THE HERBAL STREET DRUG CRISIS: AN EXAMINATION OF THE DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994

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I. Introduction

On March 6, 1996, Peter Schlendorf, a student from the State University of New York at Albany, died in Panama City Beach, Florida, while on spring break.[1] Schlendorf died from an overdose of

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[1] *See* Geoffrey Cowley, *Herbal Warning*, NEWSWEEK, May 6, 1996, at 61. Peter Schlendorf was a 20 year old junior at the State University of New York at Albany on spring break in Florida with friends. *Id.* On March 6, 1996, Schlendorf and five friends entered a "head shop called Alice s White Rabbit." Patrick Rogers et al., *Lethal But Legal. An Over the Counter High Takes the Life of a College Student*, PEOPLE, May 20, 1996, at 105. An employee of the store informed the group "about Ultimate Xphoria, an over-the-counter dietary supplement that, according to its manufacturers, boosts energy and enhances sexual sensation— the same effects attributable to the drug Ecstasy." *Id.* The group purchased 48 red pills for $50, which they subsequently took in their motel room. *Id.* Although the recommended dosage was four pills, most of the young men took twelve; Schlendorf took eight. Cowley, *supra* at 61. Later that evening, Schlendorf was not feeling well and decided to stay in the motel room while his

an herbal dietary supplement containing ephedra.[2] The product which caused Schlendorf's death is an herbal extract marketed as an alternative, legal method of obtaining a drug-like high.[3] While relatively new to the general public, tragedies like Schlendorf's are not isolated incidents. Since 1993, fifteen deaths[4] and nearly 400 adverse reactions[5] have been related to ephedra products.[6]

Ephedra, also known as ma huang, is a Chinese herb which acts on the central nervous system in the same manner as a stimulant.[7] Ephedra products, marketed as alternatives to illegal street drugs, contain labels stating that the substance will produce effects similar to illegal drugs.[8] Unfortunately, ephedra products, like the drugs they mimic, may cause a variety of adverse reactions, including death, if taken in excessive quantities.[9]

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friends went out. *Id.* When the young men returned to the motel they found Schlendorf dead. *Id.*

2 *See* Cowley, *supra* note 1, at 61-62. Ephedra may be stated as "ma huang, Chinese ephedra, ma huang extract, ephedra, Ephedra sinca, ephedra extract, ephedra herb powder, epitonin or ephedrine [ ] when listed as an ingredient in a dietary supplement." *Id.*

3 *See supra* note 1.

4 *See* Clifford Krauss, *Pataki Outlaws Herbal Stimulant Linked to Deaths*, N.Y. TIMES, May 24, 1996, at B1. *See e.g.* Laurie Loscocco, *Parents Mourn Son, Warn Young Athletes*, THE COLUMBUS DISPATCH, July 22, 1984, at 1A. Carl Richardson, an Ohio high school student, also died as a result of an ephedrine overdose on January 7, 1994. *Id.* In order to augment his weight training, Richardson had purchased a substance containing ephedra from a student at the high school he attended. *Id.* He was attempting to increase his strength to improve his performance as a high school football player. *Id.*

5 *See* Krauss, *supra* note 4, at B1. *See e.g.* Marian Burros, *Eating Well*, N.Y. TIMES, July 14, 1993, at C4. A bank branch-manager in Redmond, Washington experienced ephedra poisoning after taking a product named Lite and Rite Formula No. 1. *Id.* The bank manager "had not slept for more than an hour on each of the previous 10 nights and had been acting so irrationally . . . that he had been locked out of his office." *Id.* The primary ingredient of the product, which was recommended to him by a friend at his health club, was identified as ephedra. *Id.*

6 *See* Krauss, *supra* note 4, at B1.

7 *See* Statement on Street Drugs Containing Botanical Ephedrine, Food and Drug Administration (Apr. 10, 1996) [hereinafter *FDA Statement*]. Ephedra is a Chinese herb which acts on the central nervous system of the human body in the same manner as the "stimulant ephedrine, which can act on the body like methamphetamine, commonly known as speed." *F.D.A. Says Use of Legal Highs is Dangerous*, N.Y. TIMES, Apr. 11, 1996, at A22.

8 *See FDA Statement*, *supra* note 7. The ephedra products which are marketed as an alternative to street drugs are produced under various names containing labels that imply effects such as "euphoria, increased sexual sensations, heightened awareness, increased energy, and other effects." *Id.*

9 *See FDA Statement*, *supra* note 7. These adverse reactions range from clinically significant effects including death, heart attack, psychosis, stroke and seizures, to ef-

Despite these adverse effects, ephedra is marketed in a variety of different ways.[10] In addition to being marketed as an alternative to illegal drugs, ephedra is also utilized in weight loss products[11] and bodybuilding supplements.[12] Ephedra may also be found in over-the-counter asthma and cold medications.[13] However, it is the marketing of ephedra as an alternative to street drugs that has produced a public outcry for regulation.[14]

To fully understand the ephedra crisis, it is necessary to examine the act which many critics claim have made the marketing of ephedra as a street drug possible: the Dietary Supplement Health and Education Act of 1994 ("DSHEA").[15] DSHEA was enacted to combat the belief by dietary supplement manufacturers' that the

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fects which are clinically less significant, that may be indicative of the potential for serious problems (i.e., dizziness, gastrointestinal distress, headache, heart palpitations and irregular heartbeat). *Id.*

10 *See infra* notes 11-13.

11 *See* Marian Burros, *Eating Well*, N.Y. TIMES, June 16, 1993, at C8. Marian Burros, a writer for the New York Times, related how two of her office colleagues went on mail order herbal diets. *Id.* The two women began to utilize the pills received in the mail, each noting that she lost weight and was not hungry. *Id.* One of the women stated that the pills gave her increased amounts of energy. *Id.* The following Monday, one dieter complained that the pills made her anxious while the other complained of stomach cramps and diarrhea. *Id.* Thereafter, both ceased use of the pills. *Id.* One of the dieters "began to suspect that one of the ingredients with the Chinese names was acting just like an amphetamine." *Id.* The pills were later determined to contain ma huang (i.e. ephedra). *Id.*

12 *See* Bruce Lambert, *New Scrutiny for Sellers of Herbal Highs*, N.Y. TIMES, Apr. 23, 1996, at B4. Twin Laboratories and Weider Nutrition Group, both of whom sell products containing ephedra, market these products for building muscle and weight reduction. *Id.* Twin Laboratories utilized ephedra in its bodybuilder products "on the theory that it helps burn off fat." Yumiko Ono, *Dose of Controversy: The Blurry Line Between Drugs, Dietary Supplements*, WALL ST.J., Aug. 8, 1995, at A6. Both Twin Laboratories and Weider Nutrition Group, however, are critical of the marketing of ephedra as an avenue for a legal high. Lambert, *supra*, at B1. They are fearful that the public concern over ephedra products marketed as an alternative to street drugs will lead to a regulatory backlash jeopardizing legitimate products and consumers. *Id.*

Nonetheless, muscle building formulas are not without their problems. A police sergeant from Miami, Florida was 28 and in good health when he began utilizing a sports-training formula containing ephedra. Cowley, *supra* note 1, at 63. After using the tablets daily for several months, the police officer suffered a stroke. *Id.* As a result of the stroke, the officer claims he suffered permanent brain damage. *Id.* He subsequently instituted suit against the manufacturer and distributor. *Id.*

13 *See* Lambert, *supra* note 12, at B4. Ephedra also appears in nonprescription allergy, cold and asthma drugs, like Primatene and Sudafed, which have yet to be focused on in the debate concerning the problems with ephedra. *Id.*

14 *See generally infra* notes 133-141.

15 *See* Pub. L. No. 130-417, 108 Stat. 432 (1994).

Food and Drug Administration ("FDA") was overregulating the industry.[16] One aspect of DSHEA places the burden of proof on the FDA in an action to remove a dietary supplement from the market.[17] This burden of proof made it possible to market these types of ephedra products.

This note will examine the regulations existing prior to the enactment of DSHEA.[18] This note will also examine the lobbying efforts of dietary supplement manufacturers,[19] and will examine the explicit provisions of DSHEA.[20] In addition, this note will discuss both the States' reactions to the effect of DSHEA on herbal drugs[21] and the amendment to Federal Food, Drug and Cosmetic Act ("FDCA") proposed in the Senate to cure the problems caused by DSHEA.[22] Finally, this note will conclude with an examination of whether the actions taken in response to the herbal drug crisis will undermine the strength of DSHEA.[23]

II. History

Since the early 1990's, ephedra had been marketed in bars as an alternative to alcoholic beverages.[24] Increasingly popular among the younger crowd, trendy nightclubs in major cities within the United States began offering beverages known as "smart drinks" as an alternative to their alcoholic fare.[25] Composed of ephedra and natural ingredients, the club owners used the bever-

16 *See infra notes* 82-86 and accompanying text.

17 *See infra note* 115 and accompanying text.

18 *See infra* part III.

19 *See infra* part IV(A).

20 *See infra* part IV(B).

21 *See infra* part V(B).

22 *See infra* part V(C).

23 *See infra* part VI.

24 *See* Elizabeth Snead, *A Toast to Good Memory*, USA TODAY, Sept. 26, 1991, at 4D.

