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# Where There's Smoke There's Fire: The Dangers of the Unregulated Dietary Supplement Industry

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# WHERE THERE'S SMOKE THERE'S FIRE: THE DANGERS OF THE UNREGULATED DIETARY SUPPLEMENT INDUSTRY

## I. INTRODUCTION

Today, standards placed on the drug industry to assure safety[1] and efficacy[2] are very demanding. In contrast, dietary supplements, which are often diluted drugs[3] with similar benefits and dangers, have managed to elude the regulatory scrutiny of the Food and Drug Administration (FDA). Presently, when vitamins, minerals, herbs, botanicals, and amino acids (all classified as dietary supplements) reach the marketplace, they do so without established clinical proof of safety or efficacy.[4] Instead, the marketplace serves as the forum for such assessment.[5]

This note will discuss how under today's definition, what classifies a product as a drug or a dietary supplement is not necessarily what it does, but often what it claims to do.[6] Dietary supplements in many

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1. *See* Dixie Farley, *Benefit vs. Risk: How FDA Approves New Drugs*, FDA CONSUMER, Jan. 1995, at 23, 29 (discussing the definition of safety in terms of submitting test results adequate to show the drug is safe under the conditions of use in the proposed labeling and that safety is determined case by case in which the benefits of the drug must outweigh the risks).

2. *See id.* at 28 (discussing the absorption rates of generic and brand name drugs, their influence on a disease, and that efficacy is proven by substantial evidence consisting of well-controlled investigations, including human studies, which demonstrate that the drug will have the effect claimed in the labeling).

3. *See* Judith Mandelbaum-Schmid, *Natural Remedies*, SELF, Sept. 1996, at 206, 209 (explaining how some herbal medicines which are classified as dietary supplements are as potent and, arguably, as dangerous as drugs).

4. *See id.* at 209 (discussing how consumers cannot be sure of what they are buying when purchasing these supplements).

5. *See id.*

6. *See* Edgar R. Cataxinos, *Regulation of Herbal Medications in the United States: Germany Provides a Model for Reform*, 1995 UTAH L. REV. 561, 566 (discussing how an herbal medication's intended use determines its classification under a food or drug category and that the manufacturer, through labeling and advertising representations, can determine the herbal medication's use and thus influence the herbal product's respective classification by the FDA); *see also* Sheryl Gay Stolberg, *F.D.A. Warns Consumers About Herbal Weight Loss Mixtures*, N.Y. TIMES, Nov. 7, 1997, at A19 (stating that it is not illegal for a manufacturer to sell a dietary supplement like fen-phen, but it is illegal to refer to fen-phen as something that is exactly like a medication and to make medical claims like the prescription products do).

circumstances are drugs, and have been classified as such in the past.[7] They have also found themselves categorized under other, less restricted, classifications.[8] Presently, Congress resists classifying dietary supplements as drugs and specifically excludes them from the definition of a drug.[9]

Throughout the history of the drug approval process in the United States, three things are evident about the FDA: (1) its growing power to regulate the pharmaceutical industry; (2) its impotency over the supervision of the dietary supplement industry; and (3) its continuous struggle to gain more power over the dietary supplement industry.[10] Part II of this note will discuss how the approval process for drugs has evolved to meet the growing demands for product safety and efficacy. Part III addresses the history of the FDA's regulation of the dietary supplement industry, including how the FDA has progressively lost regulatory power; Congress's continual reclassification of dietary supplements, and their unwillingness to give the FDA enhanced regulatory power. Part IV examines the Dietary Supplement Health and Education Act of 1994 (DSHEA)[11] and how the American public has suffered as a result of its enactment. Part V concludes by recommending initiatives which Congress must adopt to ensure public safety with respect to the dietary supplement industry.

## II. THE HISTORY OF THE DRUG APPROVAL PROCESS IN THE UNITED STATES

Three governmental Acts have laid the foundation for the drug approval process in the United States; specifically: the Pure Food Act of 1906 (PFA);[12] the 1938 Food, Drug and Cosmetic Act (FDCA);[13] and the

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7. *See* Food, Drug and Cosmetic Act of 1938, 21 U.S.C. § 321(g)(1) (1994) [hereinafter FDCA] (discussing statute prior to its amendment which excluded dietary supplements from the definition of a drug).

8. *See id.* § 321(s) (discussing the classification of a product as a food additive).

9. *See id.* § 321(g)(1)(c) (discussing the amendment which excludes dietary supplements from the definition of a drug).

10. *See* Julie C. Relihan, *Expediting FDA Approval of AIDS Drugs: An International Approach*, 13 B.U. INT'L L.J. 229, 230, 233 (1995); *see also* Cataxinos, *supra* note 6, at 570 (discussing battles between the FDA and dietary supplement manufacturers and the unpopularity of the FDA regulations passed at that time).

11. *See* Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 [hereinafter DSHEA].

12. *See* Pure Food Act of 1906, ch. 3915, 1-13, 34 Stat. 768 (repealed 1938) [hereinafter PFA] (discussing not only food but also drug and chemical materials).

13. *See* FDCA, *supra* note 7, § 301.

