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COMMENT

FROM HERBAL PROZAC TO MARK MCGWIRE'S TONIC: HOW THE DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT CHANGED THE REGULATORY LANDSCAPE FOR HEALTH PRODUCTS

*Kelly Ann Kaczka**

INTRODUCTION

St. John's Wort doth charm all witches away,
If gathered on the saint's holy day.
Any devils and witches have no power to harm
Those that gather the plant for a charm.
Rub the lintels with that red juicy flower;
No thunder nor tempest will then have the power
To hurt or hinder your house; and bind
Round your neck a charm of similar kind.¹

Walk into any health food store or pharmacy and you will find rows of vitamins and minerals to supplement your daily diet. Consumers are faced with new lines of herbs and supplements making health related claims such as "feel good mentally," "relieve anxiety," and "put on 10 pounds of muscle in three weeks while adding 20 pounds to your bench press,"² none of which require a prescription. Because these

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1. Poem c.1400A.D., from St. John's Wort, Avery 1998, cited in Michael T. Murphy, *Battling the Blues with St. John's Wort*, BETTER NUTRITION, Feb. 1998, at 14.

2. Marion Jones, *Mark McGwire's Muscle Pills: Supplements or Steroids?* (last modified Aug. 26, 1998) <http://www.foxnews.com/js_index.sml?content=/health/082698/sluggdrugs.sml>.

products are labeled and marketed as "dietary supplements," there are no established standards or manufacturing controls for them, nor standards by which to judge their effectiveness or their safety.³ Yet, open almost any magazine or turn on the news, and the benefits of these supplements are praised.⁴

Supplement alternatives to established medicines are used by approximately one-third of the U.S. population.⁵ Herbal supplements are the most common,⁶ and their usage has increased since the passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA).⁷ In 1996 alone, consumers spent over \$6.5 billion on dietary supplements.⁸ In the past, these products were found mainly in health food stores and marketed principally to adults, but now they are available from a number of different sources.⁹ Dietary supplements are often introduced as offering a health benefit, but stop short of making direct therapeutic claims. Many consumers spend their money without

3. See Marian Burros, *Eating Well: Dietary Supplements: Let the Buyer Beware*, N.Y. TIMES, Oct. 16, 1991, at C1; see also, *Science Friction: Mainstream Medicine Faces a Challenge From Alternative Practices. A debate between Arnold S. Relman and Andrew Weil*, WASH. POST, May 25, 1999, §HM (Health), at 11 [hereinafter *Science Friction*].

4. See *Herbal Supplements, What You Don't Know Can Hurt You*, GLAMOUR, Oct. 1998, at 314; see also Christine Gorman, *Is it Good Medicine?*, TIME, Nov. 23, 1998, at 69.

5. See NAT'L INST. OF HEALTH/NAT'L INST. OF ENVTL. HEALTH SCI. INT'L WORKSHOP TO EVALUATE RESEARCH NEEDS ON THE USE AND SAFETY OF MEDICINAL HERBS, CONFERENCE SUMMARY 1, September 23-24, 1998, Raleigh, North Carolina [hereinafter NIH RESEARCH WORKSHOP].

6. See Paula Kurtzweil, *U.S. Food and Drug Administration, FDA Consumer Guide to Daily Supplements* (visited Oct. 20, 1998) <<http://vm.cfsan.fda.gov/~dms/fdsupp.html>>. Research shows that half of the adult U.S. population use daily supplements. See *id.*

7. See NIH Research Workshop, *supra* note 5, at 1; see also Pub. L. No. 103-417, 108 Stat. 4325 (1994).

8. See Kurtzweil, *supra* note 6 (citing Packaged Facts Inc., a market research firm in New York City).

9. See Statement by Jane E. Henney, M.D., *Commissioner Before the House Comm. on Gov't Reform*, U.S. House of Rep. (visited Mar. 5, 1999) <<http://vm.cfsan.fda.gov/~lrd/sthenney.html>> at 4. See also *Science Friction*, *supra* note 3.

knowing if these products are safe, if the claims can be trusted, or if they will actually help. In short, consumers do not know whether they are just throwing their money away on the latest fad.

The Food and Drug Administration's (FDA) mission includes protecting consumers from adulterated and misbranded foods, drugs, devices and cosmetics.¹⁰ This mission remains the same even though federal laws changed the way the FDA evaluates and regulates these products.¹¹ "Foods" and "drugs" are two different categories under the federal Food, Drug and Cosmetic Act (FDCA).¹² "New drugs" must undergo rigorous clinical testing for effectiveness and safety,¹³ while both foods and drugs are policed to insure that they are not adulterated and are correctly labeled.¹⁴ If they make a "health claim,"¹⁵ that claim must be substantiated and pre-approved by the FDA.¹⁶

Although Congress declared vitamins, minerals, and other forms of dietary supplements as a distinct category of foods in 1976,¹⁷ the FDA has always successfully controlled the more aggressive marketing of these products. This regulation, under the rubrics of food and drugs, dramatically limited the types of claims products could make in the absence of strong, scientific proof.¹⁸ As a result of lobbying efforts to prevent the FDA from having this level of control over supplements, Congress passed the DSHEA in 1994.¹⁹ This opened the floodgates for

10. See RICHARD MERRILL & PETER B. HUTT, FOOD AND DRUG LAW CASES AND MATERIALS 3-4 (1980).

11. See *infra* Part II.B. and accompanying notes.

12. 21 U.S.C. § 321 *et seq.* (1998).

13. See 21 U.S.C. § 403 (1998).

14. See 21 U.S.C. § 352 (1998). The Nutritional Labeling and Education Act now requires that food labels contain nutritional information. See Pub. L. No. 101-535, 104 Stat. 2353 (1990).

15. The Act defines a health claim as one that suggests the product to be useful for the "cure, mitigation, treatment or prevention" of disease. See 21 U.S.C. § 321(g) (1998).

16. See 21 U.S.C. § 342 (1998).

17. See 21 U.S.C. § 321(ff) (1998).

18. See *infra* Part II.A. and accompanying notes.

19. See Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994); see also William J. Skinner, R.Ph., J.D., *Allowable Advertising Claims for Dietary Supplements*, 5 J. PHARMACY & L. 309, 313 (1996). Medicinal herbs now constitute the most rapidly growing

manufacturers to produce dietary supplements with a significantly lower level of oversight by the FDA. The DSHEA departed from the established regulatory scheme and took away FDA's authority to police a market now flourishing with unproven products that may present not only efficacy issues, but safety concerns as well.

In the last few years dietary supplements received extensive media exposure.²⁰ In 1998, the world watched Mark McGwire batted his way into the history books, breaking the Major League Baseball record for most home runs in one season.²¹ As the season ended, the world also took notice of the dietary supplements McGwire was taking, particularly Androstenedione.²² This so-called "supplement" is a derivative of rigorously regulated, prescription-only anabolic steroids.²³ Like its prescription drug counterpart, Androstenedione raises the level of testosterone in the body and, arguably, helps build muscle.²⁴ Unlike its counterpart, however, Androstenedione is not rigorously regulated and can be purchased easily over the Internet.²⁵

This Comment traces the development of food and drug law leading up to the DSHEA and the issues the FDA faces in attempting to regulate dietary supplements. Part I of this Comment discusses the history of the Food Drug & Cosmetic Act (FDCA) as it relates to dietary supplements. Part II highlights the evolution of the legal classification of

segment of the dietary supplement market in the U.S. See NIH RESEARCH WORKSHOP, *supra* note 5, at 1.

20. See, e.g., Catherine Heusel, *Self's Ultimate Guide to Herbal Medicines*, SELF, Nov. 1998, at 162. In 1997, the leading uses of herbal remedies were: colds 59 percent, burns 45 percent, headaches 22 percent, allergies 21 percent, rashes 18 percent, insomnia 18 percent, PMS 17 percent, depression 7 percent, diarrhea 7 percent, menopause 4 percent. See also Jane E. Brody, *Taking a Gamble on Herbs as Medicine*, N.Y. TIMES, Feb. 9, 1999, at D7 (citing Prevention Magazine).

21. See Frank Ahrens, *Power Pill: How the Experts View Androstenedione*, WASH. POST, Oct. 20, 1998, § HM (Health), at 12.

22. See *id.*

23. See David Brown, *McGwire's Tonic is a Steroid – of Uncertain Effect*, WASH. POST, Sept. 28, 1998, at A3.

24. See Michael Colgan, *Androstenedione and Tales of Testosterone*, (visited Oct. 20, 1998) <<http://musculardevelopment.com/oct/andro1.html>>.

25. A simple Internet search on Yahoo.com produced over 500 web sites selling Androstenedione.

dietary supplements and how the FDA enforces these standards. It points out the struggle between the FDA and Congress to devise a regulatory scheme to protect consumers, while also giving freedom to supplement manufacturers. Part III of this Comment discusses how the current regulatory scheme applies to supplements such as Androstenedione and St. John's Wort and highlights some of the scientific research conducted on these products. In Part IV, this Comment argues that the DSHEA is a departure from the FDA's intended regulatory scheme. It suggests alternate ways the FDA can use DSHEA's provisions to recapture some of the regulatory authority purposely removed by the statute. Finally, this Comment recommends a more hands-on role for the Federal Trade Commission (FTC) in monitoring supplement labels and suggests possible cooperation between the FDA and dietary supplement manufacturers to ensure consumer safety.

I. NEARLY A CENTURY OF FOOD AND DRUG LAWS

The FDA's initial authority over dietary supplements started with efforts to protect consumers from bogus products marketed as having health value.²⁶ Litigation and distrust between pharmaceutical companies and the FDA permeate the history of dietary supplement regulation. The FDA and Congress sought to control dietary supplements through a variety of enforcement and regulatory controls, including classification methods, effectiveness provisions, and labeling requirements.²⁷ On a case-by-case basis, the FDA very successfully controlled the availability of products labeled as dietary supplements.²⁸ The FDA's efforts to create formal rules based on these victories did not enjoy the same level of success. Attempts at regulation met strong opposition from the dietary supplement industry. As a result, the DSHEA has weakened federal control more than any other congressional action surrounding food regulation.²⁹

26. For a thorough examination of the history of government regulation of health claims for vitamins and minerals, see Peter Barton Hutt, *Government Regulation of Health Claims in Food Labeling and Advertising*, 41 FOOD DRUG COSM. L.J. 3 (1986).

