

The National Agricultural
Law Center



University of Arkansas School of Law

NatAgLaw@uark.edu ☎ (479) 575-7646

An Agricultural Law Research Article

**Creating Balance: Problems Within DSHEA
and Suggestions for Reform**

by

Jennifer Akre Hill

Originally published in the JOURNAL OF FOOD LAW & POLICY
2 J. FOOD L. & POL'Y 361 (2006)

www.NationalAgLawCenter.org

CREATING BALANCE: PROBLEMS WITHIN DSHEA AND SUGGESTIONS FOR REFORM

*Jennifer Akre Hill**

I. INTRODUCTION

The Dietary Supplement Health and Education Act of 1994 (DSHEA) was signed into law on October 25, 1994.¹ At the signing, President Clinton endorsed the “intense efforts” of manufacturers and legislators to change the “treatment of dietary supplements under regulation and law.”² Further, the bill was signed with the hope that it would benefit consumers by permitting more access to dietary supplements and more choices for consumer directed healthcare.³

* Jennifer Akre Hill is a May 2007 Juris Doctor candidate at the University of Arkansas School of Law, Fayetteville, Arkansas. This Comment received the University of Arkansas Journal of Food Law & Policy’s 2006 Annual Arent Fox/Dale Bumpers Excellence in Writing Award. The author would like to thank her faculty advisor, Adjunct Professor Michael Roberts, an attorney with Venable LLP in Washington, D.C., for his guidance and support in preparation of this comment. The author would also like to thank 2005-06 Note and Comment Editor Jeffrey D. Wood, J.D. 2006, for his encouragement and guidance through the writing process.

1. Dietary Supplement Health and Education Act of 1994 (DSHEA), Pub. L. No. 103-417, 108 Stat. 4325, [hereinafter DSHEA] (codified as amended in scattered sections of 21 U.S.C. §§ 301-399 (2000)).

2. President William J. Clinton, statement at the signing of S. 784, Oct. 25, 1995 U.S.C.C.A.N. 3523-1 (1994). Congressional findings revealed improving the health status of citizens ranks at the top of the nation’s priorities, and that there is a link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic disease. Dietary Supplement Health and Education Act § 2. Therefore, there is a growing need for dissemination of information linking nutrition with good health. *Id.*

3. Clinton, *supra* note 2 (stating further, “[i]n recent years, the regulatory scheme designed to promote the interests of consumers and a healthful supply of good food has been used instead to complicate choices consumers have made to advance their nutritional and dietary goals”); see also Scott Bass & Emily Marden, *The New Dietary Ingredient Safety Provision of DSHEA: A Return to Congressional Intent*, 31 AM. J.L. & MED. 285, 287 (2005) (noting DSHEA was premised on the positive role of nutrition in preventative health care and supported by the recognition that consumers want information and access to a “broad range of safe products”).

In support, politicians on both sides of the aisle claimed the DSHEA as a victory for consumer freedom, populist protection, and preventative medicine.⁴

The sweeping legislation of the DSHEA leaves its mark on three influential groups: the Food and Drug Administration (FDA), an agency that serves to protect Americans from adulterated, misbranded, and dangerous food and drug products;⁵ the dietary supplement industry, represented by the manufacturers, producers, and retailers of dietary supplements;⁶ and the dietary supplement consuming public. While creating the DSHEA, Congress attempted to meet the needs of each of the three groups by striking a balance between unfettered access and strict control.⁷

Whether or not that balance exists depends on who is looking at the scale. Specifically, the DSHEA does supply “control” of dietary supplements, but only so far as it has provided the FDA with a regulatory mechanism to monitor post-manufacturing product safety.⁸ Increased access was also granted; DSHEA regulation “supersede[d] the [existing] ad hoc patchwork regulatory policy on dietary supplements”⁹ and successfully removed the regulatory barriers that limited the flow of information and products to consumers.¹⁰ In the end, however, DSHEA accomplished more than a barrier removal; it “yielded significant latitude to dietary supplement companies in manufacturing and promoting their products.”¹¹

Since the passage of DSHEA, more consumers have gained access to dietary supplements as they have become available through new venues such as grocery stores and the internet.¹² This apparent

4. Michael A. McCann, *Dietary Supplement Labeling: Cognitive Biases, Market Manipulation, and Consumer Choice*, 31 AM. J.L. & MED. 215, 246-47 (2005).

5. FDA, *FDA's Mission Statement*, <http://www.fda.gov/opacom/morechoices/mission.html> (last visited Jan. 31, 2006) (indicating that the FDA is responsible for protecting, among other things, the public health by assuring the safety, efficacy, and security of human drugs, biological products, medical devices, and the food supply).

6. See generally Iona Kaiser, *Dietary Supplements: Can the Law Control the Hype?*, 37 HOUS. L. REV. 1249 (2000).

7. Dietary Supplement Health and Education Act, *supra* note 1, 3.3 § 2.

8. Morgan J. Wais, Comment, *Stomaching the Burden of Dietary Supplement Safety: The Need to Shift the Burden of Proof Under the Dietary Supplement Health and Education Act of 1994*, 28 SEATTLE U. L. REV. 849, 878 (2005).

9. See *infra* Part II (discussing the regulatory framework prior to DSHEA).

10. McCann, *supra* note 4, at 243.

11. *Id.*

12. Joseph A. Levitt, *Regulation of Dietary Supplements: FDA's Strategic Plan*, 57 FOOD & DRUG L.J. 1, 1 (2002).

success in improving access to dietary supplements, however, must be weighed against the side effects. Access to dietary supplements has not only grown, it has changed. Where at one time adult consumers were buying products from specialized health stores,¹³ children and adolescents now have equally ready access to dietary supplements.¹⁴ The side effects of the increased access are compounded further because DSHEA allows dietary supplement products to reach the consuming public with no pre-market evaluation¹⁵ providing children with access to products that are often the equivalent of diluted drugs.¹⁶

By decisively removing regulatory barriers in order to increase consumer access to dietary supplements, the DSHEA created an atmosphere that allowed the dietary supplement industry to develop.¹⁷ Yet, the DSHEA failed to provide a framework for regulating the changing market or to give the FDA enough regulatory power to protect consumer safety in the changing marketplace.¹⁸ This failure has left many large companies basking in the glow of a bright financial forecast and has burdened the FDA with increasing regulatory challenges and obstacles to meet its burden to consumers¹⁹ and ensure product safety.²⁰

13. See, e.g., GENERAL NUTRITION CENTER (GNC), *ABOUT GNC*, <http://www.gnc.com/corp/index.jsp> (last visited Jan. 29, 2006) (stating that GNC has been in business since 1935).

14. Levitt, *supra* note 12; see also Jennifer Sardina, Note, *Misconceptions and Misleading Information Prevail—Less Regulation Does not Mean Less Danger to Consumers: Dangerous Herbal Weight Loss Products*, 14 J.L. & HEALTH 107, 125 (1999-2000) (stating that supplements are no longer confined to small, remotely located health food stores, they are now “frequently found in . . . malls, plazas, on television, in catalogs, and on-line”).

15. Dana Ziker, *What Lies Beneath: An Examination of the Underpinnings of Dietary Supplement Safety Regulation*, 31 AM. J.L. & MED. 269, 271 (2005).

16. Bruce H. Schindler, *Where There's Smoke There's Fire: The Dangers of the Unregulated Dietary Supplement Industry*, 42 N.Y.L. SCH. L. REV. 261, 261 (1998).

17. Levitt, *supra* note 12.

18. *Id.* (suggesting that although the market growth was intended, the DSHEA did not predict the regulatory challenges that would stem from the changes).

19. FDA, *supra* note 5.

20. Levitt, *supra* note 12; see generally *Nutraceutical v. Crawford*, 364 F. Supp. 2d 1310 (D. Utah, 2005) *rev'd sub nom.* *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033 (10th Cir. 2006) *petition for cert. filed*, 75 USWL 3368 (Jan. 3, 2007)(06-922) (supporting the proposition that the regulatory scheme of the DSHEA is not sufficient to ensure safety if it cannot remove products, such as ephedra, that have a well documented history of adverse events). [*Ed. Note:* The Tenth Circuit Court of Appeals reversed and remanded *Nutraceutical*, 364 F. Supp. 2d 1310, after this article was submitted. On Appeal, the Court held it was proper for the FDA to use a balancing test and the use of that balancing test did not in fact shift the burden of

This article begins with an overview of the struggle between FDA and the dietary supplement industry for the power to control dietary supplement regulation,²¹ and continues into a discussion of the current regulatory scheme, DSHEA.²² The analysis that follows indicates that DSHEA, without amendment, will not serve its purpose to protect consumers, and argues that the current shortcomings of the dietary supplement regulatory scheme are not caused by DSHEA as a regulatory mechanism, but by the ambiguous terms within its provisions.²³ Specifically, the lobbying power of the dietary supplement industry caused DSHEA to be a political compromise that promised law in a hurry without giving due care to its repercussions.²⁴ Joining cited academics, this article further suggests that DSHEA is in need of amendment if consumers are to be protected and the dietary supplement industry is to remain strong.²⁵ Finally, this article concludes by moving the dietary supplement debate forward and suggests specific amendments that if made, would move DSHEA one-step closer to creating balance.²⁶

II. OVERVIEW

The legislative history of dietary supplements in the United States details the clash of a governing body, and a strong commercial market, each maintaining the common goal of providing consumers with dietary supplements.²⁷ Since 1867, FDA and its predecessors have been charged with the responsibility of using federal law to protect consumers from adulterated²⁸ or misbranded food and drugs.²⁹ Further, because FDA is an agency under a democratic government, consumers inherently have the ability to affect the level

proof from FDA to the plaintiff. As of February 19, 2007, the petition had not been acted upon. The implications of the subsequent history are beyond the scope of this comment.]

21. See *infra* Part II.

22. See *infra* Part II.C.

23. See *infra* Part III.

24. See *infra* Part III. See also Barbara A. Noah, *Foreword: Dietary Supplement Regulation in Flux*, 31 AM. J.L. & MED. 147, 147 (2005) (stating that the DSHEA was created in response to “anxious lobbying” by the dietary supplement industry).

