods. No matter what the law requires, it is unrealistic to suggest that you would never find a retailer giving bad or illegal advice, or that you could never discover a manufacturing error.

Pharmaceuticals, conventional foods, medical devices and cosmetics—all regulated by FDA—likewise have accidents and rogue players. But our industry has made great strides in the past decade, and we pledge to continue to support reasonable regulation that makes sense for our industry, is not duplicative or contradictory to laws already in place, and that benefits our consumers. However, we will also continue to fight against unnecessarily burdensome regulation that drives up consumer prices, adds unnecessary paperwork and bureaucratic obstacles to market, or restricts truthful information about supplements from reaching consumers—all of which provide no real return or protection for health conscious consumers.

Since the passage of the Dietary Supplement Health & Education Act (DSHEA) in 1994, our industry has come of age, and as we mature, like all industries with growing consumer interest, there are some growing pains. Through the work of the five trade associations, we have fostered an understanding and acceptance, even a desire, among supplement ingredient suppliers, manufacturers and retailers, for strong and enforced regulation—separating those companies

---

[2] *See* Addendum #2.

who cannot or will not follow the law from those companies who go above and beyond what is legally required. The passage of the 2004 anabolic steroids law, the removal of ephedra, the adverse event reporting law, and the issuance of GMP regulations were all accomplished with the support of the industry associations. As your hearing today points out, clearly, there is more work to be done. As an industry, we are willing to work cooperatively with government, regulators, suppliers, manufacturers, and retailers, as well as consumers, and consumer groups who are willing to partner with us to make certain that the American public has access to the most safe, high-quality dietary supplements the marketplace can offer.

Let us also deal directly with a myth that has been fostered by our critics, perpetuated by the media since 1994, and is widely circulated in the halls of Congress. Many charge that DSHEA de-regulated the industry, stripped FDA of its power over dietary supplements, and rolled back the previous regulation of vitamins. That is simply false. The passage of DSHEA provided FDA with new enforcement authority not previously available:

- It gave FDA the ability to remove from the market supplements that pose a significant or unreasonable risk of injury or illness—a power the agency has used on several occasions since 2000;
- It authorized the creation of GMP regulations distinct for supplements and separate from food GMP regulations;
- It created the imminent hazard to public health standard which allows FDA to remove unsafe products from the marketplace immediately;
- It required notification to FDA for all new dietary ingredients, along with the submission of evidence of reasonable expectation of safety of the ingredient; and,
- It even prescribes that labeling statements about how a dietary supplement will affect the structure or function of the body, so-called "structure/function claims," must be submitted to FDA within 30 days of first use and must be truthful and not misleading with adequate substantiation.

DSHEA made certain that dietary supplements were to be regulated as a category of foods, not drugs. Prior to 1994, on some occasions, FDA regulated supplements as foods; on others, it tried to regulate them as drugs or food additives. But to be clear, FDA never had legal pre-market approval authority for dietary supplements—DSHEA did not change that fact.

The industry would like to address the three areas of highest concern to the Special Committee on Aging. For each area, we will summarize the current legal requirements, demonstrating that the existing law already addresses the concerns that have been raised. Then we will provide information on specific industry programs and voluntary efforts that are also in place to foster compliance, and in many cases, encourage responsible behavior even beyond the requirements of the law. And finally, Senators Harkin and Hatch recently introduced the Dietary Supplement Full Implementation and Enforcement Act of 2010, and we urge this committee to add its support for this legislation as it will propose increased funding for FDA. This legislation will help to ensure that the agency has sufficient focus and resources at its disposal to implement a law—DSHEA—which already provides FDA with ample authority to ensure consumer safety, while still providing consumers access to the products they seek.

Product Quality

Questions have been raised about the quality, purity and potency of dietary supplements and the commitment of supplement manufacturers to produce safe and beneficial products. Three things should be considered here. First, DSHEA requires all dietary supplements to be produced under strict manufacturing conditions to ensure product quality; second, that regulation is being enforced; third, the trade associations are aggressively educating industry of its obligations to ensure product quality.

After years of prodding, pleading and urging from industry, and indeed by some in Congress, FDA issued the final GMP regulations in 2007. Next month, the three-year phase-in of these regulations will be completed and all companies finally will be subject to supplement-specific GMPs, nearly 16 years after the passage of DSHEA. Even before the supplement GMPs went into effect for the supplement industry, manufacturers were subject to the requirements of conventional food GMP regulation.

Now, under the GMPs specific to dietary supplements, all manufacturers are required to test every lot of incoming material to confirm the identity of the ingredients. They are required to qualify their vendors so that other aspects of quality—like the purity of the ingredient from contaminants, and the consistency of the material—are assured. These rules mandate training of personnel, master batch records and production logs, calibration of equipment and measuring

devices, cleanliness of the work environment to prevent cross contamination, and testing of finished products against label claim, just to name a few. While no law can provide complete assurance against mishaps, these regulations, when fully implemented will give consumers more confidence than ever in the quality of supplements.

To its credit, after issuance of the GMPs and in the face of competing resource needs, FDA has pursued an aggressive industry education effort to be sure supplement companies understand their obligations under the new regulations. The agency has already conducted numerous inspections under the new GMPs, and the industry is encouraged that FDA has announced a robust agenda of inspections in the coming year. And while the discovery of violations is not a positive development, the issuance within the last month of a warning letter on GMP compliance issues that resulted from an inspection signals that FDA has the tools available to insist that industry members comply with the rules. What the agency needs is more resources to put sufficient, well-trained inspectors in the field.

The collective efforts of all five industry trade associations further demonstrate the commitment of this industry to full implementation of the GMPs. Over the past three years, our organizations have hosted over 25 well-attended educational events for industry to acquaint manufacturers with the new GMP rule and explore the specific requirements it imposes. Our efforts range from webinars and conference calls with industry and FDA representatives, to trade show conferences and all-day symposia, as well as creating manuals, chapters and by-lined articles on the GMPs to companies offering personalized seminars.

The trade associations have also developed the Standardized Information for Dietary Ingredients protocol, or "SIDI," for short. This collective effort, across all five associations, has helped to standardize the communications between ingredient suppliers and manufacturers so that manufacturers can compare competing ingredients, obtain all relevant information documentation about the quality of ingredients, and make smarter purchasing decisions. That effort has expanded to produce another voluntary guideline that prescribes best practices for developing the Certificate of Analysis that accompanies each lot of raw material shipped to a manufacturer—and even more industry-endorsed, voluntary guidelines are planned.

The Natural Products Association has developed the GMP Certification program, one of several opportunities for manufacturers to undergo rigorous inspection and receive certification of their products. Manufacturers voluntarily permit third party auditors to inspect their facilities

and test their products in hopes of receiving a seal of approval for their labels. Over 60 companies have participated in this program. NPA's TruLabel program randomly selects products from retail shelves and tests their contents for conformance with the label. If a product is determined to be out of conformance, the company is notified and asked to take corrective action.

The United Natural Products Alliance has offered numerous GMP and quality management seminars for industry executives in conjunction with FDA, the University of Mississippi, the United States Pharmacopeia, AOAC International and NSF International. Such training programs provide state of the art instruction on analytical methods, vendor qualification, certificates of analysis, botanical identification and other important technical subjects. (See www.unpa.com for all seminar programs.)

Do all these efforts assure with 100% certainty that a laboratory will never find a product on a store shelf that doesn't meet the GMPs? Of course not. But more than ever, dietary supplement manufacturers have every incentive to produce the best quality products, and real sanctions in place if they don't.

Related to the issue of quality, are persistent questions about the safety of some dietary ingredients. Under DSHEA, dietary supplement ingredients already on the market in the United States as of October 1994 were "grandfathered," in the same way the 1958 food additive amendments to the FDCA "grandfathered" as safe hundreds of substances already being used in foods at the time. DSHEA also established a premarket notification procedure that requires manufacturers who use new ingredients in dietary supplements after 1994 to provide a notification to FDA that sets forth the basis for considering the ingredient to be "reasonably expected to be safe," and there is clear authority in DSHEA for FDA to declare a supplement adulterated if it contains a new dietary ingredient for which an NDI notification was not filed. FDA has been receiving these notifications on a regular basis since the passage of DSHEA and has been giving them serious attention. But the agency has objected to about 70% of the more than 500 notifications it has received.

To assist industry members in filing NDI notices, the American Herbal Products Association created an NDI Database designed to ease access to and understanding of the notifications submitted to FDA. The searchable database allows companies to easily locate individual notifications by searching for key terms that include the generic and brand name of

the NDI itself and the Latin name (genus) of herbal NDIs, as well as the name of the submitting firm or the report number assigned by FDA.

What is needed, though, to increase success in filing NDI notifications, is a formal guidance from FDA that explains clearly the agency's views on what constitutes a new dietary ingredient versus a grandfathered one and provides instruction on how firms can establish the reasonable expectation of safety from the evidence they provide. Industry has been asking for this guidance for years and FDA has been promising it, but to date, it has not been issued.

Product Advertising and Labeling Claims

This Committee has also raised questions about the advertising and marketing of dietary supplements, inquiring whether there is adequate protection for consumers from false or misleading advertising. As with the product quality issue, the answers begin in the plain language of the statute. DSHEA expressly requires that all labeling claims must be truthful, not misleading, and substantiated with adequate evidence. In addition, DSHEA sets clear boundaries on permissible claims for supplements. Any claim to treat, prevent, mitigate or cure a disease is not permitted, and the statute provides that such claims render the product an unapproved new drug, subject to various civil and criminal penalties. Health claims—those that make an association between a dietary ingredient and the reduction of risk of a disease, such as calcium's ability to reduce the risk of osteoporosis—require the approval of FDA based on significant scientific agreement. Even structure/function claims that do not require the approval of FDA, nevertheless are required by the statute to be submitted to FDA within 30 days of the first use, giving the agency oversight for the kinds of claims that are made.

The Federal Trade Commission (FTC), not FDA, has jurisdiction over dietary supplement advertising. The general standards for consumer advertising apply to supplement claims, but FTC has stated that it "gives great deference to an FDA determination of whether there is adequate support for a health claim. Furthermore, FTC and FDA will generally arrive at the same conclusion when evaluating unqualified health claims."[3] Although FDA's enforcement of supplement labeling claims has been sporadic, that has not been the case for FTC. Aggressive enforcement against false or misleading advertising has led to large civil fines and disgorgement

[3] http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.shtm.

of unjust profits. In particular, FTC has collected fines and mounted aggressive enforcement of such things as bogus cures, weight loss claims and claims to prevent colds and flu—actions the five trade associations have publicly supported.

In the area of advertising, the industry associations have also pro-actively worked to remind manufacturers and marketers of the restrictions on their advertising and even developed voluntary programs to help police these ads. Four of the five associations have conducted educational programs for their members and the larger industry, to underscore the limits of permissible claims. Three years ago, CRN launched a program with the National Advertising Division (NAD) of the Council of Better Business Bureaus to raise the level of scrutiny of supplement advertising. Through a series of unrestricted grants that total almost $1.5 million funded by CRN, the NAD has been able to add a staff attorney who reviews dietary supplement claims full-time. Challenges can be brought by competitors, consumers, the trade associations or the NAD itself. Claims are evaluated by examining the data submitted by the advertiser itself and written decisions are issued and made public for each case. Since its inception three years ago, the NAD program has issued over 85 opinions that collectively form precedent that guides marketers for future ads. Advertisers who ignore the NAD process or refuse to comply with those decisions do so at their peril: the NAD routinely refers those ads to FTC for follow up and we have been assured those cases get high priority attention for federal investigation.

The Natural Products Foundation (NPF) also maintains a Truth in Advertising program, giving manufacturers the opportunity to pledge to follow FTC's advertising parameters, and notifies manufacturers that it judges to be in violation of the law. If the company does not respond or modify its ads, the NPF notifies FTC and FDA asking that they investigate the charge.

The major media operations that run annual tradeshows for suppliers, manufacturers and retailers also have advertising review programs that screen ads whose claims do not seem to be supported by the evidence. Perhaps more consumer publications should take a cue from these trade journals and institute similar policies not to accept ads containing unsubstantiated or impermissible claims.

So does this mean you will never see a late-night infomercial or a newspaper ad that makes unsupported claims for a dietary supplement? All industries are held hostage to overzealous advertisers. We acknowledge the supplement industry has companies that will push

the envelope and even flout the law. Once again, we call upon Congress to provide additional resources to support enforcement activity by both FDA and FTC, along with continued cooperation between these two agencies, to further the critical mission of assuring consumers get accurate information about the dietary supplements they use. New laws that would restrict legitimate commercial speech are neither needed nor appropriate; but rather efforts should be focused on more robust enforcement against the most outlandish of these claims without favoritism against those companies with the deepest pockets.

Product Claims at Retail

Third, the Committee has exposed some retail salespeople making misguided and impermissible statements for dietary supplements directly to their customers. This is the first time we have heard the audio recordings and we do not know their full extent, or even whether the retailers in the GAO's investigation are aware that they are breaking the law. But as with the previous topics, the Committee should be assured that this kind of behavior is patently illegal and unacceptable. Retailers who make inaccurate or impermissible claims for a dietary supplement have, by their oral comments, misbranded the product at the point of sale under section 403 or the FD&CA, and if the claim is to treat, prevent, cure or mitigate a disease, they have converted the product to an unapproved new drug. These actions also run afoul of the FTC, which has stated that supplement marketers should ensure that *anyone* involved in promoting products is familiar with basic FTC advertising principles. The FTC itself has stated that it "...has taken action not just against supplement manufacturers, but also, in appropriate circumstances, against ad agencies, distributors, retailers, catalog companies, infomercial producers and others involved in deceptive promotions. Therefore, all parties who participate directly or indirectly in the marketing of dietary supplements have an obligation to make sure that claims are presented truthfully and to check the adequacy of the support behind those claims."[4] Furthermore, making a false or misleading statement about a dietary supplement in a consumer transaction violates many states' consumer protection, anti-fraud and unfair competition statutes. In addition, in many states, the licensing requirements for healthcare professionals would make statements about the ability to treat or cure a disease illegal as the unlicensed practice of a medical

[4] http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.shtm.

professional. So there is no question that the legal authority is available to address these marketing practices.

Retailer Education

Whether it is attributable to turnover in the retail sector, new retailers entering the market, or over-enthusiastic testimonials from clerks who are supplement users themselves, the industry recognizes that it is not acceptable for salespeople to make illegal claims to consumers. Here are some of the things we are already doing about it:

- The Natural Products Association has developed a handbook for retailers to assist their retail members with determining their rights and responsibilities under the law. The handbook is clear: You may not diagnose a customer's ailments—that is the practice of medicine. You may not prescribe—suggesting a dietary supplement as an effective treatment or cure of a disease is illegal without a license.
- All the trade associations regularly engage in webinars and symposia to remind their members about what can and cannot be said about supplements. Most of these programs engage officials from FDA and FTC to remind participants of the law, and we are grateful to both agencies for their generous and enthusiastic participation in these industry events. NPA also provides an online quiz for its members "What You Can Tell About the Products You Sell."
- All three major retail vitamin/supplement chains require initial training for all their entry-level employees and provide ongoing continuing education for their retail staff. Other resources include online training, tests for proficiency, monthly newsletters to employees and offsite training sessions that repeatedly remind these employees about the limits on what they can say to consumers.
- Separately, the major direct selling companies who market dietary supplements maintain extensive compliance materials and hold training sessions with their independent distributors to instruct them and reinforce the directive that they may not promote supplement products for diseases or oversell the products' benefits.

However, based on the testimony today, the industry associations recognize that there is more we need to do to give consumers confidence in their supplement purchases. So today, the five associations pledge to the Committee that, either collectively or individually, we will increase

our efforts to educate and train retailers who sell dietary supplements and their staffs about what can and cannot legally be said to customers. These efforts may take the form of breakroom posters, brochures that are shipped along with the product, heightened visibility of training events at trade shows or individual follow-up from manufacturers' representatives, but be assured that we take this revelation seriously. We also ask the assistance of FDA and FTC to provide compliance assistance, particularly to small retailers

Consumer education

But the matter of creating more savvy, more educated consumers is not solely the responsibility of retailers. We also have some simple advice for consumers: the only medical advice consumers should take when it comes to buying supplements is from their healthcare professional—a doctor, a nurse practitioner, a pharmacist, a nurse, a registered dietitian, or a naturopath, for example. Retail professionals—sales clerks, direct sellers, customer service representatives, are there to help customers navigate the retail landscape, to distinguish products, to explain what the products do—but also what the products don't do. Dietary supplements are not intended to treat, prevent or cure disease—and unless a person is working under the guidance of a healthcare professional who is specifically prescribing their care, consumers should not purchase a dietary supplement with that expectation—and a retailer should not sell a dietary supplement with that promise.

