



A Structure That Does Not Function: An Examination of the History and Current Regulatory Status of Dietary Supplements and Their Label Claims

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A Structure That Does Not Function:

An Examination of the History and Current Regulatory Status
of Dietary Supplements and Their Label Claims

Erica Mueller
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I.

I.

INTRODUCTION

It is likely that the famed expedition of Meriwether Lewis and William Clark would not have gone down in the annals of history as such an overwhelming success¹ without the use of what is now termed “dietary supplements.” The restorative powers of various plants and herbs they discovered along their journey, as well as the natural medicines used by the native Indian tribes that they met and befriended, likely nourished the bedraggled expedition party back to health on a number of occasions.² Plants and herbs have long been a source of food and medicine, and almost all cultures developed some type of folk medicine tradition from these naturally-occurring substances;³ healers versed in the therapeutic properties of these items essentially acted as physicians.⁴ In some countries today, physicians continue to incorporate traditional knowledge into their medical practices and continue to prescribe herbal medicines as treatments.⁵ Similarly, as the science of modern nutrition evolved and individual vitamins and nutrients were isolated, people began to investigate the health benefits of these substances and their effects on the body.

¹Lewis and Clark’s Corps of Discovery only lost one man during the entire journey. This death could not have been prevented, as it was likely caused by appendicitis, which would have been a fatal condition during this time and was beyond the scope of medical knowledge. See STEPHEN E. AMBROSE, UNDAUNTED COURAGE: MERIWETHER LEWIS, THOMAS JEFFERSON, AND THE OPENING OF THE AMERICAN WEST (1996); THE JOURNALS OF LEWIS AND CLARK (Bernard DeVoto, ed. 1953).

²See generally STEPHEN E. AMBROSE, UNDAUNTED COURAGE: MERIWETHER LEWIS, THOMAS JEFFERSON, AND THE OPENING OF THE AMERICAN WEST (1996); THE JOURNALS OF LEWIS AND CLARK (Bernard DeVoto, ed. 1953).

³See Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 671 (1997).

⁴See Leticia M. Diaz, *First St. John’s Wort, Now SAM-e: Is Society as a Whole at Risk Without FDA Regulation of Psychiatric Self-Medication*, 9 KANSAS J.L. & PUB. POL’Y 279 (Winter 1999).

⁵See Leticia M. Diaz, *First St. John’s Wort, Now SAM-e: Is Society as a Whole at Risk Without FDA Regulation of Psychiatric Self-Medication*, 9 KANSAS J.L. & PUB. POL’Y 279 (Winter 1999). For example, eighty percent of physicians in Germany prescribe herbal remedies, which total 12 percent of all prescriptions. See *id.*

As emerging science enabled the development of food and drug regulation to ensure the distribution of products that were safe, pure, and effective, debates began to rage about how to appropriately regulate vitamins, nutrients, and other substances that could readily be classified as neither food nor drugs, yet demonstrated some of the nutritive or therapeutic properties of both categories of substances. So began what one jurist has termed a “bitter battle”⁶ between the Food and Drug Administration (“FDA”), the regulatory agency established to ensure safe and truthfully represented products, and the dietary supplement industry.⁷ Legislative changes, court decisions, agency regulations, and public lobbying have provided the backdrop for the tumultuous changes in the FDA’s authority and in the way dietary supplements are perceived and regulated. The stakes in this tug-of-war are high. Regulators, courts, and legislators must balance the protection of the more than 50 percent of the American population who regularly use supplements with the freedom of choice these consumers want, represented by a \$31 billion dollar market for supplements and related foods in 1999.⁸ In 1994, the debate reached a pivotal moment, as Congress passed a sweeping piece of legislation, the Dietary Supplement Health and Education Act, which dramatically redefined the approach to regulating dietary supplements. Yet contentious issues still remain as the FDA and the industry test the boundaries of this legislation. The regulation of claims that dietary supplement labels may bear remains a particularly controversial and ambiguous problem. Partially due to the erosion of distinctions between food, drugs, and dietary supplements, this issue has proved to be one on which it is extremely difficult for the industry and the regulators to reach an equilibrium.

⁶National Nutritional Foods Association v. Kennedy, 572 F.2d 377, 379 (2nd Cir. 1978).

⁷See Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 671 (1997).

⁸Analysts project that this market will greatly increase within the next ten years. See UNITED STATES GENERAL ACCOUNTING OFFICE, FOOD SAFETY: IMPROVEMENTS NEEDED IN OVERSEEING THE SAFETY OF DIETARY SUPPLEMENTS AND “FUNCTIONAL FOODS” (July 2000).

II.

HISTORY OF DIETARY SUPPLEMENT REGULATION

Early Food and Drug Laws

American colonists “brought with them the tradition of food regulation established in England.”⁹ State governments began to regulate food and drugs in colonial times,¹⁰ primarily to address basic consumer protection and trade concerns. For example, in 1785 the Commonwealth of Massachusetts responded to the problem of tainted quinine being supplied to soldiers by passing the United States’ first food safety regulation.¹¹ Other early laws included inspecting foods such as bread and exported fish, meat, and flour, in order to ensure prevent fraud, encourage international trade, and ensure “fair competition.”¹² These laws were local efforts that were sporadic and rudimentary, yet slowly became more prevalent as urbanization led to a growth in food commerce and as the safety of the food supply was increasingly questioned.¹³

The regulation of food and drugs remained largely a state and local effort throughout the 19th century. Although Congress enacted a few statutes dealing with drugs, none of these laws was comprehensive and dealt with the safety and effectiveness of drugs in general.¹⁴ Rather, such efforts were fairly limited in scope, such as a 1813 act (later repealed) to ensure a safe supply of smallpox vaccine,¹⁵ and the Import Drugs Act

⁹Peter Barton Hutt, *Government Regulation of the Integrity of the Food Supply*, 4 ANNUAL REVIEW OF NUTRITION 1 (1984) (reprinted in PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 3 (2nd ed. 1991)).

¹⁰FOOD AND DRUG ADMINISTRATION, *The Story of the Laws Behind the Labels: Part I: 1906 Food and Drugs Act*, FDA CONSUMER, June 1981 (visited Feb. 16, 2001) <<http://vm.cfsan.fda.gov/~lrd/history1.html>>.

¹¹Jennifer Kay Braman, *Food for Sport of Faustian Bargain: Regulating Performance Enhancing Dietary Supplements*, 47 CLEV. ST. L. REV. 417, 420 (1999).

¹²FOOD AND DRUG ADMINISTRATION, *The Story of the Laws Behind the Labels: Part I: 1906 Food and Drugs Act*, FDA CONSUMER, June 1981 (visited Feb. 16, 2001) <<http://vm.cfsan.fda.gov/~lrd/history1.html>>.

¹³See Peter Barton Hutt, *Government Regulation of the Integrity of the Food Supply*, 4 ANNUAL REVIEW OF NUTRITION 1 (1984) (reprinted in PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 3 (2nd ed. 1991)).

¹⁴See PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 7-8 (2nd ed. 1991)).

¹⁵See PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 7-8 (2nd ed. 1991)).

of 1848, which established national customs laboratories to ensure that drug imports met trade industry standards for purity and potency.¹⁶ Congress did not pass the first federal food laws, which primarily dealt with controlling the import or export of specific adulterated foods, until 1883.¹⁷ These national efforts at food and drug regulation, however, were not comprehensive. Fraudulent, unsafe, ineffective, and adulterated food and drug products remained prevalent.¹⁸ Thousands of “patent” medicines were readily available from so-called “snake-oil salesmen” and other medicine men. These medicines frequently contained narcotics such as opium, morphine, heroin, and cocaine, claimed to cure every disease, contained no information about ingredients on their labels, and frequently harmed unsuspecting and uninformed consumers.¹⁹

Towards the end of the 19th century, a variety of factors began to converge to advocate the creation of a comprehensive, federal law. In the 1870s, a grassroots movement called The Pure Food Movement began to push for a national law against food adulteration.²⁰ Advances in scientific methods and thought began to increase opportunities to detect food contamination.²¹ Frustrated food industry members complained of adulterated products and that the increasing state and local regulations regarding food and drugs created great disparity among food laws.²² Authors and publications began warning of the prevalence and dangers of adulterated food and drugs, creating a “full-fledged” public outcry by 1879.²³ In addition, the U.S.

¹⁶FOOD AND DRUG ADMINISTRATION, *The Story of the Laws Behind the Labels: Part I: 1906 Food and Drugs Act*, FDA CONSUMER, June 1981 (visited Feb. 16, 2001) <<http://vm.cfsan.fda.gov/~lrd/history1.html>>.

¹⁷See Peter Barton Hutt, *Government Regulation of the Integrity of the Food Supply*, 4 ANNUAL REVIEW OF NUTRITION 1 (1984) (reprinted in PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW* 4 (2nd ed. 1991)).

¹⁸See FOOD AND DRUG ADMINISTRATION, *The Story of the Laws Behind the Labels: Part I: 1906 Food and Drugs Act*, FDA CONSUMER, June 1981 (visited Feb. 16, 2001) <<http://vm.cfsan.fda.gov/~lrd/history1.html>>.

¹⁹See FOOD AND DRUG ADMINISTRATION, *The Story of the Laws Behind the Labels: Part I: 1906 Food and Drugs Act*, FDA CONSUMER, June 1981 (visited Feb. 16, 2001) <<http://vm.cfsan.fda.gov/~lrd/history1.html>>. Such quack medicines often had colorful and misleading names such as “Kick-a-poo Indian Sagwa,” “Warner’s Safe Cure for Diabetes,” and “Hamlin’s Wizard Oil.” See *id.*

²⁰See FOOD AND DRUG ADMINISTRATION, *The Story of the Laws Behind the Labels: Part I: 1906 Food and Drugs Act*, FDA CONSUMER, June 1981 (visited Feb. 16, 2001) <<http://vm.cfsan.fda.gov/~lrd/history1.html>>.

²¹See Kelly Ann Kaczka, *From Herbal Prozac to Mark McGwire’s Tonic: How the Dietary Supplement Health and Education Act Changed the Regulatory Landscape for Health Products*, 16 J. CONTEMP. HEALTH L. & POL’Y 463, 468 (2000).

²²See FOOD AND DRUG ADMINISTRATION, *The Story of the Laws Behind the Labels: Part I: 1906 Food and Drugs Act*, FDA CONSUMER, June 1981 (visited Feb. 16, 2001) <<http://vm.cfsan.fda.gov/~lrd/history1.html>>. One food packer at this time griped, “As it is now, we have to manufacture differently for every state.” *Id.*

²³See PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW* 8 (2nd ed. 1991)).

Department of Agriculture Division of Chemistry, under the direction of Dr. Harvey Wiley,²⁴ began to investigate and publish reports regarding food adulteration.²⁵

Pure Food and Drugs Act of 1906

Upton Sinclair's novel, *The Jungle*, which detailed shocking unsanitary conditions in Chicago stockyards, perhaps was the final encouragement to take action at a national level.²⁶ Congress eventually passed the Pure Food and Drugs Act of 1906,²⁷ which broadly prohibited the misbranding or adulteration of food, from tainted oysters²⁸ to unregulated elixirs.²⁹ Although this law represented a positive step, it had serious limitations and failed to address many issues. For example, the 1906 Act neither made any specific provisions for dietary supplements³⁰ nor regulated the safety³¹ or effectiveness of drugs, other than establishing "minimal standards for quality, purity, and strength."³²

Federal Food, Drug, and Cosmetic Act of 1938

²⁴Dr. Wiley was appointed Chief Chemist from 1883 through 1912. See PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 8 (2nd ed. 1991)). He is often referred to as the "Crusading Chemist" and the "Father of the Pure Food and Drugs Act." FOOD AND DRUG ADMINISTRATION, *Milestones in U.S. Food and Drug Law History*, FDA BACKGROUNDER, May 3, 1999 (visited Feb. 16, 2001) <<http://vm.cfsan.fda.gov/>>.

²⁵See PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 9 (2nd ed. 1991)); FOOD AND DRUG ADMINISTRATION, *The Story of the Laws Behind the Labels: Part I: 1906 Food and Drugs Act*, FDA CONSUMER, June 1981 (visited Feb. 16, 2001) <<http://vm.cfsan.fda.gov/~lrd/history1.html>>. Dr. Wiley's investigations are perhaps best known for his work with food preservatives, as this study involved human testing of various common preservatives on 12 volunteers, who were dramatically dubbed the "poison squad." See *id.*

²⁶See FOOD AND DRUG ADMINISTRATION, *The Story of the Laws Behind the Labels: Part I: 1906 Food and Drugs Act*, FDA CONSUMER, June 1981 (visited Feb. 16, 2001) <<http://vm.cfsan.fda.gov/~lrd/history1.html>>. On the same day as the Pure Food and Drugs Act was passed, June 30, 1906, Congress also passed a far more rigorous federal meat inspection act.

²⁷Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 768 (repealed 1938).

²⁸See I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 9 (1996).

²⁹COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Feb. 16, 2001) <<http://www.health.gov/dietsupp/ch2.htm>>.

³⁰See I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 9 (1996).

³¹Jennifer Kay Braman, *Food for Sport of Faustian Bargain: Regulating Performance Enhancing Dietary Supplements*, 47 CLEV. ST. L. REV. 417, 419-20 (1999).

³²Kelly Ann Kaczka, *From Herbal Prozac to Mark McGwire's Tonic: How the Dietary Supplement Health and Education Act Changed the Regulatory Landscape for Health Products*, 16 J. CONTEMP. HEALTH L. & POL'Y 463, 468 (2000).

The limitations of the Food and Drugs Act of 1906 became apparent in the subsequent years. In the 1930s, at the height of the New Deal, Congress began work on the Federal Food, Drug, and Cosmetic Act (“FDCA”) in an effort to expand federal protection to consumers and to cure the limitations of the 1906 Act.³³ First Lady Eleanor Roosevelt was one of the main advocates of the FDCA, and her personal appearances on its behalf and the display of the dramatically named “Chamber of Horrors”, a collection of fraudulent and dangerous products, at post offices, helped to create grassroots support for the legislation.³⁴ Further, the public was inflamed by the 1937 deaths of over 100 people, who were poisoned by “elixir of sulfanilamide.”³⁵ The ensuing comprehensive legislation focused primarily on drug safety and establishing food standards of identity.³⁶

The FDCA also established a category of foods “for special dietary use” for the first time,³⁷ and instituted specific labeling requirements for these foods.³⁸ Other than these labeling requirements, dietary supplements could not be neatly categorized under the FDCA, as regulation of “product[s] containing a vitamin, depending on the way it was marketed and labeled, could be a food, a drug, or both.”³⁹ As the FDCA had expanded the definition of drug to include non-food⁴⁰ “articles intended to affect the structure or any function of the

³³See FOOD AND DRUG ADMINISTRATION, *The Story of the Laws Behind the Labels: Part II: 1938 – The Federal Food, Drug, and Cosmetic Act*, FDA CONSUMER, June 1981 (visited Feb. 16, 2001) <<http://vm.cfsan.fda.gov/~lrd/histor1a.html>>.

³⁴See I. SCOTT BASS & ANTHONY L. YOUNG, *DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS* i (1996).

³⁵FOOD AND DRUG ADMINISTRATION, *The Story of the Laws Behind the Labels: Part II: 1938 – The Federal Food, Drug, and Cosmetic Act*, FDA CONSUMER, June 1981 (visited Feb. 16, 2001) <<http://vm.cfsan.fda.gov/~lrd/histor1a.html>>. This product was found to contain diethylene glycol, more commonly known as antifreeze. See Jennifer Kay Braman, *Food for Sport of Faustian Bargain: Regulating Performance Enhancing Dietary Supplements*, 47 CLEV. ST. L. REV. 417, 419 (1999). Congress was also concerned with regulating diet aids, which were more delicately referred to at the time as “anti-fat” or “slenderizing” products. See *id.*

³⁶I. SCOTT BASS & ANTHONY L. YOUNG, *DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS* i (1996).

³⁷See I. SCOTT BASS & ANTHONY L. YOUNG, *DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS* i (1996). Subsequently, the FDA established labeling requirements for such foods, which remained effective until 1962. See Laura A.W. Khatcheressian, *Regulation of Dietary Supplements: Five Years of DSHEA*, 54 FOOD & DRUG L.J. 623, 624 (1999).

³⁸Federal Food, Drug, & Cosmetic Act, 21 U.S.C. § 343(j) (1995). (“A food shall deemed to be misbranded (j) [i]f it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.”)

³⁹See Kelly Ann Kaczka, *From Herbal Prozac to Mark McGwire’s Tonic: How the Dietary Supplement Health and Education Act Changed the Regulatory Landscape for Health Products*, 16 J. CONTEMP. HEALTH L. & POL’Y 463, 469 (2000).

⁴⁰The FDCA explicitly exempted food items from the definition of drug. Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A.

body of man or other animals,”⁴¹ the FDA began to use these provisions to classify and regulate dietary supplements as drugs, based on claims made on supplement product labels or in literature.⁴² When using such a classification, the FDA could subject dietary supplements to the more stringent drug provisions of the FDCA, including detailed labeling, safety, and efficacy requirements.⁴³

In 1940 and 1941, shortly after the enactment of the FDCA, the FDA promulgated regulations regarding labeling requirements for dietary supplements and dietary foods.⁴⁴ These regulations established quantitative minimum daily requirements (“MDR”) as the standard for individual vitamins, minerals, and nutrients.⁴⁵ For the next twenty years or so, the FDA’s dietary supplement regulations, including its enforcement of drug provisions against supplements, were challenged in a series of court decisions. Primarily focusing on labeling issues, these rulings began to establish the limits of the FDA’s authority under the FDCA to regulate dietary supplements.⁴⁶

Food Additives Amendment of 1958

§ 321(g)(1)(C) (1994).

⁴¹Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 321(g)(1)(C) (1994).

⁴²See I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 9 (1996). Dietary supplements were often portrayed as having health or medicinal benefits.

⁴³Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. §§ 352, 355 (1994). Regulating dietary supplements as drugs was intended “to bring certain potentially dangerous products that had physiological effects unrelated to disease, within the regulatory authority of the FDA.” Roseann B. Termini, Esq., *Pharmanex v. Shalala: A Wake Up Call for Congress and a Not So Bitter Pill for the FDA*, 26 OHIO N.U. L. REV. 269, 276-77 (2000) (quoting Bruce Schindler, *Where There’s Smoke There’s Fire: The Dangers of the Unregulated Dietary Supplement Industry*, 42 N.Y.L. SCH. L. REV. 261, 268 (1998)).

⁴⁴See COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Feb. 16, 2001) <<http://www.health.gov/dietsupp/ch2.htm>>.

⁴⁵See COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Feb. 16, 2001) <<http://www.health.gov/dietsupp/ch2.htm>>; PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 212 (2nd ed. 1991)). These regulations set no maximum levels of vitamins, minerals, or nutrients that could be included in a dietary supplement or other food for special dietary use.

⁴⁶See *Kordel v. United States*, 335 U.S. 345 (1948); *United States v. Urbuteit*, 335 U.S. 355 (1948); *United States v. 8 Cartons*, Containing “Plantation ‘The Original’ etc., Molasses,” 103 F. Supp. 626 (W.D.N.Y. 1951); *United States v. . . . “Sterling Vinegar and Honey. . . .”* 338 F.2d 157 (2d Cir. 1964); *United States v. An Article of Drug Consisting of 250 Jars, etc. of U.S. Fancy Pure Honey, etc.*, 218 F. Supp. 208 (E.D. Mich 1963), *aff’d* 344 F.2d 288 (6th Cir. 1965). See generally also I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 9-10 (1996).

In 1958, concern over food safety spurred Congress to enact the first major amendment to the FDCA. The Food Additives Amendment⁴⁷ shifted the burden of proving the safety of ingredients in food from the FDA to manufacturers and marketers.⁴⁸ Modifying the old process of introducing a product first and requiring the FDA to later prove that the product was unsafe, the new provisions essentially provided the FDA with premarket approval of food additives.⁴⁹ Food additives were broadly defined as “any substance, the intended use of which results, or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of food.”⁵⁰ As the FDA believed that the ingredients incorporated into dietary supplements⁵¹ conformed to this definition, it began to regulate supplements that were not generally recognized as safe (“GRAS”) or sanctioned prior to 1958 as food additives.⁵² This classification enabled the FDA to regulate dietary supplements in a more stringent manner than it regulated conventional foods.⁵³

In the 1960s and 1970s, the FDA attempted to revise its earlier regulations regarding dietary supplements and foods for special dietary uses. Accordingly, it promulgated a series of proposed and final regulations throughout this time⁵⁴ that addressed a variety of issues, including changing labeling requirements,⁵⁵ re-

⁴⁷Food Additives Amendments of 1958, Pub. L. No. 85-929 § 1, 72 Stat. 1784 (1958), codified at 21 U.S.C. § 301 *et seq.*, 42 U.S.C. § 210.

⁴⁸21 U.S.C. § 348.

⁴⁹21 U.S.C. § 348.

⁵⁰21 U.S.C. § 301(s).

⁵¹Ingredients included vitamins, minerals and similar nutritional substances in a variety of delivery forms such as table, capsule, powder, or liquid. *See* Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,692 (June 18, 1993).

⁵²*See* Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,692 (June 18, 1993); 21 U.S.C. §§ 301(s), 348.

⁵³At this time, the term “dietary supplement” primarily referred to vitamins and minerals. As many vitamins and minerals are GRAS or prior-sanctioned, the Food Additives Amendment did not significantly increase the FDA’s authority to regulate such items. The definition of dietary supplement, however, broadened over time to include other substances, such as amino acids and herbs. Accordingly, as most dietary supplement ingredients today, other than vitamins and minerals, are not GRAS or prior-sanctioned, the food additives provisions now have a much greater effect on the FDA’s power to regulate supplement products. *See* MARK V. NADEL, ASSOCIATE DIRECTOR, NATIONAL AND PUBLIC HEALTH, GENERAL ACCOUNTING OFFICE, FDA REGULATION OF DIETARY SUPPLEMENTS 3 (1993).

⁵⁴*See* COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Feb. 16, 2001) <<http://www.health.gov/dietsupp/ch2.htm>>; I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 11 (1996); *see, e.g.*, 38 F.R. 20708-18, 20730-40 (August 2, 1973).

⁵⁵Proposed label changes included requiring a disclaimer that refuted the “myths of nutrition” by indicating that the modern

placing the MDR with the U.S. recommended daily allowance (RDA),⁵⁶ and limiting the combinations of vitamins and minerals that could be sold as dietary supplements.⁵⁷ One such proposal, which was introduced in 1962⁵⁸ and eventually published with modifications as a final regulation by the FDA on August 2, 1973,⁵⁹ was to limit the potency of vitamins, minerals, and other nutrients to specific levels of the RDA.⁶⁰ Dietary supplements containing higher potency levels or involving unauthorized vitamin and mineral combinations would be regulated as drugs,⁶¹ thereby holding manufacturers to a much higher standard, requiring expensive and time-consuming studies.⁶² Opposition from the public,⁶³ the dietary supplement industry, and, ultimately, Congress led to court challenges of the regulations⁶⁴ and to the introduction of specific legislation to address the issue.⁶⁵

diet in general contained sufficient vitamins and minerals, that there was little scientific evidence the use or specific or combinations of dietary supplements were beneficial, and that optimal nutrition did not require excessive doses of vitamins and minerals in order to avoid clinical deficiencies. See Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 673-74 (1997); COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Feb. 16, 2001) <<http://www.health.gov/dietsupp/ch2.htm>>.

⁵⁶The RDA established both minimum and maximum daily levels of recognized nutrients for both children and adults. See I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 11 (1996); COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Feb. 16, 2001) <<http://www.health.gov/dietsupp/ch2.htm>>.

⁵⁷See I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 11 (1996); COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Feb. 16, 2001) <<http://www.health.gov/dietsupp/ch2.htm>>.

⁵⁸27 Fed. Reg. 5815 (proposed June 20, 1962).