25. See *infra* Part IV.

26. See *infra* Part IV.

27. See *infra* Part II.A.

28. See *infra* Part III.B.

29. John P. Swann, *History of the FDA*, <http://www.fda.gov/oc/history/historyoffda/fulltext.htm> (last visited Jan. 3, 2007).

and types of control FDA maintains.³⁰ Recently, FDA and the dietary supplement industry have faced-off through political debates and legislative action.³¹ At present, many would say that the industry has won with the passage of DSHEA, creating both positive and negative implications for dietary supplement consumers.³²

A. The Relative Interests of FDA and the Dietary Supplement Industry

In creating dietary supplement regulation Congress is influenced by the lobbying efforts of two primary entities, FDA and the dietary supplement industry.³³ In general, Congress is required to create legislation that is in the best interest of the people, however, the relative lobbying powers of the dietary supplement industry and FDA are impossible to ignore.³⁴

The FDA, as an agency of the federal government, acts in the interest of the American people.³⁵ Charged to protect the food supply, FDA creates regulations that, at times, have the effect of limiting the number and types of products Americans have access to.³⁶ Regulation, however, is not meant to eradicate the use of products categorically, thus FDA advocates the use of dietary supplements by the American people so long as they are safe.³⁷ In order to reach this

30. *Id.* (noting that in the late 1800s, the Division of Chemistry was using human subjects to consume “questionable food additives” which spurred public outcry and urged federal law to prohibit the sale of adulterated or misbranded food and drugs).

31. *See generally* Kaiser, *supra* note 6 (discussing the legislative progression of the dietary supplement industry as influenced by the dietary supplement industry and the FDA).

32. Noah, *supra* note 24 (stating that the DSHEA would severely limit the FDA’s authority). *See generally supra* Part I (stating that while dietary supplement access has increased, safety regulation has become more difficult for the FDA and the safety of all currently marketed dietary supplements is not certain).

33. Kaiser, *supra* note 6, at 1271-72.

34. Wais, *supra* note 8, at 865-66. Wais stated that the dietary supplement industry is a very large political lobbying force. *Id.* Not only did politicians have a large monetary incentive to cooperate with the dietary supplement industry, but also, the dietary supplement industry employs tens of thousands of people directly and indirectly, creating an economic benefit to society and strong incentives for politicians to support the industry. *Id.* Further, the dietary supplement industry has been consistently among the top campaign contributors to lawmakers. *Id.* In 2000, the industry donated \$2.3 million to Representatives who worked in its favor. *Id.*

35. FDA, *supra* note 5.

36. *Id.*

37. Lester M. Crawford, Acting Commissioner of the FDA, Speech before Council for Responsible Nutrition: Annual Conference (Oct. 25, 2004), <http://www.fda.gov/oc/speeches/2004/crn1025.html> (last visited Jan. 3, 2007).

goal, FDA promotes increasing the regulation of the dietary supplement industry.³⁸ Moreover, FDA believes tightening down on the policies within DSHEA is the only way to increase consumer access and safety, simultaneously.³⁹

While the dietary supplement industry also advocates the use of dietary supplements by Americans, its interests are in profit maximization, market growth, and creating products that are safe enough to achieve repeat sales but that avoid creating expensive lawsuits.⁴⁰ Profit maximization and market growth are benefited by legislation that removes barriers to entry and that reduces costs related to product formation.⁴¹ Deregulation within the dietary supplement industry through DSHEA has also resulted in less safety regulations.⁴² Manufacturers therefore find it easier to market products that meet the legal standard of “safe” and consequently, avoid lawsuits.⁴³ Therefore, each of the dietary supplement industry’s goals has benefited by the deregulation of DSHEA.⁴⁴

B. History

The Federal Food, Drug, and Cosmetics Act of 1938 (FDCA) was the first legislation to regulate products with a quasi-therapeutic⁴⁵ effect, such as dietary supplements.⁴⁶ Also recognizing the dietary properties of vitamins and minerals,⁴⁷ FDCA recognized a need for regulation and gave FDA the power to remove these products from the market and condition the sale of such products with pre-market approval.⁴⁸ In the early days of FDCA, FDA could

38. *Id.*

39. *Id.*

40. Kaiser, *supra* note 6, at 1272.

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

42. Wais, *supra* note 8, at 878.

43. *Id.*

44. Gilhooley, *supra* note 41 (illustrating that the lack of market regulation in the 1980s spurred market growth); *see also* Wais, *supra* note 8, at 865 (stating, “[w]hen an industry stands to expand and become more profitable, legislation often accompanies the expansion to assist and maintain that industry not only for the public’s benefit, but also for the politicians’ benefit.”).

45. *See* Swann, *supra* note 29 (noting that drug products that have a therapeutic effect are those that change the chemistry of the body; however, dietary supplements, along with caffeinated beverages are considered quasi-therapeutic because they alter the chemistry of the body, but not as significantly).

46. *Id.*

47. *Id.*

48. Wais, *supra* note 8, at 852.

classify a dietary supplement as a food, drug, or food additive.⁴⁹ The classification then dictated the standards that the dietary supplement would have to satisfy before entering the market.⁵⁰ FDA's interpretation of the law at that time was that a dietary supplement should be classified based on its intended use by the manufacturer.⁵¹ This interpretation gave manufacturers the upper hand in controlling how the supplement was categorized and regulated.⁵²

The dichotomy created by FDCA, categorizing a dietary supplement as a "drug" versus a "food," is the prominent source of conflict between FDA and the dietary supplement industry.⁵³ Dictated by the considerable difference in food and drug approval methods, the controversy has manifested as a battle between FDA and industry leaders over how to regulate dietary supplements.⁵⁴

1. Food and Drug Approval Processes

In order for a new pharmaceutical, or drug, to enter the market, the manufacturer is subject to stringent pre-market approval.⁵⁵ In part, obtaining approval for a new drug's labeling and advertising requires a showing of substantial evidence of safety and efficacy through meticulous clinical research.⁵⁶ If dietary supplements were classified as drugs, manufacturers would be subject to the same requirements, including required approval and scientific testing to prove safety.⁵⁷

A "food product," on the other hand, requires no pre-market approval and is considered safe unless the government can prove

49. Kaiser, *supra* note 6, at 1251.

50. *Id.* at 1251-52. (stating that under FDCA a supplement's classification as a food additive forced the manufacturer to spend a considerable amount of time and money to market the product).

51. *Id.* at 1252.

52. Peter Barton Hutt, *FDA Statutory Authority to Regulate the Safety of Dietary Supplements*, 31 AM. J.L. & MED. 155, 157 (2005). Wais, *supra* note 8, at 852. If the product's labeling indicated a use for medicinal purposes, the product was deemed a dietary ingredient and was regulated as a drug, which required that the manufacturer prove product safety. *Id.* Products represented solely for use to supplement the diet were called dietary foods; these products were regulated under FDCA as a food, which was presumed to be safe. *Id.*

53. Gilhooley, *supra* note 41, at 671.

54. *See infra* Section III.B.1.

55. Hutt, *supra* note 52, at 182.

56. *Id.*

57. Deborah Burke & Anderson Page, *Regulating the Dietary Supplement Industry: Something Still Needs to Change*, 1 HASTINGS BUS. L.J. 191, 129 (2005).

that it may reasonably “injure the health of a consumer.”⁵⁸ Any substance that may become a component of, or change the characteristics of a food is called a “food additive;” these products are also within the category of “food.”⁵⁹ “Food additives,” however, are presumptively unsafe and require pre-market approval by (1) filing a food additives petition for the new ingredient, or (2) showing that the ingredient is “generally recognized as safe” (GRAS).⁶⁰ This requires the manufacturer to show, by scientific procedures, the new ingredient is safe under the conditions of its intended use.⁶¹ Dietary supplements are currently regulated as a food; accordingly, they are presumed to be safe and enter the market without FDA approval.⁶² The marked differences in the pre-market approval requirements for “foods” and “drugs” illustrate why the dietary supplement industry has such a strong interest in the regulatory methods of dietary supplements.⁶³

2. Continued History

In the early 1960s, through a combined effort of FDA and the Federal Trade Commission (FTC),⁶⁴ dietary supplements were heavily regulated under the Food Additive Amendment to FDCA.⁶⁵ These two organizations spent more money trying to regulate dietary supplements than in any other area.⁶⁶ The increased regulatory efforts led to a 1962 goal of only approving those supplements for which there was a recognized need and eradicating “myths of nutrition.”⁶⁷

58. U.S. v. Lexington Mill & Elevator Co., 232 U.S. 399, 411 (1914).

59. FDCA, 21 U.S.C. § 321(s) (2000) [hereinafter FDCA].

60. *Id.* § 348.

61. *Id.* § 348(a).

62. Burke & Page, *supra* note 57, at 128.

63. McCann, *supra* note 4, at 228 (stating that proof of safety and effectiveness, at least in a clinical sense, is often hard to establish for dietary supplements).

64. FTC, *A Guide to the Federal Trade Commission*, (2004), <http://www.ftc.gov/bcp/conline/pubs/general/guidetoftc.htm> (stating that the FTC has a long tradition of maintaining a competitive marketplace for both consumers and businesses by preventing unfair methods of competition in commerce).

65. Kaiser, *supra* note 6, at 1252 (stating that the amendment granted the FDA the authority to regulate dietary ingredients as food additives and to evaluate the safety of all new ingredients).