Our industry has a responsibility to protect consumers—particularly those who may be more vulnerable to sales pitches—for informing consumers about what supplements reasonably can and cannot do. We echo the well-known adage: if something sounds too good to be true, chances are it is. If, for example, a sales person advises that just by taking a supplement, a person will lose 40 pounds in four weeks, or look 20 years younger, ask for a different salesperson. If a retail clerk tells customers that a supplement product will cure cancer, they should report it to the store's management and walk out of the store immediately. CRN's "Life…supplemented"[5] consumer wellness initiative educates consumers that dietary supplements are an important part of overall wellness, but that they are just one piece of the wellness equation. Consumers shouldn't expect to pop a pill as a magic bullet that will solve their health concerns, but rather

[5] www.lifesupplemented.org.

should consider incorporating supplements as one of the smart choices they make for healthy living.

Our government has a responsibility too—a responsibility to enforce the law, and a responsibility to educate the public. One of the mandates from DSHEA was to ensure consumers have more information about dietary supplements and FDA and the then newly-formed Office of Dietary Supplements were tasked with this mandate. We would like to see more done in this area and urge the government to find ways to increase public/private partnerships to further educate consumers in this area, so consumers are better able to protect themselves from overzealous or misinformed retailers.

Lastly, despite the issues that have been raised today, we ask the Committee not to lose sight of the important health benefits dietary supplements provide to consumers, specifically to the aging and elderly populations. From the importance of a multivitamin in filling nutritional gaps and helping promote overall good health, to calcium and vitamin D for strong bones; from specialty supplements like omega-3s for supporting heart health to glucosamine and chondroitin for supporting joint health; from botanicals like lutein and bilberry for eye health to saw palmetto for prostate support and to soy and garlic for heart health—dietary supplements are mainstream, affordable options for healthy lifestyles.

The positive health effects of dietary supplements can mean not only a better quality of life for individuals, but also potential positive effects on healthcare cost savings for our country. Studies commissioned by industry and performed by the Lewin Group published between 2003 and 2008 demonstrate significant cost savings in the billions from supplements including calcium, vitamin D, omega-3 fatty acids, lutein, and the multivitamin with folic acid.[6]

Conclusion

Dietary supplements offer American consumers, and especially elderly Americans, an effective way to maintain their healthy lifestyles. The vast majority of dietary supplements are safe and beneficial. Those who say all we need to do to protect senior citizens is to change the law, are unfamiliar with the scope of existing law. The framework of the law is substantial—but

---

[6] http://www.lewin.com/content/publications/3393.pdf
http://www.lewin.com/content/publications/2833.pdf

we need more cops on the beat to make sure it is fully implemented. Give FDA the resources, the support and the clear directive to flex its regulatory muscle.

We also respectfully urge this committee to join Senator Harkin and Senator Hatch in support of their recently introduced bill, the Dietary Supplement Full Implementation and Enforcement Act of 2010; legislation that will provide increased funding for FDA to help ensure the agency has additional resources to implement the current law. This legislation directs the agency to provide annual reports to Congress making itself accountable for enforcing key provisions of the law, just as the industry is responsible for complying with them. Having more laws, without enforcement, only disadvantages the responsible members of industry who do comply with the law because it is the law and because it's the right thing to do for their consumers, and rogue companies will just have more laws to violate. As previous FDA Commissioners have testified to Congress, DSHEA provides more than adequate authority for government while still allowing consumers appropriate access to the products and health information they demand.

Thank you for the opportunity to share our views with the Committee.

This Testimony has been submitted on behalf of the following trade associations:

American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA is comprised of domestic and foreign companies doing business as growers, processors, manufacturers and marketers of herbs and herbal products, including foods, dietary supplements, cosmetics, and nonprescription drugs. Founded in 1982, AHPA's mission is to promote the responsible commerce of herbal products. Website: www.ahpa.org

Consumer Healthcare Products Association (CHPA) is the 129-year-old, not-for-profit association representing the makers of over-the-counter medicines and dietary supplements, and the consumers who rely on these healthcare products. Website: www.chpa-info.org.

Council for Responsible Nutrition (CRN) represents dietary supplement manufacturers and ingredient suppliers. Its members manufacture popular national brands as well as the store brands marketed by major supermarkets, drug store and discount chains as well as products marketed through natural food stores and direct selling companies. CRN's 70+ manufacturer and supplier members also agree to adhere to voluntary guidelines for formulation, manufacturing, and labeling as well as CRN's Code of Ethics. Website: www.crnusa.org

Natural Products Association (NPA), founded in 1936, is the nation's largest and oldest non-profit organization dedicated to the natural products industry. The Natural Products Association represents more than 10,000 retailers, manufacturers, wholesalers and distributors of natural products, including foods, dietary supplements, and health/beauty aids. Website: www.npainfo.org

United Natural Products Alliance (UNPA), founded in 1991, is an association of dietary supplement and functional food companies that share a commitment to provide consumers with natural health products of superior quality, benefit and reliability. Website: www.unpa.com.

ADDENDUM #1

Council for Responsible Nutrition
1828 L Street, NW, Suite 510 • Washington, DC 20036-5114
(202) 204-7700 • fax (202) 204-7701 • www.crnusa.org

Healthy Lifestyle Habits of Supplement Users & Non-Users

Below are findings from the 2009 CRN Consumer Survey on Dietary Supplements that examines the healthy habits of supplement users and non-users. The annual survey, which assesses U.S. adults' attitudes and usage of dietary supplements, has been conducted by Ipsos Public Affairs for nearly ten years.

Summary:

A larger percentage of supplement users are more likely than non-users to be engaged in the following behaviors: trying to eat a healthy diet, exercising regularly, visiting their doctor regularly, regularly getting a good night's sleep, and maintaining a healthy weight.

Survey question: "I..."	**% Agree – Supplement Users**	**% Agree - Don't take supplements**
Try to eat a balanced diet	88%	76%
Exercise regularly	64%	52%
Visit my doctor regularly	72%	57%
Regularly get a good night's sleep	69%	65%
Maintain a healthy weight	62%	60%

***2009 CRN Consumer Survey on Dietary Supplements Methodology**: The 2009 CRN Consumer Survey on Dietary Supplements was conducted August 26 through September 1, 2009 by Ipsos Public Affairs and funded by CRN. The survey was conducted on-line and included a national sample of 2,043 adults aged 18 and older from Ipsos' U.S. on-line panel. The survey has been conducted annually since 2000. Weighting was employed to balance demographics and ensure that the sample's composition reflects that of the U.S. adult population according to Census data and to provide results intended to approximate the sample universe. A survey with an unweighted probability sample of this size would have an estimated margin of error of +/- 2.2 percentage points.*

ADDENDUM #2

Life...supplemented.™

These are findings from nine healthcare populations surveyed for the 2007-2009 Healthcare Professionals (HCP) Impact Studies, conducted by the "Life...supplemented" consumer wellness initiative to assess healthcare professionals' personal usage of and recommendations for supplements.

	Population	Use Dietary Supplements (%)	Regular Users (%)	Recommend Dietary Supplements (%)
2007 Oct 2-11	Physicians (PCP, Ob/Gyn, Other Specialists)	72%	51%	79%
	Ob/Gyn (Also included in the results for "Physicians")	80%	56%	91%
	Registered Nurses	89%	59%	82%
2008 Aug 28-Sep 12	Cardiologists	57%	37%	72%
	Dermatologists	75%	59%	66%
	Orthopedists	73%	50%	91%
2009 Oct 3-11	Nurse Practitioners	95%	71%	96%
	Registered Dietitians	96%	74%	97%
	Pharmacists	86%	62%	93%

Survey methodologies for all populations can be found at:
http://lifesupplemented.org/supplements/healthcare_professionals_impact_study/methodology.htm.

The CHAIRMAN. Thank you very much, Mr. Mister.

As I said, and as you've indicated, you're speaking for virtually the entire dietary supplement industry. You were quoted by the New York Times as saying that you've seen late-night commercials for dietary supplement products that, "made your blood boil,". So, what more should you and your industry be seeing—be doing about this to ensure that your "blood doesn't boil" and you don't have to take excessive dietary supplements?

Mr. MISTER. Senator, I don't know if we have a product for "blood boiling."

You know, actually, the industry does have a very aggressive approach to these kinds of ads. We were very troubled about this several years ago, and it led to the formation of a program, with the Council for the Better Business Bureaus, called the National Advertising Division. Under that program, over the past 3 years, we have provided unrestricted grants of almost half a million dollars, and over the next 5 years, we will increase that to a total of 1 and a half million. It allows the National Advertising Division to look at supplement ads, so the ones like I saw on late-night television can be referred to the NAD, they can review those ads for the veracity of the claims, decide whether they're well substantiated, and issue a decision. If they recommend a change to the ad and the advertiser chooses to ignore that recommendation, then it can be referred to the Federal Trade Commission. The history is that, when those cases go there, the FTC takes high priority on those cases.

The CHAIRMAN. Well, that's well and good, but you've heard Mr. Kutz, today, talk—I mean, he has in his hand dietary supplements that make representations that are flatout not true. Now, don't you think your industry should be able to police that? Without—I mean, we understand the FDA and its importance. My committee oversees the FDA, and we've worked hard to get additional monies for enforcement; so we're not indifferent to that need, by any means. But, shouldn't your industry be able to see to it that claims that are made, like the ones Mr. Kutz has just—has right in his hand, are off the market?

Mr. MISTER. Well, I think to expect any industry association to achieve 100-percent compliance against all its actors is a little unrealistic, Senator. But, first thing I would do would be to encourage Mr. Kutz to refer those ads to the NAD—I'd be happy to talk to him about how you follow one of those challenges—and to turn over the products to the FDA, before Dr. Sharfstein leaves today, so that FDA can appropriately prosecute those companies for violating the law.

The CHAIRMAN. You refer to training employees who sell these products, very carefully and completely. Yet, as Mr. Kutz indicated here on his video, there are employees in your industry who are making sales representations that are, again, flatout untrue. When I ask you whether or not your industry can do better, of course you say, and you should say—and I'm sure you mean—that "we can do a lot better," because I understand that very carefully and clearly. But, do you think your industry needs to step up its efforts to see to it that products are not misrepresented, either in the manufacturer or in the sale?

Mr. MISTER. Senator, as I indicated in my testimony, we recognize that we can do more. In fact, one of the other associations, the Natural Products Association, already announced, this morning, a new retail toolkit that it will get out to its members, who are the retailers who sell these products. The other industry associations are also evaluating options.

So, yes, there is more that we can do to make sure that retailers, and their clerks, understand what the limits are under the law.

The CHAIRMAN. Mr. Kutz, in your testimony you outlined several examples of what appear to be misleading marketing and advertising claims. Have you reported this information to the FDA or the FTC? What do you hope or expect is going to be the outcome?

Mr. KUTZ. We did—we've met with both organizations and sent a written referral of the more egregious cases to both organizations. So, that's what we've done.

The CHAIRMAN. Have they indicated that they're going to sufficiently take additional look at these reports that you've submitted to them?

Mr. KUTZ. I can't speak with any—certainly they were concerned, and I think that they indicated some action, but time will tell whether they actually take strict action with this.

The CHAIRMAN. OK.

Senator CORKER.

Senator CORKER. Thank you, Mr. Chairman. Again, thank you for having the hearing.

I appreciate all of you, as witnesses.

Mr. Mister, the retail salesperson out in the field—I've been in a lot of these stores, as I'm sure most people in this room have, and sometimes there's a school of thought about a product. I mean, some people think garlic does certain things, how would you go about, on a realistic basis, with retailers across the country and clerks who come in to work in these various units—how would the industry go about ensuring that each of these clerks in each of these situations with—some of these products are sort of built around a belief system that exists about what certain things do. There are different beliefs around what they do. How would you, in fact, adequately police units like this? Should that even part of what your responsibility is, as an entity?

Mr. MISTER. Well, Senator, there is a lot of emerging evidence, very good scientific evidence, about the benefits of supplements, that goes beyond just general health and maintenance. So, there are research studies now looking at the ability of these products to actually prevent diseases and treat diseases. However, unlike the belief system, the law is very clear. We're not allowed to make those kinds of claims in our labeling and our advertising.

So, I think it would be very easy for the industry to develop programs that train their employees, just as some of these major retail chains already have, that make it clear that, when you're talking to a consumer, you can talk about basic nutritional information, you can talk about those things that are already on the label that deal with the structure and function of the body, but you can't take a product—no matter what you personally believe, you can't take a product off the shelf and recommend it to a consumer to treat or

cure a disease. We can make that message fairly clear to retail clerks.

Senator CORKER. The retail clerk—I expect that I could probably go get a job at one of these units pretty easily, even with my lack of experience, and would my advocating on behalf of that be based on what's on the label? I mean, is that how these are actually marketed?

Mr. MISTER. Well, as I indicated, I've had the opportunity to talk to all three major retail chains, in the last week. Their programs differ from one company to another. But, all of them have programs that start with all entry-level employees, and talk to them about what they can say about individual products. Then they have these continuing programs that go beyond just the basics of what you can and cannot say, and will get into particular lines of products. So, these are the things that they could say about weight loss, these are the things you can say about general nutrition information, these are things you can say about men's specialty supplements, or women's specialty supplements. The longer the employee is there, the more training they get.

Senator CORKER. The laboratory that you use to test these units—y'all don't actually do testing yourself. Y'all get others to do the testing and accumulate the information, is that right?

Mr. KUTZ. We use the lab that FDA had recommended——

Senator CORKER. Yeah.

Mr. KUTZ [continuing]. To us, yes.

Senator CORKER. So, when you talked about these trace amounts that you found, and they were not damaging enough to—the trace amounts that you found in most—in all of these products, were not enough to actually damage anybody, is that correct?

Mr. KUTZ. According to FDA and EPA. We do not have the in-house expertise to make that type of a conclusion, so we consulted——

Senator CORKER. Yet——

Mr. KUTZ [continuing]. With the government experts on that, yes.

Senator CORKER. So, look—each of us probably, from time to time, take prescriptions also, in addition to the dietary supplements that some of us may take daily, and many Americans do. What—do you have any idea how that would compare to trace elements that might be found in actual prescription drugs?

Mr. KUTZ. I wouldn't have that information, no.

Senator CORKER. Would that be helpful to know?

Mr. KUTZ. Perhaps other experts here might know. I just don't know that, sir.

Senator CORKER. When you test a particular product for someone, are they paying you to do that? How does that come about? Are you paid to test products, by the people that are getting ready to market them?

Mr. KUTZ. We did it on behalf of the committee, actually. We went—we paid to have these products tested, on behalf of Senator Kohl, to test for things like arsenic, pesticides, and things like that. So, that's what we did.

Senator CORKER. Yeah.

Mr. KUTZ. I think other people actually——

Senator CORKER. But, I assume you have a business model. You certainly don't rely upon this committee, hopefully, to survive. So, what do you do, on a daily basis?

Mr. KUTZ. I'm not sure what you mean. What do we do——

Senator CORKER. So, tell me what the company does, outside of work here at the committee.

Mr. KUTZ. I'm with GAO, so——

Senator CORKER. Oh, I'm——

Mr. KUTZ. Sorry.

Senator CORKER [continuing]. I apologize. I apologize. [Laughter.]

Senator CORKER. I apologize.

Mr. KUTZ. We don't typically test supplements.

Senator CORKER. I'm getting my witnesses confused. I apologize.

Mr. KUTZ. That's OK.

Senator CORKER. So, I'm actually thinking about Mr. Cooperman, here. I apologize.

Would you have any ideas as to how these would compare to other prescription drugs?

Dr. COOPERMAN. No, we also don't regularly test prescription drugs——

I'm sorry.

We do not regularly test prescription drugs. We are focused primarily on the dietary supplements.

Senator CORKER. When someone pays you to test—I assume that's what you do, before they want to market. Is that correct?

Dr. COOPERMAN. Actually, there are two things that we do, as I mention in my testimony. We were set up to help consumers identify better-quality health and nutrition products. So, what we do is go out, select, on our own, a group of products, such as the ones that you may use, and test them against standards that we can find—because again, as I mentioned, the FDA has not set standards, so we use standards from California, World Health Organization, Europe—and test these products against those standards to see how they compare, and then publish all results for all those products that we've selected for testing.

