UNITED STATES OF AMERICA
BEFORE THE SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT, RESTRUCTURING AND THE DISTRICT OF COLUMBIA
UNITED STATES SENATE

Testimony of Michael McGuffin
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My name is Michael McGuffin. I am president of the American Herbal Products Association (AHPA), the national trade association and voice of the herbal products industry. AHPA serves its members by promoting the responsible commerce of products which contain herbs and which are marketed as dietary supplements and are used to enhance health and quality of life. I have been associated with the herbal products industry for over twenty years and was an owner and manager of an herbal product company prior to taking my present position. I am pleased to respond on behalf of AHPA to the questions posed by the Subcommittee.

How does the supplement industry self-regulate and keep potentially dangerous, ineffective, or contaminated supplements from being sold to consumers?

As the Subcommittee is aware, it is a crime under the Federal Food, Drug and Cosmetic Act to sell an adulterated (contaminated or dangerous) or misbranded (falsely or misleadingly labeled) dietary supplement. In addition, the Food and Drug Administration and the Secretary of Health and Human Services have the power to regulate potentially dangerous dietary supplements and to proceed summarily against dietary supplements that pose an imminent hazard for consumers. The Federal Trade Commission, acting under the Federal Trade Commission Act, also acts against dietary supplements that are advertised falsely, or that make misleading claims or are otherwise not unfair or deceptive. Most states have laws that track these federal laws.

AHPA and its members have been and continue to be actively involved in self-regulatory activities related to dietary supplements containing herbal ingredients. One of the ways that AHPA promotes responsible commerce in herbal dietary supplements is by establishing trade recommendations for its members. These self-regulatory policies are defined as conditions of membership and are set forth in AHPA *Code of Ethics & Business Conduct*, attached hereto and should be considered as part of our response to this question. We also inform the FDA and the FTC of our policies.

Several of AHPA's trade recommendations are responsive to the issues identified in this question. Thus, in 1996 a trade recommendation was adopted to require that products containing herbs with toxic pyrrolizidine alkaloids, such as comfrey, be labeled for limited and external use only. FTC initiated enforcement against a company two years ago on grounds significantly similar to AHPA's trade recommendation on comfrey. Similarly, two policies have been adopted, one in 1997 and one in 2001, to prevent the internal use of plants that contain aristolochic acid, which is potentially nephrotoxic and carcinogenic. FDA initiated a series of product recalls in 2001 on grounds significantly similar to AHPA's policy on aristolochic acid. AHPA has also adopted specific responsible labeling recommendations for chaparral (January 1995), and kava (Sept. 1997 and revised). With respect to herbal ingredients used for weight loss, AHPA has established trade recommendations for ephedra (March 1994 and revisions) and stimulant laxatives (July 1995 and revised).

AHPA also published the *Botanical Safety Handbook* in 1997 to provide safety information for over 500 botanicals, including most of those widely sold in United States commerce. The information contained in this document is useful in providing manufacturers with information that can assist in the labeling of herbal products, and our organization has adopted a policy that will require the use of such labeling beginning in October of this year. In at least one case, FDA has utilized the recommendations in this AHPA reference to support regulatory action taken with respect to herbal product labeling.

AHPA has no monitoring or enforcement mechanism for the trade recommendations that have been adopted by our Board of Trustees on our members' behalf. We have, however, turned away prospective members who were not in compliance on at least two occasions. We firmly believe all of our self-regulatory trade recommendations and guidelines are in the public interest and promote responsible commerce in botanicals. We also believe that we have been and remain ahead of federal regulatory agencies with respect to encouraging the herbal supplement industry to label their products with useful and important information for consumers.

With regard to the issue of product contamination, AHPA was one of several trade associations who submitted a proposal to FDA for the establishment of current good manufacturing practice (cGMP) for dietary supplements in 1995. Dietary supplements are currently regulated under cGMP for foods as found in Title 21 of the *Code of Federal Regulations*, Part 110. The state and federal laws I mentioned at the outset already forbid the introduction into commerce of contaminated foods and cGMP regulations establish the appropriate practices for their manufacture. Nevertheless, AHPA believes that cGMP specific to dietary supplements may provide better protection against contamination.

AHPA is aware that other trade organizations are also engaged in activities related to the safe use of uncontaminated dietary supplement that effectively provide benefits for consumers. The National Nutritional Foods Association (NNFA), for example, has produced a number of background documents on key dietary ingredients. In addition, NNFA has established a cGMP audit program for dietary supplement manufacturers. Also, the Council for Responsible Nutrition (CRN) has published documents related to the safety and utility of numerous nutritional supplements. Both associations were part of the group that established the draft cGMP for dietary supplements in 1995.

What types of training, experience, and certification are required to become a dietary supplement manufacturer?