⁵⁹38 Fed. Reg. 20708-18, 20730-40 (Aug. 2, 1973) (codified at 21 C.F.R. s 125.1(h) and subsequently invalidated in *National Nutritional Food Association v. Food and Drug Administration*, 504 F.2d 761 (2nd Cir. 1974).

⁶⁰See I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 11 (1996); COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Feb. 16, 2001) <<http://www.health.gov/dietsupp/ch2.htm>>. For example, most vitamins and minerals could not exceed 150% of the U.S. RDA, while vitamin A's potency limit was 200% of the RDA and vitamin D's potency limit was 100% of the RDA.

⁶¹This regulation would be "even in the absence of any explicit drug claim by the manufacturer, because of the lack of any nutritional need for a higher dose." Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 673-74 (1997).

⁶²See I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 11 (1996); COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Feb. 16, 2001) <<http://www.health.gov/dietsupp/ch2.htm>>.

⁶³"Public opposition [] began to mount due to a perception that RDAs did not reflect scientific advances regarding the benefit of various nutrients in maintaining human health." I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 11 (1996).

⁶⁴See, e.g., *National Nutritional Foods Association v. Food and Drug Administration*, 504 F.2d 761 (2nd Cir. 1974) (generally agreeing that the FDA's could protect consumers by limiting the combinations and dose levels of vitamins and minerals (remanding this issue for further consideration), although finding that merely lacking nutritional usefulness was insufficient to alone classify dietary supplements as drugs).

⁶⁵See I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 11 (1996); COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Feb. 16, 2001) <<http://www.health.gov/dietsupp/ch2.htm>>.

The Proxmire Amendment of 1976

Following the publication of the aforementioned 1973 regulations by the FDA, “outraged”⁶⁶ dietary supplement manufacturers and consumers began to lobby Congress intensely to rein in the FDA.⁶⁷ In response, approximately seventy bills were introduced during a nine-month period in 1973, beginning a three-year debate on the appropriate limits of FDA authority to regulate vitamins and minerals.⁶⁸ So began what has since then become an oft-repeated event, as lobbying against unpopular rules enacted by the FDA leads to congressional action and often harsh repudiation⁶⁹ of the FDA’s proposed or final regulations.⁷⁰ Ultimately, in 1976 Congress enacted the “Proxmire Amendment”⁷¹ and added section 411 to the FDCA.⁷² The language of the Proxmire Amendment appears to be specifically targeted to striking down the August 1973 regulations that limit the potency and possible vitamin and mineral combinations of dietary supplements, and provided that the FDA:

⁶⁶Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 674 (1997).

⁶⁷See Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 674-75 (1997).

⁶⁸See I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 12 (1996).

⁶⁹During the floor debate on Senator Proxmire’s bill, he castigated the FDA’s regulation efforts:

What the FDA wants to do is to strike the views of its stable of orthodox nutritionists into ‘tablets,’ and bring them down from Mount Sinai where they will be used to regulate the rights of millions of Americans, who believe they are getting a lousy diet, to take vitamins and minerals. The real issue is whether the FDA is going to play ‘God.’

121 CONG. REC. 39,979 (1975) (statement of Senator William Proxmire) (*reprinted in* I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 12 (1996)). He further advocated, “The Proxmire-Schweiker bill is clear. Provided a vitamin or mineral is safe and not mislabeled, the consumer should have the same freedom of choice to buy it just as he may buy thousands of other food and beverages.” 121 CONG. REC. 2066 (1975) (statement of Senator William Proxmire) (*reprinted in* I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 12 (1996)).

⁷⁰As addressed later in this piece, this same chain of events seemingly occurred to instigate the passage of the Nutrition Labeling and Education Act of 1990, the Dietary Supplement Act of 1992, and the Dietary Supplement Health and Education Act of 1994.

⁷¹The amendment was named after Senator Proxmire, who was one of its sponsors. See I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 12 (1996).

⁷²See I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 12 (1996); Pub. L. No. 94-278, 90 Stat. 401 (1976), codified at 21 U.S.C. § 350 and later revised by the DSHEA.

- (A)... may not establish ... maximum limits on the potency of any synthetic or natural vitamin or mineral;
- (B)... may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which [the FDA] determines is nutritionally rational or useful;
- (C)... may not limit ... the combination or number of any synthetic or natural (i) vitamin, (ii) mineral, or (iii) other ingredient of food.⁷³

Despite the fact that the Proxmire Amendment prohibited the FDA from regulating vitamins or minerals as drugs solely on the basis of high-potency doses, the FDA persisted in its efforts. In *National Nutritional Foods v. Mathews*,⁷⁴ the FDA attempted to impute therapeutic intent⁷⁵ upon the manufacturer to sell as drugs doses of vitamins A and D that exceeded the U.S. R.D.A. The government argued that as such doses had no nutritional value and are potentially toxic, their widespread use by consumers for therapeutic purposes evidenced intent of the manufacturer to market the vitamins as drugs.⁷⁶ The Court of Appeals for the Second Circuit rejected the FDA's argument and issued a ruling consistent with the Proxmire Amendment, making further classification of dietary supplements as drugs difficult for the FDA.⁷⁷

Nutrition Labeling and Education Act of 1990

In the years following the Proxmire Amendment, the FDA relaxed its enforcement efforts against dietary supplements,⁷⁸ which allowed the introduction of a significant number of new dietary supplement products

⁷⁴National Nutritional Foods v. Mathews, 557 F.2d 325 (2nd Cir. 1977).

⁷⁵Under the FDCA, the manufacturer's intent is essential to the determination of whether a substance should be classified as a drug. 21 U.S.C.A § 321(g) (1995).

⁷⁶See National Nutritional Foods v. Mathews, 557 F.2d 325, 334 (2nd Cir. 1977).

⁷⁷See National Nutritional Foods v. Mathews, 557 F.2d 325, 334 (2nd Cir. 1977) ("There was no evidence, however, supporting the Commissioner's conclusion that, when sold at the regulated, i. e. prescription, levels, therapeutic usage of these vitamins so far outweighed their use as dietary supplements, it showed an objective intent that these products were used in the mitigation and cure of diseases. This claim furnished no contradiction to the charge that the FDA's regulations are arbitrary and capricious and not in accordance with law."); Iona N. Kaiser, *Dietary Supplements: Can the Law Control the Hype?*, 37 Hous. L. REV. 1249, 1254 (2000); Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 Fla. L. REV. 663, 675 (1997).

⁷⁸In 1993, FDA officials stated that the agency "has not systematically regulated the 1976 enactment of the Proxmire amendment," as "this amendment and actions taken by the courts relative to cases on other dietary supplements presented by

throughout the 1980s.⁷⁹ Some of these new products were herbs and other remedies that had often been used in traditional medicine, expanding the dietary supplement industry beyond its traditional realm of vitamins and minerals.⁸⁰ As supplement availability grew, consumer use also increased.⁸¹ This rise in consumer use was also spurred in part by increasing recognition and documentation of the importance of nutrition and the benefits of dietary supplements;⁸² however, ready availability of supplements also allowed “off-label uses” by consumers for therapeutic purposes suggested in magazine articles by other unregulated or unproven sources.⁸³ Further, during the mid-1980s food and dietary supplement manufacturers began to make health claims on foods, despite lack of approval by the FDA of the claims through the traditional drug approval channels.⁸⁴ Although the FDA previously had not sanctioned such claims, it became more permissive and did not bring many enforcement actions against such products as it attempted to reformulate its policy regarding health claims on food.⁸⁵

Prior to 1984, FDA policy was that a disease claim⁸⁶ on a food item effectively rendered the food a drug and made it subject to the new drug approval process.⁸⁷ The FDA’s change in position on health claims was

the FDA” discouraged them from such regulation of dietary products. MARK V. NADEL, ASSOCIATE DIRECTOR, NATIONAL AND PUBLIC HEALTH, GENERAL ACCOUNTING OFFICE, FDA REGULATION OF DIETARY SUPPLEMENTS 4 (1993).

⁷⁹ See Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 676 (1997).

⁸⁰ See Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 676 (1997). For example, items such as shark cartilage could now be found in health food stores. *See id.*

⁸¹ See S. REP. NO. 103-410, at 21 (1994).

⁸² See S. REP. NO. 103-410, at 20 (1994).

⁸³ See Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 676 (1997).

⁸⁴ See H.R. REP. NO. 101-538, at 8 (1990).

⁸⁵ See H.R. REP. NO. 101-538, at 8-9 (1990).

⁸⁶ Structure/function claims could not render a food item a drug as food was explicitly exempted from the structure/function clause of the drug definition in the FDCA. *See* 21 U.S.C. § 321(g)(1)(C).

⁸⁷ See H.R. REP. NO. 101-538, at 8 (1990). Codified in 21 U.S.C. 321(g)(1)(B), the FDCA defines a drug, in part, as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease in man.” Further 1973 regulations promulgated by the FDA provided “in part, that a food shall be deemed to be misbranded if its labeling represents, suggests, or implies that the food, because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom.” 56 Fed. Reg. 60,537, 60,637-38 (November 27, 1991) (referencing 38 Fed. Reg. 6950, 6951 (March 14, 1973), codified at 21 C.F.R. 101.9(i)(1)).

due to an increasing recognition that “certain dietary patterns, including increasing or decreasing relative intake of certain types of food, may help maintain health by decreasing the risk of developing specific health problems, including chronic diseases that account for a large proportion of morbidity and mortality in the United States.”⁸⁸ Accordingly, the FDA advocated in an advance notice of proposed rulemaking issued in 1987 that “[t]he rapid growth of scientific and public interest in nutrition argues for recognition and dissemination of such new knowledge, and food labels offer one appropriate vehicle for this dissemination. . . . In light of advances in current knowledge, [] the agency now believes that health-related messages, when appropriately formulated for use on food labels and consistent with existing law and regulations, may provide valuable information to health-conscious consumers.”⁸⁹ Under the new proposed regulations, health claims that met four criteria for truthfulness and scientific validity did not require prior FDA approval and fell within a “safe harbor” from enforcement actions.⁹⁰ Expressing skepticism at the effectiveness of and ability to isolate the importance of adding any single nutrient to the diet, the FDA warned, however, that although they would apply the same proposed criteria to dietary supplements as food, it would be more difficult for dietary supplements to satisfy these criteria.⁹¹

After publication of the 1987 proposal, the use of unsubstantiated health claims expanded,⁹² as food and dietary supplement manufacturers used “abusive marketing practices” to sell their products and promised remedies for a variety of conditions, ranging from obesity to gallstones.⁹³ As there was no system to distinguish between genuine and unsubstantiated health claims, and as “consumers are ill-equipped to evaluate the accuracy of health claims on their own, and therefore often fall prey to unprincipled sales tactics,” the

⁸⁸52 Fed. Reg. 28,843, 28,844 (August 4, 1987).

⁸⁹52 Fed. Reg. 28,843, 28,844-45 (August 4, 1987).

⁹⁰56 Fed. Reg. 60,537, 60,538 (November 27, 1991).

⁹¹52 Fed. Reg. 28,843, 28,846 (August 4, 1987).

⁹²See David C. Vladeck, *Devaluing Truth: Unverified Health Claims in the Aftermath of Pearson v. Shalala*, 54 FOOD & DRUG L.J. 535, 535 (1999); 56 Fed. Reg. 60,537, 60,538 (November 27, 1991).

⁹³See David C. Vladeck, *Devaluing Truth: Unverified Health Claims in the Aftermath of Pearson v. Shalala*, 54 FOOD & DRUG L.J. 535, 537 (1999).

potential for consumer fraud grew.⁹⁴

Partially in response to this “rising tide of unsubstantiated health claims,”⁹⁵ and in an effort to “permit health claims based on scientifically valid information,”⁹⁶ Congress finally took action.⁹⁷ In 1990, Congress responded to a lack of regulation regarding health claims and 11 years of relative inaction by the FDA to improve and modernize labeling requirements⁹⁸ by enacting the Nutrition Labeling and Education Act (“NLEA”).⁹⁹ The NLEA specifically addresses each of these concerns.

First, the NLEA provides for mandatory nutrition labeling for most food products “intended for human consumption and is offered for sale.”¹⁰⁰ The Act requires that such food products be labeled with information regarding the serving size of the product, the number of servings per container, the total number of calories per serving, the total number of calories of fat per serving, and the amount provided per serving of at least nine specific nutrients.¹⁰¹ The FDA has discretion to require the inclusion of any other vitamin, mineral, or nutrient that the agency determines “will assist consumers in maintaining healthy dietary practices.”¹⁰²

The NLEA also gives the FDA broad authority with respect to health claims by establishing detailed requirements regarding the types of claims that food labels could contain and the process the FDA should use for regulating such claims. In so doing, the NLEA requires that different types of claims be held to different

⁹⁴See David C. Vladeck, *Devaluing Truth: Unverified Health Claims in the Aftermath of Pearson v. Shalala*, 54 FOOD & DRUG L.J. 535, 537 (1999).

⁹⁵David C. Vladeck, *Devaluing Truth: Unverified Health Claims in the Aftermath of Pearson v. Shalala*, 54 FOOD & DRUG L.J. 535, 535 (1999).

⁹⁶David C. Vladeck, *Devaluing Truth: Unverified Health Claims in the Aftermath of Pearson v. Shalala*, 54 FOOD & DRUG L.J. 535, 537 (1999) (citing 136 Cong. Rec. H12953 (daily ed. Oct. 26, 1990)(remarks of Rep. Waxman); see also H.R. REP. NO. 538, 101st Cong., 2d Sess. 7, reprinted in 1990 U.S.C.C.A.N. 3336, 3337).

⁹⁷Congress’s efforts were partially based on regulations (55 Fed. Reg. 5176 (February 13, 1990)) proposed by the FDA in 1990 to revise and supercede the earlier 1987 proposed regulations for health claims. The 1990 proposed regulations more narrowly defined health claims on food. See 56 Fed. Reg. 60,537, 60,538 (November 27, 1991).

⁹⁸H.R. REP NO. 101-538, at 8 (1990). Although the FDA had held regulatory proceedings regarding new labeling, it had not issued proposed regulations. *Id.*

⁹⁹Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990), codified at 21 U.S.C. §§ 301, 343. President Bush signed this Act into law on November 8, 1990. See 56 FED. REG. 60,537, 60,537 (November 27, 1991).

¹⁰⁰21 U.S.C. § 343. Certain types of food, such as food sold in bulk containers, raw agricultural products and fish, and food served in restaurants, are covered by slightly different requirements. See *id.*

¹⁰¹21 U.S.C. § 343.

¹⁰²21 U.S.C. § 343.

levels of regulation. Section 343(r)(1)(A) defines the first, and most basic type of label claim, as one that “characterizes the level of any nutrient” that is of the type expressly required to be on the food label, as provided elsewhere in

the NLEA. In general, such nutrient level claims

- (i) may only be made if the characterization of the level made in the claim uses terms which are defined in regulations ¹⁰³
- (ii) may not state the absence of the nutrient unless –
 - (I) the nutrient is usually present in the food ¹⁰³, or
 - (II) the Secretary by regulation permits such a statement on the basis of finding that such a statement would assist consumers in maintaining health dietary practices and the statement discloses that the nutrient is not usually present in the food
- (vi) may not be made if [prohibited by regulation] because the claim is misleading in light of the level of another nutrient in the food.¹⁰⁴

Information merely noting the amount of vitamins or minerals in the food as a percentage of the recommended daily requirement is not considered to be a nutrient claim.¹⁰⁵ Further provisions for nutrient level claims require, among other things, specific action if the food contains a nutrient that increases the risk of disease, and address acceptable label claims specifically with respect to the level of cholesterol, saturated fat, and dietary fiber in the product.¹⁰⁶

The second type of label claim defined by the NLEA is one that goes beyond merely interpreting the level of the nutrient in the product. Rather, this type of claim “characterizes the relationship of any nutrient [that is of the type expressly required to be on the food label, as provided elsewhere in the NLEA] to a disease or a health-related condition.”¹⁰⁷ These types of claims, which more directly express a cause and effect relationship between a specific vitamin or nutrient and a physiological effect, correspondingly must meet stricter requirements than mere nutrient level claims. Specifically, disease or health claims may only be authorized by regulations enacted by the FDA:¹⁰⁸

¹⁰⁵21 U.S.C. § 343(r)(2)(E).

¹⁰⁶21 U.S.C. § 343(r)(2).

¹⁰⁷21 U.S.C. § 343(r)(1)(B).

¹⁰⁸In directing the FDA to enact regulations within 12 months to implement the NLEA, the statute specifically requires the FDA to consider regulations regarding whether claims regarding particular nutrients and diseases meet the requirements for disease or health claims. The FDA was directed to assess the relationship between calcium and osteoporosis, dietary fiber

The Secretary shall promulgate regulations authorizing [disease and health claims] only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.¹⁰⁹

In brief, the disease or health claims on food products must meet a standard of “significant scientific agreement.” The NLEA also prohibits claims for foods that contain (as determined by regulation) any nutrient “in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet,” unless such a claim would “assist consumers in maintaining health dietary practices.”¹¹⁰ By creating this new category of health claims for foods, Congress is effectively bypassing the drug approval process that otherwise would govern foods labeled with what had previously been considered to be drug representations.¹¹¹ Rather, disease or health-related claims merely must receive premarket approval from the FDA and no longer must worry about the rigorous drug approval regime.¹¹²

In order to implement the provisions of the NLEA, the statute requires the FDA to propose regulations within one year that address what types of nutrient level, disease, and health claims are allowed.¹¹³ Further, the NLEA establishes discrete timeframes in which the FDA must evaluate and rule on all petitions for regulations – such as those supporting a specific nutrient and disease relationship or defining terms that characterize nutrient levels – and all petitions for permission to associate nutrient characterization terms with a given nutrient level claim.¹¹⁴ These provisions ensure that statute implementation and the premarket

and cancer, lipids and cardiovascular disease, lipids and cancer, sodium and hypertension, and dietary fiber and cardiovascular disease. Nutrition Labeling and Education Act of 1990 § 3(b)(1)(A)(vi).

¹⁰⁹21 U.S.C. § 343(r)(3)(A)(ii).

¹¹¹See Arnold I. Friede, *Dietary Supplements: Background for Dialogue Between the Industry and the Medical Profession*, 53 FOOD & DRUG L.J. 413, 414 (1998).

¹¹²See Arnold I. Friede, *Dietary Supplements: Background for Dialogue Between the Industry and the Medical Profession*, 53 FOOD & DRUG L.J. 413, 414 (1998).

¹¹³Nutrition Labeling and Education Act of 1990, § 3(b)(1)(A).

¹¹⁴For example, the FDA has 100 days after receipt of a petition for regulation to accept or deny the petition and 90 days after submission of a petition to use specific nutrient characterization terms in a nutrient level claim to grant or deny permission. See 21 U.S.C. § 343(r)(4)(A)(i).

approval process for health claims will occur in a timely fashion.

Most of the language found in the NLEA expressly dealt with labels on food products; these provisions, by extension, also opened the door to authorize the FDA to regulate claims made on dietary supplement labels, as dietary supplements are merely a subset of food. Although the original bill did not include separate provisions specifically targeted towards the regulation of dietary supplement claims,¹¹⁵ such a clause was later added and appeared in the final statute.¹¹⁶ This key addition, which created a potential exception for dietary supplements from the NLEA requirements regarding claims on food, is codified in 21 U.S.C., section 343(r)(5)(D), and provides that

[a] claim [that includes a statement regarding the relationship of any nutrient in the product to a disease or health-related condition] made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances . . . shall be subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary.¹¹⁷

The NLEA also directed the FDA to evaluate the validity of several relationships between particular vitamins, minerals, herbs and other nutritional substances and disease or health-related claims.¹¹⁸ Interpretation of these provisions regarding health claims on dietary supplements generated considerable controversy. Some argued that section 343(r)(5)(D) represented an invitation by Congress to the FDA to “craft a more permissive approach” to regulation of claims on supplements than regulation of claims on foods.¹¹⁹ Others believed that by allowing the FDA to promulgate regulations that established a different approval process

¹¹⁵See H.R. REP. NO. 101-538, at 23 (1990).

¹¹⁶See 21 U.S.C. § 343.

¹¹⁸Nutrition Labeling and Education Act of 1990, § 3(b)(1)(A)(x). The FDA was directed to evaluate the relationship between folic acid and neural tube defects, antioxidant vitamins and cancer, zinc and immune function in the elderly, and omega-3 fatty acids and heart disease.

¹¹⁹I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 17 (1996). For example, Senator Hatch stated,

By their very nature, the dietary supplement must be marketed so that the consumer is informed of the health or disease-prevention benefits that may be conferred. Greater flexibility is thus required to permit communication of these benefits. This increased regulatory flexibility is also mandated by the very rapid pace of scientific advances here and abroad linking the prevention of long-term disease to improved nutritional supplementation. For these reasons, a more lenient standard for dietary supplement[s] is envisioned.

56 Fed. Reg. 60,537, 60,540 (November 27, 1991) (citing CONG. REC. S16611 (October 24, 1990) (statement of Sen. Hatch)).

and scientific evaluation standard for health claims on dietary supplement labels, Congress was suggesting that the standards and processes for supplements should be at least as restrictive and perhaps even more restrictive than those set for food.¹²⁰

As a result of this uncertainty, consumers feared that the implementation of this law would result in a denial of access to dietary supplement products.¹²¹ On November 27, 1991, consumers and dietary supplement manufacturers received their first concrete notice of how the FDA intended to interpret and implement the ambiguous provisions of the NLEA, as the FDA published proposed rules regarding the enactment of the NLEA.¹²² Specifically, the proposed rules did not take advantage of the purported leeway in section 343(r)(5)(D) and define standards for regulating health claims on dietary supplements more leniently or more strictly than the standards used for health claims on food.¹²³ Rather, the FDA took the “middle road” and proposed that health claims on dietary supplements and all other foods be held to the same scientific standard.¹²⁴ Such an approach, the FDA indicated, “strikes an appropriate balance between the desire to make information available and the desire to ensure that information is truthful, usable, and not mislead-

¹²⁰ See David C. Vladeck, *Devaluing Truth: Unverified Health Claims in the Aftermath of Pearson v. Shalala*, 54 FOOD & DRUG L.J. 535, 537-38 (1999) (referencing 136 CONG. REC. H12953 (daily ed. Oct. 26, 1990) (statements of the House Floor Managers of both parties that dietary supplements “covered by this provision should be subject to at least as strong a standard as is applicable to other foods”); see also 136 CONG. REC. S16608 (daily ed Oct. 24, 1990) (statement of Sen. Metzenbaum, sponsor of the bill)).

¹²¹ See Jennifer Sardina, *Misconceptions and Misleading Information Prevail – Less Regulation Does Not Mean Less Danger to Consumers: Dangerous Herbal Weight Loss Products*, 14 J.L. & HEALTH 107, 116 (1999-2000). For example, consumers “voiced concern that supplements would be removed from stores or only available with a doctor’s prescription. FDA officials tried to dispel these false beliefs and reassure consumers that products would not be removed but relabeled if necessary.” *Id.* “These fears were “spurred on by some makers of dietary supplements who are waging an all-out campaign, with brochures and handouts, telling consumers they can ‘kiss their supplements good-bye’ if the FDA is given jurisdiction over them.”” *Id.*, at 116 n.81 (citing Kathi Gannon, *Vitamin Showdown: Who Should Control Dietary Supplements?*, DRUG TOPICS, Jan. 24, 1994, available in 1994 WL 2886032).

¹²² See 56 Fed. Reg. 60,537 (November 27, 1991).

¹²³ See 56 Fed. Reg. 60,537 (November 27, 1991).