We also have a voluntary certification program so that any manufacturer can come to us and have a product tested. If it's certified—it passes all the same tests that we use for the products we select—it will be—also be noted, on our Web site, as having met that standard.

Senator CORKER. So, when somebody fails a test, do y'all ever follow back up with that? I mean, what happens when a product comes through your lab and actually fails?

Dr. COOPERMAN. Right. It's a good question. The products that we select for testing, if a product fails, it's reported publicly as—to our subscribers—we have about 40,000 subscribers—what happened with that product. Any manufacturer is welcome to contact us, and, within 48 hours, we'll give them the full results for that product, the—where it was purchased, the lot number—to help them try to figure out, you know, what the problem is so they can correct that problem.

Senator CORKER. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much.

Senator FRANKEN.

Senator FRANKEN. Thank you, gentlemen.

I just want to get something clear, Mr. Kutz. These claims that—these deceptive marketing practices—were these all just oral, or were they written on the packaging?

Mr. KUTZ. Both.

Senator FRANKEN. Both.

Mr. KUTZ. Both, yes.

Senator FRANKEN. OK. So, Mr. Mister talked about voluntary self-regulatory regimens. If these are marketed—if these are on the packaging, I'm not quite sure how robust this voluntary self-regulatory regimen really could be. I mean, this is—was—on the garlic packaging, for example, did it have the claims of—that you'd mentioned?

Mr. KUTZ. I think it was on the Web site, in that particular case. Again, on the packaging piece, I would say that the ones on the "prevention, cure, treat disease," those were mostly small companies; that was not your major, national chains.

Senator FRANKEN. OK, I see.

Mr. KUTZ. The oral is where the national chains were actually giving—four of the seven you saw on the——

Senator FRANKEN. I agree with——

Mr. KUTZ [continuing]. Were national chains.

Senator FRANKEN [continuing]. Senator Corker, that—I'll bet you Senator Corker could get a job—— [Laughter.]

Senator FRANKEN [continuing]. Selling. I'll bet you he'd be a manager within months. [Laughter.]

Senator FRANKEN. So, I mean, I could see how there might be some turnover and that kind of thing. So, I can't hold the industry responsible for every person working there.

Mr. Bell, how does a Minnesota senior know that the supplement that he or she is taking works, and works—and does what it claims to do?

Mr. BELL. Well, it's—you know, if the person had an advanced medical degree, it would be—probably help. It's quite challenging for consumers, on their own, to sort out the efficacy and safety of dietary supplements. We believe that there's a significant——

Senator FRANKEN. Well, you can go to your doctor.

Mr. BELL. Sure. There's a variety of methods that we advocate for people to get information. One, you know, there are good sources available through the Federal Government, through the National Institutes of Health. Office of Dietary Supplements has a very good Web site, with authoritative information. We think the standard should be, you know, what is in the comparative medical evidence. Is there comparative reviews of clinical studies——

Senator FRANKEN. What percentage of these supplements would you say live up to their claims on their labeling?

Mr. BELL. I would be hard-pressed to answer. I think it's very hard to characterize a marketplace, where you have so many different products. I think there's a large mass of products that are generally fine, and have, you know, good—vitamins, for example; you know, most vitamin products state what they contain; they're relatively straightforward products. Many minerals, and even some herbal products, have relatively standardized preparations. People can consult labels for—the U.S. Pharmacopeia-verified label is an-

other thing people can look for. But, I absolutely agree that consumers should discuss the use of supplements with their physician or——

Senator FRANKEN. Especially because——

Mr. BELL [continuing]. Medical provider——

Senator FRANKEN. I don't mean to interrupt you, but you testified to the interaction between prescription drugs and supplements, that, for example, I know I—if you eat grapefruit, that it acts bad on statins, right?

Mr. BELL. Uh-huh. There is really a lot that people need to know. In some of the journal articles I cited in my testimony, there are lists of as many as, you know, 20 to 30 different supplements that could affect cardiovascular health. They can affect it in multiple ways—you know, they can intensify the effect of medications people are taking; they can weaken it; they can interfere with clotting and other factors, so they're—people who could be at risk in surgery. So, we provide, you know, through our Web site, information for our subscribers. I know the General Accounting Office has recommended the FDA do more to inform and educate consumers. But, I would just say, it's—it is a very large task, because these are very complicated decisions. I think that the medical provider and the physician has to be a gateway, because someone needs to take a look at the medications and the particular supplements that the consumer is taking, and make sure that the harmful interactions will not be present.

In some cases, physicians have also found patients are taking supplements that are contaminated, and then they need to send that——

Senator FRANKEN. Well, as Mr. Cooperman talked about——

Mr. BELL [continuing]. Preparation out to an outside lab—yes—send it out to an outside lab to see if prescription drugs might be present in that product.

So, I would urge seniors to do their homework. We try to provide straightforward information about supplements that we think are beneficial. But, I would say there's relatively few products that we recommend. We think there is scant evidence for many, many products, and that—so consumers may be putting their money at risk——

Senator FRANKEN. Mr. Mister seemed to have a different opinion, for some reason.

Mr. Cooperman—and I'm running out of time here, and I'm sorry—you were talking about the contamination. I was picking up on Mr. Bell, there. What do you think can be done to improve—just—so that seniors are getting at least what they want, that it's at the level of what they want of the stuff that either does or doesn't do what it's supposed to do, and that they don't get the bad stuff that they don't want?

Dr. COOPERMAN. Yeah——

Senator FRANKEN. What can be done, do you think? You know, is the new law, that Senator Hatch has crafted with Senator Harkin—is that sufficient? Or is there something that you think needs to be done on a policy?

Dr. COOPERMAN. It's an excellent question. As we see it, one of the biggest problems here, as I said repeatedly in my testimony, is

that there are no quality standards built into the law, neither into the GMPs or into the wider DSHEA law. That is left to the—each manufacturer, to pick their own standard. Then, within that, they're each allowed to determine their own way of testing against that standard; and there are good tests and there are very lenient tests.

So, a first step, really, would be to set some standards, you know, rather than just having States go off, like California, and set their standards. Perhaps have some type of guidance, if not law, you know, from the Government, in terms of standards. I think——

Senator FRANKEN. I'm sorry, but we've—my time——

Dr. COOPERMAN. OK.

Senator FRANKEN [continuing]. Is up, and I've indulged the panel enough. Maybe Senator Hatch would either want to pick up on that or ask what he likes—— [Laughter.]

Senator FRANKEN [continuing]. Whatever he wants to ask.

The CHAIRMAN. Thank you, Senator Franken.

Senator FRANKEN. Thank you.

The CHAIRMAN. Senator Hatch?

Senator HATCH. Well, thank you, Mr. Chairman. I'm grateful to my colleague for recognizing that.

Have any of you ever used dietary supplements? Everybody is shaking their head.

[Witnesses indicating yes.]

Senator HATCH. You use them today?

Mr. BELL. Yes.

Dr. COOPERMAN. Sure.

Senator HATCH. How about you?

Mr. BELL. I take a multivitamin.

Senator HATCH. Multivitamin. I presume you do.

Mr. MISTER. Took a handful this morning, Senator.

Senator HATCH. OK.

It's Kutz?

Mr. KUTZ. "Kootz," yes.

Senator HATCH. "Kootz. Kootz." Mr. Kutz. Yes.

Senator HATCH. "Kootz," sorry. I wanted to thank you for your testimony. I want to ask you for yes/no answers on some questions, just to be clear for the record.

Based on your testimony, you stated that the FDA statutes and regulations do not permit sellers to make claims that their products can treat, prevent, or cure specific diseases. Is that correct?

Mr. KUTZ. Yes.

Senator HATCH. OK. When you and your staff shared these drug-type claims with the FDA and the Federal Trade Commission, both agencies agreed that these, "drug-type," claims were improper, and were in likely violation of the current statutes and regulations.

Is that correct?

Mr. KUTZ. Yes.

Senator HATCH. OK. Finally, from the samples tested, the levels of heavy metals found did not exceed any FDA or Environmental Protection Agency, or EPA, regulations governing dietary supplements or their raw ingredients. In fact, the FDA and the EPA officials did not express concern regarding any immediate negative

health consequences from consuming those 40 supplements. Am I correct on that?

Mr. KUTZ. Can I say yes, with a footnote?

Senator HATCH. Yes.

Mr. KUTZ. There were 16 that they did not have a tolerance level for, although they did say, Senator, that they were very low, based on——

Senator HATCH. OK. Nobody's more interested in making sure that this industry works properly in the best interests of our people than I am. The trouble is, FDA doesn't have the money to really do what it should do.

Mr. Cooperman, could you please explain a little bit how ConsumerLab works? Do organizations hire you to conduct tests on their products?

Dr. COOPERMAN. Right. I believe that Senator Corker just asked the same question.

We have two programs. We go out and do reviews, where we select products, test them, and report all the results. We also have a voluntary certification program, where companies can come to us voluntarily, just as the USP does and NSF does, and if that product passes that certification testing, we will note that on our Web site, as well.

Senator HATCH. What do you do with those that don't pass that certification testing?

Dr. COOPERMAN. The ones that don't pass, that information is given to the manufacturer; hopefully, they'll correct that.

Senator HATCH. But, you don't make that public at all.

Dr. COOPERMAN. The USP does not, as part of that certification program; that's a separate thing from the reviews we conduct where all the result are published.

Senator HATCH. Am I correct that ConsumerLab is a for-profit organization?

Dr. COOPERMAN. That's right.

Senator HATCH. If that is the case, what happens when one of your clients doesn't like the results of your tests, and those results show that a product may potentially pose a public health risk? What do you do?

Dr. COOPERMAN. Sure. Yeah, I mean, it's a very good question.

Senator HATCH. Are these results still made available to the public, for instance?

Dr. COOPERMAN. Yes, as I just said, in our product reviews—and there are many examples from those in the testimony I gave—all those results are published. So, there's no pulling back on any information. What a manufacturer can do is fix it later. As I said, we have a published protocol, where any manufacturer can come to us and, for free, not only get the results, but we would even send out their sample to another laboratory, of our mutual choosing, if they wish to challenge those results.

Senator HATCH. Are your lab tests and your findings peer-reviewed by scientific experts outside of your organization?

Dr. COOPERMAN. Our Web site is not a peer-reviewed Web site. Dr. William Obermeyer, who is from the FDA, chooses these laboratories. There all accredited laboratories. In fact, going even beyond what the GAO is able to do, any product that fails our tests

is sent to a second independent laboratory for confirmation before we would even publish those results.

Senator HATCH. OK. Do you have an auditing program for all the labs that you use, to ensure the accuracy and reliability of the results you're giving?

Dr. COOPERMAN. Right. I can have Dr. Obermeyer speak more toward that. It would be helpful, perhaps, if the FDA actually regulated the laboratories—they do not—in terms of the dietary supplements.

Senator HATCH. Well, they have the authority to. But, again, we—we're responsible, too, for not providing the money so that they can do a better job.

Mr. Mister, I just—I'm——

Mr. Bell, I'm not trying to ignore you, I may get to you.

But, Mr. Mister, let me ask you this. In Mr. Cooperman's testimony, he said that Current Good Manufacturing Practices—or GMPs, we call them—CGMPs—can still allow bad products on the market, because the CGMPs do not include standards for purity and ingredient identity. Is this a loophole that allows unsafe products on the market? Can you give the committee some reassurances, here?

Mr. MISTER. Well, it's certainly not a loophole, Senator. The GMP regulations do give individual companies some flexibility, when FDA comes to inspect, to demonstrate how their product identity matches to a standard, to prove that it is what it says it is.

Senator HATCH. Yeah.

Mr. MISTER. But, it does leave some flexibility to the company. However, that's not to say that the company can just pick any standard they want, the standard must be scientifically defensible to FDA during that inspection. Just saying, "We looked at the product and it looked like Vitamin D to us," is certainly not going to pass muster.

So, companies have to develop standards and use testing that FDA would agree to.

Senator HATCH. OK.

Mr. Bell, are you familiar with the Bioterrorism Act of 2002, and that it requires mandatory registration of all food facilities, including dietary supplement facilities?

Mr. BELL. Yes, I am aware that law has been passed. However, we are concerned that it does not provide the same detail and amount of information that could be available through expanded manufacturer registration requirements.

Senator HATCH. Have you ever completed this registration and seen that you can click a box to identify oneself as a dietary supplement manufacturer?

Mr. BELL. I have—I—Senator, I have not seen that registration form itself. But, my—our concerns were based on the HHS inspector general report that found that FDA often—you know, 30 percent of the time—did not have information on how to contact manufacturers who had submitted adverse event reports, and they, 60 percent of the time, did not have ingredients of products that they were investigating. I certainly hope that situation has improved. But, we would support strengthening manufacturer registration to the same level for monograph drugs.

Senator HATCH. Mr. Chairman, could I ask one more question? I notice——

The CHAIRMAN. Sure, go right ahead, Senator Hatch.

Senator HATCH. I'll finish with this last——

I noted, in—Mr. Bell, in your testimony, that Consumers Union supports S. 3002, the Dietary Supplement Safety Act of 2010. As you may know, consumers of dietary supplements let Senator McCain know that they had serious concerns with this bill, because it could jeopardize the availability and affordability of dietary supplements.

Senators Harkin, Enzi, and I worked with Senator McCain and Senator Dorgan to incorporate four concepts from this bill into S. 510, the Food Safety Modernization Act. Now, these concepts include mandatory registration of facilities, mandatory recall of dietary supplements, publication of new dietary ingredients, or NDIs, guidance in mandating the FDA to notify the DEA when a "new dietary ingredient" application is rejected because the product contains an anabolic steroid.

Now, the last two concepts were introduced in the legislation that Senator Harkin and I introduced yesterday. So, I would hope you—that would please you.

Now, could I ask you one thing? Does the Consumer Union—does it put out a list of pharmaceuticals that—with a cross-list—what dietary supplements may be harmful or may have——

Mr. BELL. Yes, sir, we do. I actually have it with—here with me, if you'd like——

Senator HATCH. Well, I'd love to have that, if you'd be——

Mr. BELL. Sure. Sure.

Senator HATCH [continuing]. Could get that to my office.

Mr. BELL. Absolutely. I——

Senator HATCH. I'd love to look that over as part of, you know, our total desire, here, to get this industry doing everything it can to be right. By and large, the vast majority of them, as you've indicated, put out pretty good products, that work, and—you know. But, we have some bad actors, too, and we've got to get those, and get them out of this business, because nobody—Mr. Mister, you don't want any bad products in this industry. It hurts everybody.

Mr. MISTER. Absolutely.

Senator HATCH. So, we need everybody working on it; but, more importantly, I'll hope you'll all advocate that we, in Congress, do our job by giving enough money to FDA to really look into these matters and do the job that DSHEA and these other bills that we have passed direct them to do. For example, it took well over 10 years to get GMPs, and they're still not done. So, Good Manufacturing Practices are still not done. We've been beating up the FDA for years to get that done. Part of the problem is money, and part of the problem is our fault, up here on Capitol Hill.

We're all concerned about the aged and those who rely on dietary supplements. Most of the aged I know do, and they feel much better because they do. So, we want to make sure that they're good-quality products and that they will continue to help people who are aging, with the problems they might have.

Thank you, Mr. Chairman. Sorry I took so long.

The CHAIRMAN. Thank you very much, Senator Hatch.

Mr. Mister, I'm sure that you represent an industry that wants, in every possible way, to be clean and above board and beyond reproach. I believe that's your goal. So, we—the GAO has done some investigation and uncovered products that may very well be misleading, in terms of what they claim. They've given their information to the FTC and the FDA.

In the event that the FTC and the FDA conclude that what GAO uncovered is basically true, I would think, then, that you, your trade organization, and your industry would want those who transgressed to be made public, and for everybody to understand and know, not only for the public's sake, but also as a lesson to those who would do wrong and, in the process, harm your industry.

Mr. MISTER. We've been a strong advocate for transparency in the enforcement actions, and also for increasement in the enforcement actions.

The CHAIRMAN. Good.

Mr. MISTER. So, we would absolutely support FDA and FTC investigating any of the claims that have been made today, because the vast majority of the industry, who are doing things right, they want a level playing field. They are disadvantaged——

The CHAIRMAN. That's good——

Mr. MISTER [continuing]. If there are rogue players out there on the fringes doing something wrong and misleading consumers.

The CHAIRMAN. That's—no, that's very good.

Mr. MISTER. Our goal is to increase——

The CHAIRMAN. I just want to ask Mr. Kutz—again, those two bottles that you have in—at the desk, tell us again what they claim, very clearly, the one and the other?