27. See *infra* Part II.

28. See *infra* Part II.A.

29. See William R. Pendergast, *Dietary Supplements*, in 1 FUNDAMENTALS OF LAW AND REGULATION 257 (FDLI 1997).

A. The Pure Food and Drugs Act of 1906

Congress enacted the Pure Food and Drugs Act of 1906³⁰ to help ensure the purity and safety of food and drugs and to prevent manufacturers from deceiving consumers.³¹ It was passed at a time when investigative journalists, among them Upton Sinclair in *The Jungle*, were disclosing the hidden side of the food industry.³² Burgeoning science also began providing increased opportunities to detect food contamination.³³ Years of study and developments in technology offered the means to chemically identify a variety of products and their possible uses and effects. Although rather limited in scope, this legislation was extraordinarily important for the safety of consumers. Drugs marketed in interstate commerce were now subject to minimal standards for quality, purity and strength.³⁴ False claims about a drug's therapeutic effect, however, were not a violation of the statute.³⁵

Although later amendments created a standard for misbranded claims,³⁶ the 1906 Act protected the public, to a degree, from unsafe drugs even though it did not require pre-market screening. The need for a drug screening regulation became apparent to Congress in 1938 when seventy-three people died after ingesting Elixir Sulfanilamide.³⁷

30. Pub. L. No. 59-384, ch. 3915, 34 Stat. 768 (1906) (repealed 1938).

31. See 40 Cong. Rec. 9068-76 (1906).

32. See George M. Burditt, Esq., *The History of Food Law*, 50 FOOD & DRUG L. J. 197 (1995).

33. See *id.*

34. See Edgar R. Cataxinos, Note, *Regulation of Herbal Medications in the United States: Germany Provides a Model for Reform*, 1995 UTAH L. REV. 561, 562-63 (1995).

35. See *United States v. Johnson*, 221 U.S. 488, 497-98 (1911) (holding that an "effective against cancer" indication on drug label did not constitute violation of 1906 Act).

36. See Cataxinos, *supra* note 34 (citing Joseph L. Fink & Larry M. Simonsmeier, *Laws Governing Pharmacy*, in REMINGTON'S PHARMACEUTICAL SCIENCES 1890, 1907 (Alfonso R. Gennaro et al. eds., 17th ed. 1985)).

37. See David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2, 20 (1939). The elixir contained the poisonous liquid diethylene glycol, also known as antifreeze. See *id.* New drug provisions now require thorough testing before a new drug can be marketed. See 21 U.S.C. § 355

B. The Federal Food, Drug, and Cosmetic Act of 1938

To remedy the limitations of the Pure Food and Drugs Act and expand federal protection of consumers from unsafe, unproven, and misleading products, Congress passed the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA).³⁸ A product containing a vitamin, depending on the way it was marketed and labeled, could be a food, a drug, or both.³⁹ No specific classification for vitamin/herbal products existed. The FDCA included a labeling requirement and gave the FDA power, under section 403(j), to regulate and declare misbranded dietary foods.⁴⁰ The section stated that a food was misbranded

[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 to fully inform purchasers as to its value for such uses.⁴¹

Foods offered for "special" dietary uses, therefore, needed greater attention and regulation than regular foods.⁴² This section and the regulations to be implemented pursuant to it in the 1940s gave the FDA the power to prescribe criteria for evaluating the nutritional properties of a product and to control how that information reached

(1998).

38. Pub. L. No. 75-717, § 675, 52 Stat. 1040 (1938).

39. See Pendergast, *supra* note 29, at 257.

40. See 21 U.S.C. § 403(j) (1998).

41. *Id.*

42. See Cavers, *supra* note 37, at 30. Some believed that products with a vitamin/herbal content needed special attention. As one FDA official wrote

At that time [1939], the marketing of special dietary products was confined largely to so-called "health-food stores." Many of the products then distributed were designed to meet the whims and fancies of food faddists which had been cultured by the unscientific teachings of nutritional quacks. There were, of course, a few bona-fide foods for special dietary uses intended for diabetics and others having special dietary needs. These, however, were few in number and were generally characterized by a tastelessness or lack of palatability which discouraged their purchase and use by others than those having a genuine need for them.

Ralph F. Kneeland, Jr., *Foods for Special Dietary Uses Under the Federal Law*, 11 FOOD DRUG COSM. L. J. 41, 41 (1956).

consumers.⁴³ Although the FDA promulgated regulations pursuant to section 403(j), the regulations were not as comprehensive as the statutory language permitted. As a result, the question of how certain products would be classified and regulated when they were labeled for "special dietary uses" was left unanswered.⁴⁴ The section 403(j) regulations focused primarily on the nutritional inadequacy of the American diet,⁴⁵ not on how to regulate or control the safety and efficacy of dietary supplements. Rather than define acceptable claims for these products, the regulations established three classes of products,⁴⁶ set minimum daily requirements (MDR) for certain vitamins and minerals, and stated that the products which fell into these categories had to list each MDR.⁴⁷ Apart from the regulations, the FDA opted to employ litigation-based authorities to regulate therapeutic or health-benefit claims made on behalf of special dietary foods as drug claims.⁴⁸ This policy decision led to FDA litigation throughout the 1940s and early 1950s concerning false claims in the labeling and advertising of vita-

43. See Pendergast, *supra* note 29, at 259.

44. See 6 Fed. Reg. 5921 (1941). The regulations' Findings of Fact stated, "[T]he value of a food for special dietary use may depend on its suitability for the treatment of a deficiency disease." *Id.* at 5921 n. 5.

45. See Michael F. Markel, *Foods for Special Dietary Uses – An Historical Outline of Regulatory Aspects*, 22 FOOD DRUG COSM. L.J. 110, 114 (1967).

46. See 6 Fed. Reg. 5921 (1941). The regulations defined "special dietary uses" as products that:

1) supply a particular dietary need "which exist[s] by reason of a physical, physiological, pathological or other condition," 2) supply a special dietary need by "which exist[s] by reason of age" and 3) are intended to supplement the diet with vitamins, minerals, or "other dietary property."

Id.

47. See 6 Fed. Reg. 5925 (1941). The agency later decided that the MDR requirements did not go far enough to control vitamin-mineral products. See MERRILL & HUTT, *supra* note 10, at 212.

48. See 6 Fed. Reg. 5921 (1941). The regulations stated: "No provision of any regulation under section 403(j) of the Act shall be construed as exempting any food from any other provision of the Act or regulations thereunder, including sections 403(a) and (g) and, when applicable, the provisions of Chapter V." *Id.*

mins.⁴⁹ This series of cases, culminating with "The Nutrilite Consent Decree,"⁵⁰ established non-binding, industry-wide guidelines for legally acceptable labeling of vitamin and mineral dietary supplements.⁵¹ The guidelines provided that a vitamin-mineral product label could not claim the product is "effective to prevent or adequately treat or cure" any disease, but could promote the product "as a food supplement to supplement or fortify the diet of any person" suffering from a disease.⁵² The FDA enforced these guidelines through aggressive and remarkably successful litigation.⁵³

C. The Regulation of Dietary Supplements Before 1990

With this regulatory construct in place, the FDA waged a battle between the 1940s and 1960s both in the courtroom and in the marketplace.⁵⁴ In particular, herbs were considered a suspect class because

49. Many of these early cases dealt with food manufacturers falsely claiming their products contained specific vitamins. See *Lekas & Drivas, Inc. v. Federal Trade Comm'n*, 145 F.2d 976, 976 (2d Cir. 1944). For an examination of the history of government regulation of health claims for vitamins and minerals see Hutt, *supra* note 26, at 3 (1986).

50. *United States v. Mytinger and Casselberry, Inc.* FDA Not. of Jud. No. 3383 (S.D. Cal. 1951), *reprinted in* FEDERAL FOOD DRUG AND COSMETIC ACT 1951-1952, at 204 (FDLI 1953).

51. For a more complete discussion of the intricacies surrounding the signing of the Nutrilite Consent Decree, see *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, 594 (1950); see also Lester L. Lev, *The Nutrilite Consent Decree*, 7 FOOD DRUG COSM. L.J. 56, 56 (1952).

52. Hutt, *supra* note 26, at 52. The Decree also found the label of the vitamin-mineral product must clearly enumerate "all the purposes and conditions for which the product is intended." *Id.*

53. See Pendergast, *supra* note 29, at 266.

54. The FDA and the AMA jointly sponsored two meetings of the National Congress on Medical Quackery, which focused primarily on nutritional quackery. See Mark A. Kassel, *From a History of Near Misses: The Future of Dietary Supplement Regulation*, 49 FOOD & DRUG L.J. 237, 254 n.134 (1994) (citing FDA's CAMPAIGN AGAINST NUTRITIONAL QUACKERY; PROGRESS REPORT (Oct. 1963)). The FDA brought over 100 actions against vitamin-mineral products between 1961 and 1963. See *id.* Many of these were won without litigation, that is, they were won either by default or a consent decree. See *id.*

they were long used by charlatans and quacks.⁵⁵ Herbs had a history of medicinal and food uses which made them difficult to classify.⁵⁶ Section 403(j) could have addressed the dietary properties of herbs, but did not.⁵⁷ Instead, the FDA pursued case-by-case enforcement of misleading claims and other forms of "quackery,"⁵⁸ yet it soon found that this was not the most efficient use of resources.⁵⁹

In 1962, in an effort to counter aspects of this inefficiency, the FDA proposed regulations, which, if the dosage levels of the supplements remained close to the U.S. Recommended Daily Allowance (RDA), would have permitted the sale of single-nutrient dietary supplements and limited the number of multi-vitamin and mineral products.⁶⁰ The regulations would have also classified and processed "high potency" type dietary supplements as drugs.⁶¹ These proposals, however, met great opposition from the public and burdened the rulemaking process.⁶²

Since dietary supplements could, under the law, be considered a food, a drug, or both, depending on how the products were marketed, it was possible to control the market through drug regulations strictly governing product labeling. The Drug Amendments of 1962 tightened controls on products classified and sold as drugs.⁶³ For the first time in

55. See Pendergast, *supra* note 29, at 262. Charlatans also promoted them for inappropriate uses, inherently placing them in the category of fraudulent products. See *id.*

56. See *id.* See also, e.g., William W. Goodrich, *Challenging Quackery with Truth*, 16 FOOD DRUG COSM. L. J. 684 (1961).