66. *Id.*

67. *Id.* at 1253. Examples of these “myths of nutrition” include statements such as, “it is essentially impossible to obtain from our daily diets the nutrients we require,” and “the modern processing of food strips them of virtually all nutritional value.” *Id.*

Until this time, FDA had retained control of dietary supplement regulation; however, the hyper-regulation of the early 1960s angered parts of the American public, causing an immediate attack on FDA's new approach.⁶⁸ It was not until 1973 that FDA retreated from its "myths of nutrition" regulatory scheme.⁶⁹

The dietary supplement industry won a small struggle when FDA adjusted this position; however, FDA was not ready to concede its position entirely.⁷⁰ In an effort to stay in control of the dietary supplement market, FDA altered its method of regulation and began prohibiting "irrational combinations" and dosages of vitamins and minerals when sold as foods.⁷¹ Specifically, FDA stated that it intended to treat high-dose supplements as drugs.⁷²

The Second Circuit gave qualified approval to this method of regulation when it held that FDA had the authority to protect consumers from irrational combinations and excessive doses in *National Nutritional Foods Ass'n v. FDA*.⁷³ The court also held, however, that FDA could not classify high-dose supplements as a drug.⁷⁴ FDA accepted this ruling as a victory.⁷⁵

The 1974 case would mark a turning point for the dietary supplement industry. The court's ruling incited a strong reaction from consumers who, through great lobbying efforts, pressured Congress to take back some control of dietary supplement regulation.⁷⁶ Congress responded with the Proxmire Amendment, which essentially revoked FDA's ability to regulate supplements based on irrational combinations or potency.⁷⁷ The amendment was further strengthened by a court decision striking down FDA attempts to limit potency.⁷⁸

68. *Id.* at 1254

69. Kaiser, *supra* note 6, at 1253.

70. *See generally id.* at 1253.

71. *Id.* at 1253.

72. *Id.*

73. 504 F.2d 761, 782 (1974). The court looked favorably on the FDA's attempt to regulate the dietary supplement market more strictly. *Id.*

74. *Id.* at 789.

75. Kaiser, *supra* note 6, at 1253-54.

76. *Id.* at 1254.

77. *See* The Proxmire Amendment, Pub. L. No. 94-278, 90 Stat. 401 (1976) (amending 21 U.S.C. § 349).

78. *See generally* *National Nutritional Foods Ass'n v. Matthews*, 552 F.2d 325 (10th Cir. 1977).

The amendment and the court decisions “dissuaded the agency [FDA] from routinely regulating these products,”⁷⁹ and so FDA entered a period of regulatory restraint, acting only when a specific safety concern arose.⁸⁰ This period of restraint made it easier for additional types of products to be sold as dietary supplements and resulted in a significant expansion in the number of supplements on the market by the 1990s.⁸¹

The dietary supplement industry was thriving until the Fall of 1989, when 38 deaths and 1,500 adverse effects were attributed to L-tryptophan, an amino acid, sold as a dietary supplement and widely used to promote bodybuilding.⁸² The health crisis led to renewed scrutiny of supplement safety.⁸³ Determined to restore its strong regulatory hold on the dietary supplement industry, FDA issued an Advance Notice of Proposed Rulemaking (Advance Notice).⁸⁴ The Advance Notice stated in part that the immediate goal was consumer safety, but also indicated that many herbal drug products would be the subject of regulatory action.⁸⁵ The Advance Notice created controversy throughout the dietary supplement industry because it was seen as an attempt by FDA to revert to the higher levels of regulation as in the 1960s, and the industry feared removal of many products from stores.⁸⁶ Leaders in the dietary supplement industry warned that increased regulations would put retailers out of business and diminish consumer rights to buy vitamins.⁸⁷

The FDA Commissioner attempted to alleviate consumer fear by making a statement that all products currently on sale would continue to be sold, so long as they did not present a safety hazard.⁸⁸

79. FDA Regulation: Compliance by Dietary Supplement and Conventional Food Establishments, (June 13, 1994) (writing by Mark V. Nadel, Associate Director, National and Public Health Issues).

80. Gilhooley, *supra* note 41.

81. *Id.*

82. See Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,695-96 (June 8, 1993).

83. Gilhooley, *supra* note 41, at 677.

84. *Id.*

85. *Id.*

86. *Id.* at 678.

87. See Peter J. Cohen, *Science, Politics, and the Regulation of Dietary Supplements: It's Time to Repeal DSHEA*, 31 AM. J.L. & MED. 175, 180 (2005). Leaders also organized a “national blackout day” where stores draped products in black that were the target of the Advance Notice so that consumers could see what the FDA was trying to take away. *Id.*

88. *Legislative Issues Related to the Regulation of Dietary Supplements: Hearings of the Senate Comm. on Labor and Human Resources*, 103d Cong. 19 (1993).

Consumer reaction to the Advance Notice, however, had already stimulated enough support for the legislative efforts that would lead to the passage of DSHEA.⁸⁹

Meanwhile, as it seemed the industry would easily take control of regulation, Congress passed the Nutrition Labeling and Education Act of 1990 (NLEA).⁹⁰ NLEA required “foods” and “food supplements” to be labeled with certain nutritional information.⁹¹ This again upset manufacturers who were concerned with the cost of additional research, and prompted an industry rally that called on Congress to rethink the new requirements.⁹² Due to pressure from the dietary supplement industry, Congress backed down by enacting the Dietary Supplement Act of 1992 that placed a one-year moratorium on NLEA.⁹³

During that year, the supplement industry lobbied heavily to have NLEA repealed.⁹⁴ The effort was unsuccessful, but those involved in the lobbying efforts were able to reorganize and consolidate into an impenetrable initiative for reforms to the laws governing dietary supplements.⁹⁵ Respected consumer protection and public health organizations lobbied against DSHEA, but eventually lost when Congress, siding with the lesser-known DSHEA supporters, enacted DSHEA.⁹⁶

C. A Look at the Current Regulatory Scheme: DSHEA

After DSHEA passed unanimously in both the House of Representatives and the Senate⁹⁷ it had four major impacts on the regulation of dietary supplements.⁹⁸ First, it created a new, broad definition of dietary supplements and identified dietary supplements as a sub-category of food.⁹⁹ This change was beneficial to manufacturers because it gave dietary supplements the advantage of being consid-

89. Gilhooley, *supra* note 41, at 678.

90. NLEA, Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified as amended in scattered sections of 21 U.S.C.) (repealed 1992).

91. *Id.*

92. Kaiser, *supra* note 6, at 1259.

93. Dietary Supplement Act of 1992, Pub. L. No. 102-571, 106 Stat. 4500 (1992) (codified as amended in scattered sections of 21 U.S.C.).

94. Kaiser, *supra* note 6, at 1259.

95. *Id.*

96. *Id.* at 1259-60.

97. *Id.* at 1260-61.

98. Wais, *supra* note 8, at 853.

99. *Id.*

ered safe without requiring any testing to substantiate the assumption.¹⁰⁰ Second, it created the Office of Dietary Supplements (ODS), a sub-agency of FDA, that was given the power to research dietary supplements and substantiate claims made by manufacturers.¹⁰¹ Third, the labeling requirements of dietary supplements became more lenient, allowing structure or function claims to appear on the supplements.¹⁰² Finally, the burden of proving product safety shifted from the manufacturer, before the product was marketed, to FDA, after the product was on the market.¹⁰³ DSHEA established an entirely new regulatory scheme for dietary supplement products.¹⁰⁴

III. ANALYSIS

DSHEA includes the following sections: definitions, safety requirements, labeling of dietary supplements, new dietary ingredients, good manufacturing practices, and administrative processes with relation to dietary supplements.¹⁰⁵ The content of each of these provisions seems, at face value, to serve a specific purpose and even to be entirely capable of serving that purpose; however, the shortcomings of DSHEA are real and should be attributed to a lack of specificity of the included definitions and the design of each section.¹⁰⁶ Three sections that have particularly noteworthy examples of ambiguity are the definitions, safety, and labeling provisions.

A. *A Lack of Important Definitions has Created Overwhelming Ambiguity within DSHEA*

The breadth of the dietary supplement definition provides a compelling source of ambiguity for DSHEA.¹⁰⁷ A “dietary supplement” is defined generally as a product that bears or contains a vitamin, mineral, herb, amino acid, other botanical, or other dietary substance for use by man to supplement the diet by increasing the total dietary intake.¹⁰⁸ Further, the dietary supplement must be a

100. *Id.* at 854.

101. *Id.*

102. *Id.* at 855.

103. Wais, *supra* note 8, at 855.

104. Robert G. Pinco & Paul D. Rubin, *Ambiguities of the Dietary Supplement Health and Education Act of 1994*, 51 *FOOD & DRUG L.J.* 383, 383 (1996).

105. Dietary Supplement Health and Education Act, *supra* note 1.

106. *See infra* Part IV.

107. Pinco & Rubin, *supra* note 104, at 384.

108. Dietary Supplement Health and Education Act § 321(ff)(1)(A)-(F) (YEAR).

product that is “intended for ingestion,” must not be represented for use as a conventional food or as a sole item of a meal or the diet, and must be labeled as a dietary supplement.¹⁰⁹ The definition specifically excludes dietary supplements from regulation as a food additive under FDCA.¹¹⁰ Finally, the definition concludes by stating that a dietary supplement shall be deemed a “food” within the meaning of this act.¹¹¹

The definition of a “dietary supplement” is expansive and representative of Congress’ intent to include the broadest possible range of ingredients.¹¹² The negative result of the broad definition has been an exploitation of its ambiguous terms.¹¹³ Three words within the definition that have been a source of controversy are “dietary substance,” “ingestion,” and “article.”¹¹⁴

1. Dietary Substance

The term “dietary substance” is found in the “catch-all”¹¹⁵ provision, under the “dietary supplement” definition, which includes “a dietary substance for use by man to supplement the diet by increasing the total dietary intake.”¹¹⁶ The phrase “dietary substance” is part of the dietary supplement definition, but is not defined by DSHEA or any other regulatory provision.¹¹⁷ As a result, even products that are not used to “supplement the diet by increasing dietary intake,”¹¹⁸ as the provision requires, are included as dietary supplements under this provision.¹¹⁹

The dietary supplement industry has historically interpreted the term “dietary substance” broadly to include such products as mela-

109. Dietary Supplement Health and Education Act § 321(ff)(2)(B)-(C)(YEAR).

110. A PRACTICAL GUIDE TO FOOD AND DRUG LAW AND REGULATION 215 (Kenneth R. Pina & Wayne L. Pines eds., 2nd ed. 2002).

111. Dietary Supplement Health and Education Act § 321(ff) (YEAR).

112. Bass & Marden, *supra* note 3, at 294 (stating that one reason for the breadth of the definition was to assure the industry that ingredients used in dietary supplements before the DSHEA would still be available).

113. *See generally* U.S. v. Ten Cartons, More or Less, of an Article Ener-B Vitamin B-12, 72 F.3d 285 (2d Cir. 1995); Pharmanex v. Shalala, 221 F.3d 1151 (10th Cir. 2000).