25 *See Id.* at 4D. The author notes that "[e]veryone who wants to be anyone is sipping 'smart drinks': the fashionable '90s refreshment now served in hip West Coast nightclubs." *Id.* at 4D. The drinks, with names like Body Batch, Mind Mix, Energy Elicksure and Psuper Psonic Tonic, were nothing more than "[j]uices with nutrients that enthusiasts say increase aptitude, awareness, energy and [ ] memory." *Id.* at 4D. The article notes the popularity of such beverages at nightclubs in San Francisco. *Id.* at 4D. *See also* Susan Kuczka, *Brain Grub Feeds New Smart Fad*, CHI.TRIB., Feb. 10, 1992, at D1 (noting that the popularity of smart drinks in Chicago has yet to reach the level of San Francisco), and Jane Weaver, *In Manhattan, Smart Bars Within Bars*, N.Y. TIMES, June 10, 1992, at C8 (noting the popularity of smart drinks in New York City).

ages' wholesome image to obtain profitable returns.[26] This club atmosphere spawned the numerous ephedra based products,[27] and the marketing of the drug as an alternative to the street drug ecstacy.[28]

In order to fully understand DSHEA, it is necessary to examine the events leading to its enactment.[29] Congress passed the Nutrition Labeling and Education Act of 1990 ("NLEA"),[30] which created a conflict between the FDA and the dietary supplement manufacturers.[31] As a result, the Dietary Supplement Act of 1992 ("DSA") placed a one year moratorium on the enforcement of NLEA.[32] A grass roots lobbying effort begun by the dietary supplement manufacturers provided the impetus for the moratorium.[33] Later attempts to extend the period of the moratorium were unsuccessful.[34]

This intense grass roots lobbying effort eventually led to the passage of the Dietary Supplement Health and Education Act of 1994 ("DSHEA").[35] DSHEA, which amended FDCA,[36] created a

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26 *See* Jane Weaver, *supra* note 25, at C8. The beverages known as smart drinks "are alcohol-free beverages made from vitamins and minerals, which adherents say boost energy, detox the body, aid in weight loss and raise intelligence." *Id.* These beverages were welcomed by the owners of the nightclubs because of their high mark up and potential for profitability. Snead, *supra* note 24, at 4D. One such smart drink, Energy Elicksure, contains ephedra. Weaver, *supra* note 26, at C8. "It comes in powdered form and is served mixed with fruit juice or seltzer." *Id.* at C8.

27 *See* Marian Burros et al., *Concern Grows Over Drug That Promises Legal High*, N.Y. TIMES, Apr. 10, 1996, at C1. Ephedra is marketed under such names as "Herbal Ecstacy, Cloud 9 and Ultimate Xphoria by small companies that have boldly marketed it as a legal high . . . ." *Id.*

28 *See* Kendall Hamilton et al., *'We're Squeaky Clean'*, NEWSWEEK, May 6, 1996, at 64. Sean Shayan, CEO of Global World Media Corporation (makers of Herbal Ecstacy), claims that he noticed "club hoppers [in Los Angeles, California nightclubs] were fueling all-night dancefests with the designer drug Ecstacy . . . ." *Id.* He and several friend realized the market for "an alternative product like [Ecstacy] which was safe, legal and natural . . . ." *Id. See FDA Statement*, *supra* note 7 (stating "'Ecstacy' is the street name for MDMA (4-methyl-2, dimethoxyamphetamine), which produces euphoria.").

29 *See infra* notes 68-97 and accompanying text.

30 *See* Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353. (1990). Under NLEA the Secretary of Health and Human Services was to promulgate regulations regarding the labeling of food. *Id.*

31 *See infra* notes 72-91.

32 *See* Dietary Supplement Act of 1992, Pub. L. No. 102-571, 106 Stat. 4500 (1992).

33 *See infra* notes 80-91.

34 *See infra* notes 95-97.

35 *See* Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417,

new set of standards for dietary supplements.[37] Containing numerous provisions, including the modification of the labeling requirement for dietary supplements,[38] DSHEA placed the burden of proof on the FDA in an action against a dietary supplement manufacturer. This aspect of DSHEA was the most detrimental to the FDA.[39] Although the FDA had reviewed the safety of ephedra products,[40] the FDA had only once released a public statement directed at the maker of an ephedra product since the promulgation of the DSHEA and the death of Peter Schlendorf.[41]

III. Federal Food, Drug and Cosmetic Act.

In 1994, the Dietary Supplement Health and Education Act

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108 Stat. 4325 (1994). DSHEA enacted "sections 343-3 and 350b of [title 21] and section 287c-11 of Title 42, The Public Health and Welfare, amend[ed] sections 321, 331, 342, 343, and 350 of [Title 21] and section 281 of Title 42, and enact[ed] provisions set out as notes under sections 321 and 343 of [Title 21]." 21 U.S.C. § 301 (1994) (Note). *See infra* section IV(B). *See also* Anthony L. Young, Esq. et al., *The Dietary Supplement Health and Education Act*, 50 Food & Drug LJ. 285 (1995).

36 *See* 21 U.S.C. § 301 et seq. (1994).

37 *See* Stephen F. McNamara, Esq., *Dietary Supplements of Botanicals and Other Substances: A New Era of Regulation*, 50 Food & Drug L.J. 341 (1995).

38 Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994). DSHEA also contained provisions regarding: claims permissible by dietary supplements, statements of nutritional support, dietary supplement ingredient labeling and nutritional information labeling, new dietary ingredients, good manufacturing processes, the commission on dietary supplement labels, and the office of dietary supplements. *Id.*

39 *See* Cowley, *supra* note 1, at 63.

40 *See* Cowley, *supra* note 1, at 68. In the fall of 1995, an advisory committee determined:

> after reviewing the safety of ephedrine . . . suggested mandatory warning labels for products like Ultimate Xphoria and Herbal Ecstacy - labels describing side effects, drug interactions and the risk of overdose. The agency has done nothing about that recommendation because, says a spokesman, the committee wasn't specific about how the label should be worded.

Cowley, *supra* note 1, at 68.

41 FDA warns consumers against Nature's Nutrition Formula One, Food and Drug Administration (Feb. 28, 1995). The FDA warned that Nature's Nutrition Formula One posed serious health threats due to the combination of ma huang [ephedra] and kola nut in the product. *Id.* The warning was issued to protect the health of the public because the manufacturer has failed to recall the products in accordance with the wishes of the FDA. *Id.* The company thereafter began production of a new reformulated product. *Id.* The statement does however, note that "[t]he agency is containing to evaluate the safety of ephedrine-containing products produced by Alliance U.S.A. and other companies." *Id.*

was passed as an amendment to the Federal Food, Drug and Cosmetic Act ("FDCA").[42] FDCA was enacted in 1938 and contains separate subchapters for the regulation of food,[43] drugs[44], devices[45] and cosmetics.[46] Under FDCA, dietary supplements can be categorized as a drug, a food or a food additive.[47] The categorization of a

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[42] *See* 21 U.S.C. § 301 et seq. (1994). FDCA was enacted in response to "the United States Department of Agriculture's Bureau of Chemistry['s] acknowledg[ment of] the proliferation of misleading product label claims and economic adulteration." Roseann B. Termini, *Product Classification Under The Federal Food Drug and Cosmetic Act: When a Food Becomes a Drug*, 2 J. Pharmacy & Law 1 (1993).

[43] *See* 21 U.S.C. § 321(f) (1990). Under FDCA, food is defined as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." *Id.*

[44] *See* 21 U.S.C. § 321(g)(1) (1994). Under FDCA, a drug is defined as:

> (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for the use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph.

Id.

[45] *See* 21 U.S.C. § 321(h) (1993). Under FDCA, a device is defined as:

> (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c) and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—
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> (1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
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> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
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> (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Id.

[46] *See* 21 U.S.C. § 321(i) (1938). Under FDCA, a cosmetic is defined as:

> (1) articles intended to be rubbed, poured or sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for such use as a component if such articles; except that such term shall not include soap.

Id.

[47] *See* 21 U.S.C. § 321(s) (1968). Under FDCA, a food additive is defined as:

> any substance the intended use of which results or may reasonably be ex-

substance is important in many aspects because ultimately it will prescribe the substance's accessibility to the general consumer.

Under FDCA, supplements which are categorized as foods are not subject to any pre-market approval process.[48] Therefore, in order to remove a food from the market, the FDA must show that the food is adulterated or misbranded.[49] Specifically, FDCA prohibits the introduction of any adulterated or misbranded food or drug into interstate commerce.[50] A food is considered adulterated if it meets one of the criteria under section 402 (also codified in 21 U.S.C. § 342) of FDCA.[51] Likewise, a food is considered mis-

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pected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, and having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

(1) a pesticide chemical in or on a raw agricultural commodity; or

(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958 pursuant to this chapter, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907, as amended and extended; or

(5) a new animal drug.

Id.

[48] *See* Roseann B. Termini, *supra* note 44, 2 J. PHARMACY & LAW 1, 3 (1993). Food additives are treated differently from food under 21 U.S.C. § 348 (1984) (the section regarding food additives). *Id.*

[49] *See infra* notes 50-52.

[50] *See* 21 U.S.C. § 331 (1994). The section specifically provides:

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

21 U.S.C. §331(a), (b), (c) (1938).

[51] *See* 21 U.S.C. § 342 (1993). Under subsection (a), a food will be considered

branded if it meets one of the criteria in section 403 (also codified in 21 U.S.C. § 343) of FDCA.[52]

If categorized as a new drug[53] under the FDCA, the manufacturers of supplements would be required to obtain FDA approval for their products prior to marketing.[54] Section 505 of FDCA (also codified in 21 U.S.C. § 355), provides the framework for obtaining approval for a new drug, which includes, *inter alia*, a notice period and expedition of hearings.[55] Therefore, any supplement catego-

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adulterated if it contains poisonous, insanitary, or ingredients of similar contamination. 21 U.S.C. § 342(a) (1993). Under subsection (b), a food will be adulterated:

> if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packaged therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

21 U.S.C. § 342(b) (1938). Subsection (c), relates to adulteration of color additives. 21 U.S.C. § 342(c) (1993). Subsection (d), regards the adulteration of "[c]onfectionary containing alcohol or nonnutritive substance." 21 U.S.C. § 342(d) (1993). Finally, subsection (e) refers to the adulteration of "[o]leomargarine containing filthy, putrid, etc. matter." 21 U.S.C. § 342(e) (1950).

[52] See 21 U.S.C. § 343 (1994) (containing the conditions under which a food will be considered under FDCA).

[53] 21 U.S.C. § 321(p) (1968). Under this section a new drug is defined as:

> (1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under conditions prescribed, recommended, or suggested in the labeling thereof, except that such drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or
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> (2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine if safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

Id.