57. See Pendergast, *supra* note 29, at 262.

58. One of the first statutes to deregulate drugs was passed in England in 1542. The "Quacks Charter" allowed registered physicians to administer internal medicines while folk healers and apothecaries were free to prescribe topical medicines. See G. CLARK, A HISTORY OF THE ROYAL COLLEGE OF PHYSICIANS OF LONDON 86 (1964).

59. See Kassel, *supra* note 54, at 254-55.

60. See 27 Fed. Reg. 5815, 5815 (1962).

61. See *id.*

62. See Kassel, *supra* note 54, at 255.

63. See Act of October 10, 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962). See also 21 U.S.C. § 408 and accompanying regulations. A new drug must undergo a series of tests and trials to prove that the drug is safe and accomplishes what it claims. See 21 U.S.C. § 355.

U.S. history, the FDA required manufacturers to demonstrate a "new drug's" effectiveness before it was marketed.⁶⁴ This change required new drug manufacturers to submit test-based information showing "substantial evidence" the drug satisfied the claims made on the label and could be used safely.⁶⁵ Thus, the manufacturers bore a substantial burden to show, through well-controlled studies, that the product was effective for each of the claims made.⁶⁶ The FDA would not allow the marketing of a product until this burden had been satisfied. The new regulations gave the FDA control over what could be claimed by a manufacturer as to how a product could be used.

Although the courts generally upheld the FDA's efforts to apply the Act's drug standards to dietary supplement manufacturers,⁶⁷ such supplements began to gain prominence in the marketplace.⁶⁸ Dietary supplements and herbs had been used for many years in limited circles, but in the 1970s they began to find a larger consumer base.⁶⁹ In response, the FDA increased its efforts to control the vitamin and supplement market.⁷⁰ For example, the FDA tried to make rules to classify and regulate large doses of vitamins A and D as drugs simply on the basis of potency, and to require labeling statements about the need for and value of vitamin supplementation.⁷¹ The U.S. Court of Appeals for the Second Circuit struck down the regulation on procedural grounds.⁷² In anticipation of further agency activity, the vitamin industry mounted a massive lobbying effort resulting in legislation slightly limiting the FDA's ability to regulate dietary supplements. The Proxmire Vitamin Mineral Amendment of 1976 expressly provided that the FDA:

64. See Act of October 10, 1962, Pub. L. No. 87-781, § 102, 76 Stat. 780 (1962).

65. See *id.*

66. See 21 U.S.C. § 355(b)(1) (1998); see also S. Rep. No. 87-1744, at 2891 (1962).

67. See *infra* Part II.A.

68. See Brody, *supra* note 20, at D7.

69. See Catherine Fahey, *Herbal Medicine Moves Into the Mainstream*, UTNE READER, Mar.-Apr. 1991, at 42.

70. See Pendergast, *supra* note 29, at 257.

71. See *National Nutritional Foods v. Matthews*, 557 F.2d 325 (2d Cir. 1977).

72. See *id.*

- (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 . . . as a drug solely because it exceeds a level of potency which (the agency) 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

These amendments were the first attempt at defining and regulating vitamins and minerals marketed for special dietary uses. Although significant for establishing a precedent, the 1976 amendments had little impact on the FDA's aggressive regulation of dietary supplements.

D. The Nutritional Labeling and Education Act of 1990

The FDA received additional labeling authority over foods, including dietary supplements, with the passage of the Nutrition Labeling and Education Act (NLEA).⁷⁴ The NLEA required food manufacturers to include nutritional labeling on most food products "intended for human consumption and offered for sale."⁷⁵ These labels required information concerning the number and size of servings in the product,⁷⁶ calorie and fat content,⁷⁷ and any vitamin, mineral or nutrient "if the Secretary determine[s] that such information will assist consumers in maintaining healthy dietary practices."⁷⁸ The NLEA also provided meaningful information about diet and health on food labels. This law opened the door for more effective, yet lenient, regulation of dietary supplement labeling. The key provision, codified at section 343(r)(5)(D) states:

[a] claim (in the label about any nutrient contained in the product relating to a disease or health related con-

73. 21 U.S.C. § 350(1) (1998).

74. Act of November 8, 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified at 21 U.S.C. §§ 343(q), 343(r) (1998)).

75. 21 U.S.C. § 343(q)(1) (1998).

76. *See id.* at § 343(q)(1)(A)(i).

77. *See id.* at § 343(q)(1)(C).

78. *See id.* at § 343 (q)(E). This statute touches a wide range of food labeling issues including nutritional content, nutritional descriptors and "health claims." *See Samia Rodriguez, Food Labeling, in 1 FUNDAMENTAL OF LAW & REGULATION ch. 8 (FDLI 1997).*

dition) 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.⁷⁹

The NLEA required the FDA to promulgate procedural regulations regarding how to establish such "health claims."⁸⁰ The FDA determined the criteria for approving health claims would apply equally to both traditional foods and dietary supplements.⁸¹

Not surprisingly, opponents mounted a legislative lobbying effort to prevent the FDA from implementing regulations regarding health claims appearing on the labels of dietary supplements.⁸² Congress reacted to the lobbying efforts by passing the Dietary Supplement Act of 1992 (DSA),⁸³ which stalled the regulation process.⁸⁴ The DSA established a one-year delay on the implementation of the NLEA and required the FDA to submit reports and studies on the issues surround-

79. 21 U.S.C. § 343(r)(5)(D) (1998). This provision has been described as a "sweeping reversal of the agency's previous policy. Until the mid-1980's, the FDA regarded all health claims as attributes . . . subject to pre-market approval." Fred R. Shank, *The Nutritional Labeling and Education Act of 1990*, 47 FOOD & DRUG L.J. 247, 251 (1992).

80. See Act of November 8, 1990, Pub. L. No. 101-535, § 2(b), 104 Stat. 2353 (1990). See also Kassel, *supra* note 54, at 261. The specific claims mentioned in the NLEA include: the link between folic acid and prevention of neural tube defects; antioxidant vitamins as a means of preventing or curing cancer; the link between zinc and immune functions in the elderly; and the omega-3 fatty acids' role in the possible prevention of heart disease. See Pub. L. No. 101-535, § 3(b)(1)(A)(x), 104 Stat. 2361 (1990).

81. See 56 Fed. Reg. 60537, 50539 (1991).

82. See, e.g., Anthony J. Iannarone, *Scientific Basis for Health Claims for Dietary Supplements*, 47 FOOD & DRUG L.J. 665, 665 (1992) (The author, the Associate Vice President of Hoffman-La Roche Inc., discusses the standards set forth in the NLEA and their opposition to the FDA's interpretation of such standards.).

83. Dietary Supplement Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491 (1992).

84. This statute indicates Congress wanted the FDA to reexamine its stance on allowable health claims for dietary supplements. See Dietary Supplement Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491, 4500 (1992).

ing dietary supplements.⁸⁵ This action aimed to limit the FDA's ability to restrict regulations and implement limits on the dietary supplement market.⁸⁶

In the years between the Proxmire Amendments and the NLEA, public health problems associated with the use of dietary supplements became more apparent. In particular, the adverse health effects and deaths associated with amino acids containing L-tryptophan came to light in 1989.⁸⁷ The FDA issued a warning, which urged the public to avoid supplements containing L-tryptophan, and detained foreign imports.⁸⁸ The FDA then established a task force to examine the problems associated with daily supplements such as vitamins and minerals, amino acids, herbs, and "other substances."⁸⁹ The task force recommended the following: (1) regulate supplements as drugs, because of the medicinal claims made by the producers, or when they are used for anything other than as food additives; and (2) regulate the supplements as food additives unless claims of drug uses are made, thus moving

85. See Dietary Supplement Act of 1992, Pub. L. No. 102-571, § 202(a), (b), 106 Stat. 4501 (1992). The Act prevented the FDA from issuing regulations concerning dietary supplements until at least December 15, 1993. These reports must include issues surrounding dietary supplements and the national health, such as a report to Congress by the FDA on the agency's enforcement priorities and practices, a General Accounting Office (GAO) study of the FDA's management activities, and an Office of Technology Assessment safety and regulatory outcomes study. See *id.* § 204-206.

86. See Pendergast, *supra* note 29, at 272.

87. See Sean Harmon, Comment, *Melatonin Mania: Can the FDA Regulate Hormonal Dietary Supplements to Protect Consumer Interests in Light of the Dietary Supplement Health Education Act of 1994?*, 22 U. DAYTON L. REV. 77, 82 (1996). See also Cathy Anne McGowan, *Learning the Hard Way: L-tryptophan, the FDA & the Regulation of Amino Acids*, 3 CORNELL J.L. & PUB. POL'Y 383 (1994). L-tryptophan was one of the ingredients in an amino acid supplement, which was found to be contaminated. The contaminated L-tryptophan led to an outbreak of eosinophilia myalgia syndrome (EMS), a disease of the systemic connective tissues characterized by an increase of a special type of white blood cells, severe muscle pain, and "cutaneous (skin) and neuromuscular manifestations." 58 Fed. Reg. 33,690, 33,696 (1993).