Kefauver-Harris Amendments of 1962 (Kefauver).[14] With each enactment, drug manufacturers were required to conform to more sophisticated scientific regulations for safety and efficacy.[15]

While the PFA initiated drug regulation, it only demanded that the labeling of a drug be "truthful."[16] As a result, manufacturers were only required to monitor product strength, quality, and purity.[17] The PFA neither protected the public from unsafe drugs, nor fraudulent health claims. Moreover, the PFA's enactment placed the burden of proof on the FDA to show "that a drug's labeling was false and fraudulent before [the drug] could be taken off the market."[18]

In 1938, Congress, prompted by the "'Elixir Sulfanilamide' tragedy,"[19] enacted the FDCA, the first legislation to ensure the safety of products reaching the marketplace. Since the PFA did not require pre-market drug testing, Elixir Sulfanilamide entered the marketplace without the guarantee of safety, resulting in the death of over one hundred people.[20] The FDCA changed the FDA's role and had a significant impact on the future of the drug approval process. Under the FDCA, the FDA became the public health protector and was empowered to regulate the approval of drugs based on safety.[21] With this authority, the FDA could prevent a new drug from reaching the market, unless data established that the drug was "safe for use under the conditions [for which] it is prescribed, recommended, or suggested in the proposed labeling thereof."[22] As a result of the FDCA, manufacturers were required to

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14. *See* Drug Amendments of 1962 (Kefauver-Harris Amendments), Pub. L. No. 87-781, 76 Stat. 780 (1962) [hereinafter Kefauver] (presenting the specific sections of the FDCA to be changed including those dealing with safety, effectiveness, and reliability of drugs).

15. *See* Relihan, *supra* note 10, at 230, 233.

16. *See* PFA, *supra* note 12, at 768-72 (stating specifically the definitions of adulterated and misbranded drugs).

17. *See id.*

18. Farley, *supra* note 1, at 26 (discussing the Pure Food Act of 1906).

19. More than one hundred people died from using Elixir Sulfanilamide, an untested, poisonous drug formulation. The product was labeled an "elixir," which implied it was an alcohol-based solution, when it was actually a lethal diethylene solution. Under the PFA, there was no requirement of safety for a product to gain access to the market. *See id.* at 27.

20. *See id.*

21. *See* FDCA, *supra* note 7, § 355(i).

22. *Id.* § 355(d) (discussing the grounds for refusing application for the approval of a drug).

submit a New Drug Application (NDA) to obtain marketing approval.[23] Submission of an NDA is still required today.[24] The FDA would decide which drugs were safe enough to be sold and would then approve the NDA so that the product could be marketed.[25] If the FDA was unsure about the safety of the drug, it would require the manufacturer to conduct further testing on humans.[26] Prior to submitting an NDA, manufacturers were not required to obtain FDA approval to conduct human studies.[27] If the FDA did not reject the NDA within 180 days of its submission, the drug was conditionally approved.[28] The FDCA was the first step toward requiring pre-market clearance for a drug before it obtained market access. Under the FDCA, however, the FDA did not have the ability to regulate new drugs until the manufacturer sought marketing approval.[29]

Unfortunately, it took the Thalidomide drug disaster[30] to prompt the next major legislative enactment, the 1962 Kefauver-Harris Amendments (Kefauver).[31] With the passage of Kefauver, Congress mandated that manufacturers prove effectiveness for the products' intended use, and not simply product safety.[32] As a result, manufacturers were required, for the

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23. *See id.* § 355(b)(1) (discussing the definition of an NDA as a compilation of the entire history of a drug, including the results of clinical tests, how the drug is constituted, results of animal studies, the way the drug behaves in the body (metabolism and excretion), and how the drug is manufactured, processed, and packaged).

24. *See id.*

25. *See* Farley, *supra* note 1, at 28 (discussing approval process to market a drug in interstate commerce).

26. *See id.* at 29 (discussing how once an NDA is submitted it must undergo human or clinical studies to demonstrate safety).

27. *See* FDCA, *supra* note 7, § 355(c).

28. *See* FDCA, *supra* note 7, § 355(c); *see also* Relihan, *supra* note 10, at 233 (discussing the NDA approval process).

29. *See generally* FDCA, *supra* note 7 (suggesting that the format of the statute is arranged to provide for regulation only after the drug has been approved and commercially distributed).

30. *See* Kevin L. Ropp, *Med Watch: On Lookout for Medical Product Problems*, FDA CONSUMER, Jan. 1995, at 42, 43. Thalidomide was used in Western Europe during the 1950s and was not approved for use in the United States. Some American physicians, however, were able to obtain Thalidomide, and used it to conduct human studies. The FDA, through its surveillance program, became aware of Thalidomide's usage and prevented the drug from being widely used in the United States. As a result, only a few American babies were born with deformities, compared with several thousand in the Western hemisphere. *See id.* at 43.

31. *See* Kefauver, *supra* note 14, at 780.

32. *See* Farley, *supra* note 1, at 27 (discussing manufacturer's burden of proving a drug safe and effective).

first time, to conduct "adequate and well-controlled"[33] clinical investigations on humans. In addition, manufacturers were required to submit an Investigational New Drug Application (IND), requesting the FDA's permission to begin clinical testing on humans.[34]

Under the current drug approval process, before a manufacturer submits an IND to the FDA, the company spends, on average, a total of eighteen months between synthesizing a drug in its laboratory and conducting animal studies.[35] The physical and chemical properties of the drug are analyzed by researchers to determine its pharmacological and toxic effects on animals.[36] If the animal study results prove promising, the manufacturer will then submit an IND to the FDA, requesting permission to conduct further testing on humans.[37]

The FDA's review board, which is comprised of scientists, ethicists, and non-scientists, analyzes the data submitted with the IND, and if satisfied, authorizes human studies to commence.[38] Human studies (clinical trials) assess the safety and efficacy of a drug, the best dosage, and what side effects can occur.[39] Clinical trials consist of three phases. In Phase I, the drug is administered to a small group of people.[40] Testing usually lasts several months, and the objective is to determine if the drug is safe and at what dosage safety can be witnessed.[41] If no major safety problems are discovered, and the FDA's permission has been granted,

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33. *See* FDCA, *supra* note 7, § 355(d).

34. *See id.* § 355(i). The IND is submitted to the FDA prior to beginning studies on humans. The IND contains the plan for the study, a complete overview of the drug, results of animal tests, the drug's structural formula, and manufacturing information; *see also* Farley, *supra* note 1, at 29.

