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# EPHEDRA AND THE FAILURE OF DIETARY SUPPLEMENT REGULATION

*Michael Sachs*<sup>\*</sup>

On Sunday, August 17, 2003, in front of friends, family, and some of her deceased husband's former teammates, a solemn Kiley Bechler spread the ashes of her husband, Steve Bechler, on the three pitching mounds in Oriole Park at Camden Yards.<sup>1</sup> This was a far cry from the scenario in which they had pictured Steve taking the mound at Camden Yards and etching his name into Orioles folklore.<sup>2</sup> As a young boy growing up in Medford, Oregon, Steve Bechler dreamed of one day pitching in the Major Leagues.<sup>3</sup> His dream came true when he made three relief appearances for the Baltimore Orioles in the summer of 2002.<sup>4</sup> Steve reported to spring training the following season weighing 250 pounds, ten pounds over his projected weight.<sup>5</sup> In order to help shed the excess weight and enhance his chances of staying with the major league team, Steve took a dietary supplement called Xenadrine RFA-1, manufactured by Cytodyne.<sup>6</sup> The main ingredient in Xenadrine is

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1. See Thom Loverro, *Bechler Has Eternal Presence at Camden*, WASH. TIMES, Aug. 18, 2003, at C1.

2. See *id.*

3. *Id.*

4. *Id.*

5. *Issues Relating to Ephedra-Containing Dietary Supplements: Hearings Before the Subcomm. on Oversight & Investigations and the Subcomm. on Commerce, Trade, & Consumer Prot. of the House Comm. on Energy and Commerce*, 108th Congress 67 (2003) [hereinafter *Ephedra-Containing Supplements Hearings*] (testimony of Pat Bechler); *id.* at 132 (statement of Rep. Greg Walden, Vice Chairman, Comm. on Energy & Commerce). Pat Bechler testified that her son reported to spring training ten pounds overweight, but with a lower percentage of body fat than the previous year. *Id.* at 67.

6. See Loverro, *supra* note 1. In addition to being implicated in the death of Steve Bechler, Cytodyne is currently being sued for the role of its product in the death of Rashidi Wheeler, a Northwestern University football player who died of heatstroke during summer workouts in 2001. Guy Gugliotta & Amy Shipley, *Ephedra Controversy Nothing New in Sports: Dietary Supplements Linked to Other Deaths*, WASH. POST, Feb. 20, 2003, at D4.

ephedra, an herbal dietary supplement, which according to the autopsy report, contributed to Steve's death.<sup>7</sup>

Ephedra is a plant species which has long been used for medicinal purposes.<sup>8</sup> The Chinese refer to ephedra as *Ma Huang* and have used it for thousands of years to help cure ailments such as the common cold, asthma, and other respiratory diseases.<sup>9</sup> Plants of the ephedra species may contain up to six types of alkaloids, the principle one being

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7. See Loverro, *supra* note 1. Robert Chinery, the former President of Cytodyne Technologies, testified in front of the House Subcommittee on Oversight and Investigations that Cytodyne's doctors conducted their own review of Steve Bechler's medical records and determined that Steve died of heat stroke which was caused by his "morbid obesity, high blood pressure and heart disease, adverse weather conditions, physical exertion and inadequate screening, monitoring and medical supervision [on behalf of the Orioles training staff]." *Ephedra-Containing Supplements Hearings, supra* note 5, at 107 (testimony of Robert Chinery, President, Cytodyne Technologie). Representative Greg Walden (R-OR) responded to this argument by entering specific evidence of Steve Bechler's official autopsy report into the record:

Dr. Baden noted correctly the patient weight at the time of the autopsy was 320 pounds and that he was 6'2" in height and therefore it concluded that he was morbidly obese. However Dr. Baden admitted 2 important facts which were, and I quote, "The fact that Mr. Bechler's weight 3 days before his demise was 250 pounds and no individual, no matter how much [he] would eat, can gain 70 pounds of weight in 3 days."

Furthermore, Mr. Bechler's gastrointestinal tract was empty. He ate very little, if at all, during the 2 to 3 days preceding his demise. At the time of the autopsy Mr. Bechler was excessively bloated and deamatose. This bloating was a result of both infusion of resuscitation fluids and his kidney failure with lack of urination.

I think it is terribly misleading to use the terminology that was used to say that part of his death was caused by severe obesity. He was 10 pounds overweight 3 days before.

*Id.* at 132.

8. Stephen Bent et al., *The Relative Safety of Ephedra Compared with Other Herbal Products*, 138 ANNALS INTERNAL MED. 468, 468 (2003) (noting that ephedra has been used in herbal formulas for thousands of years and that in the 1920s, ephedra first became popular in the United States as a stimulant, as a treatment for asthma, and as a nasal decongestant). How far back the history of use of ephedra products goes has not been determined; however, one report has noted that investigators found a species of ephedra plant that had presumably been used medicinally in a Neanderthal grave. PAUL SHEKELLE ET AL., S. CAL. EVIDENCE-BASED PRACTICE CTR., EPHEDRA AND EPHEDRINE FOR WEIGHT LOSS AND ATHLETIC PERFORMANCE ENHANCEMENT: CLINICAL EFFICACY AND SIDE EFFECTS 7 (2003). This report (*RAND Report*) also noted that "ephedra . . . gained notoriety during modern times when it was learned that the drug was given parenterally to Japanese kamikaze pilots during World War II." *Id.* at 7.

9. See ANDREW GAEDDERT, EPHEDRA (MA HUANG), at <http://www.nycacupuncture.com/ephedra.html> (last visited Dec. 28, 2004); see also Bent et al., *supra* note 8.

ephedrine.<sup>10</sup> According to a study in the *Annals of Internal Medicine*, ephedra alkaloids are naturally occurring chemical stimulants that cause numerous physiological responses in the body such as increased blood pressure, heart rate, and bronchodilation.<sup>11</sup> Today, many people purchase dietary supplements containing a botanical form of ephedra alkaloids as a means to increase energy or lose weight.<sup>12</sup>

The Federal Government regulates dietary supplements under the Dietary Supplement Health and Education Act of 1994 (DSHEA).<sup>13</sup> DSHEA changed the existing regulatory framework for dietary supplements in two ways: (1) it broadened the definition of dietary supplements; and (2) it decreased the Food and Drug Administration's (FDA) ability to regulate dietary supplements by providing them with a presumption of safety, placing the burden on the FDA to prove otherwise.<sup>14</sup> This combination of increasing the number of substances considered to be dietary supplements, while decreasing the FDA's regulatory ability, has led to the production and distribution of a plethora of dietary supplements that do not require premarket approval by the

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10. Bent et al., *supra* note 8. Ephedra contains other alkaloids in addition to ephedrine such as pseudophedrine, phenylpropanolamine, methylephedrine, methylpseudoephedrine, and norpseudoephedrine. *Id.* The alkaloid composition and strength of a particular plant varies by "species and growing conditions such as geographic location, altitude, and soil pH." See SHEKELLE ET AL., *supra* note 8.

11. Bent et al., *supra* note 8.

12. *Id.*

13. Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended in scattered sections of 21 and 42 U.S.C.).

14. Tod L. Stewart, *Getting High with a Little Help from the Feds: Federal Regulation of Herbal Stimulants*, 6 J. PHARMACY & L. 101, 107-08 (1997); Meghan Colloton, Comment, *Dietary Supplements: A Challenge Facing the FDA in Mad Cow Disease Prevention*, 51 AM. U. L. REV. 495, 525, 527 (2002). *Contra Dangers of Dietary Supplements: Hearing Before the S. Comm. on Commerce, Sci., & Transp.*, 108th Cong. (2003), LEXIS, Federal Document Clearing House Congressional Testimony [hereinafter *Dangers of Dietary Supplements Hearing*] (testimony of David Seckman, Executive Director and CEO, National Nutritional Foods Association) (arguing that "[the Dietary Supplement Health and Education Act of 1994 (]DSHEA[)] is often mischaracterized as lessening the Food and Drug Administration's ability to regulate supplements. In fact, . . . [DSHEA] . . . increased [the Food and Drug Administration's (FDA)] enforcement powers"); see also *id.* (statement of Sen. Orrin Hatch, Chairman, Judiciary Comm.). DSHEA did add three regulatory powers which the FDA did not previously have. See 21 U.S.C. § 342(f)(1)(A)-(C) (2000). However, this argument fails to account for the fact that prior to DSHEA, there were fewer substances that fit into the statutory definition of dietary supplements, and the FDA often regulated those that did as though they required premarket approval. See *infra* Part I.A. Therefore, when DSHEA broadened the definition of dietary supplements and definitively placed the burden on the FDA to disprove the safety of all dietary supplements, it dramatically decreased the regulatory power of the FDA. See *infra* notes 97-101 and accompanying text.

FDA.<sup>15</sup> The current regulatory scheme for ephedra poses a substantial health risk to Americans. For example, synthetic versions of ephedra alkaloids are regulated as drugs, while botanical versions of ephedra alkaloids are regulated as dietary supplements.<sup>16</sup> This has created a dichotomy in regulatory law where, even though dietary supplements containing a combination of botanical ephedra and caffeine have the exact same pharmacological effects in the body as a drug combination of synthetic ephedrine and caffeine, the dietary supplement combination product is legal and the drug combination is not.<sup>17</sup> Recently, dietary supplements containing caffeine and ephedra have been linked to a growing number of deaths.<sup>18</sup> This contradictory regulation of ephedra products presents a hazard to the public and highlights the limitations in existing federal law.

This Comment examines the current state of federal regulation of dietary supplements and discusses the limitations that current law imposes on the FDA's ability to provide oversight of dietary supplements. This Comment first traces the evolution of the current law and the historical relationship between the U.S. Congress and the FDA as it relates to the regulation of dietary supplements. This Comment then focuses on the FDA's attempts to regulate products containing

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15. See Colloton, *supra* note 14, at 527-28.

16. *Ephedra-Containing Supplement Hearings*, *supra* note 5, at 2 (statement of Rep. Jim Greenwood, Chairman, Subcomm. on Oversight & Investigations). In 1983, citing health concerns, the belief that there were no legitimate uses for drugs containing a combination of ephedrine and caffeine, and the fact that these products were being used recreationally to mimic the effects of illegal drugs, the FDA banned the combination in drug form. Enforcement Action Under the New Drug Provisions of the Federal Food, Drug, and Cosmetic Act; Certain OTC Drug Products; Notice of Advisory Opinion, 48 Fed. Reg. 52,513, 52,513-14 (Nov. 18, 1983). Over-the-counter (OTC) and prescription drugs that contain synthetic ephedrine are used "for temporary relief of shortness of breath, chest tightness, and wheezing due to bronchial asthma. Synthetic ephedrine can also be used as a topical nasal decongestant (nose drops, sprays, or jelly) for temporary relief of nasal congestion due to colds, hay fever, sinusitis, or other upper respiratory allergies." Michelle Meadows, *Public Health Officials Caution Against Ephedra Use*, FDA CONSUMER MAG., May-June 2003, [http://www.fda.gov/tdac/features/2003/303\\_ephedra.html](http://www.fda.gov/tdac/features/2003/303_ephedra.html). However, a study in the *New England Journal of Medicine* noted that "ephedrine is rarely prescribed today for medical purposes, because newer drugs have more specific actions and fewer side effects." Christine A. Haller & Neal L. Benowitz, *Adverse Cardiovascular and Central Nervous System Events Associated with Dietary Supplements Containing Ephedra Alkaloids*, 343 NEW ENG. J. MED. 1833, 1838 (2000).

17. *Ephedra-Containing Supplements Hearings*, *supra* note 5, at 42 (statement of Cynthia Culmo, former official, Texas Department of Health). Ms. Culmo testified that "[b]y regulation drug products containing ephedrine cannot be combined with any other stimulant, based upon the potential for abuse and safety concerns. Not so for dietary supplements." *Id.*

18. See, e.g., *infra* note 148 (detailing the death of Sean Riggins from ingesting a dietary supplement containing a combination of caffeine and ephedra).

ephedra alkaloids under existing law. Next, this Comment examines state government legislation attempting to ban the sale of ephedra products. This Comment then analyzes the impact that DSHEA has had on the FDA's ability to regulate ephedra effectively and the resulting attempts by the state governments to step in where the Federal Government has failed. Finally, this Comment proposes changes to the existing regulatory scheme that would enable the public to have access to dietary supplements while at the same time ensuring that the product is safe.

## I. THE HISTORY OF DIETARY SUPPLEMENT REGULATION

### A. *Dietary Supplement Regulation Prior to the Enactment of DSHEA*

With the passage of the Pure Food Act (PFA) in 1906, Congress, for the first time, attempted to ensure the safety and quality of food and drugs.<sup>19</sup> The 1906 Act differentiated between a substance that was a food, and one that was a drug, and prohibited the sale, shipment, or receiving of adulterated or misbranded foods or drugs through interstate commerce.<sup>20</sup> The role of the FDA, then called the Bureau of Chemistry, a subsection of the Department of Agriculture, was to examine questionable foods and drugs to determine whether they were adulterated or misbranded under the PFA.<sup>21</sup> If a product was deemed

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19. Pub. L. No. 384, ch. 3915, 34 Stat. 768 (1906) (repealed 1938). See generally John P. Swann, *Food and Drug Administration*, in A HISTORICAL GUIDE TO THE U.S. GOVERNMENT 248, 248-53 (George T. Kurian ed., 1998).