88. See 58 Fed. Reg. at 33,696.

89. 58 Fed. Reg. at 33,691.

them into the drug category.⁹⁰ Because supplement manufacturers made statements that resembled health claims, the task force recommended that dietary supplements be regulated as drugs.⁹¹ The FDA's task force signaled, yet again, an aggressive posture against dietary supplements. In the face of near certain increased FDA activity, Congress stepped in, disregarded these suggestions, and passed the DSHEA, dramatically limiting the FDA's ability to regulate these products.⁹²

E. The Dietary Supplement Health and Education Act of 1994

It was apparent the FDA was not going to change its aggressive stance on applying the NLEA to dietary supplements or the need to aggressively police the marketplace for unsafe supplements.⁹³ In response, Congress passed the DSHEA⁹⁴ as an effort to restrict the FDA's control on the dietary supplement market.⁹⁵ The DSHEA creates a broad, comprehensive definition of "dietary supplement,"⁹⁶ allows retailers to sell third-party books and other educational materials concerning dietary supplements,⁹⁷ and attempts to clarify permissible

90. See 58 Fed. Reg. at 33,697 (discussing the findings of the Dietary Supplement Task Force Report).

91. See 58 Fed. Reg. at 33,694, 33,697.

92. See Harmon, *supra* note 87, at 83.

93. In the interim between the passage of the DSA and the DSHEA, the FDA completed reports detailing the unsubstantiated claims of dietary supplements. See Pendergast, *supra* note 29, at 272.

94. Pub. L. No. 103-417, 108 Stat. 4325 (1994).

95. The DSHEA was sponsored by Sen. Orrin Hatch (R-Utah), who urged more lenient standards for dietary supplements. See 103 Cong. Rec. 16,611 (daily ed. Oct. 24, 1990). Many dietary supplement manufacturers are located in Utah. See Pendergast, *supra* note 29, at 272.

96. See Pub. L. No. 103-417, § 3, 108 Stat. 4325 (1994); see also U.S. Food and Drug Admin. Ctr. for Food Safety and Applied Nutrition, Dec. 1, 1995, (visited Oct. 20, 1998) <<http://vm.cfsan.fda.gov/~dms/dietsupp.html>>. Congress expanded the meaning of the term "dietary supplements" beyond essential nutrients to include such substances as ginseng, garlic, fish oils, psyllium, enzymes, glandulars, and mixtures of these. See *id.*

97. See Pub. L. No. 103-417, § 5(a), 108 Stat. 4325 (1994); see also U.S. Food and Drug Admin. Ctr. for Food Safety and Applied Nutrition (last

claims that may appear on the labels of dietary supplements.⁹⁸ Manufacturers may not claim their products diagnose, prevent, mitigate, treat or cure a specific disease, unless approved under the new drug provisions of the FDCA.⁹⁹ Manufacturers may, however, make claims with respect to the supplement's effects on the body's well-being, "structure or function," and even a person's mood.¹⁰⁰ Unlike health claims, FDA approval is not required for these claims before the product enters the market.¹⁰¹ If a dietary supplement manufacturer wants to make therapeutic or disease related claims, the product must be classified as a drug¹⁰² and undergo the necessary approval process. In light of the ability to make "structure or function" claims, there is a fine line between what is and is not a permissible claim.¹⁰³

DSHEA also requires the formation of various offices and commissions to recommend labeling requirements, to study the information circulating to the consumers, and to analyze the eventual health effects

modified Dec. 1, 1995) <<http://vm.cfsan.fda.gov/~dms/dietsupp.html>>.

98. See Pub. L. No. 103-417, § 6(c), 108 Stat. 4325 (1994).

99. See *id.*

100. See *id.* at § 6(a), 108 Stat. at 4325. Products may state claims such as "helps relieve anxiety," and "helps you feel good mentally." See Maria Toscano, *Risks and Rewards: What you need to know about the 22 best-sellers*, SELF, Nov. 1998, at 163.

101. To use these claims, however, manufacturers must have substantial proof that the statements are truthful, not misleading, and the product label must bear the statement: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." Pub. L. No. 103-417, § 6(c), 108 Stat. 4325 (1994). See also Food and Drug Admin. Ctr. for Food Safety and Applied Nutrition, (last modified Dec. 1, 1995) <<http://vm.cfsan.fda.gov/~dms/dietsupp.html>>.

102. The DSHEA defines "drug" as: "(B) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease . . . ; and (C) articles (other than food) intended to affect the structure or any function of the body of man. . . ." 21 U.S.C. § 321(g) (1998).

103. See Fred H. Degnan, Impact of the Agency's Sept. 1997 Dietary Supplement Regulations and April 29, 1998 Notice on "Structure or Function" Claims on Harmonizing the Regulation of Foods and Dietary Supplements (on file with author).

of the supplements.¹⁰⁴ DSHEA created a seven-member commission on Dietary Supplement Labels¹⁰⁵ with the responsibility of conducting studies on, and providing recommendations for, the regulation of label claims and statements for dietary supplements and the use of literature in connection with the sale of dietary supplements.¹⁰⁶ Another function was to make recommendations on procedures for the evaluation of such claims. Its report was released in 1997.¹⁰⁷

The DSHEA also created the Office of Dietary Supplements within the National Institute of Health.¹⁰⁸ The office has two purposes: (1) explore the potential role of dietary supplements in the U.S. and (2) promote scientific study of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions.¹⁰⁹

II. THE FDA'S "WEAPONS" AGAINST UNSAFE PRODUCTS

A. Regulation and Litigation Prior to the DSHEA

Prior to the NLEA and the DSHEA, the FDA used its litigation and rulemaking strategies to protect the public from unsafe and question-

104. See Pub. L. No. 103-417, § 12(a), 108 Stat. 4325 (1994). See also Food and Drug Admin. Ctr. for Food Safety and Applied Nutrition, (last modified Dec. 1, 1995) <<http://vm.cfsan.fda.gov/~dms/dietsupp.html>>.

105. See Pub. L. No. 103-417, 12(b), 108 Stat. 4333 (1994). The members of the Commission shall consist of individuals with expertise and experience in dietary supplements and in the manufacture, regulation, distribution, and use of such supplements. See *id.* At least three of the members of the Commission shall be qualified by scientific training and experience to evaluate the benefits to health of the use of dietary supplements. See *id.* One of the three members shall have experience in pharmacognosy, medical botany, traditional herbal medicine, or other related sciences. See *id.* Members and the staff of the Commission shall be without bias on the issue of dietary supplements. See *id.*

106. See *id.* at § 12(c), 108 Stat. at 4333.

107. See COMM'N ON DIETARY SUPPLEMENT LABELS, COMM'N ON DIETARY SUPPLEMENT LABELS REACT TO THE PRESIDENT, CONGRESS, AND THE SECRETARY OF THE DEP'T OF HEALTH AND HUMAN SERVICES (Nov. 1997). Also available at <<http://web.health.gov/dietsupp>>.

108. See Pub. L. No. 103-417, § 13(a), 108 Stat. 4334 (1994).

109. See *id.*

able products. One of the FDCA's many purposes is to protect consumers from adulterated and unsafe products.¹¹⁰ In passing the FDCA in 1938, Congress anticipated that vitamin/mineral products would be regulated closely.¹¹¹ Section 403(j) of the FDCA,¹¹² which gave the FDA the power to define and regulate misbranded food, provided the FDA with the opportunity to comprehensively oversee dietary supplements through regulations prescribing the contours of their use.¹¹³ The FDA, however, opted to follow a less comprehensive course of rulemaking by limiting the scope of section 403(j) regulations to describe the nutritional qualities of a food.¹¹⁴ The FDA controlled dietary supplement claims through aggressive and creative litigation, relying on its authority over food and drug adulteration and misbranding.¹¹⁵ Although effective in the short term, such a strategy proved to be resource-intensive, hallmarked by individual victories, but resulting in a failure to effect comprehensive control over the supplement industry.¹¹⁶

Another option available to the FDA was to regulate dietary supplements under statutory rubric applicable to foods and drugs. The FDCA contains an array of product classifications including "foods," "drugs," "new drugs," and "cosmetics."¹¹⁷ Each classification includes

110. See MERRILL & HUTT, *supra* note 10, at 3-4.

111. See Pendergast, *supra* note 29, at 259.

112. Pub. L. No. 75-757 § 403(j), 52 Stat. 1048 (1994) (codified at 21 U.S.C. § 343(j)). There is very little legislative history surrounding § 403(j), it is acknowledged, however, that the section was intended to cover products intended for "special nutritional requirements." S. Rep. No. 493, at 12 (1934). The Senate also recognized that the science of nutrition is rapidly changing and there is a serious need for regulation authority. *See id.*

113. See Pendergast, *supra* note 29, at 259.

114. Those in favor of regulating vitamins and herbs as foods argued that regardless of form, they were foods. *See* Markel, *supra* note 45, at 114. Proponents of regulating them as drugs argued that since they were packaged and marketed as drugs, they were drugs. *See id.*

115. *See* Cavers, *supra* note 37, at 30.

116. *See id.*

117. The FDCA classifies a product as a food, drug, or cosmetic. *See* 21 U.S.C. § 321 (1994). Dietary supplements are classified as foods. *See* 21 U.S.C. § 321(ff). One of the categories within the food classification is food used for dietary purposes. *See id.*

different statutory standards for product marketing. Moreover, the classifications are not mutually exclusive. For example, dependent upon how a product is used or labeled for regulatory purposes, it may be a "food," a "drug," and a "new drug" simultaneously.¹¹⁸ Some of the earliest cases under this policy struggled to determine whether substances such as processed foods¹¹⁹ and wine¹²⁰ should be considered foods. In addition, the courts attempted to determine whether water with a "therapeutic effect"¹²¹ should be classified as a "food," a "drug," or both.¹²²

Vitamin and mineral products proved to be particularly susceptible to different classifications and regulatory standards under the FDCA. For instance, such products could be regulated as "foods," "drugs," or both, depending on their actual use and their labeling.¹²³ In *U.S. v.*

118. The FDCA defines "food" as "articles used for food or drink" and components of such articles. See 21 U.S.C. § 321(f)(1994). A "drug" is a product that is used in the "diagnosis, cure, mitigation, treatment or prevention of disease . . . [or] to effect the structure or any function of the body." 21 U.S.C. § 321(g)(1994). See also Fred H. Degnan, *The Food and Drug Continuum: Safety and Labeling Considerations Regarding Food and Disease Prevention*, 8 (on file with author).

