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HEARINGS ON THE DIETARY SUPPLEMENT SAFETY ACT
HOW IS FDA DOING 10 YEARS LATER?

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Hart Senate Office Building
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Good afternoon. I am Bruce Silverglade, Director of Legal Affairs, of the Center for Science in the Public Interest (CSPI). With me today is Ilene Ringel Heller, senior staff attorney at CSPI. We are pleased to have this opportunity to testify on the Dietary Supplement Safety Act: How is FDA Doing 10 Years Later? CSPI is a nonprofit consumer advocacy organization based in Washington, D.C. We were founded in 1971 and are now supported by more than 750,000 subscribers to our *Nutrition Action Healthletter*, membership donations, and foundation grants. We accept no money from industry or government. Most of our current work focuses on improving the safety and nutritional quality of our food supply and we have worked extensively to ensure that dietary supplements are safe and honestly labeled.

I. Introduction

It has been 10 years since the enactment of the Dietary Supplement Health and Education Act of 1994 (DSHEA). It is certainly appropriate to review the impact of this legislation on consumers and discuss the need for reforms such as those included in S. 722, the Dietary Supplement Safety Act. We support this legislation and urge Congress to enact it this year. As I will explain in a moment, however, Congress needs to extend attentional protections to consumers that are not included in this bill.

Since 1994, Americans have become increasingly cognizant of the benefits that many dietary supplements can provide. Today, half of all American adults take vitamin or mineral supplements, and one in three has tried herbs. One of the reasons for this trend is that many Americans are disenchanted with a medical establishment that increasingly funnels patients through doctors’ offices as if they were on an assembly line. In addition, consumers hear more and more about promising research that some dietary supplement ingredients may hold the key to preventing cancer and other dreaded diseases. Our publication, *Nutrition Action Healthletter*, regularly reports on these developments. In light of such factors, many Americans want to take control of their own health.

Many supplements are undoubtedly beneficial. For example, millions of Americans need to consume more calcium to help prevent osteoporosis. Women of childbearing age who consume sufficient amounts of folic acid can reduce the risk of neural tube defects in their unborn children. A growing number of studies suggest that saw palmetto can help men with benign enlarged prostates. In brief, more and more Americans are getting the message that dietary supplements can play an important role in maintaining good health and can sometimes provide a valuable adjunct to conventional medical treatment.

Unfortunately benefits have not been established for all supplements, and many consumers cannot determine on their own which products are worth consuming and which are nothing more than 21st century snake oil or even dangerous. As Americans increasingly use supplements to promote their health, it is critical that Congress ensure that such products are safe and that label claims are accurate and scientifically valid.
II. History of DSHEA

Supplement manufacturers themselves deserve much of the blame for unsafe ingredients, poor quality products, and misleading promotional practices that now plague the marketplace. In 1994, the industry successfully lobbied Congress for legislation that made it more difficult for the Food and Drug Administration (FDA) to do its job. Health-food retailers were enlisted to whip consumers into a frenzy by telling them, falsely, that the FDA was about to require physicians’ prescriptions for ordinary vitamins. Consumers were then urged to write their members of Congress in support of legislation drafted by industry lobbyists that would curtail the FDA’s authority. (The same ploys are now being used to organize opposition to S. 722.)

Congress responded by passing the DSHEA. The 1994 law has led to short-term economic gains for supplement producers, but has caused a myriad of problems for consumers, including unsafe ingredients, low quality products, and a marketplace free-for-all of misleading claims. I will discuss each of these matters in turn.

III. Safety Problems

DSHEA changed the prevailing approach to product safety under the Federal Food, Drug, and Cosmetic Act. The manufacturers of food additives, drugs, and medical devices must prove that their products are safe before they can be sold. DSHEA, however, freed manufacturers from the responsibility of demonstrating that supplement ingredients are safe before they are sold. Although the FDA still has the authority to take dangerous products off the shelves, it must first prove that the products pose a “significant or unreasonable risk.” That means that the FDA must build a case before it can take action and people are often injured in the interim.