20. See Swann, *supra* note 19, at 249-50. In § 7, the Pure Food Act of 1906 (PFA) defined a drug to "include all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals." 21 U.S.C. § 7 (1934) (repealed 1938). Section 7 also defined food to "include all articles used for food, drink, confectionary, or condiment by man or other animals, whether simple, mixed, or compound." *Id.*

21. Swann, *supra* note 19, at 248-49. The FDA began as the Division of Chemistry and, in 1901, became known as the Bureau of Chemistry. *Id.* at 249. In 1927, the Bureau of Chemistry became known as the Food, Drug, and Insecticide Administration, and in 1930, the name was shortened to the present version, FDA. *Id.* The FDA originally was a division of the Department of Agriculture; in 1940, it was moved to the Federal Security Agency, where it remained until 1953 when it became part of the Department of Health, Education, and Welfare (HEW). *Id.* In 1968, the FDA moved under the Public Health Service, a division of HEW; in 1980, the FDA was moved to its present home, the Department of Health and Human Services. *Id.* Under the 1906 Act, a drug was deemed adulterated if it did not meet the standards for strength, quality, or purity as promulgated in the U.S. Pharmacopoeia or National Formulary, unless the product accurately listed the product's standard of strength, quality, or purity on its packaging if it differed from the industry standard. 21 U.S.C. § 8 (1934) (repealed 1938). However, if the product's standard of strength, quality, or purity differed from the industry standard, or the standard

adulterated or misbranded, the Secretary of Agriculture had the authority to recommend the prosecution of the offending manufacturer.<sup>22</sup> A major limitation of the PFA was that it did not require premarket approval of food or drugs.<sup>23</sup>

In 1937, 107 people died from the consumption of a new drug called Elixir Sulfanilamide.<sup>24</sup> These deaths highlighted the deficiency of the PFA because if the government had subjected Elixir Sulfanilamide to premarket testing, it is probable that the government would have detected a toxic substance found in the drug, diethelene glycol, otherwise known as antifreeze.<sup>25</sup> As a result of this tragedy, the Federal Food, Drug, and Cosmetic Act<sup>26</sup> of 1938 (FDCA) repealed the 1906 Pure Food Act.<sup>27</sup> Not surprisingly, the FDCA mandates that any new drug obtain

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on its own packaging, the drug would also be considered adulterated. *Id.* A drug was misbranded if it was an imitation, had a false name, used substitute packaging, or did not list on the packaging the quantity of any alcohol or narcotics contained in the drug. *Id.* §§ 9-10 (repealed 1938). Food was adulterated under the Act if it contained substitutes, injurious mixtures, had any valuable part of the product abstracted in part or in full, was processed or packaged in such a way as to hide any defects, contained any poisonous products, or was composed of "filthy, decomposed, or putrid animal or vegetable substance[s]." *Id.* § 8 (repealed 1938). Under the Act, food was misbranded if it was an imitation product but not listed as such on its labeling or packaging, or if it had false or misleading labeling or packaging in that the labeling or packaging did not contain accurate weight, measure, or ingredient information. *Id.* § 10 (repealed 1938).

22. 21 U.S.C. §§ 11-12 (1934) (repealed 1938).

23. See Swann, *supra* note 19, at 249-51; see also Mark A. Kassel, *From a History of Near Misses: The Future of Dietary Supplement Regulation*, 49 FOOD & DRUG L.J. 237, 251 (1994).

24. Swann, *supra* note 19, at 251; see also James D. Lewis & Brian L. Strom, *Balancing Safety of Dietary Supplements with the Free Market*, 136 ANNALS INTERNAL MED. 616, 616 (2002).

25. Lewis & Strom, *supra* note 24; Swann, *supra* note 19, at 251.

26. 21 U.S.C.A. §§ 301-399 (West 2000 & Supp. 2003).

27. Federal Food, Drug, and Cosmetic Act (FDCA), Pub. L. No. 75-717, ch. 675, § 902(a), 52 Stat. 1040, 1059 (1938).

premarket approval.<sup>28</sup> The burden to prove the safety of the new drug is on the manufacturer who has to apply to the FDA for market approval.<sup>29</sup>

The FDCA also refined the definitions of “food” and “drug.”<sup>30</sup> The roots of the dietary supplement quandary began here because, according to chapter IV of the FDCA, a food would be deemed misbranded if it claimed to have special dietary uses, “unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.”<sup>31</sup> This designation of dietary supplements as a subcategory of food meant that dietary supplements were not subject to premarket approval.

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28. 21 U.S.C. § 355(a) (2000). Anyone who wanted to introduce a new drug into the market had to

submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use . . . (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (F) specimens of the labeling proposed to be used for such drug.

*Id.* § 355(b)(1).

29. *See Swann, supra* note 19, at 251. If the FDA determines that the product is not safe, the Secretary of Agriculture must issue an order refusing to approve the application. 21 U.S.C. § 355(d) (2000). An order of refusal could be based on the need for the manufacturer to conduct more tests on the drug, or on the need for the manufacturer to make refinements in the manufacturing or labeling process of the drug. *Id.*

30. 21 U.S.C. § 321(f)-(g) (2000). Section 321(f) defines a food 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.* § 321(f). Section 321(g)(1) defines a drug as

(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for 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 clause (A), (B), or (C).

*Id.* § 321(g)(1).

31. *Id.* § 343(j). In addition to the expansion of the definitions of “food” and “drug,” and requiring premarket approval of drugs, the FDCA allows the FDA, through the Secretary of Agriculture, to set reasonable standards for identity, quality, and labeling claims of food products. *Id.* § 343(f)-(h). In order to enforce these changes, the FDCA increases the power of the FDA by enabling it to obtain injunctions against manufacturers violating the Act. *Id.* § 332. The ability to obtain an injunction operates in addition to the powers of seizure and criminal prosecution, two regulatory devices retained from the 1906 PFA. *Compare* 21 U.S.C. §§ 11-12 (1934) (repealed 1938) (authorizing criminal prosecution), *and id.* § 14 (repealed 1938) (authorizing seizure), *with* 21 U.S.C. § 333 (2000) (authorizing criminal prosecution), *and id.* § 334 (authorizing seizure).



In 1941, three years after the passage of the FDCA, the FDA promulgated regulations for dietary supplements based on the statutory authority provided under section 403(j) of the Act.<sup>32</sup> The regulations were for foods that purported to be for “special dietary use” because of the vitamin or mineral content of the food.<sup>33</sup> These regulations recognized five vitamins and four minerals as dietary supplements and established minimum daily requirements for each.<sup>34</sup> Under the rule, food product labels were required to list the percentage of minimum daily requirements for the specified vitamin or mineral, and if the product contained a vitamin or mineral not recognized by the rule, then the label must contain a disclaimer noting that the need for the listed vitamin or mineral had not been determined.<sup>35</sup>

In 1958, Congress passed the Food Additives Amendment of 1958<sup>36</sup> (FAA) in order to regulate the substances which legally could be added to food.<sup>37</sup> In an analogous situation to the underregulation of dietary supplements existing today, the FAA was a solution designed to close a loophole in existing regulatory law that allowed substances defined as “food additives” to be added to food without premarket approval.<sup>38</sup> The Government believed that food additives were underregulated because the FDCA allowed unscrupulous food processors to endanger the health of unsuspecting consumers by using untested substances as additives for

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32. 21 C.F.R. § 125 (1941).

33. *Id.* § 125.3-4

34. *Id.* (establishing labeling standards and minimum daily requirements for five vitamins: Vitamin A, Vitamin B (thiamine), Vitamin C (ascorbic acid), Vitamin D, and Riboflavin (vitamin B2, vitamin G)); *id.* § 125.4 (establishing labeling standards and minimum daily requirements for four minerals: calcium, phosphorus, iron, and iodine).

35. *Id.* §§ 125.3(2), 125.4(2) (noting that the disclaimer would read “[t]he need for \_\_\_\_\_ in human nutrition has not been established,” the blank to be filled in with the name of such vitamin [or mineral]).

36. Pub. L. No. 85-929, 72 Stat. 1784 (1958) (codified as amended at 21 U.S.C. §§ 321, 331, 342, 346, 348 (2000)).

37. *Id.* The Food Additives Amendment of 1958 (FAA) defined a food additive as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of 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, as having been adequately shown through scientific procedures (or, in the case as 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.

21 U.S.C. § 321(s) (2000).

38. S. REP. NO. 85-2422, at 1 (1958), *reprinted in* 1958 U.S.C.C.A.N. 5300, 5300.

as long as it took the Government to ban the substance.<sup>39</sup> Under the FDCA, the Government would first have to determine that there was a problem with a particular additive, then conduct an investigation to determine the safety of the substance, and finally move against the processor, a course of action that could take years to complete.<sup>40</sup> During this drawn out process the dangerous additive remained on the market.<sup>41</sup> In addressing this problem, the FAA initiated premarket approval for all food additives and assigned the burden of proof to the processor.<sup>42</sup> Thus food additives, unlike foods, are subject to premarket approval. In the

39. *See id.* at 2, reprinted in 1958 U.S.C.C.A.N. at 5301.

40. *Id.* at 3-5, reprinted in 1958 U.S.C.C.A.N. at 5301-03.

41. *Id.* at 2, reprinted in 1958 U.S.C.C.A.N. at 5301.

42. *Id.* at 3, reprinted in 1958 U.S.C.C.A.N. at 5301-02. Interested parties could show a food additive to be safe either by scientific procedure or by past experience (an option that applied only to food additives "in use prior to January 1, 1958"). *Id.* at 4-5, reprinted in 1958 U.S.C.C.A.N. at 5303. All new food additives were required to be proven safe by scientific procedure. *Id.* Under the FAA, a food processor seeking market approval for additives must file a petition with the FDA. *See* 21 U.S.C. § 348(b)(1) (2000). The FAA requires the petition to contain

(A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

(C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect;

(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

(E) full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations.

*Id.* Within ninety days of receipt of the petition, the Secretary of Health and Human Services must make a ruling on the petition. *Id.* § 348(c)(2). The standard of safety the food processor must establish is one of reasonable certainty. S. REP. NO. 85-2422, at 6, reprinted in 1958 U.S.C.C.A.N. at 5305. Congress thought it was creating a new standard of safety and in an effort to achieve this standard, it included relevant factors the Secretary should consider:

(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

(C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

21 U.S.C. § 348(c)(5) (2000). If the FDA finds this burden is met, it will grant the petition; however, the Secretary could qualify the approval by promulgating regulations as to specific conditions of use and tolerance levels for the new food additive. *Id.* § 348(c).

late 1970s, after failing to replace the 1941 regulations for dietary supplements for nearly two decades, the FDA began to regulate dietary supplements by labeling them as food additives.<sup>43</sup>

Citing concerns that the 1941 regulations governing dietary supplements were dated, as well as a need to address general consumer confusion concerning the nutritional value and effectiveness of dietary supplements, the FDA attempted to promulgate new dietary supplement regulations in 1962.<sup>44</sup> The FDA was concerned because there were a multitude of dietary supplements on the market that advertised various vitamins and minerals for which no health need was established.<sup>45</sup> The proposed rule, published in the *Federal Register* on June 20, 1962, would have set strict labeling requirements allowing the label to bear “only those nutrients recognized by competent authorities as essential and of significant dietary-supplement value in human nutrition.”<sup>46</sup> This would have excluded from dietary supplement labels such nutrients as Vitamins E and K, because “there [was] no convincing evidence that the ordinary diet requires supplementation with these nutrients.”<sup>47</sup> In addition, the proposed rule would have set minimum and maximum potency levels, referred to as the “recommended daily intake,” for the vitamins and minerals that were allowed to be on the labels.<sup>48</sup>

The proposed potency range and exclusion of certain nutrients from labels caused a groundswell of opposition as the public argued that the labeling requirements were too restrictive on dietary supplements.<sup>49</sup> Members of the public viewed dietary supplements as an efficient way to supplement their diet and increase their health and saw the proposed

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43. S. REP. NO. 103-410, at 15 (1994); *see also infra* notes 73-78 and accompanying text (regulating dietary supplements as food additives under the FAA would have required dietary supplement manufacturers to obtain premarket approval).

44. *See* Notice of Proposal To Revise Regulations, 27 Fed. Reg. 5815, 5815 (proposed June 20, 1962) (to be codified at 21 C.F.R. pts. 1, 125) (stating that major changes in the 1941 regulations were necessary in order to account for the “many advances in the science of nutrition and its commercial applications to products that are represented or which purport to be foods for special dietary uses”).

45. *See* Nat'l Nutritional Foods Ass'n v. FDA, 504 F.2d 761, 767-69 (2d Cir. 1974) (discussing the motivation of the FDA in promulgating the 1962 regulations).

46. Notice of Proposal to Revise Regulations, 27 Fed. Reg. at 5817.

47. *Id.* Other nutrients deemed essential but not significant to the ordinary diet that would have been excluded from dietary supplement labels were folic acid, pantothenic acid, linoleic acid, copper, magnesium, manganese, zinc, sodium, and potassium. *Id.*

48. *Id.* at 5816-17. The potency range for a nutrient was an amount close to the “daily requirements” for each substance. For example, because the recognized daily requirement for the mineral calcium was listed as 750 milligrams for an adult, a dietary supplement containing calcium could have a potency level within the range of the “recommended daily intake” of 400-1500 milligrams. *Id.*

49. *See* Colloton, *supra* note 14.

FDA regulations as an unnecessary hindrance on their ability to access dietary supplements.<sup>50</sup> As a result of the number of comments received, the FDA did not issue a final version of the rule until June 18, 1966, nearly four years after the initial proposal.<sup>51</sup> The final version of the rule kept many of the controversial aspects of the earlier rule, including the minimum and maximum potency levels.<sup>52</sup> In an effort to dispel consumer confusion, the rule would also have required a prominent disclaimer on the label of each dietary supplement attesting that a proper level of vitamins and minerals can be achieved through food.<sup>53</sup>

Once again, the public expressed dissatisfaction with the rule by inundating the FDA with comments.<sup>54</sup> As a result, on December 14, 1966, the day before the proposed rule was to go into effect, the FDA stayed the effective date of the regulation in order to hold public

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50. See *Nat'l Nutritional Foods Ass'n v. Kennedy*, 572 F.2d 377, 379 (2d Cir. 1978). The court stated:

[T]he battle reflects what appears to be a sincere sentiment on the part of many citizens that daily ingestion of a substantial quantity and variety of vitamins and minerals in the form of pills or liquids, in addition to those furnished by ordinary diet, is needed for good health, especially because of the increasing consumption of "the modern food fads—sweet drinks, junk foods, heavy sugar diets" and "wheat germ-free bread and nutritionally inadequate breakfast foods," and the FDA's equally sincere belief that the promotion of what, on a previous review, this court called a "dazzling array" of recommended daily dosages and combinations, is causing consumers to waste millions of dollars annually in the purchase of vitamin and mineral preparations which they either do not need at all or do not need in the potencies or combinations that are being bought.

*Id.* (citations omitted).

51. See *Dietary Foods*, 31 Fed. Reg. 8521, 8521 (proposed June 18, 1966) (to be codified at 21 C.F.R. pt. 125). The rule stated that

[t]he numerous comments received in response to a notice of proposed rule making in the above-identified matter published on the initiative of the Commissioner of Food and Drugs in the FEDERAL REGISTER of June 20, 1962 (27 F.R. 5815), have been evaluated, in addition to other pertinent information, and it is concluded that the regulations for food for special dietary uses should be revised.

*Id.*; see also Kassel, *supra* note 23, at 255.

52. *Dietary Foods*, 31 Fed. Reg. at 8525. The final minimum and maximum potency levels were slightly lower than the original proposed rule. Compare *id.*, with Notice of Proposal To Revise Regulations, 27 Fed. Reg. at 5817. The proposed rule also explained that the "recommended daily intake," now called the "recommended dietary allowance" (RDA), was created by the National Academy of Sciences-National Research Council and that RDAs "represent daily nutrient intakes judged to be adequate for maintenance of good nutrition in the population of the United States and are for the planning of food supplies and guides for interpretation of food consumption records of groups of people." *Dietary Foods*, 31 Fed. Reg. at 8522.

53. *Dietary Foods*, 31 Fed. Reg. at 8525.