114. Susan Onel, *Dietary Supplements: A Definition that is Black, White, and Gray*, 31 AM. J.L. & MED. 341, 342 (2005).

115. Pinco & Rubin, *supra* note 104, at 384.

116. Dietary Supplement Health and Education Act § 321(ff)(1)(E) (YEAR).

117. Onel, *supra* note 114, at 342.

118. DSHEA, *supra* note 116 (YEAR).

119. *See* Onel, *supra* note 114, at 342.

tonin, shark cartilage, and coenzyme Q10.¹²⁰ Ingredients such as these, however, “do not fit the definition of vitamins, minerals, botanicals or amino acid, but represent a significant portion of the dietary supplement marketplace.”¹²¹ Until recently, “little attention was given to the fact that these products do not ‘supplement the diet by increasing the total dietary intake;’” however, FDA has made statements that it would narrow the scope of the catch-all provision by reducing dietary substances to include only dietary ingredients that are commonly found in human food and drink.¹²² Narrowing the scope of the “dietary substance” provision would be helpful because a thorough reading of the “catch-all” provision, as is, would require asking three questions: (1) is it a dietary substance? (2) is it used to supplement the diet? and (3) will it increase the dietary intake?¹²³ DSHEA, however, does not provide a framework for answering these questions; therefore, they are not easily answered.¹²⁴

Narrowing the scope of the term “dietary substance” would pose problems for a large number of dietary supplement products and have a significant impact on “a coalition of three of the largest supplement associations, the National Nutritional Foods Association, the Council for Responsible Nutrition, the American Herbal Products Association, as well as manufacturers, retailers, and raw material suppliers for the supplement industry.”¹²⁵ The response, to FDA’s suggested interpretation, was a citizen petition requesting that FDA restate its position, and since then, FDA has taken no action.¹²⁶

2. Intended for Ingestion

The definition of a dietary supplement also requires that the product be “intended for ingestion.”¹²⁷ This, by definition, would exclude topical creams, nose-sprays and injectables.¹²⁸ Yet, manufac-

120. *Id.*

121. *Id.*

122. *Id.* at 342-43.

123. Pinco & Rubin, *supra* note 104, at 384.

124. *Id.*

125. Onel, *supra* note 114, at 342.

126. *Id.* at 342-43.

127. DSHEA § 321(ff)(2)(A)(i).

128. Pinco & Rubin, *supra* note 104, at 384.

turers have still attempted to pass such products as dietary supplements.¹²⁹

FDA has been able to assert some regulatory control in the form of “courtesy letters.”¹³⁰ In fact, many companies have received “courtesy letters” from FDA stating that their product does not fall under the definition of a dietary supplement.¹³¹ The letter explains, that dietary supplements must be “intended for ingestion” in “tablet, capsule, powder, softgel, gelcap, or liquid form.”¹³² The letter further explains the definition of “ingestion,” that the company’s product does not meet this definition, and therefore cannot be categorized as a dietary supplement.¹³³ In support of this decision, FDA relied on *United States v. Ten Cartons*,¹³⁴ which held that a vitamin product intended to be applied inside the nose does not come within the meaning of a dietary supplement.¹³⁵

This example illustrates an important aspect of the problems with DSHEA. Here, even where Congress has provided a clear, understandable definition, the dietary supplement industry still attempts to test boundaries, which results in litigation.¹³⁶ This time, the court agreed with FDA, but if FDA is to have any control over dietary supplements, the act should be inclusive of definitions so that companies cannot challenge each FDA decision in court before accepting FDA’s ruling.¹³⁷ In addition, even in the wake of this decision, and FDA taking an affirmative position on the definition of “ingestion,” some companies, with products such as lozenges and mouthwashes, have succeeded in marketing their products as dietary supplements by focusing on the fact that the product only has an

129. See generally *Ten Cartons*, 72 F.3d 285. The manufacturer asserted that a product topically applied on the interior nasal wall was in fact a dietary supplement. *Id.* at 287.

130. “Courtesy letters” are mailed prior to the FDA taking official action and allow the manufacturer to correct the problem without legal interference. See, e.g., Courtesy Letter from Susan J. Walker, Dir., Div. of Dietary Supplement Programs, FDA, to Sara Katz, President, Herb Pharm. (Jan. 15, 2004) (regarding herbal mouthwash), <http://www.fda.gov/ohrms/dockets/dailys/04/July04/071204/071204.htm> (last visited Jan. 3, 2007).

131. Pinco & Rubin, *supra* note 104, at 384.

132. Dietary Supplement Health and Education Act § 350(c)(1)(B)(i).

133. See Onel, *supra* note 114, at 343-44. “[I]ngestion means to take into the stomach and gastrointestinal tract by means of enteral administration and not by transmucosal or sublingual absorption.” *Id.*

134. *Ten Cartons*, 72 F.3d 285.

135. *Ten Cartons*, 72 F.3d at 286; see also Pinco & Rubin, *supra* note 104, at 384.

136. See generally *Ten Cartons*, 72 F.3d 285.

137. See generally *infra* Part IV.

effect after it is absorbed in the gastrointestinal system.¹³⁸ This suggests that there is simply not enough continuity or power in DSHEA for FDA to have effective control over dietary supplements.

3. What is an Article?

Another term that has required clarification through litigation is found in sub-part three of the statutory definition of a dietary supplement.¹³⁹ Sub-part three is divided into two provisions: the first dictates what types of products are included in the definition, and the second delineates, which types of products are excluded.¹⁴⁰ Each of these sections uses the noun “article” as a placeholder for the item in question.¹⁴¹

The ambiguity of the term “article” was assessed in *Pharmanex*,¹⁴² due to a dispute over whether the term “article” refers to a component, or a finished product.¹⁴³ *Pharmanex*, a pharmaceutical company, marketed Cholestrin as a dietary supplement for maintaining a healthy cholesterol level.¹⁴⁴ The alleged dietary supplement was composed solely of traditional milled red yeast rice, which FDA argued was a natural source of mevinolin, and is chemically indistinguishable from lovastatin, the active ingredient in the prescription drug Mevacor.¹⁴⁵ As a result, FDA advised *Pharmanex* that it considered Cholestrin to be a drug and therefore required pre-market approval by FDA.¹⁴⁶ FDA subsequently barred *Pharmanex* from importing red yeast rice, and *Pharmanex*, in turn, brought an action for preliminary injunction and declaratory judgment against FDA.¹⁴⁷

The case required the court to decide whether the product Cholestrin was subject to 21 U.S.C. § 321(ff)(3)(B).¹⁴⁸ FDA asserted that lovastatin itself, was an “article” approved as a new drug.¹⁴⁹ Therefore, according to 21 U.S.C. § 321(ff)(3)(b), the product would

138. See Onel, *supra* note 114, at 343-44.

139. See generally *Pharmanex v. Shalala*, 35 F. Supp. 2d 1341 (C.D. Ut. 1999) (reversed); see also *Pharmanex* 221 F.3d 1151.

140. Dietary Supplement Health and Education Act § 321(ff)(3).

141. *Id.*

142. 35 F. Supp. 2d 1341 (C.D. Ut. 1999) (reversed).

143. *Pharmanex*, 35 F. Supp. 2d at 1346-47.

144. *Id.* at 1344.

145. *Id.*

146. *Id.* at 1344-45.

147. *Id.* at 1344.

148. See generally *Pharmanex*, 35 F. Supp. 2d 1341.

149. *Id.* at 1346.

be excluded from the definition of a dietary supplement.¹⁵⁰ The court, however, agreed with *Pharmanex* and determined that “article” referred to the finished drug product only, and not a component of the product.¹⁵¹ Based on the district court’s ruling DSHEA was unable to keep *Cholestrin* from being marketed and regulated as a dietary supplement.¹⁵²

The decision, if implemented, would have two effects.¹⁵³ First, under the court’s interpretation, any slight variant to a prescription drug would circumvent the exclusionary component of DSHEA’s dietary supplement definition.¹⁵⁴ This would encourage dietary supplement manufacturers to find slight variants or alternatives to prescription drugs and undermine the prescription drug market by selling the variants or alternatives as dietary supplements.¹⁵⁵ Second, the decision “encourages manufacturers of dietary supplements to find and market ‘natural’ substances, which are the active ingredients in prescription drugs, without going through the [new drug approval] process otherwise required.”¹⁵⁶ Therefore, prescription drug manufacturers would be discouraged from going through clinical trials for fear that a dietary supplement manufacturer could market the same product at a lower cost and with less regulation.¹⁵⁷

FDA appealed, and the decision was overturned.¹⁵⁸ The Tenth Circuit Court of Appeals noted that definitions within DSHEA, including the word “article,” are often interpreted broadly.¹⁵⁹ The court therefore held that the act uses the term “article,” in 21 U.S.C. § 321(g)(1)(A)-(C), while referring to both products and their components.¹⁶⁰ The act also uses the terms “product” and “active ingredients” in other sections.¹⁶¹ The use of these other terms suggest that the drafters were aware of their word choice and

150. *Id.*

151. *Id.* at 1348.

152. *See generally Pharmanex*, 35 F. Supp. 2d 1341.

153. Robert C. 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, 571 (1999).

154. *Id.*

155. *Id.*

156. Laura A. W. Khatcheressian, *Regulation of Dietary Supplements: Five Years of DSHEA*, 54 FOOD & DRUG L.J. 623, 634 (1999).

157. *Id.*

158. *See generally Pharmanex*, 221 F.3d 1151.

159. *Id.* at 1159-60.

160. *Id.* at 1156.