35. *See* Ken Flieger, *Testing Drugs in People*, FDA CONSUMER, Jan. 1995, at 6, 10.

36. *See id.* at 10.

37. *See* Farley, *supra* note 1, at 28 (discussing the drug approval process in which the author aids the reader by providing a step-by-step Drug Review Glossary).

38. For the purpose of this note we will discuss "standard" drug approval, and not "priority" drug approval. "Priority" drugs are those which appear to represent an advantage over available therapies on the market. These drugs often see an expedited approval process. "Standard" drugs are those which appear to have therapeutic qualities similar to those of an already marketed drug. *See id.* at 25. For a further discussion of the "priority" drug approval process, *see generally* Ken Flieger, *FDA Finds New Ways to Speed Treatments to Patients*, FDA CONSUMER, Jan. 1995, at 19.

39. *See* Flieger, *supra* note 35, at 6.

40. *See id.* at 8 (stating that generally between 20 and 100 people participate in Phase I trials).

41. *See id.* at 7.

testing will move on to Phase II.[42] Approximately seventy percent of drugs which enter Phase I progress to Phase II.[43]

In Phase II, a group of patients with the condition the drug is intended to treat receive the drug under investigation. Others receive no drug, but rather a placebo,[44] or a drug known to be effective for the condition intended to be treated.[45] Phase II studies can consist of up to several hundred people, and can take up to two years to complete.[46] While safety is being evaluated, the main focus of Phase II is to analyze the drug's effectiveness.[47] Approximately thirty-three percent of drugs which enter clinical trials complete Phase II.[48]

In Phase III, additional studies are conducted which can consist of several hundred to several thousand people, and can take from one to four years to complete.[49] Safety, proper dosage, and effectiveness are all scrutinized.[50] Approximately twenty-five to thirty percent of the drugs tested clear this final phase of human studies.[51] In total, only about twenty percent of drugs that enter clinical trials will ultimately be approved by the FDA for marketing.[52]

The time lapse between a drug's initial synthesis and its completion of the three phases of clinical testing can last up to ten years.[53] In fact, on average, the FDA does not receive the NDA until six and a half years after initial laboratory synthesis begins.[54] Then, if approved, the drug will obtain access to the market.[55] As a result of the significant time involved, development costs of a new drug average approximately 350 million

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42. *See id.* at 6.

43. *See id.* at 8.

44. *See* THE AMERICAN HERITAGE DICTIONARY 946 (2d ed. 1985) (defining placebo as "[a]n inactive substance used as a control in an experiment.").

45. *See* Flieger, *supra* note 35, at 7 (discussing the use of controls during the experimentation process and how they are divided in order to gain an accurate picture of the drug's effectiveness).

46. *See id.* at 8 (showing the figures through a testing chart providing various categories such as phase number, length of study, purpose of study, and the percentage of drugs successfully tested).

47. *See id.*

48. *See id.*

49. *See id.*

50. *See id.*

51. *See id.*

52. *See id.*

53. *See id.* at 10.

54. *See id.*

55. *See id.*

dollars.[56] Manufacturers often spend up to one-third of total annual sales on research and development.[57]

Once a product's NDA is approved, and the product enters the marketplace, the responsibility of the drug manufacturer and the FDA does not end. Rather, post-marketing surveillance follows to monitor the product's safety in the marketplace.[58] Before FDA approval, only approximately four thousand people would have been tested with the drug.[59] After reaching the marketplace, however, many more people will use the product. Therefore, it is the continuing responsibility of the FDA to ensure that the product maintains the same standards of safety and efficacy demonstrated during clinical studies.

If an adverse event or problem is discovered, the FDA can take several steps to ensure public safety. The FDA can require the manufacturer to make appropriate label changes or place prominently featured boxed warnings on the product's packaging.[60] More drastically, the FDA can recall or remove the product from the market.[61]

The current drug approval process is stringent and highly regulated. It is in response to well-publicized and horrific tragedies[62] and has at its foundation public safety concerns and the introduction of effective medicine.[63] To date, however, dietary supplements have slipped through regulatory cracks and have not been properly classified or controlled.[64]

## III. THE HISTORY OF THE DIETARY SUPPLEMENT INDUSTRY

While the FDA has maintained and progressively tightened its hold over the regulation of drugs throughout this century,[65] the same cannot be said of the FDA's supervision of dietary supplements.[66] Dietary

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56. *See* Jeffrey P. Cohn, *The Beginnings: Laboratory and Animal Studies*, FDA CONSUMER, Jan. 1995, at 2, 3.

57. *See id.*

58. *See* Ropp, *supra* note 30, at 44.

59. *See id.* at 43.

60. *See id.* at 45.

61. *See id.*

62. *See supra* notes 19-20, 30-31 and accompanying text.

63. *See supra* notes 11-19, 21-25 and accompanying text.

64. *See* Cataxinos, *supra* note 6, at 561.

65. *See supra* notes 12-15 and accompanying text.

66. *See generally* DSHEA, *supra* note 11, §§ 2, 4; Stolberg, *supra* note 6 (stating that "[d]rug agency officials are precluded by Federal law from regulating the diet supplement industry . . . .").

supplements have never had a consistent classification,[67] bouncing around from a drug[68] to a food additive[69] to their present classification as a dietary supplement.[70] Due to Congress's reluctance to recognize dietary supplements as potentially dangerous[71] or to give the FDA the power to ensure the safety of these products, manufacturers are more likely to engage in unscrupulous and hazardous practices.[72]

Since the enactment of the FDCA, which expanded the definition of a drug to include dietary supplements,[73] dietary supplements have come under the FDA's purview.[74] This expanded definition was intended to bring certain potentially dangerous products[75] that had physiological effects unrelated to disease, within the regulatory authority of the FDA.[76] Until 1958, dietary supplements remained classified as drugs. Thereafter, they were classified as food additives.[77] As a food additive, the approval process of dietary supplements became less demanding than that of a drug.[78] The process, however, required the pre-market screening of a product.[79] If experts did not regard the product as safe, based on published scientific literature, the manufacturer was then assigned the burden of proving the safety of the product.[80] This burden required the manufacturer to conduct extensive animal feeding studies.[81]

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67. *See* Cataxinos, *supra* note 6, at 566.

