

The Natural Products Association (NPA) is the oldest and largest trade association representing the natural products industry. It has over 700 diverse member organizations united in providing consumers with access to safe products that will maintain and improve their health. NPA has taken a leadership role in promoting quality standards and has developed proactive certification programs.

The passage of the Dietary Supplement Health and Education Act (DSHEA) represented a balanced and informed approach to protecting consumer health and access to dietary supplements. With DSHEA, Congress took an essential step in recognizing supplements' role in promoting health and preventing chronic illness. In addition, DSHEA ensures access to safe products made to quality standards. The law also emphasizes the importance of communicating the positive health benefits of supplements so consumers can make informed decisions about their health.

Additionally, DSHEA included critical provisions including:

DSHEA defines a dietary supplement as any product that contains one or more dietary ingredients, such as vitamins, minerals, herbs, or other botanicals, amino acids, or other ingredients used to supplement the diet. Dietary supplement ingredients may not be regulated as food additives or drugs.

**Safety:** The legislation maintains the U.S. Food and Drug Administration's (FDA) authority to safeguard the public against unsafe products. FDA has the power to immediately remove products from the market if it believes that the product or ingredient represents a public health hazard.

**New Products/Ingredients**

**Structure/Function Claims:** Under provisions outlined in DSHEA, dietary supplement marketers may include truthful and not misleading claims on product labels that describe a nutrient's role in supporting wellness. These claims are referred to as structure/function claims or nutritional support claims. Manufacturers must provide the FDA with proof of these claims before marketing the supplement. Additionally, The Federal Trade Commission (FTC) and the FDA work together to regulate the marketing of dietary supplements. The FDA is primarily responsible for product labeling claims, including packaging, inserts, and other promotional materials distributed at the point of sale. The FTC is primarily responsible for advertising claims, including print and broadcast ads, infomercials, catalogs, and similar direct marketing materials. Marketing on the Internet is subject to regulation in the same fashion as promotions through any other media.

**Labeling:** A dietary supplement label must list the name and quantity of each active ingredient, identify the product as a dietary supplement, and, for herbal supplements, identify the part of the plant from which it is taken. Nutrition labeling must be present in a format appropriate to the product.

**Good Manufacturing Practices (GMPs):** Under DSHEA, supplements must comply with current good manufacturing practices. The FDA can issue special regulations on GMPs for dietary supplements, which are modeled after food GMPs.

Office of Dietary Supplements: DSHEA's passage established an office within the National Institutes of Health to coordinate research on dietary supplements and disease prevention, develop a database of supplement research, and advise the Secretary of Health and Human Services on supplement regulation, safety, and health claims. FDA regulates both finished dietary supplement products and dietary ingredients. The NIH dietary supplement label database houses nearly 140,000 on-market and off-market dietary supplements, providing the FDA with a picture of the dietary supplement market. FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products. The FDA enforces authorities against adulterated, misbranded, or misbranded dietary supplement products.

Adverse Event Reporting System and MedWatch: In 1993, the FDA created the adverse event reporting system (AERs) to collect and review adverse event reports on dietary supplements. The AERs provide an essential monitoring tool for identifying potential serious public health issues that may be associated with the use of a particular product or type of product that needs to be investigated and critically evaluated.

FDA's adverse event reporting system for dietary supplements is a multipronged approach that includes detecting adverse events, generating signals of possible health concerns, assessing those signals, and taking appropriate safety actions based on its assessment. An adverse event is an incident of illness or injury that may be associated with a product or ingredient. With further investigation, the association may or may not be confirmed. FDA receives reports from various sources, including consumers and health professionals.

When a signal of a possible health problem is generated from the adverse event reporting system, FDA assesses whether it is an actual health problem warranting attention. The FDA can assess these signals by reviewing scientific literature, consulting with experts, reviewing clinical data, conducting laboratory tests, and/or commissioning studies. If FDA confirms that a public health problem exists, it can take a range of safety actions, such as issuing warnings to consumers and health professionals, issuing import alerts, requesting product recalls, or seizing products. The law requires adverse event reports received by a brand owner or manufacturer must be submitted to the FDA no later than 15 business days after receiving the report.

Some have incorrectly stated that the FDA does not review dietary supplements for safety before entering the market. Additionally, many have incorrectly lumped over-the-counter diet pills, such as Alli, as dietary supplements when, in fact, they are regulated as over-the-counter drugs by the FDA, which differs from how the FDA regulates dietary supplements. The Federal Food, Drug, and Cosmetic Act requires manufacturers and distributors to notify the FDA about their ingredients. The notification must include information that is the basis on which the manufacturer or distributor has concluded the dietary supplement is expected to be safe under the conditions of use suggested in the labeling.

The AERs are a precious tool in determining a temporal relationship between a product and an eating disorder. The FDA uses this system in conjunction with the MedWatch system to add warnings to products it regulates that lead to or exacerbate eating disorders.

Additionally, many supporters of this legislation have cited studies that lack a significant testing protocol called Challenge-Dechallenge-Rechallenge (CDR). The goal of CDR is to determine whether there is a reasonable possibility that a product is etiologically related to the adverse event. Causality assessment includes, for example, the assessment of temporal relationships through CDR, a medical testing protocol in which a product is administered, withdrawn, and then re-administered while being monitored for adverse effects at each stage.

CDR is used when statistical testing is inappropriate due to an idiosyncratic reaction by a specific individual, which is very common with eating disorders or a lack of sufficient test subjects, and the unit of analysis is the individual.

Thus, the hypothesis that supplements directly lead to eating disorders would then be picked up by AERs or Medwatch if it existed.

The proposal under consideration today would place onerous restrictions, most notably on small businesses such as your local pharmacy, convenience, or health food store, by prohibiting the sale of popular products. Restricting access to them is unfair to New Jerseyans who value health and wellness, hurts responsible retailers, and drains New Jersey's budget through lost sales taxes. Nobody wins. We support efforts to stop illegal drugs masquerading as natural products. Of course, no one wants consumers to use unlawful products. Still, they are already illegal by law, and the FDA uses its enforcement authority against companies that attempt to sell these products. The federal government has vast enforcement powers and has a long track record of punishing criminals who break the law. We support vigorous enforcement of the law to protect consumers. Still, the FDA, the chief regulator of dietary supplements, found no data suggesting weight-management and muscle-building dietary supplement use is correlated to eating disorders.