161. *Id.*

therefore used the word “article” with purpose to mean both component and finished product.¹⁶²

This decision was positive for FDA and DSHEA, because it showed that DSHEA was serving its purpose to regulate dietary supplements.¹⁶³ Further, the decision became important for consumers when extended research showed that lovastatin can cause liver dysfunction and should not be used by women who are likely to become pregnant.¹⁶⁴ If lovastatin was allowed to be marketed as a dietary supplement, this information would have never reached the public given that dietary supplements require no pre-market approval.¹⁶⁵

4. Ambiguity in DSHEA has Influenced Industry Behavior

The ambiguities in DSHEA have been a source of litigation between FDA and the industry.¹⁶⁶ In addition, DSHEA regulation has affected industry behavior and the relationship between FDA and manufacturers.¹⁶⁷ Specifically, the lack of pre-market regulation has encouraged manufacturers to manipulate their products to fit within the definition of a dietary supplement.¹⁶⁸

A case on point is Johnson & Johnson’s efforts to market Benecol (a margarine that purported to lower cholesterol levels) as a dietary supplement rather than as a food or drug.¹⁶⁹ FDA made a finding that the active ingredient in the product represented an unapproved food additive and therefore required FDA pre-market approval.¹⁷⁰ Following FDA’s decision, however, FDA and Johnson & Johnson engaged in a lengthy negotiation where they compromised.¹⁷¹ The decision indicated the product would be designated as a food, not a dietary supplement, and would enjoy GRAS status (like “food”) and not subject to pre-market approval (analogous to a die-

162. *Id.*

163. Khatcheressian, *supra* note 156.

164. *Id.*

165. *Id.*

166. *See supra* Section III.A.1-3.

167. McCann, *supra* note 4, at 248.

168. This is especially true since products that are not new dietary ingredients require no pre-market evaluation. *See Ziker, supra* note 15, at 279. Indicating products will get to stay on the market until the FDA takes the affirmative step of removing them regardless of whether or not the product is in fact a dietary supplement. *Id.*

169. McCann, *supra* note 4, at 248.

170. *Id.*

171. *Id.*

tary supplement).¹⁷² It seems, the mere presence of DSHEA has given manufacturers a “certain degree of negotiating leverage” with FDA that is reducing regulatory costs outside of the dietary supplement industry.¹⁷³

B. Ambiguity in the Safety Provision of DSHEA

The concerns with the safety provisions of DSHEA are arguably based in “the essential fiction” that “because dietary supplements are considered ‘foods,’ they need not be subject to the stringent requirements for new drug approval.”¹⁷⁴ This belief has led to the statutory presumption that because a dietary supplement is a “food,” it is safe, and further, that components of food can be taken in large quantities without producing ill effects.¹⁷⁵

DSHEA explicitly removes dietary supplements from regulation as drugs, as food additives, and, interestingly, also as a conventional food.¹⁷⁶ Instead, the regulations under DSHEA are specific to dietary supplements and provide that a manufacturer must merely notify FDA and provide “some evidence” that the new dietary ingredient is “reasonably safe” seventy-five days prior to marketing the product,¹⁷⁷ with the exception that products marketed before October 15, 1994, are completely exempt from this requirement.¹⁷⁸

Once a product is on the market, FDA has three methods of regulation.¹⁷⁹ First, FDA may regulate a “grandfathered supplement,”¹⁸⁰ or other dietary supplement if it can prove that the supplement is adulterated and presents an unreasonable risk of illness

172. *Id.*

173. *Id.*

174. Cohen, *supra* note 87, at 191.

175. *See id.*; *see also* Burke & Page, *supra* note 57, at 130.

176. Foods demonstrate their safety by long-term use and presence in the market, or new foods have to prove that they are GRAS, a standard that had been tested and well understood by the FDA. *See* DSHEA § 342(f).

177. DSHEA § 350b(b).

178. These products are simply “dietary supplements” and are not subject to the regulations of a “new dietary ingredient.” *See generally* DSHEA § 350b(c). The only distinction between a new dietary ingredient, which requires pre-market approval, and “dietary supplements,” which do not require any pre-market approval, is the date of first market. *Id.* The result is that unsafe products marketed before October of 1994 will not be removed from the market until citizens are harmed by the product, while unsafe products trying to be sold after October of 1994 will be evaluated by the FDA to ensure consumer safety. *Id.*

179. *See generally* DSHEA § 342.

180. *See* DSHEA § 342. A supplement marketed before October 15, 1994, required no pre-market approval.

or injury under the conditions recommended or suggested in the labeling.¹⁸¹ Second, DSHEA provides for an emergency measure whereby the Secretary of the United States Department of Health and Human Services (HHS)¹⁸² has the authority to declare that a dietary supplement presents an imminent and substantial hazard to public safety.¹⁸³ This administrative determination results in the ban of that product from the marketplace.¹⁸⁴ Third, FDA is able to monitor supplements through Adverse Event Reports (AER), this comprises their post-market regulatory ability.¹⁸⁵ The AER system consists of voluntary reporting from industry participants, health care providers, and consumers.¹⁸⁶ The well-intentioned system, however, is less than perfect. The Inspector General¹⁸⁷ for HHS¹⁸⁸ estimates that the AER system reveals less than one percent of actual adverse reactions to dietary supplements.¹⁸⁹

At first glance, this section provides FDA with substantial discretion to take regulatory action, allowing the agency to use its judgment in determining what constitutes a significant or unreason-

181. DSHEA § 342(f)(1)(A)(i). Specifically, the dietary supplement must meet the adulteration standard under 21 U.S.C. § 342(a)(1)(YEAR?). Section 342(a)(1) states that a food is deemed adulterated “[i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.” DSHEA § 342(a)(1).

182. HHS, *Biography of Mike Leavitt: Secretary of HHS*, (Jan. 26, 2005), <http://www.hhs.gov/about/bios/dhhssec.html> (last visited Sept. 7, 2006) (stating that Michael O. Leavitt is the 20th Secretary of HHS, and as Secretary, he leads national efforts to protect the health of all Americans and provide essential human services to those in need).

183. See DSHEA § 342(f)(1)(C); see also Kaiser, *supra* note 6, at 1263 (indicating this will only happen if the secretary becomes aware of a large amount of adverse event reports).

184. Bass & Marden, *supra* note 3, at 288.

185. McCann, *supra* note 4, at 251.

186. *Id.*

187. HHS, *Office of the Inspector General (OIG), Mission*, <http://www.oig.hhs.gov/organization/OIGmission.html> (last visited Sept. 7, 2006) (stating that the OIG protects the integrity of HHS programs, and has a responsibility to report to the Secretary and to the Congress program and management problems, along with recommendations).

188. HHS, *What We Do*, (2005), at <http://www.hhs.gov/about/whatwedo.html/> (last visited Sept. 7, 2006). “The Department of Health and Human Services is the United States government’s principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.” *Id.*

189. McCann, *supra* note 4, at 251.

able risk.¹⁹⁰ If, however, FDA recognizes a problem and is inclined to remove the product, the statutory requirement is that the burden of proof must fall on FDA to show that the product is not safe or more specifically, adulterated.¹⁹¹ With the burden of proof on the government, the manufacturers are under no requirement to participate by offering adverse event reports or information on product safety.¹⁹² Further increasing FDA's burden, DSHEA lays out certain legal procedures to be followed concerning dietary supplement safety enforcement.¹⁹³ These procedures have the effect of removing some FDA power over administrative review of dietary supplements.¹⁹⁴

1. No Control: Ephedra

In 1997, FDA took its first step into the ephedra¹⁹⁵ controversy,¹⁹⁶ noting that while ephedra accounted for only one percent of dietary supplement sales it was accounting for sixty-four percent of the AERs.¹⁹⁷ FDA proceeded with proposed dosage limitations on ephedra and recommended strongly worded warnings.¹⁹⁸ Due to

190. See Bass & Marden, *supra* note 3, at 289 (arguing that the DSHEA gives the FDA substantial regulatory control); *but see* Nutraceutical v. Crawford, 364 F. Supp. 2d 1310 (D. Utah, 2005) *rev'd sub nom.* Nutraceutical Corp. v. Von Eschenbach, 459 F.3d 1033 (10th Cir. 2006) *petition for cert. filed*, 75 USWL 3368 (Jan. 3, 2007)(06-922) (holding that the FDA's use of a risk/benefit analysis was inappropriate) and *supra* note 20 and accompanying text.

191. DSHEA § 342(f)(1)(O).

192. Noah, *supra* note 24, at 150.

193. Specifically, when in court on any issue under 21 U.S.C. § 342(f)(1), such issue is to be decided *de novo* by the court rather than by deferring to the FDA interpretation. *Id.* Additionally, before the government takes action in the form of a civil proceeding concerning dietary supplements under 21 U.S.C. § 342(f)(1)(A), the adverse party must receive proper notice and an opportunity to be heard. DSHEA § 342(f)(2).

194. DSHEA § 342(f)(2).

195. Michael Sachs, *Ephedra and the Failure of Dietary Supplement Regulation*, 54 CATH. U. L. REV. 661, 662-63 (2005). "Ephedra is a plant species which has long been used for medicinal purposes." *Id.* Ephedra is a "naturally occurring chemical [stimulant] that cause[s] numerous physiological responses in the body such as increased blood pressure, heart rate, and bronchodilation." *Id.* "Today, many people purchase dietary supplements containing [ephedra] as a means to increase energy or lose weight." *Id.*

196. See *id.* at 682.

197. Ellen Relkin, *In re: Ephedra Products Liability Litigation. PCC Memorandum in Opposition to Ephedra Defendant's Motion to Preclude Plaintiff's Expert Opinion as to General Causation*, SK075 A.L.I.-A.B.A. 425, 445 (2005).

198. *Id.*

limitations in DSHEA and a lobbying against the proposed rules, however, the restrictions and warnings never became mandatory.¹⁹⁹ Over the next six years, FDA solicited comments, gathered AERs, and, hoping to strengthen its case, commissioned research studies to assess the risks versus the benefits of ephedra.²⁰⁰ The commissioned studies, however, came back with little useful information, noting inconsistent data and a low number of AERs.²⁰¹ States, concerned for their citizens, quickly recognized that the federal government was not able to regulate ephedra effectively,²⁰² and over half of the states created legislation limiting the use and sale of ephedra; three states, New York, Illinois, and California, banned the sale of ephedra.²⁰³

On February 6, 2004, FDA issued a final rule concluding that dietary supplements containing ephedra were adulterated because they presented an unreasonable risk of illness or injury.²⁰⁴ Announcing:

Government's burden of proof for 'unreasonable risk' is met when a product's risks outweigh its benefits in light of the claims and directions for use in the product's labeling or, if the labeling is silent, under ordinary conditions of use. 'Unreasonable risk' thus, represents a relative weighing of the product's known and reasonably likely risks against its known and reasonably likely benefits.²⁰⁵

This final rule, however, did not stand up in court when Nutraceutical, a dietary supplement producer, sued FDA.²⁰⁶ Nutraceutical requested that the final rule be declared invalid and FDA be enjoined from taking enforcement action against the company for its sale of certain products containing ephedra.²⁰⁷

The court never reached the issue of safety and instead focused on FDA's standard for determining "unreasonable risk."²⁰⁸ Citing

199. *Id.* See also Sachs, *supra* note 195 at 683.