68. *See* FDCA, *supra* note 7, § 321(g)(1).

69. *See* Cataxinos, *supra* note 6, at 568.

70. *See* DSHEA, *supra* note 11, § 3.

71. *See* DSHEA, *supra* note 11, § 2(14) (stating Congress's opinion that dietary supplements are safe and that safety problems associated with them are rare).

72. *See* Cataxinos, *supra* note 6, at 568 (finding that by avoiding classification as a "food additive," herbal products are presumed safe).

73. *See* FDCA, *supra* note 7, § 321(g)(1) (discussing expanded definition of a drug from articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of a disease in a man or other animals, to include, articles, other than foods, intended to affect the structure or any function of the body of man or other animals).

74. *See* Cataxinos, *supra* note 6, at 569-70.

75. *See* Robert G. Pinco & Paul D. Rubin, *Ambiguities of the Dietary Supplement Health and Education Act of 1994*, 51 FOOD & DRUG L.J. 383, 387-88 (1996).

76. *See id.* at 387-88; *see also* S. REP. NO. 74-361, at 3 (1935) (discussing the health dangers of drugs under the conditions of use prescribed in labeling or advertising).

77. *See* FDCA, *supra* note 7, § 321(s).

78. *See* Cataxinos, *supra* note 6, at 566 (discussing the requirement to prove safety, but not efficacy).

79. *See id.* at 567.

80. *See id.*

81. *See id.* at 572.

During the 1960s, dietary supplement manufacturers took advantage of the FDA's lack of regulatory authority over dietary supplements.[82] A great deal of false and misleading claims persisted.[83] As a result, the FDA sought stricter regulatory authority over product labeling and product claims.[84] The FDA also attempted to reclassify dietary supplements as drugs and place maximum daily limits on their labeling.[85]

Congress responded to the FDA with the "Proxmire Amendments,"[86] which prevented the FDA from placing maximum limits on the potency of vitamins and minerals in foods.[87] Congress also prohibited the FDA from categorizing any vitamin or mineral as a drug solely because it exceeded potency levels for what was generally recognized as proper daily amounts.[88] These proposed restrictions over regulation of dietary supplements intensified the debate between Congress and the FDA.[89]

In 1990, the L-tryptophan dietary supplement health crisis[90] caused the FDA to create the Task Force on Dietary Supplements.[91] During the previous year, the FDA banned the sale of L-tryptophan after thousands of cases of illness and several dozen deaths were associated with this amino acid.[92] The Task Force was responsible for reviewing dietary supplement regulations and for recommending regulatory changes that needed to be implemented.[93] Also in 1990, Congress passed the Nutrition

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82. *See* Mark A. Kassel, *From A History of Near Misses: The Future of Dietary Supplement Regulation*, 49 FOOD & DRUG L.J. 237, 254 (1994) (discussing how consumers were increasingly misled by vitamin and dietary supplement advertisements).

83. *See id.*

84. *See id.* at 255.

85. *See id.*

86. *See* Federal Food, Drug and Cosmetic Act of 1976, Pub. L. No. 278, 90 Stat. 410 (codified as amended at 21 U.S.C. § 350 (1992)).

87. *See id.*

88. *See id.*

89. *See* Kassel, *supra* note 82, at 242 n.40 (discussing the FDA's struggle to regulate dietary supplement claims and Congress's reluctance to grant the FDA complete authority).

90. *See id.* at 241-42 (noting that L-tryptophan is used to treat insomnia, depression, and premenstrual syndrome; a health crisis occurred related to a contaminated batch of L-tryptophan; and it is still unclear whether the contaminates, the amino acid, or both were responsible for the crisis); *see also infra* notes 147-49 and accompanying text.

91. *See id.* at 262-63.

92. *See id.* at 242 n.40.

93. *See id.* at 263 & n.197.

Labeling and Education Act (NLEA).[94] The purpose of the NLEA was to clarify and strengthen "the Food and Drug Administration's legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about nutrients in foods."[95] The NLEA mandated that nutritional labeling appear on food products as well as dietary supplements.[96] More importantly, the NLEA allowed claims of disease prevention by food only when the nutrient and disease relationship was supported by significant scientific agreement based upon publicly available scientific literature.[97] In 1991, in another attempt at regulation, the FDA proposed that the aforementioned policy of claims regarding disease prevention apply not only to foods but to dietary supplements as well.[98] Not surprisingly, in 1992, Congress passed the Dietary Supplement Act.[99] This statute imposed a moratorium on the implementation of the NLEA with regard to dietary supplements.[100] For every unsteady step forward, there were two steps back.

## IV. THE DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994

After years of debate over how to regulate dietary supplements, and based upon the premise that "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," Congress passed the Dietary Supplement Health and Education Act of 1994 (DSHEA).[101] The DSHEA further amended the FDCA and reduced the FDA's regulatory power over dietary supplements.[102] Moreover, the DSHEA weakened the FDA's legal authority to ensure that products

94. *See* Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended at 21 U.S.C. § 343 (1996)).

95. H.R. REP. NO. 101-538, at 7 (1990).

96. *See id.*

97. *See id.* at 8.

98. *See* Kassel, *supra* note 82, at 261 (discussing the FDA's failed attempt to have dietary supplements adhere to labeling requirements).

