

UCLA
Nutrition Bytes

Title

Regulating the Dietary Supplement Industry

Permalink

<https://escholarship.org/uc/item/0mp2s38h>

Journal

Nutrition Bytes, 3(2)

ISSN

1548-4327

Author

Mislich, Kim

Publication Date

1997

Peer reviewed

Messages about the importance of sound nutrition for the prevention of disease has permeated our society. Indeed, programs to promote nutrition have led to a more health conscious nation (1). More people are exercising and eating a balanced diet, and individuals are now turning to dietary supplements, from vitamins to herbal remedies, to promote good health (2).

Americans spend over one billion dollars per year on dietary supplements and megavitamins (3). Sales are predicted to grow in light of the Dietary Supplement and Health Education Act (DSHEA) of 1994. Under the provisions of the DSHEA, the dietary supplement industry holds the power to make a variety of health claims with a modicum of scientific support (4). In order to understand how this Act could affect patient care, it is important to examine the historical events which led to the passage of the DSHEA.

History of the Regulation of Foods and Supplements

The Pure Food and Drugs Act of 1906 was the government's first effort to regulate foods and drugs. Under this act, a food was considered "all articles used for food, drink, confectionery, or condiment by man or other animals whether simple mixed or compound" and a drug was defined as "all medicines and preparations recognized to be used for the cure, mitigation, or prevention of disease". By 1938, the government recognized a need to regulate drugs more stringently and to broaden the definition of a drug to "articles (other than food) intended to affect the structure or any function of the body of man or other animals" and to "articles used to diagnose or treat a disease". The distinction between a food and a drug became critical, since the rules under the Federal Food, Drug and Cosmetic Act of 1938 required that drugs, not foods, obtain premarket safety review by the FDA. The FDCA was amended in 1962 to require that a drug obtain premarket approval for both effectiveness and safety, while the burden of proof was placed on the drug manufacturer (5).

During the 1950's scientific studies began to uncover the relationship between diet and disease. Naturally, the food industry desired to use this information to market products, but the FDA flatly denied them this right. Under new amendments to the FDCA in the 1970's, a food was considered "misbranded" if a label claimed that "the food was adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom". The FDA disapproved of labels that even implied a link between the food or supplement and a disease (6).

The 1980's sparked the beginnings of the modern food and dietary supplement controversy. In 1984, Kellogg's began to market their high fiber cereal, All-Bran, with an endorsement on the back of the box from the National Cancer Institute. Statements on the box claimed that eating a high fiber diet could prevent certain types of cancer and that All-Bran contained more fiber than any other cereal available. Although the Kellogg Company clearly violated the amendments of the FDCA, the FDA took no action against them. The Federal Trade Commission (which regulated food advertisement) supported the Kellogg label and encouraged the FDA to permit health claims on an individual basis.

The FTC contended that food labels could be used to disseminate informative messages about proper nutrition provided that regulations to protect the public from fraudulent claims were enforced (5).

In 1987, the FDA proposed a new policy to permit certain health claims to be made but stipulated that information on food labels should be truthful and supported by sound scientific evidence. Under the boundaries of the law, a company was allowed to make health claims but was required to submit these claims to the FDA within 30 days of market. The FDA would then review and subsequently deem claims unlawful if they did not satisfy their criteria. The FDA was criticized by some groups for trying to enforce such an ambiguous policy and for allowing products to be sold prior to FDA review (5).

The latter criticisms did indeed prove to be the fatal flaws of the 1987 proposal. With new-found freedom, the dietary supplement industry sold a dramatically higher volume of products, but many of its claims were blatantly false. Subsequently, the FDA received numerous complaints from consumer groups about misleading and excessive claims (7). During 1989, a handful of consumers died from eosinophilia myalgia, caused by a contaminant in a batch of L-tryptophan (8). Critics of the 1987 proposal believed that manufacturers had become sloppier in their efforts to profit from the lessened regulations. Thus, the sudden cases of eosinophilia myalgia fueled arguments for tightening the regulations on the supplement industry.

In 1990, Congress enacted the Nutritional Labeling and Education Act. This Act gave supplement manufacturers the right to make claims that pertained to only eight disease relationships including calcium and osteoporosis, sodium and hypertension, and folate and neural tube defects. Congress reasoned that flooding the public with too many claims that were not strongly accepted by the scientific community would only curtail the purpose of health claims-to educate the public. Contrary to the proposal of 1987, the new Act required claims to be reviewed by the FDA before the products ever sat on consumer shelves (4).