54. See Kassel, *supra* note 23, at 255-56.

hearings.<sup>55</sup> A new rule was not proposed until January 19, 1973.<sup>56</sup> This version of the rule proposed that vitamin and mineral products containing more than the maximum potency level of the RDA would be classified as a drug.<sup>57</sup> On August 2, 1973, the FDA published a final version of the rule which was to take effect on January 1, 1975.<sup>58</sup>

In response to the rule, the Second Circuit Court of Appeals received fifteen petitions for review.<sup>59</sup> In *National Nutritional Foods Ass'n v. FDA*,<sup>60</sup> the Second Circuit found that evidence of the need for new standards was impressive because of the number of nutritionally irrational dietary supplements and the general confusion of consumers due to the lack of definitions and standards for dietary supplements.<sup>61</sup>

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55. Order Staying the Effective Date of Regulations; Amending Regulations; and Allowing Additional Time for Filing Objections, 31 Fed. Reg. 15,730, 15,730 (Dec. 14, 1966). The hearings began on May 21, 1968, "lasted for more than 22 months and developed a transcript of 32,405 pages, together with hundreds of exhibits and other record materials." *Nat'l Nutritional Foods Ass'n v. FDA*, 504 F.2d 761, 768 (2d Cir. 1974).

56. Definition, Identity, and Label Statements; Proposed Findings of Fact, Conclusions, and Tentative Order Following a Public Hearing, 38 Fed. Reg. 2152, 2152 (Jan. 19, 1973). The 1973 rule was promulgated after the FDA reviewed the transcript of the hearings and numerous public comments. *Nat'l Nutritional Foods*, 504 F.2d at 768.

57. Label Statements Concerning Dietary Properties of Food Purporting To Be or Represented for Special Dietary Uses, 38 Fed. Reg. 2149, 2149 (proposed Jan. 19, 1973) (to be codified at pts. 1, 3, 125). The text of the law reads: "Any product containing more than the upper limit of the U.S. RDA of a vitamin or mineral is a drug, except for a food represented for use solely under medical supervision in the dietary management of specific diseases and disorders." *Id.* The FDA responded to criticism of this position by stating that the FDA reviewed the records and findings of fact and concluded that there was no evidence that dietary supplements exceeding the RDA were nutritionally useful. Label Statements; Findings of Fact, Conclusions, and Final Order, 38 Fed. Reg. 20,708, 20,710 (Aug. 2, 1973). The FDA stated that dietary supplements "contain[ing] vitamins or minerals in excess of the upper limits of the U.S. RDA's are in fact articles intended for use in the cure, mitigation, treatment, or prevention of disease in man and therefore, pursuant to the definition contained in 21 U.S.C. 321(g)(1)(B), are properly classified as drugs." *Id.* On August 2, 1973, the same day as the final labeling rule was published for dietary supplements, the FDA published a rule which classified high potency Vitamin A and D dietary supplements as drugs. *See* Status of Vitamin A and Vitamin D, 38 Fed. Reg. 20,723, 20,725 (proposed Aug. 2, 1973) (to be codified at 21 C.F.R. pt. 3). These regulations were struck down by the Second Circuit Court of Appeals. *See* *Nat'l Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 338 (2d Cir. 1977); Kassel, *supra* note 23, at 257.

58. Label Statements; Findings of Fact, Conclusions, and Final Order, 38 Fed. Reg. at 20,718. The proposed rule noted that the FDA had received 790 objections to the rule and that other government offices forwarded an additional 20,000 objection letters to the agency, but that the objections offered no substantive reasons for altering the rule. *Id.* at 20,708.

59. *Nat'l Nutritional Foods*, 504 F.2d at 767.

60. 504 F.2d 761 (2d Cir. 1974).

61. *Id.* at 775-76, 778. Nutritionally irrational dietary supplements contain "quantitative levels and qualitative combinations of nutrients for which no human

Nonetheless, the Second Circuit remanded the rule to the FDA for further consideration of three main issues.<sup>62</sup> First, the court wanted the FDA to consider whether the RDA potency limits had room for upward flexibility.<sup>63</sup> Second, the court found that the exclusion of essential vitamins and minerals solely because the FDA had yet to assign RDAs to them was unreasonable, considering that the process of creating the rule had been going on for twelve years.<sup>64</sup> Finally, the Second Circuit invalidated the provision of the proposed rule that would have allowed the FDA to label vitamins and minerals exceeding the RDA as drugs.<sup>65</sup>

Before the FDA could issue new regulations, Congress passed the Proxmire Amendment on April 22, 1976.<sup>66</sup> The Proxmire Amendment was a direct response to the proposed regulations that the FDA had been attempting to implement.<sup>67</sup> The Proxmire Amendment limited the FDA's regulatory abilities by prohibiting the FDA from (1) establishing maximum potency limits for vitamins or minerals; (2) classifying certain vitamins and minerals as drugs solely because they exceeded the potency

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individual need could possibly exist." *Id.* at 776. The court also cited evidence that "[a]lthough approximately 20 percent of the users of dietary supplements of vitamins and minerals actually use those articles to supplement or balance their diet, *more than 40 percent of those persons admit they have no idea which vitamins or minerals, if any, are not sufficiently supplied by their diet.*" *Id.* (emphasis added).

62. *Id.* at 785-89.

63. *Id.* at 785. The FDA's argument for limiting the potency of the vitamin or mineral to the RDA was that studies did not show that vitamins or minerals exceeding the level of RDA served any nutritional value. See Label Statements; Findings of Fact, Conclusions, and Final Order, 38 Fed. Reg. at 20,710. In holding that the RDAs had room for upward flexibility, the court found that "vast multitudes of consumers and significant numbers of nutritionists reject, e.g., the FDA's view that 500 mg. per day of vitamin C is without nutritional value." *Nat'l Nutritional Foods*, 504 F.2d at 784. At the time, the FDA's proposed RDA for Vitamin C for adults was sixty milligrams. Label Statements; Findings of Fact, Conclusions, and Final Order, 38 Fed. Reg. at 20,713-14.

64. *Nat'l Nutritional Foods*, 504 F.2d at 786-87.

65. *Id.* at 789. The FDA justified regulating dietary supplements that exceeded the RDA as drugs because "[t]he hearing record discloses no known food or nutrition use of nutrients at such high levels." *Id.* (quoting Label Statements; Findings of Fact, Conclusions and Final Order, 38 Fed. Reg. at 20,710). The court found this justification was a "mischaracterization of the record" because certain people, such as women who take oral contraceptives, have needs for vitamins and minerals in potencies above the upper limits and because "many common foods contain potencies per serving considerably above the upper limits . . . for example . . . six ounces of fried beef liver contains 18 times the upper limit of vitamin A and . . . a glass of orange juice contains 140% the upper limit of vitamin C." *Id.* & n.34.

66. Health Research and Health Service Amendments of 1976 (HRHSA), Pub. L. No. 94-278, § 501(a), 90 Stat. 401, 410 (codified as amended at 21 U.S.C. § 305 (2000)).

67. Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 675 (1997); Jennifer J. Spokes, *Confusion in Dietary Supplement Regulation: The Sports Products Irony*, 77 B.U. L. REV. 181, 189 (1997).

level that the FDA had determined was nutritionally rational or useful; and (3) limiting the ingredient composition of vitamins, minerals, or other ingredients contained in dietary supplements.<sup>68</sup> On October 19, 1976, the FDA attempted to comply with the court order and the Proxmire Amendment's limitations by issuing a revision of the 1973 regulation.<sup>69</sup> In *National Nutritional Foods Ass'n v. Kennedy*,<sup>70</sup> the Second Circuit once again remanded the FDA's proposed rule because it found that the required public notice and comment on the regulation reflecting the changes in the FDA's regulatory power under the Proxmire Amendment was absent.<sup>71</sup> The FDA then revoked the dietary supplement regulations in 1979.<sup>72</sup> After nearly two decades of attempting to regulate dietary supplements through the rulemaking process, the FDA had nothing to show for all of its effort.

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68. 21 U.S.C. § 350(a)(1) (2000). There were a few minor alterations to the rule, such as the removal of the proposed disclaimer stating that most dietary needs are satisfied through the food people eat.

69. Label Statements Concerning Dietary Properties of Food Purporting To Be or Represented for Special Dietary Uses, 41 Fed. Reg. 46,156, 46,156 (Oct. 19, 1976).

70. 572 F.2d 377 (2d Cir. 1978).

71. *Id.* at 383. See generally Vitamin and Mineral Drug Products for Over-the-Counter Human Use; Withdrawal of Proposed Monograph, 46 Fed. Reg. 57,914, 57,914-15 (Nov. 27, 1981) (providing the history of the FDA's attempt to promulgate a rule governing dietary supplements). In reaching its decision, the Second Circuit acknowledged that the rulemaking process had devolved into a bitter battle and expressed regret in again remanding the rule back to the FDA. See *Kennedy*, 572 F.2d at 379.

72. Vitamin and Mineral Products; Revocation of Regulations, 44 Fed. Reg. 16,005, 16,005 (Mar. 16, 1979). The revocation of the dietary supplement rule appeared in the same issue of the *Federal Register* as a panel report and proposed regulations on OTC vitamin and mineral products. Vitamin and Mineral Drug Products for Over-the-Counter Human Use; Withdrawal of Proposed Monograph, 46 Fed. Reg. at 57,914-15 (explaining the coincidence of the two reports being published on the same day). The panel was created as an independent review agency to review the safety, regulation, and labeling claims of drugs containing vitamins and minerals. *Id.* at 57,914. The proposed rule was based on the panel's report and would have regulated OTC vitamin and mineral products as drugs. *Id.* at 57,914-15. In an unsuccessful attempt to avoid confusion, the rule attempted to distinguish OTC dietary supplements from other dietary supplements, which are regulated as foods. *Id.* The unfortunate coincidence of concurrent publication of the two rules, taken with the uncertainty surrounding the Proxmire Amendment, led to a great deal of confusion and widespread dissatisfaction by the public and members of Congress, which ultimately led the FDA to withdraw the OTC rule in 1981. *Id.* When the FDA withdrew the OTC rule, it acknowledged the general confusion and dissatisfaction surrounding its regulation of dietary supplements. *Id.* The FDA explained that by withdrawing the OTC rule, "the agency formally recognize[d] and respond[ed] to the growing public sentiment expressed by the thousands of comments received from the public and by recent congressional interest in vitamin and mineral regulation. It [was] indicative also of an ongoing agency reassessment of all aspects of vitamin and mineral regulation." *Id.*

Having failed to regulate the industry through the rulemaking process, the FDA attempted to regulate dietary supplements on a case-by-case basis by going after manufacturers through the court system.<sup>73</sup> The FDA's strategy was to classify vitamins and minerals as "food additives."<sup>74</sup> Under the Food Additives Amendment of the FDCA in 1958, food additives required premarket approval from the FDA before they could be marketed or sold.<sup>75</sup> In *United States v. Two Plastic Drums*,<sup>76</sup> the Court of Appeals for the Seventh Circuit emphatically rejected this strategy.<sup>77</sup> The Seventh Circuit held that "[t]he only justification for this Alice-in-Wonderland approach is to allow the FDA to make an end-run around the statutory scheme and shift to the processors the burden of proving the safety of a substance in all circumstances."<sup>78</sup> This decision seemingly foreclosed the attempt to regulate dietary supplements as food additives.<sup>79</sup>

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73. Kassel, *supra* note 23, at 259-60 (explaining that the FDA used a two-prong attack against dietary supplement manufacturers comprised of a limited number of enforcement adjudications coupled with a large number of regulatory letters).

74. Stephen H. McNamara, *Dietary Supplements of Botanicals and Other Substances: A New Era of Regulation*, 50 FOOD & DRUG L.J. 341, 343 (1995) (noting that the FDA had used this strategy against popular dietary supplements such as magnesium orotate, black currant oil, and St. John's wort). In *United States v. Two Plastic Drums*, 984 F.2d 814 (7th Cir. 1993), the Seventh Circuit Court of Appeals summarized the FDA's argument behind classifying dietary supplements as food additives: "The FDA argues that the statutory language of [21 U.S.C. § 321(s)] clearly indicates that any and every component of an article of food is a food additive," *id.* at 817.

75. *See supra* notes 37-42 and accompanying text (discussing the FAA's requirement of premarket approval for food additives and the placement of the burden of proof on the producer, not the government).

76. 984 F.2d 814 (7th Cir. 1993).

77. *See id.* at 819-20. The dispute in this case centered on the FDA's seizure of two drums of black currant oil (derived from the seeds of black currant berries). *Id.* at 815. The FDA seized the barrels and attempted to destroy them as an adulterated food additive. *Id.* at 815-16. The FDA acknowledged that had the black currant oil been produced for individual consumption, as by teaspoon, it would not be a food additive. *Id.* at 816. However, because the black current oil was produced in a capsule made from gelatin and glycerin, the FDA argued it was a food consisting of three additives. *Id.* The court rejected this logic, holding that the FDA's interpretation of food additive was so broad that it would eliminate any distinction between a food and a food additive. *Id.* at 819; *see also* *United States v. 29 Cartons of \* \* \* an Article of Food*, 987 F.2d 33, 37 (1st Cir. 1993). In the legislative history of the Dietary Supplement Health and Education Act (DSHEA), the Senate cited these two cases as examples to show that the "FDA has been distorting the law in its actions to try to prevent the marketing of safe dietary supplement substances." S. REP. NO. 103-410, at 16 (1994).

78. *Two Plastic Drums*, 984 F.2d at 819.

79. *See id.* at 819-20. In DSHEA, Congress later would state explicitly that dietary supplements are not food additives. 21 U.S.C. § 321(s)(6) (2000). In the legislative history for DSHEA, the Senate noted that, although the court decisions in *Two Plastic Drums* and *29 Cartons* should have made it clear that dietary supplements are not food additives,



In 1990, Congress passed the Nutrition Labeling and Education Act (NLEA) as an amendment to the FDCA.<sup>80</sup> The NLEA set standards for health claims for all foods and instructed the FDA to create similar standards for dietary supplements.<sup>81</sup> One year later, the FDA responded by proposing to subject dietary supplements to the same labeling regulations as food.<sup>82</sup> Although the FDA acknowledged that imposing the food labeling regulations on dietary supplements was contrary to the intentions of some members of Congress, the FDA expressed its belief that absent clear congressional direction, dietary supplement labeling claims should meet at least the same standard as food.<sup>83</sup>

Congress disagreed and responded by passing the Dietary Supplement Act (DSA) of 1992.<sup>84</sup> The purpose of the DSA was to mandate a one-year moratorium on the FDA to prevent it from implementing

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Congress found it necessary to state this holding explicitly in DSHEA out of fear that the FDA would challenge the court decisions. See S. REP. NO. 103-410, at 16-17.

80. Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified at 21 U.S.C. § 321, 343, 343-1, 371 (2000)).

81. 21 U.S.C. § 343(r) (2000). From 1986 to 1990, the FDA issued proposed regulations that would have allowed food manufacturers to make health claims concerning the product on the product label. S. REP. NO. 103-410, at 15. Congress believed that the regulations were too tough on dietary supplements because “[t]he level of proof required for dietary supplement claims was unrealistic in that the degree of scientific consensus and clinical data required eliminated almost all existing supplement claims.” *Id.* As a result, Congress enacted the Nutrition Labeling and Education Act (NLEA), which set standards for health claims for food and “specifically said that the FDA could recommend a different standard and approval procedure for supplements.” *Id.* The implication was that Congress wanted the FDA to create more lenient standards for dietary supplements. See *id.* at 14-15. The NLEA also specifically instructed the FDA to investigate the validity of health claims of ten dietary supplements and their impact on certain diseases, and to review health claims for “[c]alcium and osteoporosis, dietary fiber and cancer, lipids and cardiovascular disease, lipids and cancer, sodium and hypertension, and dietary fiber and cardiovascular disease . . . 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.” § 3(b)(1)(A)(vi), 104 Stat. at 2361. When the FDA responded to the NLEA in December 1991, the only health claim it approved was that of calcium and osteoporosis. S. REP. NO. 103-410, at 15. In 1994, in the legislative history for DSHEA, Congress noted that “[o]nly one other claim has been approved since that time, the claim for folic acid and neural tube defects, and that claim was only approved after intense public pressure.” *Id.* at 15-16.

82. Labeling; General Requirements for Health Claims for Food, 56 Fed. Reg. 60,537, 60,537 (proposed Nov. 27, 1991) (to be codified at 21 C.F.R. pts. 20, 101).

83. *Id.* at 60,539-40. The FDA was concerned that a less stringent regulatory scheme for dietary supplements would lead to consumer confusion because dietary supplements would contain health claims that foods consisting of the same substance as the dietary supplement could not. *Id.* at 60,540.

84. Pub. L. No. 102-571, 106 Stat. 4491 (1992); 138 CONG. REC. H12,597 (daily ed. Oct. 8, 1992) (statement of Rep. Waxman).

regulations for dietary supplement health claims under the NLEA.<sup>85</sup> The moratorium was intended to allow time for Congress, the Department of Health and Human Services, and industry groups to develop rules solely for dietary supplements.<sup>86</sup> In reality, Congress used the moratorium to prevent the FDA from implementing regulations that Congress felt were too strict on the health claims of dietary supplements.<sup>87</sup> Congress believed that, by requiring dietary supplements to meet the same standards as food, the FDA was attempting to limit the amount of pertinent nutritional information that the dietary supplement could contain and thereby restrict consumer access to these supplements.<sup>88</sup>

The DSA required the FDA to issue new health claim regulations for dietary supplements by June 1993.<sup>89</sup> On June 18, 1993, the FDA issued an Advance Notice of Proposed Rulemaking (ANPR), which included an in-depth review of the FDA's stance on dietary supplements, including reasons for apprehension about the proliferation of dietary supplements available on the market.<sup>90</sup> The FDA reiterated its beliefs that dietary

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85. 138 CONG. REC. H12,597 (daily ed. Oct. 8, 1992) (statement of Rep. Waxman). The theory behind the moratorium was that, because the NLEA primarily dealt with food, it was proper for Congress to prevent the FDA from using the NLEA as a basis for making rules for dietary supplements. *Id.* (stating that “[b]ecause of the differences in the history of use and function of dietary supplements and conventional foods, it is appropriate for Congress to enact this moratorium so that the issue of how best to regulate dietary supplements may be carefully considered”).

86. *Id.*

87. See 139 CONG. REC. S16,868 (daily ed. Nov. 20, 1993) (statement of Sen. Kennedy). Senators Edward Kennedy (D-Mass.) and Orrin Hatch (R-Utah) proposed the Dietary Supplement Regulation Moratorium Act of 1993 in an effort to add four months to the Dietary Supplement Act of 1992, which set a one year moratorium that would expire on December 31, 1993. *Id.* Senator Kennedy stated that Senator Hatch had introduced DSHEA in April, and Senator Kennedy believed that additional time would result in its passage. *Id.* The Senate unanimously passed the bill, but the House did not act on the legislation. S. REP. NO. 103-410, at 16 (1994).

88. See Colloton, *supra* note 14, at 522.

89. 138 CONG. REC. H12,597 (daily ed. Oct. 8, 1992) (statement of Rep. Waxman) (stating that “this legislation creates a moratorium in the implementation of the NLEA with respect to dietary supplements. This legislation also requires the Secretary to repropose NLEA regulations applicable to dietary supplements no later than June 15, 1993”).

90. Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,690, 33,692 (proposed June 18, 1993). As cause for apprehension of dietary supplements, the FDA cited two health tragedies:

In 1989, at least 1,500 cases of eosinophilia myalgia syndrome (EMS), including 38 deaths, were associated with the use of L-tryptophan-containing dietary supplements. Within the last year, there also have been a number of reports of serious illnesses associated with certain herbal and other botanical supplements.

These developments have raised significant public health concerns.

*Id.* at 33,690. The FDA also cited uncertainty surrounding herbs and other botanicals because of the lack of data for these products. *Id.* at 33,697.

supplements could be regulated as a “food” or “drug” depending upon the use of the product, and that a dietary supplement “intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure or a function of the body” should be regulated as a drug.<sup>91</sup> Congress interpreted the ANPR to mean that the FDA would continue to attempt to overregulate dietary supplements and that therefore, Congress would need to intervene in order to provide the public with access to dietary supplements.<sup>92</sup> As a result, Congress unanimously passed the Dietary Supplement Health and Education Act (DSHEA) of 1994<sup>93</sup> which declared the FDA’s ANPR to be null and void.<sup>94</sup>

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

The underlying premise of DSHEA is that dietary supplements are safe and the FDA should allow the public wider access to them.<sup>95</sup>

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91. *Id.* at 33,692. The FDA also contended that the “intended use of a product may be determined from labeling, advertising, or other sources.” *Id.*

92. S. REP. NO. 103-410, at 16-17 (stating that there is a “need for congressional action to assure citizens have continued access to dietary supplements and information about their benefits”). Part of this need was predicated on the belief that “[i]nstead of using this additional time [provided by the one-year moratorium] to rethink this heavy-handed approach to protecting consumers against misleading claims and other controversial issues, the agency simply reissued the original regulations.” 139 CONG. REC. S16,868 (daily ed. Nov. 20, 1993) (statement of Sen. Kassebaum).

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

94. *Id.* § 11, at 4332. Political support for DSHEA was so strong that, in addition to unanimous passage by both houses of Congress, the majority of the House of Representatives and two-thirds of the Senate co-sponsored the bill. *Dangers of Dietary Supplements Hearing*, *supra* note 14 (statement of Sen. Orrin Hatch, Chairman, Judiciary Comm.).

95. § 2, 21 U.S.C. § 321 note (2000) (noting that safety problems with dietary supplements are relatively rare, that nearly fifty percent of the population takes some form of dietary supplement, and that use of dietary supplements has the potential to decrease the growing cost of health care (then listed at over a billion dollars, roughly twelve percent of the GNP)); 140 CONG. REC. S11,711 (daily ed. Aug. 13, 1994) (statement of Sen. Hatch) (arguing that Congress needed to enact DSHEA because the FDA had been repressing the dietary supplement industry). Senator Hatch exhibited obvious animosity toward the FDA when he stated:

Let us remember why this legislation is necessary.

It is not one Senator versus another, nor Democrat versus Republican, nor the Senate versus the House.

It is the U.S. Congress versus the Food and Drug Administration.

It is the majority of the U.S. Senate versus the continual harassment by one tiny agency which has constantly misled the American public through deliberately false and misleading statements.

It is the 250 Members of the House of Representatives against mindless Government bureaucracy, against continual overregulation, against an agency whose guiding principle has always been: One way—their way.

DSHEA explicitly states that the dietary supplement industry is an integral part of the U.S. economy and that the Government should not impose unreasonable regulatory barriers on the industry.<sup>96</sup> In order to reach these goals, DSHEA broadened the definition of dietary supplements to include herbs and other botanicals, amino acids, and any other “dietary substance for use by man to supplement the diet by increasing the total dietary intake; or . . . a concentrate, metabolite, constituent, extract, or combination of any [of the named] ingredient[s].”<sup>97</sup> By including a wide range of substances in the definition of a dietary supplement, DSHEA greatly increased the amount of substances that could be marketed as dietary supplements and sold to the public.<sup>98</sup>

In addition to broadening the definition of a dietary supplement, DSHEA put an end to the debate on whether a dietary supplement should be regulated as a food or drug by stating: “[A] dietary supplement shall be deemed to be a food within the meaning of [the act].”<sup>99</sup> As a food, dietary supplements are not subject to premarket approval. DSHEA also foreclosed the “food additive” argument by excluding from the definition of food additives “an ingredient described in paragraph (ff) [the definition of dietary supplement] in, or intended for use in, a dietary supplement.”<sup>100</sup> Finally, DSHEA placed the burden of proving the safety of dietary supplements on the FDA by stating that “the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated.”<sup>101</sup> DSHEA thus removed all doubt regarding the regulation of dietary supplements and firmly established that they were not to be treated as drugs or food additives.<sup>102</sup>

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*Id.*

96. § 2(12)(A)-(C), 21 U.S.C. § 321 note (noting that the dietary supplement industry is an important part of the U.S. economy because “the industry consistently projects a positive trade balance; and . . . 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”).

97. *Id.* § 321(ff)(1)(E)-(F).

98. *See id.* § 321(ff).

99. *Id.*

100. *Id.* § 321(s).

101. *Id.* § 342(f).

102. *See supra* notes 99-101 and accompanying text. In the legislative history, Senator Hatch stated:

The purpose of this legislation, as enunciated in section 2, is also to clarify that dietary supplements are not drugs or food additives, that dietary supplements should not be regulated as drugs, and that burden of proof is on the Food and Drug Administration (FDA) to prove that a product is unsafe before it can be removed from the marketplace.

S. REP. NO. 103-410, at 2 (1994).

However, DSHEA did not remove all FDA authority to regulate dietary supplements.<sup>103</sup> Under DSHEA, a dietary supplement may be deemed adulterated if the supplement “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;” or if the Secretary of the Department of Health and Human Services declares the supplement “to pose an imminent hazard to public health or safety.”<sup>104</sup> A potential third avenue of regulation for the FDA is the ability to create mandatory “good manufacturing practice[s]” for the dietary supplement industry through the rulemaking process.<sup>105</sup> Good manufacturing practices are minimum procedures that manufacturers of dietary supplements would have to meet when manufacturing, packaging, or holding dietary supplements to prevent adulteration of the product.<sup>106</sup>

On March 13, 2003, nearly ten years after Congress enacted DSHEA, the FDA published a proposed rule establishing current good manufacturing practices (CGMP).<sup>107</sup> If adopted by the FDA, the CGMP

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103. 21 U.S.C. § 342(f)(1)(A)-(C) (2000). *Contra supra* note 14 (explaining that there is debate as to whether DSHEA decreased or increased the regulatory power of the FDA).

104. 21 U.S.C. § 342(f)(1) (2000).

105. *Id.* § 342(g).

106. Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements, 68 Fed. Reg. 12,158, 12,158 (proposed Mar. 13, 2003).

107. *Id.* For many members of Congress and dietary supplement manufacturers, this ten year delay was too long. See *Dangers of Dietary Supplements Hearing, supra* note 14 (statement of Sen. John McCain, Chairman, Comm. on Commerce, Sci., & Transp.); *Ephedra-Containing Supplements Hearings, supra* note 5, at 259-60 (statement of Rep. Frank Pallone, Jr., Member, Comm. on Energy & Commerce). Although it did take the FDA ten years to propose the current good manufacturing practices (CGMP), the FDA was meticulous in drafting the rule. See *Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements*, 68 Fed. Reg. at 12,160-61 (detailing goals for the CGMP). Specifically, the FDA held several public meetings in which it met with representatives of the dietary supplement industry, toured a number of manufacturing plants, and reviewed data from extensive telephone surveys in order to better understand the industry. *Id.* The telephone surveys revealed that an estimated 158.1 million people annually consumed dietary supplements in the United States at a cost of approximately \$8.5 billion and found that

41 percent of the surveyed consumers who use vitamins and minerals think they are very safe and only 50 percent think they are somewhat safe;

Only 24 percent of the surveyed consumers who use herbal products think they are very safe; and only 53 percent think they are somewhat safe; and

Twelve percent of the surveyed consumers who have used dietary supplements say they have experienced side effects or adverse reactions from their use of dietary supplements.

would create minimum specifications for purity, identity, quality, strength, and composition of dietary supplements.<sup>108</sup> The CGMP would require dietary supplement manufacturers to test their products to ensure that preset specifications are met.<sup>109</sup> The manufacturer also would need to create and retain master manufacturing records to prove that the product has been tested and meets the specifications.<sup>110</sup> If the dietary supplement does not meet the specifications, the FDA would be able to classify the dietary supplement as “adulterated.”<sup>111</sup> Additionally, the manufacturers would need to list the specifications on the label and verify that the labels accurately portray the content of the dietary supplement.<sup>112</sup> If the composition of the dietary supplement differs from what is represented on the label, the FDA may also deem the product adulterated.<sup>113</sup> The CGMP also would require the manufacturers to monitor adverse event reports and submit them to the FDA upon request.<sup>114</sup> Finally, the CGMP would establish minimum standards for the manufacturing plants for design, maintenance, and packing procedures.<sup>115</sup>

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The survey also found strong public support for increased Government regulation of dietary supplements; 74 percent of the surveyed consumers reported that they think that the Government should be more involved in ensuring that these products are safe and do what they claim to do.

*Id.*

108. Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements, 68 Fed. Reg. at 12,162.

109. *Id.*

110. *Id.* at 12,163.

111. *Id.*

112. *Id.* at 12,162. For example, “if the proposed rule is finalized, if the label for a folic acid supplement declares that the dietary supplement contains a certain level of folic acid, the folic acid supplement must actually contain that level, or we would consider the folic acid supplement to be adulterated.” *Id.* Although this seems like a basic concept, to have the label accurately portray the ingredients of the product, the FDA found that there was considerable variation from what was in the product and what was on the label. *Id.* at 12,162-63. The FDA tested twenty dietary supplements containing ephedra and discovered that “[h]alf of the products tested differed in their label claims for ephedra alkaloid content and their actual alkaloid content. In some cases, the discrepancy exceeded 20 percent. *One product did not have any ephedra alkaloids.*” *Id.* at 12,163. (emphasis added).

113. *Id.* at 12,162-63.

114. *Id.* at 12,164-65.