The FDA's cGMP for foods requires that manufacturers of foods, and so by extension dietary supplements, assure that personnel responsible for identifying sanitation failures or food contamination have education and/or experience to provide a level of competency necessary for production of clean and safe food. In addition, this regulation requires food and dietary supplement handlers and supervisors to receive appropriate training in proper food handling techniques and food-protection principles and to be informed of the danger of poor personal hygiene and unsanitary practices.

When AHPA and others submitted our proposed cGMP for dietary supplements to FDA in 1995, we suggested that the requisite training and experience for manufacturing dietary supplements be extended beyond the basic sanitary concerns identified for foods. Thus, we requested that FDA establish a requirement that **all** persons engaged in the manufacture of a dietary supplement product, not only those responsible for sanitation, should have the proper education, training, and experience (or any combination thereof) needed to perform the assigned functions. We also proposed that all training should be in the particular operation(s) that the employee performs as they relate to the employee's functions and that appropriate documentation of training be retained by the manufacturer.

The industry proposal for cGMP for dietary supplements was published by FDA as an advance notice of proposed rulemaking in the *Federal Register* on February 6, 1997. Although completion of this process has been listed as an agency priority in each of the past several years, no subsequent publication of a proposed rule for dietary supplement cGMP has been forthcoming in the intervening 5 years.

To the best of AHPA's knowledge, there are no certification requirements to become a manufacturer of a food, drug, or a medical device. Somewhat similar to the cGMP for foods but more like the cGMP proposed by dietary supplements for industry, the FDA cGMPs for these other product categories require that persons engaged in the manufacture these products must be have experience or training for their particular position.

Can you describe specific efforts the industry has made to deal with companies or individuals promoting ineffective or unsafe products?

As stated at the outset, it is a crime to market an adulterated or misbranded dietary supplement. The FDA through the Department of Justice and the FTC have authority to enforce these laws, whereas industry has no such authority. Specific efforts that the industry has made to deal with products that are not in conformity with existing laws involve communication with one or another of these enforcement agencies.

For example, FDA issued a press release in April 1996 to warn consumers regarding companies who were engaged in plainly unlawful labeling products as dietary supplements that were being marketed and sold as substitutes for illegal drugs. We subsequently submitted comments to a meeting of the Special Working Group on Foods Containing Ephedrine Alkaloids of the FDA's Food Advisory Committee on August 27, 1996 in which we suggested that such products were illegal and subject to federal enforcement under the Controlled Substances Analogue Enforcement Act of 1986. Some limited enforcement occurred about a year later, in August 1997, but it was not until almost four years later, in April 2000, that FDA actually issued guidance in this matter. Frankly, FDA's limited response with respect to what have come to be called "street-drug knockoffs" was surprising given this government's firmly established policies against substance abuse.

Another example is the action that AHPA initiated last fall when our country was dealing with the fear generated by letters delivered to U.S. Senate offices and elsewhere that contained potentially deadly anthrax spores. Within a matter of weeks of these terrorist attacks, AHPA developed a policy against the sale or marketing of any dietary supplement for treatment or prevention of anthrax. We communicated this position not only to the FDA and to the FTC but also to several organizations that represent practitioners of various disciplines of complementary and alternative therapies. Many of these organizations followed AHPA's lead in this matter, and FTC also made it clear that it would not tolerate advertising either supplements or medical devices for such a purpose.

With respect to ephedra, AHPA actively communicated its labeling recommendation for ephedra-containing dietary supplements in the spring of 1994, even before the Dietary Supplement Health and Education Act of 1994 was passed. FDA initiated an Ephedra product labeling rulemaking in 1997 and that proposal has since been essentially withdrawn. Because labeling is important, AHPA and the other trade associations of the dietary supplement industry filed a Citizen Petition with the FDA in October 2000 that would have had FDA adopt an enforcement policy essentially mandating ephedra product labeling. FDA's response has been that the proposal raises complex issues and will take a substantial time to address.

There is a limit, however, to what any trade association can do to separate out bad products or bad actors. Rather, in our system we rely on the "big stick" of the federal enforcement agencies. AHPA and other trade associations have expressed their support for Congressional appropriation of sufficient funds specifically earmarked for dietary supplement enforcement by FDA. There was an increase in such funding for the current fiscal year, and I am sure that the industry, consumers and Congress should see heightened FDA enforcement.

Can you tell us about Dr. Bill Gurley's 2000 study, in the American Journal of Health-System Pharmacy, on the high rate of variability in the quantity of active ingredients seen in ephedra-containing products?

AHPA issued a press release on May 19, 2000 that examined Dr. Gurley's article, especially in relation to products that he tested that were manufactured by AHPA member companies. A copy of that press release is attached hereto and should be incorporated into this response.

What safeguards has the industry established to ensure that the quantities included in a supplement product match the quantities listed on the label?

It is a crime to label a product as containing ingredients or amounts of ingredients that are not in the product. That has been the law since 1906.

