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Testimony of

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Consumers Union

before the

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Hearing on

Dietary Supplements: What Seniors Need to Know

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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.

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[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.

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[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.
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> 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.

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[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]

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[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

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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.