[54] *See* 21 U.S.C. § 355 (1993). Under 21 U.S.C. § 355(a): "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug." 21 U.S.C. § 355(a) (1984).

[55] *See* 21 U.S.C. § 355 (1993). Sub-section (b) provides the requirements for the application filed with the Secretary. 21 U.S.C. § 355(b) (1984). Sub-section (c) dictates the requisite period for the approval of an application, in addition to the period

rized as a drug may be removed from the market if it does not obtain FDA approval prior to marketing.[56]

Unlike foods, products categorized as food additives will be deemed unsafe unless they fail to meet one of the criteria under FDCA.[57] One exception allows the Secretary of Health and Human Services to provide for the excepting of certain food additives from regulation if they are utilized for investigational purposes by qualified experts.[58] An additional exception is provided for food additives used in conformity with a regulation providing conditions under which it may safely be used.[59] The manufacturer of a food additive bears the burden of showing that the additive meets the standard: that the additive is "Generally Recognized As

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for notice and expedition of hearings, and the period required for the issuance of an order by the Secretary. 21 U.S.C. § 355(c) (1984). Sub-section (d) provides the reasons for refusing an application. 21 U.S.C. § 355(d) (1984). Sub-sections (h) states the procedure for appealing "an order of the Secretary refusing or withdrawing the approval of an application." 21 U.S.C. § 355(h) (1964). An additional procedure for filing an abbreviated new drug application is given under sub-section j. 21 U.S.C. § 355(j) (1993).

56 *See* 21 U.S.C. § 355 (1993).

57 *See* 21 U.S.C. § 348 (1984). Under this section:

> (a) [a] food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2)(C) of section 342(a) of this title unless—
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> (1) it and its use or intended use conform to the terms of an exception which is in effect pursuant to subsection (i) of this section; or
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> (2) there is in effect, and it and its use or intended use are in conformity with, a regulation under this section prescribing the conditions under which such additive may be safely used.
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> While such a regulation relating to a food additive is in effect, a food shall not, by reason bearing or containing such an additive in accordance with the regulation be considered adulterated within the meaning of clause (1) of section 342(a) of this title.

21 U.S.C. § 348(a) (1938). Subsections (b) - (h) provide the statutory ability to petition the Secretary for a regulation stating conditions under which the food additive may be safely used. 21 U.S.C. § 348(b)-(h) (1984). An exception for investigational purposes is provided for under subsection (i):

> (i) Without regard to subsections (b) to (h), inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

21 U.S.C. § 348(i) (1938).

58 *See* 21 U.S.C. § 348 (1984). *See generally supra* note 57.

59 *See* 21 U.S.C. § 348 (1984). *See generally supra* note 57.

Safe" ("GRAS").[60]

In an effort to regulate dietary supplements, the FDA often asserts that products are food additives, thereby forcing the manufacturers to meet the higher standard of GRAS.[61] In one such action, the FDA attempted to regulate black currant oil ("BCO"), also a dietary supplement, by asserting that it was an additive because it was contained in gelatin capsules.[62] Two different federal courts, the seventh circuit in *United States v. Two Plastic Drums-Viponte Ltd. Black Currant Oil-Traco Labs Inc.*[63] and the first circuit in *United States v. 29 Cartons of * * * an Article of Food, etc,*[64] found that

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60 *See* United States v. 29 Cartons of *** an article of food, etc., 987 F.2d 33, 35-36 (1st Cir. 1993). In *29 Cartons* the court provided the conditions under which a food additive is considered unsafe, stating: "any substance that meets the Act's definition of 'food additive' is presumed to be 'unsafe' under 21 U.S.C. § 348 until the FDA, or more particularly, the Commissioner of Food and Drugs, has promulgated a regulation prescribing conditions assuring safe use." 29 Cartons, 987 F.2d at 35.

61 *See* Stephen Barrett, *Assault on FDA Continues: Food and Drug Administration's Powers of Regulation of the Health Food Industry*, NUTRITION FORUM, May 1993, at 21. "The FDA . . . attempted to regulate nonvitamin 'supplement' products, such as evening primrose, black currant oil, coenzyme Q10, and germanium, on the grounds that they are unapproved food additives. Courts have upheld this theory in some cases but rejected it in others." *Id.*

62 *See* S. REP. 103-410, 103RD Cong., 2ND Sess., (1994). The report states that FDA has stated to Congress that it is merely attempting to apply the law to the producers of dietary supplements. *Id.* However, the report recognizes that in the cases of United States v. Two Plastic Drums-Viponte Ltd. Black Currant Oil-Traco Labs Inc., 984 F.2d 814 (7th Cir. 1993) and United States v. 29 Cartons of-an Article of Food-Oakmont Investment Co., 987 F.2d 33 (1st Cir. 1993), "the FDA has been distorting the law . . . to try to prevent the marketing of safe dietary supplement substances." *Id.*

63 *See* United States v. Two Plastic Drums-Viponte Ltd. Black Currant Oil-Traco Labs Inc., 984 F.2d 814 (7th Cir. 1993). The seventh circuit was forced to determine whether BCO was a food or a food additive under FDCA. *Id.* The Court began by reviewing the definition of food additive under FDCA. *Id.* at 817. The argument made by the FDA was "that the statutory language clearly indicates that any and every component of an article of food is a food additive." *Id.* The FDA's reading of the definition of food additive would result in a substance meeting the definition "if it (1) is a component of any food, or (2) affects the characteristics of a food." *Id.* The court noted that deference is usually given to the FDA in interpretations of FDCA, however, in this instance, "deference [ ] is unwarranted since its interpretation is contrary to the language and intent of the [FDCA]." *Id.* The Court instead found that the phrase "or otherwise" in the definition of food additive should be read to mean "or similarly". *Id.* This would rule out the disjunctive reading of the definition proposed by the FDA. *Id.* The Court noted that "to hold BCO as a component of the dietary supplement would be to find that BCO is a component of itself." *Id.* The Court ultimately held "that BCO encapsulated with glycerin and gelatin is not a food additive." *Id.* at 820.

64 *See* United States v. 29 Cartons of * * * an Article of Food, etc., 987 F.2d 33 (1st Cir. 1993). In this case the FDA, as in *Two Plastic Drums*, attempted to seize a quantity

this assertion was flawed.[65] Both the first circuit and seventh circuit found that a substance must affect the characteristics of a food to meet the definition of food additive.[66] These courts determined that the BCO was not a food additive under FDCA.[67]

IV. Legislative History.

A. *Lobbying Effort By Supplement Manufacturers*

In the late 1980's, following a controversy over L-tryptophan,[68] an amino acid, FDA began to aggressively take action against foods whose labeling boasted unsubstantiated health benefits.[69] Manu-

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of BCO "alleging that BCO is a food additive of questionable safety." *Id.* at 34. The Court reviewed FDCA provisions regarding foods and food additives. *Id.* at 35. By classifying BCO as a food additive the FDA sought to take advantage of the provisions of FDCA regarding food additives. *Id.* If BCO was classified as a food, under FDCA, "the FDA [could] prevent sale . . . only if it proves by a preponderance of the evidence that the food is 'injurious to the health' 21 U.S.C. § 342(a)(1) . . . ." *Id.* As a food additive, "the food additives amendment allocates the burden quite differently: the FDA can prevent the sale of products containing a food additive unless and until the processor shows that the substance, when added to food, is generally recognized as safe (in the vernacular, 'GRAS')." *Id.* The FDA's argument in this case was similar to that made in *Two Plastic Drums. Id.* The Court in *29 Cartons* affirmed the lower court's ruling dismissing the FDA s action, "for substantially the same reasons elucidated in *Two Plastic Drums.*" *Id.* at 37. The court made four additional observations, before stating that "[t]he proposition that placing a single-ingredient food product into an inert capsule as a convenient method of ingestion converts that food into a food additive perverts the statutory text, undermines legislative intent, and defenestrates common sense." *Id.* at 39.

65 *See* S. REP. NO. 103-410, 103rd Cong., 2nd Sess., (1994).

66 *See supra* notes 63-64 and accompanying text.

67 *See 29 Cartons*, 987 F.2d at 39; *Two Plastic Drums*, 984 F.2d at 820.

68 *See* Donna V. Porter, *Dietary Supplementation Legislation: Background Events,* NUTRITION TODAY, Feb. 1995, at 43. The sale of L-tryptophan was banned by the FDA, in 1989, "after thousands of cases of illness and more than three dozen deaths were traced to the use of a contaminated batch of this amino acid." *Id.* "Despite ongoing research, it [was not determined] whether the symptoms were caused by the amino acid, the contaminates, or both." *Id.*

69 *See F.D.A. in Battle, supra* note 72, at B7. In 1988, the FDA seized more than 22 unsafe and falsely advertised health remedies. *Id.* This number was significantly up from the 7 seizures made in 1987. *Id.* The FDA created a special branch in order to facilitate the actions against these manufacturers. *Id.* "Most of the more than 100 health food products that the F.D.A. [ ] tried to eliminate [were] dietary supplements, minerals and vitamins that have been advertised with misleading or unsubstantiated claims for treating illness . . . ." *Id.* The F.D.A., when making a seizure, "confiscates the product at a distributor or manufacturer. . . . [However], the product may be available from other distributors." *Id.* The health food industry claimed that their substances were neither drug nor food and therefore, should be exempt from these regulations. *Id.*

facturers continued, however, to market products with misleading claims of food content throughout the late 1980's and early 1990's.[70] It was these unsubstantiated claims that prompted the FDA to begin its scrutiny of the dietary supplement industry.[71]

As a result, Congress passed the Nutritional Labeling and Education Act of 1990 ("NLEA").[72] Specifically, NLEA directed the Secretary of Health and Human Services ("Secretary") to promulgate regulations regarding nutritional labeling information.[73] NLEA enumerates specific information which must be included on the label of a product.[74] This information includes, among others, serving size, total weight, total sodium, total carbohydrates, and total protein.[75] The Secretary is also given discretion under NLEA to increase the list to include additional nutrients.[76] Additionally, under NLEA, the Secretary of Health and Human Services was required to issue regulations regarding the nutritional labeling of products.[77]

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70 *See* Bruce Silverglade, *The Nutritional Labeling Education Act—Progress to Date and Challenges for the Future*, JOURNAL OF PUBLIC POLICY AND MARKETING, Spring 1996, at 148. The impetus for NLEA were the "misleading claims for products ranging from 'light' cheesecake that had more fat and as many calories per serving as traditional cheesecake to high fiber breakfast cereals promoted as the newest miracle weapon in the fight against cancer." *Id.*

71 *See Health: F.D.A. in Battle on Health Food Frauds*, N.Y. TIMES, June 1, 1989, at B7 [hereinafter *F.D.A. in Battle*].

