TESTIMONY OF

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On

"THE REGULATION OF DIETARY SUPPLEMENTS A Review of Consumer Safeguards"

Before the

HOUSE COMMITTEE ON GOVERNMENT REFORM

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Good morning Chairman Davis, Congressman Waxman and distinguished members of the Committee. I am Janell Mayo Duncan, Senior Counsel for Consumers Union (CU), publisher of *Consumer Reports*® magazine *(CR)*.[1] Thank you for providing me the opportunity to come before you today to address this Committee about our perspective on inadequate government authority over, and oversight of, dietary supplements; the importance of information for consumers who choose to navigate the dietary supplement market; and how consumers can make better educated decisions when purchasing dietary supplements.

The Dietary Supplement Health and Education Act of 1994 (DSHEA) created serious regulatory loopholes that have opened the floodgates to thousands of untested dietary supplement products. Benefits and risks do not have to be established before these products are brought to market, manufactures are not required to disclose when their products cause harm, and the law requires the FDA to first prove that a supplement creates "a significant or unreasonable risk," before it can demand its removal from the market. Many dietary supplements -- including most vitamins and minerals taken within recommended limits -- are safe, and can have important health benefits for consumers. However, there are a significant and growing number of questionable products that likely would not be allowed on the market if they were subject to pre-market safety testing. Because there are no requirements that a dietary supplement be proven safe and effective before going on the market, it is very difficult

[1] Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finance. Consumers Union's income is solely derived from the sale of *CR*, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, *CR* with approximately 4.5 million paid circulation, regularly carries articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions that affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support

for consumers to determine which products are safe and worth consuming, and which are ineffective and/or dangerous.

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. In addition, consumers may experience safety problems with dietary supplements because of potential interactions with existing health conditions, such as diabetes, coronary problems or hypertension.

Over the last 10 years, FDA has typically relied on warnings and voluntary compliance to address supplement hazards, allowing many dangerous products to remain on the market. As explained in detail below, in light of the inadequacy of regulatory oversight in this area, CU believes that changes must be made to DSHEA, such as: (1) requiring an expert panel to review the safety of dietary supplement products on the market; (2) requiring dietary supplement manufacturers to tell the FDA when they become aware of serious adverse events associated with the use of their products; (3) pre-market testing requirements for certain categories of supplements; (4) product ingredient registration; and (5) risk-labeling requirements. We ask members of Congress to make it a priority to provide the FDA with needed enhanced authority and adequate funding to achieve these goals. In addition, we support the FDA in its appeal of the Utah District Court challenge to its authority to ban ephedra. We also urge you and your colleagues in Congress to eliminate any ambiguity and clarify that FDA has the authority to ban dangerous supplements such as ephedra.

What can private organizations offer consumers in the way of information and education? Although Consumers Union, and other private organizations may provide

testing to determine if certain product brands contain ingredients in amounts indicated on supplement labels, or investigate risks and benefits relating to specific dietary supplement products already on the market, these activities cannot replace the need for the FDA to have the authority and resources needed to protect consumers' interests. Private organizations, such as Consumers Union, have no ability to require dietary supplement manufacturers to submit adverse event reports; seize dangerous and adulterated supplements; or require companies to evaluate the risks and benefits of a product before it is brought to market.

Longstanding CU Concerns about Safety of Certain Supplements

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. Ephedra was finally removed from the marketplace on April 12, 2004; many years after the FDA first received reports of serious consumer health problems, including more than 100 deaths and almost 17,000 adverse events (including heart attacks, strokes and seizures). The other four supplements are still being marketed and sold in retail stores and on the Internet.

