

DSHEA'S FAILURE: WHY A PROACTIVE APPROACH TO DIETARY SUPPLEMENT REGULATION IS NEEDED TO EFFECTIVELY PROTECT CONSUMERS

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In 1994, Congress enacted the Dietary Supplement Health and Education Act (DSHEA), the first distinct regulatory scheme for dietary supplements sold in the United States. Although DSHEA is a congressional milestone as the first act to specifically address dietary supplements, it remains inadequate. DSHEA, as operated through the Food and Drug Administration (FDA), fails to adequately protect consumers from unsafe dietary supplements, such as ephedra, L-tryptophan, and Hydroxycut. Collectively, these dietary supplements have caused numerous illnesses and deaths. Under DSHEA manufacturers are required to report certain facts to the FDA, such as whether a new dietary ingredient is reasonably expected to be safe. Additionally, manufacturers are required to report serious adverse events associated with a dietary supplement. Until recently, however, the FDA retained the burden of proving that a dietary supplement was unreasonably risky. Consequently, dangerous products remained on the shelves for many years.

The European Union's Food Supplements Directive is much more restrictive than DSHEA. The Food Supplements Directive established a "positive list" that enumerates the permissible vitamins, minerals, and other ingredients permitted to be used in dietary supplements. This Note proposes that Congress amend DSHEA to incorporate several provisions of the Food Supplements Directive to better protect American consumers from the dangers associated with unsafe dietary supplements. The author argues that DSHEA limits the FDA's ability to protect consumers and Congress should adopt an intermediate approach to dietary supplement restriction. This approach would implement additional premarketing requirements through a three-tier regulatory system, treating dietary supplements differently based on their marketing dates and potential risks. This regulatory scheme would strike a balance between consumer access

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and safety and would help prevent additional dietary supplement-related tragedies.

I. INTRODUCTION

A routine trip through the health section of a local retail store can be a pretty overwhelming experience. The wide variety of vitamins, minerals, herbs, and athletic performance products makes selecting a dietary supplement quite difficult. To put this difficulty into perspective, consider that Wal-Mart currently sells over 500 different dietary supplements,¹ and specialty stores like GNC sell significantly more.² Dietary supplements vary widely, and even common multivitamins now target specific groups of people by age, gender, physical conditions, and also activity level.³ While the dietary supplement industry has grown rapidly in recent years, dietary supplements have been commercially available in the United States for almost a century. That said, Congress decided to wait until 1994 to officially define and enact dietary supplement specific regulations as part of the Dietary Supplement Health and Education Act (DSHEA).⁴

DSHEA represented a major step toward broadening the regulatory definition of dietary supplement and altered the federal government's oversight of the industry.⁵ DSHEA's implications are broad, but to understand its effect on the dietary supplement industry, one needs some foundational knowledge about dietary supplements. Congress currently defines "dietary supplement" as "a product (other than tobacco) intended to supplement the diet" that contains one or more dietary ingredients listed in DSHEA.⁶ These ingredients include—but are not limited to—vitamins, minerals, herbs, botanicals, amino acids, and dietary substances used to increase total dietary intake, as well as any combination

1. Walmart, Health & Beauty: Vitamins, <http://www.walmart.com/catalog/catalog.gsp?cat=1005863> (follow "Supplements" hyperlink) (last visited Mar. 14, 2010).

2. GNC, <http://www.gnc.com> (last visited Mar. 14, 2010). For example, GNC currently sells 480 different protein products and over 100 different diet and energy products. GNC, Sports Nutrition: Shop for All Categories, <http://www.gnc.com> (follow "Protein" or "Diet" hyperlinks) (last visited Mar. 14, 2010).

3. See, e.g., One A Day Products, <http://www.one-a-day.com/products.html> (last visited Mar. 14, 2010). One A Day, which is a well-known and popular brand of multivitamins from Bayer Healthcare, currently markets the following different formulas to consumers: Women's, Women's₂O, Men's Health Formula, Women's 50+ Advantage, Men's 50+ Advantage, Women's Prenatal, Women's Active Mind & Body, Women's Active Metabolism, Cholesterol Plus, Energy, Energy Advantage₂O, Maximum, Essential, Teen Advantage, and Vitacraves Gummies. *Id.*

4. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended in scattered sections of 21 and 42 U.S.C.).

5. HEATHER HEDRICK FINK ET AL., PRACTICAL APPLICATIONS IN SPORTS NUTRITION 259 (2006).

6. § 3, 108 Stat. at 4327 (codified as amended at 21 U.S.C. § 321(ff)(1) (2006)). The adopted definition is very similar to Merriam-Webster's definition of dietary supplement as being "a product taken orally that contains one or more ingredients (as vitamins or amino acids) that are intended to supplement one's diet and are not considered food." MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 348 (11th ed. 2006).

of these ingredients.⁷ As a result, the congressional definition of dietary supplement encompasses everything from sport performance products like creatine, protein powders, and weight loss products, to vitamins, mineral extracts, and most herbal remedies.⁸

Whereas most consumers would have no problem distinguishing between dietary supplements, drugs, and foods, Congress waited over eighty years from the introduction of vitamin tablets to actually establish a separate regulatory scheme for dietary supplements.⁹ This delay is quite puzzling considering many consumers likely would expect substantial governmental regulation in this area. Therefore, during the period of congressional silence, the Food and Drug Administration (FDA) was forced to regulate dietary supplements under the existing congressional standards for food or drugs.¹⁰

The impact of dietary supplements on the average consumer is considerable and can be demonstrated by a simple Internet search. For example, a search for the term “supplement” on Bodybuilding.com, a popular exercise and nutrition Web site, yields almost 4500 results,¹¹ and a more refined search for “dietary supplement” yields almost 1200 results.¹² Meanwhile, a similar search on Google yields over 5.5 million results.¹³ The economic impact of dietary supplements is equally significant. In 2002, the sports nutrition market (comprised of sports energy bars, drinks, and other performance supplements) generated sales of over six billion dollars,¹⁴ and the dietary supplement industry as a whole has grown significantly since DSHEA's passage.¹⁵ Despite this growth

7. § 3, 108 Stat. at 4327 (codified as amended at 21 U.S.C. § 321(ff)(1)).

8. See generally Nutrition Guide, Common Vitamins and Minerals, http://www.dcoctor.com/pages/rightpages_wellnesscenter/dietandnutrition/nutritionguide/nutriguide_vitamins.html (last visited Mar. 14, 2010) (listing common vitamins and minerals).

9. See Lewis A. Grossman, *Food, Drugs, and Droids: A Historical Consideration of Definitions and Categories in American Food and Drug Law*, 93 CORNELL L. REV. 1091, 1119 (2008). During the early 1900s there was a struggle over whether vitamins should be considered foods or drugs. Congress failed to address this question specifically, but vitamins nonetheless typically were considered to be food. *Id.* at 1119–23.

10. Not surprisingly, Congress delegated the authority to regulate dietary supplements to the FDA, as it had previously done for food and drugs. See generally U.S. Food & Drug Administration, Overview of Dietary Supplements, <http://www.cfsan.fda.gov/~dms/ds-oview.html#regulate> (last visited Mar. 14, 2010).

11. Bodybuilding.com, <http://www.bodybuilding.com/fun/bbmainsupp.htm> (enter “supplement” in the search box at top of the page) (last visited Mar. 14, 2010).

12. *Id.* (enter “dietary supplement” in the search box at top of the page). The common use of the word “supplement” in the context of weightlifting and exercise would likely explain the difference in the overall number of results for searches for “supplement” and “dietary supplement,” along with the other possible uses of the word supplement, beyond referencing dietary supplements.

13. Google, <http://www.google.com> (enter “dietary supplements” in the search box) (last visited Mar. 14, 2010).

14. FINK ET AL., *supra* note 5, at 259 (citing *Sports Nutrition and Weight Loss Market III*, 7 NUTRITION BUS. J. 1, 1–8 (2002)).

15. For example, the FDA estimated that Sports Nutrition Products accounted for only \$927 million in sales in the year 1996. MARY K. MUTH ET AL., ECONOMIC CHARACTERIZATION OF THE DIETARY SUPPLEMENT INDUSTRY 5-2 (1999). This growth has not been limited to consumer spending as it has been estimated that one thousand new dietary supplements are marketed each year, raising

and DSHEA being the first legislation directed specifically at dietary supplements, it has failed to effectively protect consumers from potentially harmful dietary supplements.