72 *See generally* Nutritional Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990). *See also* Porter, *supra* note 68, at 43. NLEA required that, "specific nutrient information be provided and allowed for the definition and use of nutrient content claims." *Id.* It also provided that disease-prevention claims could be made on the package of foods "where the nutrient and disease relationship was supported by significant scientific agreement based on the totality of the public available scientific literature." *Id.* The FDA was left to decide whether supplements should be treated the same as conventional foods under NLEA. *Id.*

73 *See* Pub. L. No. 101-535, 104 Stat. 2353 (1990).

74 *See* Pub. L. No. 101-535, § 2(a), 104 Stat. 2353 (1990). The section contained provisions mandating that the foods provide nutritional information regarding: serving size ("expressed in a common household measure"), total number of serving per container, total number of calories, the amount of total fat, saturated fat, sodium, total protein, total carbohydrates, complex carbohydrates, dietary fiber, sugars, and cholesterol "contained in each serving size or other unit of measure . . . ." *Id.* The Secretary was also given the discretion to add additional items to the list of required information. *Id.*

75 *See* Pub. L. No. 101-535, § 2(a), 104 Stat. 2353 (1990).

76 *See* Pub. L. No. 101-535, § 2(a), 104 Stat. 2353, 2354 (1990).

77 *See* Pub. L. No. 101-535, § 2(b), 104 Stat. 2356 (1990). The section specifically provides:

(b) REGULATIONS.—

NLEA also described circumstances under which food labeling is required with respect to the claims on the labels of foods.[78] The Secretary was also required to issue regulations concerning claims which would be permitted on the labels of food products.[79] The

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(1) The Secretary of Health and Human Services shall issue proposed regulations to implement section 403(q)of the Federal Food, Drug, and Cosmetic Act within 12 months after the date of the enactment of this Act. Not later than 24 months after the date of the enactment of this Act, the Secretary shall issue final regulations to implement the requirements of such section. Such regulations shall—

(A) require the required information to be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of total daily diet,

(B) include regulations which establish standards, in accordance with paragraph (1)(A), to define serving size or other unit of measure for food,

(C) permit the label or labeling of food to include nutrition information which is in addition to the information required by such section 403(q) and which is of the type described in subparagraph (1) or (2) of such section, and

(D) permit the nutrition information on the label or labeling of a food to remain the same or permit the information to be stated as a range even though (i) there are minor variations in the nutritional value of the food which occur in the normal course of the production or processing of the food, or (ii) the food is comprised of an assortment of similar foods which have variations in nutritional value.

(2) If the Secretary of Health and Human Services does not promulgate final regulations under paragraph (1) upon the expiration of 24 months after the date of the enactment of this Act, the proposed regulations issued in accordance with paragraph (1) shall be considered as the final regulations upon the expiration of such 24 months. There shall be promptly published in the Federal Register notice of new status of the proposed regulations.

(3) If the Secretary of Health and Human Services does not promulgate final regulations under section 403(q)(4) of the Federal Food, Drug, and Cosmetic Act upon the expiration of 6 months after the date on which the Secretary makes a finding that there has been no substantial compliance with section 403(q)(4)(C) of such Act, the proposed regulations issued in accordance with such section shall be considered as the final regulations upon the expiration of such 6 months. There shall be promptly published in the Federal Register notice of new status of the proposed regulations.

Id.

78 *See* Pub. L. No. 101-535, § 3(a), 104 Stat. 2357 (1990).

79 *See* Pub. L. No. 101-535, § 3(b), 104 Stat. 2360, 2361-62 (1990). The section, in relevant part, provides:

(b) REGULATIONS.—

(1)(A) Within 12 months of the date of the enactment of this Act, the Secretary of Health and Human Services shall issue proposed regulations to implement section 403(r) of the Federal Food, Drug and Cosmetic Act. Such regulations—

(i) shall identify claims described in section 403(r)(1)(A) of such Act which comply with section 403(r)(2) of such Act,

(ii) shall identify claims described in section 403(r)(1)(B) of such Act which comply with section 403(r)(3) of such Act,

(iii) shall, in defining terms used to characterize the level of any nutrient in food under section 403(r)(2)(A)(i) of such Act, define—

(I) free,

(II) low,

(III) light or lite,

(IV) reduced,

(V) less, and

(VI) high,

unless the Secretary finds that the use of any such term would be misleading,

(iv) shall permit statements describing the amount and percentage of nutrients in food which are not misleading and are consistent with the terms defined in section 403(r)(2)(A)(i) of such Act,

(v) shall provide that if multiple claims subject to section 403(r)(1)(A) of such Act are made on a single panel of the food label or page of a labeling brochure, a single statement may be made to satisfy section 403(r)(2)(B) of such Act,

(vi) shall determine whether claims respecting the following nutrients and diseases meet the requirements of section 403(r)(3) of such Act: Calcium and osteoporosis, dietary fiber and cancer, lipids and cardiovascular disease, lipids and cancer, sodium and hypertension, and dietary fiber and cardiovascular disease,

(vii) shall not require a person who proposes to make a claim described in section 403(r)(1)(B) of such Act which is in compliance with such regulations to secure the approval of the Secretary before making such claim,

(viii) may permit a claim described in section 403(r)(1)(A) of such Act to be made for butter,

(ix) may, in defining terms under section 403(r)(2)(A)(i), include similar terms which are commonly understood to have the same meaning, and

(x) shall establish, as required by section 403(r)(5)(D), the procedure and standard respecting the validity of claims made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances and shall determine whether claims respecting the following nutrients and diseases meet the requirements of section 403(r)(5)(D) of such Act: folic acid and neural tube defects, antioxidant vitamins and cancer, zinc and immune function in the elderly, and omega-3 fatty acids and heart disease.

applicability of NLEA to dietary supplements was left to the discretion of the Secretary.[80] The Secretary was required to issue regulations concerning health claims which created dissent among the dietary supplement manufacturers.[81]

In response to the continued effort by the FDA to regulate dietary supplements, supplement manufacturers began a grass roots lobbying campaign to fight such regulation.[82] This effort by the manufacturers took many forms, however the message was always the same: the FDA is attempting to take away your supplements and will be successful if nothing is done.[83] This message was not entirely correct.[84] The goal of the FDA was to regulate the health claims made by dietary supplements, rather than remove

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(B) Not later than 24 months after the date of the enactment of this Act, the secretary shall issue final regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act.

(2) If the Secretary does not promulgate final regulations under paragraph (1)(B) upon the expiration of 24 months after the date of the enactment of this Act, the proposed regulations issued in accordance with paragraph (1)(A) shall be considered as the final regulations upon the expiration of such 24 months. There shall be promptly published in the Federal Register notice of the new status of the proposed regulations.

Id.

80 *See* Porter, *supra* note 68, at 43.

81 *See* Marian Burros, *F.D.A. is Again Proposing to Regulate Vitamins and Supplements*, N.Y. TIMES, June 15, 1993, at A25.

82 *See* Stephen Barrett, *Assault on FDA continues: Food and Drug Administration's Powers of Regulation of the Health Food Industry*, 10 NUTRITION FORUM 21 (1993).

83 *See* Dante E.A. Ramos, *Vitamin Makers Try a Dose of Lobbying*, 25 NAT'L HEALTH J. 1879 (1993). The Nutrition Health Alliance distributed leaflets in health stores urging customers to "write to Congress today or kiss your supplements good-bye!" *Id.* Manufacturers and sellers of dietary supplements informed millions of consumers that the FDA was attempting to drive up the prices of supplements, require a doctor's prescription for their purchase, or take supplements off the shelves altogether. Alan C. Miller, *The Potent Politics of Vitamins; The Industry Has Launched a Controversial Campaign Against FDA Regulation. It's Had a Surprising Impact*, L.A. TIMES, July 2, 1994, at A24.

84 *See The 1993 Snake Oil Protection Act*, N.Y. TIMES, Oct. 5, 1993, at A26. The new regulations proposed by the FDA would not completely remove products from the market, but rather regulate the claims that the products make on their labels. *Id.* Under the new rules, products that claim to remedy baldness or male impotence may have to alter their labels. *Id.* The products themselves, however, would not be banned. *Id.* Bruce Silverglade, director of legal affairs for the Center for Science in the Public Interest, referred to this campaign by the manufacturers as "the big lie of 1993." Miller, *supra* note 83, at A25. Additionally, he noted that the consumers who appealed to Congress either had an interest in outcome or were fooled into believing that the FDA was using going to prohibit the sale of their favorite vitamins. *Id.*

the products from the market.[85]

In its efforts to combat the actions taken by the FDA, the dietary supplement industry's lobbying effort utilized various methods.[86] In early 1992, the Nutritional Health Alliance ("NHA") was formed by members of the supplement industry to oppose the FDA's regulation of dietary supplements.[87] In an attempt to press its position in Congress, the NHA hired a veteran lobbyist.[88] A national "Blackout Day" was engineered by thousands of retailers of dietary supplements.[89] A lobbying day on Capital Hill was staged

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85 *See* Mirian Shuchman & Michael Wilkes, *Good Health: The Vitamin Uprising*, N.Y. TIMES MAGAZINE, Oct. 2, 1994, at 79. Mitch Zeller, a special assistant to the deputy commissioner for policy at the F.D.A. claimed that the federal government's only aim is to enforce the provisions of NLEA by protecting the public from false health claims. *Id.*

86 *See* Miller, *supra* note 83, at A24. The article recognizes the lobbying effort of the manufacturers and citizens, stating:

> In the last year, Capitol Hill has been flooded by correspondence urging Congress to keep the government's hands off vitamins and related health products. The grass-roots campaign has been stoked by supplement manufacturers and distributors. The effort has reached millions of supplement users through a nationwide network of mail-order flyers, fax bulletins, TV spots, form letters, petitions, videos, books and other materials distributed through legislative action tables at health food stores. The target is the Food and Drug Administration, which is implementing a law restricting health claims for supplements.