May 2004 *CR* Article on the Dangerous Dirty Dozen Supplements

In May 2004, *Consumer Reports* published a list of 12 hazardous dietary supplements (including the four herbs named in the 1995 report) that are too dangerous to be on the market based on government warnings, adverse-event reports, and medical experts. These "dirty dozen" unsafe supplements, which *CR* purchased in stores and online, included: aristolochic acid, comfrey, androstenedione, chaparral,

germander, kava, bitter orange, organ/glandular extracts, pennyroyal oil, skullcap and yohimbe. Six of these products have been linked to cancer, kidney failure, liver disease, and even death. Despite this fact, with the exception of androstenedione, these supplements continue to be widely available to consumers in the United States on store shelves and online. The dangers associated with these supplements include the following:

- **Aristolochia:** A herb conclusively linked to kidney failure and cancer.
- **Yohimbe:** A sexual stimulant linked to heart and respiratory problems.
- **Chaparral, comfrey, germander, and kava:** All known or likely causes of liver failure.
  Bitter orange: Its ingredients have effects similar to the banned weight-loss supplement ephedra.

The potentially dangerous effects of most of these products have been known for more than a decade, and at least five of them are banned in Asia, Europe, or Canada.

How Many Other Dangerous Supplements Are On the Market?

In addition to the 12 supplements named in the May 2004 article, CU believes there likely are other dietary supplement products that pose unacceptable risks to consumers.

Three other ingredients of concern are:

- Colloidal silver. Long-term use of dietary supplements containing colloidal silver can lead to agyria, a condition that turns skin gray and/or blue. According to several experts and respected sources, in recent years silver-containing products have been marketed with unsubstantiated claims that they are effective against AIDS, cancer, and many other diseases and conditions;[2]

[2] For example, see "Rosemary's Story," by Rosemary Jacobs, available on the Web at: http://homepages.together.net/~rjstan/rose2.html

- Usnic acid. A supplement ingredient derived from lichens, may be highly toxic to the liver, and has been linked to reports of liver failure.[3] The FDA has issued warnings about products containing usnic acid; and

- 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 American Society of Anesthesiologists, advises consumers to discontinue the use of herbal medicine at least 2 to 3 weeks prior to surgery.[4]

Given that there are currently 30,000 dietary supplement products on the market, and 1,000 new products entering the market each year, it is important for Congress and the FDA to take a broad view of supplement safety. While most supplements likely are safe, consumers face particular risks from certain herbs that are highly toxic, could alter effectiveness of prescription medications, or that contain untested steroid equivalents. Without additional resources and regulatory authority, it simply is not possible for FDA or anyone to know exactly how many more of these products pose serious hazards to consumers. The fact that we lack information on the full extent of dangers relating to dietary supplement is cause for serious concern.

Inadequate Regulatory Oversight

U.S. Food and Drug Administration

Over the years, consumers have come to rely on the FDA to ensure that products that appear on the shelves in their local retail store or pharmacy have been tested and are safe for their use. By exempting dietary supplements from most types of

[3] Grady, Denise. "Seeking to Fight Fat, She Lost Her Liver," The New York Times, March 4, 2003, p.1."
[4] American Society of Anesthesiologists, "Anesthesiologists Warn: If You're Taking Herbal Products, Tell Your Doctor Before Surgery," posted on the Web at http://www.asahq.org/patientEducation/herbal.htm.

oversight required for prescription and over-the-counter drugs, DSHEA has created a troubling and unexpected gap in consumer protection. The federal government's inability to act promptly on available signals of serious consumer health problems with a dietary supplement, such as ephedra, is very disturbing. Consumers expect the government to take an active role in ensuring that dietary supplements are safe and effective.

Many consumers are surprised to learn the government does not currently evaluate the safety of dietary supplements before they are sold.[5] 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 believed the government requires warning labels on supplements' potential side effects or dangers. Fifty-five percent thought supplement manufacturers cannot make safety claims without solid scientific support.

Unfortunately, the respondents in the poll were incorrect. Instead of being equipped to take swift action when the FDA believes that a supplement may be unreasonably harmful, this watchdog agency has been relegated instead mostly to highlighting dangerous supplements on its website. For example, supplements such as aristolochic acid, featured in the May 2004 *CR* article, are highlighted by the FDA on its website under "Warnings and Safety Information." We are concerned that the warnings and information contained in our report, and featured by the agency will not reach

[5] For example, see "Widespread Ignorance of Regulation and Labeling of Vitamins, Minerals and Food Supplements*," Health Care News*, Harris Interactive, December, 2002; and Blendon, R. et al., "Americans' Views on the Use and Regulation of Dietary Supplements," Arch. Intern. Med., Vol 161, March 26, 2001, p. 805-810.

enough unsuspecting consumers – some of whom may suffer serious harm or even death.