Mr. KUTZ. The garlic "prevents and cures cancer," and the other——

The CHAIRMAN. It what? Say it again, loud.

Mr. KUTZ. "Prevents and cures cancer."

The CHAIRMAN. Wow.

Mr. MISTER.

What does the other one say?

Mr. KUTZ. This "reverses the effects of a stroke."

The CHAIRMAN. Mr. Mister. Mr. Mister. [Laughter.]

Now, I know—I know how hard it is. I've been in business all my life, and I understand how it's hard to be 100 percent. So, this is not personal or wanting to be overly critical. But, at least on the basis of what he says there, believing he's representing what's on the labels, that's pretty shocking, isn't it?

Mr. MISTER. It's very disturbing, Senator. Those claims are illegal and most likely untrue.

The CHAIRMAN. Now, doesn't your trade association have a way of seeing to it that those things don't occur?

Mr. MISTER. Well, I can say with relative certainty, Senator, that the manufacturers of those products are not our members. We're a trade association, we're not a police organization. So, we can't police the industry for companies that are not our members.

The CHAIRMAN. I see.

Mr. MISTER. But, certainly, we use our trade association, and the other four associations in the industry, likewise, use theirs, as a soapbox to preach what companies should do, and then to urge

companies to do the right thing, to recognize companies that do, with certifications programs, and then to hold up those who don't, through programs like our NAD program, to public scrutiny. So, we do as much as we can as a trade association. At some point, we have to rely on the enforcement agencies, like FDA and FTC to do their jobs, too.

The CHAIRMAN. Very well said.

Senator CORKER.

Senator CORKER. Mr. Mister, what kind of process would a company go through at the FDA to make sure the claims that my product was making were actually valid?

Mr. MISTER. Well, the first thing you would have to do is register your facility, wherever you are making the product or storing it, under the Bioterrorism Act. They are already required to have a onetime registration. The Food Safety legislation would increase that to an annual registration, and the industry is on record supporting that.

The second thing you would do is, you would have to notify FDA of the claims you are making. Depending on the kind of claims they were, there are different levels of scrutiny. If it is what's called a "structure function claim," which means you're simply saying that this has some affect on the normal function of the body, like maintaining a healthy immune system, then you'd have to notify them within 30 days of marketing the product. If you're going to make a claim that you help to reduce the risk of a disease, then you're a "health claim," and you actually have to submit evidence to the agency, and they have to give you approval to make that claim. Then the third thing you do is on the ingredients. Regardless of the claims you make, if you're bringing a new dietary ingredient to market that was not on the market prior to 1994, you also have to give FDA a notification 75 days before when you want to bring the product to market. You have to submit evidence to the agency that there is a reasonable basis for the expectation of safety of the ingredient.

Senator CORKER. So, the claims that one would make on a label would be claims that, assuming everything worked properly, the FDA would have had to validate that product actually does that. Is that correct?

Mr. MISTER. If the law were working properly, those claims would have been submitted to FDA, and FDA would know that they were out there.

Senator CORKER. So, in essence, the fact that these two products were sold—and, while that hurts your industry and y'all are self-policing and not really charged with making sure that these things occur—the fact is, the FDA and the FTC should have caught that. Is that correct?

Mr. MISTER. We would like to see those cases prosecuted. I mean, as——

Senator CORKER. But, should——

Mr. MISTER. We put an awful lot of attention on garlic and ginseng and ginkgo today——

Senator CORKER. But, are these——

Mr. MISTER [continuing]. Which disturbs consumers.

Senator CORKER [continuing]. Are these issues that those two organizations should have caught? I mean, who polices that?

Somebody behind you is shaking their head, "No, no, no." So, who—I don't know which one of you is right, but who, in fact, is supposed to——

Mr. MISTER. Well, the question is, you know, How many resources does the agency have to police everything that's on the Internet? You know, some of the——

Senator CORKER. Well, no, no. No——

Mr. MISTER [continuing]. Some of the products——

Senator CORKER [continuing]. No, no. No, that's not the question. The resource issue is one I know that Senator Hatch has mentioned earlier, but under whose jurisdiction is it to actually ensure that somebody's not out there selling products that are making claims that are not warranted?

Mr. MISTER. Well, it depends, Senator, on whether the claim is made in the form of advertising or made in the form of labeling. FDA has jurisdiction over the labeling. FTC has jurisdiction over the advertising. The interesting thing about——

Senator CORKER. So, in these cases, these were labels, and so, that would have been the FDA's responsibility. So, they're not carrying out their responsibilities in that regard. Is that correct?

Mr. MISTER. Yes, sir.

Senator CORKER. So, it's—but—and again, I'm not trying to shift blame—it's not really your responsibility. Y'all do that because you want your industry to be healthy. A lot of industries set up organizations like yours to ensure that's the case. But, it's really FDA's responsibility, ultimately, to do the real policing. Is that correct?

Mr. MISTER. Yes, sir. They have—they're the ones that have the regulatory authority.

Senator CORKER. Mr. Bell, Senator Hatch asked you the question about his legislation and the four points that were added in trying to accommodate, I guess, and to get to a place where there's a lot of support. He asked you if you, in fact, supported his legislation, in its form, or whether you thought other actions were necessary. You didn't really respond. I think he was trying to lobby for your support, and you didn't answer. So, I'm asking.

Mr. BELL. Well, thank you, Senator. You know, we've just had a chance to look at the bill that came out. On the four points that you mentioned, those are points that we support, and we're pleased to see that there is emerging agreement around those four points.

I guess we had also been concerned that we would like to see expanded reporting of the nonserious adverse events for the mild and moderate events that are required to be reported for prescription drugs and over-the-counter drugs.

We think that those should be reported for dietary supplements, as well, because it would give FDA a much fuller record to warn the public about emerging safety problems.

In the recent Hydroxycut recall, where—or the removal from the marketplace—the public never got any information, even though the FDA had received about 72 serious, you know, adverse-event reports about that product. So, we would like to see more transparency and realtime information flowing to consumers, because

we think consumers are put at risk when that information is not there.

The FDA estimates that there's about 50,000 adverse events taking place related to dietary supplements each year, but GAO said, under the expanded reporting of serious events, we only got about 900 reports to FDA last year. So, there's a lot more information out there that could potentially be helpful for—to consumers, in our opinion.

Senator CORKER. So, to educate a layman and others who may be tuning in, give me an example of one of those types of events that you would like for consumers to know about.

Mr. BELL. Well, it could be things like headache or temporary nausea. The standard for the serious event is really something that puts consumer in a hospital, that maybe causes organ damage or a stroke. You know, it's a pretty high level of medical events that require some sort of detailed intervention. But, there's a lot of other types of events that consumers may experience and complain to manufacturers about that would be useful for FDA to know.

Senator CORKER. So, Senator Hatch may respond to this himself, but, these are the types of things, I guess—when we all see advertising with pharmaceuticals; they're always talking about the disclaimers and the minor things that may occur if you take this, that are sort of side-effects. Would that be something that would be difficult for the industry, if it was added in to the legislation he's talking about, that component?

Mr. BELL. You know, I think that's—given that the prescription drug companies are able to deal with it, it is a reasonable requirement. The reporting requirement is actually just an annual requirement; it's not the 15-day requirement. So, it's—and they maintain records in their offices. So, we think this would strengthen the safety profile, because we're mostly catching problems after the fact with these products, given that there wasn't a lot of premarket safety testing for them. We think having a fuller information base would really be helpful both for the agency and for physicians around the country.

Senator CORKER. So, Mr.—I hate to call you this. I'm going to call you Steve Mister. The other sounds so odd. What is your response to that? I mean, is that a burden on the industry, for that additional portion that Mr. Bell is referring to, to be added in?

Mr. MISTER. Well, first of all, I want to correct something that was said earlier. Over-the-counter drugs are subject to the same adverse-event reporting requirement as dietary supplements. So, they only report their serious adverse events, as well. Both of those categories were in the same——

Senator CORKER. Say that one more time.

Mr. MISTER. Over-the-counter drugs only report their serious adverse events. I think Mr. Bell said that they have to report their mild and their moderate. Senator Hatch introduced this legislation several years ago, on the Adverse Event Reporting Law, and it holds dietary supplements to the same standards as over-the-counter drugs when it comes to reporting your adverse events.

But, second, when the GAO——

Senator CORKER. Hold on—let me—so, just to close this loop—Mr. Bell, so——

Mr. BELL. Yeah. No, he's correct, I did misspeak. So——

Senator CORKER. So—just out of curiosity—why would you want the dietary portion to have a higher standard than over-the-counter?

Mr. BELL. Well, we are concerned about the—I think the drug interaction issues is another huge component of this, that—it's——

Senator CORKER. Well, would that same——

Mr. BELL [continuing]. Largely——

Senator CORKER [continuing]. Be true, though, with over-the-counter?

Mr. BELL. Over-the-counter has additional premarket safety requirements that they need to make, so there are—we think there are fewer hazards of the type that we see in the dietary supplement world. Again, you know, the difference between 900 reports and 50,000 reports is a pretty big gap, in our opinion.

Senator CORKER. Yeah.

Mr. BELL. So, we would like to see a larger base of information collected. We don't think it's an inordinate burden on the industry, which doesn't spend a lot on safety testing for these products.

Senator HATCH. Would you yield——

Senator CORKER. Yup.

Senator HATCH [continuing]. For just one comment, Senator——

Senator CORKER. Yes, sir.

Senator HATCH [continuing]. On this issue?

It is true that—I think Mr. Mister could help us to understand—it is true that, even though you report the serious adverse events, you have to keep track of all of the adverse events that come in.

Mr. MISTER. That's correct. We have to keep——

Senator HATCH. That's similar——

Mr. MISTER [continuing]. Them for 6 years.

Senator HATCH [continuing]. To the pharmaceutical industry, as well.

Mr. MISTER. Yes, sir.

Senator HATCH. OK. I mean, that's something I think people just——

Senator CORKER. But——

Senator HATCH [continuing]. Don't realize.

Senator CORKER. But, would this additional requirement that Mr. Bell would like to see——

Thank—no, thank you.

Would that additional requirement be a large burden to the industry?

Mr. MISTER. It would be a burden on the industry, but, more than that, it would be a burden on the FDA. The interesting thing is that, when the GAO report came out last year making that recommendation, that it—we should be reporting not just serious adverse events, but all adverse events, FDA responded, at the time, saying that they don't have the resources to process that kind of information. It's enough for them to have to process the serious ones that come in from drugs and supplements and OTCs. To increase that to every time somebody called because they had a headache or thought they had a freckle that was——

Senator CORKER. Yeah.

Mr. MISTER [continuing]. Related to their supplement, you can imagine how that would——

Senator CORKER. But, let's move away from——

Mr. MISTER [continuing]. Multiply the number of events.

Senator CORKER [continuing]. The FDA, in that I think the issue—Senator Hatch has talked about the funding of FDA, and I have a sense he's gonna want to address that through appropriations and other efforts. Let's move that aside and just talk about the industry itself.

From the standpoint of the industry, if the FDA had those resources, would that issue be something that, on the industry itself, is an undue burden?

Mr. MISTER. It would be a burden, Senator, because the way the standard is, is, if the adverse event is associated with the supplement, then the manufacturer turns it over. There's not a causality standard. The manufacturer does not have an opportunity to evaluate whether they really think it's connected to the supplement. If the consumer says it's associated, they have to turn it over.

So, there is a large number of consumer complaints and calls that come in to any industry where consumers have questions or say, "Well, I think maybe I got a little bit of a headache or something," or, "It didn't taste quite right in my mouth as it went down." All those kinds of things would be considered mild adverse events. You can imagine, that's quite a burden on a industry, to say, "You must report all of those within 14 days."

Senator CORKER. This is my last question. I thank you for the time, Mr. Chairman, and certainly thank all of you for coming. As Senator Hatch has said, the industry itself is something that I think is important, and certainly want to make sure that it flourishes, but, at the same time, has proper checks and balances, so that consumers are protected. That's good for the industry, too.

I understand the gentleman who was shaking his head vigorously in the background is our next witness, the FDA, or part of the FDA, saying that, in fact, it is not their responsibility, if his body language is correct, to actually check these labels. Before you leave the dais do you want to say anything else about that? Apparently he feels 180 degrees the opposite. I find that kind of odd.

Mr. MISTER. Well, maybe he and I are interpreting the question differently. Do they have a legal obligation to prereview that label before it gets on the market? The answer to that, I would agree, is no. But, if there is a product out there making those claims, and it's brought to the agency's attention, then absolutely they have authority to enforce the law and to prosecute that company.

Senator CORKER. So, if I want to make a product that does, whatever, I can make that product and make those claims and put it on the label, and there's no preapproval process as to whether that's valid, or not.

Mr. MISTER. There is no preapproval process——

Senator CORKER. It's only if somebody complains or somebody——

Mr. MISTER. You do that at your peril, and we hope the FDA would bring its resources to bear and enforce against that company.

Senator CORKER. I find that to be kind of odd, but I'll move on.

The CHAIRMAN. Yeah—I—we want to move on, because we have the deputy commissioner of the FDA here.

But, I just want to reenforce what he said. I used the word "odd." Again, I know how hard it is to be perfect. I've been in business all my life. But, there should be, hopefully, some mechanism whereby those who make false claims—even though they don't belong to your organization, inasmuch as you represent all the major players, or most of the major players—those who make false claims and stain the industry, there should be some way in which you can shame them into taking their products off the shelf. If nothing else, notify the FDA. I mean, there's some way.

Mr. MISTER. Yes, Senator, we do that. We have written to the FDA, on any number of occasions, when we are aware of these kinds of products or these claims that are being made.

The CHAIRMAN. OK. All right, so let's move on now to the——

Senator HATCH. Mr. Chairman, can I——

The CHAIRMAN. Oh, yes, go ahead, Senator Hatch.

Senator HATCH. There is no formal obligation for FDA to check before the product is made, and the—but, there is a tremendous liability if you represent—and tell me if I'm wrong, Mr. Mister—there's tremendous liability if you misrepresent what's on that label.

Mr. MISTER. We should never forget that the Food and Drug Act is, at its heart, a criminal statute. So, there are criminal sanctions for misbranding or mislabeling a product.

Senator HATCH. Yes.

Now, Dr. Cooperman, I just want to understand the service you provide to dietary supplement manufacturers. For those companies that pay ConsumerLab to test their products, if unsatisfactory results are found, do you still make those results public?

Dr. COOPERMAN. We——

Senator HATCH. For people who pay?

Dr. COOPERMAN. Yeah, as I said before, we have a certification program, a voluntary certification program, and we have our product reviews. The way that the certification program operates is the same as the way that the USP operates its certification program, which is, a company comes to you voluntarily, pays a testing fee, you run it through all the rigorous tests that you see as appropriate—which are the same we use for the ones that we select on our own—and in that voluntary program, if it is certified, we will publish that. Those results are the property of the manufacturer, so they can do what they want with those results.

Senator HATCH. But, you don't make them public, though.

Dr. COOPERMAN. No, those are those results. Those are their results, just in the USP program.

Senator HATCH. I just wanted to make that clear.

Dr. COOPERMAN. Right.

Senator HATCH. Mr. Mister, one last question. Would you just talk to us about the outreach efforts your industry has made to consumers so that they might have more information about dietary supplements? Also, what type of education could be provided to better educate medical professionals to prevent bad interactions between drugs and dietary supplements?

Mr. MISTER. I think all of the associations have various programs that do outreach to consumers. At CRN, we have a program called "Life Supplemented." We have our own Web site, and we try to educate consumers, through the Web site, that dietary supplements are not a magic bullet. They are not a magic cure for any disease. They are part of an overall wellness regimen. They should be incorporated into your lifestyle, along with diet, exercise, seeing a doctor regularly, getting a good night's sleep, all of those kinds of healthy behaviors. So, that's one of the things that we're doing at CRN.

When it comes to medical professionals, again, we have funding issues, just like the government does. We would like to see more emphasis being placed in pharmacy schools, in medical schools, to teach these would-be doctors and pharmacists more about the use of supplements, both the benefits and then the interactions. Supplements can also have positive interactions and can be used to augment drug therapy. So, we'd like to see that done.

We've also done continuing education with both nurse practitioners and pharmacists, to educate them on some of these issues. Again, with more funding, we could do more of that.

Senator HATCH. Thank you, Mr. Chairman.

The CHAIRMAN. OK, thank you, everyone.

Just one—Mr. Kutz, the manufacturers of those two labels, are they obscure manufacturers, or—what's on the label?

Mr. KUTZ. They would be—do you want me to read them to you?

