



TESTIMONY OF

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CONSUMERS UNION OF U.S., INC.**

ON

**"DIETARY SUPPLEMENTS SAFETY ACT:
HOW IS FDA DOING 10 YEARS LATER?"**

BEFORE THE

**SENATE COMMITTEE ON GOVERNMENTAL AFFAIRS,
SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT, THE FEDERAL
WORKFORCE AND THE DISTRICT OF COLUMBIA**

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Good morning, Chairman Voinovich, Ranking Member Durbin, 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.¹ 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.

The Dietary Supplement Health and Education Act of 1994 (DSHEA) created a very serious regulatory loophole that has opened the floodgates to thousands of untested dietary supplement products. 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 pre-market safety testing.

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 10 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

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.

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; and to initiate and cooperate with individual and group efforts to maintain and enhance the quality of life for consumers. Consumers Union's income is solely derived from the sale of *Consumer Reports*, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, *Consumer Reports* and *Consumer Reports Online* (with approximately 5 million paid circulation) regularly carry articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions which affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

Nine years later, 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 deaths and disabling injuries. The other four supplements are still being marketed and sold in retail stores and on the Internet.

In May 2004, *Consumer Reports* published a new 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 in February, include:

- **Aristolochia:** An 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.

The *Consumer Reports* article describes 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 addition to being a powerful kidney toxin, *Aristolochia* is on the World Health Organization's list of human carcinogens. The herb has been banned in seven European countries, Egypt, Japan and Venezuela. In the U.S., the FDA issued a warning to consumers and industry and an import alert in April 2001. And most recently on May 19th, DHHS's National Toxicology Program nominated *Aristolochia* for review for possible listing in the upcoming 12th edition of the governments' Report on Carcinogens.²

While we believe that all of the 12 supplements named in our report 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. We believe that the consumer interest also requires establishment of an effective preventive safety system that would include pre-market safety evaluation, mandatory reporting for adverse events, and increased FDA regulatory authority to take prompt action against known and emerging hazards.

² Federal Register, 5/19/04, p. 28940

HOW MANY OTHER HAZARDOUS SUPPLEMENTS ARE THERE?

In addition to the 12 priority supplements named in our article, we think it is likely that there are other dietary supplement products that pose unacceptable risks to consumers.

To take just three other examples:

- Long-term use of dietary supplements containing colloidal silver can lead to argyria, 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.³
- Usnic acid, a supplement ingredient derived from lichens, may be highly toxic to the liver, and has been linked to reports of liver failure. The FDA has issued warnings about products containing usnic acid, and is investigating whether to take further action.⁴
- 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.⁵

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 are probably safe, consumers face particular risks from certain herbs that are highly toxic, and supplements that contain untested steroid equivalents. Without additional resources and regulatory authority, it simply is not possible for the FDA or anyone to know exactly how many more of these products pose serious hazards to consumers. The fact that we don't know the full extent of the supplement dangers ought to be serious cause for alarm.

EPHEDRA SUPPLEMENTS FINALLY REMOVED FROM MARKET IN APRIL 2004

Like many consumer and public health organizations, we were very pleased that the FDA finally took action to remove dietary supplements containing ephedra from the marketplace in January 2004. However, we are very concerned that the FDA's action came too late for many consumers, who experienced unacceptable health damage, including strokes, seizures, heart

³ For example, see "Rosemary's Story," by Rosemary Jacobs, available on the Web at: <http://homepages.together.net/~rjstan/rose2.html>

⁴ Grady, Denise. "Seeking to Fight Fat, She Lost Her Liver," The New York Times, March 4, 2003, p.1. "After ephedra ban, FDA is checking other supplements, says Crawford," Nutraceuticals International, Vol 9., No. 5, May 2004.

⁵ 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>

attacks and deaths. Despite numerous serious warning signals, the agency failed to take action in a timely way to remove the product from the marketplace.

By the time the FDA finally moved to ban ephedra sales, ephedra was already being driven out of the marketplace by high profile deaths of athletes, the resulting negative media attention, litigation, rising insurance costs, and statewide bans in three states (Illinois, New York and California). Professional sporting organizations had taken action to prevent use of ephedra by athletes. The U.S. Army and Air Force military exchanges had moved to remove dietary supplements containing ephedra from military commissary shelves worldwide.

Ephedra is a poster child for a failed policy. We need to examine what went wrong in this instance, because new dietary supplements that contain existing or novel ingredients, and reformulations or new combinations of those ingredients, are being constantly introduced, at a rate of 1,000 new supplement products per year. We need to understand why the signals of an urgent public health problem failed to trigger prompt action by the federal government.