A return to the retail store example emphasizes the problem. Besides the difficulty in selection, it is nearly impossible for consumers to know which dietary supplements are actually safe and which may be harmful. Take, for example, the millions of consumers who took Hydroxycut products before they were voluntarily recalled in May 2009.¹⁶ The FDA issued a consumer warning only after it had received twenty-three reports of serious health problems related to liver damage and a teenager had died.¹⁷ Although the FDA was ultimately able to take action and encourage the manufacturer to recall the product, DSHEA limits its ability to take proactive measures.¹⁸ DSHEA's flawed and ineffective reactive regulatory approach prevents the FDA from acting swiftly to protect consumers from unsafe dietary supplements.

Under DSHEA, the FDA has the burden of proving that a particular dietary supplement is unsafe for consumer use before it can be taken off the market. This Note proposes that Congress enact more proactive legislation using the European Union's Food Supplements Directive as a model.¹⁹ In doing so, Congress should place a greater premarket burden on manufacturers seeking to market new dietary supplements and grant the FDA greater authority to investigate and ensure they are safe for consumption.

In Part II, this Note presents a substantive history of the FDA and its regulation of dietary supplements before and after DSHEA. Part III continues with an analysis of DSHEA's specific provisions and the requirements placed specifically on the manufacturers²⁰ and the FDA. Part III then compares those requirements with the Food Supplements Directive. Part IV closes by proposing legislative changes that would enable the FDA to effectively regulate dietary supplements and ensure consumer safety.

the total number to over twenty-nine thousand. NWEZE EUNICE NNAKWE, COMMUNITY NUTRITION: PLANNING HEALTH PROMOTION AND DISEASE PREVENTION 328 (2009).

16. See Sandra Young, *Stop Using Hydroxycut Products, FDA Says*, CNN, May 1, 2009, <http://www.cnn.com/2009/HEALTH/05/01/hydroxycut.fda.recall/index.html>.

17. See U.S. Food & Drug Administration, *Warning on Hydroxycut Products*, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm152152.htm> (last visited Mar. 14, 2010).

18. In fact, the FDA did not even learn about the death until 2009 even though it occurred in 2007. Kathleen Doheny, *Hydroxycut Recall Due to Liver Injuries*, EMEDICINEHEALTH, May 1, 2009, <http://www.emedicinehealth.com/script/main/art.asp?articlekey=99885>.

19. Council Directive 2002/46, *On the Approximation of the Laws of the Member States Relating to Food Supplements*, 2002 O.J. (L 183) 51 (EC) [hereinafter *Food Supplements Directive*].

20. The majority of DSHEA's requirements apply to both manufacturers and distributors. See, e.g., *Dietary Supplement Health and Education Act of 1994*, Pub. L. No. 103-417, § 8, 108 Stat. 4325, 4331 (codified as amended at 21 U.S.C. § 350b (2006)). For the purposes of this Note, I refer to them collectively as the manufacturer. This is to prevent confusion and unnecessary verbiage.

II. BACKGROUND

The FDA is a regulatory agency within the U.S. Department of Health and Human Services.²¹ Its primary mission is to “protect[] the public health by assuring the safety, efficacy, and security of . . . drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation.”²² In executing this mission, the FDA has the duty to “ensur[e] that foods are safe, wholesome and sanitary” and that they are “honestly, accurately and informatively represented to the public.”²³ This duty applies to dietary supplements because they currently fall within the overarching category of food.²⁴ Nevertheless, Congress has consistently altered the FDA’s ability to regulate dietary supplements during the last century, which is why an analysis of DSHEA requires an understanding of the FDA’s traditional role in dietary supplement regulation.

This Part begins by describing the historical backdrop of the FDA and how dietary supplement regulation has evolved over time. Next, this Part continues by discussing the FDA’s ability to regulate dietary supplements under DSHEA and how its limitations delayed the ephedra ban. Finally, this Part compares DSHEA’s reactive scheme with the European Union’s proactive scheme, the Food Supplements Directive.

A. *Historical Regulation of Dietary Supplements*

The FDA impacts U.S. consumers on a daily basis. FDA regulated products²⁵ account for an astounding twenty percent of consumer spending—over one trillion dollars each year.²⁶ Meanwhile, dietary supplement sales account for over twenty billion dollars each year,²⁷ a figure that continues to rise.²⁸ The number of U.S. consumers who purchase and use dietary supplements is just as significant. A recent compilation of studies revealed that fifty-two percent of consumers over nineteen

21. U.S. Food & Drug Administration, Centers & Offices, <http://www.fda.gov/opacom/7org.html> (last visited Mar. 14, 2010).

22. U.S. Food & Drug Administration, What Do We Do, <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last visited Mar. 14, 2010).

23. U.S. Food & Drug Administration, What FDA Regulates, <http://www.fda.gov/comments/regs.html> (last visited Mar. 14, 2010).

24. See U.S. Food & Drug Administration, Foods, <http://www.fda.gov/Food/default.htm> (last visited Mar. 14, 2010).

25. These products include—but are not limited to—food, drugs, cosmetics, animal products, and dietary supplements. See generally U.S. Food & Drug Administration, *supra* note 23.

26. Carol Rados, *FDA Law Enforcement: Critical to Product Safety*, FDA CONSUMER, Jan.–Feb. 2006, <http://www.fda.gov/AboutFDA/WhatWeDo/History/FOrgsHistory/ORA/ucm084102.htm>.

27. MARY FRANCES PICCIANO, OFFICE OF DIETARY SUPPLEMENTS, WHO IS USING DIETARY SUPPLEMENTS AND WHAT ARE THEY USING? 5 (2005), <http://ods.od.nih.gov/pubs/fnce2005/M%20F%20Picciano-Who%20Is%20Using%20Dietary%20Supplements%20and%20What%20are%20They%20Using.pdf>.

28. See MUSCLE & FITNESS, Dec. 2008, at 50. The current estimate is twenty-two billion dollars each year. *Id.*

years of age reported taking dietary supplements.²⁹ Others have estimated that between 100 and 150 million³⁰ Americans currently use dietary supplements.³¹ It is also significant that many people use several at a time. Of the fifty-two percent reported above, almost twenty percent reported taking at least four dietary supplements each day.³²

The wide use of dietary supplements in the United States is not a recent phenomenon, as dietary supplements have been available for several generations. Nevertheless, dietary supplements have recently increased in popularity and have become more widely available in the last two decades.³³ This popularity increase helps explain why Congress finally decided in 1994 to separately define and regulate dietary supplements. In doing so, Congress codified the means by which the FDA could monitor and evaluate dietary supplements. With DSHEA, however, Congress actually limited the FDA's ability to effectively regulate dietary supplements because now, the FDA may only remove a dietary supplement from the market if an extensive review indicates that it poses a significant and unreasonable health risk.³⁴ This was not an unintended result, as Congress intentionally responded to political pressure urging a less restrictive regulatory approach in the wake of years of regulatory uncertainty.

29. PICCIANO, *supra* note 27, at 12. Another study conducted by Harris Interactive in 2001, showed that nearly sixty percent of the 1027 American adults surveyed reported regularly taking dietary supplements. See Michael Devitt, *Supplement Use Continues to Rise in the U.S.*, ACUPUNCTURE TODAY, Oct. 2001, <http://www.acupuncturetoday.com/mpacms/at/article.php?id=27871>.

30. See S. REP. NO. 109-324, at 2 (2006) (noting that critics of DSHEA have urged requirements of premarket approval for at least some dietary supplements).

31. For example, the 2006 U.S. census report found the population of the United States to be 300 million with 72.5 percent of the population being twenty years of age or older. United States Census Bureau, Age and Sex, http://factfinder.census.gov/servlet/STTable?_bm=y&-geo_id=01000US&-qr_name=ACS_2006_EST_G00_S0101&-ds_name=ACS_2006_EST_G00_ (last visited Mar. 14, 2010). Applying these figures results in a finding that 217.5 million Americans are in that age group, and if fifty-two percent of Americans in this age range are taking dietary supplements, then over 113 million Americans consume dietary supplements. Though the 150 million estimate may seem high, the 113 million estimate does not include anyone under the age of nineteen, and there are numerous vitamin supplements available for children as well as adults.

32. PICCIANO, *supra* note 27, at 18. In athletes, the usage rate of dietary supplements is even greater, with twenty-three percent of National Collegiate Athletic Association (NCAA) athletes reporting taking dietary supplements at least five times per week. FINK ET AL., *supra* note 5, at 259. Considering the NCAA places restrictions on the types of dietary supplements and performance-enhancing substances that may be used, this figure is likely an underestimate of the actual usage among NCAA athletes. See National Collegiate Athletic Association, Nutritional Supplements, <http://www.ncaa.org/wps/ncaa?ContentID=8787> (last visited Mar. 14, 2010).