The CHAIRMAN. Pardon me?

Mr. KUTZ. You want me to read the labels to you?

The CHAIRMAN. You ever heard of that name, Mr. Mister?

Mr. KUTZ. You want me to tell you, I mean?

Senator CORKER. He, yes, wants you to read it.

Mr. KUTZ. All right, the first one is American Ginseng capsules, and the second is 88herb.com garlic powder.

The CHAIRMAN. You've never heard of those companies, Mr. Mister?

Mr. MISTER. No, sir. According to the law that Senator Hatch helped pass, there should be a name of a company and an address on the label.

The CHAIRMAN. That's what I was—that's what I was wonder—that's what I was asking Mr. Kutz.

Mr. KUTZ. You want to know?

The CHAIRMAN. Yeah. [Laughter.]

Mr. KUTZ. Sure. The first one is Marathon, WI.

The CHAIRMAN. Oh my God, that's my State. [Laughter.]

Mr. KUTZ. That's why I asked you twice. [Laughter.]

The CHAIRMAN. Forget it. Forget the whole thing. I never asked anything. [Laughter.]

Senator HATCH. Most of your players are taking them—— [Laughter.]

Senator CORKER. I think that's his uncle. So. [Laughter.]

Mr. KUTZ. The second one, I think it came from overseas. We can't tell for sure.

The CHAIRMAN. You've not heard—I mean, that those—those are names that you've not heard of.

Mr. MISTER. No, sir.

The CHAIRMAN. OK.

Senator CORKER. Can I——

The CHAIRMAN. Go ahead.

Senator CORKER. What is a standard? You talked about the criminal process if somebody makes a claim. What standard is it that one uses in trying to establish criminality in that regard?

Mr. MISTER. It's a strict liability standard under the Food, Drug, and Cosmetic Act. So, if you say it, you're responsible for it.

Senator CORKER. So, based on what you're saying, these two companies would—based on what you're saying, these companies would have been liable to undergo criminal proceedings?

Mr. MISTER. Yes, sir. Not only the companies themselves, but the officers of those companies can be prosecuted as misdemeanors.

Senator CORKER. Do you know if that occurred?

Mr. MISTER. In this case? I don't.

Senator CORKER. OK.

Senator HATCH. It's been a good——

The CHAIRMAN. Thank you very——

Senator HATCH [continuing]. Good panel.

The CHAIRMAN. Go ahead.

Senator HATCH. It's been a good panel.

The CHAIRMAN. Thank you very much. Been a great panel. We appreciate your coming, and you're now excused.

We're calling the next panel, Dr. Joshua Sharfstein, who's the Deputy Commissioner of the FDA.

Are you happy you're here, Dr. Sharfstein? [Laughter.]

[Pause.]

The CHAIRMAN. All right, Dr. Sharfstein went to Harvard Medical School, and he was formerly the Commissioner of Health for the city of Baltimore. As I said, he's now the Deputy Commissioner of the FDA, second ranking individual in that very important commission.

So, we're happy you're here. Please limit your comments, maybe to 5 minutes, so we can have enough time to dialog with you. Go right ahead, sir.

STATEMENT OF JOSHUA SHARFSTEIN, DEPUTY COMMISSIONER, FOOD AND DRUG ADMINISTRATION, SILVER SPRING, MD

Dr. SHARFSTEIN. Great. Thank you very much, Chairman Kohl, Senator Corker, Senator Hatch. I very much appreciate the opportunity to be here with the committee.

I am Dr. Joshua Sharfstein, the Principal Deputy Commissioner of the U.S. Food and Drug Administration, an agency of the Department of Health and Human Services.

Thank you for the opportunity to discuss FDA's role in the regulation of dietary supplements, as well as the findings of the study on botanical dietary supplements by the GAO.

As you've heard, modern FDA oversight of dietary supplements began with the 1994 enactment of the Dietary Supplement Health and Education Act. This regulatory system now includes the following key elements:

First, prior to its marketing, the manufacturer of a dietary supplement is responsible for ensuring the supplement is safe. Manufacturers register their facilities, but not their products.

Second, manufacturers are only permitted to make certain types of claims, and may not make false or misleading claims of any time—of any kind. After marketing, for most products, companies notify us of the claims.

I apologize for shaking my head. Dr. Hamburg has told me I should not give up my day job to become a poker player. [Laughter.]

But, I think you got it all sorted out, that people tell us about the claims after they start marketing. They don't give us the substantiation. There's not a review, before marketing, by the FDA. Under no—under only very rare circumstances are companies permitted to make disease-related claims.

Third, manufacturers must abide by good manufacturing practices, which have—are now in effect for large- and medium-sized firms, and shortly will be for small firms.

Fourth, manufacturers must submit to FDA all reports of serious adverse events associated with the product that are manufactured. We—as—through our agency program performance initiative, called FDA Track, will be posting, monthly, how many reports like this we get, and from how many firms. As part of our transparency initiative, we have proposed making—the idea of making specific information about those complaints, along with disclaimers about the limitation of those information, available over the Internet. We're now taking public comment on that proposal.

Fifth, a manufacturer must submit a notification to FDA before it markets a dietary supplement containing a new dietary ingredient. We do get some of those notifications now. Also, through FDA Track, we will be telling the public, every month, how many we're getting, and whether we're able to review them within the period of time that we need to. In addition, we're working on guidance that, hopefully, will make it possible for us to get a lot more of those notifications.

Let me, next, turn to our enforcement priorities, because I think you heard very clearly wide agreement—I met extensively with industry and others—wide agreement that FDA's enforcement role is extremely important under DSHEA.

We enforce by reviewing adverse-event reports, we obtain information from inspections, we review consumer and trade complaints, we perform laboratory analyses, and we monitor retail outlets, including the Internet. We also monitor product information. We work closely with the FTC, which is responsible for advertising.

Currently, we focus on three main areas:

First, adulteration with drug substances. Products that are marketed as dietary supplements, but contain active ingredients in FDA-approved drugs, analogs of approved drugs, and other compounds that do not qualify as dietary ingredients, present an emerging and expanding challenge, particularly in three areas: sexual enhancement products, weight-loss products, and bodybuilding products; also, I would say, in some cases, cholesterol products. These products are often sold with misleading labeling, and are frequently manufactured without quality controls.

Enforcement in this area is challenging. Nonetheless, in the last 2 years, FDA has participated in the voluntary recall of many dozens of tainted supplement products, including more than 50 sexual

enhancement products, more than 40 weight-loss products, and more than 80 bodybuilding supplements, by two distributors, alone.

We've issued multiple consumer alerts and press announcements to warn consumers about hazardous products. These include four warnings about firms marketing sexual enhancement products, multiple consumer alerts about 70 tainted weight-loss supplements, and a public health advisory about bodybuilding products that are represented as containing steroids or steroid like substances.

We have also participated in seizures and criminal prosecutions to disrupt the distribution of illegal products, including two civil seizures of illegal sexual enhancement supplements in 2009, two individuals arrested for illegally trafficking weight-loss supplements, and multiple search affidavits on firms marketing bodybuilding products that were represented as containing steroids or steroidlike substances, with one manufacturer pleading guilty.

Second major area of our focus is illegal claims, and you've heard about some illegal claims from GAO today. This is an important area of enforcement for FDA. We are concerned that unsubstantiated and illegal claims that—for—such as the one you heard, about cancer—can encourage consumers to self-treat for a serious disease without the benefit of medical diagnosis. FDA conducts a number of enforcement activities against supplements that make these type of claims, and in the last several years, have issued, you know, hundreds of enforcement actions against these types of products.

Most recently, we really focused on illegal claims around H1N1, because we were very concerned that people wouldn't get the appropriate treatment for flu. We worked jointly with other agencies, and wound up issuing warning letters to about 70 supplement manufacturers for illicit claims. We even did a first joint FDA and FTC advisory letter.

We appreciate the help of the GAO in this effort, the help of the committee by having this hearing, and the help of the industry by their efforts to really try to clamp down on these types of claims.

The third major area of focus is unsafe ingredients. A dietary supplement is adulterated if it bears or contains any poisonous or deleterious substance that may render it injurious to health, if it presents a significant or unreasonable risk. We can ban a dietary supplement if it is an imminent hazard. We have taken these sorts of actions against dietary supplements that concern us.

Very briefly, let me mention the GAO study, which you heard at length about. In general, there were a number of claims that they found that were illegal claims. We just got, I believe in the last couple days, the referral from GAO, where they actually named the companies, and we will, in fact, investigate and take action if we find those to be still in effect.

They also analyzed, as you heard, 40 dietary supplements for heavy-metal contaminants. I think, given the expected generally small consumption of the supplements, we do not believe these levels represent a significant risk to health. For example, the cadmium levels reached to about 1.4 micrograms per day. This compares to FDA's tolerable daily intake level of 60 micrograms per day.

The lead levels reached to 1.9 micrograms per day, which is about a third of the FDA's tolerable daily intake. This is not a dangerous level, but it does represent a reasonable fraction of daily intake, and we believe it's possible that preventive standards, of the type authorized by the pending food safety legislation, could help FDA and supplement manufacturers keep the lead levels as low as feasible.

Recently, FDA and the New York City Health Department identified lead in a dietary supplement at a level of 1100 parts per million. We immediately notified the public of a potential risk, and the manufacturer recalled the supplement.

You also heard about the pesticide residues. There were 41 residues found, none of which FDA believed posed a threat to health. Most of them—seven of them were in—within EPA tolerances for dietary supplements, 31 were within tolerances used for fruits and vegetables, but there was no tolerance set for the dietary supplement. For example, there was a one that was found at .01 parts per million in Echinacea, but the residue levels are allowed at 15 parts per million for celery and 5 parts per million for tomatoes. So, in terms of—there was a legal violation, but it wasn't—it was something that was well within what we would see in a fruit or vegetable.

Then, a couple others were for pesticides that are not permitted on any food right now in the United States, but are also at very low levels and within what, for example, the European Union permits.

We do have a program where we routinely test supplements for pesticides, and we—it leads to recalls, if we find a problem.

So, let me stop there, and thank you for the opportunity to discuss FDA's activities on dietary supplements. We look forward to working with you and answering your questions.

[The prepared statement of Dr. Sharfstein follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

STATEMENT OF

JOSHUA M. SHARFSTEIN, M.D.

PRINCIPAL DEPUTY COMMISSIONER

U.S. FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SPECIAL COMMITTEE ON AGING

UNITED STATES SENATE

HEARING ON

OVERSIGHT OF DIETARY SUPPLEMENTS

MAY 26, 2010

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Dr. Joshua Sharfstein, Principal Deputy Commissioner at the Food and Drug Administration (FDA or the Agency), an agency of the Department of Health and Human Services (HHS).

Thank you for the opportunity to discuss FDA's role in the regulation of dietary supplements, as well as the findings of the study on botanical dietary supplements by the Government Accountability Office (GAO).

Modern FDA oversight of dietary supplements began with the 1994 enactment of the Dietary Supplement Health and Education Act (DSHEA).[1] This regulatory system now includes the following key elements.

1) Prior to its marketing, the manufacturer of a dietary supplement is responsible for ensuring that the supplement is safe;

[1] The Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) defines a "dietary ingredient" as a vitamin, a mineral, an amino acid, an herb or other botanical, or a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above dietary ingredients. Dietary supplements must be intended for ingestion and may be found in many forms such as tablets, capsules, powder, liquids, softgels, or gelcaps. Importantly, under the Act, a dietary supplement may not contain an article approved as a new drug or an article authorized for investigation as a new drug for which substantial clinical investigations have been instituted and made public, unless the article was first marketed as a dietary supplement or conventional food. DSHEA defines the term "dietary supplement" as a product that, among other things, is not represented for use as a conventional food or sole item in a meal or diet; is intended to supplement the diet; and contains at least one or more dietary ingredients.

2) Manufacturers are only permitted to make certain types of claims, and may not make false or misleading claims of any kind;
3) Manufacturers must abide by current Good Manufacturing Practices (cGMPs);
4) Manufacturers must submit to FDA all reports that they receive of serious adverse events associated with a product that it manufactures; and
5) A manufacturer must submit a notification to FDA before it markets a dietary supplement containing a "New Dietary Ingredient."

1. RESPONSIBILITY FOR SAFETY

FDA does not approve dietary supplements before they reach the consumer. Rather, manufacturers of dietary supplements are responsible for ensuring that the supplement is safe before marketing.

In the case of a new dietary ingredient (described further below), a premarket submission of data and information regarding the safety of the product is required by law. Otherwise, a firm does not have to provide FDA with the evidence on safety before it markets its products.

Generally, manufacturers register their facilities but do not register their products with FDA.

2. CLAIMS

Under the law, claims that are allowed to be used on food and dietary supplement labels fall into three categories: health claims, nutrient content claims, and structure/function claims. Disease-related claims are generally not permitted for dietary supplements.

Health Claims

Health claims describe a relationship between a dietary supplement ingredient and a reduction in the risk of a disease or health-related condition.[2] FDA's oversight has three components:

First, under the Nutrition Labeling and Education Act of 1990 (NLEA), FDA issues regulations authorizing health claims for dietary supplements after FDA's review of the scientific evidence submitted in health claim petitions.

Second, the 1997 Food and Drug Administration Modernization Act authorizes health claims based on an authoritative statement of a scientific body of the U.S. government with official responsibility for public health protection or research directly related to human nutrition, or the National Academy of Sciences. Such claims may be used after submission of a health claim notification to FDA.

[2] A health claim by definition has two essential components: 1) a substance (the dietary supplement or ingredient) and 2) a characterization of its relationship to a disease or health-related condition.

Third, FDA permits some health claims that are not authorized by regulation but are supported by credible evidence and accompanied by a non-misleading disclaimer. Such claims are referred to as "qualified health claims." For example: "One small study suggests that chromium picolinate may reduce the risk of insulin resistance, and therefore possibly may reduce the risk of type 2 diabetes. FDA concludes, however, that the existence of such a relationship between chromium picolinate and either insulin resistance or type 2 diabetes is highly uncertain."

Nutrient Content Claims

NLEA permits the use of claims that characterize the level of a nutrient in a food or dietary supplement made in accordance with FDA regulations.

Nutrient content claims describe the level of a nutrient or dietary substance in the product, using terms such as free, high, and low, or they compare the level of a nutrient in a food to that of another food, using terms such as more, reduced, and "lite." Most nutrient content claim regulations apply only to those nutrients or dietary substances that have an established daily value.

The regulations that govern the use of nutrient content claims help ensure that descriptive terms, such as high or low, are used consistently for all types of food products (including dietary supplements) and are meaningful to consumers.

Percentage claims for dietary supplements are another category of nutrient content claims. These claims are used to describe a level of a dietary ingredient for which there is no established Daily Value. Examples include simple percentage statements such as "40% omega-3 fatty acids, 10 mg per capsule," and comparative percentage claims, e.g., "twice the omega-3 fatty acids per capsule (80 mg) as in 100 mg of menhaden oil (40 mg)."

Structure/Function Claims

DSHEA established special regulatory procedures for structure/function claims for dietary supplement labels.

Structure/function claims describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans. Examples of these claims include "calcium builds strong bones" and "fiber maintains bowel regularity."

Structure/function claims may also describe a benefit related to a nutrient deficiency disease, as long as the statement also tells how widespread such a disease is in the United States.

Manufacturers are responsible for ensuring the accuracy and truthfulness of these claims. Such claims are not pre-approved by FDA. If a dietary supplement label includes a structure/function claim, Section 403(r)(6) of the Act and its implementing regulation at 21 *Code of Federal Regulations* 101.93(b) require that the label state in a "disclaimer" that FDA has not evaluated

the claim. The disclaimer must also state that the dietary supplement product is not intended to "diagnose, treat, cure or prevent any disease," because only a drug can legally make such a claim under the FD&C Act.

Dietary supplement manufacturers that make structure/function claims on labels or in labeling must submit a notification to FDA no later than 30 days after marketing the dietary supplement that includes the text of the claim. FDA has provided industry with guidance on these requirements.

Generally Not Permitted: Disease-Related Claims

Dietary supplements are generally not permitted to claim to act as a treatment, prevention or cure for a disease or condition. Such claims are generally reserved for drugs and require pre-approval by FDA. The only exception is that supplements may claim a benefit related to a classical nutrient deficiency disease, provided that they also disclose the prevalence of the disease in the United States.

3. CURRENT GOOD MANUFACTURING PRACTICES

DSHEA provides express authority for regulations establishing cGMP requirements for dietary supplements.