Id. at A24. However, some mainstream members of the dietary supplement industry noted that the tactics were excessive and the rhetoric, overblown. *Id.* The criticized tactics include: attempting jamming FDA telephone lines and statements which compare the FDA to the Gestapo. *Id.* at A1.

87 *See* Barrett, *supra* note 87, at 21. The NHA was created to oppose increased regulation by the FDA and to oppose bills which strengthen FDA's ability to regulate the marketplace. *Id.*

88 *See* Ramos, *supra* note 83, at 1879. The Nutrition Health Alliance hired Anthony T. Podesta is former aide to Edward M. Kennedy (D-Mass.), the chairman of the Senate Labor and Human Resources Committee. *Id.* Senator Kennedy has endorsed restrictions on supplements in the past. *Id.* Podesta was hired due to his close connections with congressional Democrats and President Clinton's Administration. *Id.* Prior to the hiring of Podesta, the Alliance, which had been formed one year earlier, had utilized no outside lobbyists. *Id.*

89 *See* Michael Weisskopf, *In the Vitamin Wars, Industry Marshals an Army of Citizen Protesters*, WASHINGTON POST, Sept. 14, 1993, at A7. The Blackout Friday, held on 13 August 1993, was an endeavor to dramatize the industry's concern that the FDA might soon take many of their products off the market. Edward R. Blonz, *Calling In Claims, The Supplement Industry Prepares For Battle With the FDA. Will It Be War or Compromise?*, CHI.TRIB., Aug. 12, 1993, at 6C. On the national Blackout Day, "[p]roducts were shrouded in black crepe and put off-limits to buyers. A San Francisco chain offered customers a 20 percent discount 'if you make your voice be heard.'" Weisskopf, *supra* at A7.

by the dietary supplement manufacturers.[90] Additionally, several articles, written by Thomas H. Rawls, encouraged the numerous consumers of dietary supplements to write to Congress.[91]

Congress subsequently passed the Dietary Supplement Act of 1992 ("DSA")[92] on October 29, 1992.[93] DSA placed a one year moratorium on the regulations the FDA would issue pursuant to NLEA.[94] Two later attempts to extend the moratorium, the Dietary Supplement Regulation Moratorium Act of 1993[95] and the Dietary

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90 *See* Weisskopf, *supra* note 89, at A7. On the lobbying day, held on September 13, 1993, a group of merchants visited each office in attempt to garner support for the Hatch and Richardson bills. *Id.*

91 *See* Thomas H. Rawls, *Act Now! To Prevent Food and Drug Administration From Regulating Dietary Supplements; Editorial*, NATURAL HEALTH, Sept., 1993, at 4 [hereinafter *Act Now!*]; Rawls, *Trouble in Washington; Regulation of Dietary Supplements; Editorial*, NATURAL HEALTH, July, 1993, at 4 [hereinafter *Trouble in Washington*]. Mr. Rawls implored the reader to:

> [p]lease write to your senators and representative to express your hope that they will support this legislation. Further, please write Representative Henry A. Waxman of California and Senator Edward M. Kennedy of Massachusetts to express your support for these bills [i.e. both DSHEA introduced by Hatch and Richardson]. Messrs. Waxman and Kennedy head committees that play crucial roles in this legislation, and they need to hear it from you if the bills are to have any chance of passing.

Act Now!, *supra*, at 4. In an additional article he noted the manner in which the writer should prepare his letter: "[i]n your letter, be respectful of your representative and of the FDA. Slanging letters belittle the sender, not the recipient." *Trouble in Washington*, *supra*, at 4.

92 *See* Dietary Supplement Act of 1993, Pub. L. No. 102-571, § 210, 106 Stat. 4491 (1992).

93 *See Id.* Section 202(a)(1) of DSA provided:

> [n]otwithstanding any other provision of law and except as provided in subsection (b) and in the amendment made by paragraph (2)(A), the Secretary of Health and Human Services may not implement the Nutrition Labeling and Education Act of 1990 (Public Law 101-535; 104 Stat. 2353), or any amendment made by such Act, earlier than December 15, 1993, with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances.

Id.

94 *See* Porter, *supra* note 68, at 44. DSA, which was attached to the Prescription Drug Users Free Act, allowed Congress time to examine the issue by placing a moratorium on any change in dietary supplement labeling regulations promulgated pursuant to NLEA. *Id.* Health claims for the supplements existing at the time of the passage of DSA were allowed to remain in effect. *Id.* DSA required the FDA to develop labeling regulations for these dietary supplements by June 15, 1993, with final regulations to be published by December 15, 1993. *Id.*

95 Porter, *supra* note 68, at 45. The Dietary Supplement Regulation Moratorium Act of 1993 (S. 1762) was introduced on November 19, 1993, and would have extended the moratorium on any final regulations concerning dietary supplements is-

Supplement Access and Claims Moratorium Act of 1993,[96] were unsuccessful.[97]

In response to the growing unrest caused by the FDA's attempt to implement NLEA, Senators Orrin G. Hatch (R-Utah), Harry Reid (R-Nev.) and Frank H. Murkowski (R-Ark.) introduced the Dietary Supplement Health and Education Act of 1993 ("DSHEA") in the Senate on April 7, 1993.[98] A similar bill was introduced in the House of Representatives on the same day.[99]

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sued pursuant to NLEA until April 15, 1994. *Id.* The Senate passed the measure unanimously on November 20, 1993, but the House of Representatives did not act upon it before the end of the first session of the 103d Congress. *Id.*

96 Porter, *supra* note 68, at 45. The Dietary Supplement Access and Claims Moratorium Act of 1993 (H.R. 3650) was introduced on November 22, 1993. *Id.* The bill was intended to prevent the FDA from restricting access to supplements by mandating prescriptions or regulating dietary supplements as either drugs or food additives. *Id.* This bill would have extended the moratorium on the issuance of final regulations of health claims until June 30, 1994. *Id.* Like S. 1762, this measure was not acted upon prior to the 103d Congress went to recess at the conclusion of the first session. *Id.*

97 Porter, *supra* note 68, at 45. *See supra* notes 95-96 and accompanying text.

98 *See* 139 CONG. REC. S4577 (daily ed. Apr. 7, 1993) (statement of Sen. Hatch). Senator Hatch stated that "the purpose of [the] legislation is straightforward: To bring some much needed sanity and order to the regulation of the dietary supplement industry. . . . to establish a regulatory structure that will encourage good health through the use of nutritional supplements while, at the same time, protecting consumers from unsafe products." *Id.* Senator Hatch noted that Americans spend more than 2 billion dollars a day on health care, stating that the use of dietary supplements may be useful in the promotion of health along with the prevention of disease. *Id.* He claims this would be an inexpensive method of cutting health care costs. *Id.* Additionally, Senator Hatch recognized that the FDA for more than three decades "has tried to restrict severely the ability of the dietary supplement industry to sell and market its products and, consequently, the ability of consumers to buy them. The agency has repeatedly attempted to impose unnecessarily stringent standards that would leave many if not most supplement companies with no practical choice but to close their doors." *Id.* Finally, Senator Hatch stated that S. 784 "empowers consumers to make choices about their personal preventative health care regiments based on accurate health benefits related to particular dietary supplements. These claims will be based on either an FDA-approved claim or on a claim that accurately reflects the current state of scientific evidence concerning a dietary supplement's health benefits. The FDA will continue to have the responsibility and power to ban a supplement found to present a substantial risk to consumers." *Id.*

99 *See* 139 CONG. REC. H1894 (daily ed. Apr. 7, 1993). The bill H.R. 1709 was introduced by Representative William Richardson (D-N.M.) for himself, Rep. James Mountain Inhofe (R-Okla.), Rep. Edolphus Towns (D-N.Y.), Rep. Sherwood L. Boehlert (R-N.Y.), Rep. Steven Harvey Schiff (R-N.Y.), Rep. Martin Frost (D-Tex.), Rep. Eleanor Holmes Norton (D-D.C.), Rep. Frederick C. Boucher (D-Va.), Rep. John Andrew Boehner (D-Ohio), Rep. Collin C. Peterson (D-Minn.), Rep. Ralph M. Hall (D-Tex.), Rep. Frederick Stephen Upton (R-Mich.), and Rep. Frank J. Pallone, Jr. (D-N.J.). *Id.*

DSHEA amended FDCA provisions regarding the circumstances under which a food will be considered adulterated.[100] Although many organizations supported DSHEA,[101] various consumer protection and health organizations opposed it.[102]

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100 *See* 139 CONG. REC. S4578 (daily ed. Apr. 7, 1993). S. 784 amended section 402 of FDCA (21 U.S.C. 342) providing:

> (f) If it is a dietary supplement that contains an ingredient that is intended to be consumed for its dietary properties and-
>
> (1) the Secretary finds, after rulemaking, that the ingredient presents a substantial and unreasonable risk of illness or injury; or
>
> (2) no manufacturer of the supplement, or manufacturer of the raw material comprising the ingredient, has adequately substantiated the safety of the ingredient-
>
> (A) through evidence of a history of safe use of the ingredient (as part of any intended use prior to the use of the ingredient in such dietary supplement), and through the absence of substantial information that brings the safety of the ingredient into question;
>
> (B) by well-designed scientific studies conducted in a manner that is consistent with generally recognized scientific procedures and principles; or
>
> (C) by other appropriate means,
>
> unless-
>
> (i) the Secretary has established, in consultation with the Director of the Center for Disease Control and Prevention, the Director of the National Institutes of Health, and the National Academy of Sciences, a recommended dietary allowance, or an estimated safe and adequate dietary intake level, with respect to the ingredient;
>
> (ii) the Secretary has determined, prior to the date of enactment of this paragraph, that the ingredient has been generally recognized as safe; or
>
> (iii) the ingredient is used in conformity with a regulation relating to food additives that is described in section 409(a)(2) and is issued prior to the date of enactment of this paragraph.