¹²⁴ See 56 Fed. Reg. 60,537 (November 27, 1991). Although the FDA acknowledged that proposing the same standard runs contrary to the opinions expressed by some members of Congress, it believed that the legislative history of the NLEA did not require the FDA to promulgate different standards for dietary supplements, but rather authorized discretion to adopt any appropriate scientific standard. Although statements of various members of Congress differ with respect to whether the FDA should adopt stricter, more lenient, or the same standards for dietary supplements, most of such statements emphasize the need for FDA flexibility in this area. See *id.*, at 60,540. Such flexibility would allow the FDA to base its approach on the considerations of “[p]ublic health, sound scientific principles, and consumer fraud.” *Id.* (citing CONG. REC. S16611 (October 24, 1990) (statement of Sen. Metzenbaum)).

ing.”¹²⁵ Further, the FDA found that holding both dietary supplements and conventional food to the same standards reflects the idea that it is the nutrient content of the diet that is important, not the source of the nutrient.¹²⁶ These proposed regulations defined dietary supplements in fairly broad terms, moving away from the more limited definition of supplements that the FDA had embraced in the past.¹²⁷

Dietary Supplement Act of 1992

Many consumers, dietary supplement manufacturers, and other industry groups found these proposed regulations to be unduly restrictive.¹²⁸ Accordingly, these groups began to lobby Congress to stop implementation of the NLEA at least, and possibly to repeal the whole act altogether.¹²⁹ Congress listened and responded to the lobbying efforts by passing the Dietary Supplement Act of 1992 (“DSA”).¹³⁰ Essentially, this Act instituted a one-year moratorium on the implementation of the provisions of the NLEA that pertained to dietary supplements.¹³¹ Specifically, the DSA prohibits the FDA from implementing any provision of the

¹²⁵56 Fed. Reg. 60,537, 60,540 (November 27, 1991).

¹²⁶See 56 Fed. Reg. 60,537, 60,541-42 (November 27, 1991).

¹²⁷See 56 Fed. Reg. 60,537, 60,542 (November 27, 1991). Under the new definition, a dietary supplement is considered to be a food, “other than a conventional food, that supplies a component with nutritive value to supplement the diet by increasing the total dietary intake of that substance,” including “food for special dietary use[s] that is conventional food form.” *Id.*, at 60,542-43. Thus herbs and other nutritional substances that did not provide essential nutrients were now considered to be supplements, although they had not been so considered previously. *See id.*, at 60,543.

¹²⁸See Jennifer Sardina, *Misconceptions and Misleading Information Prevail – Less Regulation Does Not Mean Less Danger to Consumers: Dangerous Herbal Weight Loss Products*, 14 J.L. & HEALTH 107, 116 (1999-2000); Iona N. Kaiser, *Dietary Supplements: Can the Law Control the Hype?*, 37 Hous. L. Rev. 1249, 1259 (2000). One issue that manufacturers were unhappy about was the amount of additional research that would be required for each new claim. *See* Iona N. Kaiser, *Dietary Supplements: Can the Law Control the Hype?*, 37 Hous. L. Rev. 1249, 1259 (2000). The industry also cited several other specific concerns, including the following items: requiring that health claims on supplements be subject to the same “significant scientific agreement” standard as food, especially in light of the FDA’s earlier comments that it “had seen no scientific support for supplement claims; treating herbs as lacking the baseline nutritive value required in order to bear a health claim; stripping vitamins and minerals of their status as supplements if present in “therapeutic” rather than “nutritional” amounts; disallowing several essential nutrients from being sold as supplements as they were “unsafe food additives”; and requiring full nutrition labeling on certain supplement products. *See* I. SCOTT BASS & ANTHONY L. YOUNG, *DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS* 18 (1996).

¹²⁹See Jennifer Sardina, *Misconceptions and Misleading Information Prevail – Less Regulation Does Not Mean Less Danger to Consumers: Dangerous Herbal Weight Loss Products*, 14 J.L. & HEALTH 107, 116 (1999-2000); Iona N. Kaiser, *Dietary Supplements: Can the Law Control the Hype?*, 37 Hous. L. Rev. 1249, 1259 (2000).

¹³⁰Dietary Supplement Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491 (1992), codified at 21 U.S.C. §§ 301, 343. President Bush signed this Act into law on November 8, 1990. *See* 56 FED. REG. 60,537, 60,537 (November 27, 1991).

¹³¹See Dietary Supplement Act of 1992, § 202; CONG. REC. S17239 (October 7, 1992).

NLEA regarding dietary supplements prior to December 15, 1993.¹³² In the interim, the moratorium will “provide time for the Congress, HHS, consumer groups, industry, and other affected parties to identify more fully and to consider the public health issues associated with the use of dietary supplements, and to develop a comprehensive approach for reforming the regulation of dietary supplements.”¹³³ To facilitate the examination of dietary supplements, the DSA also requires three separate analyses of different aspects of the issue by government agencies.¹³⁴

The 1992 Act thus gave a temporary reprieve to Congress from having to take a stand on the growing controversy between dietary supplement manufacturers, consumers, and the FDA. Congress’s decision to punt the question of how supplements should be regulated was unsurprising, given the popular volatility of the issue. In addition to debates over appropriate labeling, tensions were mounting due to a few other factors. First, the dietary supplement market had changed significantly in recent years, as consumer use of supplements grew dramatically.¹³⁵ These market variations were attributable to consumers’ increasing interest in the health benefits of supplements,¹³⁶ increasing advertising of certain products, and the growing

¹³² See Dietary Supplement Act of 1992, § 202(a)(1). The FDA, however, must repropose regulations to enact these provisions of the NLEA by June 15, 1993 and have final regulations in place no later than December 31, 1993. See *id.*, at § 202(a).

¹³³ CONG. REC. S17239 (October 7, 1992). As a justification for this moratorium, Congress notes that the NLEA primarily focused upon food products. As the use of dietary supplements and food products differ historically, “it is appropriate for Congress to enact this moratorium so that the issue of how best to regulate dietary supplements may be carefully considered.” *Id.*

¹³⁴ Dietary Supplement Act of 1992, §§ 204, 205. Under the Act, the FDA must prepare and submit a report within 30 days detailing its “enforcement priorities and practices . . . with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances.” The Comptroller General was similarly required to conduct a study of the FDA’s practices regarding regulation and enforcement of dietary supplements; the Office of Technology Assessment was commissioned a study of whether and how other industrialized countries regulate dietary supplements and what effects such schemes have on health outcomes. See *id.* These reports ultimately proved not to be very useful in analyzing the controversy and in shaping future regulation; “none of these reports played an identifiable role in the legislative discussions that followed.” I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 21 (1996).

¹³⁵ Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,690 (June 18, 1993). One report stated that “[a]n estimated 35 to 60 percent of the population use dietary supplements daily or occasionally, and up to 60 million users take supplements daily.” MARK V. NADEL, ASSOCIATE DIRECTOR, NATIONAL AND PUBLIC HEALTH, GENERAL ACCOUNTING OFFICE, FDA REGULATION OF DIETARY SUPPLEMENTS 4 (1993). Overall, more than 100 million Americans were at this time attempting to enhance their diet through some sort of supplement product. See Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,690 (June 18, 1993). These estimates are perhaps a bit modest, as the statistics presented by Congress in support of the Dietary Supplement Health and Education Act of 1994 suggest somewhat higher usage. See S. REP. NO. 103-410, at 5, 20-21 (1994).

¹³⁶ Although wide variation in usage was reported according to factors such as “age, lifestyle, socioeconomic status, and geographic location,” reasons commonly cited for using dietary supplements included “cultural and ethnic practices, perceived health and nutritive effects including emotional and psychological needs, and perceived insurance against dietary insufficiency.” Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,690 (June 18, 1993).

availability of dietary supplements through a variety of channels.¹³⁷ Any attempt to impose restrictions on these increasingly popular products would likely not be well received. Second, the FDA had been targeting supplements for increased regulation for some time in response to significant public safety concerns. In 1989, use of L-tryptophan, a popular amino acid often used to treat insomnia or depression,¹³⁸ resulted in at least 1,500¹³⁹ cases of eosinophilia myalgia syndrome (EMS) and resulted in 38 deaths.¹⁴⁰ This tragedy provoked the agency¹⁴¹ to establish the Dietary Supplement Task Force in May 1991 to reevaluate the FDA's regulations regarding dietary supplements, with a specific focus upon safety concerns.¹⁴² Finally, the ongoing debate between the FDA and dietary supplement industry over the proper legal basis for regulation loomed ominously behind the other controversies surrounding these products.¹⁴³ In general, since Congress passed the Food Additives Amendments in 1958,¹⁴⁴ the FDA had considered dietary supplements to be food additives.¹⁴⁵ Accordingly, it had used its authority granted under this amendment of the FDCA to ensure that dietary supplements are safe and their labels are truthful and not misleading.¹⁴⁶ Such regulation essentially allowed the FDA to require premarket approval of supplements and placed the burden on supplement man-

¹³⁷ See Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,690 (June 18, 1993). In 1993, dietary supplements were widely available at "grocery stores, drug stores, health food stores, and specialty nutrition stores, as well as by mail order." *Id.*

¹³⁸ See MARK V. NADEL, ASSOCIATE DIRECTOR, NATIONAL AND PUBLIC HEALTH, GENERAL ACCOUNTING OFFICE, FDA REGULATION OF DIETARY SUPPLEMENTS 2 (1993).

¹³⁹ More than 1,500 cases were reported to and confirmed by the Centers for Disease Control and Prevention (CDC). One FDA official indicated that these number are misleadingly low because the vast majority of illnesses attributable to L-tryptophan were never reported; rather, she estimated that this supplement caused between 5,000 and 10,000 people to become ill. See MARK V. NADEL, ASSOCIATE DIRECTOR, NATIONAL AND PUBLIC HEALTH, GENERAL ACCOUNTING OFFICE, FDA REGULATION OF DIETARY SUPPLEMENTS 2 n.1 (1993).

¹⁴⁰ See Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,690 (June 18, 1993).

¹⁴¹ Although the L-tryptophan crisis undoubtedly galvanized the agency into action, it was not an isolated incident, as the FDA also received reports of serious illnesses associated with other dietary supplements. See Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,690 (June 18, 1993).

¹⁴² See Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,691 (June 18, 1993).

¹⁴³ See MARK V. NADEL, ASSOCIATE DIRECTOR, NATIONAL AND PUBLIC HEALTH, GENERAL ACCOUNTING OFFICE, FDA REGULATION OF DIETARY SUPPLEMENTS 3 (1993).

¹⁴⁴ 21 U.S.C. § 348.

¹⁴⁵ See *supra* note 53. In practice, the FDA regulated dietary supplements as a food, a drug, or both depending on its intended use. See Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,692 (June 18, 1993) ("[I]ngredients incorporated into dietary supplements (vitamins, minerals, amino acids, herbs, and other similar nutritional substances that are processed in tablet, capsule, powder, or liquid form) are food additives unless they are [GRAS] or prior-sanctioned.")

¹⁴⁶ See MARK V. NADEL, ASSOCIATE DIRECTOR, NATIONAL AND PUBLIC HEALTH, GENERAL ACCOUNTING OFFICE, FDA REGULATION OF DIETARY SUPPLEMENTS 4 (1993).

ufacturers to establish product safety.¹⁴⁷ In contrast, dietary supplement manufacturers believed that their products should be regulated as food that is not subject to premarket approval.¹⁴⁸

All of these issues played a role in formulating the FDA's regulatory approach to supplements. Pursuant to Congress's order in the DSA, on June 18, 1993, the FDA published two sets of regulations regarding dietary supplements.¹⁴⁹ The first notice was a proposed rule regarding appropriate labeling requirements for dietary supplements. This proposed rule echoed many aspects of the FDA's proposed rule regarding dietary supplements published in 1991. In essence, the agency recommended that nutrient claims, health claims, and other labeling issues regarding dietary supplements be treated in much the same fashion as labels on conventional foods.¹⁵⁰ The second set of proposed regulations published at this time were much more controversial, as they went further than merely addressing labeling issues.¹⁵¹ Rather, the FDA published a comprehensive advance notice of proposed rulemaking ("ANPR") regarding the regulation of dietary supplements in general, "in response to the Dietary Supplement Act of 1992 (the DS act), recent developments and events in the marketplace, and the report of an outside expert body on the safety of amino acid supple-

¹⁴⁷See MARK V. NADEL, ASSOCIATE DIRECTOR, NATIONAL AND PUBLIC HEALTH, GENERAL ACCOUNTING OFFICE, FDA REGULATION OF DIETARY SUPPLEMENTS 4 (1993); Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,692 (June 18, 1993). Certain vitamins and minerals were either generally recognized as safe (GRAS) or prior-sanctioned and thus not subject to premarket review. This premarket review is generally not carried out with respect to dietary supplements. Rather, the FDA's regulation of supplement products occurs more on a case-by-case basis as specific examples of safety concerns or misbranding are brought to the agency's attention. See MARK V. NADEL, ASSOCIATE DIRECTOR, NATIONAL AND PUBLIC HEALTH, GENERAL ACCOUNTING OFFICE, FDA REGULATION OF DIETARY SUPPLEMENTS 4 (1993);

¹⁴⁸See MARK V. NADEL, ASSOCIATE DIRECTOR, NATIONAL AND PUBLIC HEALTH, GENERAL ACCOUNTING OFFICE, FDA REGULATION OF DIETARY SUPPLEMENTS 3 (1993).

¹⁴⁹Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,690 (proposed June 18, 1993) (to be codified at 21 C.F.R. Ch.1); Food Labeling: Requirements for Nutrient Content Claims for Dietary Supplements of Vitamins, Minerals, Herbs, and Other Similar Nutritional Substances, 58 Fed. Reg. 33,731 (proposed June 18, 1993) (to be codified at 21 C.F.R. §101).

¹⁵⁰See Food Labeling: Requirements for Nutrient Content Claims for Dietary Supplements of Vitamins, Minerals, Herbs, and Other Similar Nutritional Substances, 58 Fed. Reg. 33,731, 33,731-32 (June 18, 1993). Pursuant to the provisions of the NLEA, the FDA promulgated final regulations regarding nutrient content and health claims for conventional foods on January 6, 1993. Final Rule on Nutrient Content Claims, 58 Fed. Reg. 2302 (January 6, 1993) (codified at 21 C.F.R. § 101). As the "FDA [] tentatively concluded that it would be helpful to continue to minimize inconsistencies in nutrient content claims between dietary supplements and foods in conventional food form," it proposed that "similar nutritional substances should generally be subject to the same requirements as other foods." Food Labeling: Requirements for Nutrient Content Claims for Dietary Supplements of Vitamins, Minerals, Herbs, and Other Similar Nutritional Substances, 58 Fed. Reg. 33,731, 33,731-32 (June 18, 1993). The agency conceded, however, that several sections of the regulations pertaining to conventional foods may require revision to be applied appropriately to dietary supplements. *Id.*, at 33,732.

¹⁵¹Regulation of Dietary Supplements, 58 Fed. Reg. 33,690 (June 18, 1993).

ments.”¹⁵² This notice incorporated the findings of the Dietary Supplement Task Force, various meetings with “industry, public health, and consumer group representatives,”¹⁵³ and an independent expert body contracted to evaluate the safety of amino acids after the L-tryptophan crisis.¹⁵⁴ Based on this data, the various provisions of the ANPR included, among other things, several suggestions about regulation of various types of dietary supplements, primarily focusing on safety concerns.¹⁵⁵ First, the ANPR recommended that the FDA establish a maximum dosage level for vitamins and minerals due to toxicity concerns at high levels of intake.¹⁵⁶ Second, the FDA indicated that it intended to bring “into compliance with the law”¹⁵⁷ many amino acids currently on the market, as they are unapproved food additives and “adequate scientific evidence to ensure their safe use does not exist.”¹⁵⁸ Further, due to their wide use and marketing for therapeutic purposes, the ANPR proposed regulating amino acids as drugs.¹⁵⁹ Third, the ANPR noted that many herbs sold as supplements “have no known history of food use and, even without drug claims, are used for medical purposes.”¹⁶⁰ Accordingly, the FDA proposed to remove hazardous herbs from the market and to bring regulatory action against herbal products that are marketed for drug use.¹⁶¹

The proposed actions embodied in the June 1993 regulatory notices set off a maelstrom of controversy and spurred considerable protest from both consumers and the dietary supplement industry.¹⁶² The regulations

¹⁵²Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,690 (June 18, 1993).

¹⁵³Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,691 (June 18, 1993).

¹⁵⁴After the EMS outbreaks associated with L-tryptophan use, the FDA contracted with the Life Sciences Research Office, Federation of American Societies of Experimental Biology (LSRO/FASEB) to evaluate the safety of amino acids. *See* Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,691 (June 18, 1993).

¹⁵⁵*See* Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,691 (June 18, 1993). Such safety concerns included both “direct” and “indirect” hazards associated with supplement use. The FDA defined direct hazards as those “adverse health effects directly attributable to the components of dietary supplement products,” such the effect of a particular ingredient or the presence of a contaminant. Indirect hazards, on the other hand, resulted when “the use of a supplement product delays the diagnosis or treatment of a health disorder [such as when the product claims benefits that are unfounded or exaggerated].” *Id.*, at 33,692.

¹⁵⁶*See* Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,694-95 (June 18, 1993).

¹⁵⁷Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,697 (June 18, 1993).

¹⁵⁸*See* Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,697 (June 18, 1993).

¹⁵⁹Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,697 (June 18, 1993).

¹⁶⁰Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,697 (June 18, 1993). This medical use of many herbs may stem from the fact that many herbs have historically and currently been used as traditional medicines in many countries. *See id.*, at 33,698.

¹⁶¹*See* Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,698 (June 18, 1993).

¹⁶²*See* Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of*

were viewed as a warning that the FDA was going to restrict access to supplements severely, by removing them from stores¹⁶³ or by classifying them as drugs that required a prescription. Further, the regulations were seen by many as an attempt to reinstate regulations that had been struck down by courts or specific legislation.¹⁶⁴ Dietary supplement manufacturers also saw the FDA's intention to hold label claims on dietary supplements to generally the same standards as label claims on food products as a warning of a harsher regulatory regime.¹⁶⁵ These concerns so inflamed industry and consumer sentiment that dietary supplement supporters organized a "National Blackout Day," during which supplement products "targeted" by the FDA regulations were draped in black crepe paper to emphasize the potential impact of unfettered regulation of supplements.¹⁶⁶ The FDA Commissioner unsuccessfully attempted to assuage public concerns, but the dramatic yet effective demonstration had already provoked a "public outcry" against the FDA.¹⁶⁷

Dietary Supplement Health and Education Act of 1994

The dietary supplement industry and consumers¹⁶⁸ began to lobby Congress heavily to restrict the FDA's

Choice, 49 FLA. L. REV. 663, 678 (1997); COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Feb. 16, 2001) <<http://www.health.gov/dietsupp/ch2.htm>>.

¹⁶³For example, "[t]he application of the food additive provisions to amino acids, as suggested by the FDA Advance Notice, would effectively remove many of these supplements from stores" absent scientific evidence of their safety. Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 678 (1997).

¹⁶⁴See COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Feb. 16, 2001) <<http://www.health.gov/dietsupp/ch2.htm>>. To illustrate, the restrictions proposed for "high-dosage" vitamins and minerals are arguably analogous to the ones struck down by the courts in the 1970s and barred through the Proxmire Amendment. The FDA's efforts to regulate dietary supplements as unsafe food additives have been similarly questioned by courts. In 1993, two unanimous decisions by different courts of appeal dismissed the FDA's efforts to regulate black currant oil as an unsafe food additive as "nonsensical" and as an "Alice in Wonderland" approach. SEN. REP. NO. 103-410, at 10-11 (1994) (referencing *United States v. Two Plastic Drums*, 984 F.2d 814 (7th Cir. 1993); *United States v. 29 Cartons of . . . an Article of Food*, 987 F.2d 33 (1st Cir. 1993)).

¹⁶⁵See Iona N. Kaiser, *Dietary Supplements: Can the Law Control the Hype?*, 37 Hous. L. Rev. 1249, 1257-58 (2000).

¹⁶⁶See Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 678 (1997); Iona N. Kaiser, *Dietary Supplements: Can the Law Control the Hype?*, 37 Hous. L. Rev. 1249, 1257-58 (2000).

¹⁶⁷See Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 678 (1997); Iona N. Kaiser, *Dietary Supplements: Can the Law Control the Hype?*, 37 Hous. L. Rev. 1249, 1257-58 (2000).

¹⁶⁸In this era of self-treatment and preventive health, many consumers preferred to make their own decision about products rather than having the FDA filtering out the information that would be made available. See I. SCOTT BASS & ANTHONY L.

regulatory authority over supplements and to prevent the FDA from finalizing the 1993 proposed regulations.¹⁶⁹ In the summer of 1993, Congress began to receive a tremendous volume of mail,¹⁷⁰ telephone calls, and constituent pressure to ensure access to dietary supplements.¹⁷¹ This overwhelming lobbying effort continued in 1994, as “[m]any members of the House of Representatives and Senate stated that they were receiving more [communications and demands] on this subject than on anything else – including health care reform, abortion, or the deficit.”¹⁷²

Once again, Congress responded to public and industry protests regarding unpopular FDA regulations by passing legislation to amend the FDCA. On October 25, 1994, President Clinton signed into law the Dietary Supplement Health and Education Act of 1994 (“DSHEA”),¹⁷³ which was passed unanimously by both the House of Representatives and the Senate.¹⁷⁴ The DSHEA represents Congress’s efforts to improve public access to and information regarding safe dietary supplement products and to create a “rational Federal framework” for supplement regulation to replace “the current ad hoc, patchwork regulatory policy”.¹⁷⁵ In addition, the DSHEA recognizes that improving the health of Americans is a top priority and that mil-

YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS i (1996).

¹⁶⁹See David C. Vladeck, *Devaluing Truth: Unverified Health Claims in the Aftermath of Pearson v. Shalala*, 54 FOOD & DRUG L.J. 535, 538-39 (1999).

¹⁷⁰“Later in 1993, Congressman Waxman, then chairman of the House Health Subcommittee of the Commerce Committee, wrote to other members about ‘the large volume of mail on the issue of dietary supplements.’ Waxman said much of the mail was generated by scare tactics to lead the public to believe the FDA was about to take vitamins, herbs and other dietary supplements off the market or to require prescriptions for them.” William J. Skinner, R.Ph., J.D., *Allowable Advertising Claims for Dietary Supplements*, 5 J. PHARMACY & L. 309, 314 (1996) (citing a letter from Congressman Henry Waxman, Chairman of House Health Subcommittee of Committee to other members of Committee (Oct. 14, 1993) (reproduced at 55 FOOD & DRUG REPORT 737 (1994))).

¹⁷¹See William J. Skinner, R.Ph., J.D., *Allowable Advertising Claims for Dietary Supplements*, 5 J. PHARMACY & L. 309, 309 (1996); Stephen H. McNamara, *FDA Regulation of Ingredients in Dietary Supplements After Passage of the Dietary Supplement Health and Education Act of 1994: An Update*, 51 FOOD & DRUG L.J. 313, 313 (1996).

¹⁷²Stephen H. McNamara, *FDA Regulation of Ingredients in Dietary Supplements After Passage of the Dietary Supplement Health and Education Act of 1994: An Update*, 51 FOOD & DRUG L.J. 313, 313 (1996). One observer suggested that the dietary supplement lobbying campaign was “solely responsible for the purchase of many telephone answering machines” by congressional offices. William J. Skinner, R.Ph., J.D., *Allowable Advertising Claims for Dietary Supplements*, 5 J. PHARMACY & L. 309, 309 (1996).

¹⁷³Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994), codified at 21 U.S.C. § 301 *et seq.*, 42 U.S.C. § 287.