In June 2007, FDA promulgated a final rule establishing these cGMPs, under which manufacturers are required to evaluate the identity, purity, quality, strength, and composition of dietary supplements. The final rule aims to avoid wrong ingredients; too much or too little of a dietary ingredient; improper packaging; improper labeling; or contamination problems due to natural toxins, bacteria, pesticides, glass, lead, or other substances.

To limit any disruption for dietary supplements produced by small businesses, the rule has a three-year phase-in for small businesses. The largest firms, with more than 500 employees, were subject to compliance beginning in June 2008; mid-size firms in June 2009; the smallest firms, with fewer than 20 employees, will be expected to be in compliance with the cGMPs this June.

Since the final rule was released, FDA has trained both industry stakeholders and FDA staff on the requirements of the regulations. Violations of the regulations are violations of the law and can lead to both civil and criminal penalties.

Since the rule went into effect in June 2008, we have conducted approximately 55 inspections for compliance with the new regulations. The majority of facilities have been found to be in substantial compliance.

4. ADVERSE EVENT REPORTING

As of December 2007, manufacturers, packers, and distributors of dietary supplements must forward to FDA any reports they receive of serious adverse events associated with the use of those products. These firms must also keep records about each adverse event report they receive and provide FDA with access to these records during inspections.

The Agency evaluates the serious adverse event reports, and any other adverse event information reported voluntarily by healthcare providers, firms, or consumers, to identify signals that a product may present safety risks to consumers. FDA received 1,107 serious adverse event reports in 2008 and 1,275 reports in 2009.

5. NEW DIETARY INGREDIENTS

The FD&C Act requires that manufacturers and distributors who wish to market dietary supplements that contain "new dietary ingredients" (NDIs) provide FDA with information regarding the safety of such a dietary supplement before marketing.[3] Ingredients marketed in food in the United States prior to passage of DHSEA are not "new dietary ingredients" and are

[3] A "new dietary ingredient" (NDI) is a dietary ingredient not marketed in the United States in a dietary supplement before October 15, 1994. The notification must include information on the basis on which the manufacturer or distributor concluded that a dietary supplement containing a new dietary ingredient will reasonably be expected to be safe. For 75 days after the filing date, the notifier may not market the dietary supplement that contains the NDI. During the 75-day period, FDA may ask the notifier for more information, which may reset the review clock. If FDA has no objection, it can acknowledge the notification but does not issue an "approval" regulation as it does for drugs or food additives.

thus grandfathered out of this requirement, as are many ingredients introduced into the food supply after 1994, such as those introduced for use in conventional foods.

There is no authoritative list of ingredients that were marketed prior to 1994, which creates a significant challenge to FDA in enforcing this provision of the Act.

FDA is developing a guidance document on what should be considered in determining the status of an ingredient as an NDI, what information should be submitted about a dietary supplement containing the NDI, and how a reasonable expectation of safety of the NDI should be established. We expect this guidance document to be ready by the end of this year.

FDA'S ENFORCEMENT PRIORITIES

FDA monitors products on the market for safety by reviewing adverse event reports, obtaining information from inspections of dietary supplement manufacturers and distributors, reviewing consumer and trade complaints, performing laboratory analyses of product samples, and monitoring retail outlets, including the Internet.

The Agency also monitors product information, such as labeling, package inserts, and accompanying literature, for potentially false or misleading claims. Our regulatory partners at the Federal Trade Commission (FTC) have authority over dietary supplement advertising.

Currently, the Agency focuses enforcement actions related to dietary supplements on three areas that pose the greatest risk to public health.

Adulteration with Drug Substances

Products that are marketed as dietary supplements but contain active ingredients in FDA-approved drugs, analogs of approved drugs, and other compounds that do not qualify as dietary ingredients, present an emerging and expanding challenge.

FDA has found that certain products in the following categories have been illegally represented as dietary supplements: sexual enhancement or erectile dysfunction, weight loss, cholesterol reduction, and body building products. These products have been found to be intended for use as drugs and to contain active prescription pharmaceutical ingredients including PDE-5 Inhibitors (e.g., sildenafil or Viagra), controlled substances for obesity (e.g., sibutramine or Meridia), lovastatin, and synthetic steroids or steroid-like substances.

These products are often sold with misleading labeling and are frequently manufactured without quality controls.

A challenge for enforcement is that some of these chemicals can be difficult to detect. Nonetheless, in the last two years:

FDA has participated in the voluntary recall of dozens upon dozens of tainted supplement products, including:

- More than 50 sexual enhancement supplements, including a rare "FDA-requested" recall;
- More than 40 weight loss supplements; and
- More than 80 body building supplements by two distributors alone.

The Agency has issued multiple consumer alerts and press announcements to warn consumers about hazardous products. These include:

- Four warnings about individual firms marketing sexual enhancement products in cases in which FDA was unable to secure acknowledgement of an appropriate action to remove the products from commerce;
- Multiple consumer alerts concerning more than 70 tainted weight loss supplements; and
- A public health advisory issued about body building products that are represented as containing steroids or steroid-like substances.

We have has participated in seizures and criminal prosecutions to disrupt the distribution of illegal products, including:

- Two civil seizures of illegal sexual enhancement supplements in 2009;
- Two individuals arrested for illegally trafficking weight loss "supplements"; and

- Multiple search warrant affidavits served on firms marketing body building products that are represented as containing steroids or steroid-like substances, with one manufacturer pleading guilty to selling the illegal products.

Illegal Claims

Dietary supplements with unsubstantiated and illegal claims may encourage consumers to self-treat for a serious disease without the benefit of a medical diagnosis or treatment. FDA conducts enforcement activities against supplements that make these types of claims.

For example, on March 31, 2010, the United States Marshal for the Western District of Wisconsin seized a range of dietary supplements and other products from a firm that was promoting the products for unapproved uses. The firm promoted its bee-derived products to treat, cure or prevent diseases and conditions such as cancer, asthma, arthritis and hypertension.

In response to the H1N1 flu crisis of 2009, FDA launched an initiative to address the numerous fraudulent products that were promoted to treat, prevent, or cure H1N1 flu. The Agency targeted products that were promoted on the Internet and issued Warning Letters to the owners of the websites. Approximately 70 products were supplements. In addition to the Warning Letters issued solely by FDA, FDA and FTC issued one joint letter to a supplement firm. This was the first joint FDA/FTC advisory letter.

Unsafe Ingredients

A dietary supplement is adulterated, and subject to enforcement action, "if it bears or contains any poisonous or deleterious substance which may render it injurious to health" or if it presents a "significant or unreasonable" risk to consumers. DSHEA allows the HHS Secretary to ban a dietary supplement if she finds it to be an "imminent hazard."

Under the current regulatory framework, FDA looks for such problems after marketing through reviewing the medical literature and analyzing adverse event reports. Because many products have multiple ingredients, it is challenging to identify causal connections between specific ingredients and adverse effects.

In 2009, FDA became aware of serious problems associated with a supplement product called Hydroxycut. Many of the reports advised of serious liver injuries, including liver damage that required transplants. After discussion with the Agency, the manufacturer voluntarily recalled Hydroxycut and subsequently reformulated the products.

GAO STUDY

Since October 2009, GAO has been conducting an investigation, at the request of this Committee, into the manufacturing and marketing of dietary supplements, particularly botanical

products. GAO has discussed its findings with FDA and we have provided GAO with our comments.

During their inquiry into the marketing of herbal dietary supplements, GAO investigators found a number of claims that appear to cause the products to be illegal. In general, these claims promised cures for diseases and conditions. When FDA identifies such claims in the labeling of products on the market, the Agency takes action.

GAO also analyzed 40 dietary supplements for heavy metal contaminants. All of the products were found to contain trace amounts of lead, cadmium, arsenic and mercury. Given the expected generally small consumption of the supplements, we do not believe these levels represent a significant risk to health. For example, the cadmium levels reached to about 1.4 μg/day (micrograms per day). This compares to FDA's tolerable daily intake level of 60 μg/day.

The lead levels reached to 1.9 μg/day, which is about a third of FDA's tolerable daily intake. While this is a not a dangerous level, it is a significant fraction of daily intake. It is possible that preventive standards of the type authorized by pending food safety legislation could help FDA reduce lead levels in dietary supplements as much as feasible.

Recently, FDA and the New York City Health Department identified lead in a dietary supplement at a level of 1,100 parts per million (ppm) -- more than 10,000 times higher than FDA's maximum recommended level for lead in certain candies. We immediately notified the

public of a potential risk and inspected the facility, and the manufacturer recalled the supplement.

GAO also analyzed supplements for pesticide residues. The 41 residues listed in Appendix IV of GAO's statement of facts fall into four groups.

- Seven residues were found at levels within the Environmental Protection Agency (EPA) tolerances for dietary supplements. For example, two samples of ginseng had residues of metalaxyl at .01 and .03 parts per billion (ppb), while the tolerance level for metalaxyl in ginseng is set by EPA at 3.0 ppb.

- Thirty-one (31) residues were at levels within tolerances used for fruits and vegetables, but there are no tolerances in the law for dietary supplements. For example, the pesticide chlorpyrifos has no set tolerance level for residue in Echinacea, where it was found at a level of .01 ppm. However, residue levels for chlorpyrifos have been set for celery at 15 ppm and for tomatoes at 5 ppm.

- One residue found was a low level of carbofuran, a pesticide that had its tolerances canceled by EPA in 2009.

- Two residues were low levels of pesticides that were either never approved for use in the United States (tolclofos-methyl) or had their use banned in the United States over 40 years ago (hexachlorobenzene, or HCB). These findings are within or very close to the allowable residue levels set by the European Union.

FDA presently analyzes close to two hundred herbal and botanical products annually in our pesticide monitoring program. When violations are found on imported dietary supplements, products are typically put on Detention Without Physical Examination, under which entries of such products are refused admission into United States commerce unless acceptable evidence is provided to the Agency demonstrating compliance with applicable requirements. Likewise, when violations are found on domestically-produced dietary supplements, the product is removed from commerce.

CONCLUSION

Thank you for the opportunity to discuss FDA's activities with regard to dietary supplements. FDA looks forward to working with Congress on this important public health issue.

I look forward to your questions.

The CHAIRMAN. Dr. Sharfstein, as a former commissioner of health with city of Baltimore, and as a current Deputy Commissioner of the Food and Drug Administration, right now, before a prescription drug goes to market, it has to be authorized and OKed. That's not true of dietary supplements, as you know. You have a recall, but they don't have to be examined and authorized and OKed by the FDA or any other authority. Are you satisfied, at least at that point, that what we're doing is the right thing?

Dr. SHARFSTEIN. Well, I think that the framework for—that DSHEA puts on dietary supplements is very different than prescription drugs. Congress's thinking about dietary supplements was very different than the framework for prescription drugs. The way I think about DSHEA is that it balances access against risk. There is a very clear feeling in the law, like Congress and the public, that they want access to supplements that they—that are important to people, and many people in the United States, and so that people can put them on the market without a prereview by FDA, and particularly for the products that have been marketed, historically. That's not the case at all for drugs.

On the other hand, there are provisions in the law that mitigate risk. So, you could have a situation where, you know, you only care about risk and it'd be very hard to have access, or you could say, "We will let everything on there," and there would be no risk provisions. But, I think DSHEA tries to strike a balance.

FDA needs to do a few things to maximize the risk part of the equation, I think, from what the law permits. That includes getting out the guidance on the new dietary ingredients. We have to do our enforcement, like you've heard. We need to fully implement the Good Manufacturing Principles.

I think, as you think about that balance—the question is, Are we striking the right balance? I think, for the most part, the answer to that is yes.

The area where I think—that gives the FDA the most concern with that question relates to the pharmaceutical spiking of dietary supplements, because we're talking about very serious risks and injuries that can happen to people. Often they're, you know, young people who don't really understand and they're—that they're taking what are actually prescription drugs or steroids through dietary supplements. There has been testimony by FDA, that while we are at—being as aggressive as we can with enforcement, we are very concerned about the state of the market for these products. I think that's the area that gives us the greatest concern.

The CHAIRMAN. Thank you.

Senator CORKER.

Senator CORKER. It seems, also, that, in earlier testimony, that the disease claims—and you said so, just a minute ago—the claims of these particular products, and their ability to keep a disease from occurring or getting it—is the most serious claim that one might make on a label. Is that correct?

Dr. SHARFSTEIN. Correct.

Senator CORKER. I know the distinction is food not being preapproved, drugs being preapproved, and that's part, I think, of the tension that Senator Hatch is trying to keep from happening, actually. Again, I'm a strong supporter of the dietary supplement

industry, from the standpoint of being a consumer and just seeing so many people use these types of products. But, in that particular area, is there a way to—with the retailers, for instance—is there not some shelf notification or something that the FDA could do to say that, if a product of X claims Y, it just, should not be sold? Is there a way for the retailers to actually check against that without a preapproval process actually having to occur?

Dr. SHARFSTEIN. Well, I think that's a great idea. I think we would be happy to hear from retailers that are concerned about products that are being, you know, peddled to them, that they're concerned about a particular product, and we would then be able to look at it.

But, we do take all these disease claims very seriously, and we would pursue enforcement action, if we could. It's relatively easy for us to do, because it's just the claim, alone, that makes that illegal. So, we see that someone's trying to market something for cancer, and, boom, you know, you're not allowed to do that.

So, you know, I think we—FDA should be doing outreach, and working with the industry and the companies that are selling these products, to get the word out that, if they have concerns like that about products, that we would immediately take a look at them.

Senator CORKER. But, are there not guidelines that you guys have published, where any retailer that's serious would know that some claim by an entity that's producing a particular product that has the ingredients that it says it has in it, there's no way that that claim could be valid? Is there not some commonsense test that retailers would know a product that claims that absolutely could not be valid?

Dr. SHARFSTEIN. You know, I'm not—I think we do work with retailers, and we would give them that guidance. I think it's a very good idea, that they should—people—you know, the—generally—typically, we don't think of the retailer as, like, a place to catch problems.

But, in this case, and particularly where there are some major retailers, working with them would give us an opportunity to catch products.

The—one of the challenges is the Internet, because, even though there are some major retailers, you know, anyone can set up a Web site and sell something. So, it gets a—it would get us, I think—if we had an effective relationship with the big retailers, we would be able to protect those areas from claims, perhaps, but we'd still be dealing with, probably, some problems through the Internet and other mechanisms.

Senator CORKER. The good manufacturing practices that we referred to earlier, that, have not yet been implemented—and I'm going to leave and go to another meeting, and I thank you for your testimony and certainly the early witnesses. I know, you know, Senator Hatch certainly has talked about the funding that has lacked at the FDA, but is that the only issue that has kept y'all, for 16 years, from implementing some of the things that originally were put in place in 1994? Is it simply funding, or is it will? What is it that has kept you from implementing much of that law?

Dr. SHARFSTEIN. Well, I think that—and I think you heard Mr. Mister talk about the fact that we are committed to implementing

DSHEA, and we have made progress. We have, now, those GMPs in place for the small—the large and medium firms, and, very shortly, for the small firms. We are committed to getting the guidance, which is very important, on the new dietary ingredients out.

You know, I've been at the agency for a year, so I can't speak to, you know, what happened before, but a lot of these, you know, things are—can be quite complicated and take much more time than you wish that they were going to take. I can—I've learned that already.

But, I think, in general, I can say that we do think it's important for FDA to do what it can under the law to really manage the risk side of the access/risk balance that I think DSHEA strikes.

Senator CORKER. So, we had people in, earlier, on both sides of the issue—that some have concerns about the industry, people from the industry here feeling like they are doing what's necessary to self-police. Senator Hatch has introduced legislation. That's obviously one of the reasons we're having this hearing today. Do you think that what he has addressed in his legislation seeks the balance that's appropriate for this industry and, if implemented, and certainly funded, would do those things, as responsible department head, you would think would be appropriate?

Dr. SHARFSTEIN. I think it—that that legislation—all the provisions of it make sense to FDA. There's also language in the Food Safety bill that we think would be helpful, as you heard, I think, also, from different people in the last panel, including Mr. Mister.

I think that the one—you know, one particular area where we—I have met, multiple times, with industry, because I know they're very concerned about—relates to this issue of pharmaceutical spiking. I think that's an area that really requires the industry, the agency, and others to think through the kind of science, law, resources, other things we can do to really make a lot more progress on that. I think, even though we have taken a lot of enforcement there, we feel like we need to do better.

Senator CORKER. Does his legislation deal appropriately with pharmaceutical spiking?