33. For example, in the ten year span from 1991 to 2001, dietary supplement sales tripled from five billion to fifteen billion dollars. Scott Eric Barrett, *Supplementing Your Profits: Health Supplement Sales Continue to Rise*, LOOKING FIT, Feb. 1, 2003, <http://www.lookingfit.com/articles/321feat2.html>.

34. Iona N. Kaiser, Comment, *Dietary Supplements: Can the Law Control the Hype?*, 37 HOUS. L. REV. 1249, 1262 (2000).

1. *The Origins of the FDA*

The FDA, as it exists today, was established in 1906³⁵ with the passing of the Pure Food and Drugs Act.³⁶ The Act's main feature was the implementation of distinct regulatory schemes to prevent the sale of adulterated and misbranded food, drugs, liquor, and medicine.³⁷ At the time, Congress did not need to create a separate scheme for dietary supplements because they were not yet marketed to U.S. consumers.³⁸ This need arose shortly thereafter, however, as vitamin tablets were marketed less than a decade later.³⁹ Nevertheless, the Act was the controlling legislative act at the time so dietary supplements were necessarily grouped into the preexisting categories. This was problematic because none of the categories was a perfect fit for dietary supplements, an issue that would persist until they were uniformly classified by DSHEA.

Under the Pure Food and Drugs Act, "food" included "all articles used for food, drink, confectionery, or condiment by man or other animals, whether simple, mixed, or compound."⁴⁰ Meanwhile, drugs were "any substance . . . intended to be used for the cure, mitigation, or prevention of disease of either man or other animals."⁴¹ The introduction of vitamins established the need for an additional category because vitamin tablets do not fall completely within either category. Vitamins do not cure, mitigate, or prevent disease (although some were historically advertised as doing so),⁴² but are generally not a food, drink, confectionery, or condiment either. Despite this inherent classification issue, the problem was initially tolerable because the vitamin industry, like many others, began as a small entity.

As vitamins became more established and other dietary supplements began to be marketed, the need for an additional regulatory category increased. As a result, there was an ongoing debate as to whether

35. U.S. Food & Drug Administration, History, <http://www.fda.gov/AboutFDA/WhatWeDo/History/Default.htm> (last visited Mar. 14, 2010). Prior to the passing of the Pure Food and Drugs Act, the FDA began as the Division of Chemistry, which was modified in 1901 to be the Bureau of Chemistry. John P. Swann, FDA's Origins, <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm> (last visited Mar. 14, 2010). The 1906 Act began the modern era of the FDA as it added regulatory functions to the agency's mission. *Id.*

36. Pure Food and Drugs Act, ch. 3915, 34 Stat. 768, 768–72 (1906), *repealed by* Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040, 1040.

37. Pure Food and Drugs Act §§ 3–4.

38. In fact, it was not until 1911 that scientists isolated and identified the substances now known as vitamins. HARVEY A. LEVENSTEIN, *REVOLUTION AT THE TABLE: THE TRANSFORMATION OF THE AMERICAN DIET* 148 (1988).

39. Grossman, *supra* note 9, at 1119 ("[I]n 1911, scientists isolated and identified a series of substances they called 'vitamins' . . .").

40. Pure Food and Drugs Act § 6.

41. *Id.*

42. See Grossman, *supra* note 9, at 1119. In addition to being advertised as preventing ailments, vitamins were also at the time marketed in both "drug-like dosage forms and in drug-like packaging." *Id.* at 1120. It would not be surprising then that the general public likely misconceived the properties of vitamins and their actual functionality.

vitamins and minerals should be considered foods or drugs.⁴³ The Pure Food and Drugs Act did not make this an easy question.

Likely because Congress did not provide sufficiently detailed definitions, the FDA established its own regulatory definitions. According to the FDA, vitamins are “essential nutrients that contribute to a healthy life.”⁴⁴ Congress has also decided to address the inherent problems in its earlier definitions and currently defines 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.”⁴⁵ Despite the change, neither the original nor the current definition of food is completely clear.⁴⁶ Congress has retained much of the original definition of drug, however, so dietary supplements fit better within the current definition of food. The FDA definition of vitamins supports this conclusion because there is clearly a difference between nutrients that contribute to a healthy life and “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.”⁴⁷

For regulatory purposes, the distinction between dietary supplements and drugs is significant. In the Pure Food and Drugs Act, Congress emphasized that drugs and food are different, not only by establishing separate definitions, but also by subjecting drugs to more stringent requirements.⁴⁸ This distinction remains today as Congress considers dietary supplements a subset of food,⁴⁹ and distinguishes them from drugs by definition and in regulation.⁵⁰

A glance at the two industries emphasizes the differences. Although U.S. consumers annually spend a significant amount on dietary supplements, that figure pales in comparison to the amount spent on prescription drugs. For example, in 2005 consumers spent over \$250 billion

43. See *id.* at 1115–16.

44. U.S. FOOD & DRUG ADMIN., FDA CONSUMER HEALTH INFORMATION, FORTIFY YOUR KNOWLEDGE ABOUT VITAMINS 1 (2009), <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/ucm142298.pdf>.

45. 21 U.S.C. § 321(f) (2006).

46. The lack of clarity is primarily caused by the fact that both definitions of food are circular and use the word “food” in the definition.

47. 21 U.S.C. § 321(g)(1)(B).

48. Pure Food and Drugs Act, ch. 3915, § 7, 34 Stat. 768, 769–70 (1906), *repealed by* Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040, 1040. Drugs were deemed adulterated if when “sold under or by a name recognized in the United States Pharmacopoeia or National Formulary, it differ[ed] from the standard of strength, quality, or purity, as determined by the test laid down in the United States Pharmacopoeia or National Formulary official at the time of investigation” *Id.* § 7. Meanwhile, foods were deemed adulterated only if they contained specific deleterious ingredients or failed to satisfy other mixture and appearance requirements. *Id.*

49. The heading for section 3 is “Definition of Certain Foods as Dietary Supplements.” Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 3, 108 Stat. 4325, 4327 (codified as amended at 21 U.S.C. § 321(ff)(1)); U.S. Food & Drug Administration, Dietary Supplements, <http://www.fda.gov/Food/DietarySupplements/default.htm> (last visited Mar. 14, 2010).

50. See 21 U.S.C. § 321(ff).

on prescription drugs,⁵¹ ten times the amount spent each year on dietary supplements.⁵² Furthermore, the Department of Health and Human Services found that in 1999–2000, over forty-five percent of the U.S. population had taken at least one prescription drug in the previous month, with the number being significantly higher in older age groups.⁵³

Besides the sheer volume of drugs in the United States, prescription and over-the-counter drugs also have significant side effects⁵⁴ and may cause adverse-to-severe health effects when taken improperly. For example, acetaminophen, a common over-the-counter pain reliever, can cause severe liver damage as well as gastrointestinal bleeding when taken frequently or in high doses.⁵⁵ Not surprisingly, the current definition of drug is significantly more detailed and specific than the corresponding definition for food.⁵⁶ Therefore, considering the traditional notion that drugs require more stringent regulation than foods, it is not surprising that Congress's initial attempts at regulating dietary supplements were in the realm of food and food additives.

2. *The FDCA and Subsequent Amendments*

Congress's first, but indirect, attempt at regulating dietary supplements⁵⁷ was the Food, Drug, and Cosmetic Act of 1938⁵⁸ (FDCA). Under FDCA, vitamins and minerals were considered foods so they were subject to the corresponding misbranding and adulteration requirements

51. Matthew Herper & Peter Kang, *The World's Ten Best-Selling Drugs*, FORBES, Mar. 22, 2006, http://www.forbes.com/home/sciencesandmedicine/2006/03/21/pfizer-merck-amgen-cx_mh_pk_0321topdrugs.html.

52. See *supra* notes 27–28 and accompanying text.

53. NAT'L CTR. FOR HEALTH STAT., HEALTH, UNITED STATES, 2004: WITH CHARTBOOK ON TRENDS IN THE HEALTH OF AMERICANS 91 (2004), <http://www.cdc.gov/nchs/data/hs/hs04.pdf>. Although these numbers seem equivalent to the number of Americans reporting using dietary supplements, these figures include the entire population, including those persons under eighteen years old. The statistics on dietary supplement statistics are only based on adult usage. See *supra* note 31 and accompanying text.

54. PRISCILLA EBERSOLE ET AL., TOWARD HEALTHY AGING: HUMAN NEEDS AND NURSING RESPONSE 320–21 (6th ed. 2004).

55. U.S. Food & Drug Administration, Use Caution with Pain Relievers, <http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm133425.htm> (last visited Mar. 14, 2010). Additionally, Lipitor, a common prescription drug used to fight high cholesterol, has side effects ranging from headache and stomach pain to serious muscle and liver problems. Lipitor, Lipitor Side Effects, <http://www.lipitor.com/about-lipitor/side-effects.aspx> (last visited Mar. 14, 2010).