200. See Sachs, *supra* note 195, at 682-84.

201. See *id.* at 683-85.

202. *Id.* at 685.

203. *Id.* at 685-87.

204. Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk, 69 Fed. Reg. 6788 (2004)[hereinafter Final Rule Ephedra].

205. *Id.* at 6822.

206. See generally *Nutraceutical v. Crawford*, 364 F. Supp. 2d 1310 (D. Utah, 2005) *rev'd sub nom.* *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033 (10th Cir. 2006) *petition for cert. filed*, 75 USWL 3368 (Jan. 3, 2007)(06-922). But see *supra* note 20 and accompanying text.

207. *Id.* at 1311.

208. *Id.* at 1313-14.

the language of DSHEA, FDA argued that the standard of proof required FDA to prove a “significant” or “unreasonable risk”.²⁰⁹ Further, FDA argued that the words “significant” and “unreasonable” have two distinct meanings.²¹⁰ The term “significant” requires an inquiry into the risk of a product alone, while the “unreasonable” standard requires a comparison of the risks and benefits.²¹¹ Moreover, “[a] risk could be significant, but reasonable if the benefits were great enough to outweigh the risks.”²¹² Further, FDA believed that in using the “significant risk” standard was unnecessary since it is included in the statute only as an alternative to the “unreasonable risk” standard.²¹³ The plaintiff’s motion for summary judgment asked the court to determine whether FDA’s risk benefit analysis was appropriate under DSHEA and whether its findings support the final rule that some ephedra products pose a “significant” or “unreasonable risk.”²¹⁴ The court held that the use of a risk-benefit analysis was not appropriate under DSHEA and therefore failed to prove the findings of the final rule, that certain ephedra products were adulterated.²¹⁵

The outcome of this case illustrates problems within DSHEA. First, DSHEA does not provide a definition of an “unreasonable risk,” forcing FDA to rely on the statutory language of FDCA.²¹⁶ Second, the lack of definition and explanation of terms such as, “unreasonable risk,” forces FDA to rely on statutes outside DSHEA and in doing so, the agency risks losing the benefit of deference in

209. *Id.* at 1314.

210. *Id.*

211. *Id.* at 1314.

212. *Nutraceutical v. Crawford*, 364 F. Supp. 2d 1310 (D. Utah, 2005) *rev’d sub nom.* *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033 (10th Cir. 2006) *petition for cert. filed*, 75 USWL 3368 (Jan. 3, 2007)(06-922) (citing Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk, 69 Fed. Reg. 6,788 (Feb. 11, 2004)).

213. *Id.*

214. *Id.* at 1316.

215. *Id.* at 1318.

216. *Id.* at 1318. The FDA refers the court to the provisions of the FDCA governing medical devices and to the Toxic Substances Control Act (TSCA). *Id.* FDCA states in part, “the requirement that risk be unreasonable contemplates a balancing of the possibility that illness or injury will occur against the benefits of use.” FDCA, 21 U.S.C. § 360c(a)(1) (1976). TSCA defines unreasonable risk as, “balancing the probabilities that harm will occur and the magnitude and severity of that harm against the effect of proposed regulatory action on the availability to society of the benefits of the substance or mixture.” Regulation of Hazardous Chemical Substances and Mixtures, 15 U.S.C. § 2605(a)(1976).

court.²¹⁷ Finally, the decision that held the balancing test inappropriate, did not offer a suggestion as to what analysis would be appropriate,²¹⁸ and while the court noted a possible problem with the exclusion of the “significant” provision from the risk assessment, it failed to rule on the matter.²¹⁹ What FDA, industry, and consumers are now faced with is an assurance of further litigation, no clear standard of how to prove “unreasonable risk,” and the precedent that FDA rulings are subject to court approval.²²⁰ The result was and still is that FDA has minimal ability to police the safety of dietary supplements.²²¹

C. Labeling

A final area of concern within DSHEA is the labeling portion because where labels on dietary supplements should be the first line of defense for consumers who are trying to find safe products, the regulation is minimal and the language is open for exploitation.²²² The section of DSHEA, titled “Statements of Nutritional Support,” involves the statements that are permissible on dietary supplement labels.²²³ This section includes three types of claims: health claims,

217. See *Id.* at 1317-18. The court applies deference to an agency when the statute is found to be ambiguous. See generally *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, (1984). A statute is found to be ambiguous if it is “capable of being understood in two or more possible senses or ways.” *Houghton ex rel. Houghton v. Reinertson*, 382 F.3d 1162, 1169 (10th Cir. 2004). (quoting *Chickasaw Nation v. United States*, 634 U.S. 84, 90 (2001)). In *Nutraceutical*, the court found that congressional intent was for the FDA to bear the burden of proof to show that a dietary supplement is adulterated and therefore, since the balancing test would require the manufacturer to offer proof of benefit, the statute is unambiguous, and the balancing test is inappropriate. *Nutraceutical*, 364 F. Supp. 2d 1310. But see *supra* note 20 and accompanying text.

218. *Nutraceutical v. Crawford*, 364 F. Supp. 2d 1310 (D. Utah, 2005) *rev'd sub nom.* *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033 (10th Cir. 2006) *petition for cert. filed*, 75 USWL 3368 (Jan. 3, 2007)(06-922) (stating that “FDA’s definition of ‘unreasonable’ entailing a risk-benefit analysis is [sic] improper”). But see *supra* note 20 and accompanying text.

219. *Id.* at 1318 (ruling only that the analysis was inappropriate).

220. See generally *id.*

221. See generally *id.*

222. Stephanie Kauflin, *Dietary Supplements: Is Availability Worth the Risks? Proposed Alternatives to the Present DSHEA Scheme*, 33 SETON HALL L. REV. 411, 422-23 (2003).

223. DSHEA § 301(m). Labeling is defined as “all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” *Id.* While, historically, FDA has interpreted this definition to include all literature in conjunction with the sale of a product, DSHEA, exempts certain types of literature and therefore has granted greater free-

structure/function claims, and nutrient content claims.²²⁴ Health claims, and their sub-category of “qualified health claims,” require some FDA approval, while nutrient content claims and structure/function claims do not require any specific approval.²²⁵ As to all types of claims, however, 21 U.S.C. § 343(r) indicates that a statement may be presented to the public if the statement claims a health benefit that is not a claim to diagnose, mitigate, treat, cure, or prevent a specific disease.²²⁶ The statements must be truthful, not misleading, and the manufacturer must have substantiation that the claim is truthful and not misleading.²²⁷ A label publishing one of these types of claims, also must include the following statement, prominently displayed in boldface type: “This statement has not been evaluated by the Food and Drug Administration.”²²⁸

Prior to enactment of DSHEA, a product was regulated based on its label’s suggested function.²²⁹ Therefore, any product that suggested that it could cure or mitigate a disease or affect the structure and function of the body, was considered a drug and required FDA approval.²³⁰ Congress, however, sought to remove dietary supplements from the regulation of drugs; therefore, DSHEA stipulates that dietary supplements are food, and structure/function claims are permissible without specific approval.²³¹

On April 29, 1998, FDA proposed, Regulations on Statements Made for Dietary Supplements Concerning the Effects of the Product on the Structure or Function of the Body.²³² The proposed regulations became the final rule, which was issued in January of 2000.²³³ The final rule prohibited disease related claims and allowed struc-

dom for the supplement industry. Kauflin, *supra* note 222, at 422-23. The specific guidelines for the labeling exemption are included in section five of DSHEA codified at DSHEA § 343-42.

224. Kauflin, *supra* note 222, at 422-23.

225. Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition (CFSAN), *Claims That Can Be Made for Conventional Foods and Dietary Supplements*, (Sept. 2003) at <http://www.cfsan.fda.gov/~dms/hclaims.html> (last visited Jan. 29, 2006).

226. DSHEA § 343(r).

227. DSHEA § 343(r).

228. DSHEA § 343(r)(6).

229. Hutt, *supra* note 52; Wais, *supra* note 8, at 852.

230. See Hutt, *supra* note 52; Wais, *supra* note 8, at 852.

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

232. Cohen, *supra* note 87, at 185.

233. 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).

ture/function claims.²³⁴ Like DSHEA legislation, the final rule neither included pertinent definitions nor did it define the permissible types of structure/function claims.²³⁵ As a result, the limits on these statements are still not clear.²³⁶

1. Structure Function Claims: A Dietary Supplement to Fix Your Abnormal Structure

Although there is no definition for a structure/function claim, the final rule issued in 2000 did attempt to clarify the structure/function claim by clearly defining the term “disease.”²³⁷ The expectation was that by implication of the “disease” definition, permissible structure/function claims would be obvious.²³⁸ The vague definition of “disease,” however, allows manufacturers to claim that their products affect the structure and function of the body without stating that they have the ability to cure disease.²³⁹ The definition specifically states, “[t]hese criteria are not intended to classify as disease claims, statements that refer to the ability of a product to maintain healthy structure or function.”²⁴⁰ Therefore, the definition of “disease” impliedly creates two categories, “disease” and “abnormal structure and function.”²⁴¹ For the layperson, it is virtually impossible to distinguish between the disease and the abnormal structure and function, and the statute fails to provide a bright line.²⁴²

As an example, arthritis is a disease caused by the inflammation of the joints and soft tissue.²⁴³ Therefore, while a dietary supplement may not claim to cure arthritis, the disease, it may claim to “maintain joint health and flexibility,” the abnormal structure and func-

234. Cohen, *supra* note 87, at 185.

235. Friede, *supra* note 231.

236. See Pinco & Rubin, *supra* note 104, at 388.

237. Food Labeling, 21 C.F.R. § 101.93(g)(1) (2005).

238. Friede, *supra* note 231, at 417.

239. “For purposes of [DSHEA § 343(r)(6)], a ‘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 dysfunction (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition.” 21 C.F.R. § 101.93(g)(1) (2005); see also Cohen, *supra* note 87, at 185.