99. *See* Dietary Supplement Act of 1992, Pub. L. No. 102-571, Title II, 106 Stat. 4491, 4500 (codified at 21 U.S.C. § 343 (1994)).

100. *See* Dietary Supplement Act of 1992, 106 Stat. at 4500; National Council for Improved Health v. Shalala, 893 F. Supp. 1512, 1514 (D. Utah 1995).

101. *See* DSHEA, *supra* note 11, § 1.

102. *See* Cataxinos, *supra* note 6, at 566 (discussing how dietary supplements can now be classified as a food, thereby escaping the need to show the FDA that the product is safe).

reaching the market were safe.[103] The DSHEA also introduced a new definition for dietary supplements which stated that:

> The term 'dietary supplement'
> (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
> (A) a vitamin;
> (B) a mineral;
> (C) an herb or other botanical;[104]
> (D) an amino acid;[105]
> (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
> (F) a concentrate, metabolite,[106] constituent, extract[107] or combination of any ingredient described in clause (A), (B), (C), (D), or (E).[108]

Dietary supplements now fell within an all-encompassing definition, one that included everything from cinnamon to melatonin,[109] and are now no more regulated than fruit from the local market.

Of even greater concern, dietary supplements are no longer regulated as food additives or drugs, but now enjoy their own classification as "dietary supplements,"[110] and are regulated as foods. Under the DSHEA, the same exact product that would have been classified under the FDCA as a drug in 1938,[111] and as a food additive in 1958,[112] would now be

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103. *See id.*

104. *See* THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 154 (Family ed. 1979) (defining botanical as "[a] drug, medicinal preparation, or similar substance obtained from a plant or plants.").

105. *See id.* at 43 (defining an amino acid as "[a]ny organic compound containing both an amino group . . . and a carboxylic acid group . . . .").

106. *See id.* at 824 (defining metabolite as "[a]ny of various organic compounds produced by metabolism.").

107. *See id.* at 465 (defining extract as "[a] concentrated preparation of the essential constituents of a food, flavoring, or other substance . . . .").

108. DSHEA, *supra* note 11, § 3.

109. Melatonin is a hormone marketed as a dietary supplement for the treatment of insomnia and jet lag. The purity of Melatonin, and the adverse effects associated with taking Melatonin, which is sold in drug stores, are unknown. *See Melatonin*, MED. LETTER (The Medical Letter, Inc., New Rochelle, N.Y.), Nov. 24, 1995, at 111, 111-12 [hereinafter MEDICAL LETTER].

110. *See* DSHEA, *supra* note 11, § 3.

111. *See* FDCA, *supra* note 7, § 2.

classified as a dietary supplement, which entitles it to the limited regulatory processes to which foods are amenable.[113] Since dietary supplements are regulated as foods, manufacturers are now permitted (under the 1938 expanded definition of a drug, which excludes foods) to make structure and function claims relating to the body without being classified as a drug.[114] Under the DSHEA, for the first time, it became legal if a dietary supplement:

> claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient.[115]

### A. *Pandora's Box Is Open*

The FDA's haphazard regulation of dietary supplements has left an open door through which manufacturers can send untested products. With dietary supplements such as melatonin,[116] which claims to help you sleep, and DHEA,[117] which claims to restore youth, product introduction without any assurance of safety, not to mention efficacy, is sharply on the rise.

The DSHEA does, however, require manufacturers to be able to substantiate that the statements made about their products are truthful and not misleading based on significant scientific agreement.[118] In addition, a manufacturer's statement about its product must contain a bold face disclaimer that the dietary supplement "has not been evaluated by the Food and Drug Administration," and that the product "is not intended to

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112. *See* Cataxinos, *supra* note 6, at 569.

113. *See* Dietary Supplement Act of 1992, Pub. L. No. 102-571, Title II, 106 Stat. 4491, 4500 (codified at 21 U.S.C. § 343 (1994)).

114. *See* DSHEA, *supra* note 11, § 6 (discussing how claims by dietary supplements are permitted without risking classification as a drug). Prior to the enactment of the Act, courts held that dietary supplements could be classified as drugs for making structure and function claims. *See* Nutrilab, Inc. v. Schweiker, 713 F.2d 335, 338 (7th Cir. 1983).

115. *See* DSHEA, *supra* note 11, § 6.

116. *See* MEDICAL LETTER, *supra* note 109, at 111-12.

117. *See* Christine Gorman, *Can This Pill Really Make You Younger?*, TIME, Sept. 23, 1996, at 66 (discussing DHEA, a hormone created by the adrenal glands, "which claims to restore sexual vigor, prevent cancer and heart disease, and add decades to your life . . . .").

118. *See* DSHEA, *supra* note 11, § 5.

diagnose, treat, cure, or prevent any disease."[119] Further, if manufacturers make these types of structure or function claims, they must notify the FDA of their claim no later than thirty days after the marketing of their product.[120] Unfortunately, even though courts have found that significant scientific substantiation is needed,[121] manufacturers are not required to make such information available to the FDA until a health claim is challenged.[122] Therefore, manufacturers have few obstacles preventing them from making faulty health claims and from those claims remaining on the market unchallenged.[123]

Dietary supplement manufacturers have challenged the FDA's requirement of a finding of significant scientific agreement of nutrient-disease relationship as an infringement on their First Amendment right to free speech.[124] This argument has been struck down in court.[125]

The way a manufacturer presents its product through advertising and labeling, and how it states the product's intended use, can significantly influence the product's categorization as a drug or dietary supplement.[126] What classifies a product as a drug or as a dietary supplement is not necessarily what the products' chemical composition is—or what it actually does—but rather what the manufacturer claims the product can do.[127] There appears to be a great deal of ambiguity regarding what language classifies a product as a drug and what classifies it as a dietary

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119. DSHEA, *supra* note 11, § 6.