In addition, manufacturers have no legal obligation to turn over reports of adverse health reactions to the FDA. Such information is essential to ascertaining whether a product is causing harm, especially in the absence of any pre-market approval system. Without such data, it is extremely difficult for FDA to obtain both the quality and quantity of information needed to demonstrate that a product causes a “significant or unreasonable risk” under current law.

Thus, as a practical matter, the FDA has not been able to effectively utilize the authority granted to it by DSHEA. Consequently, the agency has been forced to rely on woefully inadequate remedies such as issuing public warnings and requesting voluntary recalls. Clearly, a more effective regulatory approach must be found if consumers are to be protected from unsafe products.

Now we all know that the FDA banned ephedra this year (10 years after it issued its first medical bulletin that raised health concerns). But as newspaper editorial boards across the
country noted, ephedra simply epitomized why the current law fails to protect consumers from hazardous products. The *Washington Post* called DSHEA a “truly terrible law” and the *New York Times* called the ephedra ban “not enough” and urged Congress to “revise the ill-conceived 1994 legislation.”

The agency has tried to put the best light on what most FDA staff would acknowledge privately is a bad law. For example, media accounts of a speech by former FDA Commissioner Mark McClellan state that the agency is becoming more aggressive in gathering safety evidence about other supplements beyond ephedra that it views as potentially harmful. The FDA’s statements to the media specifically mentioned that the agency was tracking three weight loss supplements posing risks similar to ephedra: bitter orange, aristolochic acid, usnic acid — as if this were an important new development. However, aristolochic acid was already the subject of an FDA consumer advisory in 2001, a health professionals alert in May 2000, and an import alert in July 2000 and April 2001. Usnic acid was an ingredient in the dietary supplement LipoKinetix that FDA warned consumers not to use in 2001.

Since 2001, FDA’s Compliance Program has instructed inspectors to collect samples of both aristolochia and bitter orange so that FDA can “evaluate the possible health risks.” It is interesting to note that the 2001 compliance program which is still in effect, states that “At this time, no regulatory/enforcement actions are planned or anticipated for products containing these ingredients.” Thus while FDA may be “talking a new talk, it is walking the same walk.” The root problem is that the 1994 law that the FDA must administer relies on manufacturers to determine whether a product is safe and then prevents the agency from acting promptly and decisively when problems arise.

The FDA takes the same all-talk, no action, approach with respect to other types of dietary supplements as well. For example, St. John’s wort, used to treat mild cases of depression (its purported benefits are controversial and not established) can interact with oral contraceptives and reduce their effectiveness. It may also interfere with a protease inhibitor used to treat HIV infection and drugs used to treat heart disease or to prevent conditions such as transplant rejection. The FDA has issued an alert about such problems, but how many consumers are actually aware of that information?

The safety problem is compounded by manufacturers that sell traditional herbal medicines for non-traditional purposes. A herb that may have produced minimal side effects when used for a traditional purpose may cause severe adverse reactions when used for a different purpose. Consumers may assume that the herb is safe because it has been used in China for hundreds of years. What people do not realize is that while a botanical may be safe for some uses, it may not be safe for other uses.

Also, many consumers do not understand that if a supplement such as a herbal medicine has health benefits, it probably also has health risks simply because it is pharmacologically active. Many prescription drugs come from plants, and the dangers of prescription drugs are
well known. But supplement consumers often mistakenly believe that “if it is natural it must be safe.” Unfortunately, nothing could be further from the truth. All of these considerations call for a reexamination of the regulatory framework set out in DSHEA to ensure supplement safety.

S. 722 would help address some of these problems by requiring that manufacturers report serious adverse reactions to the FDA. The agency could then insist that the manufacturer demonstrate the safety of the product or take it off the market. Under DSHEA, the FDA has no authority to require that firms report consumer complaints about adverse reactions. Instead, the agency must rely on companies to voluntarily report problems. The extent of under reporting is illustrated by the fact that in just one private law suit involving a weight-loss product containing ephedra, lawyers uncovered 3,500 complaints that had never been forwarded to the FDA. Clearly, this situation must change.