56. See 21 U.S.C. § 321(f)–(g)(1) (2006). In fact, “drugs are required to undergo a series of pre-clinical and clinical studies to determine effectiveness, safety, possible interactions with other substances, and appropriate dosages.” SHAWN M. TALBOTT, A GUIDE TO UNDERSTANDING DIETARY SUPPLEMENTS 1 (2003). The FDA does not authorize or test dietary supplements before marketing. *Id.* at 1–2.

57. Remember that Congress did not actually define dietary supplements until DSHEA's enactment in 1994. Therefore, any use of the term dietary supplement before then is merely to reference those products which are now officially considered dietary supplements.

58. Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040. Note that FDCA remains good law and subsequent legislation, including DSHEA, are simply amendments or additions to FDCA. See generally 21 U.S.C. § 301.

of food.⁵⁹ Nevertheless, this initial categorization was short lived because under the 1958 Food Additives Amendment⁶⁰ Congress classified dietary supplements as food additives.⁶¹ Dietary supplements were thereafter considered “substance[s] the intended use of which results or may reasonably be expected to result . . . in its becoming a component or otherwise affecting the characteristics of any food.”⁶² Regulating dietary supplements as food additives was a tenuous match, however, because the definition of food additive did not clearly include vitamin or mineral tablets.⁶³

Despite the definitional incongruence, the timing of the Food Additives Amendment represented a growing congressional concern for consumer safety as dietary supplements were becoming increasingly popular. In fact, by the late 1930s, vitamins had already become the second most popular item purchased in drugstores.⁶⁴ Considering that one of the first dietary supplements, Cod Liver Oil, was first available in the 1920s,⁶⁵ and other vitamin tablets were commercially synthesized in the early 1930s,⁶⁶ the popularity of dietary supplements increased rapidly.⁶⁷

What is most noteworthy about the Food Additives Amendment is that despite the growing popularity of dietary supplements, Congress placed the burden on manufacturers to “establish that the proposed use of the . . . [dietary supplement], under the conditions of use to be specified in the regulation . . . [would] be safe.”⁶⁸ This required the manufacturer to present sufficient evidence demonstrating that a dietary supplement was safe before it could be marketed. This also enabled the FDA to increase its regulatory efforts by targeting potentially unsafe dietary supplements and new dietary ingredients.⁶⁹ As a result, the FDA was

59. See Federal Food, Drug, and Cosmetic Act §§ 201, 402–403; see also W. STEVEN PRAY, A HISTORY OF NONPRESCRIPTION PRODUCT REGULATION 205 (2003).

60. Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784.

61. See Kaiser, *supra* note 34, at 1252.

62. Food Additives Amendment § 2.

63. An in-depth discussion of the scientific differences and chemical reactions within the body is outside the scope of this Note, but it is important to note that vitamins which naturally exist in foods react differently in the body than do over-the-counter vitamin pills. For this reason, the FDA and the 2005 Dietary Guidelines for Americans advise that nutrient needs be met through food consumption and only suggest vitamin supplementation for certain sensitive population groups. See U.S. FOOD & DRUG ADMIN., *supra* note 44.

64. HARVEY A. LEVENSTEIN, PARADOX OF PLENTY: A SOCIAL HISTORY OF EATING IN MODERN AMERICA 20 (1993).

65. Peter Barton Hutt, *FDA Statutory Authority to Regulate the Safety of Dietary Supplements*, 31 AM. J.L. & MED. 155, 158 (2005).

66. See Grossman, *supra* note 9, at 1119.

67. The rise in vitamin popularity has often been linked with the changing perceptions of body image and the incredible claims scientists were making about vitamins throughout the early twentieth century and the Depression Era. See, e.g., LEVENSTEIN, *supra* note 64, at 11–14.

68. Food Additives Amendment of 1958, Pub. L. No. 85-929, § 4(c)(3)(A), 72 Stat. 1784, 1786 (codified as amended at 21 U.S.C. § 348(c)(3)(A) (2006)).

69. For example, Congress primarily focused on regulating herbal supplements using tactics aimed at irrational combinations or potency levels. See Reilley Michelle Dunne, Note, *How Much Regulation Can We Swallow? The Ban on Ephedra and How It May Affect Your Access to Dietary Supplements*, 31 J. LEGIS. 351, 353–54 (2005).

able to take additional steps to ensure that all dietary supplements were labeled correctly and ultimately safe for consumers.⁷⁰ Compared with the Food Additives Amendment, DSHEA enables manufacturers to market products much more easily as dietary supplements because they can only be removed if the FDA demonstrates that they bear a significant or unreasonable risk to consumers.⁷¹

In response to the Food Additives Amendment, there was a significant outcry from dietary supplement manufacturers as well as consumers.⁷² Congress, obviously affected by the negative response, responded by passing the relaxed Health Research and Health Services Amendments of 1976.⁷³ These amendments effectively limited the FDA's ability to evaluate dietary supplements and "seemed to signal congressional intent that supplement-type products not be regulated without indications of real danger to health."⁷⁴ The Amendments also forced the FDA to scale back its regulatory efforts throughout the 1980s, resulting in an influx of new dietary supplements.⁷⁵

One of these supplements was L-tryptophan, a substance used to increase strength and muscle mass.⁷⁶ Within months of being marketed in 1989, however, L-tryptophan was linked to over 1500 adverse effects and thirty-eight deaths.⁷⁷ After such devastating consequences, the FDA was no longer willing to take a backseat and established a task force, which

70. See *id.* at 353 (citing Kaiser, *supra* note 34, at 1252) ("As a result of the [Food Additives Amendment], the FDA devoted considerable resources to protecting the public from potential dangers presented by dietary supplements . . . [and] in the 1960s, the FDA . . . spent more money trying to regulate dietary supplements than in any other area.")

71. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 4, 108 Stat. 4325, 4328 (codified as amended at 21 U.S.C. § 342(f)).

72. Dunne, *supra* note 69, at 354. Furthermore, the costs associated with a food additive petition to the FDA are immense. The Committee on Labor and Human Resources estimated that such a petition can cost two million dollars and that it typically takes between two and six years to receive FDA approval. See S. REP. NO. 103-410, at 21 (1994).

73. Health Research and Health Services Amendments, Pub. L. No. 94-278, 90 Stat. 401, 410 (1976) (codified at 21 U.S.C. §§ 350, 321, 341, 343). The section of this Act that amends the FDCA is commonly referred to as the Proxmire Amendments. See, e.g., PRAY, *supra* note 59, at 205; Dunne, *supra* note 69, at 353-54.

74. *FDA's Regulation of the Dietary Supplement L-tryptophan: Hearing Before the Human Resources and Intergovernmental Relations Subcomm. of the Comm. on Government Operations H.R.*, 102d Cong. 98 (1991) (statement of Douglas L. Archer, Deputy Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration). Prior to the amendment, the FDA had the authority to "limit[] the potency of a vitamin or mineral supplement based on either food misbranding charges or on the grounds that the supplement would be a drug if it exceeded the level of potency that FDA considered to be rational or useful." *Id.* at 105.

75. Dunne, *supra* note 69, at 354. The result of this scaled-back effort was that herbal supplements became more popular and the industry grew considerably. Grossman, *supra* note 9, at 1139. This growth allowed the industry to put considerable pressure on Congress as well as mount an organized and well-funded defense if the FDA sought to increase its regulations on dietary supplements. See Dunne, *supra* note 69, at 355.

76. Kaiser, *supra* note 34, at 1255.

77. *Id.* These deaths were primarily caused by increased incidents of eosinophilia-myalgia syndrome (EMS), which was linked to L-tryptophan usage. *Id.*

advocated an aggressive dietary supplement regulatory scheme.⁷⁸ Furthermore, whereas Congress was willing to advocate a more liberal standard for dietary supplement disease prevention claims,⁷⁹ the FDA refused and proposed that these claims be subject to the same “significant scientific agreement” standard that applied to conventional foods.⁸⁰

Despite the FDA’s efforts to tighten dietary supplement regulation, Congress ultimately decided to deregulate dietary supplements. Again, like with the Health Research and Health Services Amendments, this change was a specific response to pressure from consumers and manufacturers to increase consumer access to dietary supplements.⁸¹ This deregulation was the Dietary Supplement and Health Education Act of 1994.⁸²

B. *The FDA’s Regulatory Powers Under DSHEA*

When it enacted DSHEA, Congress understood that although dietary supplements were historically regulated as a subset of food, most consumers did not consider them to be food in the general sense of the word.⁸³ Nonetheless, Congress decided that a consistent regulatory approach was ideal and stated that dietary supplements were “deemed to be a food” for most purposes under FDCA.⁸⁴ As a result, Congress continued to regulate dietary supplements as a food, but created a separate definitional and regulatory scheme.