120. *See id.*

121. *See* National Council For Improved Health v. Shalala, 893 F. Supp. 1512, 1517 (D. Utah 1995) (discussing the standard for approval of health claims based on the totality of publicly available scientific evidence and significant scientific agreement among experts).

122. *See id.* at 1517; *Supplements: Let the Buyer Do Homework,* N.Y. TIMES, Nov. 26, 1997, at A18 (discussing a recommendation by a Presidential commission to have companies supply scientifically valid evidence to nutritional claims and discussing the potential for the public to assume that these products "had some sort of F.D.A. approval when, in fact, they did not.").

123. *See* Collen Dunn Bates, *Herbs: Tonic or Toxic,* SHAPE, Oct. 1996, at 106 (discussing how a dangerous dietary supplement can remain on the market).

124. *See National Council For Improved Health,* 893 F. Supp. at 1515.

125. *See id.* at 1520.

126. *See* Cataxinos, *supra* note 6, at 566.

127. *See* DSHEA, *supra* note 11, § 3 (explaining how under the DSHEA, an ingredient which is first marketed as a dietary supplement and subsequently approved as a new drug, may continue to be marketed as a dietary supplement, but, conversely, if a product is first approved as a drug it cannot then later be marketed as a dietary supplement).

supplement.[128] "Structure and function claims related to the body" discussed in the DSHEA are not defined, and court decisions tell us even less.[129] One decision tells us that statements purporting to induce sleep are permissible structure and function claims by a dietary supplement,[130] yet, this is in direct conflict with a warning letter authored by the FDA to a manufacturer who marketed an herbal product as a sleep aid.[131]

It is overwhelmingly obvious that there is no clear cut standard. The DSHEA does not define the relationship amongst permissible structure and function statements and impermissible health claims, or even explain if any relationship exists.[132] Dietary supplement manufacturers regularly push the limits with respect to product claims, hoping that their statements—if they ever come to the FDA's attention—are construed as a structure or function claim and not as an impermissible claim purporting to "diagnose, treat, cure, or prevent any disease."[133] The ambiguity of the DSHEA invites manufacturers of dietary supplements to infer disease mitigating claims by masking them as structure and function claims.[134] There is no fine line, rather it appears to be dotted, dashed, or perhaps invisible. Does a product claiming to promote restful sleep purport to cure insomnia? Does a product claiming to relieve aches and pains allege to treat arthritis? Questions like these are left unanswered. Under the DSHEA, the dividing line between classifying a product as a drug or as a dietary supplement is remarkably unclear.

Since the FDA is forbidden from interfering with a dietary supplement as long as it does not claim to "diagnose, treat, cure, or prevent any disease,"[135] products reach the market without any requirement of pre-market testing, or proof of safety.[136] Even if a product is perceived as unsafe, it is extremely difficult for the FDA to remove the product from the marketplace.[137] Moreover, in order to have a product removed from

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128. *See id.* (emphasizing the ambiguous language in the statute).

129. *See* United States v. 23, More or Less, Articles, 192 F.2d 308 (2d Cir. 1951).

130. *See id.* at 309.

131. Warning Letter: Miracle Exclusives, Inc., WL 53-NYK-95 (June 8, 1995) [hereinafter Warning].

132. *See generally* DSHEA, *supra* note 11, § 6.

133. *See* DSHEA, *supra* note 11, § 6.

134. *See* Warning, *supra* note 131 (discussing sleep-aid manufacturer's claim to treat insomnia).

135. *See generally* DSHEA, *supra* note 11.

136. *See* Stephen H. McNamara, *FDA Regulation of Ingredients in Dietary Supplements after Passage of the Dietary Supplement Health and Education Act of 1994*, 51 FOOD & DRUG L.J. 313, 318 (1996).

137. *See generally* DSHEA, *supra* note 11.

the marketplace, the FDA has the burden to prove that the dietary supplement "presents a significant or unreasonable risk."[138] Prior to the enactment of the DSHEA, in order to remove a dietary supplement (which was classified as a food additive) from the market, the manufacturer had the burden of proving product safety, while, contemporaneously, the FDA only had to prove a product was generally not recognized as safe.[139] Now it can take an average of sixty-five days for the FDA to obtain a court order to seize an unsafe product and remove it from the market.[140] This means that an unsafe product can remain on the market for over two months before the FDA can remove it.

While the DSHEA attempted some type of regulation, its efforts were hollow. For example, if a dietary ingredient was not marketed in the United States before October 15, 1994, it is considered a "new dietary ingredient."[141] As a "new dietary ingredient," the manufacturer must notify the FDA of its intentions to market the ingredient within seventy-five days of the product's introduction to the market.[142] The notification must establish that the ingredient will be "reasonably" safe.[143] If it can be shown, however, that the "new dietary ingredient" contains only dietary ingredients that have already been present in a food and it has not been chemically altered, there is no requirement to prove safety.[144] Even though the "new dietary ingredient" provision may prove to be an obstacle to the introduction of some dietary supplements, the majority will gain market exposure with little difficulty.

### B. *Dietary Supplements Are Dangerous and Out of Control*

Under the DSHEA, the federal government "is not to take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to the consumers."[145] The reasoning behind this policy is that Congress believes "dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare."[146] Perhaps it is this excessive confidence by Congress that keeps the FDA at bay and has led to tragedy.

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138. DSHEA, *supra* note 11, § 4.

139. *See* Cataxinos, *supra* note 6, at 568; Kassel, *supra* note 82, at 265.

140. *See generally* DSHEA, *supra* note 11.

141. *See* H.R. DOC. NO. 84-61 (1984).

142. *See* DSHEA, *supra* note 11, § 8.

143. *See id.*

144. *See id.*

145. *See* DSHEA, *supra* note 11, § 2(13).

146. *See id.* § 2(14).