119. See *United States v. Ninety-Five Barrels*, 265 U.S. 438 (1924) (finding that vinegar, produced from dried apples by dehydration process employing chemicals, was food); see also *Union Dairy Co. v. United States*, 250 F. 231 (7th Cir. 1918) (holding that milk was a food even though it was shipped for treatment and purification).

120. See *United States v. Sweet Valley Wine Co.*, 208 F. 85 (D. Ohio, 1913).

121. See *Bradley v. United States*, 264 F. 79 (5th Cir. 1920).

122. See *id.* (finding that it was not a drug). Other examples of the FDA's struggle to classify foods include: *United States v. Six Dozen Bottles*, 55 F. Supp. 458 (D. Wis. 1944) (which concerned fennel); *United States v. Five Cases*, 62 F. Supp. 736 (S.D.N.Y. 1945), *rev'd on other grounds*, 156 F.2d 493 (2d Cir. 1946); *Research Lab., Inc. v. United States*, 167 F.2d 410 (9th Cir. 1948), *cert. denied*, 335 U.S. 843 (1948) (concerning ginseng and sage).

123. The FDA attempted to set upper limits for vitamin and mineral ingredients, but these regulations were lost to challenges. See *National Nutritional Food Ass'n v. FDA*, 491 F.2d 1141 (2d Cir. 1974); see also *National Nutritional Food Ass'n v. FDA*, 504 F.2d 761 (2d Cir. 1965). The Proxmire amendments ensured that products could not be defined as drugs based on

Vitasafe,¹²⁴ vitamin and mineral supplements were found to be both "foods" and "drugs" within the meaning of the FDCA, and regulated accordingly.¹²⁵ A single item may be classified not only as a "food" because it has value as a dietary supplement, but also as a "drug" if it claims to affect the body's structure and function, particularly with regard to curing or preventing disease.¹²⁶

Further, a product's intended use can be determined from the label or its accompanying material.¹²⁷ If it appears that a "food" product is used for medical purposes, then that product would be brought within the definition of a "drug" and therefore mislabeled.¹²⁸ In addition, a food product can also be considered a "new drug" and be subject to pre-market approval.¹²⁹ Regulation as a "drug" and "new drug" imposes burdensome regulatory standards on a manufacturer to establish the safety of drugs for their recommended uses.¹³⁰ A dietary supplement product can easily fall within the "drug" definition, provided it is labeled or promoted to have some benefit relating to the cure, treatment, prevention or mitigation of disease.¹³¹ A vitamin supplement bearing an unsubstantiated claim can be misbranded as a "food" or a "drug" as well as a "new drug," thus requiring extensive pre-market

their vitamin and mineral content. These amendments also prohibited the FDA from putting limits on the amounts of vitamins and minerals in products except for safety concerns. See Health Research and Health Services Amendments of 1976, Pub. L. No. 94-278, 90 Stat. 401, 410 (1976); H.R. Conf. Rep. No. 1005 (1976). Congress did, however, give the FDA the authority to pursue those products with false or misleading advertising after first notifying the FTC. The FTC has the opportunity to take action first. See Pub. L. No. 94-278, 90 Stat. 401, 412 (codified at 21 U.S.C. § 378) (1998); see also *National Nutritional Food Ass'n. v. Kennedy*, 572 F.2d 377 (2d Cir. 1978).

124. 345 F.2d 864 (3d Cir. 1965).

125. See *Vitasafe*, 345 F.2d at 864.

126. See *United States v. Vitasafe*, 226 F. Supp. 266 (D. N.J. 1964).

127. See *United States v. Article . . . Consisting of 216 Cartoned Bottles, More or Less*, 409 F.2d 734 (2d Cir. 1969).

128. See *id.*

129. See 21 U.S.C. § 355 (1998) (describing the new drug approval process).

130. See 21 U.S.C. § 360(e) (1998).

131. See 21 U.S.C. § 321(g) (1998).

safety testing before being able to be lawfully marketed.

It was to the FDA's advantage to try to classify those vitamin supplements it viewed to be problematic as drugs for regulatory purposes. To this end, the FDA successfully interpreted the definition of "labeling" in the FDCA to encompass a variety of practices employed by manufacturers to promote their products.¹³² By broadly construing labeling to encompass pamphlets, articles and even radio broadcasts, the FDA was able to successfully establish supplement manufacturers' "intent" to market drug-like therapeutic products.¹³³ By applying this statute broadly, the FDA, through enforcement via litigation, ensured the removal of unsafe or bogus vitamin and mineral products from the marketplace with relative promptness.¹³⁴

Supplement manufacturers became more circumspect in making therapeutic claims in the late 1970s and 1980s and therefore the FDA attempted to classify certain dietary supplements as "food additives."¹³⁵ This statutory standard required pre-market demonstration of product safety.¹³⁶ Although proving that a supplement qualified as a food additive was difficult, the agency succeeded in its efforts and forced manufacturers to use only "safe" ingredients.¹³⁷

132. See Pendergast, *supra* note 29, at 263-64.

133. See *United States v. Storage Spaces*, 777 F.2d 1363 (9th Cir. 1985) (intent can be determined from promotional materials or any other relevant source of information). This broad interpretation of labeling helped to invoke drug misbranding provisions and drug provisions. See also *United States v. Allen Drug Corp.*, 357 F.2d 713 (10th Cir. 1966); *United States Article of Drug*, 263 F. Supp. 212 (D. Neb. 1967); *United States v. 363 Cases, More or less, Mountain Valley Mineral Water*, 143 F. Supp. 219 (W.D. Ark. 1956); *United States v. 8 Cartons*, 97 F. Supp. 313 (W.D.N.Y. 1951). This broad interpretation of labeling helped to invoke drug misbranding provisions and drug provisions. See *id.*

134. The DSHEA drastically changed this requirement, which now encourages information on supplements, so long as it is not brand particular, to be available in the same area as the product. See *infra* note 146.

135. 21 U.S.C. §§ 321(s), 348 (1994).

136. See 21 U.S.C. § 360(e) (1994).

137. See *United States v. Two Plastic Drugs . . . Viponte Ltd. Black Current Oil*, 984 F.2d 814 (7th Cir. 1993); *United States v. Article of Food*, 792 F. Supp. 139 (D. Mass. 1992).

B. "Weapons" under the NLEA

Passage of the NLEA gave the FDA a new weapon to regulate claims made on behalf of dietary supplements. The NLEA gives the FDA the authority to allow health claims¹³⁸ to be placed on a supplement only if the FDA "determines, based on the totality of publicly available scientific evidence . . . 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."¹³⁹

The FDA has been very conservative with respect to the evaluation of health claims. In the early 1990s, various studies showed that if an expectant mother took proper amounts of folic acid, it could prevent a variety of serious birth defects.¹⁴⁰ The FDA did not approve the claim until a year after the Public Health Service recommended that all pregnant women consume adequate amounts of folic acid.¹⁴¹ This delay prevented manufacturers from using the claim on labels and in advertisements.¹⁴² The FDA made it clear that they would not jeopardize public safety in the interests of expediency.¹⁴³ Further, interpreting the NLEA's application to supplements so conservatively gave the FDA additional control over the benefits manufacturers could attribute to

138. See Nutrition Labeling and Education Act, Pub. L. No. 101-535 § 3(b)(1)(A)(vi) (1990). The NLEA allows claims regarding calcium and osteoporosis, dietary fiber and cancer, lipids and cardiovascular disease, lipids and cancer, sodium and hypertension, and dietary fiber and cardiovascular disease. See *id.*

139. 21 U.S.C. § 343(r)(3)(B)(i) (1998). Many researchers agree that there are some supplements that work, and that manufacturers must carefully test the products so that what is written on the label matches what is inside the bottle. See Susan Okie, *Information Gap on Herbal Products: All Parties Agree More Research is Needed, but Who's Going to Foot the Bill?*, WASH. POST, Sept. 29, 1998, § HM (Health), at 7.

140. See S. Rep. No. 410, at 7 (1994).

141. See *id.* at 16.

142. See Harmon, *supra* note 87, at 84.

143. In the Senate report, the FDA commissioner, Dr. David Kessler, expressed the importance of "striking the right balance between ensuring the safety and proper labeling of all these products while at the same time preserving consumers' freedom of choice." S. Rep. No. 410, at 17 (1994).

their products.

C. The DSHEA: Limiting FDA's Regulatory Weapons

Against the backdrop of President Clinton's health care reform in 1993-94, Congress saw dietary supplements as an inexpensive way to promote public health.¹⁴⁴ Congress passed the DSHEA in an effort to reconfigure how the FDA regulated dietary supplements.¹⁴⁵ The DSHEA has three main concerns: research, labeling, and standard of proof for safety. The DSHEA now allows certain types of statements to be made without FDA approval. A statement can be made if it:

[C]laims 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, describes general well-being from consumption of a nutrient or dietary ingredient.¹⁴⁶

These statements are not subject to pre-market review and approval by the FDA.¹⁴⁷ Moreover, difficulties and problems arise in distinguishing between permissible and impermissible claims.¹⁴⁸ For exam-

144. See Harmon, *supra* note 87, at 84.

145. See Pub. L. No. 103-417, 108 Stat. 4325 (1994). The Act is based on the consumers' desire to learn about and take control of their own health and diet to reduce the potential for disease. See Anthony L. Young & I. Scott Bass, *The Dietary Supplement Health and Education Act*, 50 FOOD & DRUG L. J. 285 (1995). "The purpose of creating this new framework was to strike the right balance between providing consumers access to both products and truthful information about the products while retaining authority for FDA to take action against products that present safety problems or are improperly labeled." Henney, *supra* note 9, at 15.

146. 21 U.S.C. § 343(r)(6)(A).

147. See 21 U.S.C. § 342(f) (1998). The FDA needs to only review the product if it contains a new dietary ingredient. See 21 U.S.C. § 413(a)(2).