115. *Id.* at 12,162. Minimum maintenance standards for manufacturing plants are necessary because the FDA found unsanitary conditions during their plant inspections. *Id.* (specifying that the FDA found “[p]est infestation, building and equipment defects, and leaking pipes that drip onto dietary supplements”).

### C. The FDA's Attempts to Regulate Ephedra

In 1993, the FDA began to receive adverse event reports (AERs) concerning products containing ephedrine alkaloids.<sup>116</sup> The AERs documented adverse events ranging from relatively minor symptoms, such as increased blood pressure, anxiety, and insomnia, to severe symptoms, such as strokes and heart attacks.<sup>117</sup> In response to the AERs, the FDA evaluated 125 different products containing ephedra.<sup>118</sup> The FDA discovered that the majority of ephedra products on the market contained anywhere from six to twenty other ingredients, many of which had the ability to boost the effects of ephedra.<sup>119</sup> Based on the study of ephedra products and the information contained in the AERs, the FDA proposed a rule for dietary supplements containing ephedrine alkaloids on June 4, 1997.<sup>120</sup>

The proposed rule identified three ways in which dietary supplements containing ephedra alkaloids would be considered adulterated: (1) if the dietary supplement had a dosage of eight milligrams or more of any ephedra alkaloid per serving; (2) if the product's label suggested taking more than eight milligrams in one six-hour period or twenty-four milligrams in one day; or (3) if the product contained a combination of an ephedra alkaloid and another stimulant, such as caffeine.<sup>121</sup> The

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116. Dietary Supplements Containing Ephedrine Alkaloids, 62 Fed. Reg. 30,678, 30,679 (proposed June 4, 1997) (noting that the FDA had received over 800 adverse event reports (AERs) concerning ephedra products since 1993). In response to the AERs the FDA received, the Working Group, the FDA's Food Advisory Committee, held a meeting concerning ephedra based dietary supplements. *Id.* at 30,679-80. The Working Group concluded that products containing ephedrine alkaloids posed a health risk, and recommended the FDA move to regulate them. *Id.* at 30,680. Over the next six months, the FDA received double the amount of AERs. *Id.*

117. *Id.* at 30,679. The list of adverse symptoms associated with ephedra use also included irregular heart rhythms, chest pain, hyperactivity, nervousness, psychoses, and seizures. *Id.* The *Federal Register* further noted that "[m]any of these signs and symptoms occurred in young adults who generally would not have been expected to be at high risk for such conditions (e.g., heart attack and stroke) [and m]any adverse events were reported to occur with the first use or within the first 2 weeks." *Id.*

118. *Id.* In evaluating the dietary supplements, the FDA found that the products marketed were for many different purposes including "weight loss, body building, increased energy, increased mental concentration, increased sexual sensations, or euphoria or as alternatives to illicit street drugs." *Id.*

119. *Id.*

120. *Id.*

121. *Id.* at 30,692-96. In choosing eight milligrams, the FDA noted that doses of twenty milligrams or higher can lead to adverse events occurring in a significant percentage of obese persons and that adverse events, such as high blood pressure, cardiac arrest, and death had been associated with ephedra products containing as little as ten milligrams per serving. *Id.* at 30,692-93. The FDA also noted that some adverse events occurred with servings of eight and nine milligrams of ephedra; however, limitations in the

proposed rule also would have required prominent warnings on the label cautioning against extended use and a health disclaimer cautioning against exceeding the recommended amount or using the product for longer than one week.<sup>122</sup> This proposed rule was unpopular with consumers and manufacturers because of the dosage restrictions and led to a massive lobbying effort against the proposed rule and the FDA.<sup>123</sup>

In response, Congress, through the House Committee on Science, requested that the General Accounting Office (GAO) examine the FDA's process in proposing the rule.<sup>124</sup> In July 1999, the GAO concluded that additional studies were needed before the proposed rule could go into effect.<sup>125</sup> The GAO Report called for more information, concluding that, although the AERs seemed to signal a health risk, they failed to demonstrate a causal relationship between ephedra products and the adverse events contained in the reports.<sup>126</sup> The GAO questioned the validity of the AERs because in some instances, the reports did not contain, or had inconsistent data on, the amount, length, and use of the product.<sup>127</sup> As a result, the GAO found that relying primarily on the AERs made the proposed one week limitation on duration of use and the maximum dosage level appear arbitrary.<sup>128</sup>

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available data did not show that a lesser serving would be safer. *Id.* at 30,693. As a result, the FDA tentatively proposed the eight milligram limit and stated that the "FDA cannot say that it is a safe level, nor has it been arrived at in a way that factored in some margin of safety. The evidence does not exist to establish a safe level." *Id.* at 30,693-94. The FDA also observed that the combination of ephedrine alkaloids with other stimulants tended to "produce more frequent, more severe, or potentially different patterns of adverse effects than those noted with the use of an ephedrine alkaloid alone." *Id.* at 30,695.

122. *Id.* at 30,700-02.

123. See Guy Gugliotta, *Dietary Supplement Makers Flex Muscle: \$15 Billion Industry Fends Off Attempts To Regulate Ephedra over Health Risks*, WASH. POST, Dec. 25, 2000, at A1. At the head of the lobbying effort against the FDA were Senators Orrin Hatch and Tom Harkin. *Id.* Buoyed by financial support from dietary supplement manufacturers (by 2000, Senator Hatch had received more than \$80,000 since 1994 and Senator Harkin had received more than \$72,000), the two senators "coordinate[d] lobbying efforts and co-signed letters to the FDA that repeated the companies' arguments almost verbatim." *Id.*

124. Dietary Supplements Containing Ephedrine Alkaloids; Withdrawal in Part, 65 Fed. Reg. 17,435, 17,474 (proposed Apr. 3, 2000); Gugliotta, *supra* note 123.

125. See U.S. GEN. ACCOUNTING OFFICE, DIETARY SUPPLEMENTS 3 (1999), available at [www.gao.gov/archive/1999/h299090.pdf](http://www.gao.gov/archive/1999/h299090.pdf) (concluding that more information was necessary because of the FDA's reliance on AERs as a basis for the rule and because the FDA had based the rule in part on faulty assumptions in its cost-benefit analysis).

126. See *id.*

127. *Id.* at 11. From a random sample taken from the total amount of reports, the General Accounting Office (GAO) determined that "[a] total of 45 percent of the AERs lacked information on either dose, frequency, or duration, and 24 percent lacked information on all three dimensions." *Id.*

128. *Id.* at 13-16.



In April 2000, the FDA responded to the GAO findings by withdrawing the dosage restrictions, the proposed one week duration limit, and most of the labeling claims in order to conduct further study.<sup>129</sup> The two regulations that remained were the proposed restriction on the combination of ephedrine alkaloids with other stimulants and the proposed warning statements.<sup>130</sup> These regulations were never implemented, and three years later, on February 28, 2003, the FDA announced a reopening of the comment period for the 1997 proposed rule in its entirety.<sup>131</sup> The FDA cited new scientific evidence contained in the *RAND Report* as the impetus behind the renewal.<sup>132</sup>

The *RAND Report* was an independent review of the available literature and research concerning the effectiveness of ephedra and ephedrine products on weight loss and athletic performance.<sup>133</sup> The *RAND Report* concluded that short-term use of ephedra and ephedrine products taken in combination with caffeine produce statistically significant increases in short-term weight loss; that available evidence suggested that “ephedrine alone . . . has little or no effect on athletic performance”; and that there was no evidence to suggest that the effects of a drug combination of ephedrine plus caffeine was any different from the effects of ephedra and caffeine.<sup>134</sup> The *RAND Report* also cited evidence suggesting that ephedra or ephedrine, taken with or without caffeine, leads to a higher risk of “nausea, vomiting, psychiatric symptoms such as anxiety and change in mood, autonomic hyperactivity, and palpitations.”<sup>135</sup> Although more serious events such as heart attacks,

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129. Dietary Supplements Containing Ephedrine Alkaloids; Withdrawal in Part, 65 Fed. Reg. at 17,474-75.

130. *Id.* at 17,476. Had the prohibition on the combination of ephedra with other stimulants been enacted, it is possible that Sean Riggins would not have died from consuming a dietary supplement containing a combination of ephedra and caffeine. See *infra* note 148 and accompanying text.

131. Meadows, *supra* note 16.

132. See U.S. FOOD & DRUG ADMIN., EVIDENCE ON THE SAFETY AND EFFECTIVENESS OF EPHEDRA: IMPLICATIONS FOR REGULATIONS, <http://www.fda.gov/bbs/topics/NEWS/ephedra/whitepaper.html> (last visited Dec. 29, 2004); see also SHEKELLE ET AL., *supra* note 8, at 3.

133. SHEKELLE ET AL., *supra* note 8, at 3. The *RAND Report* was funded by the Agency for Healthcare Research and Quality, in conjunction with the National Institute of Health, Office of Dietary Supplements, and the National Centers for Complementary and Alternative Medicine. *Id.* The *RAND Report* relied on reviews of clinical studies, AERs, and case studies. *Id.* at v. It also reviewed fifty-two controlled clinical trials of ephedrine or herbal ephedra products and excluded eighteen trials for a lack of sufficient duration of study. *Id.* The FDA provided over 1000 AERs for ephedra products and 125 for ephedrine products. *Id.* Finally, the *RAND Report* reviewed 18,502 case reports relating to the dietary supplement manufacturer Metabolife. *Id.*

134. *Id.* at 202.

135. *Id.* at 202-03.

seizures, and death were associated with the taking of ephedra, the *RAND Report* concluded, just as the GAO had in 1999, that more scientific studies were needed to assess the possible causal connection because the majority of the AERs were incomplete and causal conclusions remained undetermined from the existing evidence.<sup>136</sup>

#### D. State Regulation of Ephedra

In response to the inability of the Federal Government to effectively regulate ephedra, state governments have begun to enact legislation banning the sale of ephedra products.<sup>137</sup> Almost half of the states have regulations concerning products containing ephedrine alkaloids.<sup>138</sup> State statutes regulate ephedrine alkaloid products in three situations: (1) regulating products containing ephedrine alkaloids as precursors and essential elements of illegal drugs; (2) regulating products containing ephedrine alkaloids because they purport to be legal substitutes for illegal drugs; and (3) banning all sales of products containing ephedra.<sup>139</sup>

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136. *Id.* The *RAND Report* found that “[t]he majority of FDA case reports [(AERs)] are insufficiently documented to make an informed judgment about the relationship between the use of ephedra-containing dietary supplements and the adverse event in question.” *Id.* at 203. The *RAND Report* also found that nearly all of the AERs provided by Metabolife were “too poorly documented to permit us to make any judgments about the potential relationship between ephedra use and the event.” *Id.* The *RAND Report* therefore concluded that the strongest evidence of causation would come not from AERs, but from clinical studies. *Id.* at 202.

137. See *Ephedra-Containing Supplements Hearings*, *supra* note 5, at 43 (testimony of Cynthia Culmo, former official, Texas Department of Health); Gugliotta, *supra* note 123. At the hearing before the House Committee on Energy and Commerce, Ms. Culmo stated that “DSHEA shifted the requirement of proving a product is unsafe to the government. Many States have had to pick up this tremendous burden because of the apparent inability of the Federal Government to effectively address safety issues associated with these products.” *Id.*; see also 148 CONG. REC. S11,674 (daily ed. Nov. 20, 2002) (statement of Sen. Durbin). Senator Durbin stated:

Over 20 different States have enacted their own State laws restricting the sale of products containing ephedra.

Think about that for a second. It is usually the Federal Government that shows the leadership when it comes to protecting people against dangerous drugs and substances sold. In this case, exactly the opposite is the case; the States have seen the adverse consequences, the States understand the danger, and the States are moving ahead of the Federal Government. How bad is this, that our States are leading when it comes to national health standards, and the Federal Government is silent? And why?

*Id.*

138. 148 CONG. REC. S11,674 (daily ed. Nov. 20, 2002) (statement of Sen. Durbin).

139. See Stewart, *supra* note 14, at 109 (explaining that state legislation initially sought to prohibit use of ephedrine to create illicit drugs and the recent trend sought to prohibit products containing ephedrine which advertised that they produced a “high”); see also Ephedra Prohibition Act, 720 ILL. COMP. STAT. §§ 602/1, /5, /10, /15, /20, /25, /99 (Supp.

The purpose behind the states' initial regulation of ephedrine was to prevent its "use as a precursor to illegal drugs."<sup>140</sup> Ephedrine is a component of illegal drugs such as ecstasy, and, in an effort to decrease ecstasy production, a number of states enacted legislation closely regulating the sale of ephedrine.<sup>141</sup> The second type of state regulation targeted dietary supplements alleging to produce the same effects as illegal drugs.<sup>142</sup> Florida was the first state to pass this type of regulation.<sup>143</sup> Florida's legislation was enacted in response to the death of Peter Schlendorf, a twenty-year-old college student who overdosed on a dietary supplement containing ephedra that purported to produce a high.<sup>144</sup> Florida's legislation only allows the sale of ephedrine alkaloid products by prescription.<sup>145</sup>

The most recent trend in state regulation, banning the sale of all ephedra products, is currently in effect in three states: Illinois, New York,

2004). By enacting the Ephedra Prohibition Act in May 2003, Illinois was the first state to ban sales of all dietary supplements containing ephedra. *See id.*

140. *See* Stewart, *supra* note 14, at 109 (noting that ephedrine could be used in the production of illegal drugs such as ecstasy and methamphetamine).

141. *Id.*; *see, e.g.*, CAL. HEALTH & SAFETY CODE § 11100 (West 1991) (requiring manufacturers and sellers of ephedrine to (1) obtain a letter of authorization and proper identification from the potential buyer and (2) file a sales report with the Department of Justice at least twenty-one days before the delivery of the substance).

142. *See* Stewart, *supra* note 14, at 109-10.

143. *Id.* at 109. Florida's statute banned dietary supplements which contained high levels of ephedrine and purported to mimic the effects of ecstasy or produce "a 'natural high' or increased 'cosmic consciousness.'" *Id.* at 109-10.