FDA's Failure to Finalize Good Manufacturing Practice (GMP) Regulations

CU is concerned that in an area in which the FDA has clear authority under DSHEA – to issue Good Manufacturing Practice Regulations – the Agency has failed to issue a final rule for almost ten years. This is an unconscionable delay. Under DSHEA, the FDA has the clear authority to issue GMPs for dietary supplements. FDA issued an Advance Notice of Proposed Rulemaking in 1997, and sent a proposed rule to OMB on November 8, 2000. On February 1, 2001, OMB returned the proposed rule to FDA – delaying publication. The FDA published proposed GMPs on March 13, 2003, and a final rule has yet to be issued. Until this proposed rule (describing conditions under which dietary supplements must be prepared, packed, and stored, and intended to ensure accurate labels and unadulterated dietary supplements) is finalized, dietary supplements must comply with food GMPs, which are primarily concerned with safety and sanitation rather than dietary supplement quality. Although the authority under DSHEA for the FDA to issue GMPs should require the issuance of GMPs more closely resembling those for non-prescription drugs (and require supplements to be manufactured to the same quality standards), we strongly urge the FDA to finalize these proposed regulations in order to set clear quality standard for dietary supplements.

Ephedra: Poster Child for Failed Policy

In February of 2003, the FDA published a final rule to ban dietary supplements containing ephedra. Prior to its action, the Agency had received almost 17,000 adverse event reports relating to the use of ephedra, including heart attacks, strokes, seizures and fatalities. The delay in removing products containing ephedra from the market occurred, in large measure, because the FDA currently bears the burden of showing that a dietary supplement is unsafe before it is able to halt its sale. At the same time, FDA is kept in the dark by manufacturers that are not required to inform FDA when they learn that their products have harmed, or even killed consumers.

We strongly support the FDA's action to ban ephedra. However, we believe that the dangers relating to the use of dietary supplements are not limited to ephedra. In the absence of sufficient FDA action, *CR* continues to strongly urge consumers to avoid all weight-loss and energy-boosting supplements, especially those that are now touted as "ephedra-free."

As reported in the January 2004 issue of *CR*, herbal supplements that are labeled 'ephedra-free' are not necessarily safer than ephedra. Many include similar central nervous stimulants, such as synephrine-containing bitter orange (citrus aurantium). Synephrine is not only structurally similar to ephedrine but also may affect the body in ways similar to ephedra. Because there is no required pre-market safety evaluation for those products, consumers have no assurance that the problems experienced by ephedra users will not continue with a switch to ephedra-free products. By the time we have sufficient information on potential hazards posed by bitter orange, many consumers may have experienced serious adverse health events, including

seizures or strokes. This clearly illustrates why the burden of proof for establishing that dietary supplements are safe and effective ought to be on the manufacturer – not on consumers, health professionals, consumer groups, or the government.

Of additional concern is the fact that these supplements may interact unfavorably with other medicines that consumers are taking. Unfortunately, not all consumers will receive our message, and may pay with their lives.

Utah District Court Ephedra Court Decision

CU is deeply concerned about an opinion issued by a Utah District Court in April 2005 allowing sales of products containing low doses of ephedra. We strongly support the FDA ban on ephedra on the grounds that it presents "an unreasonable risk of illness or injury." Unfortunately, the Court decided that the Agency: (1) was wrong to weigh the supplement's risks against its minimal benefits; and (2) presented insufficient evidence to ban low-dose ephedra products. The decision will allow the plaintiff manufacturer to market its dietary supplements containing ephedrine alkaloids of 10 mg or less per daily dose. The Court's interpretation of the DSHEA incorrectly calls into question the agency's implementation of the Act, including its ability to weigh the benefits against the risks of supplements—a core precept of FDA regulation.