¹⁷⁴See Stephen H. McNamara, *FDA Regulation of Ingredients in Dietary Supplements After Passage of the Dietary Supplement Health and Education Act of 1994: An Update*, 51 FOOD & DRUG L.J. 313, 313 (1996). The House of Representatives passed the DSHEA on October 7, 1994, and the Senate approved the measure on October 8, 1994. *See id.*

¹⁷⁵Dietary Supplement Health and Education Act of 1994, Pub L. 103-417, 108 Stat. 4325, 4325-26 (1994).

lions of Americans rely on use of dietary supplements as a preventive health measure.¹⁷⁶ Accordingly, the DSHEA finds that taking legislative action that protects access to safe preventive health measures will not only empower consumers to make informed health choices but also extend lives while reducing individual and national health care expenditures.¹⁷⁷ In a harsh criticism of the FDA, Congress notes that the agency’s “heavy-handed enforcement agenda” against dietary supplements for decades despite a “voluminous scientific record” supporting the health benefits these supplements has “forced” Congress to intervene on several occasions; the DSHEA is merely the latest in the series of such efforts.¹⁷⁸ The DSHEA, however, is unique in that it represents Congress’s first concrete foray into comprehensive regulation specifically tailored to concerns relating to the dietary supplement industry.¹⁷⁹ In an interesting political move, sponsors of the bill negotiated a “Statement of Agreement” to limit the legislative history of the DSHEA to five stipulated resolutions.¹⁸⁰ This effort perhaps reflected a need to present a united front on this controversial and bitterly fought battle between the industry and the FDA.¹⁸¹ The Statement of Agreement may also have been a strategy to forestall the FDA “from seizing upon certain language to continue its efforts to invoke the most stringent requirements possible.”¹⁸²

¹⁷⁶Dietary Supplement Health and Education Act of 1994, § 2. The findings of the DSHEA indicate 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.” *Id.*

¹⁷⁷Dietary Supplement Health and Education Act of 1994, § 2. The economics of health care expenditures and the size of the dietary supplement industry are somewhat staggering. In 1994, national health care costs totaled over one trillion dollars, approximately 12 percent of the gross national product (“GNP”). Sales of dietary supplement products exceeded 4 billion dollars in 1994. *See id.*

¹⁷⁸S. REP. NO. 103-410, at 10 (1994).

¹⁷⁹Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994), codified at 21 U.S.C. § 301 *et seq.*, 42 U.S.C. § 287. Previous Congressional interventions either were not specifically targeted at dietary supplements, such as the NLEA, or were not comprehensive in their scope, such as the Proxmire Amendment.

¹⁸⁰140 CONG. REC. S14801 (daily ed. Oct. 7, 1994).

¹⁸¹*See* William J. Skinner, R.Ph., J.D., *Allowable Advertising Claims for Dietary Supplements*, 5 J. PHARMACY & L. 309, 309 (1996). One “inside [] beltway political observer” even hypothesized that “the pent-up disgust with the Congress on this one issue is just as likely a cause of the Democratic Party’s downfall [in the November 1994 elections, in which Republicans gained control for the first time in 40 years] as was the ‘Contract with America.’” *Id.*

¹⁸²William J. Skinner, R.Ph., J.D., *Allowable Advertising Claims for Dietary Supplements*, 5 J. PHARMACY & L. 309, 309 (1996).

Several of the key provisions of this comprehensive legislation are briefly described below.

Definitions

The DSHEA attempted to clarify years of uncertainty by defining the term “dietary supplement” for the first time.¹⁸³ This broad definition moved beyond the traditional notion that dietary supplements are merely made up of vitamins, minerals, proteins, and other essential nutrients;¹⁸⁴ rather, the new definition also included herbs, amino acids, and other substances used to supplement the diet in its scope.¹⁸⁵ Dietary supplements must be clearly labeled as such,¹⁸⁶ and may appear in conventional food form¹⁸⁷ or as tablets, capsules, powders, softgels, or liquids¹⁸⁸ if they are “not represented for use as conventional food or as a sole item of a meal or the diet.”¹⁸⁹ More importantly, the DSHEA specifically confirms that products meeting the new definition of dietary supplement should be regulated as food, not as drugs, provided that the label does not make a prohibited disease claim.¹⁹⁰ Products that are approved as drugs, licensed

¹⁸³S. REP. NO. 103-410, at 22 (1994).

¹⁸⁴See Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 666 (1997).

¹⁸⁵See 21 U.S.C. § 321(ff).

(ff) 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).

Id. Congress intended that this definition “encompass all those substances and materials that are presently contained in dietary supplements as well as substance[s] derived from foods.” S. REP. NO. 103-410, at 22 (1994). Under the expanded definition, dietary supplements “include such substances as ginseng, garlic, fish oils, psyllium, enzymes, [and] glandulars.” CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, U.S. FOOD AND DRUG ADMINISTRATION, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994 (December 1, 1995) (visited Feb. 4, 2001) <<http://vm.cfsan.fda.gov/~dms/>>.

¹⁸⁶21 U.S.C. § 321(ff)(2)(C).

¹⁸⁷These forms may include powders, bars or drinks. S. REP. NO. 103-410, at 22 (1994).

¹⁸⁸21 U.S.C. § 350(c)(1)(B)(i).

¹⁸⁹21 U.S.C. § 321(ff)(2)(B).

¹⁹⁰21 U.S.C. § 321(ff)(3). As dietary supplements are not considered to be foods for the purposes of the drug definition of the FDCA, they do not receive the same safe harbor as foods. Specifically, the provision that exempts “articles (other than food) intended to affect the structure or any function of the body of man or other animals” from the definition of drug does not apply to supplements. 21 U.S.C. § 321 (g)(1)(C).

as biologics, or certified as antibiotics that were previously marketed as dietary supplements or food are also considered to be dietary supplements unless the Secretary of Health and Human Services waives this provision.¹⁹¹ The DSHEA further explicitly forbids the FDA from regulating dietary supplement ingredients as food additives.¹⁹² The expanded definition of dietary supplements combined with the exemption of dietary supplements from regulation as drugs or food additives represents a major victory for the supplement industry and tremendously restricts the FDA's authority to regulate such products.

Dietary Supplement Label Exemption

In the DSHEA, Congress also relaxed standards regarding what constitutes the "labeling" of a dietary supplement product.¹⁹³ Prior to the passage of the DSHEA, literature "used in connection with the sale or distribution of a product" was considered to be part of the supplement's labeling.¹⁹⁴ Accordingly, the claims and endorsements found in these pamphlets, articles, brochures, and other accompanying pieces of literature

¹⁹¹21 U.S.C. § 321(ff)(3).

¹⁹²21 U.S.C. § 321(s). An unfortunate result of this change is that dietary supplements are exempt from the Delaney Clause, which protects consumers from carcinogenic substances. See 21 U.S.C. § 348(c)(3). "This is a potential health hazard as many of the herbal supplements are plant-derived and exposed to cancer-causing pesticides. They are extracted and further concentrated during the final stages of production, thereby increasing the concentration of the carcinogen in the final product." Leticia M. Diaz, *First St. John's Wort, Now SAM-e: Is Society as a Whole at Risk Without FDA Regulation of Psychiatric Self-Medication*, 9 KANSAS J.L. & PUB. POL'Y 279 (Winter 1999).

¹⁹³See 21 U.S.C. § 343-2.

¹⁹⁴S. REP. NO. 103-410, at 23 (1994). For more than 50 years, the FDA had pursued this policy of associating books and other publications to the foods and dietary supplements that they promoted. See I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 49 (1996). Courts often had to intervene in the ongoing battle between the dietary supplement industry, health food stores (that often stocked both books and products), and the FDA. See, e.g. *Kordel v. United States*, 335 U.S. 345 (1948) (finding that "labels" included associated materials, even if physically separate from the product or package); *United States v. Urbuteit*, 335 U.S. 355 (1948) (holding that literature sent "in a separate mail does not save the article from being misbranded"); *United States v. Taller*, 394 F.2d 435 (2d Cir.), cert. denied, 393 U.S. 839 (1968); *United States v. . . . Cove Vitamin and Pharm Inc.*, 204 F. Supp. 283 (E.D.N.Y. 1962); *United States v. 8 Cartons, More or Less, Molasses, etc.* 97 F. Supp. 313 (W.D.N.Y. 1951); *United States v. An Article of Drug Consisting of 250 Jars, etc. of U.S. Fancy Pure Honey, etc.*, 218 F. Supp. 208 (E.D. Mich. 1963), *aff'd* 344 F.2d 288 (6th Cir. 1965); *United States v. "Sterling Vinegar and Honey"*, 338 F.2d 157 (2d Cir. 1964); *United States v. General Nutrition, Inc.*, 638 F. Supp. 556 (W.D.N.Y. 1986).

were held to the same standards as information contained on a label attached to the product itself.¹⁹⁵ As a result, the FDA often seized either the literature itself or the products whose health benefits the literature promoted.¹⁹⁶

The DSHEA effectively changed this law to exempt literature from the definition of “labeling” for dietary supplement products provided that the materials meet certain criteria.¹⁹⁷ Specifically, retailers may now make “third party” literature¹⁹⁸ – including articles, book chapters, and scientific abstracts – available to dietary supplement consumers if the literature is “reprinted in its entirety” and conforms to the following provisions:

(1)

(2)

(3)

(4)

¹⁹⁵ See S. REP. NO. 103-410, at 23 (1994).

¹⁹⁶ See, generally, I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 49-50 (1996).

¹⁹⁷ See 21 U.S.C. § 343-2(a).

¹⁹⁸ Although this section is commonly referred to as allowing “third party” literature, the language does not actually limit who may author a publication. Accordingly, it appears that manufacturers and distributors of supplements can commission or publish such literature themselves provided that it meets all of the statute’s requirements, including nonpromotion of a specific manufacturer or brand. See I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 51 (1996).

(5)

These new labeling exceptions not only limited the FDA's ability to regulate the dissemination of health claims and other information regarding supplements, but also explicitly placed the burden of proof on the FDA "to establish that an article or other such matter is false or misleading."²⁰⁰

Nutritional Support, Structure/Function, and Health Claims

By explicitly authorizing the use of various types of statements and claims on dietary supplement labels, the DSHEA broadened the scope of the exemption from the drug provisions of the FDCA, as set forth in NLEA.²⁰¹ As previously discussed, the NLEA created a type of safe harbor for food – and, by extension, for supplements – by establishing a mechanism through which manufacturers could make label claims that characterized the relationship of a given nutrient to a specific disease or health-related condition.²⁰² These claims would ordinarily be considered drug claims²⁰³ and thereby be subject to the arduous new drug application requirements.²⁰⁴ The NLEA, however, provides such claims will not be considered to be drug claims if they conform with a standard of "significant scientific agreement" and are authorized in advance through FDA regulation.²⁰⁵ The DSHEA leaves the NLEA health claims standard largely intact with respect to dietary supplements, and merely establishes a Commission to study how to regulate label claims most effectively.²⁰⁶

²⁰⁰21 U.S.C. § 343-2(c).

²⁰¹See 21 U.S.C. § 343(r)(1)(B).

²⁰²See 21 U.S.C. § 343(r)(1)(B).

²⁰³See 21 U.S.C. § 321(g).

²⁰⁴See 21 U.S.C. § 355.

²⁰⁵See 21 U.S.C. § 343(r)(3).

²⁰⁶See Dietary Supplement Health and Education Act of 1994, § 12. As will be discussed in greater depth later in this piece, the Commission ultimately recommended that the same standards apply to both dietary supplements and conventional foods, as detailed in the NLEA. See Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 680 (1997).

More importantly, however, the DSHEA further qualified the scope of the FDA's regulatory authority with respect to dietary supplements by creating several new categories of allowable claims that require no pre-market approval or preclearance by the FDA.²⁰⁷ In essence, the DSHEA allows manufacturers to make a variety of statements that do not claim a direct correlation between a particular nutrient or ingredient and a disease or health-related condition. Specifically, manufacturers can now make claims about their supplement products if

[t]he statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient.²⁰⁸

This provision expands a supplement manufacturer's power to make product claims in several key aspects. First, this provision created a blanket safe harbor for any claims regarding nutrient deficiency diseases. Second, it establishes an affirmative right for supplement manufacturers to make claims regarding the effect of a nutrient or dietary ingredient on the "structure/function" of the body or on a person's general well-being. This right confirms the traditional notion that food labeled with structure/function claims is not considered to be a drug. Although the DSHEA's new definition of dietary supplements clearly indicates that supplements are not food for the purpose of the structure/function exemption from the drug definition of the FDCA,²⁰⁹ this new labeling provision ensures that supplements may still make such claims. As a result, the DSHEA explicitly authorizes structure/function and other claims for supplements due to their status as supplements rather than allowing structure/function claims for supplements based upon their status as food.²¹⁰ By allowing supplement claims based on not only nutrients but also dietary ingredients²¹¹ with no

²⁰⁷ See 21 U.S.C. § 343(r)(6).

²⁰⁹ See Dietary Supplement Health and Education Act of 1994, §3(a).

²¹⁰ Conforming amendments to the DSHEA revised the definition of drug under the FDCA to reflect such changes. See 21 U.S.C. § 321(g)(1).

²¹¹ The Act does not explicitly define "dietary ingredient."

known nutritive value, the DSHEA creates an exemption from the drug definition that is arguably larger for dietary supplements than it is for conventional foods.²¹²

A manufacturer may make any such nutritional support or structure/function claim on the label of a dietary supplement without FDA review.²¹³ Such statements merely must be “truthful and not misleading”²¹⁴ and contain a disclaimer indicating that the statement has not been evaluated by the FDA and that the product is not intended to “diagnose, treat, cure, or prevent any disease.”²¹⁵ These new labeling guidelines are among the most important provisions of the DSHEA, as the safe harbors created for dietary supplements allow manufacturers to make label claims that would previously have been either outright prohibited or allowed only after some level of FDA review and approval.

Commission on Dietary Supplement Labels and Office of Dietary Supplements

The DSHEA also established two groups to help study and provide recommendations on the regulation of dietary supplements. The first group, the Commission on Dietary Supplement Labels (the “Commission”), was an independent, temporary body charged with the task studying label claims and the use of literature in supplement sales to “evaluate how best to provide truthful, scientifically valid, and not misleading information to consumers.”²¹⁶ The Act directed that the seven members of this Commission were to be appointed by the President and comprised of various unbiased scientific and nonscientific experts in the “manufacture, regulation, distribution, and use” of supplement products.²¹⁷ The Commission was allotted two years to

²¹²One court suggested that a common-sense definition of food covered articles primarily used for “taste, aroma, or nutritive value.” *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, 338 (7th Cir. 1983).

²¹³The manufacturer, however, must notify the FDA within “30 days after the first marketing of the dietary supplement . . . that such a statement is being made.” 21 U.S.C. § 343(r)(6)(C).

²¹⁴21 U.S.C. § 343(r)(6)(B).

²¹⁵21 U.S.C. § 343(r)(6)(C).

²¹⁶Dietary Supplement Health and Education Act of 1994, § 12.

²¹⁷Dietary Supplement Health and Education Act of 1994, § 12.

submit a final report and recommendations regarding supplement regulation; subsequently, the FDA would have 90 days to issue proposed regulations on the recommendations and two years to complete the rulemaking process.²¹⁸

The second group was a permanent Office of Dietary Supplements (“Office”), established within the National Institutes of Health to explore the potential role of dietary supplements in healthcare improvement and “to promote scientific study” of the health benefits of supplements.²¹⁹ Essentially, this Office was intended to be a clearinghouse for the results of scientific research regarding supplements and would advise other governmental agencies, such as the FDA, on various supplement issues.²²⁰

Other Provisions

Several other important provisions of the DSHEA deserve a brief mention. One of the immediate effects of the DSHEA was to once again upend the FDA regulatory scheme regarding dietary supplements. The Act expressly declared the controversial June 18, 1993 ANPR to be “null and void and of no force or effect.”²²¹ The FDA was instead again directed to restudy the issue, with the assistance of the Commission on Supplement Labels and the Office of Dietary Supplements, and to issue a new set of regulations incorporating these groups’ recommendations and the changes embodied in DSHEA.²²² Another set of provisions established requirements for dietary supplement ingredient and nutrition information labeling.²²³

The DSHEA also addressed the issue of supplement safety in several ways. Taken as a whole, it is unclear whether the safety provisions have an overall effect of improving or reducing the safety of supplement prod-

²¹⁸Dietary Supplement Health and Education Act of 1994, § 12.

²¹⁹42 U.S.C. § 287c-1(b).

²²⁰See 42 U.S.C. § 287c-1(c). The Act specifically directed the Office of Dietary Supplements to provide advice regarding dietary intake regulations, supplement safety, health-related and disease claims, and “scientific issues arising in connection with the labeling and composition of dietary supplements.” 42 U.S.C. § 287c-1(c)(3).

²²¹Dietary Supplement Health and Education Act of 1994, § 11.

²²²See Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994).

²²³See 21 U.S.C. § 343(s); 21 U.S.C. § 343(q)(5)(F).

ucts. In some instances, the FDA appears to be given additional opportunities to closely regulate supplement safety, and in other provisions the DSHEA seems to place additional burdens on the FDA. To illustrate, one provision gives the FDA authority to set regulations prescribing good manufacturing practices for dietary supplements.²²⁴ The FDA is stripped of its power to regulate supplements under the food additive provisions,²²⁵ but the Act also imposes new conditions,²²⁶ under which supplements may be deemed to be adulterated.²²⁶ One significant result of these various provisions is that the burden of proof regarding safety and effectiveness shifts from supplement manufacturers to the FDA.²²⁷

III.

1994-2001: THE IMPLEMENTATION AND IMPACT OF DSHEA

As is evident from the provisions described above, the DSHEA effectively strips the FDA of much of its regulatory authority regarding dietary supplements. The practical impact of the limitations that the DSHEA established upon the FDA has been “enormous,”²²⁸ and some commentators have even criticized the DSHEA as “the greatest removal of FDA jurisdiction in the 90-some-year history of the FDA.”²²⁹ Many of such critiques reflect the fact that the DSHEA blurred the boundary between drug claims that require premarket

²²⁴See 21 U.S.C. § 342.

²²⁵See 21 U.S.C. § 321(s).

²²⁶See, e.g., 21 U.S.C. § 342 (adding new dietary supplement-specific safety requirements to the adulterated food section of the FDCA); 21 U.S.C. § 350(b) (establishing safety requirements for new dietary ingredients).

²²⁷See, e.g., 21 U.S.C. § 321(s); 21 U.S.C. § 342(f)(1)(B); 21 U.S.C. § 343-2(c).

²²⁸Michael Higgins, *Hard to Swallow: While Federal Law Shut the Door on Regulation of Dietary Supplements, Marketing Hype May be Leading the Popular Aids Up Courthouse Steps*, 85 A.B.A. J. 60, 62 (June 1999).

²²⁹Michael Higgins, *Hard to Swallow: While Federal Law Shut the Door on Regulation of Dietary Supplements, Marketing Hype May be Leading the Popular Aids Up Courthouse Steps*, 85 A.B.A. J. 60, 62 (June 1999) (quoting “James O’Reilly, health law professor at the University of Cincinnati and a former chair of the ABA Administrative Law and Regulatory Practice Section”).

approval and testing and food claims that are not subject to any such restrictions prior to being introduced into the consumer market.²³⁰ Prior to the DSHEA, the FDA had fairly broad jurisdiction to evaluate and restrict label claims that appeared to be making a drug claim, as defined in section 201 of the FDCA.²³¹ The DSHEA, however, eviscerated the traditional notion of what constituted a drug claim by attempting to categorize and distinguish among various types of label statements.²³² Accordingly, after the enactment of the DSHEA, fewer types of claims remained within the scope of the FDA's drug enforcement power, and the FDA was faced with the challenge of publishing regulations that elaborated upon the subtle distinctions established by Congress.

Specifically, the DSHEA instructed the FDA to evaluate and enact rules regarding four categories of label claims for dietary supplements. To help illustrate the framework that the DSHEA set in place, a description of each of these types of claims is briefly reviewed below. Each type of claim described below can be conceptualized as a part of a continuum from claims that make extremely general promises of well-being or nutritional support to claims that promise disease cure, treatment, or prevention.

The first two types of claims may be considered together as statements of nutritional support. First, the DSHEA allowed manufacturers to make statements that "claim[] a benefit related to a classical nutrient deficiency disease" or describe "general well-being from consumption of a nutrient or dietary ingredient," provided that the manufacturer could substantiate that the statement was truthful and not misleading.²³³ Such claims do not require any sort of premarket approval by the FDA; manufacturers are merely required to notify the FDA that the statement was being made within 30 days of first marketing the product.²³⁴

²³⁰ See Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 666 (1997).

²³¹ 21 U.S.C. § 321(g).

²³² 21 U.S.C. § 343

²³³ 21 U.S.C. § 343(r)(6).

²³⁴ 21 U.S.C. § 343(r)(6)(C).

These claims also require use of a disclaimer indicating that the FDA has not evaluated the statement.²³⁵ Second, the DSHEA authorized label claims that either describe “the role of a nutrient or dietary ingredient intended to affect the structure of function in humans” or characterize “the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function.”²³⁶ As with the first category of claims, these “structure/function” claims do not require premarket review. Rather, manufacturers are free to release products bearing such statements provided that they meet the aforementioned conditions of notice, disclaimer, and truthfulness.²³⁷

The third and fourth categories of claims are those that establish a more direct causal relationship between a particular nutrient or dietary ingredient and its alleged curative or preventative properties. Accordingly, the third category of label statements is comprised of health claims, which are defined by the NLEA as a claim that characterizes the relationship between a nutrient and a specific disease or health-related condition.²³⁸ Although such claims would ordinarily be considered to be drug claims, establishing the category of health claims provides manufacturers with the opportunity to make such label statements without going through the rigorous new drug approval process.²³⁹ Instead, the health claims category establishes the possibility of a different procedural avenue to receive FDA premarket approval. Under this alternate system, dietary supplements may bear disease or health-related statements if the FDA determines that the claim is supported by “significant scientific agreement” and issues a corresponding regulation.²⁴⁰ Finally, the fourth category, drug claims, also applies to statements that bear a disease or health-related claim. Any such statement that

²³⁵21 U.S.C. § 343(r)(6)(C).

²³⁶21 U.S.C. § 343(r)(6)(A).

²³⁷21 U.S.C. § 343(r)(6).

²³⁸21 U.S.C. § 343(r)(1)(B).

²³⁹Some critics argue that the FDA’s strict interpretation of the “significant scientific agreement” standard for health claims makes the standard for these claims as stringent as the standard used for approving new drugs. *See infra* 45-54.

²⁴⁰21 U.S.C. § 343(r)(3)(B). Any manufacturer may petition the FDA to evaluate a health claim; the NLEA gives the FDA 100 days to make a decision on the claim or to take further action. 21 U.S.C. § 343(r)(4)(A)(i). Once the FDA issues such a regulation, any company, not just the one that originally petitioned the FDA, can use the claim on a product meeting criteria outlined in the regulations. *See UNITED STATES GENERAL ACCOUNTING OFFICE, FOOD SAFETY: IMPROVEMENTS NEEDED IN OVERSEEING THE SAFETY OF DIETARY SUPPLEMENTS AND “FUNCTIONAL FOODS”* 10 (July 2000).

has not been authorized as a health claim is treated as a drug claim. Accordingly, drug claims must undergo extensive premarket testing and review prior to use.²⁴¹ The time and expense involved for processing a new drug claim is much greater than for a health claim that does not require any independent study by the manufacturer if it is supported by “significant scientific agreement.”

Issuing regulations to implement these categories in practical terms, however, was not to be an easy task. In particular, the establishing the actual distinction between structure/function claims that do not require premarket approval and health or drug claims that do require premarket approval proved to be one of the most highly controversial aspects of the DSHEA, as this dividing line was clouded with great ambiguity.

Report of the Commission on Dietary Supplement Labels

The FDA, fortunately, did not have to attack this problem alone. The DSHEA had established a Commission on Dietary Supplement Labels to help investigate label statements and to recommend to the FDA appropriate action for implementation.²⁴² Yet this help was a long time in coming, as President Clinton “took a year” after enactment of the DSHEA to appoint the seven members of the Commission.²⁴³ Subsequently, the Commission researched the issues for two years and did not publish a final report until November 1997, more than three years after the President signed the DSHEA into law.²⁴⁴ The Commission’s final report included, among other things, an analysis of health claims, structure/function claims, and the degree of

²⁴¹21 U.S.C. § 355.

²⁴²Dietary Supplement Health and Education Act, § 12.