148. The FDA has found instances where products with ingredients that simulate illicit street drugs are being sold over the Internet to adolescents. The statute's broad language which "must not allow the inclusion of ingredients never intended to fit within the universe of dietary supplements" has

ple, the "structure or function" claim that a supplement "supports the body's antiviral capabilities," would be questioned by the FDA as a veiled drug claim.¹⁴⁹ On the other hand, a "supports the immune system" claim would be viewed by the FDA as permissible.¹⁵⁰ In the first statement, there is a suggested relationship between the product and a health-related occurrence, which according to the statute, constitutes an implied disease claim. Viruses are connected to human health while the generality of boosting the immune system does not create such a connection. In support of these distinctions, the FDA proposed redefining "disease" as:

[a]ny 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

created problems for the FDA. *See Henney, supra* note 9, at 17.

149. *See* Fred Degnan, Making Sense Out of the Food/Dietary Supplement Regulatory Dichotomies Created by the Dietary Supplement Health Education Act, 11 [hereinafter *Regulatory Dichotomies*](on file with author).

150. *See id.* Other examples of impermissible claims are "reduces the pain and stiffness associated with arthritis," "antibiotic," "antiseptic," "anti-depressant," "lowers cholesterol," and "Herbal Prozac." *Id.* Claims such as the following would be permissible: "[H]elps promote urinary tract health," "promotes relaxation," "an energizer," "reduces stress and frustration," and "improves absentmindedness." *Id.* Supplement marketers petitioned the FDA to approve four additional claims for supplements. *See Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999). The four proposed claims were: "consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers," "consumption of fiber may reduce the risk of colorectal cancer," "consumption of omega-3 fatty acids may reduce the risk of coronary heart disease," and ".8mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form." *Id.* at 652. The FDA refused to authorize the claims, arguing that there was no "significant scientific agreement" concerning the claims. *See id.* The court held that the decision not to authorize the claims violated the First Amendment because the FDA did not consider evidence which could make the claim non-misleading by adding qualifying language. *See id.* at 653. In response, the FDA has called for a public meeting to discuss implementation of the Pearson decision. *See Public Meeting Concerning Implementation of Pearson Court Decision and Whether Claims of Effects on Existing Diseases May be Made as Health Claims*, 65 Fed. Reg. 14219 (2000).

manifested by a characteristic set of one or more signs or symptoms, . . . includ[ing] laboratory or clinical measurements that are characteristics of a disease.¹⁵¹

Under this definition, an ailment can be described within certain parameters. If a dietary supplement claims to treat symptoms within these parameters, it will be regulated by the FDA as a disease claim. This proposed definition is designed to give the FDA enough flexibility to clarify and prohibit "structure or function" claims that imply more than they can deliver.¹⁵²

Not surprisingly, supplement manufacturers have strongly objected to the FDA's proposed definition, alleging it exceeds the agency's authority under the DSHEA and inappropriately restricts the dietary supplement manufacturers.¹⁵³ As a result of this opposition, the FDA's Final Rule omits the proposed definition and retains the definition used in the NLEA.¹⁵⁴ The FDA concluded that the existing definition covers conditions medically understood to be diseases. As such, the FDA felt it unnecessary to adopt the proposed definition.¹⁵⁵ Rather than tighten the controls on manufacturers, the Final Rule gives many

151. Proposed Rule, Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23625 (1998) (proposed to be codified at 21 C.F.R. pt. 101).

152. See Degnan, *Regulatory Dichotomies*, *supra* note 149, at 10. "The American Medical Association supports the FDA's definition and would like to expand it to include states of health leading to deviation, impairment, or interruption. . ." Mike Mitka, *FDA Never Promised an Herb Garden - But Sellers and Buyers Eager to See One Grow*, 280 JAMA 1554, 1555 (1998).

153. The FDA received over 230,000 submissions in response to the proposed rule. See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1000 (2000).

154. *See id.*

155. *See* 65 Fed. Reg. at 1010. The FDA now defines disease as "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 in this definition." 65 Fed. Reg. at 1050 (to be codified at 21 C.F.R. § 101.93) (1998).

examples of conditions that are not diseases and therefore are allowable claims.¹⁵⁶

In addition, the DSHEA changed the standard of proof required before the FDA can remove a product from store shelves.¹⁵⁷ Manufacturers are responsible for providing information to support their claims and need not prove safety or effectiveness.¹⁵⁸ Instead, under the DSHEA, the FDA bears the burden of proving the products are unsafe.¹⁵⁹ Prior to the DSHEA, the FDA needed only to prove the product contained a "poisonous or deleterious" substance that "may render [it] injurious to health,"¹⁶⁰ or that the product contained an unapproved food additive. Now the FDA must prove an ingredient "presents a significant or unreasonable risk of illness or injury under . . . ordinary conditions of use,"¹⁶¹ a much more difficult standard.¹⁶² Moreover, supplements are expressly removed from the definition of "food additive" and can no longer be regulated as such. These new standards turn attention away from the product itself and towards the "intended use" of the product. While a supplement in itself may not pose an unacceptable health risk, the risk could be very high if used for a specific purpose. For example, a supplement recommended for athletic performance may cause cardiovascular problems, but if the product is not promoted for athletic use, the supplement would not be

156. See 65 Fed. Reg. 1000 (2000).

157. See Pub. L. No. 103-417, 108 Stat. 4325, 4328 (codified at 21 U.S.C. § 342).

158. See Rebecca Porter, *Supplements Supply Dietary Danger as FDA Looks On*, TRIAL: J. OF THE ASS'N OF TRIAL LAW. OF AM., Oct. 1998, at 12.

159. See *id.*; see also, Usha Lee McFarling, *Herbal Medicines Surge, an Effort Opens to Promote Safety*, PHILA. INQUIRER, Sept. 24, 1998, at A24.

160. 21 U.S.C. § 342(a)(1) (1998). The Supreme Court has not required a finding that the product affected health and has found it sufficient that it "may possibly injure the health" of humans. See *U.S. v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 411 (1914); see also *Flemming v. Florida Citrus Exch.*, 358 U.S. 153 (1958).

161. 21 U.S.C. § 342(f)(1)(a) (1998).

162. According to the FDA Commissioner, DSHEA provides broad access to dietary supplements while at the same time provides FDA with the framework to remove products "that pose a 'significant or unreasonable' risk to consumers or that are otherwise adulterated." Henney, *supra* note 9, at 5.

considered adulterated.¹⁶³ This, in turn, places the burden on the FDA, to substantiate concerns regarding both the ingredients and the claims made by the product manufacturers.¹⁶⁴ Accordingly, attention is not focused on the actual toxicity of the product itself, but the toxicity of the product when used under ordinary conditions. Thus, even though a supplement can be abused, leading to serious health risks, it may nevertheless be allowed to remain in the marketplace. Simply put, under the DSHEA a product does not raise actionable safety hazard concerns if it can be shown that the supplement does not present a significant or unreasonable risk of illness or injury under either the conditions of use recommended in its labeling or, if no conditions of use are recommended, under its "ordinary" conditions of use. This standard does not provide anything comparable to the assurance of safety that normally accompanies lawfully marketed food additives and drugs.

III. WHERE DO ANDROSTENEDIONE AND ST. JOHN'S WORT FIT INTO THE REGULATORY SCHEME?

Through the Food and Drug Act of 1938 and subsequent statutes, the FDA possesses broad power to regulate substances consumed by the public. The DSHEA creates an exception to this authority and permits pharmacologically active substances like Androstenedione¹⁶⁵ and St. John's Wort¹⁶⁶ to be regulated as dietary supplements. These products currently are not subject to the FDCA's demanding standards for assuring the safety and efficacy of food additives and drugs. They

163. See Pendergast, *supra* note 29, at 278.

164. See *id.*

165. Androstenedione is a steroid hormone taken as an anabolic steroid. However, unlike steroids, it is perfectly legal. See Brown, *supra* note 23, at A3; see also *Going for the Gold: Hard Work, Dedication – and Drugs*, NEWSWEEK, Feb. 15, 1999, at 51.

166. St. John's Wort is one of the most popular herbal supplements. It is reported to relieve anxiety and mild depression. See Jane E. Brody, *In the Garden of Herbal Remedies, Weeding Out the Bad Choices*, N.Y. TIMES, Feb. 9, 1999, at D7; Catherine Heusel, *What's Really in the Bottle: All St. John's Wort is Not Alike*, SELF, November 1998, at 166; Toscano, *supra* note 100, at 165; VARRO E. TYLER, *HERBS OF CHOICE: THE THERAPEUTIC USE OF PHYTOMEDICINALS* (1999); Phytochemical and Ethnobotanical Databases (visited Feb. 13, 1999) <<http://www.ars-grin.gov/duke>>.

must be labeled, however, as "dietary supplements"¹⁶⁷ and must not expressly indicate their use in the diagnosis, cure, mitigation, treatment or prevention of disease.¹⁶⁸

Studies show Androstenedione and St. John's Wort act like drugs when consumed and may produce adverse effects.¹⁶⁹ St. John's Wort may cause nausea, stomach aches, fatigue, skin reactions and developmental problems in children whose mothers take the herb during pregnancy.¹⁷⁰ It also weakens the effect of prescription medications such as those taken for heart disease, cancer, and HIV.¹⁷¹ If these products were regulated as drugs, the FDCA would require explicit proof that the products could be safely used for their intended purposes. When labeled as dietary supplements, however, no such re-

167. 21 U.S.C. § 321(ff) defines a dietary supplement as a product that contains "a vitamin; mineral; herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet . . . a concentrate, metabolite, constituent, extract, or combination of any ingredient described [above]." The statute further states that dietary supplements are "to be a food within the meaning of this Act." 21 U.S.C. § 321(ff)(3) (1998).