139 CONG. REC. S4578 (daily ed. April 7, 1993). Senator Murkowski claimed that the Act contained several positive provisions noting that it places a burden on the manufacturers of supplements to demonstrate the safety of their products. *Id.* at S4581(statement of Sen. Murkowski).

101 *See* 139 CONG. REC. S4578 (daily ed. Apr. 7, 1993) (statement of Sen. Hatch). Senator Hatch additionally noted that the bill has the support of Citizens for Health, the National Council for Improved Health, the Council for Responsible Nutrition, the Nutritional Health Alliance, the National Nutritional Foods Association, and the Utah Natural Products Allaince. *Id.*

102 *See* Bruce Silverglade et al., *The Vitamin Wars—Marketing, Lobbying and the Consumer*, 13 JOURNAL OF PUBLIC POLICY & MARKETING 152, 154 (1994). The article notes that many consumer protection and public health organizations, including Consumer Federation of America, Consumers Union, American Association of Retired Persons, Center for Science in the Public Interest, American Cancer Society, American Heart

B. *The Dietary Supplement Health and Education Act of 1994.*

The Senate passed a version of the Dietary Supplement Health and Education Act of 1994 ("DSHEA") on August 13, 1994.[103] The House of Representatives passed the amended version of the bill on October 7, 1994,[104] and the Senate ratified it shortly after midnight on October 8, 1994.[105] Both the House of Representatives and the Senate unanimously passed the measure.[106] DSHEA was thereafter signed by President William J. Clinton on October 25, 1994.[107]

Among the Congressional findings which justified DSHEA were the magnitude of the dietary supplement industry, the link between dietary supplements and preventative health care, and the large number of citizens using dietary supplements.[108] DSHEA

Association, American College of Physicians and American Diabetic Association opposed DSHEA. *Id.*

103 *See* 140 CONG. REC. S11712 (daily ed. Aug. 13, 1994).

104 *See* Philip J. Hilts, *Bill Allowing Vitamin Claims Wins Approval*, N.Y. TIMES, Oct. 8, 1994, at 10. DSHEA ended a two-year dispute concerning vitamin labeling that pitted the FDA against lobbyists for the supplement industry. *Id.* Gerald Kessler, executive director of the Nutrition Health Alliance (a industry pro-supplement organization), "said the bill would help to keep our industry alive." *Id.* However, James O'Hara, Associate Commissioner of Food and Drugs, stated that "[w]e are concerned that some dietary supplement manufacturers will try to interpret this legislation to let them make deceptive claims. Consumers need to exercise vigilance in judging claims made for supplements." *Id.*

105 *See* Stephen H. McNamera, *Dietary Supplements of Botanicals and Other Substances: A New Era of Regulation*, 50 FOOD & DRUG L.J. 341 (1995).

106 *See id.* at 341.

107 *See* Statement by President William J. Clinton Upon Signing S. 784, 30 WEEKLY COMP. PRES. DOC. 2158 (Oct. 31, 1994). President Clinton, in his signing statement for DSHEA, recognized the Act as a compromise between government and the dietary supplement manufacturers. *Id.* He noted that "[w]ith perhaps the best of intentions agencies of government charged with protecting the food supply and the rights of consumers have paradoxically limited the information to make healthful choices in an area that means a great deal to over 100 million people." *Id.* President Clinton felt DSHEA "balances [the interests of people] with the Nation s continued interest in guaranteeing the quality and safety of foods and products available to consumers." *Id.* He concluded by recognizing the grass roots lobbying efforts which brought about DSHEA, noting "the diligence with which an unofficial army of nutritionally conscious people worked democratically to change the laws in an area deeply important to them." *Id.*

108 *See* Pub. L. No. 103-417, § 2, 108 Stat. 4325 (1994). In DSHEA, the explicit findings of Congress are as follows:

> (1) improving the health status of United States citizens ranks at the top of the national priorities of the Federal Government;
>
> (2) the importance of nutrition and the benefits of dietary supplements

to health promotion and disease prevention have been documented increasingly in scientific studies;
(3) (A) there is a link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease, osteoporosis; and (B) clinical research has shown that several chronic diseases can be prevented simply with a healthful diet, such as a diet that is low in fat, saturated fat, cholesterol, and sodium, with a high proportion of plant-based foods;
(4) healthful diets may mitigate the need for expensive medical procedures, such as coronary bypass surgery or angioplasty
(5) preventative health measures, including education, good nutrition, and appropriate use of safe nutritional supplements will limit the incidence of chronic diseases, and reduce long-term health care expenditures;
(6)(A) promotion of good health and healthy lifestyles improves and extends lives while reducing health care expenditures; and (B) reduction in health care expenditures is of paramount importance to the future of the country and the economic well-being of the country;
(7) there is a growing need for emphasis on the dissemination of information linking nutrition and long-term good health;
(8) consumers should be empowered to make choices about preventative health care programs based on data from scientific studies of health benefits related to particular dietary supplements;
(9) national surveys have revealed that almost 50 percent of the 260,000,000 American regularly consume dietary supplements of vitamins, minerals, or herbs, as a means of improving their nutrition;
(10) studies indicate that consumers are placing increased reliance on the use of nontraditional health care providers to avoid the excessive costs of traditional medical services and to obtain more holistic consideration of their needs;
(11) the United States will spend over $1,000,000,000,000 on health care in 1994, which is about 12 percent of the Gross National Product of the United States, and this amount and percentage will continue to increase unless significant efforts are undertaken to reverse the increase;
(12)(A) the nutritional supplement industry is an integral part of the economy of the United States; (B) the industry consistently projects a positive trade balance; and (C) the estimated 600 dietary supplement manufacturers in the United States produce approximately 4,000 products, with total annual sales of such products alone reaching at least $4,000,000,000;
(13) although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers;
(14) dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare; and
(15)(A) legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness; and (B) a rational Federal framework must be established to supersede the current ad hoc, patchwork regulatory policy on dietary supplements.

Id.

amended the Federal Food, Drug and Cosmetic Act ("FDCA") classifying dietary supplements[109] as a new category of food.[110] As a result of this classification, manufacturers no longer have to prove

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109 *See* Pub. L. No. 103-417, § 3, 108 Stat. 4327 (1994)(amending 21 U.S.C. § 321 (1993)). The act defines dietary supplement as follows:

> (1) [ ] a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
>
> (A) a vitamin;
>
> (B) a mineral;
>
> (C) an herb or other botanical;
>
> (D) an amino acid;
>
> (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
>
> (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);
>
> (2) means a product that—
>
> (A)(i) is intended for ingestion in a form described in section 411(c)(1)(B)(i); or (ii) complies with section 411(c)(1)(B)(ii);
>
> (B) is not represented for use as a conventional food or as a sole item of a meal or diet; and
>
> (C) is labeled as a dietary supplement; and
>
> (3) does—
>
> (A) include an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Service Health Act (42 U.S.C. 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f); and
>
> (B) not include—
>
> (i) an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), or
>
> (ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been made public,
>
> which was not before such approval, certification, licensing, or authorization, marketed as a dietary supplement or as a food unless the Secretary, in the Secretary s discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act.
>
> Except for purposes of section 201(g), a dietary supplement shall be deemed to be a food within the meaning of this Act.

Id.

110 *See* Anthony L. Young & I. Scott Bass, *The Dietary Supplement Health and Education Act*, 50 FOOD & DRUG L.J. 285 (1995). DSHEA "creates a new framework for the regulation of dietary supplements by the Secretary of the Department of Health and

a product's safety prior to its entry into the market.[111] To prevent the FDA from claiming that a dietary supplement is in fact a food additive, DSHEA amended the definition of food additive to explicitly exclude a dietary supplement.[112]

Under DSHEA, the FDA may remove a dietary supplement from the market if it can show that the product is adulterated.[113] DSHEA amended FDCA conditions under which a dietary supplement will be considered adulterated.[114] The new sections are aimed at the safety[115] and the manufacturing processes of the sup-

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Human Services and his or her other delegate, the Commissioner of Food and Drugs." *Id.*

111 *See supra* notes 48-50 and accompanying text.

112 *See* S. Rep. No. 103-410, 103RD Cong., 2ND Sess. (1994). Specifically, DSHEA amended the definition of food additive, located in section 201(s) of FDCA (21 U.S.C. 321(s)), excluding dietary supplements: "(1) by striking 'or' at the end of subparagraph (4); (2) by striking the period at the end of subparagraph (5) and inserting '; or'; and (3) by adding at the end of the following new subparagraph: '(6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.'" *Id.*

113 *See* Pub. L. No. 103-417, § 4, 108 Stat. 4328 (1994). This provision was necessitated by the actions of the FDA in the two cases concerning the status of BCO as either food or food additive. S. Rep. No. 103-410, 103rd Cong., 2nd Sess. (1994). The Labor and Human Resources Committee was "concerned that the FDA will persist in such litigation, and thereby continue to subject small manufacturers to the choice of abandoning the production and sale of lawful products, or accepting the significant financial burden of defending themselves against baseless lawsuits." *Id.* at pt. V, § 4.

114 *See* Pub. L. No. 103-417, §§ 4, 9, 108 Stat. 4328, 4332 (1994).