²⁴³William J. Skinner, R.Ph., J.D., *Allowable Advertising Claims for Dietary Supplements*, 5 J. PHARMACY & L. 309, 309 (1996). Commission members included Malden C. Nesheim, Ph.D., Professor of Nutrition and Provost Emeritus of Cornell University; Annette Dickinson, Ph.D., Director of Scientific and Regulatory Affairs for the Council for Responsible Nutrition; Norman R. Farnsworth, Ph.D., Research Professor of Pharmacognosy and Senior University Scholar of the College of Pharmacy at the University of Illinois at Chicago; Margaret Gilhooley, L.L.B., professor at Seton Hall University School of Law; Shiriki K. Kumanyika, Ph.D., M.P.H., Professor and Head of the Department of Human Nutrition and Dietetics at the University of Illinois at Chicago; Robert S. McCaleb, President of the Herb Research Foundation; and Anthony Podesta, President of Podesta Associates. See COMMISSION ON DIETARY SUPPLEMENT LABELS, MEMBERSHIP OF THE COMMISSION ON DIETARY SUPPLEMENT LABELS (visited Mar. 26, 2001) <<http://www.health.gov/dietsupp/member.htm>>.

²⁴⁴See COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Mar. 26, 2001) <<http://www.health.gov/dietsupp/ch3.htm>>. President Clinton signed the DSHEA on October 25, 1994.

substantiation required for each.²⁴⁵

With respect to health claims, the Commission found that a high standard of evidence is appropriate, as valid health claims may have tremendous public health benefits and invalid health claims may encourage behavior that results in harmful and costly health consequences.²⁴⁶ The Commission also recognized that differing standards for health claims on food and health claims on dietary supplements might lead to consumer confusion and be bad public policy.²⁴⁷ Accordingly, the Commission recommended that the FDA use the same process for health claim approval for supplements and for conventional foods. The report cautioned, however, that although “significant scientific evidence” is an appropriate standard to use in evaluating such claims, the FDA should not interpret the standard so strictly “as to require unanimous or near-unanimous support” and should obtain “broad input,” such as from panels of scientists or other government agencies.²⁴⁸ Dissenting views within the Commission indicated that the interpretation of allowable structure/function claims was a more contentious issue.²⁴⁹ Acknowledging that neither the DSHEA nor FDA regulations had “specifically outlined” allowable claims and the differences between allowable structure/function claims and unauthorized health or drug claims was difficult to distinguish, the Commission concluded that “the lack of definition of the clear boundaries of these statements leaves many uncertainties.”²⁵⁰ The Commission was also divided with respect to several specific issues, including the following: whether claims may imply disease prevention, how to regulate claims that indicate “an acute effect on the structure or function of a major system,” what the appropriate distinction was between allowable structure/function claims and drug claims

²⁴⁵ See COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Mar. 26, 2001) <<http://www.health.gov/dietsupp/ch3.htm>>.

²⁴⁶ See COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Mar. 26, 2001) <<http://www.health.gov/dietsupp/ch3.htm>>.

²⁴⁷ See COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Mar. 26, 2001) <<http://www.health.gov/dietsupp/ch3.htm>>.

²⁴⁸ See COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Mar. 26, 2001) <<http://www.health.gov/dietsupp/ch3.htm>>. The report suggested that the views of other government agencies be given “serious consideration” and “considerable weight” in the FDA’s analysis. *See id.*

²⁴⁹ See COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Mar. 26, 2001) <<http://www.health.gov/dietsupp/ch3.htm>>.

²⁵⁰ COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Mar. 26, 2001) <<http://www.health.gov/dietsupp/ch3.htm>>.

referring to organs associated with major clinical conditions,²⁵¹ and whether structure/function claims that suggest an effect on a immune function or disease resistance are appropriate.²⁵² Despite these differences in opinion, the Commission proposed some general guidelines for the FDA; however, they did not issue distinct recommendations.²⁵³ These guidelines do not appear to be too helpful, as they indicate that the FDA will need to employ a case-by-case analysis and primarily seem to make generic comments that statements should be useful, truthful, not misleading, and should not directly refer to or imply relationships to diseases or health-related conditions.²⁵⁴

The Commission also considered what types of substantiation would be sufficient for a nutritional support claim. For statements involving the relationship of a nutrient to a classic nutrient deficiency disease, the Commission agreed that data should come from “recognized sources.”²⁵⁵ Once again, structure/function claims

²⁵¹Conditions include heart, liver, prostate, or circulatory problems. COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Mar. 26, 2001) <<http://www.health.gov/dietsupp/ch3.htm>>.

²⁵²COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Mar. 26, 2001) <<http://www.health.gov/dietsupp/ch3.htm>>.

²⁵³According to the report, guidelines are advice that agencies should consider as “they develop or implement activities related to the availability of dietary supplements in the marketplace,” whereas recommendations “call for consideration of changes in existing regulations, development of new regulations, or legislative action.” COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT: EXECUTIVE SUMMARY (visited Mar. 27, 2001) <<http://www.health.gov/dietsupp/execsum.htm>>.

²⁵⁴COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Mar. 26, 2001) <<http://www.health.gov/dietsupp/ch3.htm>>. In the FDA’s case-by-case assessment of statements, the Commission suggested the following seven guidelines:

1. Statements of nutritional support should provide useful information to consumers about the intended use of a product.
2. Statements of nutritional support should be supported by scientifically valid evidence substantiating that the statements are truthful and not misleading.
3. Statements indicating the role of a nutrient or dietary ingredient in affecting the structure or function of humans may be made when the statements do not suggest disease prevention or treatment.
4. Statements that mention a body system, organ, or function affected by the supplement using terms such as stimulate, maintain, support, regulate, or promote can be appropriate when the statements do not suggest disease prevention or treatment or use for a serious health condition that is beyond the ability of the consumer to evaluate.
5. Statements should not be made that products restore normal or correct abnormal function when the abnormality implies the presence of disease. An example might be a claim to restore normal blood pressure when the abnormality implies hypertension.
6. Health claims are specifically defined under NLEA as statements that characterize the relationship between a nutrient or a food component and a specific disease or health-related condition. Statements of nutritional support should be distinct from NLEA health claims in that they do not state or imply a link between a supplement and prevention of a specific disease or health-related condition.
7. Statements of nutritional support are not to be drug claims. They should not refer to specific diseases, disorders, or classes of diseases and should not use drug-related terms such as diagnose, treat, prevent, cure, or mitigate.

The guidelines also indicated that the FDA should provide manufacturers with letters of notification if a statement is deemed to be an inappropriate structure/function claim. *See id.*

²⁵⁵Recognized sources would include “surveys that are components of the National Nutrition Monitoring and Related Research Program, the publications derived from this program or publications in peer-reviewed journals.” COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Mar. 26, 2001) <<http://www.health.gov/dietsupp/ch3.htm>>.

proved to be more difficult to analyze and the Commission did not reach a clear recommendation. Rather, the report merely acknowledges that substantiation can include various types of evidence²⁵⁶ developed either by the manufacturer or another party, and that the level of substantiation required for a particular claim will vary depending on the specific claim being made.²⁵⁷ For the purpose of practical application, such musings are largely inconclusive.

Health Claims

In order to elucidate the difficulties stemming from the ambiguous difference between structure/function claims and unauthorized health or drug claims fully, it is important to explore health claims as an alternate avenue of allowing statements on supplements. Capturing the distinction between health and structure/function claims would have been much less critical to supplement manufacturers if the FDA was quick or liberal in granting health claims. Instead, structure/function claims perhaps became more important because the FDA was notoriously slow and reluctant to approve health claims, especially on dietary supplements. As previously discussed, the FDA decided to apply the same standard to health claims made on dietary supplement labels and on food labels.²⁵⁸ As the Commission's final report supported this conclusion, the FDA did not revise these rules in the aftermath of the DSHEA. Yet the FDA has only approved a fraction of the claims it has considered and has labored over some of these decisions for years on end. Specifically, the FDA initially approved seven claims in 1993 and has authorized only seven more claims in the intervening

²⁵⁶The report suggests that substantiation evidence may include clinical studies, epidemiologic data, historical usage, animal testing, and studies from peer-reviewed scientific journals. See COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Mar. 26, 2001) <<http://www.health.gov/dietsupp/ch3.htm>>.

²⁵⁷COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Mar. 26, 2001) <<http://www.health.gov/dietsupp/ch3.htm>>.

²⁵⁸See Food Labeling; General Requirements for Health Claims for Dietary Supplements, 59 Fed. Reg. 395 (January 4, 1994), codified at 21 CFR §§ 20, 101.

years.²⁵⁹ Only four of these fourteen total claims apply to dietary supplements,²⁶⁰ possibly due to the difficulties in attributing a result to a specific nutrient, as discussed earlier in this piece. The FDA's treatment of the claim regarding folic acid and neural tube defects is often cited as the quintessential example of how such claims can labor through the regulatory system for tremendous lengths of time; the FDA did not authorize this claim until 1996, four years after the CDC had originally recommended its adoption.²⁶¹ Congress,²⁶² the courts,²⁶³ and the public²⁶⁴ were disenchanted with the FDA's slow, restrictive procedure to evaluate and approve health claims. Accordingly, in addition to the public pressure to approve more health claims or at least to review health claims more promptly, the FDA faced challenges on two fronts, as both Congress and the courts forced the FDA to modify its procedural regime regarding health claims.

²⁵⁹ See FOOD AND DRUG ADMINISTRATION, *Staking a Claim to Good Health: FDA and Science Stand Behind Health Claims on Foods*, FDA CONSUMER, Nov.-Dec. 1998 (visited Feb. 2, 2001) <<http://vm.cfsan.fda.gov/~dms/>>. Subject to certain requirements, the FDA has approved claims between calcium and osteoporosis; sodium and hypertension (high blood pressure); dietary fat and cancer; dietary saturated fat and cholesterol and risk of coronary heart disease; fiber-containing grain products, fruits, and vegetables and cancer; fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease, fruits and vegetables and cancer, folate (folic acid) and neural tube birth defects; dietary sugar alcohol and dental caries (cavities); dietary soluble fiber, such as that found in whole oats and psyllium seed husk, and coronary heart disease; soy protein and coronary heart disease; plant sterol and plant stanol esters and coronary heart disease; whole grain foods and coronary heart disease and certain cancers; potassium and blood pressure and stroke. See *id.*; OFFICE OF NUTRITIONAL PRODUCTS, LABELING AND DIETARY SUPPLEMENTS, FOOD AND DRUG ADMINISTRATION, HEALTH CLAIM NOTIFICATION FOR POTASSIUM CONTAINING FOODS, Oct. 31, 2000 (visited Mar. 27, 2001) <<http://vm.cfsan.fda.gov/~dms/>>; OFFICE OF FOOD LABELING, FOOD AND DRUG ADMINISTRATION, *Health Claim Notification for Whole Grain Foods*, July 1999 (visited Feb. 2, 2001) <<http://vm.cfsan.fda.gov/~dms/>>. All of the authorized health claims to date relate a nutrient to a reduced risk of disease; the FDA has not allowed any statements that claim to treat or mitigate disease. See UNITED STATES GENERAL ACCOUNTING OFFICE, FOOD SAFETY: IMPROVEMENTS NEEDED IN OVERSEEING THE SAFETY OF DIETARY SUPPLEMENTS AND "FUNCTIONAL FOODS" 3 n.2 (July 2000).

²⁶⁰ Certain dietary supplements may include the health claims involving calcium, folic acid, dietary soluble fiber, and plant sterol. See FOOD AND DRUG ADMINISTRATION, *Staking a Claim to Good Health: FDA and Science Stand Behind Health Claims on Foods*, FDA CONSUMER, Nov.-Dec. 1998 (visited Feb. 2, 2001) <<http://vm.cfsan.fda.gov/~dms/>>. According to another source, the four health claims that may be used by supplements are the ones regarding calcium, folic acid, dietary soluble fiber in the form of psyllium husk, and soy protein. See UNITED STATES GENERAL ACCOUNTING OFFICE, FOOD SAFETY: IMPROVEMENTS NEEDED IN OVERSEEING THE SAFETY OF DIETARY SUPPLEMENTS AND "FUNCTIONAL FOODS" 18-19 (July 2000). The reasons for these discrepancies are unknown.

²⁶¹ See Robert G. Pinco & Todd H. Halpern, *Guidelines for the Promotion of Dietary Supplements: Examining Government Regulation Five Years after Enactment of the Dietary Supplement Health and Education Act of 1994*, 54 FOOD & DRUG L.J. 567, 568 (1999). In 1992, the CDC recommended that neural tube defects at birth could be reduced by up to fifty percent if women of childbearing age received adequate folic acid. Despite this recommendation, the FDA banned the claim in 1993 and only reversed its stance in 1996 after intense public pressure. See *id.*

²⁶² See Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997), codified at 21 U.S.C.

²⁶³ See, e.g., *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

²⁶⁴ See Robert G. Pinco & Todd H. Halpern, *Guidelines for the Promotion of Dietary Supplements: Examining Government Regulation Five Years after Enactment of the Dietary Supplement Health and Education Act of 1994*, 54 FOOD & DRUG L.J. 567, 568 (1999).

In 1997, Congress passed sweeping legislation, the Food and Drug Administration Modernization Act (“FDAMA”), designed to update the almost 60-year-old FDCA. Title III of the FDAMA included various provisions designed to improve the regulation of food, including dietary supplements, and to ensure that consumers are promptly informed of “scientifically sound nutritional and health information,” including the “nutritional and health benefits of food.”²⁶⁵ To facilitate these goals, Congress amended section 403(r) of the FDCA to provide for an expedited review of health claims. This amendment attempts to bypass the FDA in many respects by allowing health claims based on authoritative statements. Under this new law, claims that are not authorized by the FDA through a regulation may be made if

a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement,²⁶⁶ which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers.²⁶⁷

A manufacturer hoping to take advantage of this provision must also comply with certain other requirements, such as notice.²⁶⁸ The clause allows the FDA to retain some authority in this area, however, as it further provides that such claims based on authoritative statements may only be made until the FDA issues a regulation prohibiting or modifying the claim.²⁶⁹ Nevertheless, it seemed that the provisions in the FDAMA could be interpreted to be essentially directing the FDA to recognize authoritative statements as sufficient to satisfy the “significant scientific agreement” standard of the NLEA.

Although the FDAMA only referred to health claims on conventional foods, regulations proposed by the

²⁶⁵21 U.S.C. § 343(r)(7).

²⁶⁸120 days before the product is introduced into interstate commerce, the manufacturer must submit: (1) notice of the claim, using the exact language that is to appear, and accurately representing the authoritative statement relied upon; (2) a copy of the authoritative statement relied upon; and (3) “a balanced representation of the scientific literature” relating to the health claim. 21 U.S.C. § 343(r)(3)(C).

²⁶⁹21 U.S.C. § 343(r)(3)(D)(i). A district court can also ascertain that the claim has not met all of the requirements and prohibit its use. *See* 21 U.S.C § 343(r)(3)(D)(ii).

FDA to implement the FDAMA provisions extended the use of authoritative statements as an alternative to significant scientific agreement to dietary supplements.²⁷⁰ Such an interpretation was consistent with FDA policy since January 4, 1994 of applying the same health claims standard to dietary supplements and food.²⁷¹ Although Congress intended that the FDAMA streamline the health claims process and the FDA has extended these provisions to dietary supplements, the practical effect of the authoritative statement provision is unclear. The FDA is adopting the view that Congress intended the authoritative statement “to serve as a presumptive surrogate for FDA’s deliberative review of scientific evidence” and therefore authoritative statements must also be based upon such a deliberative review of the evidence.²⁷² The FDA is also looking closely at whether the organization can be considered “authoritative” and whether the statement can be attributed to the organization or is merely the product of certain employees.²⁷³ The FDA’s efforts with respect to authoritative statements may just be a thorough and precise application of the statutory language contained in the FDAMA. Some commentators, however, have argued that the FDA’s view is unduly restrictive and is tantamount to obliterating all practical effect of the FDAMA and returning to the former standard with respect to health claims.²⁷⁴ To date, the FDA has only approved two health claims based on authoritative statements.²⁷⁵ The overall effect of the FDAMA on streamlining the health

²⁷⁰ See Food Labeling: Use on Dietary Supplements of Health Claims Based on Authoritative Statements, 64 Fed. Reg. 3250 (proposed January 21, 1999).

²⁷¹ See Food Labeling; General Requirements for Health Claims for Dietary Supplements, 59 Fed. Reg. 395 (January 4, 1994).

²⁷² Food Labeling: Health Claims; Antioxidant Vitamins C and E and the Risk in Adults of Atherosclerosis, Coronary Heart Disease, Certain Cancers, and Cataracts, 63 Fed. Reg. 34,084, 34,086 (June 22, 1998).

²⁷³ Food Labeling: Health Claims; Antioxidant Vitamins C and E and the Risk in Adults of Atherosclerosis, Coronary Heart Disease, Certain Cancers, and Cataracts, 63 Fed. Reg. 34,084 (June 22, 1998).

²⁷⁴ See Robert G. Pinco & Todd H. Halpern, *Guidelines for the Promotion of Dietary Supplements: Examining Government Regulation Five Years after Enactment of the Dietary Supplement Health and Education Act of 1994*, 54 FOOD & DRUG L.J. 567, 574 (1999). Expressing concern that the FDA denied several health petitions, Representative Dan Burton, Chairman of the House Committee on Government Reform and Oversight commented that FDA’s interpretation of the FDAMA would “only reinforce the existing censorship effected by the [significant] scientific agreement standard.” *Id.*, quoting a letter from Rep. Dan Burton to Michael Friedman, Lead Deputy Commissioner, Food and Drug Administration (Aug. 13, 1998).

²⁷⁵ See Robert G. Pinco & Todd H. Halpern, *Guidelines for the Promotion of Dietary Supplements: Examining Government Regulation Five Years after Enactment of the Dietary Supplement Health and Education Act of 1994*, 54 FOOD & DRUG L.J. 567, 574 (1999); FOOD AND DRUG ADMINISTRATION, *Staking a Claim to Good Health: FDA and Science Stand Behind Health Claims on Foods*, FDA CONSUMER, Nov.-Dec. 1998 (visited Feb. 2, 2001) <<http://vm.cfsan.fda.gov/~dms/>>; OFFICE OF NUTRITIONAL PRODUCTS, LABELING AND DIETARY SUPPLEMENTS, FOOD AND DRUG ADMINISTRATION, HEALTH CLAIM NOTIFICATION FOR POTASSIUM CONTAINING FOODS, Oct. 31, 2000 (visited Mar. 27, 2001) <<http://vm.cfsan.fda.gov/~dms/>>; OFFICE OF FOOD LABELING, FOOD AND DRUG ADMINISTRATION, *Health Claim Notification for Whole Grain Foods*, July 1999 (visited Feb. 2,

claims process and encouraging approval of more claims remains uncertain, as the evidence thus far has not demonstrated a marked increase in the number of allowable health claims.

A recent court decision, *Pearson v. Shalala*,²⁷⁶ bites more deeply into the FDA's regulatory power over health claims and forces a reevaluation not only of the significant scientific agreement standard, but also of the underlying concept of limiting the types of allowable label claims. In 1999, the D.C. Circuit Court reversed the district court ruling and struck down FDA's approach to authorizing health claims under the NLEA, finding that these regulation were too restrictive and violated manufacturers' First Amendment freedoms.²⁷⁷

Pearson v. Shalala involved a challenge brought by marketers of dietary supplements, joined by two health care advocacy organizations,²⁷⁸ against the rejection of four health claims that they had submitted to the FDA. The FDA had rejected each of these four claims on the basis that they failed to meet the standard of significant scientific agreement established by the NLEA and further detailed by FDA regulations.²⁷⁹ Using this test, the FDA found the scientific evidence to be inconclusive and refused to allow disclaimers in attempt to cure the situation.²⁸⁰ In its evaluation, the court of appeals applied the three-part test used to evaluate government regulation of commercial speech²⁸¹ and found the FDA's restrictions to be impermissible, as there was not a "reasonable" fit between the restrictions and the agency's goals of advancing consumer health²⁸²

2001) <<http://vm.cfsan.fda.gov/~dms/>>.

²⁷⁶*Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir 1999).

²⁷⁷*See Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

²⁷⁸The American Preventive Medical Association and Citizens for Health joined as appellants. *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

²⁷⁹*See Pearson v. Shalala*, 164 F.3d 650, 653-54 (D.C. Cir. 1999). The FDA adopted the significant scientific agreement standard via regulations promulgated at 21 C.F.R. § 101.14.

²⁸⁰*See Pearson v. Shalala*, 164 F.3d 650, 653-54 (D.C. Cir. 1999).

²⁸¹The three factors used in the commercial speech doctrine, commonly referred to as the "Central Hudson test," include the following considerations: (1) whether the government interest is substantial; (2) whether the regulation directly advances the government interest asserted; and (3) whether there is a reasonable fit between the government interest and the restriction. *See Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557 (1980).

²⁸²The court found that advancing consumer health through supplement regulation is at best a indirect effect and therefore encounters difficulty with the second prong of the *Central Hudson* test. *See Pearson v. Shalala*, 164 F.3d 650, 656 (D.C. Cir. 1999).

and protecting against consumer fraud.²⁸³ Rather, the court found that the FDA's blanket refusal to consider use of disclaimers for each of the health claims ran afoul of the principle that disclaimers are "constitutionally preferable to outright suppression."²⁸⁴ Although acknowledging that the government should have more leeway to suppress speech in order to prevent consumer confusion about a health product,²⁸⁵ the court nonetheless rejected the government's argument that such use of disclaimers would confuse consumers "by a multitude of claims with differing degrees of reliability."²⁸⁶ Accordingly, the court held that the FDA may not reject potentially misleading health claims if a disclaimer could eliminate the potential deception; the court conceded that if the evidence weighs against the health claim, the FDA "could deem it incurable by a disclaimer and ban it outright."²⁸⁷ Appellants also challenged the FDA's use of the significant scientific agreement standard to screen health claims as being vague and lacking sufficient definitional content or guidance.²⁸⁸ Although the court of appeals did not reach this issue in its analysis, it nevertheless suggested that the FDA might be violating the Administrative Procedure Act's prohibition on arbitrary and capricious agency action.²⁸⁹ The court further indicated that the FDA is "entitled to proceed case by case, or, more accurately, sub-regulation by subregulation [stet], but it must be possible for the regulated class to perceive the principles which are guiding agency policy."²⁹⁰ Accordingly, it directed the FDA to explain this standard on remand.²⁹¹

²⁸³Pearson v. Shalala, 164 F.3d 650, 656-57 (D.C. Cir. 1999).

²⁸⁴Pearson v. Shalala, 164 F.3d 650, 657 (D.C. Cir. 1999). The court further explained that "when government chooses a policy of suppression over disclosure – at least where there is no showing that disclosure would not suffice to cure misleadingness – government disregards a 'far less restrictive' means." *Id.*, at 658.

²⁸⁵Pearson v. Shalala, 164 F.3d 650, 659 (D.C. Cir. 1999).

²⁸⁶Pearson v. Shalala, 164 F.3d 650, 659 (D.C. Cir. 1999) (quoting Food Labeling; General Requirements for Health Claims for Dietary Supplements, 59 Fed. Reg. 395, 405 (1994)).

²⁸⁷See Pearson v. Shalala, 164 F.3d 650, 659 (D.C. Cir. 1999).

²⁸⁸See Pearson v. Shalala, 164 F.3d 650, 660 (D. C. Cir. 1999).

²⁸⁹See Pearson v. Shalala, 164 F.3d 650, 660 (D. C. Cir. 1999) (referencing 5 U.S.C. § 706(2)(A) (1994)).

²⁹⁰Pearson v. Shalala, 164 F.3d 650, 661 (D.C. Cir. 1999). The court stated that the "I know it when I see it" approach once used by Justice Stewart with respect to obscenity is inappropriate for the FDA. *Id.*, at 660 (quoting *Jacobellis v. Ohio*, 378 U.S. 184, 197 (1964)).

