THE PIONEERING US DIETARY SUPPLEMENT LAW

THE ROAD TO DSHEA

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International Alliance of Dietary/
Food Supplement Associations

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MAKING HISTORY

On 25 October 1994, the US Congress passed the Dietary Supplement Health and Education Act (DSHEA). It was a truly historic moment. For the first time, the dietary supplement category was legally recognised in the United States and subject to a dedicated regulatory framework.

This heralded a new dawn. But getting to this point had not been easy and there were many dark moments along the way. Indeed, the supplement sector endured several decades of challenges in the run-up to the adoption of DSHEA. At times, some people wondered whether the industry had any future at all, in a regulatory environment that was at best indifferent to dietary supplements. This gave rise to fears that Americans would be denied the right to include vitamins and herbs in their personal health decisions.

TRADITION UNDER THREAT

The US has a long tradition of consuming supplements for health reasons. In the 1600s, the Shakers, a Christian community, emigrated from England to start a new life in America. They brought with them a culture of using plants and herbs to enhance wellbeing and in 1699 they became the first people on record to sell botanical products commercially in the US. Furthermore, when the Shakers and others arrived on the new continent, they encountered numerous indigenous tribes. The first Europeans keenly observed and recorded the extensive use of many plant species by these native cultures for health reasons.

Two centuries later, however, a process was beginning which meant these traditions were in danger of disappearing. In 1906, the Pure Food and Drug Act was enacted, which prohibited interstate commerce in adulterated and misbranded food and drugs. This statute was replaced and significantly expanded in 1938 with the passage of the Food, Drug, and Cosmetic Act. To enforce these laws, the Food and Drug Administration (FDA) was created (although it wouldn't be known by that name until 1930).

The predicament for the vitamin, mineral and botanical products industry was manifested in the names of the laws and the agency established to enforce them. There was no mention of supplements or botanicals, which were addressed instead as forms of foods, or as drugs if medicinal claims were made. While they were not made illegal by either of these legislative actions, nor were they recognised or legitimised in law.

Supplements became enormously popular in the US in the last half of the 20th century. Reflecting their long tradition of use, Americans were, and still are, avid users of the natural products that have come to be called dietary or nutritional supplements. The sector was highly fragmented, with supplements manufactured by hundreds of companies and sold through independent family-owned health food stores, as well as in chain drugstores and by other mass marketers.

HEALTH CLAIMS PERMITTED FOR FOOD

In the early 1970s, FDA issued a regulation that set quantitative limits on the levels of vitamin and mineral nutrients allowed in dietary supplements. For example, supplements labelled for use by adults could not contain more than 90mg of vitamin C or 1,500mg of calcium (higher levels of 120mg and 2,000mg, respectively, were allowed in products for pregnant and nursing women). Although this rule was overturned by the US Congress, FDA continued its efforts to limit access to supplement products and ingredients. Similar challenges had arisen in 1975 with the publication of an FDA internal memo titled Safe and Unsafe Herbs in Herbal Teas.

In 1990, Congress passed the Nutrition Labeling Education Act (NLEA). This gave food companies the right to make nutrient-related health claims for their products, provided they were able to provide sufficient scientific substantiation. However, the new legislation was not specifically directed at the supplement sector. Things had improved marginally, since it was now easier for companies to make limited health claims for supplements containing vitamins and minerals. And though it was eventually acknowledged that NLEA also applied to other substances, such as botanicals, fish oil, probiotics and amino acids, it would take another ten years for the courts and FDA to recognise that these ingredients could be labelled with health claims.

Following the enactment of NLEA, the FDA set up a task force to investigate the dietary supplement category, which produced a report recommending ways to regulate it. This was made public in May 1992 and, to the industry's shock, it concluded that, while vitamins and minerals were of no concern, herbs should be regulated as food additives (i.e., in the same category as artificial sweeteners and synthetic flavours) and amino acids as either food additives or as drugs.

For the supplement sector this was the trigger to organise collectively. In the first instance, there was a desire to see what solutions might exist without resorting to new legislation, which would be the most difficult route to take. However, after consideration, it was concluded that a new supplement statute was the only option.

PRESSURE FOR CHANGE BUILDS

While the regulatory climate was challenging, public perception of supplements remained overwhelmingly positive. US consumers continued to buy supplements and the market was growing. This gave the industry great confidence in its belief that effective regulation for the sector was desirable. Several leading politicians concurred, including Republican Senator Orrin Hatch of Utah. He agreed to put a bill before the Senate provided that a Democratic Representative was able to put forward a similar, companion bill before Congress. Hatch believed that the legislation stood a much better chance of success if it was bipartisan. Like Hatch, Democratic Representative Bill Richardson was an enthusiastic supporter of supplementation and he lent his support, too. In addition, Senator Tom Harkin, a Democrat from Iowa, became a bipartisan advocate with Hatch in the Senate.

Initially the bill was titled the Health Freedom Act. This name reflected the sense that the legislation would give consumers greater control and choice over decisions related to supplements. There was strong support up and down the country, with millions of US citizens signing petitions supporting the cause. Hundreds of thousands of people contacted their Senators and Representatives to demand they support the bill. Protesters marched on Washington in support of the bill and many Hollywood actors, including Mel Gibson and Ali MacGraw, queued up to back the campaign.