Before DSHEA, food was deemed misbranded if it “purport[ed] to be or . . . [was] represented for special dietary uses, unless its label b[ore] such information.”⁸⁵ This definition generally applied to dietary supple-

78. *Id.* In fact, the FDA argued that amino acids were not actually dietary supplements, but were “unapproved food additives that did not have ‘adequate scientific evidence to ensure their safe use.’” *Id.* at 1256 (quoting Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,697 (proposed June 18, 1993)).

79. See Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 3, 104 Stat. 2353, 2360 (codified as amended at 21 U.S.C. § 343 (2006)).

80. Labeling; General Requirements for Health Claims for Food, 56 Fed. Reg. 60,537, 60,539 (proposed Nov. 27, 1991) (to be codified at 21 C.F.R. pts. 20, 101).

81. Dunne, *supra* note 69, at 354. For example, dietary supplement manufacturers organized a “National Blackout Day” where retailers covered the bottles of potentially affected dietary supplements with black cloths to emphasize to consumers that Congress was seeking to limit access to them. *Id.* at 354–55; see also Kaiser, *supra* note 34, at 1258.

82. Clearly, Congress had difficulty making up its mind and withstanding pressure from the public and manufacturers because the L-tryptophan scare was likely still fresh in the minds of legislators when the initial bill seeking to amend the FDCA came before the Senate in March of 2002, less than three years later. See S. 2835, 102d Cong. (1992).

83. Grossman, *supra* note 9, at 1144.

84. 21 U.S.C. § 321(ff) (2006). There are two primary exceptions to this rule. *Id.* The first is under subsection (g), which defines the term “drug” and establishes that dietary supplements meeting the definition of drug shall be considered drugs. *Id.* § 321(g). The second falls under § 350f, which requires a report to the FDA when the food will cause serious health consequences or death. *Id.* § 350f.

85. Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, § 403(j), 52 Stat. 1040, 1048 (codified as amended at 21 U.S.C. § 343(j)). This information must include the different vitamin, mineral, and other dietary properties in order to fully inform purchasers as to its value as determined

ments because most were not “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.”⁸⁶ Because FDCA’s definition of drug was specific, products like dietary supplements were necessarily considered food. The lack of a standard dietary supplement definition, however, was problematic because although most dietary supplements were regulated as food, those with labels or advertisements alleging therapeutic uses were often regulated as drugs.⁸⁷ And under FDCA, drugs were subject to additional premarketing requirements.⁸⁸ Therefore, it was a manufacturer’s labeling and advertising decisions, not a dietary supplement’s ingredients, which was the determinative factor.

It may have taken decades, but Congress ultimately recognized the need for a uniform system of dietary supplement regulation.⁸⁹ DSHEA remedied the situation by defining “certain foods as dietary supplements,”⁹⁰ with Congress codifying dietary supplements as a subgroup of food and granting the FDA regulatory authority over them.⁹¹

DSHEA was also an effort to balance access to dietary supplements with consumer safety concerns.⁹² Congress declared that “the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies” and “legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness.”⁹³ Congress relied on the fact that over “100 million Americans supplement their diets through the regular or occasional use of [dietary supplements].”⁹⁴ At the same time, however, Congress seemed to disregard the L-tryptophan tragedy, which took place a mere five years earlier.⁹⁵ In fact, the Senate Report recommending DSHEA’s enactment never even mentions L-tryptophan or the problems associated with it.⁹⁶ It seems Congress looked at the overall statistics, decided dietary supplements were safe, and concluded the federal government should avoid taking actions that would “impose

by the Secretary and prescribed by the regulations as necessary for such special dietary use. 21 U.S.C. § 343(j).

86. 21 U.S.C. § 201(g).

87. Hutt, *supra* note 65, at 156.

88. These premarket requirements remain in effect today. *See* 21 U.S.C. § 360e.

89. *See* S. REP. NO. 103-410, at 1 (1994).

90. Dietary Supplement Health and Education Act, Pub. L. No. 103-417, § 3, 108 Stat. 4325, 4327 (codified as amended at 21 U.S.C. § 321(ff)).

91. *See id.*

92. TALBOTT, *supra* note 56, at 4–5; Dunne, *supra* note 69, at 355.

93. §§ 2(2), (15)(A), 108 Stat. at 4325, 4326 (codified as amended at 21 U.S.C. § 321). This legislation may also account for the growing impact and size of the dietary supplement industry as Congress also noted that in 1994, the six hundred United States-based dietary supplement manufacturers produced around 4000 products with annual sales from those products totaling more than four billion dollars. *Id.* § 2(12)(C), 108 Stat. at 4326.

94. S. REP. NO. 103-410, at 6.

95. *See supra* notes 76–78 and accompanying text.

96. S. REP. NO. 103-410. The only mention of tryptophan is that it is an essential amino acid because it is not synthesized by the human body. *Id.* at 12.

unreasonable regulatory barriers limiting or slowing the flow of safe products . . . to consumers.”⁹⁷

Despite its outspoken position that dietary supplements were safe, Congress still instructed the FDA to “take swift action” against unsafe or adulterated dietary supplements.⁹⁸ Although this was a laudable instruction, DSHEA actually made it easier for manufacturers to market dietary supplements and more difficult for the FDA to restrict unsafe dietary supplements. Notwithstanding the instruction, DSHEA places a greater priority on consumer access than on safety. Nevertheless, Congress did place several safety provisions in DSHEA, which are outlined in the two Sections below. The first Section focuses on the safety provisions in DSHEA, and the second Section outlines the safety provisions added by the 2006 amendments to FDCA. Together, these Sections provide a foundation for understanding the current interaction between dietary supplement manufacturers and the FDA.

1. *DSHEA’s Regulatory Scheme*

DSHEA was the first legislation implementing a distinct regulatory scheme for dietary supplements. With DSHEA, Congress codified dietary supplements as a distinct subset of food; no longer are they considered food additives or conventional food ingredients. As a result, dietary supplements are no longer subject to the heightened requirements of the Food Additive Amendment.⁹⁹ This change was crucial because unlike food additives, dietary supplements normally are not required to satisfy premarket notification requirements under DHSEA.¹⁰⁰ Therefore, manufacturers generally do not need to submit any scientific evidence demonstrating safety prior to marketing a dietary supplement unless it contains a “new dietary ingredient[].”¹⁰¹

New dietary ingredients are ingredients not marketed in the United States prior to DSHEA.¹⁰² Under DSHEA, manufacturers are required to submit to the FDA information regarding the “safety and efficacy”¹⁰³

97. § 2(13), 108 Stat. at 4326 (codified as amended at 21 U.S.C. § 321). Obviously no one would argue that Congress should not limit the flow of “safe products and accurate information.” *Id.* (emphasis added). The main purpose of this Note, however, is that DSHEA generally fails to limit the flow of any dietary supplement or information about them. *Id.*

98. *Id.*

99. See Grossman, *supra* note 9, at 1141; see also Food Additives Amendment of 1958, Pub. L. No. 85-929, § 409, 72 Stat. 1784, 1785 (codified as amended at 21 U.S.C. § 341). This Act defined the requirements for food ingredients by taking a German Rule approach, deeming such ingredients unsafe unless satisfying the requirements set forth in the act.

100. Hutt, *supra* note 65, at 156. This change is important because food additives still require premarket approval from the FDA whereas dietary supplement manufacturers no longer must meet such a burden. See Dunne, *supra* note 69, at 355.

101. Grossman, *supra* note 9, at 1147 n.405 (citing Federal Food, Drug, and Cosmetic Act § 413(a) (1938) (codified as amended at 21 U.S.C. § 350b(a))).

102. § 8, 108 Stat. at 4331 (codified as amended at 21 U.S.C. § 350b(c)).