In 1989, L-tryptophan,[147] an amino acid, was sold in health food stores and pharmacies across the country. Unlike amino acids produced naturally in the human body, those sold in stores, like L-tryptophan, are isolated in a way not found in nature.[148] Advertised as a "natural" sleep aid, an answer to depression and premenstrual syndrome, L-tryptophan was responsible for the mysterious crippling illness, Eosinophilia-Myalgia Syndrome, which plagued over 1500 people and caused 38 deaths.[149]

In 1996, while on Spring Break in Florida, twenty-year-old Peter Schlendorf died only hours after ingesting eight herbal stimulant pills containing ephedrine[150] (only twice the recommended dosage). Herbal stimulant pills are advertised as producing euphoria, increasing sexual sensations, heightening awareness, and increasing energy.[151] These stimulants, sold under the brand names "Herbal Ecstacy" and "Ultimate Xphoria" (the brand Peter Schlendorf ingested), are replicates of the illegal street drug Ecstasy (MDMA).[152] Since the manufacturer changed the spelling of the illegal street drug, and used the ingredient ephedrine, which is classified as a dietary supplement, many people erroneously assumed that the product was safe. The truth, however, is that it can cause heart attacks, strokes, seizures, psychosis, and as in the case of Peter Schlendorf, death.[153]

The list of the DSHEA's so-called "safe" products is extensive. Germanium and Comfrey have been shown to cause fatal liver damage.[154] Also, Jin Ba Huan has provoked life-threatening reactions in children, Kombucha mushroom tea has killed at least one person, Royal Jelly has

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147. *See* Kassel, *supra* note 82, at 241 (describing L-tryptophan as a popular dietary supplement which was used to combat insomnia, premenstrual syndrome, and uncontrollable appetite).

148. *See id.*

149. *See* Carter Anne McGowan, *Learning the Hard Way: L-Tryptophan, the FDA, and the Regulation of Amino Acids*, 3 CORNELL J.L. & PUB. POL'Y 383, 383-84 (1994).

150. *See* THE NEW WEBSTER'S MEDICAL DICTIONARY (Lewtan Line 1992) (defining ephedrine as "a synthetically produced compound generally used for the treatment of asthma.").

151. *See* Karyn Snyder, *Ecstatic Exit*, DRUG TOPICS, May 20, 1996, at 40 (discussing Peter Schlendorf's death caused by taking the dietary supplement ephedrine).

152. *See id.*

153. *See id.*

154. *See* Bruce A. Silverglade, *Regulating Dietary Supplement Safety Under the Dietary Supplement Health and Education Act: Brave New World or Pyrrhic Victory?*, 51 FOOD & DRUG L.J. 319, 320 (1996) (discussing various dietary supplements and the safety hazards that have resulted from them).

caused fatal asthma attacks in people, and some diet teas containing stimulants and laxatives have caused severe dehydration and death.[155]

Research has shown that mega-doses of dietary supplements can be associated with toxic reactions, illness and death.[156] Between 1993 and October 1995, there have been more than 650 reported adverse events pertaining to dietary supplements.[157] From October 1995 to June 1996, the number of reported complications have more than doubled.[158] In consideration of the DSHEA's lax attitude and the sudden influx of dietary supplements—which promise everything from better sleep to revitalized youth[159] without any proof of safety needed—one can only stand back and await the inevitable hazards.

### C. *Why Have Dietary Supplements Presented Such Problems?*

Almost fifty percent of Americans regularly consume dietary supplements in the form of vitamins, minerals, or herbs.[160] With approximately six hundred manufacturers and over four thousand dietary supplements on the market,[161] there has been an increasing trend to forego traditional medical care and rely solely on dietary supplements.[162] It is astonishing to average consumers when they learn that dietary supplement manufacturers are subjected to barely any pre-market scrutiny. While each unfortunate pharmaceutical tragedy has been met with tighter safety regulations,[163] dietary supplement disasters have become all too common and continue to grow without any real consequences being imposed on the manufacturers.[164]

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155. *See id.* at 320.

156. *See* Kassel, *supra* note 82, at 238.

157. The Tan Sheet 1996; 4 (30): 1-3 (expressing the prevalence of safety problems associated with dietary supplements).

158. *See id*; *see also* Kathleen Doheny, *It's Only Natural*, SHAPE, Jan. 1998, at 119-20 (explaining that "since 1993, the [FDA] has received more than 800 reports of adverse health effects linked with the use of ephedrine . . . .").

159. *See* Gorman, *supra* note 117, at 66; *see also* Jane E. Brody, *In Vitamin Mania, Millions Take a Gamble on Health*, N.Y. TIMES, Oct. 26, 1997, at 1.

160. *See* DSHEA, *supra* note 11, § 2(9).

161. *See id.* § 2(12)(C).

162. *See id.* § 2(10).

163. *See supra* notes 19-64 and accompanying text.

164. *See supra* notes 157-159 and accompanying text.

Under the DSHEA, an Office of Dietary Supplements (ODS) within the National Institute of Health has been developed.[165] At a cost of five million dollars, the ODS will conduct their own scientific research on dietary supplements in order "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."[166] While this is a positive step, the ODS does not serve as a pre-clearance department for products seeking market exposure, nor will it protect the public from unsafe products presently on the market.[167]

It has been shown that some dietary supplements can improve health and save lives.[168] They can, and they do.[169] There is, however, a potential for grave danger. Therefore, a laboratory, under the regulatory supervision of the FDA, rather than the marketplace, should serve as the clinical arena. Like any drug, dietary supplements have the potential to offer a cure or cause a catastrophe. The passage of the DSHEA has shifted the burden of proving the danger of a dietary supplement to the FDA, and has allowed products to gain market access (often carrying ambiguous health and nutritional support statements) without the need for FDA pre-clearance.[170] When the FDA has concerns about a product, it is too late, the product is already on the market. The FDA must react on a product-by-product basis. The FDA's regulatory authority has been delegated primarily to the post-market arena, and even there, a dangerous product can remain on the market unchecked. As the system stands now, the FDA must wait for a tragedy to occur and then shoulder the burden of proving that the hazard is real.