144. *See id.* Peter, a college football player on spring break in Panama City, Florida, ingested a dietary supplement called Ultimate Xphoria, suffered a heart arrhythmia, and died. Michael O'Keeffe, *Banning Together: Suffolk County Citizens, Pols Aim To Outlaw Ephedra Products*, N.Y. DAILY NEWS, Dec. 1, 2002, at 62. Peter's parents, Tom and Karen Schlendorf, have been vocal advocates for legislation completely banning the sale of ephedra products since Peter's death. Ann Givens, *Ephedra Ban Takes Effect: Parents Lobbied for State Law*, NEWSDAY, Oct. 18, 2003, at A08. The Schlendorfs also received a \$2.5 million settlement from the dietary supplement manufacturer. *Id.*

145. Stewart, *supra* note 14, at 110 (stating that Florida law also prohibits marketing a dietary supplement containing ephedrine for "the indication of stimulation, mental alertness, weight loss, appetite control, energy, or other indication not approved under the FDA's OTC Final Monograph"). In response to the recent health concerns touched off by the death of Steve Bechler, Florida has enacted legislation which bans the sale of any weight loss dietary supplement to people under the age of eighteen. *See* Phil Wallace, *Illinois Ephedra Sales Ban Draws Industry Criticism*, FOOD CHEMICAL NEWS June 2, 2003, at 20, 20. This ban includes dietary supplements that contain ephedra. *Id.* The effectiveness of banning sales of dietary supplements to minors has been called into question. *See* O'Keeffe, *supra* note 144. Karen Schlendorf, Peter's mother, argues that a full ban on ephedra is needed because "[t]here's a ban on the sale of tobacco and alcohol to teenagers, but we know they get them without many problems. A ban on the sale of ephedra to minors will be just as effective." *Id.*

and California.<sup>146</sup> In May 2003, Illinois became the first state to ban sales of dietary supplements containing ephedra when it enacted the Ephedra Prohibition Act in the wake of Sean Riggins's death.<sup>147</sup> Sean was a sixteen-year-old high school football player who died from a heart attack after taking a dietary supplement containing a combination of caffeine and ephedra.<sup>148</sup> The Ephedra Prohibition Act bans the sale or offer of sale, but not the use, of all dietary supplements containing ephedrine alkaloids in the State of Illinois.<sup>149</sup> The statute states that the purpose of the legislation is to protect the health and safety of the residents of Illinois.<sup>150</sup> This rationale underscores the fact that neither Congress nor

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146. *Dangers of Dietary Supplements Hearing*, *supra* note 14 (statement of Sen. Richard Durbin).

147. See 720 ILL. COMP. STAT. § 602/20 (Supp. 2004). Governor Rod Blagojevich signed the Ephedra Prohibition Act into law in the presence of Sean's parents. Wallace, *supra* note 145. On June 2, 2003, the legislature in Westchester County, New York, followed the Illinois example and banned the sale of any products with any quantity of ephedra, excluding "any drug which contains ephedrine and which is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the [FDCA]." WESTCHESTER COUNTY, N.Y., LAWS OF WESTCHESTER COUNTY § 863.902, <http://www.westchestergov.com/consumer/ephedra/ephedra.htm> (last visited Dec. 29, 2004). Westchester County was the second county in New York to pass legislation banning ephedra sales. Phil Wallace, *Civil Suits Mount as Food and Drug Administration Weighs Ephedra Regulation*, FOOD CHEMICAL NEWS, June 9, 2003, at 27, 27 (noting that in New York, Suffolk County passed similar legislation on February 11, 2003).

148. L. Jon Wertheim, *Jolt of Reality*, SPORTS ILLUSTRATED, Apr. 7, 2003, at 69, 69. The danger of products combining ephedra and other stimulants such as caffeine is illustrated by the death of Sean Riggins. Sean died from a heart attack after consuming a Yellow Jacket pill, a dietary supplement containing a combination of caffeine and ephedra. *Id.* Intrigued as to what would cause a healthy sixteen-year-old who did not smoke, drink, or take drugs to suffer a massive heart attack, health officials conducted an investigation and discovered that the local high school students had a pregame ritual to boost their energy. *Id.* at 69-70. This ritual was called "jacketing" and it consisted of taking a Yellow Jacket pill while drinking a highly caffeinated beverage such as Mountain Dew or Red Bull. *Id.* at 69. By the time medical officials discovered this, it was too late to run a toxicology test on Sean's body to discover what role ephedra might have played in Sean's death. *Id.* at 70, 72. Yellow Jackets were manufactured by NVE Pharmaceuticals, and its president, Robert Occhifinto, testified before Congress that his company had never employed a medical doctor, pharmacologist, or chemist to formulate any of the company's ephedra-containing products. See *Ephedra-Containing Supplements Hearings*, *supra* note 5, at 119, 121-22 (testimony of Robert Occhifinto, President, NVE Pharmaceuticals). Instead, Mr. Occhifinto—a man with no college, medical, or any other graduate degree in pharmacology, chemistry, or nutrition—created the formulas himself. *Id.* at 121-22. Incidentally, Mr. Occhifinto has a criminal record with a conviction for money laundering for a deal that involved selling synthetic ephedrine to a known methamphetamine dealer. *Id.* at 122.

149. 720 ILL. COMP. STAT. § 602/20 (Supp. 2004). Legally sold drug products containing ephedrine alkaloids are exempted by the ban. *Id.*

150. *Id.* § 602/10. In addition to Sean's death, the Illinois Legislature relied on the number of significant adverse events reported for ephedra products, and the fact that

the FDA has enacted legislation applicable to protect the health and safety of all residents of the United States from dietary supplements containing ephedra.<sup>151</sup>

## II. THE FAILURE OF THE CURRENT REGULATORY SYSTEM UNDER DSHEA

### A. *Limitations on the FDA's Ability to Regulate Ephedra*

DSHEA placed the burden of proof on the FDA to show that a dietary supplement is a "significant or unreasonable risk" before it can be taken off the market.<sup>152</sup> The FDA is therefore charged with investigating and making the case that this burden has been met. The FDA first attempted to regulate dietary supplements containing ephedra in 1997.<sup>153</sup> The FDA withdrew this initial attempt in 2000 due to the GAO Report, which called for more causal evidence linking ephedra products to the reported adverse events.<sup>154</sup>

Three years later, in February 2003, the FDA repropoed the rule citing the *RAND Report*, a comprehensive evaluation of all available data on products containing ephedra and ephedrine alkaloids, as new evidence.<sup>155</sup> Nevertheless, the *RAND Report*, like the GAO, concluded

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ephedra products had been banned in a number of countries and by a large number of professional sports, to determine that ephedra was a health risk. *Id.* § 602/5. Specifically, the statute noted that the National Collegiate Athletic Association, National Football League (NFL), International Olympic Committee, the U.S. Army, Canada, Britain, Germany, and Australia had all banned the use of ephedra products. *Id.* § 602/5(7)-(9). In addition to the NFL, Major League Soccer also bans the use of ephedra, *Ephedra-Containing Supplements Hearings, supra* note 5, at 199 (testimony of Donald P. Garber, Commissioner, Major League Soccer), and while NASCAR does not ban it, it does test to ensure that drivers do not exceed a preset limit, *id.* at 198-99 (testimony of Mike Helton, President, NASCAR). Conspicuously absent from the list, especially in light of Steve Bechler's death, is professional baseball. Although minor league baseball bans dietary supplements containing ephedra, Major League Baseball does not. *Id.* at 207 (testimony of Robert D. Manfred, Jr., Executive Vice President, Labor Relations/Human Resources, Major League Baseball). The Players Association's position is "that the players should not be prohibited from using any substances that the U.S. Government has effectively determined are not unsafe for consumption by other American consumers." *Id.* at 211 (statement of Rep. James C. Greenwood, Chairman, House Subcomm. on Oversight & Investigations).

151. See *Ephedra-Containing Supplements Hearings, supra* note 5, at 43 (testimony of Cynthia Culmo, former official, Texas Department of Health).

152. 21 U.S.C. § 342(f) (2000).

153. See *supra* notes 120-23 and accompanying text (detailing the provisions of the 1997 proposed rule).

154. See *supra* notes 124-29 and accompanying text (explaining that the GAO questioned the proposed rule due to the FDA's reliance on AERs).

155. See *supra* notes 131-35 and accompanying text.

that more scientific research was needed to establish a causal relationship.<sup>156</sup> Therefore, the “significant or unreasonable risk” standard is highly suspect as applied to dietary supplements containing ephedrine alkaloids and will almost certainly require a judicial interpretation.<sup>157</sup> The fact that after nearly a decade of investigation, the FDA has been unable to answer the question of whether there is enough evidence to prove that dietary supplements containing ephedra pose a “significant or unreasonable risk” illustrates the FDA’s inability to perform the oversight function that DSHEA thrust upon it.<sup>158</sup>

### *1. Adverse Event Reports (AERs)*

The main roadblock in the FDA’s ability to maintain the burden of proof is its inability to effectively gather evidence.<sup>159</sup> Mark McClellan, Commissioner of the FDA, testified repeatedly in front of the House Subcommittee on Commerce, Trade, and Consumer Protection that under DHSEA the FDA cannot compel the production of the data that would enable the agency to determine whether a dietary supplement is

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156. See SHEKELLE ET AL., *supra* note 8, at 201-05; *supra* note 136 and accompanying text.

157. See *Ephedra-Containing Supplements Hearings*, *supra* note 5, at 245, 247-48 (testimony of Hon. Mark B. McClellan, Commissioner, FDA). Mr. McClellan attributed part of the delay in promulgating ephedra regulations to the fact that no court had ever ruled on the “significant or unreasonable risk” standard, leaving the FDA with the difficult task of gathering evidence for an undefined legal standard. *Id.* In 2003, the FDA released its interpretation of the standard:

“Unreasonable risk” clearly implies a risk-benefit calculus. Such a calculus should be able to examine the available scientific evidence and take it into account in assessing whether the product’s known or suspected risks outweigh its known or suspected benefits, in light of the claims the product makes or under ordinary conditions of use.

U.S. FOOD & DRUG ADMIN., *supra* note 132.

158. *But see* Stephen H. McNamara & A. Wes Siegner, Jr., *FDA Has Substantial and Sufficient Authority To Regulate Dietary Supplements*, 57 FOOD & DRUG L.J. 15, 15 (2002) (arguing that the FDA’s existing regulatory power under DSHEA is adequate and that DSHEA need not be amended).

159. See *Ephedra-Containing Supplements Hearings*, *supra* note 5, at 233-34, 247, 249-50 (testimony of Hon. Mark B. McClellan, Commissioner, FDA); *see also Dangers of Dietary Supplements Hearing*, *supra* note 14 (statement of Sen. Richard Durbin). Senator Hatch, one of the main sponsors of DSHEA, believes that DSHEA provides the FDA with sufficient tools to remove unsafe products from the marketplace and the current regulatory problem with dietary supplements results from the FDA’s lack of proper implementation of DSHEA. *Id.* (statement of Sen. Orrin Hatch, Chairman, Judiciary Comm.). Senator Hatch further argues that while the FDA is at fault, the lack of implementation of DSHEA is not completely the FDA’s fault because the agency lacks adequate resources, such as funds, to investigate potentially harmful dietary supplements. *Id.*

safe.<sup>160</sup> DSHEA does not require dietary supplement manufacturers to maintain standardized adverse event reports or to turn the reports over to the FDA.<sup>161</sup> As a result, the FDA must ask manufacturers to voluntarily turn over potentially damaging information when they are under no legal obligation to do so.<sup>162</sup> The extraordinary lengths through which the FDA had to go to gather information on ephedra products demonstrates the problem with this method of fact finding.<sup>163</sup> The FDA ultimately resorted to bringing criminal charges against Metabolife International in order to gain access to the company's AERs.<sup>164</sup> Once Metabolife turned over the AERs, they were of little use because Metabolife redacted pertinent information.<sup>165</sup> It was not until July 2003, one year later, that Metabolife finally turned over the unredacted AERs.<sup>166</sup> In addition to the potential for undue delay from self-serving manufacturers, another concern with AERs is that there is no guarantee that the AERs will provide complete or accurate information because DSHEA does not require standardized forms.<sup>167</sup> The GAO and the *RAND Report* both documented concerns about relying on adverse event reports as evidence for a proposed rule because the AERs were often incomplete, inaccurate, or contradictory.<sup>168</sup> This means that in

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160. *Ephedra-Containing Supplements Hearings*, *supra* note 5, at 233-34, 247, 249-50 (testimony of Hon. Mark B. McClellan, Commissioner, FDA).

161. *See id.* (differentiating the drug approval process which requires post-market reporting requirements from the approval process of dietary supplements).

162. *Id.*; *see also* Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medwatch: The FDA Medical Products Reporting Program, 65 Fed. Reg. 69,314, 69,315 (Nov. 16, 2000) (noting that the FDA "is totally dependent on voluntary reporting by health professionals and consumers about problems with the use of dietary supplements").

163. *See Ephedra-Containing Supplements Hearings*, *supra* note 5, at 249-50 (testimony of Hon. Mark B. McClellan, Commissioner, FDA); *see also* Colloton, *supra* note 14, at 536 (discussing how the FDA had to purchase samples of ephedra products in order to do research on them because DSHEA does not require dietary supplement manufacturers to provide the FDA with label or ingredient information).

164. *Ephedra-Containing Supplements Hearings*, *supra* note 5, at 250 (testimony of Hon. Mark B. McClellan, Commissioner, FDA).

165. *See id.*

166. *Id.*

167. *See Ephedra-Containing Supplements Hearings*, *supra* note 5, at 233-34 (testimony of Hon. Mark B. McClellan, Commissioner, FDA).

168. *See supra* notes 127-28, 136 and accompanying text. The *RAND Report* found that many of the AERs acquired from the dietary supplement manufacturers were unusable because they did not contain enough pertinent information:

The information was not recorded in an organized fashion, leaving it up to us to interpret its meaning. A good example of this was MIPER 23695 that we (but not Metabolife) classified as a "death." This file consisted of handwritten notes that stated, "migraine HA, wants refund, sister's husband died." Does this mean the customer is the sister's husband, who had a migraine and then died? Or did the

order for the FDA to prove that a dietary supplement is a “significant or unreasonable risk” the evidence must come from scientific data.

## 2. *Scientific Studies*

The *RAND Report* noted that the strongest causal evidence showing that a dietary supplement containing ephedra has caused the reputed harm should come from clinical studies; however, the studies conducted on ephedra did not contain a large enough sample of the population “to adequately assess the possibility of rare outcomes.”<sup>169</sup> The FDA acknowledged that more studies would be useful, but that any study would be expensive and take years to complete and analyze.<sup>170</sup> Prohibitive cost and undue delay may not pose the biggest hurdle for the FDA in regulating dietary supplements. The biggest hurdle could be that any new research may be unethical because of the suspected harm posed by ephedra products.<sup>171</sup> Given that the FDA has published reports concerning the fear that consumption of ephedra increases the risk of heart attack, stroke, and psychotic episodes, and medical reports have confirmed this fear, it may be unethical for the FDA to condone the type of long-term studies that are needed.<sup>172</sup> In the event that such tests could

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customer have a migraine headache, perhaps in part because her sister’s husband died? Without additional information it is impossible to tell.

SHEKELLE ET AL., *supra* note 8, at 199. Senator Durbin, upon review of another Metabolife AER, stated that it resembled a “doodle pad.” 148 CONG. REC. S11,6723 (daily ed. Nov. 20, 2002) (statement of Sen. Durbin).