103. FINK ET AL., *supra* note 5, at 263.

of a dietary supplement containing a new dietary ingredient.¹⁰⁴ This submission must take place at least seventy-five days before the manufacturer introduces or delivers the dietary supplement into interstate commerce.¹⁰⁵ Nevertheless, the manufacturer must merely demonstrate that the new dietary ingredient can “reasonably be expected to be safe.”¹⁰⁶ This is not a difficult showing because “manufacturers are only obligated to provide ‘some’ evidence of safety to the FDA and are not responsible for *proving* that a new ingredient is indeed safe.”¹⁰⁷ As long as it makes the requisite demonstration, the manufacturer is free to market the dietary supplement once the seventy-five day submission period concludes. Therefore, a significant aspect of DSHEA is that the FDA does not actually have to approve the new ingredient or dietary supplement before it is marketed.¹⁰⁸

Although new dietary supplements do not require actual approval, the premarket notification requirement is not meaningless. First, the premarket notification requirement places a greater burden on manufacturers. Failure to make an adequate premarket demonstration seventy-five days before marketing may result in the dietary supplement being deemed adulterated. New dietary ingredients are considered adulterated if the FDA can demonstrate, by a preponderance of the evidence, that there is “inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.”¹⁰⁹

With DSHEA, Congress also restricted the type of information that can be placed on dietary supplement labels.¹¹⁰ Manufacturers are no longer permitted to make claims that a dietary supplement “diagnose[s], mitigate[s], treats, cure[s], or prevent[s] a specific disease or class of diseases.”¹¹¹ This provision was enacted to avoid dietary supplements being classified based on labels and advertisements. Now, only drugs may make such claims under FDCA unless the manufacturer first notifies the FDA,¹¹² and does so within a thirty-day notification period.¹¹³

104. § 4, 108 Stat. at 4328 (codified as amended at 21 U.S.C. § 342(f)(1)). The information must be submitted to the Office of Nutritional Products, Labeling, and Dietary Supplements. 21 C.F.R. § 190.6(a) (2009). This regulatory subsection also outlines in detail what information must be submitted as well as the duties of the FDA to acknowledge the receipt of such information. *Id.* § 190.6(b)–(c).

105. 21 C.F.R. § 190.6(a).

106. *Id.*

107. TALBOTT, *supra* note 56, at 10. Talbott also notes that “[a]lthough one would hope that all supplement manufacturers would exercise the highest ethical and scientific standards to develop strong safety evidence before introducing a new product, such is not always the case.” *Id.*

108. FINK ET AL., *supra* note 5, at 263.

109. 21 U.S.C. § 342(f)(1)(B). Section (f)(1) explicitly specifies that the FDA bears the burden of proof because it states “the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated.” *Id.* § 342(f)(1).

110. *See id.* § 343(r).

111. *Id.* § 343(r)(6).

112. *See id.* § 321(g)(1)(B).

113. *Id.* § 343(r)(6).

In marketing dietary supplements, manufacturers are allowed to make statements that claim a “benefit related to a classical nutrient deficiency disease.”¹¹⁴ These statements must describe the prevalence of such a disease in the United States and explain how the dietary supplement acts to maintain the “structure or function” of the body affected by the disease.¹¹⁵ The statement must also be backed by scientific evidence so that the manufacturer has “substantiation”¹¹⁶ that it is truthful and not misleading. Finally, the dietary supplement must contain a boldface disclaimer that the statement has not been evaluated by the FDA on its outer packaging.¹¹⁷ As a whole, these requirements seek to ensure that consumers are able to make informed decisions without being misled.

Finally, DSHEA also requires that dietary supplements meet “good manufacturing practice regulations.”¹¹⁸ These regulations apply to how a dietary supplement is “prepared, packed, or held.”¹¹⁹ Despite this provision, the FDA chose to wait over ten years to enact regulations describing good manufacturing practices for dietary supplements.¹²⁰ Nevertheless, during that period, the FDA was able to rely on the similar regulations it had promulgated for food.¹²¹

2. *The Dietary Supplement and Nonprescription Drug Consumer Protection Act*

Over the years, Congress has often been criticized because DSHEA prevents the FDA from acting aggressively and effectively to protect consumers from unsafe dietary supplements.¹²² DSHEA’s limitations were highlighted during the 1990s as dietary supplements containing ephedrine alkaloids caused a significant number of injuries and deaths.¹²³

114. *Id.* § 343(r)(6)(A).

115. *Id.*

116. The Federal Trade Commission has defined “advertising substantiation” as a reasonable basis for believing that each claim in the advertisement is true. BLACK’S LAW DICTIONARY 63 (9th ed. 2009). Again, because the burden is placed on the FDA under DSHEA, although the manufacturer under § 343(r)(6)(B) must have substantiation, in reality the standard is that the FDA must show they did not have substantiation.

117. 21 U.S.C. § 343(r)(6)(C).

118. *Id.* § 342(g)(1). Congress thereafter granted the FDA the authority to “prescribe good manufacturing practices for dietary supplements” by regulation. *See id.* § 342(g)(2).

119. *Id.* § 342(g)(1). The typical good manufacturing practices in place for food generally require that “personnel follow sanitary procedures and have suitable training; processing facilities be clean; processing equipment be designed to permit thorough cleaning and be properly maintained; and . . . finished products be appropriately packaged, labeled, stored, and shipped.” *See* Council for Responsible Nutrition, Before and After DSHEA, http://www.crnusa.org/about_pubs_DSHEA_facts.html (last visited Mar. 14, 2010).

120. *See* Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 72 Fed. Reg. 34,752 (June 25, 2007) (codified at 21 C.F.R. pt. 111).

121. *See, e.g.*, 21 C.F.R. pt. 110 (2009).

122. RICHARD R. ABOOD, PHARMACY PRACTICE AND THE LAW 48 (4th ed. 2005).

123. *See id.*

A detailed discussion of ephedrine-containing products and the fallout is discussed at length below in Part II.C.

In response to the criticism, Congress decided in 2006 to enact the Dietary Supplement and Nonprescription Drug Consumer Protection Act (2006 Act).¹²⁴ The purpose of the 2006 Act was to enhance the FDA's ability "to identify potential public health issues . . . associated with the use of [dietary supplements], . . . and [to] enable the government, manufacturers, and retailers to respond more quickly to problems which may be identified."¹²⁵ The 2006 Act primarily added the requirement that a "responsible person" submit to the FDA all reports of a "serious adverse event" associated with a dietary supplement.¹²⁶ Though this seems simple, the requirement has several significant implications.

First, Congress defined responsible person as "[t]he manufacturer, packer, or distributor of a dietary supplement whose name . . . appears on the label of a dietary supplement marketed in the United States . . ."¹²⁷ Therefore, the term "responsible person" encompasses individual persons and partnerships, as well as corporations, because all could potentially be the manufacturer, packer, or distributor of a given dietary supplement. Second, under the 2006 Act, "serious adverse event" is defined as an "adverse event"¹²⁸ that results in death, "a life threatening experience," "inpatient hospitalization," "persistent or significant disability or incapacitation," "a congenital anomaly or birth defect," or that requires medical intervention to prevent one of the previous outcomes based on reasonable medical judgment.¹²⁹ Finally, to help ease manufacturer transition, this requirement did not come into effect until December 2007, more than one year after the Act was passed.¹³⁰

Although DSHEA and the 2006 Act contain several consumer protection provisions, neither is particularly effective. Most consumers would likely be surprised to hear that the FDA was simply unable to ban an unsafe dietary supplement for over ten years—a period in which thousands of adverse events were reported and over one hundred deaths, including several professional athletes, were caused by the supplement. The culprit was the dietary supplement commonly known as ephedra.¹³¹

124. Dietary Supplement and Nonprescription Drug Consumer Protection Act, Pub. L. No. 109-462, 120 Stat. 3469 (2006) (codified as amended at 21 U.S.C. § 371).

125. S. REP. NO. 109-324, at 2-3 (2006).

126. § 761, 120 Stat. at 3472 (codified as amended at 21 U.S.C. § 379aa-1).

127. *Id.* § 761(b)(1).

128. An adverse event is "any health-related event associated with the use of a dietary supplement that is adverse." *Id.* § 761(a)(1). Note that although this definition is circular, it is pretty clear that Congress meant adverse to mean "causing harm." See MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 19 (11th ed. 2006).

129. § 761(a)(2)(A)-(B), 120 Stat. at 3472 (codified as amended at 21 U.S.C. § 379aa-1).

130. Draft Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act; Availability, 72 Fed. Reg. 58,313, 58,314 (Oct. 15, 2007).