S. 722 would also require pre-market approval for stimulants, one category of dietary supplements that pose some of the most severe hazards. These are useful reforms that we support. But Congress should go further:

• Safety standards for dietary supplements intended for use by children, pregnant women, the elderly, and other vulnerable sub-populations determined by the agency to be at particular risk should be raised and manufacturers should be required to submit evidence of safety to FDA before such products are sold.

• In addition, manufacturers should only be permitted to make safety-related claims in labeling and advertising if the agency has determined by regulation, prior to marketing, that the particular ingredient satisfies the safety standard for that category of supplements.

These steps, together with the provisions incorporated in S. 722, would go a long way to ensuring that supplements in the U.S. are safe.

IV. Good Manufacturing Practice Regulations

The current law fails to require the supplement industry to adhere to strict quality standards. Such rules, which have been in place for over-the-counter and prescription drugs for decades, would help ensure that products are, among other things, free of contaminants. Poor quality has been a nagging concern for the industry. For example, an independent study by Consumerlab.com revealed that eight of 21 brands of ginseng had unacceptable levels of pesticide residues. Two brands contained residues at more than 20 times the amount considered safe. Further, two other brands tested contained high levels of lead. In addition, some dietary supplements containing calcium made from bone meal and consumed by pregnant women have had high levels of lead that potentially could harm the fetus. Others supplements
sold to improve brain function contain concentrated raw brain tissue from cows. That practice is considered inappropriate given the prevalence of mad-cow disease in Europe and the potential that it can lead to a new variety of Creutzfeldt-Jakob disease (CJD) in humans.¹

DSHEA authorized the FDA to issue Good Manufacturing Practice Regulations (GMPs) based on those established for foods.² That requirement is a bit odd because dietary supplements more closely resemble non-prescription drugs and should be manufactured to the same quality standards as those products. In any event, GMPs help ensure that the product contains the precise amounts of ingredients specified on the label and specify production processes that reduce the chances that products are contaminated with undesirable substances.

The FDA issued an Advance Notice of Proposed Rulemaking on GMPs in 1997 and sent a proposed rule to the Office of Management and Budget (OMB) on November 8, 2000.³ However, on February 1, 2001, after the Bush Administration took office, the FDA withdrew the proposed rule, thus delaying publication of the proposal.⁴ After OMB review by the current administration, the FDA ultimately proposed a GMP rule on March 13, 2003. However, many segments of the industry still opposed the proposed rule as too strict. Consequently, a final rule has not yet been issued.

• Given this track record, Congress should intervene and require that an adequate GMP rule be finalized by a deadline imposed by Congress.

I should note that while the development of GMPs is important, they do not ensure that supplement ingredients themselves are safe and effective for their intended use. For example, even if all St. John’s wort tablets manufactured in the U.S. met rigorous GMPs, consumers could still suffer adverse health consequences if they consumed this herbal supplement while also taking various prescription medications.

V. Misleading Labeling Claims

The 1994 law allows manufacturers to make health-related labeling claims – so-called

¹ Geoffrey Cowley, Cannibals to Cows: The Path of a Deadly Disease, Newsweek, Mar. 12, 2001 at 53, 61.
² FDCA § 402(g)(2), 21 U.S.C. § 342(g)(2).
⁴ Id.
structure/function claims – without first proving to the FDA that the claims are valid. An avalanche of misleading claims has resulted. One can find products in health-food stores for almost every ailment under the sun, ranging from improving sex drive to burning fat. But even some nationally advertised, brand-name products sold in large supermarket chain stores have crossed the line.