169. SHEKELLE ET AL., *supra* note 8, at 202.

170. U.S. FOOD & DRUG ADMIN., *supra* note 132 (stating that “[w]hile additional studies of ephedra’s safety and efficiency would clearly be useful, it is unlikely that any studies that could be conducted or completed, at least in the near term, would be powerful enough to resolve these safety questions”). The FDA further noted that “[i]t would take some years for such a study to accumulate enough cases to have the statistical power to detect a significant difference in serious adverse events.” *Id.*

171. *See id.* (stating that “[e]ven if a very costly, definitive large randomized clinical trial could be funded, it might be unethical to carry it out, given the risks suspected from ephedra and the likelihood that its health benefits are modest at best”); *Ephedra-Containing Supplements Hearings*, *supra* note 5, at 33 (testimony of Raymond Woosley, Vice President for Health Sciences, Arizona Health Sciences Center). Woosley testified that it would be unethical to conduct further tests on ephedra given its known health risks. *Id.* Cynthia Culmo, former director for Drugs and Medical Devices for the Texas Department of Health, agrees with Woosley and testified that the only ethical step would be to ban ephedra products. *Id.* at 44.

172. *See Ephedra-Containing Supplements Hearings*, *supra* note 5, at 33 (testimony of Raymond Woosley, Vice President for Health Sciences, Arizona Health Sciences Center); *id.* at 103 (testimony of Carol Boozer, Obesity Research Center, St. Luke’s Roosevelt Hospital); *see also* Bent et al., *supra* note 8, at 470 (concluding that “the risk for an adverse reaction after the use of ephedra is substantially greater than with other herbal products. The sale of ephedra as a dietary supplement should be restricted or banned to prevent serious adverse reactions in the general population”); Christine A. Haller & Neal L.



be conducted, it is unlikely that the test results would provide an adequate representation to the public.<sup>173</sup> Furthermore, given the risks associated with ephedra, any such test would include intense prescreening of subjects to ensure that the subjects do not have any underlying health risks that may be aggravated by the consumption of ephedra.<sup>174</sup> Any prescreening would effectively ensure that only healthy, nonrisk subjects are a part of the test.<sup>175</sup> However, this is not how companies market and sell dietary supplements; they are available to the *entire* public regardless of the health of the individual.<sup>176</sup> In fact, many dietary supplements are taken to *improve* the health of individuals.<sup>177</sup> Therefore, the results from tests of prescreened healthy individuals in clinical trials, where the test regulates variables such as caffeine consumption, probably are not going to be representative of the average American.

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Benowitz, *Adverse Cardiovascular and Central Nervous System Events Associated with Dietary Supplements Containing Ephedra Alkaloids*, 343 *NEW ENG. J. MED.* 1833, 1838 (2000) (concluding that the use of “dietary supplements that contain ephedra alkaloids pose a serious health risk to some users”).

173. See *Ephedra-Containing Supplements Hearings*, *supra* note 5, at 32-33 (testimony of Raymond Woosley, Vice President for Health Sciences, Arizona Health Sciences Center). Woosley argued that scientific studies are “not even relevant to the way ephedra is used in this nation today . . . [b]ecause these products are taken as nonprescription dietary supplements and they are used without any medical supervision or medical screening.” *Id.* Additionally, Representative Diana DeGette identified that, unlike controlled scientific studies, the government cannot limit the distribution of dietary supplements to people who may be least susceptible to the product’s adverse effects. See *id.* at 129 (Rep. Diana DeGette, Member, Subcomm. on Oversight & Investigations).

174. See *id.* at 33 (testimony of Raymond Woosley, Vice President for Health Sciences, Arizona Health Sciences Center).

175. *Id.* For example, Woosley stated that

in the study by Boozer et al., it is often cited as evidence for the safety of these products, the investigators excluded one of every 10 subjects that they interviewed because they had medical conditions that made ephedra and the caffeine product combination that they were studying, in their estimation unsafe.

*Id.* Dr. Boozer is an accomplished doctor in the areas of nutrition and obesity who conducted two studies of ephedra products and found that ephedra with caffeine led to weight loss in the short term. *Id.* at 103-04 (testimony of Carol Boozer, Obesity Research Center, St. Luke’s Roosevelt Hospital). However, Dr. Boozer would not say that her studies showed ephedra was safe nor would she recommend its use for anyone out of the particular parameters of her test subjects, namely otherwise healthy prescreened overweight men and women. *Id.* at 143-44.

176. *Id.* at 145-46, 158.

177. *Dangers of Dietary Supplements Hearing*, *supra* note 14 (statement of Sen. Orrin Hatch, Chairman, Judiciary Comm.).

### B. Current Good Manufacturing Practices (CGMP)

The proposed CGMP would set minimum specifications for purity, identity, quality, strength, and composition for dietary supplements and require that the product and label accurately reflect these specifications.<sup>178</sup> The CGMP would also require the supplement manufacturer to monitor the products through AERs and submit them to the FDA.<sup>179</sup> The problem with the CGMP, however, is that it does not address the main issue with dietary supplements, namely their safety.<sup>180</sup> The CGMP does not regulate the safety of dietary supplements because compliance with the CGMP ensures only the safety of the process of making and packaging the dietary supplement, not that the dietary supplement itself is sound.<sup>181</sup> Similarly, the AERs that the manufacturers would have to monitor and report would pertain to the process of making the product, not the product itself.<sup>182</sup> The CGMP is a step in the right direction for consumers of dietary supplements, and long overdue according to many; however, the CGMP does not address the key issue: whether the dietary supplement itself is safe. Therefore, an additional solution is needed.

### C. State Regulation

The states have been more successful than the FDA at regulating products containing ephedrine alkaloids.<sup>183</sup> The most recent trend in state legislation, banning the sale of all ephedra products, has two limitations: (1) the laws only ban the sale of ephedra in the state, not its use; and (2) the laws only specifically regulate ephedra products, not all dietary supplements.<sup>184</sup> By banning the sale of ephedra products, state laws have placed a stumbling block in front of their residents' access to such products.<sup>185</sup> However, other avenues of supply, such as purchasing ephedra products in sister states or over the Internet, still provide the

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178. See *supra* notes 106-15 and accompanying text.

179. See *supra* note 112.

180. See Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements, 68 Fed. Reg. 12,158, 12,164 (proposed Mar. 13, 2003) (to be codified at 21 C.F.R. pts. 111-12).

181. *Id.* (stating that “[c]ompliance with any final rule, based on the [CGMP] proposal, will not ensure that the dietary ingredient or dietary supplement itself is safe or effective”).

182. *Id.*

183. Compare *supra* notes 137-51 and accompanying text with notes 116-36 (describing the success states have had implementing ephedra regulation laws and the difficulty the FDA has had in attempting to regulate ephedra).

184. See Stewart, *supra* note 14, at 109-10.

185. See *Dangers of Dietary Supplements Hearing*, *supra* note 14 (discussion between Senators John McCain and Richard Durbin).

public with access to the products.<sup>186</sup> The other shortcoming with state regulations applying only to ephedra products is that nothing prevents manufacturers from simply substituting another unproven dietary supplement ingredient for the ephedra.<sup>187</sup> Already, manufacturers of ephedra products are marketing their products as “ephedra free.”<sup>188</sup> These ephedra free products contain ephedra substitutes, many of which have the same pharmacological effects of ephedra and are not safety tested.<sup>189</sup> As these two limitations of state regulations show, in order to effectively solve the dietary supplement quandary, the solution must apply across the board to the entire country and to all dietary supplements.

### III. WHY CONGRESS NEEDS TO AMEND DSHEA AND NOT MERELY BAN DIETARY SUPPLEMENTS CONTAINING EPHEDRA

The attempts by the FDA and the states to regulate dietary supplements containing ephedra illustrate the shortcomings of DSHEA.<sup>190</sup> The FDA, constrained by DSHEA, has been working on ephedra regulation for nearly ten years and to date, has not implemented

186. See *id.* Senators Durbin and McCain discussed the fact that Health Canada, Canada’s equivalent to the FDA, had banned the sale of ephedra products nearly two years before. *Id.* They theorized that the ban made it more difficult, but not impossible, for people to acquire ephedra products through the Internet. *Id.*

187. Andrea Petersen, *The Search for the Next Diet Elixir*, WALL ST. J., June 4, 2003, at D1 (noting that consumers have already begun to purchase ephedra free alternatives and that “[t]he alternatives are made from substances such as bitter orange, green tea and banaba . . . While preliminary science indicates that some of them may help people lose weight, there are few studies that prove they are safe and effective”).

188. Press Release, United States Senate, Senator Charles Schumer (D-NY), *Schumer: Banning Ephedra Great First Step, Now We Must Clamp Down on Copycats Before New Deaths Occur* (May 9, 2003), [http://schumer.senate.gov/SchumerWebsite/pressroom/press\\_releases/PR01688](http://schumer.senate.gov/SchumerWebsite/pressroom/press_releases/PR01688). Senator Schumer listed

over 30 products now being sold or on their way to the market that are touted as “ephedra-free” alternatives to products. Schumer noted that the six most popular ephedra copycats are: Betalean Ephedra-Free from Experimental and Applied Sciences, Inc.

Hydroxycut Ephedra Free from Muscletech Research and Development

*Stacker 2 Ephedra Free from NVE Pharmaceuticals*

Takeoff Hi-Energy Fat-Burner—Ephedra Free from Maximum Health Performance Inc.

Total Lean Ephedra-Free from the General Nutrition Corporation

*Xenadrine EFX Ephedrine Free from Cytodine Technologies[.]*

*Id.* (emphasis added). NVE Pharmaceuticals manufactured the Yellow Jacket dietary supplement that Sean Riggins ingested prior to his death. See Wertheim, *supra* note 148. Xenadrine with ephedra was the dietary supplement that, according to the autopsy report, contributed to Steve Bechler’s death. See *supra*, note 7.

189. See Press Release, *supra* note 188.

190. See *supra* Part II.

a rule.<sup>191</sup> The states, not constrained by DSHEA, have been more successful than the FDA in regulating dietary supplements containing ephedra, including a total ban in three states.<sup>192</sup> The downside of state legislation is that the legislation is not applicable to all states or all dietary supplements.<sup>193</sup> The shortcomings of the FDA and the state attempts at regulation make it paramount that Congress act to create new legislation.

The simplest but least likely amendment to DSHEA would require dietary supplements, like drugs and food additives, to have premarket approval. This amendment is the least likely because Congress has historically held that the American public should have wide access to dietary supplements.<sup>194</sup> Another reason this amendment is unlikely is because of the political influence of the dietary supplement industry.<sup>195</sup>

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191. See *supra* Part I.

192. See *supra* notes 137-51 and accompanying text.

193. See *supra* notes 183-89 and accompanying text.

194. See, e.g., 21 U.S.C. § 342 (2000). The legislative findings of DSHEA note:

(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 . . . .

Dietary Health and Education Act of 1994, Pub. L. No. 103-417 § 2(13)-(15)(A), 108 Stat. 4325, 4326.

195. See Gugliotta, *supra* note 123. Dietary supplement manufacturers have aggressively resisted any attempt to regulate their products using a number of means to combat legislation such as “high-paid lobbyists and increasing campaign contributions to influence and support friendly politicians; high-profile ads to sway public opinion; grass-roots letter-writing campaigns to pressure government agencies; and rapid-response denials to any news or academic report describing ephedra’s dangers.” *Id.*; O’Keefe, *supra* note 144, at 62. The author noted that

[t]he dietary-supplement industry has spent millions on campaign donations and includes congressional powerbrokers such as Sen. Orrin Hatch (R-Utah) and Rep. Dan Burton (R-Ind.) among its supporters. Retailers and multi-level marketers can quickly mobilize thousands of supporters to send a flood of letters, phone calls and E-mails to legislators. Metabolife and other industry giants intimidate critics with lawsuits and an army of high-powered lobbyists.

*Id.*; see also 148 CONG. REC. S11,674 (daily ed. Nov. 20, 2002) (statement of Sen. Durbin). Senator Durbin stated:

[T]he dietary supplement[] industry—is a big political player. When I called for this hearing on ephedra products, and particularly Metabolife, to investigate these adverse event reports and that cases that were showing up in court[,] I will tell you this: In 20 years of service on Capitol Hill, I have never faced more political pressure in my life. I have taken on the big tobacco companies and other pretty big players. On this one, all of a sudden, my colleagues were saying:

As the findings of DSHEA noted, the dietary supplement industry is a multi-billion dollar industry and an integral part of the U.S. economy.<sup>196</sup> In June 2003, *The Wall Street Journal* reported that the dietary supplement industry was an \$18.4 billion dollar industry.<sup>197</sup> Requiring premarket approval for all dietary supplements would effectively grind the dietary supplement industry to a halt because all dietary supplement manufacturers would have to apply for premarket certification, and an overwhelmed FDA would be unable to act quickly to handle the requests efficiently.<sup>198</sup> Another concern with requiring premarket approval is that it may push the cost of dietary supplements too high for the average consumer because manufacturers would need to raise the cost to cover the added expense of the premarket approval process.<sup>199</sup> Finally, requiring premarket approval of all dietary supplements would be too severe given the fact that many dietary supplements are safe and have been proven to be safe over the years.<sup>200</sup>

A less severe amendment to DSHEA would be to narrow the definition of dietary supplement. DSHEA expanded the definition of

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Dick, are you sure you want to have a hearing about Metabolife? Do you realize what a big political player they are and this industry is? Do you realize how good they have been to our party? Do you realize this person and that person is associated with them?

*Id.*

196. *See supra* note 96 (noting that when DSHEA was enacted, the dietary supplement industry consistently had a positive trade balance and was a four billion dollar industry).

197. *See Petersen, supra* note 187. Petersen also reported that the weight loss sector of the dietary supplement industry was worth \$3.6 billion and that ephedra products accounted for thirty-three percent of that amount. *Id.*

198. *See Dangers of Dietary Supplements Hearing, supra* note 14 (statement of Sen. Orrin Hatch, Chairman, Judiciary Comm.) (stating that the FDA is currently undermanned and underfunded to handle the investigative burden of DSHEA).

199. *Id.* (stating that “there are a number of current bureaucrats at the FDA who hate dietary supplements and want to get pre-market approval, which would drive the costs of Vitamin C and other vitamins and minerals and even herbal products out of sight”).