131. See Dunne, *supra* note 69, at 359-60.

C. DSHEA and the Ephedra Debacle

Ephedra is the common name for a group of dietary supplements containing ephedrine alkaloids,¹³² powerful stimulants naturally produced in botanical plants.¹³³ During the 1990s, ephedra was commonly marketed and used “to promote weight loss, increase energy, and enhance athletic performance.”¹³⁴ Ephedrine alkaloids, the primary ingredient in ephedra, work by boosting metabolism and increasing the amount of calories the body burns during activity because they excite the nervous system through blood vessel dilation and heart stimulation.¹³⁵ Although ephedrine alkaloids have performance benefits, they have been linked to serious adverse health effects, including heart attack and stroke.¹³⁶ The cause of these harmful effects is that ephedrine alkaloids take several hours to metabolize in the body, leading users to take multiple doses, which exacerbates the harmful effects.¹³⁷

Ephedra initially gained notoriety for its ability to accelerate weight loss. Over time it became incredibly popular, and in 2002, the dietary supplement industry claimed Americans consumed three billion servings each year.¹³⁸ Nevertheless, the positive publicity quickly turned negative after it became known that ephedra had caused nearly 150 deaths, including Major League Baseball pitcher Steve Bechler and National Football League player Corey Stringer.¹³⁹ Despite the strong media reaction and the overwhelming number of adverse event reports submitted, the FDA was unable to definitively act to protect consumers for several years.

In 2004, the FDA and the Department of Health and Human Services finally banned the sale of ephedra in the United States.¹⁴⁰ In its fi-

132. I refer to ephedrine as ephedrine alkaloids because this is how it is referred to by the FDA in its final register ruling. *See infra* note 140; *see also* FINK ET AL., *supra* note 5, at 260.

133. NCAAM, FDA Has Banned Ephedra: Consumer Advisory, <http://nccam.nih.gov/news/alerts/ephedra/consumeradvisory.htm> (last visited Mar. 14, 2010).

134. *Id.*

135. Dunne, *supra* note 69, at 358.

136. Press Release, U.S. Food & Drug Admin., FDA Issues Regulation Prohibiting Sale of Dietary Supplements Containing Ephedrine Alkaloids and Reiterates Its Advice that Consumers Stop Using These Products (Feb. 6, 2004), http://www.thenhf.com/FDAPressRelease_02062004.pdf.

137. Dunne, *supra* note 69, at 358.

138. Jaime Holguin, *Pressure on to Ban Ephedra*, CBS EVENING NEWS, Aug. 13, 2002, <http://www.cbsnews.com/stories/2002/08/13/eveningnews/main518563.shtml>.

139. Dunne, *supra* note 69, at 351–52. Furthermore, the FDA received over 16,000 adverse event reports related to the use of ephedra before enacting the ban. *Id.* at 352. Though some have disagreed with the FDA’s conclusion that ephedra caused a significant number of deaths, critics like Mike Fillon, the author of *Ephedra: Fact or Fiction*, have not stated that ephedra products were safe, but that they were not convinced ephedra was unsafe. Larry M. Edwards, *Metabolife: Morally Corrupt or Misunderstood Victim?*, SAN DIEGO MAG., Mar. 2004, at 52 (citing MIKE FILLON, EPHEDRA: FACT OR FICTION (2004)).

140. *See* Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk, 69 Fed. Reg. 6788, 6853 (Feb. 11, 2004) (codified at 21 C.F.R. pt. 119) (promulgating that all dietary supplements containing ephedrine alkaloids are considered to be adulterated under FDCA).

nal rule summary, the FDA stated that “dietary supplements containing ephedrine alkaloids pose a risk of serious adverse events, including heart attack, stroke, and death, and that these risks are unreasonable in light of any benefits that may result from the use of these products.”¹⁴¹ The ban itself was gradually implemented and began with an initial consumer alert notifying all manufacturers that products containing ephedrine alkaloids were subject to a future ban.¹⁴² This preliminary notification was followed by a final rule and press release stating that ephedra was considered adulterated under FDCA.¹⁴³ The reasons for the ban were obvious, but the reasons for the delay revert back to Congress and DSHEA.

The FDA’s explanation for the delay accentuates DSHEA’s inability to adequately protect consumers. The FDA explained that it “first proposed regulating Ephedra in 1997, but . . . [it was] believed that FDA had not developed sufficient evidence for certain actions proposed.”¹⁴⁴ This statement is telling because it shows the FDA was aware of the harmful effects of ephedra for at least seven years prior to the ban. Other evidence supports that the FDA was aware of such effects, however, even prior to DSHEA’s enactment.

In September 1994, a month before Congress enacted DSHEA, the FDA issued a Medical Bulletin regarding the effects of ephedra.¹⁴⁵ The purpose of the bulletin was to inform the public that it had received a significant number of adverse event reports related to dietary supplements containing ephedrine.¹⁴⁶ The FDA reported that consumer reactions to ephedra varied from mild symptoms like nervousness, dizziness, and blood pressure changes, to serious ones such as chest pain, infarction, and death.¹⁴⁷ These symptoms occurred both in healthy persons and specifically in those with high blood pressure.¹⁴⁸ Therefore, although the 2006 Act implemented the serious adverse event reporting requirement,¹⁴⁹ the FDA actually received similar reports more than ten years earlier.

The delay in the ephedra ban was a proximate result of Congress limiting the FDA’s authority to regulate dietary supplements under DSHEA. Congress established that the FDA may only ban a dietary

141. Press Release, Nat’l Health Fed’n, Dietary Supplements Containing Ephedrine Alkaloids Final Rule Summary (2004), <http://www.thenhf.com/EphedrineBanSummary.pdf>.

142. Press Release, U.S. Food & Drug Admin., FDA Acts to Remove Ephedra-Containing Dietary Supplements from Market (Nov. 23, 2004), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108379.htm>.

143. *Id.*

144. WILLIAM B. SCHULTZ & LISA BARCLAY, A HARD PILL TO SWALLOW: BARRIERS TO EFFECTIVE FDA REGULATION OF NANOTECHNOLOGY-BASED DIETARY SUPPLEMENTS 18 (2009).

145. U.S. Food & Drug Administration, Adverse Events with Ephedra and Other Botanical Dietary Supplements (Sept. 1994), <http://www.fda.gov/Food/DietarySupplements/Alerts/ucm111208.htm>.

146. *See id.*

147. *Id.*

148. *Id.*

149. *See supra* notes 124–27 and accompanying text.

supplement if it “presents a significant or unreasonable risk of illness or injury when used according to its labeling or under ordinary conditions of use.”¹⁵⁰ Nevertheless, the FDA sought to impose regulations on ephedra in 1997,¹⁵¹ but the U.S. Government Accountability Office (GAO)¹⁵² determined that the “FDA had not been thorough in its investigation and requested further research.”¹⁵³ In light of the GAO report, criticism and opposition to the proposed rule were strong and the FDA was forced to withdraw it.¹⁵⁴

Obviously, despite the FDA withdrawing its proposed rule, ephedra was still harmful, and other private organizations decided to take action. In fact, the National Football League, the National Collegiate Athletic Association, and the International Olympic Committee instituted ephedra bans to protect their athletes from the publicized harmful effects.¹⁵⁵ Even states were unwilling to wait for a federal ban as Illinois and New York implemented statewide bans in 2003.¹⁵⁶

Eventually in 2006, after a decade of waiting, significant test results, organizational bans, individual statewide bans, and several years of litigation,¹⁵⁷ the FDA successfully banned ephedra.¹⁵⁸ With dietary supplements becoming so prevalent, other countries also began to implement their own dietary supplement regulatory schemes. The European Union is an example of this, but the European Commission sought to avoid DSHEA’s regulatory deficiencies and instead enacted the much more proactive Food Supplements Directive.

150. Press Release, U.S. Food & Drug Admin., *supra* note 136. The statement explicitly refers to section 4 of DSHEA, which states that the “United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated.” Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 4, 108 Stat. 4325, 4328 (codified as amended at 21 U.S.C. § 342(f)(1) (2006)).

151. See Dietary Supplements Containing Ephedrine Alkaloids, 62 Fed. Reg. 30,678 (proposed June 4, 1997) (to be codified at 21 C.F.R. pt. 111).

152. See U.S. Government Accountability Office, <http://www.gao.gov/> (last visited Mar. 14, 2010). The GAO is a nonpartisan agency that seeks to “provide Congress with timely information that is objective, fact-based, nonpartisan, nonideological, fair, and balanced.” *Id.* (follow “About GAO” hyperlink) (last visited Mar. 14, 2010).

153. *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033, 1036 (10th Cir. 2006) (citing GOVERNMENT ACCOUNTING OFFICE, DIETARY SUPPLEMENTS: UNCERTAINTIES IN ANALYSES UNDERLYING FDA’S PROPOSED RULE ON EPHEDRINE ALKALOIDS 11 (1999), <http://www.gao.gov/archive/1999/h299090.pdf>).

154. See Dietary Supplements Containing Ephedrine Alkaloids; Withdrawal in Part, 65 Fed. Reg. 17,474 (proposed Apr. 3, 2000) (to be codified at 21 C.F.R. pt. 111).