On 25 October 1994, after two years of intense discussion, negotiation and diplomacy, the bill passed as the Dietary Supplement Health and Education Act. At last, supplements were an officially recognised category under US law. President Bill Clinton issued a statement on signing the Act, in which he praised the legislation for bringing "common sense to the treatment of dietary supplements under regulation and law", attributing this to "several years of intense efforts [by] manufacturers, experts in nutrition, and legislators, acting in a conscientious alliance with consumers at the grassroots level."

He added: "In an era of greater consciousness among people about the impact of what they eat on how they live, indeed, how long they live, it is appropriate that we have finally reformed the way Government treats consumers and these supplements in a way that encourages good health."

POSITIVITY TRIUMPHS

Echoing President Clinton's words, the text of DSHEA is preceded by a statement from Congress that underlines the strength of feeling that supplements, when safe, are very positive:

Congress finds that

1 improving the health status of United States citizens ranks at the top of the national priorities of the Federal Government;

2 the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies;

3a there is a link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease, and osteoporosis; and

3b clinical research has shown that several chronic diseases can be prevented simply with a healthful diet, such as a diet that is low in fat, saturated fat, cholesterol, and sodium, with a high proportion of plant-based foods;

4 healthful diets may mitigate the need for expensive medical procedures, such as coronary bypass surgery or angioplasty;

5 preventive health measures, including education, good nutrition, and appropriate use of safe nutritional supplements will limit the incidence of chronic diseases, and reduce long-term health care expenditures;

6a promotion of good health and healthy lifestyles improves and extends lives while reducing health care expenditures; and

6b reduction in health care expenditures is of paramount importance to the future of the country and the economic well-being of the country;

7 there is a growing need for emphasis on the dissemination of information linking nutrition and long-term good health;

8 consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements;

9 national surveys have revealed that almost 50 percent of the 260,000,000 Americans regularly consume dietary supplements of vitamins, minerals, or herbs as a means of improving their nutrition;

10 studies indicate that consumers are placing increased reliance on the use of nontraditional health care providers to avoid the excessive costs of traditional medical services and to obtain more holistic consideration of their needs;

11 the United States will spend over $1,000,000,000,000 on health care in 1994, which is about 12 percent of the Gross National Product of the United States, and this amount and percentage will continue to increase unless significant efforts are undertaken to reverse the increase;

12a the nutritional supplement industry is an integral part of the economy of the United States;

12b the industry consistently projects a positive trade balance; and

12c the estimated 600 dietary supplement manufacturers in the United States produce approximately 4,000 products, with total annual sales of such products alone reaching at least $4,000,000,000;

13 although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers;

14 dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare; and

15a legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness; and

15b a rational Federal framework must be established to supersede the current ad hoc, patchwork regulatory policy on dietary supplements.

Having set the scene in this way, DSHEA goes on to define supplements as follows:

The term "dietary supplement"

1 means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

A a vitamin;

B a mineral;

C an herb or other botanical;

D an amino acid;

E a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

F a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

IN WITH THE OLD

The US supplements sector had been in business long before DSHEA came into force, which meant there were many hundreds of supplement brands and ingredients on the market. To remove these products from shelves to undergo an approval process would be impractical and unnecessary. Congress therefore decided that it would be best to introduce a 'grandfather' clause so that any existing ingredient on the market sold as a dietary supplement before 15 October 1994 would be assumed to be safe, but subject to FDA enforcement action if not. The new law stipulated that any new dietary ingredients (NDIs) not on sale before that date would be required to make a pre-market notification to FDA.

This approach ensured that herbal products used safely for generations did not suddenly find themselves facing the prospect of potential prohibition. Nevertheless, DSHEA made it clear that FDA has the right to remove any ingredient or product from the market that is found to be unsafe, regardless of whether it is an 'old' dietary ingredient or a new one. However, in either case, FDA bears the burden of demonstrating the ingredient or product is unsafe.

Another key element of DSHEA was a provision that allowed FDA to establish good manufacturing practice (GMP) regulations designed for dietary supplements. At the time, supplements were held to the same GMP standard as conventional foods, so a supplement-specific rule was developed. This process took 10 years to finalise, with smaller companies given more time to comply than larger companies. The rule has been fully implemented by companies since 2010.

The GMP standards now enshrined in law in the US are very robust. Consequently, they have become a model the world over, with many other countries and regions looking to US GMPs as a basis for their own standards. The US supplement industry welcomed GMPs as a way to ensure product quality for all supplement companies that operate in the domestic supplement market. It also increased trust in US-made products in overseas markets, helping exporters. In addition, US GMPs apply to supplements manufactured overseas and imported into the US and this means overseas manufacturers are becoming familiar with the US GMP requirements.

Another important DSHEA innovation was the creation of the Office of Dietary Supplements (ODS) within the National Institutes of Health. Previously there was no department or agency within the federal government that was responsible for organising and conducting research on supplements, or for keeping consumers and other government departments informed and educated about supplements. Among its many activities, ODS organises an annual symposium to update key stakeholders – including medical professionals and nutrition scientists – on the most recent developments in the world of supplements. It also maintains a voluntary Dietary Supplement Label Database of products in the US market.

ALIVE AND THRIVING

Nearly three decades after it was passed by Congress, DSHEA continues to function as an effective regulatory framework. There is no doubt that it has helped transform the US supplement industry into a highly professional sector. In the wake of its adoption, DSHEA generated much greater interest and confidence in the supplement category. The US supplement sector is almost unrecognisable from the days before DSHEA, reflecting how this legislation has transformed the industry. Three-hundred years after the Shakers sold their first botanicals, DSHEA has ensured America's great supplement tradition remains very much alive and thriving today.

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