168. See 21 U.S.C. § 342(r).

169. See Okie, *supra* note 139, at 7; Porter, *supra* note 158, at 12; *Real-life Herbal Horror Stories*, GLAMOUR, Feb. 1999, at 215-16; *First U.S. Clinical Trial of St. John's Wort*, INSIDE MS, Summer 1998, at 30. See also J. Parasrampur, et al., *Quality Control of Dehydroepiandrosterone Dietary Supplement Products*, 280 JAMA 1565, 1565 (1998); Lynn R. Grush et al., *St. John's Wort During Pregnancy*, 280 JAMA 1566, 1566 (1998); Fact sheets on Alternative Medicine (visited Mar. 20, 1999) <<http://cpmcnet.columbia.edu/dept/rosenthal/factsheets.html>>; Edmund R. Burke, *Androstenedione Caution*, MotherNature.com Health Journal Newsletter (visited Aug. 2, 1999) <http://www.mothernature.com/news/1999_0609/ms.stm>; D. King, R. Sharp, M. Vukovich et al., *Effect of Oral Androstenedione on Serum Testosterone and Adaptations to Resistance Training in Young Men, A Randomized Trial*, 281 JAMA 2020 (1999); *Consumer Guide to St. John's Wort*, (visited Aug. 2, 1999) <<http://www.mothernature.com/cg/stjohnswortcg.stm>>.

170. See Grush et al., *supra* note 169 at 1566 (1998); *Consumer Guide to St. John's Wort*, (visited Aug. 2, 1999) <<http://www.mothernature.com/cg/stjohnswortcg.stm>>.

171. See FDA Public Health Advisory: Risk of Drug Interactions with St. John's Wort and Other Drugs (last modified Feb. 10, 2000) <<http://www.fda.gov/cder/drug/advisory/stjwort.htm>>.

quirements apply, even though consumers may use them for drug-like purposes.

According to one group, Androstenedione should not be classified as a dietary supplement because it is not part of a normal diet.¹⁷² Androstenedione is a steroid hormone that is one metabolic step away from testosterone.¹⁷³ Testosterone produces increased body hair, acne and muscle growth.¹⁷⁴ It also boosts aggressiveness and stimulates formation of red blood cells, giving the blood a higher "oxygen-carrying capacity."¹⁷⁵ This physiological effect is usually referred to as "anabolic" because it helps the body to build proteins, of which muscles are the largest source in the body.¹⁷⁶

St. John's Wort has been called the all natural anti-depressant or "herbal Prozac."¹⁷⁷ In Germany, St. John's Wort is prescribed more than any other prescription anti-depressant.¹⁷⁸ Much like anti-depressant drugs, St. John's Wort has multiple effects on the brain's neurotransmitters.¹⁷⁹ Since the manufacturers cannot make actual medical claims, they purport that it can "help you feel good mentally,"¹⁸⁰ and "help fight the blues."¹⁸¹

A problem with marketing these products as "supplements" is many

172. See Endocrine Society Alert: "Andro" Use by Athletes (visited Oct. 5, 1998) <http://www.endo-society.org/news_g/press/andro.htm> [hereinafter Endocrine Society Alert]. See also Frank Ahrens, *How the Experts View Androstenedione*, WASH. POST, Oct. 20, 1998, § HM (Health), at 13.

173. See Brown, *supra* note 23, at A3.

174. See Endocrine Society Alert, *supra* note 172.

175. See Brown, *supra* note 23, at A3.

176. See *id.*

177. See J. Madeleine Nash, *Nature's Prozac?*, TIME, Sept. 22, 1997, at 80. Prozac is one of the most commonly prescribed anti-depressant drugs in the United States. See Michael T. Murray, *Battling the Blues with St. John's Wort*, BETTER NUTRITION, Feb. 1998, at 14. Under DSHEA, "Herbal Prozac" is not a permissible labeling term.

178. See *Researcher Writes the A to Z of St. John's Wort*, NEW ORLEANS TIMES PICAYUNE, July 21, 1998, at D5.

179. See Toscano, *supra* note 100, at 165. For a discussion of the effects of St. John's Wort, see Murray, *supra* note 177, at 14, and Nash, *supra* note 177, at 80.

180. Brody, *supra* note 166, at D7.

181. Heusel, *supra* note 20, at 163; Mitka, *supra* note 152, at 1555.

medical questions are left unanswered concerning the safety and efficacy of long-term use. While athletes take Androstenedione to improve their athletic performance,¹⁸² there is no proof of its effectiveness in this regard.¹⁸³ Additionally, scientists do not know how much Androstenedione is converted into steroids, how much is absorbed by the body, or whether it causes liver cancer and heart disease like other oral androgens.¹⁸⁴ Similarly, there are unanswered questions concerning St. John's Wort. No one has determined a set dosage or whether it is the herb alone or the combination of ingredients that make the product useful.¹⁸⁵ Each brand of St. John's Wort contains different amounts of the herb and various directions for use.¹⁸⁶ Since these products are not subject to any meaningful approval or substantiation process, unless the government places more stringent requirements on them, these questions may remain unanswered and standards will go unchecked.¹⁸⁷

IV. CONGRESS CREATES A UNIQUE SITUATION FOR CONSUMERS

A. *The DSHEA Is a Departure from the Current Regulatory Scheme*

With the help of Congress, anyone can walk into a health food store

182. Major League Baseball allows athletes to use Androstenedione, however, the National Football League, National Collegiate Athletic Association and the International Olympic Committee ban its use. See Brown, *supra* note 23, at A3. See also Sharon Begley, *The Real Scandal*, NEWSWEEK, Feb. 15, 1999, at 48.

183. See Endocrine Society Alert, *supra* note 172.

184. See *id.*

185. See, e.g., *Efforts Under Way to Prove Herbal Supplements Work*, OMAHA WORLD, Oct. 23, 1998, at 7 [hereinafter *Effects Under Way*]

186. See Heusel, *supra* note 166, at 166-67.

187. The New Jersey Assembly proposed a law that bans the sale of Androstenedione to persons under age 18 but the Assembly session ended before the bill was passed. See Bob Groves, *Nutritional Supplement Restriction Sought*, BERGEN RECORD (New Jersey), Sept. 15, 1998, at A3. A similar bill was introduced in December 1999 and referred to the Committee on Health. See AB 44, 209th Leg. (N.J. 1999).

and purchase products which have effects on the human body similar to many prescription drugs. Consumers are buying and using more of these products¹⁸⁸ and the risks associated with them are increasing. Although these products clearly indicate that the FDA has not conducted evaluations, and the products do not make express disease-related claims,¹⁸⁹ many manufacturers try to imply therapeutic benefit. Further, many manufacturers successfully word claims so that they fall within the DSHEA's regulatory safe harbors, thereby avoiding the need to clearly demonstrate the safety and efficacy of their products.

Although the FDA controls these products, it does not do so to the extent that many consumers might expect. Unlike vitamins, the long and short-term health consequences that may result from the use of these unproven remedies are not known by scientists.¹⁹⁰ Congress created an atmosphere encouraging consumers to use dietary supplements, but failed to provide a meaningful, working mechanism for the FDA to ensure consumers' safety and efficacy expectations. The tools the DSHEA gives the FDA to protect the public are less efficient than those it takes away. Consumers can now educate themselves from a variety of sources. For example, the World Wide Web has hundreds of sites dedicated to alternative medicines.¹⁹¹ The Internet, however, is notorious for giving veiled advice in the form of advertisements.¹⁹² Television programs or book stores often cause similar problems for consumers.¹⁹³

188. In the United States, consumers spend approximately \$10 to \$12 billion annually on various forms of dietary supplements. See Jill Ellis, abstract of Panel Discussion, in NIH Research Workshop, *supra* note 5.

189. See Heusel, *supra* note 20, at 162. See also Dietary Supplement Health Education Act of 1994, Pub. L. No. 103-417, § 6(c), 108 Stat. 4325 (1994).

190. See Lise Alschuler, et al, *Herbal Medicine: What Works, What's Safe*, PATIENT CARE, Oct. 15, 1997, No. 16, vol. 31, at 49.

191. See, e.g., HealthWorld's Online Herbal Medicine section (visited Oct. 20, 1998) <<http://www.healthy.net/clinin/therapy/herbal/index.html>>; U.S. FDA Dietary Supplement Information Page (visited Oct. 20, 1998) <<http://vm.cfsan.fda.gov/~dms/supplmnt.html>>; The U.S. Pharmacopoeia (visited Oct. 20, 1998) <<http://www.usp.org/mgraphs/botanica>>.

192. See Heusel, *supra* note 166, at 166.

193. See, e.g., Varro E. Tyler, *THE HONEST HERBAL* (1998); Varro E. Tyler, *HERBS OF CHOICE* (1999); Andrea Peirce, *AMERICAN PHARMACEUTICAL*

In enacting the DSHEA, Congress departed from the FDA's regulatory path for controlling dietary supplements.¹⁹⁴ Congress reasoned the interests of the public would be better served through less regulation of dietary supplements. The DSHEA represented a significant change in the FDA's authority over a product.¹⁹⁵ After the FDA spent years trying to develop greater controls over vitamins and herbs through regulations and enforcement,¹⁹⁶ the DSHEA created an entirely new way of looking at dietary supplements.

B. Information and Advertising Concerns

The FDA must balance the interests of the consumers and the interests of the dietary supplement manufacturers. Because consumers possess a desire for dietary supplements,¹⁹⁷ a means for disseminating reliable information must be created. The DSHEA no longer prohibits the marketing of information or studies about a dietary supplement in stores that carry the product.¹⁹⁸ The statute does not consider publications, articles and other sources as labeling, so long as these sources are printed in their entirety and

- (1) [the source] is not false or misleading;
- (2) does not promote a particular manufacturer or brand of dietary supplements;
- (3) is displayed or presented, or is displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement;

ASSOCIATION PRACTICAL GUIDE TO NATURAL MEDICINES (1998).

194. As one commentator noted, "DSHEA was passed without people realizing what the significance would be in terms of tying the FDA's hands." Porter, *supra* note 158, at 12 (quoting Virginia Buchanan, plaintiff's attorney in a suit against a supplement containing ephedrine.).