Consumer groups and medical providers had been urging the federal government to take action against ephedra literally for years. Consumers Union worked very hard to get the states of Illinois, New York and California to ban ephedra at the state level, which they did successfully, months before the FDA finally took action. We did this because consumers were at risk and in real danger. State legislators could see this was an important community issue, that the federal government was failing to address.

As long ago as September 1994, the FDA had reported that it was receiving consumer complaints about health effects associated with the use of ephedra.⁶ From January 1993 through October 2000, the FDA received 1,398 reports of adverse events linked to herbal supplements containing ephedra, including 81 deaths, 32 heart attacks, 62 reports of cardiac arrhythmia, 91 reports of hypertension, 69 strokes and 70 seizures. By June 2003, the GAO reported the FDA had received a total of 2,277 adverse event reports about ephedra.

These reports are likely just the tip of the iceberg. The vast majority of adverse reactions to dietary supplements or medications are never reported to the FDA, or indeed to any health professional or agency. A study commissioned by the FDA estimated that the adverse event reports the FDA receives represent less than 1 percent of all the adverse events associated with dietary supplements.⁷

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”

⁶ “Adverse Events with Ephedra and Other Botanical Dietary Supplements,” FDA Medical Bulletin, September 1994, posted on the Web at: <http://vm.cfsan.fda.gov/~dms/ds-ephe2.html>

⁷ Walker, A. “The Relation Between Voluntary Notification and Material Risk in Dietary Supplement Safety,” FDA Commissioned Paper, March 9, 2000.

because of inadequate authority and organizational capacity to collect and take action on adverse event reports.⁸ 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.⁹

POISON CONTROL CENTERS RECEIVED MANY REPORTS REGARDING ADVERSE REACTIONS TO SUPPLEMENTS CONTAINING EPHEDRA

However, in addition to the direct reports that the FDA receives, there were other important signals of problems with dietary supplements containing ephedra. According to the American Association of Poison Control Centers, accidental or intentional incidents involving ephedra have resulted in thousands of consumers visiting emergency rooms and health care facilities for treatment.

In its most recent annual report, the AAPCC indicates that in the year 2002 alone there were:

- 1,556 reported events relating to exposure to dietary supplements containing ephedra as a sole ingredient, including one death, 248 adverse reactions, 20 "major effects" (defined as exhibiting signs or symptoms that were life-threatening or resulted in significant residual disability) and 274 "moderate effects" (defined as exhibiting symptoms or signs that were more pronounced, more prolonged or more systemic in nature than minor symptoms--and where usually some form of treatment is indicated). Of the 1,556 exposures, 843 persons (54%) were treated in a health care facility.
- 8,770 reported events linked to exposures to multi-botanical supplements containing ephedra as an ingredient, including two deaths, 1,180 adverse reactions, 88 "major effects" and 1,531 "moderate effects." Of the 8,770 exposures, 4,827 persons (55%) were treated in a health care facility.¹⁰

For herbal and homeopathic dietary supplements as a whole, the AAPCC estimates that there were nearly 22,928 reported exposure events in the year 2002. Of this total, 8,831 people were treated in health care facilities.

MANUFACTURERS HAVE SUPPRESSED INFORMATION REGARDING DIETARY SUPPLEMENT ADVERSE EVENTS

⁸ Office of Inspector General, Department of Health and Human Services, "Adverse Event Reporting For Dietary Supplements: An Inadequate Safety Valve," April 2001, OEI-01-00-00180.

⁹ Ibid, p. ii.

¹⁰ Watson, et al, "2002 Report of the American Association of Poison Control Centers Toxic Exposure Surveillance System," American Journal of Emergency Medicine, Vol. 21, No. 5, September 2003, p. 351-421.

A second very important source of data on problems with ephedra were adverse event reports received by manufacturers. Strong evidence has now emerged that manufacturers of ephedra supplements concealed substantial numbers of consumer complaints regarding their products:

- 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.¹²
- Two years ago, 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.¹³

While it isn't clear how many other manufacturers and sellers of other dietary supplement products may be suppressing information regarding potential health effects, those examples do not inspire confidence that serious health impacts arising from the use of herbal supplements will be promptly reported to responsible health authorities under a voluntary reporting system. This also underscores the dangers of allowing herbal medicines in the marketplace without premarket safety testing and a rigorous post-marketing surveillance system.

In the five years after DSHEA took effect, from 1994 to 1999, fewer than 10 of the more than 2,500 reports that the FDA received came from manufacturers, according to a 2001 estimate from the inspector general of the U.S. Department of Health and Human Services.

THE FDA'S INABILITY TO COLLECT AND ACT ON MOUNTING ADVERSE EVENT REPORTS CREATED A SERIOUS GAP IN CONSUMER PROTECTION

When we add this all up, the federal government's failure to promptly act on available signals of serious consumer health problems with a particular dietary supplement is very disturbing. Consumers expect government to take an active role in ensuring that dietary supplements are safe and effective.