For example, one of the most popular herbs, garlic, has been widely promoted for maintaining heart health and/or healthy cholesterol levels. Typical claims include statements such as “regular consumption of garlic may help promote healthy heart function and regulate cholesterol levels.” However, a review commissioned by the Agency for Healthcare Research and Quality (AHRQ) concluded that garlic does not appear to have benefits that endure beyond six months and “does not appear to offer long-term protection against cardiovascular disease.” The inability of garlic supplements to reduce cholesterol levels beyond six months is crucial because it is the prolonged elevation of blood cholesterol levels that raises the risk of cardiovascular disease. Thus, a product that does not work beyond six months is virtually useless. (Preliminary evidence, however, still holds out hope that garlic pills may help prevent blood clots, another risk factor in heart disease.)

FDA has recently begun challenging a few structure/function claims as misleading. But without the authority to demand that such claims be authorized prior to marketing, the FDA is unable to protect the public; the agency lacks the resources to engage in lengthy “after-the-fact” litigation against the hundreds, perhaps thousands, of products that make misleading claims.

While the law still requires companies to get FDA pre-market authorization to make expressed disease prevention claims, often referred to as “health claims,” firms are free to make a myriad of other health-related structure/function claims by simply notifying the agency within 30 days after marketing a product. This problem is not addressed by S. 722. We hope it could be. Specifically,

- Structure/Function claims should be subject to the same procedures required in the law for “health claims” for foods. The Act requires that the agency determine, through notice and comment rulemaking, that health claims for foods be supported by “significant scientific agreement.”

The distinctions between the types of claims requiring FDA pre-market authorization

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6 In December 2002, the FDA attempted to reinterpret that statutory requirement. That action had been challenged in court in 2003, See, *Public Citizen v. Food and Drug Administration*, Federal District Court for the District of Columbia, Docket No. 03-1962.
and those that do not are often meaningless to consumers. For example, under FDA rules that attempt to implement this portion of DSHEA, companies can claim that a supplement maintains healthy lung function but cannot say, without first obtaining FDA approval, that a supplement maintains healthy lungs in smokers. However, in both cases, consumers are likely to assume that the products will decrease their risk of lung disease.

As the General Accounting Office (GAO) noted, “FDA conducted nine focus groups on dietary supplement labeling in three cities around the country. Among other things, this research found, ‘there was no indication that participants differentiated at all between structure/function claims and health claims.’ . . . As such, consumers incorrectly view claims to maintain health (structure/function claims) as claims to reduce the risk of, or treat a disease. Consequently, we believe that consumers may attempt to treat a disease with a product not capable of producing this benefit.”

This loophole in the law is particularly disturbing considering that the presumed benefits of some supplements are based on anecdotal evidence or studies that were not conducted in accordance with modern scientific techniques. Moreover, many, if not most, companies making health-related structure/function claims have reportedly failed to even comply with the weak FDA notification requirement contained in DSHEA. Not surprisingly, many outlandish claims on supplements have appeared on store shelves since DSHEA was enacted.

VI. Conclusion

Unsafe ingredients, poor quality products, and misleading claims may now be adversely affecting sales; recent figures suggest that some supplement sales are declining. The industry is running a public relations and lobbying campaign in an attempt to woo consumers back to supplements. But by continuing to demand weak regulation, the dietary supplement industry is essentially "shooting itself in the foot." And, as more and more adverse reactions to supplements are reported in the media, and misleading health-related claims proliferate, consumers will likely turn away from supplements in greater and greater numbers. That would be unfortunate as many supplements provide real health benefits.

7 Food and Drug Administration Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Final Rule, 65 Fed. Reg. 999, 1018 (Jan. 6, 2000).

8 General Accounting Office, Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and ‘Functional Foods,’ at 23 (GAO/RCED--00-156 July 2000)

As Americans come to depend on supplements to address serious health concerns, it is all the more important that government ensure that products are safe and that claims on labels are backed by solid scientific evidence. We support S. 722 and urge Congress to go further as we have suggested.

We wish to thank the Committee for the opportunity to testify.