195. See Fred Degnan, Dietary Supplements, § 6 The Passage of DSHEA (on file with author).

196. See *supra* Part II.A. and accompanying notes.

197. Alternative medicine advocate Andrew Weil recognizes the consumer's desire for these products: "I think that there is a deep suspicion that pharmaceutical medicine is dangerous, and people have a very great longing for treatments that are more natural and gentler." *Herbal Rx: The Promises and Pitfalls*, CONSUMER REP., Mar. 1999, at 46 [hereinafter *Herbal Rx*].

198. See Young & Bass, *supra* note 145, at 288.

(4) if displayed in an establishment, is physically separate from the supplements; and

(5) does not have appended to it any information by sticker or other method.¹⁹⁹

The FDA also recently issued guidelines requiring "supplemental facts" panels to be placed on dietary supplements.²⁰⁰ These panels are similar to the "nutritional facts" panels required under the NLEA.²⁰¹ There is, however, still very little guidance concerning permissible claims.

The FTC is responsible for monitoring and creating standards on claims made to consumers through advertising.²⁰² The FTC identifies two challenges they have in dealing with dietary supplements.²⁰³ They are educating the industry about their legal obligations and creating a workable policy to "police the more unscrupulous members of [the dietary supplement] industry."²⁰⁴ The DSHEA created many questions regarding the FTC's approach to dietary supplements.²⁰⁵

In response, the FTC issued a policy statement outlining the appli-

199. 21 U.S.C. § 343-2(a) (1994).

200. See 61 Fed. Reg. 49826, 49849 (1997) (to be codified at 21 C.F.R. § 103.36); see also *The Selling of Supplements: Trust Me it Works*, CONSUMER REP., Mar. 1999, at 48 [hereinafter *The Selling of Supplements*]. These labels will make it easier for the consumer to compare products, but the labels do not claim to certify the exact percentage of ingredients in the product. See *id.*

201. See Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements; Compliance Policy Guide, Revocation, 62 Fed. Reg. 49826 (1997); Food Labeling; Requirement for Nutrient Content Claims, Health Claims and Statement of Nutritional Support for Dietary Supplements, 62 Fed. Reg. 49859, 49865 (1997).

202. See 15 U.S.C. § 52 (1998). "It shall be unlawful . . . to disseminate, or cause to be disseminated, any false advertisement . . . [with] the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of foods, drugs, devices, services, or cosmetics." *Id.*

203. See Jodie Bernstein, Director, Bureau of Consumer Protection, "FTC and Dietary Supplements" FDLI Conference on Substantiating Claims for Dietary Supplement Advertising and Labeling, Nov. 13, 1997 (visited July 26, 1999) <<http://www.ftc.gov/speeches/other/jodie2.htm>>.

204. *Id.*

205. See Dietary Supplements: An Advertising Guide for Industry, (visited July 26, 1999) <<http://www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm>>.

cation of FTC law to dietary supplements.²⁰⁶ Advertising must be truthful, not misleading and advertisers must have adequate substantiation for all objective product claims;²⁰⁷ anecdotal evidence is not enough.²⁰⁸ The guidelines give examples to highlight the most common violations.²⁰⁹ Recent FTC guidelines require labeling claims to be based on reliable scientific evidence.²¹⁰

Both agencies are trying to ensure that the public is protected. Since the FDA has more expertise with the actual products, establishing standards for determining when a claim is false or misleading is a wise step. A joining of forces between the FDA and the FTC to determine whether adequate substantiation for a claim exists would increase enforcement. Heightened FTC involvement would serve as an additional source of monitoring for the dietary supplement industry. For example, the FTC has already taken an active role in monitoring labels. In 1998, the FTC took action against seven manufacturers for violating regulations regarding truthfulness and verifiability of claims.²¹¹

C. Safety Research

Although the possibility of further regulation can have immediate negative consequences for the industry, the long-term results will prove to be beneficial.²¹² If each manufacturer sponsored one well-

206. *See id.*

207. *See id.*

208. *See id.*

209. *See id.* These violations include misleading advertisements, fine printed disclosures, claims that refer to a specific level of support such as "scientists now agree," and claims surrounding evidence and effectiveness. *See id.*

210. *See The Selling of Supplements*, *supra* note 200, at 48. *See also* 16 C.F.R. § 225.2(a).

211. *See* Jane E. Brody, *Law Calls Herbs Food, Not Drugs*, N.Y. TIMES, Feb. 9, 1999, at D7. The Commission has also warned 1,200 Internet sites that made "incredible claims" for drugs and supplements and issued advertising guidelines aimed at the dietary supplement industry. *See id.*

212. The FTC Director of the Bureau of Consumer Protection stated that basing claims on scientific evidence will give "good players in the industry . . . the guidance they need. Others will continue to face vigorous enforcement

conceived and supported test highlighting the effects of dietary supplements, advertisers could use the evidence. Many manufacturers, however, shy away from investing in research to show a product's health value. Once the evidence is available, other manufacturers would be able to tout such attributes on their label without having to engage in any research.²¹³ Not surprisingly, it is reported that only two companies are currently testing the safety and efficacy of their herb products.²¹⁴ Unfortunately, these companies are the exception to the rule. In the alternative, an industry-wide fund, would increase the availability of clinical research. Rather than have each company sponsor research, supplement manufacturers would pay into the fund based on their market share.²¹⁵

Several reasons compel the dietary supplement manufacturers to clinically test their products. First, the industry receives the benefit from marketing products. Second, manufacturers have the resources for this funding. Third, neither the FDA nor the Office of Dietary Supplements at the National Institutes of Health, which was created by the DSHEA, has the funding to research all of the products that need to be tested.²¹⁶ Fourth, even limited safety and efficacy tests could be used for a variety of helpful purposes such as: helping to satisfy FTC advertising regulations, attaining the DSHEA goal of presenting bal-

by the FTC." *The Selling of Supplements*, *supra* note 200, at 48.

213. *See id.*

214. *See Efforts Under Way*, *supra* note 185, at 7. A third company, PharmaPrint of Irvine, California had stated an interest in asking the FDA to approve its herbal supplements as drugs. *See Herbal Rx*, *supra* note 197, at 48.

215. *See Michael Higgins, Hard to Swallow*, 85 A.B.A. J. 63 (June 1999). Bruce Silverglade of the Center for Science in the Public Interest says members of his group have talked about the idea but nothing has "gotten off the ground yet." *Id.*

216. *See NIH Research Workshop*, *supra* note 5, at 2; *see also* Jane E. Brody, *Trying to Evaluate Effectiveness*, N.Y. TIMES, Feb. 9, 1999, at D7. The Office of Dietary Supplements is currently helping to finance a three-year multi-center study of St. John's Wort as a treatment for clinical depression. *See id.* Sadly, the FDA spends three times more resources monitoring drugs for pet and farm animals than it does for dietary supplements. *See* Thomas J. Moore, *Messing with Mother Nature*, WASHINGTONIAN, July 1999, at 59.

anced information to the consumer concerning the biological effects of the products, and assuring consumers steps are taken to systematically consider the safety and reliability of supplement products.²¹⁷

D. Standardization of Dietary Supplements

One of the few powers the DSHEA gave the FDA was the authority to require "good manufacturing practices."²¹⁸ FDA standards specify factory conditions but do not guarantee the efficacy or purity of the products.²¹⁹ These standards ensure only that all products are handled and made the same way and that sanitary practices are followed.²²⁰ In February 1997, the FDA published an Advance Notice of Proposed Rulemaking and requested comments on manufacturing practices for dietary supplements.²²¹ To date, no further action has been taken.²²²

The lack of standardization of supplement ingredients has had adverse effects on consumers, including death.²²³ Companies are allowed to promote the effectiveness of their products, but at the same time are not required to provide expansive health warnings. A study of the most popular brands of St. John's Wort showed a significant discrep-

217. There are a number of completed studies abroad. For example, Germany's Commission E has approved 254 botanicals as safe and reasonably effective and found 126 ineffective, unsafe or both. See Brody, *supra* note 216, at D7.

218. Dietary Supplement Health Education Act of 1994, Pub. L. No. 103-417 § 402(g) (codified at 21 U.S.C. § 342(g) (1994)).

219. See *id.* There have been dangerous instances concerning supplements that lack purity. See, e.g., Jim Ritter, *Herbal Warning: Concerns Raised About Quality of Supplements*, CHI. SUN TIMES, Oct. 13, 1998, at 1.

220. See Dietary Supplement Health Education Act of 1994, Pub. L. No. 103-417 § 402(g)(2) (codified at 21 U.S.C. § 342(g)(2)). These regulations must be modeled after comparable food regulations. See *id.*

221. See Current Good Manufacturing Practice in Manufacturing, Packing or Holding Dietary Supplements, 62 Fed. Reg. 24,619 (1997) (proposed Feb. 6, 1997).

222. See Henney, *supra* note 9, at 8 (Commissioner Henney stated that although the agency has not moved rapidly on this topic, it is now considered a high priority).

223. See NIH Research Workshop, *supra* note 5, at 3; see also Okie, *supra* note 139, at 77.

ancy between the actual and claimed amount of St. John's Wort in the product.²²⁴ As a result, some consumers are purchasing products that are much stronger than desired, while others are buying no more than a very expensive placebo.²²⁵

Set standards for quality, strength and purity can help solve some of the problems with dietary supplements. To fully address these problems, safety and labeling authority that DSHEA does not provide for, and in fact, was expressly taken away is needed.

CONCLUSION

The DSHEA deviates from the direction in which food and drug law had been headed this century. Consumers are unknowingly taking their health into their own hands through the use of dietary supplements. Although the DSHEA proposes to protect the consumer, it actually works against the FDA's ability to do so. Until the dietary supplement industry can offer the assurance that it can fill that role, consumers risk misinformation as well as physical harm. In many instances, dietary supplements are as potent as prescription drugs, yet the FDA can only prosecute manufacturers for mislabeling a product or clearly making health-related claims. Under the DSHEA, the FDA retains the authority to investigate claims relating to dietary supplements. This authority, in the context of a joint regulatory scheme with the FTC, could result in greater enforcement ability. A coordinated effort between the government and industry could one day bring about the degree of safety that consumers have come to expect.

224. See Heusel, *supra* note 166, at 166.

225. See Heusel, *supra* note 20, at 162.