240. Food Labeling, 21 C.F.R. § 101.93(g)(2) (2005).

241. See Cohen, *supra* note 87, at 185.

242. *Id.* at 185-86.

243. Encarta Online Encyclopedia, *Arthritis*, http://encarta.msn.com/encyclopedia_761561517/Arthritis.html (last visited Jan. 29, 2006).

tion.²⁴⁴ At issue is the prospect that the allowance of structure/function claims will encourage undesirable word phrasing to avoid the regulation required of health claims.²⁴⁵ As another example, if a supplement label claimed to “reduce the onset of cataracts” it would be a health claim, and therefore require FDA approval.²⁴⁶ Yet the same label that claims to “promote healthy vision,” will require no approval as a structure/function claim.²⁴⁷ Although the structure/function claim is clearly less specific, laypersons may easily assume the two claims represent similar therapeutic value.²⁴⁸ Allowing dietary supplements to make these kinds of claims does align with the Congressional intent to increase consumer access to dietary supplements and information.²⁴⁹ Yet, realistically, the new information is useless, since the long-term health effects of supplement use, or how supplements interact with prescription medications is not known.²⁵⁰

2. Substantiation: Believing Everything You Read

Once a claim is decidedly a structure/function claim, the only safety requirement is that a manufacturer must be able to substantiate its claim.²⁵¹ The ambiguity rests in the fact that it is not clear how much data a manufacturer needs to substantiate a structure/function claim sufficiently.²⁵² It is also unclear if the substantiation has to be product specific.²⁵³ There is no indication as to whether the substantiation of a claim for one product indicates a green light for a product that is the same consistency or substantially the same consistency to make the same claim.²⁵⁴

The “substantiate” standard actually appears twice in DSHEA: first, in the New Dietary Ingredients section and again in reference to label claims.²⁵⁵ Neither section defines the term “substantiate,”

244. Cohen, *supra* note 87, at 186.

245. See McCann, *supra* note 4, at 248.

246. *Id.* at 249.

247. *Id.*

248. *Id.*

249. Bass & Marden, *supra* note 3, at 287.

250. See Sardina, *supra* note 14, at 129.

251. DSHEA § 343(r)(6)(B).

252. Pinco & Rubin, *supra* note 104, at 393.

253. *Id.*

254. *Id.* at 394.

255. Gilhooley, *supra* note 41, at 702.

and FDA guidance on the topic is unclear.²⁵⁶ Therefore, manufacturers have again taken advantage of the vagueness of DSHEA and the substantiation requirement by the use of inconclusive preliminary results as substantiation for structure/function claims.²⁵⁷

In November of 2004, FDA announced initiatives to provide guidance to the dietary supplement industry.²⁵⁸ Among these initiatives is "draft guidance" to attempt to define the level of substantiation necessary to make a structure function claim while also maintaining "flexibility in the precise amount and type of evidence that constitutes adequate substantiation."²⁵⁹ The press release announcing the initiative indicated the FDA's hope to coordinate with FTC efforts to stamp out fraud in dietary supplement labeling.²⁶⁰ Chairman Deborah Platt Majoras added, "[t]he guidance FDA has issued today sends a clear and strong reminder to marketers that claims about the benefits of dietary supplements, wherever they appear, must be truthful and substantiated by high quality scientific evidence."²⁶¹ These are strong words; however, the proposal is only guidance and, as such, the industry is not legally obligated to follow it.²⁶² The draft guidance, though a step in the right direction, fails to draw a bright line rule for manufacturers to follow.

IV. AMENDING DSHEA: PROPOSALS ON THE FLOOR OF THE 109TH CONGRESS

DSHEA was premised on the positive role of nutrition in preventative health care and supported by the recognition that consumers want information and access to a "broad range of safe products."²⁶³ Yet, however pure the intent of the legislature, the fact re-

256. Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, 69 Fed. Reg. 64,962 (Nov. 9, 2004)[hereinafter Guidance].

257. Pinco & Halpern, *supra* note 153, at 576.

258. FDA, FDA Announces Major Initiatives for Dietary Supplements (Nov. 4, 2004), available at <http://www.fda.gov/bbs/topics/news/2004/NEW01130.html>.

259. Guidance, *supra* note 256, at 64,962.

260. Kaiser, *supra* note 6, at 1252.

261. Guidance, *supra* note 256, at 64,962.

262. See generally FDA, *Fact Sheet on FDA's Draft Guidance for Industry: Substantiation for Dietary Supplement Claims*, Nov. 4, 2004, available at <http://www.cfsan.fda.gov/~dms/dsclmfs.html>.

263. Bass & Marden, *supra* note 3, at 287.

mains that DSHEA has not reached this goal.²⁶⁴ This notion has been recognized by lawmakers since the inception of DSHEA, as each new Congressional session has witnessed an array of proposed legislation, all attempting to reconcile the shortcomings of DSHEA.²⁶⁵

At the close of the 108th Congress there were three bills left on the floor that would have affected the dietary supplement industry and FDA regulation.²⁶⁶ Now, in the 109th congress, each of the three bills has returned with a few changes.

One of the bills currently before the House of Representatives is the Dietary Supplement Access and Awareness Act.²⁶⁷ This bill would affect marketers of herbal dietary supplements by amending the law in several ways.²⁶⁸ First, it would require companies to report to the Secretary of HHS a list of their products, product labels, and at the discretion of FDA, a quantitative listing of all ingredients.²⁶⁹ Second, it would mandate submission of serious adverse event reports to FDA.²⁷⁰ Third, it would authorize the Secretary of HHS to require a manufacturer to conduct post-market research, or prove a product is not adulterated.²⁷¹

A second bill, Consumers Access to Health Information Act, would “permit the accurate label and labeling claims of the curative, mitigation, treatment and prevention effects of foods and dietary supplements on disease and health-related conditions.”²⁷² This bill changes the expansive definition of the word disease and is hoped to have a significant effect on structure/function claims.²⁷³

Finally, a third bill, DSHEA Full Implementation and Enforcement Act of 2005, proposes to ensure the goals of DSHEA are met by authorizing appropriations to fully enforce and implement DSHEA.²⁷⁴ Specifically, the proposed act will meet these goals by

264. See Sardina, *supra* note 14, at 124 (stating that “[e]ven a principal sponsor of DSHEA, Congressman Bill Richardson, admitted there was a need to reform DSHEA”).

265. See generally H.R. 4747, 108th Cong. (2003); H.R. 4760, 108th Cong. (2003); H.R. 3811, 107th Cong. (2001); H.R. 3306, 106th Cong. (1999); H.R. 4581, 105th Cong. (1998); H.R. 1951, 104th Cong. (1995).

266. H. R. 4760, 108th Cong. (2003); H.R. 4747, 108th Cong. (2003).

267. H.R. 3156, 109th Cong. (2005).

268. See *id.*

269. *Id.*

270. *Id.*

271. *Id.*

272. H.R. 2352, 109th Cong. (2005).

273. See *id.*

274. *Id.*

increasing the ability of FDA to expand the research and development of consumer information.²⁷⁵

Each of these bills, if passed, would be a step in the right direction toward implementing DSHEA in a manner that is more likely to create a market of safe dietary supplements and allow consumers to access increasing amounts of accurate information. Each bill also serves as notice that legislators are aware of DSHEA's shortcomings and its need for amendment.²⁷⁶

A. Conceding Ground: Making Changes that will have a Substantial Effect on DSHEA

The following discussion identifies concepts that should be incorporated into any future legislation that proposes to amend DSHEA. This list is not exhaustive, however, and is limited to the three sections of DSHEA discussed in this comment: definitions, safety, and labeling.²⁷⁷ In addition, the proposals are based in the reality that, to be successful, an amendment must be able to satisfy both FDA and the dietary supplement industry.²⁷⁸ These ideas intend to illustrate ways that Congress can tighten the language of DSHEA, giving FDA more regulatory power to protect Americans and still allow the dietary supplement industry to grow.²⁷⁹ These goals can be met through changes to the definition of "dietary supplement," by increasing the post-market inspection powers of FDA, and, most importantly, by shifting the burden back to the manufacturers.²⁸⁰

1. Redefining Dietary Supplements

Before all else, DSHEA should be amended by narrowing the definition of "dietary supplement."²⁸¹ The broad definition was

275. *Id.*

276. *See supra* Section IV.

277. *See infra* Section IV.A.1.

278. *See supra* Section II.

279. Schindler, *supra* note 16, at 281 ("acknowledging that approximately half of the United States population takes dietary supplements on a regular basis and knowing the potential hazards posed by dietary supplements, Congress must grant FDA more power to regulate the dietary supplement industry and safeguard the public from impending disaster").

280. *See infra* Section IV.A.1.

281. *See* Sachs, *supra* note 195, at 696-97 (arguing that amending the definition of a dietary supplement is vital, and while his comment takes a different approach and

meant to encompass as many items as possible under the umbrella of dietary supplements, so that all of the products already on the market in 1994 would be included.²⁸² Since 1994, however, the definition of “dietary supplement” has been exploited because of its breadth and overall lack of boundaries.²⁸³ In order to narrow the scope of this definition, more definitions should be included.²⁸⁴ Specifically, where the dietary supplement definition uses terms such as “dietary substance,” “ingestion,” and “article,” there should be a subsequent definition of that term provided so that all readers have a common understanding of the definition’s requirements.²⁸⁵ Dietary supplement regulation is rooted in the legal definition of “dietary supplement,” as provided by DSHEA, so most of the ambiguity-induced litigation has also stemmed from that definition.²⁸⁶ Presumably, the legislature’s purpose was to create a broad definition with an intent to create boundaries, however expansive. Those boundaries have proven too wide and narrowing the language of DSHEA will maintain its goals without increasing costs for current products.²⁸⁷

A second proposal, linked to a lack of definition and specificity, would require legislative action to create standards of substantiation.²⁸⁸ FDA has provided guidance in response to the problems and a lack of consistency with the “substantiation” standard.²⁸⁹ The issued guidance, however, is unenforceable because it is not mandatory.²⁹⁰ The lack of clarity concerning this standard is dangerous for consumers and should be resolved by including required minimum

intends to use a revised definition to exclude certain groups, it is important to note that there are many reasons that the definition should be shortened and many results that could stem from such an amendment).