The new, stricter rules stirred the public and the supplement industry. The anger that ensued was the result of misinformation conveyed to the public. Health food stores hung signs saying "Don't let the FDA have control over your vitamins", and consumers protested the FDA's plan to "ban the sale of vitamins without a prescription" even though no such plan existed (9). Articles in magazines such as Forbes described FDA Commissioner Dr. David Kessler as an overzealous dictator (10). However, Dr. Kessler supported the public's freedom to choose among safe and validated products. He maintained that the NLEA was enacted to encourage the dissemination of safe and scientifically substantiated claims on dietary supplement labels. (11)

In 1993, a study was published in JAMA that supported Kessler's concerns. The study surveyed nutritional supplement advertising in health and bodybuilding magazines and discovered dozens of products whose labels had not only violated the NLEA but contained substances that had either been shown to be harmful (or lethal) to human consumption or had never been subjected to scientific study (12). Despite the restrictions

placed on the supplement industry, the sale of "misbranded" supplements had not been controlled.

Meanwhile, public opinion continued to grow against the NLEA. One senator said that he received more calls from constituents angry over the NLEA than over any other issue (13). The propaganda was powerful enough to incite new laws to diminish the FDA's regulatory power. Extreme public pressure resulted in the Dietary Supplement and Health Education Act (DSHEA).

Passed unanimously in 1994, the DSHEA closely resembles the proposal of 1987. A manufacturer may sell a product with any health claim as long as the FDA is notified within 30 days of market. Manufacturers determine for themselves if a claim is scientifically substantiated. Therefore by allowing this conflict of interest, the DSHEA lowers the standards for scientific proof. Once the item is marketed, the burden of proving inadequate substantiation is the responsibility of the FDA (14). An unprecedented provision of the Act allows a supplement to declare that it can alter body composition, a claim that was previously reserved for FDA approved drugs (16).

Conclusions

The implications of the DSHEA are not difficult to imagine. The Act allows consumers easier access to dietary supplements, but it also permits more unsubstantiated claims and potentially unsafe products to be distributed. Because the burden of proof lies with the FDA, many years could pass before a harmful product is removed from the market. A supplement that causes acute illness or death will be removed only as quickly as this causal relationship is discovered.

What is the best way to protect consumers yet allow them access to safe, effective products? As this question is debated over the next few years, physicians should expect that patients will continue to consume dietary supplements. Many of these products may provide health benefits, and others may cause serious health problems. As future physicians we must not underestimate the importance of determining whether our patients are using dietary supplements. Eliciting this information requires compassion and an objective attitude. Furthermore, we should remember that a thorough history of the patient's dietary supplement consumption could explain symptoms that might otherwise remain a mystery

REFERENCES

- 1) Klassen, Michael L., Wauer, Suzanne, McCassel, Sheila (1990) J. Advertising Res. 30, 32-38.
- 2) Williams, Doris K., Bock, Margaret A., Medeiros, Denis M., Ortiz, Melchor, et al. (1993) Journal of Home Economics 85, 23-30.

3) Eisenberg, David M.; Kessler; Ronald C.; Foster, Cindy; Norlock, Frances E.; Calkins, David R.; and Delbanco, Thomas L. (1993) *The New England Journal of Medicine* 328, 246-252.

4) Hyman, Douglas W. (1996) *Food and Drug Law* 51, 191-205.

5) Cooper, Richard M., Frank, Richard L. O'Flaherty, Michael Jwazzu . (1990) *Food Drug Cosmetic Law Journal* 45, 655-691.

6) Food Labeling; Hearings, 43 Fed. Reg. 25,296, 25,302. (June 9, 1978).

Journal 7) Curtis, Gary L. (1993) *Nutrition Reviews* 51, 310-312.

8) Slutsker, Laurence, Hoesly, Frederick D., Miller Lynn; Williams, Paul; Watson, John C. and Fleming, David W. (1990) *JAMA* 264, 213-217.

9) Elliott, Jeff (1994) *National Review* 46, 52-56.

10) Forbes, Steve (1993) *Forbes* 152,24.

11) Hearings before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, United States House of Representatives, 103rd Congress, 1st Session, July 29, 1993.

12) Philen, Roseanne, Ortiz, Diana I., Auerbach, Steven B., and Falk, Henry (1992) *JAMA* 268,1008-1011.

13) McNamara, Stephen H. (1996) *Food and Drug Law Journal* 51, 313-321.

14) Pinco, Robert G. and Robin, Paul D. (1996) *Food and Drug Law Journal* 51, 383-400.

15) Young, Anthony L. and Bass, Scott I. (1995) *Food and Drug Law Journal* 50, 286-292.