²⁹¹Pearson v. Shalala, 164 F.3d 650, 661 (D.C. Cir. 1999). On April 2, 1999, the U.S. Court of Appeals for the D.C. Circuit denied the FDA's petition for a rehearing en banc. See Food Labeling: Health Claims and Label Statements for Dietary Supplements; Strategy for Implementation of the Pearson Court Decision, 64 Fed. Reg. 67,289, 67,290 (December 1, 1999); Pearson v. Shalala, 172 F.3d 72 (D.C. Cir. 1999). In a related matter, more than 18 months after the *Pearson* decision, after conducting various information-gathering measures – such as soliciting scientific data and contracting with an outside

Almost eleven months later, on December 1, 1999, the FDA published a notice outlining its strategy for implementing the *Pearson* decision. This initial notice was vague and only provided a general overview of the steps the FDA needed to take.²⁹² In addition, the notice indicated that until the FDA completes the rulemaking to reconsider its treatment of health claims for dietary supplements, it will deny without prejudice all claims that do not meet the significant scientific agreement standard.²⁹³ The FDA later revised this interim enforcement strategy to allow an intermediate step between authorization and denial of a health claim.²⁹⁴ For claims that do not meet the significant scientific agreement standard but are supported by more scientific evidence than weigh against the claim, the FDA “will consider exercising enforcement discretion”

organization to conduct a literature review regarding the health claims – the FDA ultimately refused to authorize the folic acid claim even with clarifying disclaimers, finding the claim to be “inherently misleading.” *Pearson v. Shalala*, 130, F. Supp. 2d 105, 110-11 (D.D.C. 2001). As a result, the dietary supplement manufacturers and sellers party to the original suit (“Pearson”) filed another lawsuit in November 2000 in an attempt to enjoin the FDA’s refusal of their health claim, arguing that the FDA’s actions have “fundamentally misread and misapplied the legal standard articulated by the Court of Appeals in *Pearson*.” *Id.* at 112.

In granting the preliminary injunction, the district court agreed that the FDA “appears to have at best, misunderstood, and at worst, deliberately ignored, highly relevant portions of the Court of Appeals opinion.” *Id.* at 112. The decision further confirmed the *Pearson* holding that the agency must consider the use of disclaimers to cure only potentially misleading claims, as such statements enjoy First Amendment protection, recognizing that such a standard places a “very heavy burden” on the FDA if “it seeks to totally ban a particular health claim.” *Id.* at 118-20. The court’s remedy, however, was rather limited in scope and was confined to a declaration that the FDA had acted unconstitutionally and in violation of the 1999 appellate court decision in *Pearson* by refusing to authorize the claim. *Id.* at 120. Pearson was denied broader injunctive relief, as the court again remanded to the FDA the task of drafting succinct and accurate disclaimers, noting that such a task was the role of the agency, not of the courts. *Id.* at 120.

Although this decision reinforced the holding in *Pearson* and reconfirmed the constitutional protections of supplement claims, it is yet unclear what impact this recent development will have on the FDA’s regulation and assessment of health claims. After finding that the agency acted with “less than reasonable speed” by delaying its actions for 18 months after the appellate court decision in *Pearson*, the district court noted that although it was not setting an absolute deadline for the formulation of appropriate disclaimers by the FDA, it “anticipate[d]” that this task would be completed within 60 days. *Id.* at 120 n.34. Almost three months later, it does not yet appear that the FDA has completed the review mandated by the district court. Rather, the only perceivable agency response is a March 30, 2001 letter noting that its review is ongoing and hopefully will be completed by April 20, 2001. *See* LETTER REGARDING CONTINUING REVIEW OF A HEALTH CLAIM THAT WAS THE SUBJECT OF THE PEARSON COURT DECISION, letter from Christine J. Lewis, Ph.D., Director, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, FDA, to Jonathan W. Emord, Emord & Associates (Mar. 30, 2001) (available at <<http://www.cfsan.fda.gov/~dms/>>).

²⁹²*See* Food Labeling: Health Claims and Label Statements for Dietary Supplements; Strategy for Implementation of the Pearson Court Decision, 64 Fed. Reg. 67,289, 67,290 (Dec. 1, 1999). The strategy included reexamining the four claims at issue in *Pearson*, issuing guidance on the “significant scientific agreement standard,” and holding public meetings regarding other changes that needed to be made to the FDA’s policies regarding health claims. *See id.*

²⁹³*See* Food Labeling: Health Claims and Label Statements for Dietary Supplements; Strategy for Implementation of the Pearson Court Decision, 64 Fed. Reg. 67,289, 67,290 (Dec. 1, 1999).

²⁹⁴*See* Food Labeling: Health Claims and Label Statements for Dietary Supplements; Update to Strategy for Implementation of Pearson Court Decision, 65 Fed. Reg. 59,855, 59, 856 (Oct. 6, 2000).

and allowing “appropriate qualifying language” for the statement.²⁹⁵ In the interim, while the FDA debated how best to regulate disclaimers on health statements, it published guidance for the industry regarding the application of the significant scientific agreement standard.²⁹⁶ Characterizing the standard as an objective determination of whether qualified experts would support the substance/disease relationship of a health claim with a high level of confidence, this document detailed the process used by the FDA and the types of data that the agency evaluates.²⁹⁷

It is yet unclear how this definitional guidance will affect the approval of health claims, if at all, as in theory the FDA is merely articulating its present definition of significant scientific agreement and is not developing or employing a new standard. Mandating the consideration and use of disclaimers will likely have much greater actual impact on the labels of commonly used supplement products. Although critics and supporters of *Pearson* agree that the court’s ruling will have significant and sweeping implications, their speculations regarding the scope and nature of such effects vary widely.²⁹⁸ Some commentators laud the court’s decision as one that “revives the notion” of consumer empowerment²⁹⁹ and “ensure[s] that FDA adopt sufficiently flexible policies that foster the broad dissemination of useful information to consumers.”³⁰⁰ Others worry that the ruling will hamstring FDA’s powers to prevent deceptive conduct and fraudulent claims, noting that the court failed to distinguish “among studies that are tentative, inconclusive, preliminary, non-replicable, or

²⁹⁵Food Labeling; Health Claims and Label Statements for Dietary Supplements; Update to Strategy for Implementation of Pearson Court Decision, 65 Fed. Reg. 59, 855, 59, 856 (Oct 6, 2000).

²⁹⁶See OFFICE OF SPECIAL NUTRITIONALS, FOOD AND DRUG ADMINISTRATION, *Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements*, Dec. 22, 1999 (visited Mar. 28, 2001) <<http://vm.cfsan.fda.gov/~dms/>>.

²⁹⁷See OFFICE OF SPECIAL NUTRITIONALS, FOOD AND DRUG ADMINISTRATION, *Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements*, Dec. 22, 1999 (visited Mar. 28, 2001) <<http://vm.cfsan.fda.gov/~dms/>>.

²⁹⁸See, e.g., Michael H. Cohen, *U.S. Dietary Supplement Regulation: Belief Systems and Legal Rules*, 11 HASTINGS WOMEN’S L.J. 3, 20 (2000); Steven B. Steinborn & Kyra A. Todd, *The End of Paternalism: A New Approach to Food Labeling*, 54 FOOD & DRUG L.J. 401, 411-12 (1999); David C. Vladeck, *Devaluing Truth: Unverified Health Claims in the Aftermath of Pearson v. Shalala*, 54 FOOD & DRUG L.J. 535, 552 (1999).

²⁹⁹Michael H. Cohen, *U.S. Dietary Supplement Regulation: Belief Systems and Legal Rules*, 11 HASTINGS WOMEN’S L.J. 3, 20 (2000).

³⁰⁰Steven B. Steinborn & Kyra A. Todd, *The End of Paternalism: A New Approach to Food Labeling*, 54 FOOD & DRUG L.J. 401, 411-12 (1999).

even out of step with mainstream science.”³⁰¹ Further, the generous acceptance of health claims arguably will allow dietary supplements to be effectively marketed as drugs, removing many advantages of drug designation and manufacturers’ incentives to undergo the now superfluous but still arduous new drug evaluation.³⁰² Until the FDA issues final regulations on this issue and begins to apply its rules on a regular basis,³⁰³ the ultimate effect of the *Pearson* decision on health claims and the likelihood of the above scenarios coming to fruition remains uncertain. Similarly, it is too soon to ascertain the practical effect of the recent affirmation of the *Pearson* opinion by the D.C. District Court³⁰⁴ and its corresponding reprimand to the agency for failing to adequately consider or implement the *Pearson* holding and to act in a timely manner.

Structure/Function Claims

While manufacturers hoping to include health claims on their products had won a couple of victories with the enactment of the authoritative statement provisions of the FDAMA and the ruling in *Pearson v. Shalala*, health claims still faced intense premarket scrutiny by the FDA and the application of disclaimers to cure misleading claims remained in a regulatory morass. The DSHEA, however, also provided manufacturers with another path to making label claims without fear of sanction as a misbranded product. Structure/function claims do not need premarket agency approval and could only be challenged if the FDA bore the burden of proof to show that they were misleading or otherwise impermissible.³⁰⁵ Further, such claims arguably require a lesser standard of proof for their claims, as the statute refers to “substantiation” rather than

³⁰¹David C. Vladeck, *Devaluing Truth: Unverified Health Claims in the Aftermath of Pearson v. Shalala*, 54 FOOD & DRUG L.J. 535, 552 (1999).

³⁰²David C. Vladeck, *Devaluing Truth: Unverified Health Claims in the Aftermath of Pearson v. Shalala*, 54 FOOD & DRUG L.J. 535, 552 (1999).

³⁰³Frustrated with the FDA’s inaction on this issue, dietary supplement manufacturers “complain[] the agency is dragging its feet in establishing new regulations.” Dierdre Davidson, *Food Lobby Nibbles at FDA*, LEGAL TIMES, May 8, 2000, at 15. In addition, the food and beverage industry is lobbying the FDA to apply the decision in *Pearson* to food products as well as to supplement products. *See id.*

³⁰⁴*See supra* note 291.

³⁰⁵21 U.S.C. § 343(r).

“significant scientific agreement” as the level of acceptable support.³⁰⁶ Most importantly, the DSHEA did not provide clear guidance on the distinction between structure/function claims and disease claims. Absent further regulation by the FDA, this created a potential loophole for manufacturers to make essentially disease claims without complying with either the new drug application process or the more forgiving health claim procedure.

As suggested by the DSHEA, the FDA skirted the controversial issue of where to draw the appropriate line between structure/function and drug claims while it waited for guidance from the final report of the Commission.³⁰⁷ In the interim, the FDA began to promulgate proposed and final regulations interpreting and enacting other various provisions of the DSHEA.³⁰⁸ Although some of these regulations addressed the mechanics of structure/function claims,³⁰⁹ none really tackled the heart of the issue. As previously discussed, the Commission issued its draft report regarding labeling issues on June 24, 1997 and its final report on November 24, 1997.³¹⁰ Subsequently, on April 28, 1998, the FDA proposed long-awaited regulations that

³⁰⁶21 U.S.C. § 343(r)(6)(B); 21 U.S.C. § 343(r)(3)(B).

³⁰⁷See Dietary Supplement Health and Education Act of 1994, § 12(e)(3).

³⁰⁸See, e.g., Food Labeling; Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements, 60 Fed. Reg. 67,176 (proposed Dec. 28, 1995); Food labeling: Nutrient Content Claims: Definition for “High Potency” Claim for Dietary Supplements and Definition of “Antioxidant” for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods, 60 Fed. Reg. 67,184 (proposed Dec. 28, 1995); Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements, 60 Fed. Reg. 67,194 (proposed Dec. 28, 1995); Food Labeling; Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements, 62 Fed. Reg. 49,859 (Sept. 23, 1997).

³⁰⁹For example, the FDA promulgated both a proposed and final rule regarding the precise placement and appearance of the disclaimer that must be contained in statements of nutritional support. See Food Labeling; Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements, 60 Fed. Reg. 67,176 (proposed Dec. 28, 1995); Food Labeling; Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements, 62 Fed. Reg. 49,859 (Sept. 23, 1997). Regulations further stated that a “dietary supplement could bear a structure/function claim under the ‘(other than food)’ exception to the drug definition in section 201(g)(1)(C) of the [FDCA], provided that the claim was truthful, nonmisleading and derived from nutritive value.” Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Availability of Citizen Petitions for Comment, 65 Fed. Reg. 63,256, 63,256 (Oct. 23, 2000) (citing Food Labeling; Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements, 62 Fed. Reg. 49,859, 49,860, 49,863, 49,864 (Sept. 23, 1997)). In addition, the FDA finalized the procedure by which manufacturers and other distributors of dietary supplements must notify the agency of statements of nutritional support that appear on a product label. See Food Labeling; Dietary Supplement; Nutritional Support Statement; Notification Procedure, 61 Fed. Reg. 50,771 (proposed Sept. 27, 1996); Food Labeling; Notification Procedures for Statements on Dietary Supplements, 62 Fed. Reg. 49,883 (Sept. 23, 1997).

³¹⁰See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,624 (proposed Apr. 29, 1998).

defined the types of statements that could be used in structure/function claims.³¹¹

Relying heavily on the commentary and guidelines in the Commission's Final Report, the April 1998 proposed regulations attempted to clarify the distinction between structure/function claims and disease claims.³¹² The proposed regulations embraced the Commission's guidelines that structure/function claims should not imply treatment or prevention of disease.³¹³ Specifically, the proposal indicated that statements that expressly or implicitly "claim[] to diagnose, mitigate, treat, cure, or prevent disease" are considered to be disease claims that would render the product a drug or would require it to have these claims preapproved through the health claims process.³¹⁴ To elaborate, the proposal lists criteria for determining whether a specific statement satisfies the above definition of disease claim and notes that "[a] statement that by itself would be considered an acceptable structure/function claim could become a disease claim if, in context, an effect on disease were expressed or implied."³¹⁵ First, the proposal states that statements cannot expressly or implicitly³¹⁶ claim "an effect on a specific disease or condition."³¹⁷ Second, claims may not indicate "an effect, using scientific or lay terminology, on one or more signs or symptoms that are recognizable to health care professionals or consumers as being characteristic of a specific disease or of a number of different specific diseases."³¹⁸

Through this provision, the FDA attempts to establish a distinction between maintaining normal function

³¹¹See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624 (proposed Apr. 29, 1998).

³¹²See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,625 (proposed Apr. 29, 1998).

³¹³See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,625 (proposed Apr. 29, 1998).

³¹⁴Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,632 (proposed Apr. 29, 1998) (to be codified at 21 C.F.R. § 101.93(g)(1)).

³¹⁵Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,626 (proposed Apr. 29, 1998).

³¹⁶The remaining criteria detailed in this paragraph similarly are prohibited from both explicit and implied claims. See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,632 (proposed Apr. 29, 1998) (to be codified at 21 C.F.R. § 101.93(g)(2)).

³¹⁷Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,632 (proposed Apr. 29, 1998) (to be codified at 21 C.F.R. § 101.93(g)(2)(i)).

³¹⁸Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,632 (proposed Apr. 29, 1998) (to be codified at 21 C.F.R. § 101.93(g)(2)(ii)).

as an allowable structure/function claim and preventing or treating abnormal function as a disease claim.³¹⁹ Third, structure/function statements may not claim “an effect on a consequence of a natural state that presents a characteristic set of signs or symptoms recognizable to health care professionals or consumers as constituting an abnormality of the body.”³²⁰ The proposal defines “abnormalities” to include pregnancy, aging, and premenstrual syndrome.³²¹ Under the fourth criteria, the product may not claim an effect on a disease through use of the product’s name, use of the term “disease,” use of “pictures, vignettes, symbols, or other means,” or citation to a publication title that refers to disease use.³²² Manufacturers also cannot associate structure/function claims with a particular class of products used for diseases, such as laxatives.³²³ Improper structure/function claims further include statements that a product substitutes or augments a particular disease therapy or “treats, prevents or mitigates” characteristic adverse signs or symptoms resulting from disease treatment.³²⁴ Finally, two catch-all provisions indicate that structure/function claims may not claim that the product helps the body respond to disease or “otherwise suggests an effect on a disease or diseases.”³²⁵

Although the above list of prohibited claim types already seems comprehensive, the FDA suggested in the April 1998 proposed regulations that it intended to extend its power over nutritional support statements still further. Specifically, the agency proposed that a new definition of disease control consideration of structure/function and health claims. Arguing the current definition is too narrow and fails to include certain

³¹⁹ See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,632 (proposed Apr. 29, 1998).

³²⁰ Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,632 (proposed Apr. 29, 1998) (to be codified at 21 C.F.R. § 101.93(g)(2)(iii)).

³²¹ See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,627 (proposed Apr. 29, 1998).

³²² Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,632 (proposed Apr. 29, 1998) (to be codified at 21 C.F.R. § 101.93(g)(2)(iv)).

³²³ See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,627 (proposed Apr. 29, 1998) (to be codified at 21 C.F.R. § 101.93(g)(2)(v)).

³²⁴ Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,627-28 (proposed Apr. 29, 1998) (to be codified at 21 C.F.R. § 101.93(g)(2)(vi,vii,ix)).

³²⁵ Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,627-28 (proposed Apr. 29, 1998) (to be codified at 21 C.F.R. § 101.93(g)(2)(viii,x)).

conditions, such as headaches, that are understood to be diseases, the FDA stated that a revised definition is appropriate and would more accurately reflect the medical understanding of disease.³²⁶ Under the current definition at the time, disease “is damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included. . . .”³²⁷ The new proposed definition broadened the scope of this provision considerably by referring not specifically to damage of the body but more generally to “any deviation from, impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms (including laboratory or clinical measurements that are characteristic of a disease), or a state of health leading to such deviation, impairment, or interruption; except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included. . . .”³²⁸

The proposed regulations for structure/function claims set off a firestorm of controversy, as the FDA was flooded by more than 100,000 comments before the deadline of September 28, 1998.³²⁹ Accordingly, the FDA extended the comment period to August 4, 1999,³³⁰ ultimately receiving more than 235,000 comments

³²⁶ See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,626 (proposed Apr. 29, 1998).

³²⁷ Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,626 (proposed Apr. 29, 1998)(quoting 21 C.F.R. § 101.14(a)(6)). The definition of disease is now found at 21 C.F.R. § 101.14(a)(5).

³²⁸ Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,632 (proposed Apr. 29, 1998) (to be codified at 21 C.F.R. § 101.93(g)(1)).

³²⁹ See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Public Meeting, 64 Fed. Reg. 36,824, 35,824 (July 8, 1999).

³³⁰ See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Public Meeting, 64 Fed. Reg. 36,824, 36,824 (July 8, 1999).

in response to the proposed rule,³³¹ and scheduled a public meeting for August 4, 1999.³³² Three issues in particular generated the greatest controversy. First, critics decried the FDA's definitional revision as an end-run attempt to circumvent legislative intent and to regain the control over dietary supplements that Congress had deliberately removed through the NLEA, the DSA, the DSHEA, and the FDAMA.³³³ The reliance on "normal function" or a normal body as a basis for the disease claim was further seen as flawed, as commentators observed that "[t]here is no such thing as a normal body" and "[v]irtually anything is a deviation from a normal body."³³⁴ Accordingly, a literal reading of the new definition could theoretically classify any claim as a drug or disease claim.³³⁵ Second, comments strongly objected to the classification of natural states, such as aging, menopause, and pregnancy, as diseases.³³⁶ Finally, comment submitters asserted that prohibiting implied disease claims contradicts congressional intent in the DSHEA.³³⁷ Through this process, the FDA received comments on every provision of the proposed regulations, including ones that supported the rule, ones that indicated the restrictions were too harsh, and ones that stated that the FDA had not gone far enough in its proposed structure/function regulations.³³⁸ Facing the virtually impossible situation of satisfying all interested parties, complying with statutes and court decisions, and upholding the mission of the FDA, the agency finally published a final rule regarding dietary supplements on

³³¹ See 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. 1000, 1000 (Jan. 6, 2000). Although the majority of the submissions were form letters, more than 22,000 comments were individual letters. See *id.*

³³² See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Public Meeting, 64 Fed. Reg. 36,824, 36,824 (July 8, 1999).

³³³ See, e.g., Robert G. Pinco & Todd H. Halpern, *Guidelines for the Promotion of Dietary Supplements: Examining Government Regulation Five Years after Enactment of the Dietary Supplement Health and Education Act of 1994*, 54 FOOD & DRUG L.J. 567, 577-78 (1999); Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Public Meeting, 64 Fed. Reg. 36,824, 36,825 (July 8, 1999).

³³⁴ Peter B. Hutt, Edited Transcript of Remarks of Peter Barton Hutt to NDMA Government Affairs Committee, Sept. 23, 1998, at 4-5 (cited in Laura A.W. Khatcheressian, *Regulation of Dietary Supplements: Five Years of DSHEA*, 54 FOOD & DRUG L.J. 623, 638 (1999)).

³³⁵ See Laura A.W. Khatcheressian, *Regulation of Dietary Supplements: Five Years of DSHEA*, 54 FOOD & DRUG L.J. 623, 638 (1999); Jenna Greene, *Definition of Disease Sparks Furor*, LEGAL TIMES, July 19, 1999, at 1.

³³⁶ See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Public Meeting, 64 Fed. Reg. 36,824, 36,825 (July 8, 1999).

³³⁷ See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Public Meeting, 64 Fed. Reg. 36,824, 36,825-26 (July 8, 1999).

³³⁸ See 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. 1000 (Jan. 6, 2000).

January 6, 2000.³³⁹ The bulk of the lengthy 50-page publication consisted of summarizing and responding to comments, and the final rule itself was for the most part identical to the regulation proposed in April 1998. Perhaps in response to the public outcry,³⁴⁰ however, the FDA relaxed its regulations in a few key areas.

The modified provisions contained in the final rule generally corresponded to the three most contested issues. First, the FDA abandoned the new definition of disease that it had proposed and instead retained the preexisting definition. According to the final regulations, this action was in direct response to the large number of comments that objected to the change in definition.³⁴¹ Second, the FDA revised the proposed rule 21 C.F.R. section 101.93(g)(2)(iii), which had characterized as disease natural states or conditions of the body. The final regulations qualify this rule to exclude from the definition of disease those “common conditions associated with natural states or processes that do not cause significant or permanent harm,” such as normal pregnancy and hair loss due to aging.³⁴² Finally, the FDA declined to revise its treatment of implied health claims significantly or to exclude all such implied claims from classification as drug claims. In a small concession, however, the agency agreed that “the use in labeling of a publication title that refers to a disease will be considered a disease claim only if, in context, it may be used to diagnose, treat, mitigate, cure, or prevent disease,” and modified this provision accordingly.³⁴³

In addition, the FDA reconsidered its stance on disclaimers and reversed the position it had taken in the final

³³⁹Regulations 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. 1000 (Jan. 6, 2000).

³⁴⁰See Robert G. Pinco & Todd H. Halpern, *Guidelines for the Promotion of Dietary Supplements: Examining Government Regulation Five Years after Enactment of the Dietary Supplement Health and Education Act of 1994*, 54 FOOD & DRUG L.J. 567, 579 (1999).

³⁴¹See 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. 1000, 1000 (Jan. 6, 2000).

³⁴²See 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. 1000, 1000 (Jan. 6, 2000) (codified at 21 C.F.R. § 101.93(g)(2)(iii)).

³⁴³See 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. 1000, 1000 (Jan. 6, 2000) (codified at 21 C.F.R. § 101.93(g)(2)(iv)(C)).

rule published on September 23, 1997.³⁴⁴ Rather, the January 2000 final rule states that there is no longer an exception from use of the required disclaimer for supplement claims that are “truthful, non-misleading, and derived from nutritive value.”³⁴⁵ The final rule clarified, however, that structure/function claims that meet the same criteria do not require a disclaimer when used on conventional foods.³⁴⁶

The January 2000 final rules did not, unfortunately, settle the issue of structure/function statements. Rather, the process of rulemaking and guidance continues. In February 2001, more than six years after the enactment of the DSHEA, the FDA published a notice requesting comments for guidelines in applying the January 2000 rules.³⁴⁷ To date, these guidelines have yet to be proposed. Further, the FDA has not addressed the issue of what constitutes adequate substantiation of claims made under the structure/function rules. The FDA has indicated that such rules or guidance will be forthcoming in the future.³⁴⁸

IV.