282. Bass & Marden, *supra* note 3, at 294.

283. See Pinco & Rubin, *supra* note 104, at 384.

284. Onel, *supra* note 114, at 348 (arguing that the ambiguities within the dietary supplement statute have already been exploited by the industry in order to best position their products in the marketplace).

285. See generally *supra* Section III.–III.A.4.

286. *Id.*

287. Presumably, this amendment would “grandfather” all current supplements, and therefore pose no immediate costs to sellers. See generally Onel, *supra* note 114. Further, the narrowing of the language would reduce the number of new products trying to pass as dietary supplements and serve as a measure to protect consumers. *Id.*

288. Margaret Gilhooley, *Deregulation and the Administrative Role: Looking at Dietary Supplements*, 62 MONT. L. REV. 85, 128 (2001)

289. See generally Burke & Page, *supra* note 57, at 147.

290. *Id.*

standards of substantiation and examples for the industry to follow.²⁹¹

Also, within the safety provision, FDA, in order to declare a product unsafe, is required to show a significant risk through a balancing test.²⁹² The efforts of FDA throughout the ephedra controversy, however, provide evidence that this section is unclear and unenforceable as written.²⁹³ Removal of unsafe products should be a top priority of FDA and therefore, altering DSHEA so that FDA has a clear understanding of its duty to remove products is vital.²⁹⁴

2. Empowering FDA to Investigate Dangerous Supplements

Once the definition of “dietary supplement” becomes more specific, it will then be important to amend the legislation so FDA has more power to regulate the safety of products on the market and investigate those that may be unsafe.²⁹⁵ Therefore, FDA should be given more power to react once a health threat is discovered.²⁹⁶ When there is a health threat, FDA should have the ability to force an ingredient change or pull a product from the market immediately.²⁹⁷ Currently, in order for FDA to remove a product, they first must prove the product presents a significant risk and is unreasonably dangerous.²⁹⁸ A proposed change of this type would result in the

291. There are two types of substantiation in DSHEA. First, in the labeling provisions, manufacturers are required to be able to substantiate their claims, however, without standards it is unclear how much substantiation is needed, and there is no enforcement or checks on the types of substantiation being offered. *See supra* Section III.C.2; The second type of substantiation is part of adulteration requirements that, currently, FDA bears the burden of substantiating that a product bears an unreasonable risk. This standard was discussed in the ephedra litigation, but no ruling was ever made as to the appropriate level of substantiation. *See supra* Section III.B.1.

292. *See* DSHEA § 342(f)(1)(C).

293. Sachs, *supra* note 195, at 689 (stating that after a decade of investigation the FDA is still unable to answer the question of whether or not there is enough evidence to prove a “significant and unreasonable risk” of ephedra products illustrates FDA’s inability to perform the oversight function DSHEA thrusts upon it).

294. *See* Kaiser, *supra* note 6, at 1273.

295. Kauflin, *supra* note 222, at 442 (arguing that DSHEA should be amended so as to give FDA more investigatory power).

296. *See* Kaiser, *supra* note 6, at 1273 (arguing that “once a health threat becomes known, [FDA] should have wide authority to require labeling changes, ingredient changes, or total market withdrawal of the product”).

297. *Id.*

298. *See* DSHEA § 342(f)(1)(D).

faster removal of a public safety hazard and, optimistically, would create some sense of deference for FDA.²⁹⁹

Naturally, if FDA were given more power to react to a health crisis, then DSHEA should also construct a system that brings news of a health problem promptly to FDA. The current warning system to tell FDA that there is a problem consists of AER, but AERs are not mandatory for manufacturers and historically have proven to be ineffective.³⁰⁰

The first step to improving this system is to require mandatory reporting from the manufacturer.³⁰¹ The current system allows “bad actors” within the dietary supplement industry to tarnish the record of the entire industry.³⁰² By requiring AERs, however, consumers and FDA would have direct knowledge of who the “bad actors” were without passing judgment on the entire market.³⁰³ Further, mandatory AERs should be beneficial to manufacturers, as it would result in a system that allows manufacturers to show off a clean record.³⁰⁴

Additionally, to streamline the system, an AER form should be standardized.³⁰⁵ A common form would be easily accounted for and tracked by FDA to provide more precise data as to actual problems with specific products and ingredients.³⁰⁶

299. McCann, *supra* note 4, at 265-66.

300. See Kaiser, *supra* note 6, at 1263; see generally Sachs, *supra* note 175, at 698; see generally Ziker, *supra* note 15.

301. McCann, *supra* note 4, at 265-66.

302. See Ziker, *supra* note 15, at 278-79 (arguing that the failure to require adverse event reporting “does not serve to facilitate market access,” it serves to discourage market exit). Unsafe products stay on the shelf longer because consumers and FDA do not hear about the adverse reactions. *Id.* at 278.

303. Ziker, *supra* note 15, at 278.

304. *Id.* at 278. “By requiring [AERs], dietary supplement manufacturers will enjoy the privilege of market access afforded by DSHEA while earning the right to continued market presence by helping to gather product safety information derived from general consumer use.” *Id.*

305. McCann, *supra* note 4, at 264-65 (arguing for amendments that would increase communication between the dietary supplement industry, consumers, and FDA).

306. See generally *Nutraceutical v. Crawford*, 364 F. Supp. 2d 1310 (D. Utah, 2005) *rev'd sub nom.* *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033 (10th Cir. 2006) *petition for cert. filed*, 75 USWL 3368 (Jan. 3, 2007)(06-922). FDA spent three years collecting adverse event reports and was still unable to collect enough information to satisfy the burden of proof. *Id.* Streamlining AER retrieval will be a valuable tool in removing unsafe products. *Id.* But see *supra* note 20 and accompanying text.

A final addition to the safety requirements would require registration of products and product ingredients prior to marketing.³⁰⁷ Implementing a registration process would increase the amount of information FDA has about products it is supposed to regulate and allow FDA to identify problem ingredients more easily when all adverse events are reported.³⁰⁸

3. Shifting the Burden from FDA to the Industry

Many areas within DSHEA seem murky; however, the one facet of DSHEA that has remained clear is the congressional intent to increase consumer access to dietary supplements and control product safety and efficacy.³⁰⁹ The inability of FDA to remove ephedra from the market demonstrates the need for legislative reform.³¹⁰

DSHEA should be amended to focus on methods that offer the best protection for consumers.³¹¹ Specifically, the burden of proving safety of dietary supplements should rest on the industry, because, while DSHEA has given FDA discretion in deciding which supplements to challenge, its authority to remove unsafe products has been tested and has failed.³¹²

Shifting the burden of proving product safety back to the manufacturers will not be an inconvenience.³¹³ Research is not always prohibitively expensive,³¹⁴ and this should be especially true in an industry with such tremendous recent growth and consumer support.³¹⁵ In addition, most dietary supplements are simply variations on a few key compounds; once the staple compounds have been researched, the time and tests required for each marketed

307. McCann, *supra* note 4, at 264-65 (arguing that the absence of registration for dietary supplement products increases safety concerns). As it stands, FDA cannot determine ingredients for nearly one third of the supplements for which adverse events are reported. *Id.* Further, it should not impose extra material costs to the manufacturer, assuming that the “manufacturers are aware of their own products ingredients.” *Id.* at 265.

308. McCann, *supra* note 4, at 265 (stating that the dietary supplement industry would receive the benefit of a continued no pre-market approval requirement in exchange for enhanced registration and mandatory adverse event reporting).

309. Bass & Marden, *supra* note 3, at 287.

310. *See generally supra* Section III.B.1.

311. Wais *supra* note 8, at 851.

312. *Id.* at 868; *see generally Nutraconnect*, 364 F. Supp. 2d 1310. *But see supra* note 20 and accompanying text.

313. Wais, *supra* note 8, at 851.

314. *Id.* at 878.

315. *See generally Gilhooley, supra* note 41.

supplement would decline.³¹⁶ Further, manufacturers of truly safe products, such as vitamin C, would not be affected since there is already copious evidence that the ingredient is safe and beneficial.³¹⁷

Shifting the burden of proving safety back to the dietary supplement industry is the only way for Congress to remain consistent with its original purpose to protect consumers by controlling product safety.³¹⁸ Additionally, a positive side effect of shifting the burden of proving safety would be the removal of the procedural uncertainty regarding standards for what is an “unreasonable risk,” relieving DSHEA of some ambiguity.³¹⁹ Under the current regime, products with no known level of safety, but a widely known record of deleterious effects, such as ephedra, are allowed to stay on the market too long while FDA is trying to meet its ostensible burden.³²⁰ Until the industry can show that no dietary supplement on the market presents a significant or unreasonable risk, consumers will not be able to rely on dietary supplements.³²¹

V. CONCLUSION

DSHEA was created to meet the needs of our society in the early 1990s. The act delegated to the Food and Drug Administration (FDA) the needed power to regulate an industry that was growing stronger each year, and offered the dietary supplement industry needed instruction and guidance, so that it could continue to develop within the boundaries of the law.³²² The legislation was written and passed unanimously in one year, and successfully provided a framework to support the burgeoning industry.³²³ This hurried legislation, however, was unprepared for the repercussions its ambiguous language would create.³²⁴ Although DSHEA removed much of FDA’s power to regulate dietary supplements, it would not be fair to say the fight has ended. Since the enactment of DSHEA in 1994, FDA has acted with determination; and even where the agency has not been successful, the failures have become pedestals on which

316. Wais, *supra* note 8, at 878.

317. *Id.* at 851.

318. *Id.* at 878.

319. *Id.* at 879.

320. *Id.* at 851.

321. Wais, *supra* note 8, at 870.

322. *See supra* Section II.

323. Kaiser, *supra* note 6, at 1260-61.

324. *See generally* Section III.

DSHEA critics stand and pronounce that change is necessary and imminent.