As discussed above, the dietary supplement industry submitted a proposal for cGMP regulations to FDA in 1995. Some elements of this industry proposal were designed to assure that the identity and quantity of ingredients added to dietary supplements are accurate when they are manufactured. Botanical ingredients in dietary supplements present unique analytical challenges for companies that choose to identify and quantify an herb's constituents on their product's label. Several companies have therefore provided funding for the past several years to support nonprofit organizations such as the American Herbal Pharmacopoeia (AHP) and the Institute for Nutraceutical Advancement (INA). These organizations have published quality monographs and analytical methods for a number of botanicals (AHP) and have developed such methods for other herbs and non-herbal ingredients (INA). More recently, AOAC International has become actively

involved in the process of validating these and other analytical methods.

The validation of analytical methods is an expensive process as it involves the efforts of multiple qualified analytical laboratories in the simultaneous review of a target method. Often this is done on a voluntary basis, producing inevitable delays in the process. In order to accelerate this important work, AHPA communicated actively with the U.S. Senate's Committee on Appropriations to recommend funding to support this work. Our efforts were ultimately successful, resulting in appropriations through the National Institute of Health's Office of Dietary Supplements in the current fiscal year. These funds are earmarked for the development of additional analytical methods for ingredients in dietary supplements.

What safeguards does the industry have to ensure that contamination doesn't occur as just recently happened with the product Nettle, by Nature's Way Products, which was found to be contaminated with high amounts of lead?

Contamination or adulteration of products occurs in all of the FDA regulated industries. The FDA urges companies to report such situations to the agency when they find adulteration or when it is brought to their attention. Nature's Way acted responsibly by reporting to FDA and conducting a recall. Their response was similar to that taken by ConAgra with the announcement last week of the recall of 19 million pounds of beef potentially contaminated by pathogens.

FDA's website (www.fda.gov/oc/po/firmrecalls/archive.html) maintains records of all recalls conducted for products that it regulates. A review of all such records from January 1, 2002 records 39 incidents of food recalls, usually for undeclared ingredients or pathogenic contamination. In addition, four drugs have been recalled in 2002, as have two medical devices, one feed supplement and one infant formula. Besides the Nature's Way product there has been one other recall of a dietary supplement this year.

AHPA has adopted two trade recommendations that deal directly with adulteration of herbal dietary ingredients. In 1997, AHPA adopted a policy to recommend that appropriate steps be taken to assure that four specifically identified herbs are not inadvertently confused with known potential adulterants. AHPA has developed a proposal to provide better information to manufacturers to assist in this process. In addition, AHPA issued a trade recommendation in 1999 related to the potential presence of pesticides in ginseng. This trade recommendation was issued after our industry became aware that ginseng growers and shippers in the Far East were using pesticides in the growing and storing of ginseng. Industry representatives met with source country regulatory authorities and expressed concern over the situation. FDA was kept fully apprised of our efforts in this regard and in fact detained a number of ginseng shipments coming into the United States.

It is our intention to address the issue of heavy metals in botanicals in a similar fashion. In this regard, we are working to develop a comprehensive testing program that will include testing of botanical raw materials prior to their shipment to the United States. In addition, we intend to work with our supplier members and with the governments of supplier countries to assure that this problem is addressed at it source.

How do members of your organization handle adverse event reports?

Based on conversations with several AHPA members in preparation for this hearing, it appears as if most marketers of dietary supplements are prepared to receive calls from their customers who may have complaints, including adverse event reports. Some companies employ staff or consultants who are health professionals to handle all calls that are identified as adverse event reports. Others employ staff who the company judges to be qualified by training or experience to handle such calls.

One of the elements of the proposed cGMP for dietary supplements submitted to FDA in 1995 included a requirement for the retention and follow-up on consumer complaints, including complaints of adverse events.

What is the industry's position on registration of supplement manufacturers and distributors?

The Public Health Security and Bioterrorism Preparedness and Response Act was signed into law by President Bush on

June 12, 2002. This law amended the Federal Food, Drug and Cosmetic Act by requiring that any facility engaged in manufacturing, processing, packing or holding food for consumption in the United States be registered with the Secretary of Health and Human Services (HHS). This new statutory requirement will take effect not later than 18 months after the passage of this law and will apply to any facility engaged in manufacturing, processing, packing or holding dietary supplements for consumption in the United States. This is because dietary supplements are regulated in the main as foods. I will have attended a meeting at FDA on July 30, 2002 where the food and dietary supplement industry were briefed on FDA's plans to implement this law.

It is AHPA's position and the industry's position generally that companies engaged in the dietary supplement industry should be in conformity with all federal, state and local laws. In order to assist in this process, AHPA informed its members on June 17, 2002 of the passage of the new law and will continue to actively communicate with industry and the relevant regulatory agencies to assure wide conformity with facility registration rules.