ASSESSMENT AND ANALYSIS OF THE CURRENT REGULATORY SCHEME: A CRITIQUE OF THE DSHEA AND ITS IMPLEMENTATION

Almost seven years after the enactment of the DSHEA, the FDA and the dietary supplement industry

³⁴⁴See Food Labeling; Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements, 62 Fed. Reg. 49,859 (Sept. 23, 1997); *supra* note 309.

³⁴⁵Regulations 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. 1000, 1033 (Jan. 6, 2000).

³⁴⁶See 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. 1000, 1033 (Jan. 6, 2000).

³⁴⁷Guidance on Applying the Structure/Function Rule; Request for Comments, 66 Fed. Reg. 11,172 (Feb. 22, 2001).

³⁴⁸See Guidance on Applying the Structure/Function Rule; Request for Comments, 66 Fed. Reg. 11,172 (Feb. 22, 2001).

still have not reached a comfortable working equilibrium in the ongoing battle regarding supplement labeling. Some commentators suggest that the distinction between structure/function and health or drug claims perhaps remains “the most controversial issue in the area of dietary supplement regulation today.”³⁴⁹ In enacting the DSHEA, Congress intended to establish the legislative framework to enable consistent regulation of supplements to guide industry compliance, and to empower consumers to make their own choices regarding supplement use through accurate, scientifically-based label claims.³⁵⁰ The ensuing Act significantly undermined the FDA’s power to regulate supplements and enabled increased consumer access to supplements. Despite these limitations on its authority, the FDA, for the most part, has done an admirable job in promulgating regulations that are faithful to the DSHEA and that attempt “to strike the right balance between ensuring the safety and proper labeling of all these products while at the same time preserving consumers’ freedom of choice.”³⁵¹ The resulting rules strive to placate both sides of the debate, although satisfying everyone involved is undoubtedly an impossible task. Although there are some notable gaps and flaws in the FDA’s regulatory scheme, as will be addressed below, many of the problems with the current regulatory scheme do not lie with the FDA’s interpretation of the DSHEA. Rather, in fostering a system that encouraged widespread access to and use of dietary supplements, Congress failed to provide the FDA with an actionable scheme that would allow the agency to achieve its lofty legislative goals, comply with constitutional limits, and fulfill the mission of the FDA to protect the American public from fraudulent and ineffective products. Accordingly, the current regulatory system fosters consumer confusion and does not provide clear guidance to the dietary supplement industry.

³⁴⁹Robert G. Pinco & Todd H. Halpern, *Guidelines for the Promotion of Dietary Supplements: Examining Government Regulation Five Years after Enactment of the Dietary Supplement Health and Education Act of 1994*, 54 FOOD & DRUG L.J. 567, 568 (1999).

³⁵⁰See Dietary Supplement Health and Education Act of 1994, § 2.

³⁵¹S. REP. NO. 103-410, at 11 (1994) (citing statement of Dr. David Kessler, then Commissioner of the FDA to the Committee on Labor and Human Resources (Oct. 21, 1993)).

Industry Guidance

The current regulatory scheme does not provide clear, actionable guidance to industry regarding what constitutes an acceptable dietary supplement label claim. First, neither the DSHEA nor FDA regulations provide a clear definition of a structure/function claim. Rather than affirmatively defining what an acceptable structure/function claim is,³⁵² the regulations enacted in January 2000 focus upon defining a disease claim and excluding such statements from use as structure/function claims. The FDA admits that under these rules “it may be very difficult to draw clear lines between structure/function claims and disease claims,” especially on any principled basis.³⁵³ Yet the DSHEA did not provide any guidance to the agency regarding how to establish this boundary. Although the DSHEA makes a linguistic differentiation between claims that are allowable without premarket approval by the FDA and claims that are considered drug claims, the lack of legislative guidance on this area seems to make this distinction one that does not identify any true difference. Attempting to reconcile the various provisions as the DSHEA as consistently as possible and to identify a distinction where there appears to be none,³⁵⁴ the FDA has left the industry with a series of confusing rules. For example, the final rule tries to distinguish between maintaining healthy function and treating abnormal function, between health maintenance claims such as “maintains healthy cholesterol levels” and implied disease claims such as “lower cholesterol,”³⁵⁵ and between “mild common conditions associated with

³⁵²See Arnold I. Friede, *Dietary Supplements: Background for Dialogue Between the Industry and the Medical Profession*, 53 FOOD & DRUG L.J. 413, 417 (1998).

³⁵³Regulations 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. 1000, 1005 (Jan. 6, 2000). Despite this confusion, the agency asserts that “[t]he final rule creates uniform, enforceable requirements for structure/function claims. By doing so, the final rule establishes a ‘level playing field for all members of the dietary supplement industry, and permits rational use of FDA’s limited enforcement resources.’” See *id.*, at 1008.

³⁵⁴The FDA notes that “[d]espite [this] difficult, implementing section 403(r)(6) of the act requires the agency to draw these lines. FDA would not be carrying out its statutory obligations if it abdicated responsibility for distinguishing between the two types of claims, and instead permitted dietary supplements to disseminate information about specific disease states.” 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. 1000, 1005 (Jan. 6, 2000).

³⁵⁵Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function

natural states” and serious conditions associated with a stage of life or normal physiological process.³⁵⁶ Interpretation of these regulations often depends on the circumstances of use³⁵⁷ or the context in which the claim is presented.³⁵⁸ Comments to the January 2000 rule indicate that the supplement industry is not sure how to apply these regulations in practice;³⁵⁹ the agency has also recognized that the industry needs further guidance.³⁶⁰

Second, the lack of guidance regarding adequate or appropriate substantiation of structure/function claims is a major regulatory hole. The DSHEA provides that manufacturers must have “substantiation that [statements of nutritional support] are truthful and not misleading,” but does not define “substantiation.”³⁶¹ In 1997, the Commission’s Final Report documented that the industry had been asking for guidance on “what constitutes appropriate documentation for a statement of nutritional support” from a “responsible vendor.”³⁶² Accordingly, the Report provided guidance to the FDA regarding what types of substantiation might be adequate to support a nutritional support claim.³⁶³ In addition, several comments regarding the April 1998 proposed structure/function rule requested FDA guidance on claim substantiation, noting that “adequate substantiation is critical to ensuring that consumers receive truthful and accurate information about the benefits of dietary supplements.”³⁶⁴ Nevertheless, the FDA expressly declined to address this

of the Body; Final Rule, 65 Fed. Reg. 1000, 1018 (Jan. 6, 2000).

³⁵⁶Regulations 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. 1000, 1020 (Jan. 6, 2000).

³⁵⁷See 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. 1000, 1006 (Jan. 6, 2000).

³⁵⁸See 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. 1000, 1011 (Jan. 6, 2000).

³⁵⁹See 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. 1000 (Jan. 6, 2000).

³⁶⁰See Guidance on Applying the Structure/Function Rule; Request for Comments, 66 Fed. Reg. 11,172 (Feb. 22, 2001).

³⁶¹21 U.S.C. § 403(r)(6).

³⁶²COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Mar. 26, 2001) <<http://www.health.gov/dietsupp/ch3.htm>>.

³⁶³COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Mar. 26, 2001) <<http://www.health.gov/dietsupp/ch3.htm>>.

³⁶⁴See 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. 1000, 1031-32 (Jan. 6, 2000); UNITED STATES GENERAL ACCOUNTING OFFICE, FOOD SAFETY: IMPROVEMENTS NEEDED IN OVERSEEING THE SAFETY OF DIETARY SUPPLEMENTS AND “FUNCTIONAL FOODS” 5 (July 2000) (“[B]oth food and dietary supplement industry associations have said they believe it is important for FDA to take enforcement actions against unsupported claims.”). One of the submitted comments originated with the Bureau

issue when promulgating its final structure/function rule. Instead, the FDA indicated that it “may provide additional guidance” regarding substantiation at a future date, suggesting for the time being that manufacturers look to the Commission report for guidance.³⁶⁵ Unfortunately, the Commission report does not detail the circumstances in which the different types of substantiation it suggests may be appropriate, and members of the Commission disagreed on some critical points, such as whether historical use would alone be sufficient to substantiate a claim or whether scientific support is needed for all health statements.³⁶⁶ More than a year after publishing the January 2000 final rule, the FDA issued another notice that acknowledged the agency had yet to address the question of substantiation, but gave no indication of when such guidance would be forthcoming.³⁶⁷ Absent such guidance, even the most carefully delineated rules regarding appropriate structure/function claims lose much of their bite. Members of the dietary supplement industry cannot know which nutritional support statements, even if in compliance with the definitional limitations of the structure/function rule, are authorized under the DSHEA and safe from FDA enforcement action, as the statements may be found to have insufficient scientific support.³⁶⁸ Further, a lack of substantiation guidance will likely increase the costs of industry compliance with FDA regulations. Without guidance on the substantiation standard, this issue is roughly analogous to the one addressed by the court in *Pearson*, which decried “arbitrary and capricious” agency action and noted that “it must be possible for the regulated

of Consumer Protection of the Federal Trade Commission. This comment recommended that “any final rule reiterate explicitly the requirement that structure/function claims be adequately substantiated” and that “FDA include guidance in the final rule as to what constitutes adequate substantiation of a structure/function claim.” BUREAU OF CONSUMER PROTECTION, FEDERAL TRADE COMMISSION, COMMENTS REGARDING REGULATIONS ON STATEMENTS MADE FOR DIETARY SUPPLEMENTS CONCERNING THE EFFECT OF THE PRODUCT ON THE STRUCTURE OR FUNCTION OF THE BODY; PROPOSED RULE (Aug. 27, 1998) (visited Mar. 31, 2001) <<http://www.ftc.gov/be/v980023.htm>>.

³⁶⁵See 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. 1000, 1031-32 (Jan. 6, 2000).

³⁶⁶COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Mar. 26, 2001) <<http://www.health.gov/dietsupp/ch3.htm>>.

³⁶⁷See Guidance on Applying the Structure/Function Rule; Request for Comments, 66 Fed. Reg. 11,172, 11,172 (Feb. 22, 2001).

³⁶⁸The Commission on Dietary Supplement Labeling notes that “[f]ollowing appropriate guidelines for substantiation could allow manufacturers to have more confidence that a statement will be sustained if challenged by regulatory agencies.” See COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Mar. 26, 2001) <<http://www.health.gov/dietsupp/ch3.htm>>.

class to perceive the principles which are guiding agency action.”³⁶⁹ Under the current system, the industry is still left guessing as to which statements will not be deemed misbranding.

Further confusing the issue, manufacturers cannot look to anecdotal evidence of acceptable or unacceptable label claims for guidance, as resource constraints have generally precluded the FDA from enforcing the structure/function notice rules and ensuring the accuracy of label statements.³⁷⁰ The FDA estimated that as of April 1998, approximately 22,500 dietary supplement labels included structure/function claims, yet the agency had received only 2,300 claim notifications.³⁷¹ By January 6, 2000, the agency had received a total of 5,200 claim notices and had objected to 336 of these claims.³⁷² None of these objections, however, raised the issue of claim substantiation; the FDA has never requested such information from dietary supplement manufacturers nor initiated enforcement action to investigate questionable claims.³⁷³ Manufacturers therefore cannot look to enforcement proceedings to benchmark their own actions. Absent a clear definition of a structure function claim, guidance regarding adequate claim substantiation, or consistent enforcement of applicable rules, manufacturers have little concrete guidance to rely on and regulation remains largely ad hoc.

³⁶⁹Pearson v. Shalala, 164 F.3d 650, 660-61 (D.C. Cir. 1999).

³⁷⁰See UNITED STATES GENERAL ACCOUNTING OFFICE, FOOD SAFETY: IMPROVEMENTS NEEDED IN OVERSEEING THE SAFETY OF DIETARY SUPPLEMENTS AND “FUNCTIONAL FOODS” 5 (July 2000) (“According to an FDA official, the agency has chosen to use its limited resources on regulating product safety rather than on taking enforcement actions against problematic label claims.”).

³⁷¹See 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. 1000, 1004 (Jan. 6, 2000). The DSHEA requires that a manufacturer making a nutritional support claim notify the FDA of the claim within 30 days of first marketing the supplement. See 21 U.S.C. § 343(r)(6)(C). In citing these statistics, the agency conceded that some notifications contain multiple claims, but noted that “they do not average 10 claims per notification,” indicating that many manufacturers were failing to comply with the notice requirement. 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. 1000, 1004 (Jan. 6, 2000).

³⁷²See UNITED STATES GENERAL ACCOUNTING OFFICE, FOOD SAFETY: IMPROVEMENTS NEEDED IN OVERSEEING THE SAFETY OF DIETARY SUPPLEMENTS AND “FUNCTIONAL FOODS” 21 (July 2000).

³⁷³See UNITED STATES GENERAL ACCOUNTING OFFICE, FOOD SAFETY: IMPROVEMENTS NEEDED IN OVERSEEING THE SAFETY OF DIETARY SUPPLEMENTS AND “FUNCTIONAL FOODS” 5, 18, 21 (July 2000).

Consumer Confusion

The effects on consumers of the DSHEA and subsequent FDA regulation are arguably more important than the lack of industry guidance. Consumer implications are especially critical as the dietary supplement market has continued to grow rapidly since the enactment of the DSHEA. In 1994, an estimated 50 percent of Americans regularly consumed supplements.³⁷⁴ By 1997, this figure had grown to an estimated 70 percent of households,³⁷⁵ and is likely higher today. Correspondingly, consumer sales of dietary supplements totaled at least \$4 billion in 1994³⁷⁶ and reached \$14.7 billion in 1999. As consumer reliance on dietary supplements has appeared to increase at the same time that legislative changes relaxed the standards for supplement manufacturers, allowing more products and more health and nutritional support claims on the market, this has compounded the possibilities of consumer confusion over supplement products.

Regulatory Framework

The current regulatory process is flawed, as it fails to ensure that consumers receive accurate information based on scientific studies of the health and nutrition benefits related to supplement use. Rather than empowering consumers to make positive and informed health choices regarding dietary supplements, the current method of disseminating supplement information often leads to consumer confusion and perhaps even consumer fraud.

³⁷⁴Dietary Supplement Health and Education Act of 1994, § 2.

³⁷⁵According to 1997 survey conducted by the Hartman and New Hope research group, “approximately 70 percent of all households reported using vitamins, minerals, or herbal supplements in the past 6 months. 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. 1000, 1045 (Jan. 6, 2000).

³⁷⁶Dietary Supplement Health and Education Act of 1994, §2. In a slightly different analysis, the General Accounting Office reported \$9.8 billion in sales in 1995. Although it is conceivable that the market grew rapidly, it is probably unrealistic that it more than doubled in size in one year. Rather, a slightly different estimation of sales or attribution of what is considered a dietary supplement likely accounts for a portion of this variance.

First, the lack of substantiation guidelines and the FDA's failure to enforce notice rules or to investigate questionable claims, as discussed above, have significant implications for consumers as well as the industry. The patchwork, ad-hoc regulatory approach currently in place does little to assist consumers in making informed choices, as there is no guarantee that such claims are truthful, nonmisleading, or meet any level of scientific agreement. At the worst, such claims may be false, misleading, or inaccurate. At best, this system results in the proliferation of a number of claims supported by vastly different amounts of evidence; for example, consumers have no way to distinguish those structure/function claims based solely on historical use from those supported by a significant body of scientific evidence.³⁷⁷ In this regulatory mayhem, manufacturers who are unethical or loosely interpret the definition of "substantiation" do not fear that the FDA will either catch or bring enforcement actions against their questionable claims; the system provides little or no incentive for them to study products more thoroughly and to ensure that claims are scientifically-based and accurate, as Congress intended in the DSHEA.³⁷⁸ Unwitting consumers either are unaware that claims are of varying levels of quality or are forced to bear the burden of self-evaluation of claims, a technical task that few consumers can do themselves.³⁷⁹ As noted by the Commission in its Final Report, "[establishing guidelines that manufacturers could follow] would increase the likelihood that statements are will be appropriately supported and would provide consumers with some basis for judging the soundness of the statements that are made."³⁸⁰

The decision in *Pearson v. Shalala* further erodes assurances that any claims have met a specified scientific standard, as now consumers may not be able to rely on even health claims as having passed "significant

³⁷⁷See, e.g., Robert G. Pinco & Todd H. Halpern, *Guidelines for the Promotion of Dietary Supplements: Examining Government Regulation Five Years after Enactment of the Dietary Supplement Health and Education Act of 1994*, 54 FOOD & DRUG L.J. 567, 568 (1999) ("Inexpensive products marketed by marginal companies with no manufacturing standards and minimal scientific support appear on the same shelves as products of more reputable companies that meet strict quality standards and have been subjected to extensive scientific study.").

³⁷⁸Dietary Supplement Health and Education Act of 1994, § 2. In brief, the process has no "bite."

³⁷⁹See FEDERAL TRADE COMMISSION, DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY (visited Mar. 31, 2001) <<http://www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm>>.

³⁸⁰See COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Mar. 26, 2001) <<http://www.health.gov/dietsupp/ch3.htm>>.

scientific scrutiny.” Theoretically, this ruling suggests that manufacturers can make health claims that are “tentative, inconclusive, preliminary, non-replicable, or even out of step with mainstream science,”³⁸¹ provided that the claim also includes a specifically-worded disclaimer. Under such a system, consumer confusion would escalate, as manufacturers could frequently change the wording of disclaimers to reflect new studies. Market research academics have indicated that consumers understand short label messages better than complicated legal disclaimers on packages,³⁸² and it is unlikely that “consumers would be rereading labels of familiar products for updated information.”³⁸³ Under this system, it is possible that neither structure/function claims nor health claims with an appropriate disclaimer will be held to a consistent or scientifically-based standard.

Second, inconsistent standards used by agencies with jurisdiction over the marketing and labeling of supplements fosters consumer confusion. Under a long-standing agreement, the FDA and the Federal Trade Commission (“FTC”) share joint responsibility for the marketing of dietary supplement products.³⁸⁴ The FDA’s authority extends to supplement labeling, package inserts, and other point-of sale promotional materials.³⁸⁵ The FTC maintains primary jurisdiction over the advertising of dietary supplement products, including print and broadcast advertisements, infomercials, Internet advertisements catalogs, and other direct marketing materials.³⁸⁶ In a guide compiled specifically for the dietary supplement industry, the FTC outlined its general approach to truthful advertising as being comprised of the following two issues: “1)

³⁸¹David C. Vladeck, *Devaluing Truth: Unverified Health Claims in the Aftermath of Pearson v. Shalala*, 54 FOOD & DRUG L.J. 535, 552 (1999).

³⁸²Statement of Bruce Chassy, University of Illinois (cited in Phil Wallace, *FDA’s Quandary Over How to Regulate Health Claims After Pearson Reflected at Meeting*, 42 FOOD CHEMICAL NEWS, Apr. 10, 2000, at 14).

³⁸³Statement of Alice Lichtenstein, Tufts University (cited in Phil Wallace, *FDA’s Quandary Over How to Regulate Health Claims After Pearson Reflected at Meeting*, 42 FOOD CHEMICAL NEWS, Apr. 10, 2000, at 14).

³⁸⁴See BUREAU OF CONSUMER PROTECTION, FEDERAL TRADE COMMISSION, COMMENTS REGARDING REGULATIONS ON STATEMENTS MADE FOR DIETARY SUPPLEMENTS CONCERNING THE EFFECT OF THE PRODUCT ON THE STRUCTURE OR FUNCTION OF THE BODY; PROPOSED RULE (Aug. 27, 1998) (visited Mar. 31, 2001) <<http://www.ftc.gov/be/v980023.htm>> (referencing FTC-FDA Liaison Agreement, 4 Trade Reg., Rep. (CCH)

¶ 9851 (1971)).

³⁸⁵See FEDERAL TRADE COMMISSION, DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY (visited Mar. 31, 2001) <<http://www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm>>.

³⁸⁶See FEDERAL TRADE COMMISSION, DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY (visited Mar. 31, 2001) <<http://www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm>>.

advertising must be truthful and not misleading; and 2) before disseminating an ad, advertisers must have adequate substantiation for all objective product claims.”³⁸⁷ Supplement advertising is primarily addressed through three sections of the FTC Act. Section 5 of the FTC Act prohibits “deceptive advertising” and other “deceptive or unfair acts or practices;” sections 12 and 15 forbid “advertisements that are misleading in a material respect” for a variety of products, including food and supplements.³⁸⁸ The FTC typically requires that supplement claims in advertising be substantiated by “competent and reliable scientific evidence.”³⁸⁹ Problems for consumers arise as the “competent and reliable scientific evidence” seems less stringent than the “significant scientific agreement” standard the FDA requires for health claims. It is unclear how the FTC standard compares to yet-undefined “substantiation” requirement for structure/function claims, although it appears that the FTC’s standard here may also be more relaxed than the requirements the FDA may impose.³⁹⁰ It is clear, however, that although the FTC will generally defer to the FDA’s assessment of whether a specific health claim has adequate substantiation, “there may be certain limited instances when a carefully qualified health claim in advertising may be permissible under FTC law, in circumstances where it has not been authorized for labeling.”³⁹¹ In other words, consumers may be barraged with supplement claims in

³⁸⁷FEDERAL TRADE COMMISSION, DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY (visited Mar. 31, 2001) <<http://www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm>>.

³⁸⁸BUREAU OF CONSUMER PROTECTION, FEDERAL TRADE COMMISSION, COMMENTS REGARDING REGULATIONS ON STATEMENTS MADE FOR DIETARY SUPPLEMENTS CONCERNING THE EFFECT OF THE PRODUCT ON THE STRUCTURE OR FUNCTION OF THE BODY; PROPOSED RULE (Aug. 27, 1998) (visited Mar. 31, 2001) <<http://www.ftc.gov/be/v980023.htm>>

³⁸⁹See FEDERAL TRADE COMMISSION, DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY (visited Mar. 31, 2001) <<http://www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm>>.

³⁹⁰For example, the FDA historically has been criticized for being overly cautious and restrictive in its evaluation of supplement claims. Although, as previously discussed, structure/function claims have yet to be subjected to this type of intense scrutiny, it is conceivable that FDA guidance will require rigorous support for these claims as well. Further, the FDA suggests in its January 2000 final rule regarding structure/function claims that it agrees with much of the guidance of the Commission and that the supplement industry might consider following these guidelines as a proxy for FDA regulation for the present time. See 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. 1000, 1031 (Jan. 6, 2000). One of the issues discussed by the Commission was whether historical use alone would be sufficient to substantiate a statement of nutritional support; Commission members were divided on this issue. See COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Mar. 26, 2001) <<http://www.health.gov/dietsupp/ch3.htm>>. The FTC’s guide for the dietary supplement industry suggests, however, that claims based solely on historical use may be allowed if consumers understand this purpose. See FEDERAL TRADE COMMISSION, DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY (visited Mar. 31, 2001) <<http://www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm>>.