We support the FDA's appeal of this decision, and recent enforcement actions taken against products containing ephedra.[6] We also have strongly urged the Agency

[6] At the request of the FDA, the U.S. Attorney's Office for the Northern District of Georgia recently filed a Complaint for Forfeiture against "Lipodrene," "Stimerex-ES," and "Betadrene" – dietary supplements manufactured, marketed, and distributed by Hi-Tech Pharmaceuticals – labeled as containing 25 mg of ephedrine alkaloids per tablet. The Complaint for Forfeiture also included the ephedrine alkaloid raw materials used to manufacture these dietary supplements. The U.S. Marshals Service began seizing these dietary supplements and ingredients located at Hi-Tech's facilities in Norcross, GA on February 24, 2006. See http://www.fda.gov/bbs/topics/NEWS/2006/NEW01325.html.

to ask Congress to clarify that DSHEA provides it with authority to ban dangerous products such as ephedra, and for new authority to mandate that dietary supplement manufacturers report all adverse events that may be related to the use of their products. The latter will help FDA gather the evidence it needs to demonstrate the risks of dangerous supplements and protect the consuming public.

Federal Trade Commission

We commend the work of the Federal Trade Commission (FTC) to combat false and deceptive practices on the part of companies that market dietary supplements without proper substantiation for claims made. However, we believe that improvements in FDA's authority (the agency with primary authority over these products under DSHEA) discussed in this testimony are of paramount importance, and will go a long way to protect consumers.

Nutritional Supplement Testing at *CR*: Independent, Unbiased Evaluations Offer Meager Protection against Unregulated Products

Unlike modern pharmaceutical drugs that are virtually all produced and purified from chemicals in a factory, herbal medicines—extracted from plants—are notoriously difficult to standardize. Individual plants can vary greatly in their content of key active chemicals. While the labels of herbal medicines and other nutritional supplements list their ingredients, the lack of meaningful government regulation of these products means that consumers have virtually no protection against inaccurate labeling or substandard preparations.

For these reasons, *CR* has a program of testing the ingredients of selected nutritional supplements. CR has, working with labs that specialize in analyzing herbal products, tested representative brands of a variety of alternative medicines. Our findings are published in *CR* magazine and on *ConsumerReports.org*. Excerpts are often published in the *CR on Health* newsletter.

CR purchases samples in several locations, and publishes the brand names of products that pass or fail our test standards or other widely accepted standards. In analyzing nutritional supplements, *CR* follows our usual rigorous testing methods, described below:

How We Choose Brands to Test

For each supplement type, we conduct a market survey and choose a sample of the most widely available brands to test. Current market surveys are done for brands available on the Internet as well as those in stores.

How We Acquire Samples

We order on the Internet, and send shoppers to purchase samples at a variety of outlets in different parts of the country to assure that the products we test are truly representative of what is available to consumers nationwide.

How We Test

The samples of nutritional supplements purchased by our shoppers are prepared in “blinded” sample containers so that the testers are not aware of which brand(s) they are testing. We sample from several production lots of each brand in order to account for any variability of products, and for production quality control problems. We only test samples that are well within the “use by” or “sell by” date indicated on the label. When

available, official methods are used for all analyses. When no official method exists, our experts use an appropriate testing method based on sound science and/or acceptable industry practice. Analyses are carried out under well-established quality assurance and quality control measures.

What We Test For

Whenever the "active" ingredient in a nutritional supplement is known, we test specifically for that ingredient with the dosage proven in clinical trials as effective. In analyzing saw palmetto, for example, we targeted the amount of extract specific to the herbal rather than the total amount of fatty acids which can come from extraneous ingredients.

How We Report Our Results

CR reports the results for all brands tested: those that fulfill their labeling promise and those that do not. We present our findings in practical ways, indicating how much it would cost a consumer to take each supplement brand in a dosage that has been shown to be effective in randomized controlled clinical trials. *CR* examines product labels for ambiguity and for outright mislabeling and reports on these findings.