¹¹ Neergaard, L. Feds investigate top ephedra seller, Associated Press, August 15, 2002.

¹² Crabtree, P. Metabolife understated danger: firm glossed over complaints about herb ephedra, panel told. San Diego Union Tribune, October 9, 2002.

¹³ Howe, K. FDA Stops Tracking Herbal Remedies: Agency says it doesn't have the funding to assess adverse reactions, San Francisco Chronicle, February 14, 2000, p. A1.

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 oversight required for prescription and over-the-counter drugs, DSHEA has created a troubling and unexpected gap in consumer protection.

Many consumers are surprised to learn the government does not currently evaluate the safety of dietary supplements before they are sold.¹⁴ 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, testified in Congress in March 2001 that the current "regulation of dietary supplements is, for the most part, a post-marketing program."¹⁵

As noted above, 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.

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 the poll were 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 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. But as we have just seen, supplement makers are not required by law to report adverse events. The reporting system is strictly voluntary, and apparently yields very few reports to the FDA.

We wonder, as we sit here today, what else manufacturers may have known about the dangers of ephedra and other dietary supplements, including those on our "dirty dozen" list. Unless the

¹⁴ 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.

¹⁵ Statement by Joseph Levitt, Esq., Director, CFSAN/FDA, before the Committee on Government Reform, March 20, 2001, available on the Web at <http://www.fda.gov/ola/2001/dietary.html>

Congress acts to tighten requirements for adverse event reporting by manufacturers, FDA will continue to lack vital information that is needed to ensure the safety of dietary supplements.

CONSUMERS WANT ADDITIONAL PROTECTIONS TO ENSURE SUPPLEMENTS ARE SAFE

Last month, Consumers Union conducted an online survey of a random sample of 1,221 adults regarding dietary supplements, as part of a regular national consumer issue survey that we perform. We read respondents a short factual statement about the recent ephedra ban, *Consumer Reports'* findings regarding dangerous supplements, and gaps in dietary supplement regulation. We then asked whether they agreed or disagreed with five statements. The survey found that:

- More than 8 in 10 respondents agree that poor regulation of supplements posed a personal risk to themselves and their families.
- More than 9 in 10 want the sale of supplements to be conditioned on safety and efficacy.
- Virtually everyone (96%) agreed that supplement producers should be required to report adverse events, as is required for prescription drugs.
- Similarly, 96% want product risk information to be included on dietary supplement labels.
- Fewer than 1 in 5 respondents feel that supplements already are sufficiently regulated.

Concern about dietary supplements was broader than for any other consumer issue in our multi-issue survey, which also included questions about car safety, cable television, fuel efficiency, and cell phones.¹⁶

We believe very strongly that the current serious gaps in consumer protection in DSHEA are not in the interest of dietary supplement consumers. 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.

DIETARY SUPPLEMENTS MARKETED AS “EPHEDRA-FREE” ARE NOT NECESSARILY SAFE

Many companies are currently rushing to market with 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.”¹⁷

¹⁶ Consumers Union Dietary Supplement Survey, June 4, 2004. A total of 1,221 online surveys were conducted among a random sample of U.S. adults. Interviewing took place over May 12-17, 2004. Agreement varied little by gender, age, income or region of residence.

¹⁷ Jill Burcum, “Your Health: Ephedra-free products loaded with new herbs of concern,” Minneapolis Star Tribune, April 29, 2003.

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.

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.

In May, the *Annals of Pharmacotherapy* published a detailed case-report describing a possible association of heart failure (acute lateral-wall myocardial infarction) with the use of a dietary supplement containing bitter orange.¹⁸

Of course, it is difficult to extrapolate from individual reports such as these to establish definitively that a product is unsafe. However, this illustrates perfectly the inappropriate burden-shifting for safety established under DSHEA. 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.

DSHEA LOOPHOLES PERMIT SALE AND MARKETING OF UNTESTED STEROID EQUIVALENTS

Dangerous loopholes in DSHEA and the Controlled Substances Act permit manufacturers to aggressively market and sell untested, unregulated steroid equivalents to the public, including persons under 18. A national survey conducted for the Blue Cross Blue Shield Association in 1999 found that six percent of youths ages 15 to 16 and eight percent of 17- and 18-year-olds had taken a sports supplement. Yet as we noted in *Consumer Reports* magazine in June 2001, sports-medicine researchers have only tested products like androstenedione and creatine in adults.¹⁹ There has been no systematic testing of these drugs in minors, and for ethical reasons, such tests probably will not be conducted. For safety reasons, numerous sporting and medical

¹⁸ Nykamp, Diane L., Fackih, M.N., and Compton, A. L., “Possible Association of Acute Lateral-Wall Myocardial Infarction and Bitter Orange Supplement,” *The Annals of Pharmacotherapy*, May 2004, Vol. 38, p. 812-815.