115 *See* Pub. L. No, 103-417, 108 Stat. 4328 (1994). DSHEA altered the burden of proof for declaring a food adulterated under section 402 (21 U.S.C. § 342) of FDCA. Specifically, DSHEA altered section 402 by adding another subsection which provided:

(f)(1) If it is a dietary supplement or contains a dietary ingredient that—

(A) presents a significant or unreasonable risk of illness or injury under—

(i) conditions of use recommended or suggested in labeling, or

(ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;

(B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;

(C) the Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of title 5, United States Code to affirm or withdraw the declaration; or

(D) is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.

plements.[116] The FDA bears the burden of proving that a dietary supplement is adulterated.[117]

In order to administer the provisions of DSHEA, Congress established a Commission on Dietary Supplement Labels within the executive branch.[118] DSHEA establishes the following: the criteria for choosing the membership of the seven person Commission;[119]

In any proceeding under this sub-paragraph, the United States shall bear the burden of proof in each element to show that a dietary supplement is adulterated. The court shall decide any issue under this paragraph on a de novo basis.

(2) Before the Secretary may report to a United States attorney a violation of paragraph (1)(A) for a civil proceeding, the person against whom such proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally, and in writing, at least 10 days before such notice, with regard to such proceeding.

Pub. L. No, 103-417, 108 Stat. 4328 (1994).

116 *See* Pub. L. No. 103-417, § 9, 4332 (1994). The section specifically provides: Section 402 (21 U.S.C. 342), as amended by section 4, is amended by adding at the end the following:

(g)(1) If is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).

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(2) The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modified after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter 5 of title 5, United States Code.

Id.

117 *See supra* note 115 and accompanying text.

118 *See* Pub. L. No. 103-417, § 12(a), 108 Stat. 4332 (1994). The section states: "(a) ESTABLISHMENT.—There shall be established as an independent agency within the executive branch a commission to be known as the Commission on Dietary Supplement Labels (hereafter in this section referred to as the 'Commission')." *Id.*

119 *See id.* at § 12(b), 108 Stat. 4333 (1994). The President will appoint the seven members of the Commission. *Id.* The expertise requirements for the members of the Commission set forth in subsection (b):

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. 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 and one of such three members shall have experience in pharmacognosy, medical botany, traditional herbal medicine, or other related

the functions of the Commission;[120] and the administrative powers of the Commission.[121] DSHEA also requires the Commission to submit a final report on their study to the President and Congress.[122]

Additionally, under DSHEA the Secretary of Health and Human Services must create an Office of Dietary Supplements within the National Institute of Health.[123] The purpose of the Office of Dietary Supplements is to study supplements and explore their role in health care.[124] DSHEA also sets forth certain duties

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sciences. Members and the staff of the Commission shall be without bias on the issue of dietary supplements.

Id.

120 *See id.* at § 12(c), 108 Stat. 4333 (1994). Under subsection (c) the Commission is to:

> conduct a study on, and provide recommendations for, the regulation of label claims and statements for dietary supplements, including the use of literature in connection with the sale of dietary supplements and procedures for the evaluation of such claims. In making such recommendations, the Commission shall evaluate how best to provide truthful, scientifically valid, and not misleading information to consumers so that such consumers may make informed and appropriate health care choices for themselves and their families.

Id.

121 *See id.* at § 12(d), 108 Stat. 4333 (1994). The powers as set forth in subsection (d) are:

> (1) HEARINGS.—The Commission may hold hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Commission considers advisable to carry out the purposes of this section.
> (2) INFORMATION FROM FEDERAL AGENCIES.—The Commission may secure directly from any Federal department or agency such information as the Commission considers necessary to carry out the provisions of this section.
> (3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

Id.

122 *See id.* at § 12(e), 108 Stat. 4333 (1994). The report is to be submitted within 24 months of the enactment of DSHEA. *Id.* It "shall contain such recommendations, including recommendations for legislation, as the Commission deems appropriate." *Id.*

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

124 *See id.* The purposes of the Office of Dietary Supplements are:

> (1) to explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care; and
> (2) to promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions.

Id.

for the Director of the Office of Dietary Supplements, including: coordinating and conducting scientific research relating to dietary supplements; compiling such information; advising on issues regarding dietary supplements; and coordinating funding for the National Institutes of Health for dietary supplement issues.[125]

V. Analysis.

A. *DSHEA Limits the FDA's Regulatory Strength.*

The lobbying efforts which brought about DSHEA have been criticized.[126] Critics recognized the problems with placing the bur-

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125 *See id.* The duties of the Director of the Office of Dietary Supplements as specifically set forth in DSHEA include:

> (1) conduct and coordinate scientific research within the National Institutes of Health relating to dietary supplements and the extent to which the use of dietary supplements can limit or reduce the risk of diseases such as heart disease, cancer, birth defects, osteoporosis, cataracts, or prostatism;
> (2) collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources or the Office of Alternative Medicine;
> (3) serve as the principal advisor to the Secretary for Health and provide advice to the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs on issues relating to dietary supplements including—
> (A) dietary intake regulations;
> (B) the safety of dietary supplements;
> (C) claims characterizing the relationship between—
> (i) dietary supplements; and
> (ii)(I) prevention of disease or other health related conditions; and
> (II) maintenance of health; and
> (D) scientific issues arising in connection with the labeling and composition of dietary supplements; and
> (4) compile a database of scientific research on dietary supplements and individual nutrients; and
> (5) coordinate funding relating to dietary supplements for the National Institutes of Health.

Id.

126 *See* Bruce A. Silverglade, *Regulating Dietary Supplement Safety Under the Dietary Supplement Health and Education Act: Brave New World or Pyrric Victory*, 51 FOOD & DRUG L.J. 319 (1996). The article notes the lobbying effort of the dietary supplement industry:

> As a result of the rhetoric, hyperbole, and misinformation, many people became concerned that the FDA was on the verge of restricting access to dietary supplements as a part of a crusade against alternative medicine. The alleged purpose of the legislation thus became to preserve the consumer's right to purchase dietary supplements, although this right was never actually in question.

Id.

den of proof on the FDA in DSHEA's regulation of dietary supplements even prior to its enactment.[127] Applying this burden, the FDA may only remove dietary supplements on an individualized basis, upon a showing that the product "presents a significant and unreasonable risk of illness."[128]

The FDA contends that this provision hinders its ability to protect the general public from unsafe dietary supplements.[129] The FDA is forced to target specific products, rather than being permitted to proceed against a class of products.[130] The FDA claims that these restrictions are responsible for their weakened reaction to the ephedra street drug crisis.[131] Advocates of the supplement industry, however, counter that DSHEA provides sufficient avenues for the regulation of harmful products.[132]

B. *The State Reactions To DSHEA.*

While Peter Schlendorf's death was only one of several occurring subsequent to the enactment of DSHEA, his death intensified

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127 *See* Silverglade, *supra* note 102, at 153 n. 5. The article notes that:

> The bills also would provide consumers with less protection against unsafe dietary supplements by eliminating the burden of proving safety, which now rests with manufacturers, and substituting a legal presumption that all supplements are safe. To remove a supplement of questionable safety from the market, the FDA would have to prove that the supplement was dangerous.

Id.

128 *See supra* note 115 and accompanying text.

129 *See FDA Statement, supra* note 7 and accompanying text.

130 *See* 142 CONG. REC. S5583 (daily ed. May 23, 1996)(Statement of Senator D'Amato) (noting that the FDA is forced to bring actions against each herbal street drug individually, because under DSHEA it may not proceed against the drugs as a class.); *F.D.A. Says Use of 'Legal Highs' is Hazardous*, N.Y. TIMES, Apr. 11, 1996, at A22 (noting that under DSHEA, the FDA may not require testing or pre-approval of dietary supplement prior to sale, however the FDA may remove a supplement if it is individually shown to be harmful.).

131 *See FDA Statement, supra* note 7 and accompanying text.

132 *See* Karyn Snyder, *Ecstatic Exit*, DRUG TOPICS, May 20, 1996, at 40. The Council for Responsible Nutrition (CRN), a body representing a number of dietary supplement manufacturers, commented on the FDA's assertion the it was powerless under FDCA as amended by DSHEA, stating:

> CRN strongly objects to the misleading assertion in FDA's statement of April 10 that the agency's hands are tied in dealing with safety issues relating to dietary supplements. FDA has full authority to regulate the safety of dietary supplements. Under DSHEA, just as under previous law, it is a criminal offense to market an unsafe dietary supplement.

Id.

public concern for regulation of the over-the-counter ephedra-based street drugs.[133] One month later, the FDA responded with a public statement warning consumers of the dangers of botanical ephedrine.[134] Additionally, several states have responded by enacting anti-ephedrine laws.[135]

Nassau County, New York, for example, quickly responded to the FDA public warning of the dangers of ephedra, by proposing a ban on the sale of dietary supplements containing the substance.[136] Prior to enactment, this measure was limited to provide for the over-the-counter sale of some ephedra products that are not used for medicinal purposes.[137]

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133 *See supra* notes 1-3 and accompanying text(talking about the death of Peter Schlendorf). Peter's death spawned intense reaction from the scientific community. *See* Marian Burros et al., *Concern Grows Over Herb That Promises A Legal High*, N.Y. TIMES, Apr. 10, 1996, at C1. The article notes that Dr. David A. Kessler, the Commissioner of the Food and Drug Administration, stated that "he planned to issue a warning about potential dangers of the herb [ephedra] . . . ." *Id.* The article additionally noted that "[a]t least 20 states have enacted or are considering laws to restrict the sale of ephedra and ephedrine . . . ." *Id.* Finally, the article notes the opinions of two professionals concerning the ephedra-herbal street drug problem. *Id.* Annette Dickenson, the director of scientific and regulatory affairs for the Council for Responsible Nutrition, claimed that "'[c]are needs to be taken that the dietary supplement act [DSHEA] is not being misused.'" *Id.* Dr. Varro Tyler, professor of pharmacognosy at Purdue University and an authority on herbal drugs contends that "'[t]he misuse or abuse of the product has increased so rapidly in the last couple of years that I now believe that products containing ephedra should be sold only by professionals who are competent to provide adequate advice.'" *Id.*