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165. *See* DSHEA, *supra* note 11, § 13(a); *see also* Brody, *supra* note 159, at 28 (discussing the establishment of an Office of Dietary Supplements).

166. *Id.* § 13(b)(1).

167. *See id.* § 13(c) (discussing the general duties of the Office of Dietary Supplements).

168. *See, e.g.*, Meir J. Stampfer et al., *Vitamin E Consumption and the Risk of Coronary Disease in Women*, 328 NEW ENG. J. MED. 1444, 1446 (1993) (discussing how studies have shown that by taking a specified quantity of vitamin E for at least two years the prevalence of heart disease was reduced by 40%); Gladys Block, *Vitamin C and Cancer Prevention: The Epidemiologic Evidence*, 53 AM. J. OF CLINICAL NUTRITION 270s (1991) (discussing how studies have shown that intakes of antioxidant nutrients can reduce certain types of cancer); Brody, *supra* note 159 (discussing how vitamins and mineral pills can reverse or prevent deficiencies that can result in diseases like scurvy and rickets). *But see supra* notes 147-153 and accompanying text.

169. *See* Stampfer, *supra* note 168, at 1444; Block, *supra* note 168, at 270s.

170. *See* McNamara, *supra* note 136.

## V. CONCLUSION

The DSHEA has not answered what should be done with dietary supplements or how they should be regulated. By enacting the DSHEA, Congress obviously sides with dietary manufacturers. But at what cost? The DSHEA has taken us back to 1906 when products entered the market without any assurance of safety.[171] The health hazards associated with ephedrine [172] have been met with apathy. Perhaps we have to wait until society is confronted with another "Elixir Sulfanilamide,"[173] "Thalidomide,"[174] or "L-tryptophan"[175] disaster to convince Congress to grant the FDA broader regulatory power over the dietary supplement industry.[176]

One viable solution is for dietary supplement manufacturers to conform to the same pre-market regulations as drug manufacturers. Dietary supplement manufacturers would be required to conduct studies to establish the safety and efficacy of a product before obtaining marketing approval.[177] However, in order for manufacturers of dietary supplements to obtain scientific evidence, they must undertake extremely expensive studies.[178] As expected, manufacturers of dietary supplements argue against this demanding standard.[179] They assert that since dietary supplements (unlike drugs) are not patentable, companies could never recoup the several hundred million dollar investment necessary to conduct the required research.[180]

While monetary reasons should never justify a lack of public safety, dietary supplement manufacturers do make a valid point. If they cannot patent their products, the manufacturers cannot recoup, and without reimbursement there is no incentive to introduce products into the market. Bills proposing regulatory legislation akin to the drug industry have been consistently struck down by Congress.[181] A potential answer lies in

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171. *See generally* PFA, *supra* note 12.

172. *See* Snyder, *supra* note 151, at 40.

173. *See* Farley, *supra* note 1, at 26.

174. *See* Ropp, *supra* note 30, at 43.

175. *See* Kassel, *supra* note 82, at 254.

176. *See supra* notes 23-27 and accompanying text (discussing a potentially effective model for dietary supplement regulation).

177. *See supra* notes 33-38 and accompanying text (discussing the FDA regulation of drugs).

178. *See* Mandelbaum-Schmid, *supra* note 3, at 209.

179. *See id.*

180. *See id.*

181. *See, e.g.*, S. 2835, 102nd Cong. (1992).

patenting. New and untested dietary supplements could have special patenting rights which would give manufacturers exclusivity in their compound. Accompanying these special patenting rights, should be more stringent FDA oversight to ensure product safety. If implemented, this would enable manufacturers to recoup their investment, the FDA would gain more regulatory control, and public safety would not be compromised.

A less radical and more practical approach to regulation re-classifies dietary supplements as food additives. Under this classification the burden of proving safety would lie with the manufacturer.[182] As a food additive, if the FDA determines that a product is unsafe for its intended use, the manufacturer must establish the product's safety before it could obtain access to the marketplace.[183] This would require manufacturers to produce established proof of a product's safety, yet would still not require any proof of efficacy.[184] ODS should be utilized here. As long as a product is proven safe, ODS can assess efficacy once a product is on the market. The food additive classification may not be the complete answer, but some of the regulations food additives undergo, combined with some of the regulations drugs undergo, could serve as a good model for dietary supplement regulation.[185]

The most logical solution would be for the FDA to adopt an approval process for dietary supplements similar to the approval process for a drug in 1938.[186] Manufacturers would need to apply for an NDA[187] in order to obtain marketing approval, and the burden of proving product safety would shift back to the manufacturer. This regulatory model would give the FDA the power to require studies in humans if deemed necessary. Moreover, the 1938 model leaves the ultimate determination of product safety, and the decision for marketing approval, where it should be, in the hands of the FDA.

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182. *See* Cataxinos, *supra* note 6, at 567.

183. *See generally* DSHEA, *supra* note 11.

184. *See generally* FDCA, *supra* note 7.

185. *See supra* notes 13-22 and accompanying text (discussing the governmental Acts regulating the drug approval process in the United States).

186. *See generally* FDCA, *supra* note 7 (describing the approval process for drugs).

187. *See supra* notes 14-29 and accompanying text (discussing the new drug application process).

Acknowledging that approximately half of the United States population takes dietary supplements on a regular basis,[188] and knowing the potential hazards posed by dietary supplements, Congress must grant the FDA more power to regulate the dietary supplement industry and safeguard the public from impending disaster.

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188. *See* DSHEA, *supra* note 11, § 2(9).