¹⁹ “Sports Supplement Dangers,” *Consumer Reports*, June 2001, p. 40.

organizations, including the AMA and the American Academy of Pediatrics, believe that steroid precursors should be classified as Controlled Substances. Because of the safety issues involved, we support this approach, and urge Congress to regulate all steroid precursors under the Controlled Substances Act—including DHEA.

POTENTIAL FOR ADVERSE REACTIONS WITH PREEXISTING HEALTH CONDITIONS AND/OR OTHER MEDICATIONS

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.

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 use 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.²⁰

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. However, according to the American Society of Anesthesiologists, seven in 10 consumers do not discuss the use of supplements with their doctor.

RECOMMENDATIONS

As a nation, we stand at a crossroads regarding dietary supplement safety. For the last ten years, consumers have borne the unacceptable risks and consequences of a law that allows untested

²⁰ Grollman, Arthur, MD. Testimony before Senate Commerce Committee hearing on dietary supplements, October 28, 2003.

supplements to be aggressively marketed and sold, with no prior safety testing and evaluation. This situation 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 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. We also believe that the existing dangers will be very difficult to address by banning or restricting individual substances or groups of substances, because such restrictions can be easily bypassed as new supplements are introduced with different ingredients or formulations.

- 1. Congress should make appropriate modifications to DSHEA to create a sensible preventive safety system that ensures that dietary supplement products are reviewed for safety prior to marketing and sale. The safety system must also include effective post-marketing surveillance so that the government can take prompt safety actions as needed, including product recalls, warnings, and import alerts. 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.**

At a minimum, we strongly support the provisions in the "Dietary Supplement Safety Act of 2003" (S. 722) that would enable the FDA to take unsafe products off the market more quickly. S. 722 would require stimulants to be approved as new drugs, would declare foods containing unapproved stimulants to be adulterated, and prohibits the introduction into interstate commerce of a supplement containing a stimulant unless it is approved by the Secretary. These provisions would also be extremely helpful for addressing the hazards posed by other weight loss supplements that contain dangerous stimulants, and steroid precursors.

We also support the provisions in S. 722 that would authorize the Secretary of the Department of Health and Human Services (DHHS) to require the manufacturers of dietary supplements, or any ingredient in a dietary supplement to submit data demonstrating that the dietary supplement is safe. The Secretary would then be authorized to review the data and issue a determination that either the ingredient is safe and that continued marketing is approved, or that continued marketing is disapproved because either it is unsafe, or it has not been shown to be safe.

- 2. Dietary supplement manufacturers should be required to report adverse events to the FDA.**

The current voluntary reporting system provides insufficient information for public health authorities to take prompt action regarding harmful products that put consumers at serious risk. We strongly support provisions in S. 722 that would require manufacturers, packers and distributors of dietary supplement products to collect, review, and report serious adverse events suffered by consumers using their products to the Secretary of the Department of Health and Human Services (DHHS), within 15 days of receiving notice of the event. In addition, the bill

would require dietary supplement manufacturers to report on all adverse events to DHHS annually.

There is broad consensus among many parties that adverse event reporting is critical to ensuring the safety of dietary supplements. In April 2004, the Institute of Medicine urged the Congress to amend DSHEA to require mandatory manufacturer reporting of serious adverse events. The American Medical Association supports this position. While noting that the requirement may not be necessary for all supplements, the Inspector General of DHHS called in its April 2001 report for mandatory reporting for some products. Also, in March 2002, the White House Commission on Complementary and Alternative Medicine Policy called for supplement manufacturers and suppliers to be required to maintain records and report serious adverse events to the agency. In the press conference at which the federal ephedra ban was announced in December 2003, Secretary of Health and Human Services Tommy Thompson stated that “it would be nice” to have authority to require mandatory adverse event reporting. Finally, even some industry trade associations have stated that they could support mandatory reporting of serious adverse events.

We believe that the FDA must be given additional resources and a resounding mandate from Congress to strengthen post-marketing surveillance of dietary supplements. As a first step, we support the provisions of S. 722 that would authorize the Secretary of DHHS to require manufacturers of dietary supplements to conduct post-market surveillance if the Secretary determines that consumer use of a manufactured dietary supplement may result in serious adverse events.

Consumers Union also support the provisions in a House measure, HR 3377, introduced by Representatives Susan Davis, John Dingell and Henry Waxman, that would enhance the FDA’s authority to ensure supplements are safe, provide additional information to consumers, and require manufacturers to report adverse events.

Once again, I thank the Chairman, Ranking Member Durbin and the Committee for the opportunity to testify, and I look forward your questions and comments.