Dr. SHARFSTEIN. I think that there are gaps in what—in our understanding of what we can do to make a difference. So, I think it does what it can. I think it's a good provision to have us, you know, kind of insist on FDA to be working with DEA. I think that makes sense. But, it's very challenging, because, particularly for certain types of claims, we can't—like I was saying before, if there's a claim someone says cures cancer, than, boom, it's illegal.

The problem with have with pharmaceutical spiking is that the claims are not illegal. The claim will be muscle bulking or sexual enhancement or weight loss, which are permit—can be permitted claims. So, in order for us to get to the point of enforcement, we often have to do very sophisticated lab analysis, and that can be very time consuming and challenging.

One project I saw at FDA, they found 37 varieties of Viagra. You know, basically they took pharmaceutical Viagra and they—somebody changed little bits of it, as a chemical entity, and put it in, to evade detection. It took, you know, Ph.D. chemists quite a long time to unpack that.

To do that kind of testing on so many different products is extremely challenging. That's what makes it—there was a—FDA testified at a hearing last fall about this, and really went into tremendous detail about the challenge facing the agency here. I don't think that we've really solved that challenge. I'm not sure that we had—have the answer to that, but I do think, in this area, that's probably our biggest concern right now.

Senator CORKER. Mr. Chairman, thank you.

Thank you for your testimony and for your service.

Thank you.

The CHAIRMAN. Thank you for being here, Senator Corker, and thank you for contributing as much as you have to this hearing.

Senator HATCH.

Senator HATCH. Thank you, Mr. Chairman.

Mr. Sharfstein—no, Dr. Sharfstein, first, I want to thank you for your testimony here today, and for acknowledging that DSHEA strikes the right balance. Every FDA commissioner since DSHEA has told me that they have enough authority under DSHEA to resolve the conflicts in this industry. We've tried, in addition, to pass additional statutes that will give you even more authority and would help you.

So, there's a desire here to do what's right. Please know that I agree with you that enforcement of DSHEA is our top priority; I mean, when it comes to dietary supplements. So, I'm grateful for much of your testimony here today.

Now, Dr. Sharfstein, the FDA has recently received more funds, and appears to be taking more—a great deal more action. Would you agree with that statement?

Dr. SHARFSTEIN. Yes. I would agree with that.

Senator HATCH. OK. Now, that being said, is it fair to say that the FDA does need additional funding before we implement and enforce the current laws with—which regulate dietary supplements?

Dr. SHARFSTEIN. Well, I think we're on track to fully implement and enforce. We're going to be putting all the GMPs in place and we—we are on track for the new dietary guidance to—"new dietary ingredient" guidance to come out, albeit a lot later than a lot of us would want.

Senator HATCH. But, you still could use more money, because of the monumental number of companies and number of products in this industry.

Dr. SHARFSTEIN. Well, we're anticipating doing about 250 GMP inspections in fiscal year 2010. We think there are about 1500, roughly, companies out there. So, you know, it's a pretty good fraction to do, as we're learning about it. I mean, I think it's obvious, with more resources, we would do more, but I think we're on—we feel like we're on a pretty good track. It's been frustrating to you, members of the industry, us, and others, that these pieces haven't been in place. But, I think we are beginning to see those pieces fall into place.

Senator HATCH. Well, I'm happy to hear that. I'm looking at the FDA's Total Diet Study statistics on element results for various food products, and in this report I see that a number of milk and cheese products contain arsenic, cadmium, lead, and other heavy metals.

I also have a study here that are—that was published in the Journal of Dairy Science. The study is titled, "A Survey of Selected Heavy Metal Concentrations in Wisconsin Dairy Feeds." I'm trying to help my colleague from Wisconsin to—you know, to—we've got to work together on these matters. It surveys the heavy metal content of 203 typical dairy feed products from 54 dairy farms in Wisconsin. It found that there were various levels of heavy metals throughout the dairy food chain. Now, am I saying that—that this poses some sort of a—or a kind of health concern?

Dr. SHARFSTEIN. Well, I'll tell you how I think about these levels of various heavy metals. There's sort of two categories that I put it in.

One category is the—you know, what most people would characterize as very low levels, and we want to keep them as low as possible——

Senator HATCH. Right.

Dr. SHARFSTEIN [continuing]. Just to reduce over—you know, overall levels. That's pretty much how I would characterize the findings of the GAO report.

Senator HATCH. Right.

Dr. SHARFSTEIN. Right—in that category. I think, in food, it's a similar type of thing. There are low levels of things, and we want to, generally, figure out how to keep them low, and lower, if possible.

The other category are levels that actually pose a real threat to health, and that was—there was recently a recall of a dietary supplement, for 1100 parts per million of lead, which is more—almost twice the legal limit for lead in paint. That's not a safe amount, and we really had to take action there.

I do think that, you know, it's important to distinguish those. I consider that a little bit of a warning that it's very important. I know that the industry is very serious about this, to—that the companies understand their supply chain, and really make sure the ingredients they're using are not contaminated with lead.

Senator HATCH. Well, that report does confirm that Wisconsin dairy products are safe. I, personally, would put that State's dairy products at the top of the list, right under Utah's dairy products, of course.

But—so, let me ask your—you this. Hasn't the FDA already established safe levels of heavy metals and trace elements in our food products? Don't those standards already allow the FDA to determine safe levels for dietary supplements?

Dr. SHARFSTEIN. I'd have to get back to you with a complete answer on that.

Senator HATCH. OK.

Dr. SHARFSTEIN. I mean, I think our testimony here is that the levels that GAO found in the supplements are not of significant health concern. I do think that that one recent recall was, though.

Senator HATCH. OK. Let me just ask one more question. In 1994, DSHEA set forth the definition of a "new dietary ingredient." I know the FDA has been working on a "new dietary ingredient," or NDI, guidance document to better clarify when a dietary supplement is considered a "new dietary ingredient." The evidence needed to document the safety of new dietary ingredients, and the appro-

priate methods for establishing the identity of a new dietary ingredient, they're working on.

In addition, in a January 2009 GAO report entitled, "Dietary Supplements: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding," one of the GAO's recommendations was that the FDA should promptly issue the NDI guidance. Now, could I ask why it's taken so long for the FDA to issue guidance—you know, these particular guidance documents? What is the current status of the NDI guidance document?

Dr. SHARFSTEIN. Sure. I think it's taken so long, in part, because it's a challenging topic to figure out how to define, how to help people think through both what qualifies as an NDI and what kind of information that we'd have.

I tell people in this job, I've got, you know, two lists of things on my desk: one list of things that are—need to be moving much faster than they're actually moving forward; and the other list of things that are moving at about the right speed. There's nothing on the second list, you know. [Laughter.]

So, you know, I think that everybody wants this guidance out. The industry wants it out, we want it out. I think that there—it's challenging science, in part, and law. We're anticipating having it out by the end of the calendar year.

Senator HATCH. Well, as I—if I recall it correctly, it took since 1994 to 2007 to get GMP recommendations. That's one of the reasons why I think you do need some more money or you do need some help here. That's really important, especially in an industry that takes a certain amount of criticism, even though by and large, most all the products are good products. But, I'm going to help you in every way I possibly can.

Let me just close by saying that, since you left Henry Waxman, we haven't been able to get together on anything. So, you'd better get back up here on Capitol Hill. We feel badly that you——

Dr. SHARFSTEIN. OK.

Senator HATCH [continuing]. Betrayed us by leaving here and going to the FDA. But, we compliment you on being in your present position, and how important it is, in my eyes, and how important you really are to the people in America. I've really have appreciated your testimony here today.

Dr. SHARFSTEIN. OK, thank you very much.

The CHAIRMAN. Thank you very much, Senator Hatch. With respect to your budget, Senator Hatch indicated that we may have to take another look at your budget. He's certainly right about that. But, I am pleased, as I'm sure you were, when the committee, of which I'm chairman, increased the budget for the FDA by $152 million last year, and much of that has gone into, I think, food safety examination and enforcement and oversight, hasn't it?

Dr. SHARFSTEIN. That's absolutely true. I think the—those increases have really revitalized the food program, and it—you and the committee really deserve tremendous thanks, not only by the agency, but all the people who rely on the agency's evaluation of food.

The CHAIRMAN. No question, food safety in America is paramount. The results of your investigation into the information that

you got from the GAO recently, that will be made public when those results are finished—when that examination is finished?

Dr. SHARFSTEIN. Sure. We'd be happy to write the committee and release those results.

The CHAIRMAN. Thank you so much.

Normally, how long does that take? Several weeks, or a month or two, or——

Dr. SHARFSTEIN. Well, it depends, in part, on the level of our engagement. If we decide that we're going to pursue enforcement action against a company, that sometimes takes a while, because we work with the U.S. attorneys and, you know, there's a whole enforcement process that has to play out. We can get results—we can get significant ill-gotten gains back for the—to people, we can—you know, there can be criminal prosecutions—but, those things can take time.

So, we could, you know, probably give you an interim update at a certain point, but I don't want to promise a particular timeframe, because sometimes the—you know, the really intense enforcement can take a little while.

The CHAIRMAN. Certainly.

Well, I'd like to compliment you, Dr. Sharfstein, as well as Dr. Hamburg. I think you're doing a great job at the FDA. A very, very important part of America, in terms of ensuring the safety of the products that we eat and ingest. We owe you much appreciation for what you do, and we look forward to continuing our efforts with you and with your organization.

Thank you all for being here today.

We will now close our hearing.

[Whereupon, at 4:08 p.m., the hearing was adjourned.]

APPENDIX

PREPARED STATEMENT OF SENATOR AL FRANKEN

Thank you, Mr. Chairman, for holding today's hearing on such an important topic for Minnesota seniors and all Americans.

It's important to understand that the issue of dietary supplements is fundamentally about enabling Americans to make informed choices about their health. For example, several years ago, researchers discovered that grapefruit interacts with cholesterol-lowering medications. It interferes with enzymes that metabolize these drugs in the digestive system. So if you eat grapefruit while you're on a statin, you can end up with excessive levels of the drug in your blood, and an increased risk of serious side effects.

Although this interaction is potentially harmful, it does not mean that we need to outlaw grapefruit! Rather, it means we can avoid problems by educating consumers and doctors. Research and education are crucial to ensuring dietary supplements are taken safely and effectively. This is especially true for older Americans, who take more supplements and more prescriptions than younger adults.

I believe all Americans who want them—and especially seniors—should have access to safe dietary supplements. I'd like to thank our witnesses for being here today to share their expertise on this issue. I look forward to your testimony.

MR. MISTER'S RESPONSE TO SENATOR FRANKEN'S QUESTION

Question. Mr. Mister, I'm a big fan of Medication Therapy Management, a service in which pharmacists sit down with seniors and other patients with chronic illness to make sure multiple prescriptions are taken properly and safely. Today we've heard about the risks of potential interactions between dietary supplements and prescription drugs. What role can pharmacists and medication therapy management play to educate consumers about the potential interactions of dietary supplements?

Answer. Pharmacists play an instrumental, important and trusted role in providing information to their consumers utilizing multiple prescriptions. Medication therapy management (MTM) is another useful tool pharmacists can use to educate elderly consumers about the potential interactions that may occur with their medications and other products they may be ingesting. Pharmacists, in particular, are in an ideal position to provide key information about drug/nutrient interaction and drug/nutrient deficiency health advice, as well as be an information resource for senior citizens on the benefits of many health related products. Conversely, it is equally important that pharmacists provide information in context and not unnecessarily alarm senior citizens. To benefit their consumer, the pharmacists should not only focus on pill interactions, but be aware of potential issues caused by foods in the diet, too.

The Coalition for Dietary Supplements

575 7th St. NW ◊ Washington, DC 20004

Written Testimony Submitted to the
United States Senate Special Committee on Aging

"Dietary Supplements: What Seniors Need to Know"
May 26, 2010

The Coalition for Dietary Supplements ("CDS") is a non-profit trade association that represents manufacturers, distributors, and marketers of dietary supplements in the United States. We thank the Committee for this opportunity to provide written testimony on behalf of the dietary supplement industry.

Chairman Kohl, you opened the hearing by stating that consumers should have access to comprehensive and accurate information about supplements so they are empowered to make the best decisions about their health. We couldn't agree with you more and share the Committee's concern for the health and safety of older Americans.

And that's why we are testifying today. Yes, we are here today to help determine the future of our businesses. But we're also here to determine the future of health in America. Most of us got into this business not only to make a living, but because we're passionate about helping people gain access to the best ways to take care of their health.

Not only do we take pride in the products we sell to our customers, but we also take these products ourselves, give them to our children, and recommend them to our friends, parents and grandparents. We comb through the scientific literature, consult with doctors and researchers, and listen to our customers to formulate and market solutions that we can stand behind.

In short, we do our very best to help the millions of people who depend on our products for their health. And that's why we are disturbed by some of the oral testimony made today.

In this written testimony, we address the concerns raised by this oral testimony and the Government Accountability Office report. We also make recommendations on how to address the issues brought forth today.

GAO Testimony on Contaminants Uses Faulty Methodology and Is Misleading

"Herbal Supplements Contain Contaminants" makes for a great headline. Unfortunately, it is misleading and leaves a false impression. Although herbal supplements do contain trace amounts of heavy metals, so does the parsley on your kitchen spice rack and the lettuce in your refrigerator. The fact is that any herb, fruit, or vegetable that is grown in soil will contain traces of heavy metals. That's because the soil contains these metals.

And it's not just food that contains these contaminants. According to the Environmental Protection Agency, 40 million households have drinking water with lead levels above the EPA standard of 15 parts per billion.[1]

Clearly, heavy metals are ubiquitous. They are part of a larger concern about the contamination of our natural resources, and not one confined to the dietary supplement industry.

Indeed, the point that the GAO should have trumpeted was the remarkably *low* levels in the supplements they tested. The GAO report did not identify a single harmful dietary supplement and instead *confirmed* that all of the sampled supplements were safe for human consumption. This is despite the fact that testing was admittedly designed to screen for contaminants "based on prevalence and the likelihood of negative health consequences as a result of consumption."

This is the story that the GAO should have told the committee and the media. Instead, the GAO created unnecessary alarm in the public (including releasing the findings early to the *New York Times*) with the "revelation" that herbal dietary supplements tested positive for heavy metal contaminants.

Statistics from Both the Government and the Private Sector Show that the Safety Record of Supplements is Unmatched

Contrary to the impression left by today's testimony, dietary supplements have been shown to be very safe. As pointed out by Rep. Dan Burton of Indiana, "it is more likely that you will be struck by lightning and die in this country than it is you will die from using a dietary supplement."[2]

Representative Burton's comments are not mere hyperbole; they are fact. Between 1999 and 2008, the number of people killed by lightning ranged between 27 and 51 per year.[3] During the same period, the number of people who died from taking nutritional supplements ranged between 0 and 12 per year.[4]

Indeed, supplement-related deaths are so rare that whenever a death does occur, it becomes front-page news. A recent example is Hydroxycut™, a weight-loss supplement that was recalled in 2009 by its manufacturer after causing 23 adverse effects and 1 death over a period of many years.

We at the CDS feel that even one death is too many. And we are dedicated to improving the safety of all supplements so that tragedies like this do not occur.

---

[1] http://www.epa.gov/ogwdw000/lead/lead1.html
[2] http://commdocs.house.gov/committees/gro/hgo57333.000/hgo57333_0f.htm
[3] http://www.nws.noaa.gov/om/hazstats.shtml
[4] http://www.aapcc.org/dnn/NationalPoisonDataSystem/AnnualReports/tabid/125/Default.aspx. These numbers are based on reports submitted to poison control centers.

Nonetheless, we would be remiss if we didn't point out the huge disparity between supplement deaths and deaths due to prescription drugs. In 2008, 1.6 million prescriptions for the drug Avandia were filled, resulting in roughly 1,000 deaths.[5] At the time of the Hydroxycut recall in early 2009, the manufacturer was selling at least 9 million units each year. And this resulted in one death.[6]

In other words, in one year, one drug alone caused 1,000 deaths, while one of the biggest dietary supplement recalls in history, Hydroxycut, which was sold to more than five times as many people, resulted in one death.

It is also worth noting that such reported deaths are not necessarily due to the supplements themselves. When asked about the total of 5 deaths recorded by the FDA during 2008, FDA spokesman Michael Herndon was quoted in USA Today as saying, "Some of these deaths were likely due to underlying medical conditions."[7]

N.I.H. Finds Dietary Supplements Effective For Many Health Concerns

Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), it is unlawful for the dietary supplement industry to discuss the ways our products prevent, cure, or mitigate diseases, except on the rare occasion when FDA approves a health claim (which it has only done a handful of times since 1994).[8]

This restriction was placed so that we could market our products under the same laws as foods. We understand the rationale behind this restriction, and we abide by it and support it being enforced.