How We Arrive at Our Recommendations

Who might benefit from taking a particular supplement? What dosage should they take? Which side effects and drug interactions should consumers watch for? CU's experts evaluate the clinical evidence regarding the nutritional supplement, and help our readers understand what is known and unknown about various products. Thus far *CR* has published its findings on products including the following: Bitter Orange (January 2004); Hoodia (March 2006); Multivitamins (and concerns with dollar store vitamins)

(February 2006); Probiotics (July 2005); Calcium (January 2005); Soy (July 2004); Echinacea (February 2004); Omega-3 Oil (July 2003); Kava (March 2003); Glucosamine and Chondroitin (January 2002); Kava, SAM-e, and St. John's Wort (December 2000); Saw Palmetto (September 2000); Echinacea and Ginkgo Biloba (March 1999 CR); Ginseng (November 1995). *CR* also conducted surveys on supplements and other alternative treatments in August 2005 and May 2000.

CU Recommendations to Consumers in Light of Limited Regulation and Information

Until the law is substantially changed and the FDA is adequately funded, CU has advised consumers not to rely on the federal government to ensure that dietary supplements are safe and effective. The following are some steps we have given to our readers (in print an online) to minimize their risk from any supplements they decide to take:

1. **Stay away from the dirty dozen.** All carry risks that in our view are unacceptable. In combination products, consumers need to read the detailed list in the tiny print on the back to determine (assuming labels are accurate) exactly which ingredients are included.

2. **Do not take daily doses of vitamins and minerals that exceed the safe upper limits.** While vitamins and minerals are by far the safest and best-studied of supplements, it is possible to overdose on some of them. For more information, consumers can refer to CR's October 2003 report on fortified foods (available to subscribers). Recommended allowances and safe upper limits also can be found online at *www.ific.org/publications/other/driupdateom.cfm*.

3. **Limit your intake of other supplements.** Over the years, CU's medical and nutritional consultants have identified and tested a few products, other than standard multivitamins, with possible benefits and sufficiently low risks to recommend for general use, including: saw palmetto for benign enlarged prostate in men, glucosamine and chondroitin for arthritis, and fish-oil capsules (omega-3 fatty acids) for heart disease.

4. **Tell your doctor about your supplements.** Arthur Grollman, M.D., professor of pharmacological sciences at the State University of New York, Stony Brook has said "[t]he Achilles' heel of unregulated supplements is the risk created by herb-prescription drug interactions." He said, "St. John's wort, used to treat depression, for instance, may reduce the effectiveness of prescription drugs used by millions of Americans for hypertension, AIDS, heart failure, asthma, and other chronic diseases."

5. **Stay away from supplements for weight control.** These products frequently contain several stimulants that have never been adequately tested separately, let alone in combinations.

6. **Do your own research.** Health-food-store clerks and marketers, alternative-medicine practitioners, herbal company web sites, and even physicians are not necessarily knowledgeable about the scientific evidence regarding dietary supplements. However, two Web sites that contain reliable information are: the National Institutes of Health site at *ods.od.nih.gov/databases/ibids.html* and Memorial Sloan-Kettering Cancer Center's site at *www.mskcc.org/mskcc/html/11570.cfm*.

7. **Watch for adverse events.** Let your doctor know if you experience anything worrisome after starting a supplement. If your doctor concludes that the side effect may be related to the supplement, be sure to report it to the FDA, by calling 800-332-1088 or by visiting *www.fda.gov/medwatch*.

CU Recommendations for Legislative and Regulatory Change

CU believes that important consumer protection functions in this area must be undertaken by the government. Changes must be made to DSHEA in order to prevent additional deaths and serious injuries caused by dietary supplements.

We urge you and your colleagues in Congress to make it a priority to provide the FDA with enhanced authority and funding to act quickly when it receives reports regarding unsafe supplements. We believe that dietary supplement manufacturers must be required to submit adverse event information to the FDA. Finally, the federal government should not permit dietary supplements (especially stimulants and

supplements intended for use by children, pregnant women, the elderly, and other vulnerable populations) to be sold without adequate pre-market safety testing.

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I thank the Chairman, Congressman Waxman, and the Committee for the opportunity to testify, and I look forward to any questions you may have.