200. *See supra* note 194 (stating that the findings of DSHEA noted that dietary supplements are widely known to be safe). A possible solution to this concern would be to create an exemption for dietary supplements which have a history of “safe use”; however, ephedra would have met such an exception because of its history of use dating back over 5000 years. *See supra* note 8. This demonstrates the deficiency with “safe use” exceptions, namely, that a number of dietary supplement manufacturers do not manufacture dietary supplements in a manner that conforms to the way the substances have been safely used through the years. *See Ephedra-Containing Supplements Hearings, supra* note 5, at 229-34 (testimony of Hon. Mark B. McClellan, Commissioner, FDA) (explaining that historically, ephedra products used medicinally in China consisted of low concentrations of ephedra alkaloids). Therefore, any “safe use” exception would need to set standards for composition and dosage limitations that would ensure that the dietary supplement would be manufactured and used in a manner consistent with its history. *See id.* at 229, 231, 233-35.

dietary supplements to include herbs and other botanicals, amino acids, and any other “dietary substance for use by man to supplement the diet.”<sup>201</sup> Prior to DSHEA, the FDA considered only substances “composed of essential nutrients” to be dietary supplements.<sup>202</sup> Opposition to this definition led the FDA to propose defining a dietary supplement as “a food, other than a conventional food, that supplies a component with nutritive value to supplement the diet by increasing the total dietary intake of that substance.”<sup>203</sup> In proposing this definition, the FDA specifically mentioned herbs as an example of substances that should not be considered dietary supplements because they generally lack significant amounts of essential nutrients.<sup>204</sup> Congress could amend the definition of dietary supplements by excluding some categories of dietary supplements, such as herbs, botanicals, and steroids, and requiring the excluded categories to obtain premarket approval.<sup>205</sup> If herbs and botanicals were excluded from the definition of dietary supplements, then products containing ephedra could be required to demonstrate their safety before they are allowed back onto the market.<sup>206</sup>

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201. See *supra* notes 97-98 and accompanying text; see also *Dangers of Dietary Supplements Hearing*, *supra* note 14 (statement of Sen. Richard Durbin). Senator Durbin stated:

[Y]ou remember when DSHEA was being debated, and I do, too. We talked about Vitamin C and multiple vitamins and garlic and the basic things that frankly cause no problems to anyone. Did anyone in the course of that debate imagine we'd be reaching a point where we'd be selling, under the name of dietary supplements, these witches' brews of chemicals that no one has ever tested in terms of their safety and efficacy?

*Id.*

202. Labeling: General Requirements for Health Claims for Foods, 56 Fed. Reg. 60,537, 60,543 (proposed Nov. 27, 1991).

203. *Id.* at 60,542-43.

204. *Id.* at 60,543.

205. See *Dangers of Dietary Supplements Hearing*, *supra* note 14 (statement of Sen. Richard Durbin). Senator Durbin sponsored the Dietary Supplement Safety Act (DSSA) of 2003 currently before the Senate. S. 722, 108th Cong. (2003). The DSSA would restrict from the definition of dietary supplements substances such as steroids and stimulants. *Id.* §§ 3-4. Senator Durbin's bill would also exempt certain types of stimulants, such as caffeine, but the Senator noted: “We know by human experience the difference between decaf and regular coffee, regular coffee and espresso, caffeine-free Coke and regular Coke. But the average consumer walking into the drugstore won't know that the diet pill Zanrex-3 contains the equivalent stimulant of a six-pack of Coke in each pill.” *Dangers of Dietary Supplements Hearing*, *supra* note 14 (statement of Sen. Richard Durbin); S. 722 § 3.

206. See *Dangers of Dietary Supplements Hearing*, *supra* note 14 (testimony of Dr. Arthur Grollman, Distinguished Professor, Pharmacological Sciences and Medicine). Dr. Grollman testified that DSHEA allows the incorrect labeling of botanical substances as dietary supplements and that many of these substances “include highly toxic and even some carcinogenic herbs creating a serious public health hazard.” *Id.*

This approach would limit the number of dietary supplements that require premarket approval and lessen the burden on the FDA of certifying the products.<sup>207</sup>

Another possible solution would be to amend DSHEA to empower the FDA to be effective investigators. DSHEA implemented a postmarket review framework for dietary supplements, and in such a framework, the FDA must have access to adverse event reports if it is to adequately review the industry.<sup>208</sup> This would require the FDA to have the power to compel the production of scientific data and adverse event reports.<sup>209</sup> A corollary amendment would be for Congress to develop a standardized form for adverse event reports and require that dietary supplement manufacturers accurately record them.<sup>210</sup> Congress should also require dietary supplement manufacturers to register their products and labeling claims with the FDA.<sup>211</sup> The FDA would have more efficiency in the search for products which fail to meet safety standards.<sup>212</sup> Although the FDA would be in a stronger position to enforce DSHEA under these amendments, it would take years for the FDA to gather the

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207. See *id.* Senator Hatch, an ardent supporter of DSHEA, and Senator Durbin, an ardent supporter of revising DSHEA, both agreed that the FDA currently does not have the resources to adequately investigate all dietary supplements. *Id.*

208. See *Ephedra-Containing Supplements Hearing*, *supra* note 5, at 233-34 (testimony of Hon. Mark B. McClellan, Commissioner, FDA); see also *Dangers of Dietary Supplements Hearing*, *supra* note 14 (statement of Sen. Richard Durbin). Senator Durbin referred to the lack of mandatory AERs as an "obvious weakness[]" in DSHEA." *Id.* Senator Durbin's proposed bill, the DSSA, would require dietary supplement manufacturers to develop review procedures for AERs and submit to the FDA any AERs that disclose a serious adverse event, such as death or other serious adverse health conditions resulting in hospitalization or persistent disability. S. 722 § 2.

209. See *Ephedra-Containing Supplements Hearings*, *supra* note 5, at 230 (testimony of Hon. Mark B. McClellan, Commissioner, FDA); Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medwatch: The FDA Medical Products Reporting Program, 65 Fed. Reg. 69,314, 69,315 (Nov. 16, 2000).

210. See *Ephedra-Containing Supplements Hearings*, *supra* note 5, at 43-44 (testimony of Cynthia Culmo, former official, Texas Department of Health); Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medwatch: The FDA Medical Products Reporting Program, 65 Fed. Reg. at 69,315 (noting that the FDA requires mandatory reporting of adverse events for drug, biologic, and medical device products).

211. See *Ephedra-Containing Supplements Hearings*, *supra* note 5, at 43-44 (testimony of Cynthia Culmo, former official, Texas Department of Health); Colloton, *supra* note 14, at 547-50 (arguing that registration of dietary supplement manufacturers and their products would not be overly burdensome on the dietary supplement industry).

212. See Colloton, *supra* note 14, at 547-50.

needed evidence against potentially harmful dietary supplements and then move to ban the product.<sup>213</sup>

The most likely, but least effective, solution would be for Congress or the FDA to ban ephedra completely. As with the state laws that ban the sale of ephedra, this type of solution is shortsighted in that it would only treat a symptom of the illness, not the illness itself, namely the failure of the regulatory framework under DSHEA.<sup>214</sup> This solution may be irrelevant by the time it is passed because the states and public have started to enact their own solutions while the FDA and Congress debate; three states have banned the sale of ephedra products outright, and recently major drug store chains such as Rite Aid, CVS, and Wal-Mart have refused to sell dietary supplements containing ephedra.<sup>215</sup> A number of dietary supplement manufacturers, including General Nutrition Centers (GNC) and Twinlab, have stopped manufacturing dietary supplements with ephedra.<sup>216</sup> Although this is probably a self-serving attempt to avoid escalating insurance costs due to the rising number of deaths and lawsuits associated with ephedra products, the manufacturers themselves have removed ephedra products from the market, something that neither Congress nor the FDA have been able to accomplish.<sup>217</sup>

The current regulatory framework for dietary supplements is analogous to the regulatory framework for food additives prior to

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213. *Cf. supra* notes 38-43 and accompanying text (reporting that the FAA was passed in order to close a similar loophole in regulatory law which allowed substances defined as food additives to be added to food without premarket approval).

214. *See supra* Part II.

215. *Dangers of Dietary Supplements Hearing, supra* note 14. (statement of Sen. Richard Durbin).

216. *See* O'Keeffe, *supra* note 144, at 62; Petersen, *supra* note 187.

217. *See* Petersen, *supra* note 187. Petersen notes that

companies continue to pull their ephedra products off store shelves on their own, after being hit with consumer lawsuits or seeing their insurance premiums skyrocket. "*The insurance industry has been able to do what the FDA hasn't,*" says Mark Blumenthal, executive director of the American Botanical Council, a nonprofit herbal education group.

*Id.* (emphasis added); *see also* O'Keeffe, *supra* note 144 (explaining that dietary supplement manufacturer "Herbalife decided earlier this year to discontinue sales of ephedra after its premiums jumped to \$2.5 million in 2001 up from \$400,000 in 2000" and that "Twinlab cited 'escalating insurance costs and regulatory uncertainties' when it announced that it will stop all sales of ephedra products"). Recent judgments against ephedra manufacturers have awarded plaintiffs large sums of money and have encouraged similar suits. *See* Wallace, *supra* note 147, at 27 (noting that many civil suits have been filed against ephedra manufacturers, including a nationwide lawsuit filed on behalf of all ephedra users in a U.S. district court in Illinois).



Congress's enactment of the FAA in 1958.<sup>218</sup> A loophole exists for dietary supplements allowing a manufacturer to put a product on the market without proving that it is safe; the burden is on the FDA to prove the product is unsafe before it can be removed from the market.<sup>219</sup> As the FDA's battle to regulate ephedra indicates, this is a time consuming process, during which time the dangerous product remains on the market.<sup>220</sup> The best solution is one that would allow the public access to only *safe* dietary supplements. Congress should amend the definition of dietary supplements to remove unproven substances such as herbs and botanicals and require these products to obtain premarket approval.<sup>221</sup> At the same time, Congress needs to increase the regulatory power of the FDA by giving it the power to obtain standardized AERs from dietary supplement manufacturers who would also be required to register their products and labeling claims with the FDA. This combination would ensure that safe dietary supplements are available to the public, enable the FDA to be more effective investigators, and allow dietary supplement manufacturers a chance to put potentially harmful substances on the market by proving their safety.

#### IV. CONCLUSION

This Comment has argued that the current regulatory scheme for dietary supplements under DSHEA has created a dangerous situation where unsafe dietary supplements are sold to unsuspecting consumers. The failures of the existing law are demonstrated through the health risks presented by dietary supplements containing ephedrine alkaloids and the FDA's inability to remove these products from the market. In response to the inability of the Federal Government to protect consumers from unsafe dietary supplements such as ephedra products, state governments have passed legislation protecting their residents. Although state legislation, and potentially federal legislation—if the FDA enacts a ban—will adequately protect the American public from the dangers of ephedra products, a need still exists for Congress to enact legislation that will protect all Americans from all unsafe dietary supplements. In an effort to prevent the death of the next Steve Bechler, Sean Riggins, or

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218. See *supra* notes 38-43 and accompanying text (discussing how prior to enactment of the FAA, Congress believed that a loophole existed in regulatory law because unsafe food additives were allowed to stay on the market while the FDA built a case against it).

219. *Id.*

220. See *Ephedra-Containing Supplements Hearings, supra* note 5, at 32 (testimony of Raymond Woosley, Vice President for Health Sciences, Arizona Health Sciences Center) (lamenting that while the RAND analysis was being conducted, people needlessly died as ephedra products were still on the market).

221. See *supra* notes 204-06 and accompanying text.

Peter Schlendorf, this Comment has proposed that Congress amend the definition of dietary supplement in DSHEA to limit the broad range of untested substances currently allowed, and has called for an increase in the regulatory power of the FDA in order to allow the agency to be more effective in carrying its burden under DSHEA.

#### V. ADDENDUM

On February 6, 2004, after nearly ten years of study, the FDA issued a final rule concluding that dietary supplements containing ephedrine alkaloids are adulterated because they “present an unreasonable risk of illness or injury.”<sup>222</sup> This rule effectively bans the manufacture or sale of dietary supplements containing ephedrine alkaloids, and thus ephedra.<sup>223</sup> In reaching its determination, the FDA adopted a balancing test as the proper standard to determine whether an “unreasonable risk” exists.<sup>224</sup> The unreasonable risk standard requires a “relative weighing of the product’s known and reasonably likely risks against its known and reasonably likely benefits.”<sup>225</sup>

The FDA found dietary supplements containing ephedrine alkaloids to be an unreasonable risk because of the lack of scientific data supporting health benefits and the fact that use of ephedra products increased the risk of stroke and heart attack by causing an increase in blood pressure and heart rate.<sup>226</sup> This rule banning ephedra became effective on April 12, 2004.<sup>227</sup> Two dietary supplement manufacturers, NVE Pharmaceuticals and the National Institute for Clinical Weight Loss, sued the FDA in the U.S. District Court for the District of New Jersey for a temporary injunction against the rule going into effect.<sup>228</sup> Although the court denied the injunction, further litigation on the legality of the rule is likely.<sup>229</sup>

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222. 21 C.F.R. § 119.1 (2004).

223. Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk, 69 Fed. Reg. 6788, 6788 (proposed Feb. 11, 2004) (to be codified at 21 C.F.R. pt. 119).

224. *Id.*

225. *Id.*

226. *Id.* at 6789.

227. Press Release, FDA Announces Rule Prohibiting Sale of Dietary Supplements Containing Ephedrine Alkaloids Effective (Apr. 12, 2004), <http://www.fda.gov/bbs/topics/News/2004/NEW01050.html>.

228. *Id.*; see also Marc Kaufman, *FDA Ban on Ephedra Upheld by Federal Judge*, WASH. POST, Apr. 13, 2004, at A6.

229. See Kaufman, *supra* note 228; Press Release, *supra* note 227.

The day the rule was published, the FDA posted questions and answers regarding the new rule.<sup>230</sup> The explanations to the questions “Why didn’t the FDA reach this conclusion sooner?” and “What has the FDA been doing to meet the requirements to take action under the dietary supplement law?” are defensive and further illustrate the failure of the current dietary supplement regulatory system.<sup>231</sup> The FDA explains that under DSHEA the FDA has the burden of proof to establish that dietary supplements are unsafe, but the “FDA *has no authority to require any studies of safety or effectiveness for dietary supplements.*”<sup>232</sup> The FDA then defends the ten years of work it put into banning ephedra by stating that the “FDA has gone to great lengths to obtain and review all of the relevant scientific evidence on ephedra, as well as adverse event information, *even though FDA’s legal authorities to obtain this information are limited.*”<sup>233</sup> The ban on ephedra therefore has ended the threat posed by dietary supplements containing ephedra; however, the need for Congress to act to protect consumers from the dangers of other untested dietary supplements remains.

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230. U.S. FOOD & DRUG ADMIN., QUESTIONS AND ANSWERS ABOUT FDA’S ACTIONS ON DIETARY SUPPLEMENTS CONTAINING EPHEDRINE ALKALOIDS, [http://www.fda.gov/oc/initiatives/ephedra/february2004/qa\\_020604.html](http://www.fda.gov/oc/initiatives/ephedra/february2004/qa_020604.html) (Feb. 6, 2004).

231. *Id.*

232. *Id.* (emphasis added).

233. *Id.* (emphasis added).