³⁹¹See FEDERAL TRADE COMMISSION, DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY (visited Mar. 31, 2001) <<http://www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm>>.

advertising that the product labels cannot bear themselves. It is likely that consumers either will not read to the supplement label and realize the inconsistency or will not understand what the inconsistency means. Further, as the FTC has limited enforcement resources, outrageous advertising statements and marketing hype easily slide by.³⁹² Finally, the provisions in the DSHEA that exempt point-of-sale publications from labeling status potentially exacerbate this inconsistency, as such publications are essentially removed from the scope of the FDA's jurisdiction, are constrained by relatively few restrictions, and may contain claims not authorized on supplement labels.³⁹³ In a climate where “[e]vidence suggests that the American public obtains more information about diet and health from the media than from physicians and dietitians,” using more relaxed standards for claims via these forms of expression may not significantly further the cause of consumer protection.³⁹⁴

Blurring of Boundaries

The DSHEA and subsequent regulations, legislative action, and court decisions have blurred the lines between food, drugs, and dietary supplements. The elimination of sharp demarcations has resulted in a system

³⁹² See Michael Higgins, *Hard to Swallow: While Federal Law Shut the Door on Regulation of Dietary Supplements, Marketing Hype May be Leading the Popular Aids up Courthouse Steps*, 85 A.B.A. J. 60, 60 (June 1999). For example, marketers have hyped a supplement with supposed aphrodisiacal qualities as “Excellent Viagra Alternative! Increase Sex Drive! Build Muscle Faster! Feel Younger!” and another supplement with alleged antiviral effects as being “designed for patients suffering from rheumatoid arthritis” or “designed for patients suffering from frequent herpes syndrome.” *Id.* at 62. The FDA would clearly classify such claims as disease claims. See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624 (proposed Apr. 29, 1998); 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. 1000 (Jan. 6, 2000). Dietary supplement executives note, however, that taking risks and puffing up claims used in advertising is an industry trend. Unauthorized advertising on the Internet may be especially difficult for the FTC to regulate, given the scope of the medium. In 1998, the FTC coordinated a “surf day” with various consumer groups to attempt to locate Web sites on which members of the dietary supplement industry made prohibited claims about their products. Although 1,200 sites were identified through this effort, a FTC attorney noted that a FTC crackdown on such ads is unlikely given the volume of violations. Michael Higgins, *Hard to Swallow: While Federal Law Shut the Door on Regulation of Dietary Supplements, Marketing Hype May be Leading the Popular Aids up Courthouse Steps*, 85 A.B.A. J. 60, 60 (June 1999) (citing statements of Michelle Rusk, an attorney at the FTC's Division of Advertising Practices).

³⁹³ See 21 U.S.C. § 343-2; Michael H. Cohen, *U.S. Dietary Supplement Regulation: Belief Systems and Legal Rules*, 11 HASTINGS WOMEN'S L.J. 3, 12 (2000).

³⁹⁴ See COMMISSION ON DIETARY SUPPLEMENT LABELS, 1997 REPORT (visited Mar. 26, 2001) <<http://www.health.gov/dietsupp/ch4.htm>>.

that erodes the ability of consumers to make informed health choices yet simultaneously overwhelms them with a barrage of new information and products. Rather than fulfilling the stated goals of the DSHEA,³⁹⁵ the prevailing atmosphere of ambiguity is responsible for consumer confusion, claim puffery by manufacturers, an increasing reliance on dietary supplements as a replacement for traditional medical treatment, and inconsistent treatment of claims on food and dietary supplements.

In a regulatory scheme where the dietary supplement industry – which has a significant financial stake in reviewing, commenting upon, understanding, and properly implementing regulations regarding label claims – remains confused about the distinctions between health claims and structure/function claims and the FDA itself notes that such distinctions are elusive and difficult to define, it is of little wonder that preliminary FDA research indicates that consumers also do not understand the intended differences between these types of claims.³⁹⁶ Although the FDA has noted that its attempts to clarify the distinction between structure/function and disease claims are intended to help “consumers make more informed and wiser choices,”³⁹⁷ it does not appear that the agency successfully reached these policy goals. Rather, comments submitted to the FDA document that consumers incorrectly view both structure/function and health claims as “disease treatment or prevention claims.”³⁹⁸ Accordingly, consumers may misinterpret structure/function claims as indicating that a product can help prevent, treat, or cure a disease rather than understanding them for their more qualified purpose of merely describing how a product affects the body’s structure, function, or general well-being.³⁹⁹

³⁹⁵ See Dietary Supplement Health and Education Act of 1994, § 2.

³⁹⁶ See UNITED STATES GENERAL ACCOUNTING OFFICE, FOOD SAFETY: IMPROVEMENTS NEEDED IN OVERSEEING THE SAFETY OF DIETARY SUPPLEMENTS AND “FUNCTIONAL FOODS” 23 (July 2000).

³⁹⁷ Statement of William Shultz, Deputy Commissioner for Policy, FDA (quoted in Michele Simon, *Still Cloudy, With Little Chance of Clearing: FDA’s Proposed Rule on Structure/Function Claims for Dietary Supplements*, 11 HASTINGS WOMEN’S L.J. 23, 23 (2000)).

³⁹⁸ UNITED STATES GENERAL ACCOUNTING OFFICE, FOOD SAFETY: IMPROVEMENTS NEEDED IN OVERSEEING THE SAFETY OF DIETARY SUPPLEMENTS AND “FUNCTIONAL FOODS” 23 (July 2000).

³⁹⁹ See UNITED STATES GENERAL ACCOUNTING OFFICE, FOOD SAFETY: IMPROVEMENTS NEEDED IN OVERSEEING THE SAFETY OF DIETARY SUPPLEMENTS AND “FUNCTIONAL FOODS” 5, 18, 23 (July 2000).

The use of the statutorily-required disclaimer⁴⁰⁰ or of carefully constructed language restraints in claims will likely be insufficient to cure this problem of claim misinterpretation. As previously noted, the lay consumer is unlikely to notice or to attach great significance to the required disclaimer on structure/function claims. One commentator further hypothesized that the “alluring promises” made in these claims contribute to this cavalier dismissal of disclaimers.⁴⁰¹ If consumers truly discounted the accuracy of structure/function claims based on label disclaimers, it seems unlikely that consumers would support the supplement lobby as strongly or that the dietary supplement market would be realizing such rapid growth.⁴⁰² The linguistic manipulations required by the final January 2000 structure/function rule may only exacerbate consumer confusion. Carefully worded claims such as “helps maintain intestinal flora”⁴⁰³ or “cleanses the blood”⁴⁰⁴ will likely baffle, rather than illuminate, the average consumer. Similarly, consumers will probably fail to understand the distinction between “supports the immune system” as an allowable structure/function claim and “supports the body’s ability to resist infection” as a prohibited disease claim.⁴⁰⁵

The natural tendencies of merchants to attempt to improve sales by bolstering the public perception of their products’ qualities, within legal limits, further confounds the issue of consumer confusion. With the difficulties inherent in successfully gaining premarket approval of a health claim, stretching the seemingly ambiguous and malleable boundaries of structure/function claims likely appears as an particularly attrac-

⁴⁰⁰ See 21 U.S.C. § 343(r)(6)(C).

⁴⁰¹ Leticia M. Diaz, *First St. John’s Wort, Now SAM-e: Is Society as a Whole at Risk Without FDA Regulation of Psychiatric Self-Medication*, 9 KANSAS J.L. & PUB. POL’Y 279 (Winter 1999).

⁴⁰² The growth of supplements cannot be solely attributed to perceived health benefits based on label health claims, as the FDA has only authorized a handful of health claims for dietary supplements. See *supra* note 259, 260. In contrast, at least 22,500 products bear structure/function claims. See UNITED STATES GENERAL ACCOUNTING OFFICE, FOOD SAFETY: IMPROVEMENTS NEEDED IN OVERSEEING THE SAFETY OF DIETARY SUPPLEMENTS AND “FUNCTIONAL FOODS” 21 (July 2000). See also Leticia M. Diaz, *First St. John’s Wort, Now SAM-e: Is Society as a Whole at Risk Without FDA Regulation of Psychiatric Self-Medication*, 9 KANSAS J.L. & PUB. POL’Y 279 (Winter 1999).

⁴⁰³ 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. 1000, 1029 (Jan. 6, 2000).

⁴⁰⁴ UNITED STATES GENERAL ACCOUNTING OFFICE, FOOD SAFETY: IMPROVEMENTS NEEDED IN OVERSEEING THE SAFETY OF DIETARY SUPPLEMENTS AND “FUNCTIONAL FOODS” 20 (July 2000). The GAO further criticized that such a claim is “so vague or general that [it has] little or no scientific meaning and would be very difficult to prove.” *Id.*

⁴⁰⁵ Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,627 (proposed Apr. 29, 1998).

tive option to the dietary supplement industry. It is advantageous for manufacturers to attempt to “bend” the structure/function rules as far as possible and to further blur the line between dietary supplements and drugs. Given the FDA’s lackluster enforcement record to date, unscrupulous manufacturers arguably may be able even to cross the line between allowable structure/function and prohibited disease claims without facing a significant risk of regulatory action.⁴⁰⁶ Accordingly, manufacturers can carefully nuance the wording of label claims to safely stay within the safe harbor provisions set forth in the DSHEA, while making essentially drug promises.⁴⁰⁷ In short, the dietary supplement industry can “suggest[] miracle health benefits without quite promising them,”⁴⁰⁸ thereby influencing unsuspecting consumers who see structure/function claims as implying therapeutic benefit.⁴⁰⁹

The erosion of boundaries between dietary supplements and drugs assumes potentially dangerous implications, as many consumers rely on supplements as a form of self-treatment for various medical conditions.⁴¹⁰ A variety of factors likely contribute to this trend, including consumer misinterpretation of structure/function claims as disease claims; manufacturers’ eagerness to impute therapeutic benefit to boost sales of their products; increasing study and documentation of health benefits of supplements; escalating consumer interest in preventive health measures and self care; and new reliance on alternative therapies due to the growing

⁴⁰⁶One commentator noted that “the deluge of products – as many as 28,000 currently on the market, according to a government estimate – has made it much harder for the government to police extravagant claims.” Michael Higgins, *Hard to Swallow: While Federal Law Shut the Door on Regulation of Dietary Supplements, Marketing Hype May be Leading the Popular Aids up Courthouse Steps*, 85 A.B.A. J. 60, 60 (June 1999).

⁴⁰⁷See Roseann B. Termini, Esq., *Pharmanex v. Shalala: A Wake Up Call for Congress and a Not So Bitter Pill for the FDA*, 26 OHIO N.U. L. REV. 269, 283-84 (2000); Kelly Ann Kaczka, *From Herbal Prozac to Mark McGwire’s Tonic: How the Dietary Supplement Health and Education Act Changed the Regulatory Landscape for Health Products*, 16 J. CONTEMP. HEALTH L. & POL’Y 463, 493 (2000).

⁴⁰⁸Michael Higgins, *Hard to Swallow: While Federal Law Shut the Door on Regulation of Dietary Supplements, Marketing Hype May be Leading the Popular Aids up Courthouse Steps*, 85 A.B.A. J. 60, 62 (June 1999).

⁴⁰⁹See also UNITED STATES GENERAL ACCOUNTING OFFICE, FOOD SAFETY: IMPROVEMENTS NEEDED IN OVERSEEING THE SAFETY OF DIETARY SUPPLEMENTS AND “FUNCTIONAL FOODS” 25 (July 2000) (“[G]iven the significance of consumer understanding of label claims and potential for miscommunication the Commission urged that consumers’ understanding of structure/function and health claims receive continued attention.”).

⁴¹⁰See, e.g., Michael H. Cohen, *U.S. Dietary Supplement Regulation: Belief Systems and Legal Rules*, 11 HASTINGS WOMEN’S L.J. 3, 11-12 (2000); Michele Simon, *Still Cloudy, With Little Chance of Clearing: FDA’s Proposed Rule on Structure/Function Claims for Dietary Supplements*, 11 HASTINGS WOMEN’S L.J. 23, 25 (2000); *Research Firms Suggest Market for Nutraceuticals is Maturing*, 8 DIETARY SUPPLEMENT & FOOD LABELING NEWS, Sept. 6, 2000, at 19.

cost of health care.⁴¹¹ As many consumers believe that supplements can help people with illnesses, they are beginning to shun traditional medical treatment in favor of supplement use.⁴¹² Real concerns arise when consumers move beyond use of supplements for basic nutritional support and maintenance of well-being but instead rely on unsubstantiated claims and marketing hype to treat more serious conditions. Especially as many available supplements contain the same ingredients as prescription drugs, the inclination to self-medicate without physician supervision and to forego routine doctor-patient consultations raises serious health concerns.⁴¹³ Further, evidence suggests that consumers are shunning prescribed medication and instead using supplements to treat such conditions as high blood pressure, diabetes, high cholesterol, and cancer.⁴¹⁴ One survey suggests that consumer self-treatment and use of supplements in place of traditional medications is becoming widespread, reporting that more than 30 million individuals relied on supplements instead of over-the-counter (“OTC”) drugs and that 19 million additional consumers used both supplements and OTC drugs for therapeutic treatment.⁴¹⁵ Arguably, neither Congress nor the FDA intended that structure/function claims be interpreted as disease claims and used for treatment or prevention purposes, especially on such a grand scale.⁴¹⁶ The FDA explicitly noted that it is important that structure/function

⁴¹¹ See Dietary Supplement Health and Education Act of 1994, § 2; *Research Firms Suggest Market for Nutraceuticals is Maturing*, 8 DIETARY SUPPLEMENT & FOOD LABELING NEWS, Sept. 6, 2000, at 19.

⁴¹² See Laura A.W. Khatcheressian, *Regulation of Dietary Supplements: Five Years of DSHEA*, 54 FOOD & DRUG L.J. 623, 630-31 (1999).

⁴¹³ See Arnold I. Friede, *Dietary Supplements: Background for Dialogue Between the Industry and the Medical Profession*, 53 FOOD & DRUG L.J. 413, 419 (1998); Laura A.W. Khatcheressian, *Regulation of Dietary Supplements: Five Years of DSHEA*, 54 FOOD & DRUG L.J. 623, 629 (1999).

⁴¹⁴ See Laura A.W. Khatcheressian, *Regulation of Dietary Supplements: Five Years of DSHEA*, 54 FOOD & DRUG L.J. 623, 629 (1999).

⁴¹⁵ See *Research Firms Suggest Market for Nutraceuticals is Maturing*, 8 DIETARY SUPPLEMENT & FOOD LABELING NEWS, Sept. 6, 2000, at 19. This study, entitled “The U.S. Market for Vitamins, Supplements, and Minerals,” was conducted by Kalorama Information.

⁴¹⁶ See 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. 1000, 1003 (Jan. 6, 2000); SEN. REP. NO. 103-410, at 17 (1994). Congress noted in the DSHEA that dietary supplements and good nutrition play a role in “health promotion and disease prevention” and that “preventive health measures, including . . . good nutrition and appropriate use of safe nutritional supplements will limit the incidence of chronic diseases.” Dietary Supplement Health and Education Act of 1994, § 2. The DSHEA further reflects congressional findings that “there is a definitive link between the ingestion of certain nutrients or dietary supplements and the prevention of disease.” S. REP. NO. 103-410, at 2. These statements, however, do not reflect congressional intent to allow structure/function claims to carry information about disease treatment or prevention. Rather, Congress intended that the relationship between supplements and disease or health-related conditions be reflected as health claims, which are subject to increased FDA review and scrutiny. See S. REP. NO. 103-410, at 15-17. The requirement that all structure/function claims bear a disclaimer stating that the “product is not intended to diagnose, treat, cure, or prevent any disease” further supports

claims “do not promote products for disease treatment or prevention claims,” and warned that relying on such claims for disease treatment “pose[s] serious risks to consumers if they induce consumers to substitute ineffective or less effective treatments for proven ones, especially if the disease involved is serious or life-threatening.”⁴¹⁷ Several comments to the FDA also added concerns that use of dietary supplements for treatment purposes, especially absent a physician’s supervision, could lead to “potentially harmful drug-supplement interactions” and create “false hopes” in consumers.⁴¹⁸ Not surprisingly, members of the medical profession are among those critical of the DSHEA.⁴¹⁹

Finally, the fairly recent introduction of functional foods into the market has begun to further obfuscate the distinctions between dietary supplements and food (and hence between drugs and food). Functional foods, which are regulated by the FDA under the same rules as traditional foods, are products that provide the basic attributes of food but claim an additional health benefit, often obtained through the incorporation of additional ingredients.⁴²⁰ For example, orange juice is often fortified with calcium and existing dietary supplements such as echinacea may be added to foods such tea.⁴²¹ Accordingly, both foods and dietary supplements may include health claims or structure/function claims on their product labels.⁴²² The FDA’s procedure for health claims is the same for both foods and supplements; claims must be preap-

the assertion that Congress did not intend structure/function claims to be interpreted as disease claims and used for treatment or prevention purposes. Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 343(r)(6)(C).

⁴¹⁷Regulations 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. 1000, 1003 (Jan. 6, 2000). The FDA further noted that the DSHEA, ultimately, bears responsibility to the extent which truthful, non-misleading information is withheld from structure/function labels, explaining that section 403(r)(6) of the Act, not the FDA, precluded “unreviewed claims that the product diagnoses, treats, mitigates, cures, or prevents disease.” *Id.*, at 1002-03.

⁴¹⁸Regulations 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. 1000, 1002 (Jan. 6, 2000).

⁴¹⁹See Roseann B. Termini, Esq., *Pharmanex v. Shalala: A Wake Up Call for Congress and a Not So Bitter Pill for the FDA*, 26 OHIO N.U. L. REV. 269, 285 (2000).

⁴²⁰See UNITED STATES GENERAL ACCOUNTING OFFICE, FOOD SAFETY: IMPROVEMENTS NEEDED IN OVERSEEING THE SAFETY OF DIETARY SUPPLEMENTS AND “FUNCTIONAL FOODS” 3, 8 (July 2000). Functional foods, dietary supplements, and drugs have also been collectively defined as “nutriceuticals,” indicating that they have a purported nutritive or pharmaceutical health benefit. See Eric F. Greenberg, *Food for Thought? Sorting out Consumer Products*, CHICAGO DAILY LAW BULLETIN, March 29, 2000, at 5.

⁴²¹See UNITED STATES GENERAL ACCOUNTING OFFICE, FOOD SAFETY: IMPROVEMENTS NEEDED IN OVERSEEING THE SAFETY OF DIETARY SUPPLEMENTS AND “FUNCTIONAL FOODS” 6 (July 2000).

⁴²²See UNITED STATES GENERAL ACCOUNTING OFFICE, FOOD SAFETY: IMPROVEMENTS NEEDED IN OVERSEEING THE SAFETY OF DIETARY SUPPLEMENTS AND “FUNCTIONAL FOODS” 3 (July 2000).

proved through FDA regulation and based on significant scientific agreement or an authoritative statement. Structure/function claims for functional foods and dietary supplements, however, are subject to different standards. The primary distinction is that structure/function claims on functional foods do not need to bear a label disclaimer and are exempt from the notification requirement.⁴²³ Therefore, the FDA has no process to identify those structure/function claims on foods that were poorly substantiated or were unauthorized drug/disease claims.

As previously discussed, prior to January 2000, the FDA advocated that structure/function claims on supplements were exempt from the disclaimer and notice provisions provided that the claim was “truthful, nonmisleading, and derived from nutritive value.”⁴²⁴ The January 2000 regulations reflected an abrupt departure from this earlier position and instead required all dietary supplements to bear a label disclaimer and to comply with the notification provisions of the DSHEA.⁴²⁵ Subsequently, in February 2000, the FDA’s reversal of position was challenged by three citizen petitions.⁴²⁶ Although the FDA filed a notice for comment,⁴²⁷ it has yet to affirm or rescind its January 2000 notice and disclaimer rules. Rather, the agency has merely restated that the mandatory use of disclaimers and notice is based on interpretation of the DSHEA.⁴²⁸ As a result, current FDA regulations regarding disclaimer use for structure/function statements on dietary supplements and on food products lead to inconsistent, misleading, and inaccurate information to consumers.

First, due to the different standards for foods and dietary supplements, a functional food may bear a claim

⁴²³ See 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. 1000, 1033 (Jan. 6, 2000).

⁴²⁴ See 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. 1000, 1033 (Jan. 6, 2000).

⁴²⁵ See 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. 1000, 1033 (Jan. 6, 2000).

⁴²⁶ Nutraceutical Corporation, Petition for Reconsideration and for Stay of Action, No. 98N-0044 (Feb. 4, 2000); American Herbal Products Association, Petition for Reconsideration and Petition for Stay of Action, No. 98N-0044 (Feb. 7, 2000); Council for Responsible Nutrition & Consumer Healthcare Products Association, Petition for Reconsideration and Stay of Action, No. 98N-0044 (Feb. 7, 2000).

⁴²⁷ See Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Availability of Citizen Petitions for Comment, 65 Fed. Reg. 63,256 (Oct. 23, 2000).

⁴²⁸ See Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Availability of Citizen Petitions for Comment, 65 Fed. Reg. 63,256, 63,256 (Oct. 23, 2000).

unqualified by a disclaimer, while a supplement that derives its structure/function benefit from the same nutrient or ingredient cannot. For example, calcium marketed as a supplement could only bear the statement “calcium builds strong bones” if it also included a disclaimer that the statement had not been evaluated by the FDA. If the calcium supplement was added to orange juice, however, the juice could make the claim absent the disclaimer.⁴²⁹ This disparate treatment over the same nutrient can lead to consumer confusion regarding the true benefits of a product. Arguably, the inconsistency also discriminates against dietary supplements and implicitly suggests that the claim on the food product is more “deserving” of acceptance than the claim on the supplement label.⁴³⁰ In addition, the lack of a disclaimer on foods may also imply that the FDA has evaluated the validity of and authorized the structure/function claim for foods but not for supplements.⁴³¹ Finally, requiring manufacturers to provide a disclaimer indicating that the FDA has not evaluated the structure/function claim on all supplement products may be misleading because the FDA has evaluated many commonly accepted structure/function claims on supplements, such as the aforementioned calcium statement.⁴³² Consequently, these inconsistencies are likely to confound “consumers’ ability to distinguish FDA-authorized claims from other claims that have not been reviewed and authorized.”⁴³³

The regulatory discrepancies regarding structure/function claims in different types of products are merely more obstacles in the path to consumer understanding and informed choices. The difficulties inherent in understanding the distinctions between structure/function claims and health claims, in ascertaining the underlying message of marketing hype and cryptic claim wording, and in successfully using supplements to complement necessary traditional medicine are confusing enough without the FDA or the DSHEA making the use of health and structure/function claims inconsistent across product lines.

⁴²⁹ See, e.g., *CHPA and CRN Press for Nutrient Claims Parity in the USA*, NUTRACEUTICALS INTERNATIONAL (Feb. 1, 2001).

⁴³⁰ See Council for Responsible Nutrition & Consumer Healthcare Products Association, *Petition for Reconsideration and Stay of Action*, No. 98N-0044, at 6 (Feb. 7, 2000).

⁴³¹ See *CHPA and CRN Press for Nutrient Claims Parity in the USA*, NUTRACEUTICALS INTERNATIONAL (Feb. 1, 2001).

⁴³² See *CHPA and CRN Press for Nutrient Claims Parity in the USA*, NUTRACEUTICALS INTERNATIONAL (Feb. 1, 2001).

⁴³³ See UNITED STATES GENERAL ACCOUNTING OFFICE, *FOOD SAFETY: IMPROVEMENTS NEEDED IN OVERSEEING THE SAFETY OF DIETARY SUPPLEMENTS AND “FUNCTIONAL FOODS”* 26 (July 2000).

V.

CONCLUSION

After years of ad hoc regulation of dietary supplements, attempting to strictly curtail access to and claims attributed to these products, the DSHEA was a positive step. Both Congress and the FDA were hopeful that it would strike the right balance between ensuring safe, accurate products and information, providing guidance to the industry, and enabling consumers to be more assertive and proactive in making informed health choices. Despite these good intentions and the strong public support for the policy changes the DSHEA suggested, the resulting system fails to fully realize these goals. The resulting consumer confusion prevents them from making informed health choices; lack of adequate industry guidance and regulation enforcement has not entirely produced the “rational Federal framework”⁴³⁴ that Congress had envisioned. Although the situation is not as dire as attempting to cure all health problems with the untested products of a snake oil salesman, the analogy may still be surprisingly appropriate. Today, consumers continue to rely on confusing and sometimes overstated product claims of often questionable substantiation; now, however, many of them are sacrificing proven medical treatment in the process.

The problems in the system, however, are not insurmountable. It is also not possible or realistic to hope to cure all defects and to produce a framework that will satisfy all interests. A solution will likely entail a combination of a variety of factors, including amended regulations, greater FDA funding, legislative action

⁴³⁴Dietary Supplement Health and Education Act of 1994, § 2.

to provide more direction, and consumer or physician education. Given the reward of access to safe, accurate products and information, empowering people to take control of decisions and have better long-term health, it is worth a bit more effort to tweak the system and make it work as planned.