134 *See FDA Statement, supra* note 7 and accompanying text. The statement also provided consumers with a hot line for persons who suffered an adverse reaction to an ephedrine product. *Id.*

135 See *infra* notes 138-141 and accompanying text.

136 *See* Bruce Lambert, *Nassau to Ban Sale of Herbal Stimulant Linked to a Death*, N.Y. TIMES, Apr. 17, 1996, at B1 [hereinafter *Nassau to Ban Sale*]. The measure, sought by Nassau County Executive Thomas S. Gulotta, was "a blanket ban on the sale of products containing the herb ephedra . . . . The only exception would have been for medications that use ephedra as a decongestant for allergy, cold, flu and asthma." Bruce Lambert, *Nassau Enacts Weakened Ban on Herbal Stimulant*, May 14, 1996, at B1 [hereinafter *Nassau Enacts Weakened Ban*]. Under the proposed law there would be no penalty for possession of an ephedra supplement. *Nassau to Ban Sale, supra* at B1. The measure was criticized by "Steve Blechman, a vice President of Twin Laboratories in Ronkonkoma, L.I., [N.Y.,] makers of Ripped Fuel [, a supplement containing ephedra,] said: 'We don't target our drugs as an alternatives to illegal street drugs. Ours is legitimate use for weight loss. There are hundreds of papers on its effectiveness.'" *Id.*

137 *Nassau Enacts Weakened Ban, supra* note 136, at B1. Rather than enacting a total ban on ephedra products (with a medication exception), the Nassau County Legislature passed a bill which "allow[ed] the sale of ephedra-based products marketed as

Following the precedent set by Nassau County, Florida became the first state, after the death of Peter Schlendorf,[138] to ban the sale of ephedrine-based supplements.[139] New York followed by an order of the Governor banning the sale of ephedra products.[140] Other states, however, have been reluctant to regulate ephedra largely because it is safe if used as directed.[141]

C. *Proposed Amendment To DSHEA.*

In the wake of the overwhelming concern over ephedra exhibited by the States, the Senate introduced Senate Bill 1804 on May 23, 1996.[142] The purpose of the bill was to clarify what constitutes a

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weight-loss or body-building supplements." *Id.* "The modified ban covers products promoted as giving feelings of 'euphoria, increased sexual sensations, heightened awareness, increased energy, legal highs and other similar effects.'" *Id.* The law also makes it illegal to sell any ephedra product to a person under the age of 18. *Id.* The maximum penalty for a violation of the law is a fine of $1,000 and one year in jail. *Id.*

138 *See supra* note 4 and accompanying text.

139 *See* Karyn Snyder, *Ecstatic Exit: Sale of Herbal Stimulant Now Banned In Florida. Ecstasy-Like Herbal Products*, DRUG TOPICS, May 20, 1996, at 40. The article notes that Florida is the first state to ban herbal stimulants which mimic MDMA (the street drug ecstasy). *Id.* The State Agricultural Commissioner banned the sale of ephedra products utilized for mood altering purposes, leaving other ephedra supplements unaffected. *See Nassau Enacts Weakened Ban, supra* note 136, at B1. The FDA claims that it is hindered in its regulation of these herbal street drugs by DSHEA. *See* Snyder, *supra,* at 40. The Council for Responsible Nutrition rebutted this claim by pointing out that the "FDA has full authority to regulate the safety of dietary supplements. Under DSHEA, just as under previous law, it is a criminal offense to market an unsafe dietary supplement." *Id.*

140 *See* Clifford Krauss, *Pataki Outlaws Herbal Stimulant Linked to Deaths*, N.Y. TIMES, May 24, 1996, at B1. Governor George E. Pataki, pursuant to state health laws, banned the sale of "so-called Herbal Ecstacy and other herbal products containing the stimulant ephedra." *Id.* In a press conference announcing the ban, Governor Pataki stated that "[o]bviously the best solution would be a Federal role, but we can't sit back and wait for our young people to die." *Id.* The ban was criticized by Konstantine Theoharis, the executive media coordinator of Global World Media Corporation, producers of Herbal Ecstacy. *Id.* He stated that "[p]oliticans and bureaucracies usually overreact, ... We feel there is tons of misinformation out there and once we have a fair chance to represent ourselves our products will be shown to be harmless and beneficial." *Id.* Companies were given an opportunity to appeal the ban at a hearing on June 4, 1996 in Albany, New York. *Id.* Under the order, "the State Health Department [ ] issued a ban on the sale of 20 specific ephedra-based products whose marketing is aimed explicitly at people looking for a drug high or that do not include directions on appropriate dosage." *Id.* The ban does not effect the sale of over-the-counter asthma and allergy medications. *Id.* A person violating the ban could face a maximum fine if $2,000 and up to one year in prison. Id

141 *See* Krauss, *supra* note 140, at B6.

142 *See* Michael F. Conlan, *Senators Seek to Ban Products Sold as 'Herbal Highs'*, DRUG

drug. The bill provides that the FDA will treat any dietary supplement which makes claims similar to those made by the herbal street drugs as a drug.[143] The result of this classification is that supplements would be subject to premarket approval.[144] While the bill does not single out a particular herbal supplement, it does target the claims made by over-the-counter herbal street drugs.[145] No Congressional action has yet been taken on this new legislation.

VI. Conclusion

DSHEA was enacted to protect the perceived over-regulation of the dietary supplement industry by the FDA.[146] As such, DSHEA

TOPICS, June 10, 1996, at 39. The measure was introduced by Sen. Alphonse D'Amato (R-N.Y.), and cosponsored by Sens. Christopher Dodd (D-Conn.) and William Frist (R-Tenn.). *Id.* Senator D'Amato cited the "growing problem of dangerous herbal stimulants that are marketed and sold as alternatives to powerful and illegal street drugs[ ]" as the purpose of the legislation. 142 CONG. REC. S5582 (daily ed. May 23, 1996) (Statement of Sen. D'Amato). He later noted that "herbal street drugs are not legitimate dietary supplements. . . . [But rather], simply dangerous products masquerading as dietary supplements to evade Government review and sanctions." *Id.* Additionally, he recognized that DSHEA protects the herbal street drug by limiting the FDA's power to regulate them. *Id.* "[T]he FDA cannot regulate herbal street drugs as a class, but instead must take action against each product individually. Indeed, the FDA must prove that a particular formulation of an herbal street drug presents significant or unreasonable risk of illness or injury before it can take any action against the product." *Id.* He also noted that "under current law, an herbal street drug can easily evade an FDA enforcement action simply by changing the composition of its product, while continuing to make the same labeling claims for drug-like mental and psychological effects." *Id.*

143 *See* S. 1806, 104TH Cong., 2ND Sess. (1996). The bill states:

> Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(g)(1) is amended by adding at the end thereof the following sentence: Notwithstanding the preceding sentence, a dietary supplement shall be considered a drug under clause (C) if the label or labeling of such drug claims or implies that the dietary supplement produces euphoria, heightened awareness, or similar mental or psychological effects.

Id. Therefore, the bill would amend the current definition of drug to include dietary supplements which make narcotic drug-like claims. *Id.*

144 *See supra* notes 53-56 and accompanying text.

145 142 CONG. REC. S5582 (daily ed. May 23, 1996) (statement of Sen. D'Amato). Senator D'Amato states that the purpose of the bill is to "amend[ ] the Federal Food, Drug and Cosmetic Act to clarify that a dietary supplement shall be considered a drug if its label or labeling claims or implies that the dietary supplement produces euphoria, heightened awareness or similar mental or psychological effects." *Id.* The Senator did note that the "bill has been carefully drafted to maintain the public's continued access to either over-the-counter drugs, such as Sudafed, or legitimate supplements, such as herbal teas, that contain ephedra or its related products." *Id.*

146 *See supra* notes 70-97 and accompanying text.

has been successful in protecting the interests of the millions of American citizens who use dietary supplements on a daily basis. In its attempt to provide for continuous access to the supplements, however, Congress has placed the burden of proof on the FDA to show that a product presents a substantial risk of harm before it may be removed from the market.[147]

Placing the burden of proof on the FDA has had a detrimental impact on FDA's attempts to regulate the marketing of ephedra as an alternative to street drugs.[148] Under DSHEA, the FDA bears too great a burden.[149] Senate Bill 1806 would provide the FDA with the assistance necessary to manage the ephedra drug crisis.[150] By expanding the definition of a "drug" to include ephedra products marketed as alternatives to illegal street drugs, the FDA would therefore be able to provide for the health and safety of users.[151]

Until Senate Bill 1806 is passed, however, the FDA will be forced to regulate these ephedra products under FDCA, as amended by DSHEA.[152] This enables many ephedra supplement manufacturers to circumvent FDA regulation.[153] In the meantime, the FDA will have to labor diligently to protect the safety and health of the users of ephedra supplements.

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147 *See supra* note 115 and accompanying text.

148 *See supra* notes 127-32 and accompanying text.

149 *See supra* notes 127-32 and accompanying text.

150 *See supra* notes 142-45 and accompanying text.

151 *See* 142 CONG. REC. S5582 (daily ed. May 23, 1996) (statement of Sen D'Amato). Senator D'Amato stated:

> [S. 1806] amends the Federal Food, Drug and Cosmetic Act to clarify that a dietary supplement shall be considered a drug if its label or labeling claims or implies that the dietary supplement produces euphoria, heightened awareness or similar mental or psychological effects. As a result, this narrow class of dangerous products will be subject to the same premarket safety reviews as other drugs, and the FDA will have enhanced authority to take prompt and decisive action against them. Now, the FDA will be able to quickly pull these herbal street drugs . . . from stores before they kill again. This legislation is necessary to protect the health of the American public, particularly its youth, who are obviously the target of these dangerous herbal street drugs.

Id.

152 *See supra* notes 115-17 and accompanying text.

153 *See supra* note 111 and accompanying text.