However, we would be remiss if we didn't point out that there are volumes of studies supporting the use of dietary supplements in combating disease. Many of these studies were conducted with funding from the National Institutes of Health, the Department of Agriculture and other government organizations. For example:

- A National Center for Complementary and Alternative Medicine (NCCAM) study found that glucosamine combined with chondroitin sulfate provided statistically significant pain relief compared with placebo in participants with moderate-to-severe pain.[9]

- Studies that have led institutions like the National Cancer Institute to create a fact sheet stating that garlic consumption may indeed reduce the risk of several cancers, particularly those of the gastrointestinal tract.[10]

---

[5] http://www.mmm-online.com/fda-reconsiders-avandia-safety-problems/printarticle/164360/
[6] http://www.msnbc.msn.com/id/30518843/
[7] http://www.usatoday.com/news/health/2008-09-22-supplements-adverse-events_N.htm
[8] http://www.fda.gov/Food/LabelingNutrition/LabelClaims/HealthClaimsMeetingSignificantScientific AgreementSSA/default.htm
[9] http://nccam.nih.gov/research/results/gait/qa.htm
[10] http://www.cancer.gov/cancertopics/factsheet/Prevention/garlic-and-cancer-prevention

- A study on fish oil and depression prompted NIH psychiatrist Dr. John Hibbeln to note that "This is one of the largest potential associations of a nutrient with depression. The important issue in this study is that the omega-3 worked above and beyond the antidepressants."[11]

Certainly, there are some bad apples within our industry making claims that are irresponsible and have no support. But on the other hand there are many claims that are fully justified. We're just not allowed to make them.

GAO Examples of Allegedly Deceptive Practices Paint a Misleading Picture of the Dietary Supplement Industry

The GAO report implies that deceptive marketing practices are widespread in the dietary supplement industry. This is simply false. The vast majority of dietary supplement manufacturers and marketers are conscientious, law-abiding companies that strive to provide customers with accurate information about their dietary supplement products.

As with any industry, there are bad apples that break the rules. And, as with other industries, the FDA and FTC have aggressively pursued companies that make unsubstantiated and unlawful claims about dietary supplements, such as the types of claims summarized in the GAO's report.

***Product Labeling*:** The GAO report alleges that several products sampled contained deceptive product labels. We find it interesting that out of the thousands of products available, GAO chose products from companies so obscure that none of us had even heard of them.

Nonetheless, based on these isolated, cherry-picked cases, the GAO report gives the impression that additional federal regulation is needed to police the labeling of dietary supplements. Yet, as explained by the FDA in response to the GAO's report, the FDA already regulates product labels, and "[w]hen FDA identifies such claims in the labeling of products on the market, the Agency takes action."[12] In particular, the FDA has the authority to conduct "seizures and order the destruction of misbranded product."[13]

For example, the FDA recently worked with the United States Marshal for the Western District of Wisconsin to seize "a range of dietary supplements and other products from a firm that was promoting the products for unapproved uses."[14] Similarly, the FDA took aggressive action against claims related to the H1N1 flu crisis of 2009 by sending Warning Letters to websites that marketed products as cures for the H1N1 flu.[15]

---

[11] http://www.psychologytoday.com/articles/200301/omega-3s-boosting-mood
[12] *Hearing on Oversight of Dietary Supplements: Before the S. Special Committee on Aging* (2010) (Statement of Joshua M. Sharfstein, M.D., Prin. Deputy Comm'r U.S. Food and Drug Admin. Dept. of Health and Human Services) at 14.
[13] *Id.* at 11.
[14] *Id.*
[15] *Id.*

The FTC, which shares jurisdiction over dietary supplements with the FDA, has been extremely aggressive in pursuing claims of deceptive marketing of dietary supplements. Over the past decade, the FTC "has filed well over 100 law enforcement actions challenging claims about the efficacy or safety of a wide variety of supplements."[16] And in the past two years alone, the "FTC has filed or settled 30 cases involving supplements promoted with false or unsubstantiated claims ...."[17] In addition, the FTC sends out warning letters to companies to stop or modify claims.[18]

The FTC has powerful tools at its disposal to challenge the types of practices alleged in the GAO's report. These include:

1. the power to compel production of documents relating to the substantiation of claims;

2. the ability to obtain preliminary and permanent injunctive relief, consumer redress, or disgorgement of ill-gotten gains;

3. the ability to appoint a receiver to take control of a fraudulent business;

4. the power to freeze assets; and

5. in cases of fraud or repeated law violations, the ability to ban the marketing of certain categories of products.

Moreover, the FTC focuses on holding responsible all "parties involved in the creation or dissemination of the deceptive claims, including company owners and key officers, ad agencies, infomercial producers, distributors, and retailers."[19]

***Retail Sales Staff Practices*:** We don't know if the GAO cherry-picked the retail stores it investigated. But we do know that we were appalled at some of the irresponsible behavior exhibited by the sales staff on the GAO's recordings.

Unfortunately, we as manufacturers and distributors of supplements cannot control, and should not be held responsible for, the unauthorized and impromptu statements made by an unrelated retailers' over-zealous sales staff.

Fortunately, the FTC and state attorneys general already have the authority to deal with these types of false advertising. As with any industry, additional regulation would not curb the types of sales practices summarized in the GAO report. For this reason, the dietary supplement industry has been pro-active in developing a range of training programs to help retailers and sales staff understand the types of claims that can be made regarding dietary supplements. The

---

[16] *Id.* at 4.
[17] *Hearing on Oversight of Dietary Supplements: Before the S. Special Committee on Aging* (2010) (Statement of the Federal Trade Commission on Deceptive Marketing of Dietary Supplements FTC Enforcement Activities) at 7.
[18] *Id.*
[19] *Id.*

dietary supplement industry will continue to take the lead on this issue, and looks forward to working with the FDA and FTC to develop additional training programs and resources.

Drug Interactions: According to the GAO report, undercover agents 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."[20]

In a few isolated cases, sales staff responded to the undercover agents' leading questions with inaccurate information concerning potential drug interactions. The GAO's implied solution, hinted at later in the report, is that additional government regulation of dietary supplements is necessary as "[m]any herbal supplements have not been exhaustively tested for hazardous interactions with prescription drugs, other supplements, or foods."[21]

First, as explained above, manufacturers, distributors, and marketers of dietary supplements (or any other industry) cannot control, and should not be held responsible for, unauthorized and impromptu statements made by an unrelated retailer's over-zealous or misinformed sales staff. None of the examples concerning hazardous interactions set forth in the GAO report involved statements made by manufacturers or distributors of dietary supplements.

Second, the federal government already requires prescription drug companies, in appropriate circumstances, to inform customers of any potentially hazardous interactions with other prescription drugs, dietary supplements, and foods. This system is appropriate, safe, and cost effective, as many prescription drugs are not taken with regularity by consumers and are most likely to be the variable that causes a hazardous interaction. In addition, the prescription drug industry's cost structure is more amenable to conducting comprehensive testing than the dietary supplement or food industries

Third, millions of Americans consume safe and beneficial dietary supplements and food every day that have no risk of hazardous interactions with other dietary supplements or food.

Given the safety track record of dietary supplements and food, it would impose an unnecessary and potentially debilitating burden on dietary supplement and food manufacturers to test for potentially hazardous interactions with prescription drugs.

Imagine walking into your local supermarket and picking up a banana only to find a sticker containing a list of potentially hazardous interactions with prescription drugs, dietary supplements, and other foods. Such a scenario would not only dramatically increase the cost of bananas, but would also prove completely unnecessary, at least with respect to other dietary supplements and food.

Thus, the CDS supports the current system where the potential interactions are listed on prescription drugs, as this system has worked effectively for many years.

---

[20] GAO, *Herbal Dietary Supplements: Examples of Deceptive or Questionable Marketing Practices and Potentially Dangerous Advice*, GAO-10-662T (Washington, D.C.: May 26, 2010).
[21] *Id.* at 3.

Current Law Gives the FDA and FTC Broad Powers to Ensure Consumer Safety

Contrary to the impression created by the testimony of the GAO, and to a lesser degree the Consumers Union and Consumer Lab.com, the federal government does not need additional regulatory authority over the dietary supplement industry.

As explained by Dr. Joshua Sharfstein, Principal Deputy Commissioner at FDA, current law provides the FDA with authority over every aspect of the dietary supplement industry. This includes the manufacturing process, use of ingredients, marketing claims, registration of facilities, and the removal of unsafe products from the marketplace.

Dr. Sharfstein is not alone. Senator Hatch listed several past FDA commissioners who also felt that DSHEA provided them with adequate authority to address supplement safety. And the senator added that all of the concerns raised by the GAO were addressed in DSHEA.

In addition, the FTC has the ability to take enforcement action against any dietary supplement manufacturer, distributor, retailer, or marketer that makes false or misleading claims about the product, as explained by the Commission in its written statement.

Here are some ways that current law ensures consumer safety:

1. Current Law Requires all Dietary Supplement Facilities to Register with the FDA

All dietary supplement facilities are required to register with the FDA under the Bioterrorism Act of 2002 (P.L. 107-188).[22] In addition, current law requires product labels to list either the manufacturer or distributor of a product, as well as a full mailing address or telephone number for that company.[23] Thus, additional registration requirements are unnecessary and would serve no purpose other than imposing a financial and administrative burden on both supplement companies and the FDA.

2. Current Law Mandates Good Manufacturing Practices that Ensure Consistent Quality and Limit Contamination

In June 2007, the FDA established a final rule establishing Good Manufacturing Practices ("GMP") for dietary supplements.[24] The GMP requirements, which have been phased in on a rolling basis according to the size of a manufacturer, will be effective as to all firms manufacturing, packaging, labeling, or holding dietary supplements on June 25, 2010, and they are already in effect for all such companies with 20 or more employees.

---

[22] 21 U.S.C. § 350d; 21 C.F.R. Part 1, Subpart H.
[23] 21 C.F.R. § 101.5; 21 U.S.C. § 343(y).
[24] Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 72 Fed. Reg. 34,752 (June 25, 2007) (codified at 21 C.F.R. Part 111).

The GMP requirements limit the possibility of contamination by ensuring dietary supplements are manufactured using proper ingredients and contain appropriate labeling. The dietary supplement industry has embraced the new GMP requirements and launched several industry initiatives to further good manufacturing practices. Indeed, even prior to the 2007 final rule, the industry created its own independent GMP certification program and audit process for companies wishing to obtain third-party certification of GMP compliance.[25]

3. Current Law Gives FDA and FTC the Power to Regulate All Types of Dietary Supplement Advertising and Marketing Claims

As explained in detail in the FDA's written testimony, current federal law provides the FDA with authority to regulate all manner of claims regarding dietary supplements. This includes health claims, nutrient content claims, structure/function claims, and disease-related claims. In addition, the FTC Act prohibits "unfair or deceptive acts or practices" involving the marketing of dietary supplements. Together, the FDA regulations and the FTC enforcement authority ensure that the federal government has sufficient regulatory authority over all aspects of the advertising and marketing of dietary supplements.

4. Current Law Requires Adverse Event Reporting and Removal of Unsafe Products from the Market

The current law requires manufacturers and private-label distributors of dietary supplements to notify the FDA of any reports they receive of serious adverse events associated with use of their dietary supplement products.[26] These reports are evaluated by the FDA to identify products that may present safety risks to consumers.

It should be further noted that under DSHEA, the FDA may remove any dietary ingredient from the marketplace it believes poses a significant or unreasonable risk of injury or illness[27], which it did with ephedra. Moreover, DSHEA also created the imminent hazard to public health standard which allows FDA to remove unsafe products from the marketplace immediately without notice and comment rulemaking.[28]

These powers are in addition to the FDA's ability to have adulterated and misbranded dietary supplements seized.[29] Thus, the persistent urban myth that the FDA lacks sufficient regulatory authority to ensure the public safety from unsafe dietary supplement products is false.

FDA Working to Provide Additional Guidance on New Dietary Ingredients

DSHEA prohibits marketing a dietary supplement containing a New Dietary Ingredient ("NDI") *unless*: (1) the dietary ingredient as been present in the food supply as an article used for food in a form in which the food has not been chemically altered; or (2) the manufacturer or

---

[25] *E.g.*, The National Nutritional Foods Association's Dietary Supplement Manufacturing Certification Program.
[26] 21 U.S.C. § 379aa-1.
[27] 21 U.S.C. § 342(f)(1)(A).
[28] 21 U.S.C. § 342(f)(1)(C).
[29] See 21 U.S.C. § 334(a)(1).

distributor submits an NDI notification 75 days prior to marketing the new ingredient.[30] DSHEA defines a new dietary ingredient as any ingredient not marketed in a dietary supplement prior to October 15, 1994.[31]

Implicit in DSHEA is that manufacturers and marketers must have reasonable substantiation that a product was marketed prior to that deadline. Indeed, without such evidence, the ingredient is subject to the notification provision unless it can be established that the ingredient has been used as an article of food. DSHEA also requires that manufacturers bear adequate evidence of the safety of the new dietary ingredient regardless of whether it is the subject to the notification provision.

The FDA is working to provide the dietary supplement industry with additional guidance on the definition of an NDI, the type of information that should be submitted in connection with an NDI, and how to define a reasonable expectation of safety for an NDI. Accordingly, we oppose mandating a list of "Accepted Dietary Ingredients" to replace the current in commerce pre-DSHEA test as there is already sufficient regulatory authority to ensure the quality and safety of dietary supplements.

CDS Recommendations

The CDS respectfully advises the Committee to look past the GAO report's narrow focus and recognize the important and safe role that dietary supplements play in consumers' daily lives.

The CDS joins the FDA and FTC in concluding that current federal law regarding dietary supplements provides the FDA and FTC with sufficient authority to protect consumers from deceptive marketing practices and contamination. Congress should focus on providing the FDA with additional funding and resources to ensure enforcement of current law, rather than promoting additional legislation.

We believe that current legislation, while well-intentioned, would result in unforeseen negative consequences. Specifically, it would impose undue hardship on the dietary supplement industry, stifle innovation, raise prices, and harm consumers – *without any corresponding gains in safety.*

Although the CDS is opposed to any additional regulation of dietary supplements, the CDS provides the following comments regarding potential legislation:

- The CDS supports providing increased funding to the FDA to ensure the full implementation of current law.

- The CDS supports requiring the FDA to notify the Drug Enforcement Administration ("DEA") when a new dietary ingredient premarket notification is rejected because the product contains a synthetic anabolic steroid.

---

[30] Pub. L. No. 103-417, § 8.
[31] *Id.*

- As dietary supplement facilities are already required to register with the FDA, the CDS opposes additional registration requirements. This includes any requirement that dietary supplement facilities file a registration statement that includes a list of all dietary supplements manufactured by the facility, a copy of all labeling, a list of all ingredients for each dietary supplement, or a requirement that registered facilities update their registration before any new dietary supplement or reformulation is introduced into the marketplace.

  Additional registration would serve no purpose other than to burden industry and the FDA. Indeed, the deluge of paperwork could divert FDA resources away from the important task of enforcing regulations that protect the safety of the public.

- The CDS opposes granting the FDA mandatory recall authority unless the authority is narrowly-tailored. The problem with mandatory recall is that 1) it is a "shoot first, ask questions later" approach that deprives the accused of due process; and 2) it is unnecessary because the FDA already has the authority to remove unsafe products from the marketplace.

  For example, two years ago, the FDA warned consumers to avoid certain varieties of tomatoes due to a salmonella scare. In the end, it turned out that the tomatoes were not the source of the salmonella. But the damage was done. The industry lost $100 million in sales, and smaller growers went out of business.[32]

  Thus, if the Committee is to consider a new standard, the CDS suggests that the FDA have authority to order a mandatory recall only if the FDA finds that the food is adulterated and likely to cause serious adverse health consequences or death to humans or animals.

- The CDS supports any Congressional initiatives designed to help the dietary supplement industry continue to implement training and self-regulatory programs.

In sum, on behalf of the dietary supplement industry, the CDS assures the Committee that the industry will continue to take a proactive and aggressive role in policing the marketplace and ensuring that Americans have access to high-quality, affordable, and safe dietary supplements.

Please join us in furthering this effort by supporting appropriate regulation, as discussed above, only when necessary. We hope that you will take these comments into consideration as you consider current and future regulation affecting the dietary supplement industry.

* * * * *

[32] http://www.scientificamerican.com/article.cfm?id=news-bytes-tomatoes-peppers-salmonella&print=true.

○