155. Dunne, *supra* note 69, at 363.

156. See 720 ILL. COMP. STAT. ANN. 602/10 (West 2004); see also N.Y. GEN. BUS. LAW § 391-o (McKinney 2009).

157. This litigation culminated in the Tenth Circuit case of *Nutraceutical Corp. v. Von Eschenbach*, which is discussed at length *infra* Part III.A.4.

158. The actual ban was first promulgated in 2004, but it was not until the Court of Appeals in *Nutraceutical* reversed the lower court’s overturning of the ephedra ban that it was fully implemented. See *infra* notes 216–22 and accompanying text.

D. *The European Union's Food Supplements Directive*

In 2002, after much debate and deliberation, the European Commission enacted a uniform dietary supplement policy entitled the Food Supplements Directive.¹⁵⁹ Similar to DSHEA, the Food Supplements Directive was enacted with two primary goals in mind: (1) to protect consumers from unsafe and misleading products, and (2) to prevent food from being represented as medicine.¹⁶⁰ The European Commission stated publicly that it sought to ensure “a high degree of protection of consumer health.”¹⁶¹ Although DSHEA and the Food Supplements Directive share similar purposes, the European Commission took a much more deliberate approach to consumer safety. The primary feature of the Food Supplements Directive is that it contains a “positive list” of vitamins and minerals permitted to be used in dietary supplements.¹⁶² The title is fitting because any ingredient not on the positive list may not be sold to consumers in any member State of the European Union.¹⁶³ Therefore, manufacturers must exclusively rely on the positive list when developing new dietary supplements.

The positive list contains just over one hundred different vitamins, minerals, and other substances.¹⁶⁴ Not surprising, the list includes well recognized vitamins and minerals such as vitamin C, calcium, iron, and zinc.¹⁶⁵ Nevertheless, the positive list remains exclusive and restrictive; several formulations of vitamin E commonly sold in the United States have not been given clearance by the European Commission.¹⁶⁶ Manufacturers most certainly appreciate the lax standards of DSHEA when compared with the Food Supplements Directive as getting ingredients placed on the positive list is both an absolute priority and a necessity.

159. Food Supplements Directive, *supra* note 19, at 51.

160. Nicole Coutrelis, *The Legal Status and Regulatory Context of “Health Foods” in the European Union*, 58 FOOD & DRUG L.J. 35, 36 (2003).

161. See Health Supreme News Blog, EU Food Supplements Directive: Scientists Challenge Philosophy of Precaution, Apr. 4, 2007, http://www.newmediaexplorer.org/sepp/2007/04/04/eu_food_supplements_directive_scientists_challenge_philosophy_of_precaution.htm.

162. See Food Supplements Directive, *supra* note 19, art. 4.

163. This includes states such as the United Kingdom, as European legislation overrides domestic legislation within the individual member states. See Fiona LeCong, *Food Supplements Directive: An Attempt to Restore the Public Confidence in Food Law*, 29 LOY. L.A. INT'L & COMP. L. REV. 105, 108 (2007).

164. Food Supplements Directive, *supra* note 19, Annex II.

165. *Id.*

166. The reason for the regulatory differences is that eight different compounds may comprise vitamin E tablets, but only alpha-tocopherol is on the positive list and permitted to be sold in the European Union, while the other seven are permitted in the United States. See *id.* Compare European Union Directive on Dietary Supplements, <http://www.thefactsaboutfitness.com/news/eu.htm> (last visited Mar. 14, 2010) (noting the several “victim” vitamins left off the positive list), with U.S. Food & Drug Administration, Dietary Supplement Alerts and Safety Information, <http://www.fda.gov/Food/DietarySupplements/Alerts/default.htm> (last visited Mar. 14, 2010) (advising consumers of the many supplement risks). Additionally, other dietary supplements such as selenium yeast, tin, manganese, and vitamin K2 were not on the “positive list” as of summer 2004 and were the subject of over 500 separate appeals. See Sam Lister, *Health Groups Lose Appeal on EU Food Supplement Ban*, TIMES (London), July 13, 2005, <http://www.timesonline.co.uk/tol/news/uk/article543347.ece>.

The burden on a manufacturer seeking to have a dietary ingredient added to the positive list is significant. The process itself can be both arduous and expensive. Reports have estimated costs between €100,000 and €400,000 just to conduct the tests necessary for a dietary ingredient to even receive list consideration.¹⁶⁷ Even then, the process can take years.¹⁶⁸ This is because actually obtaining high quality information and test results demonstrating the safety of a vitamin, mineral, or other dietary ingredient generally takes two to three years to complete.¹⁶⁹ These time and cost restraints would likely impair all but large, established dietary supplement manufacturers. Smaller companies or start-ups would also be less likely to risk such tests when actually gaining admission to the positive list is not guaranteed. As might be expected, the Food Supplements Directive, like the more restrictive historic schemes in the United States, has been criticized significantly since its passing.

The critical reaction was, in fact, quite swift because in 2004, just two years after the Food Supplements Directive was enacted, over one million Britons signed a petition, three hundred doctors and scientists sent a protest letter to then Prime Minister Tony Blair, and the legislation was challenged and reviewed by the European Court of Justice (ECJ).¹⁷⁰ Despite the public and professional outcry, the ECJ unanimously upheld the Food Supplements Directive in a decision favoring consumer protection over the free movement of goods.¹⁷¹ Although reaction to the decision was mixed,¹⁷² the ECJ decision was the law and ultimately carried the day.

Overall, there are significant differences between DSHEA and the Food Supplements Directive. Parts III and IV discuss the differences and emphasize the need for Congress to adopt a more proactive approach to dietary supplement regulation. By emulating some of the provisions in the Food Supplements Directive, the FDA would be able to effectively protect consumers from dangerous dietary supplements and avoid future tragedies like those involving ephedra and L-tryptophan.

167. Kathrin Jungbeck, *Food Supplements Directive Set to Overhaul Europe*, EUROMONITOR INT'L, June 15, 2004, http://www.euromonitor.com/Food_supplements_directive_set_to_overhaul_Europe; see also LeCong, *supra* note 163, at 109 (estimating the costs at £80,000 to £250,000). Based on the exchange rate as of February 2, 2009, a single euro traded for \$1.29050, meaning that getting a dietary ingredient added to the positive list would cost between \$129,050 and \$516,200. See U.S. Dollar Exchange Rate Graph-Euro, <http://www.exchange-rates.org/history/USD/EUR/T> (last visited Mar. 14, 2010).

168. See LeCong, *supra* note 163, at 109.

169. *Id.*

170. Lister, *supra* note 166.

171. Joined Cases C-154/04 & C-155/04, *The Queen, In re Alliance for Natural Health v. Sec'y of State for Health*, 2005 E.C.K. I-6451, I-6524. Jim Murray, the Director of the European Consumers' Organisation, even opined that the decision was "a clear victory for consumers and for the EU's right to regulate on the safety of food products." Lister, *supra* note 166.

172. In fact, even celebrities spoke out against the Food Supplements Directive, including Paul McCartney and Elton John. LeCong, *supra* note 163, at 109.

III. ANALYSIS

The Senate Committee on Labor and Human Resources, in supporting DSHEA's enactment, stated that the appropriate use of "safe dietary supplements," along with other preventive measures, would "limit the incidence of chronic diseases and reduce long-term health care expenditures . . ." ¹⁷³ Though open access to *safe* dietary supplements is a worthwhile goal, DSHEA fails to protect consumers from *unsafe* dietary supplements. This Part addresses this ongoing problem and proceeds as follows. First, this Part discusses the FDA's limited ability to classify dietary supplements as adulterated and subsequently remove them from the market. Then this Part compares DSHEA with the Food Supplements Directive and demonstrates why the latter is a much more effective approach to dietary supplement regulation. ¹⁷⁴

A. *The FDA's Limited Ability to Protect Consumers from Unsafe Dietary Supplements*

The first major problem with DSHEA is that it limits the FDA's ability to classify unsafe dietary supplements as adulterated and remove them from the market. Under DSHEA, a dietary supplement is adulterated if it "presents a significant or unreasonable risk of . . . injury under conditions of use recommended or suggested in labeling . . ." ¹⁷⁵ On its face, this provision seems a reasonable implementation of Congress's goal to provide consumers with only safe dietary supplements. ¹⁷⁶ In the entire context of DSHEA, however, this provision is nothing more than cautionary language and is mostly ineffective.

An effective analysis of DSHEA begins with the understanding that the FDA bears the burden of showing, by a preponderance of the evidence, that a dietary supplement, when taken as recommended, presents a significant or unreasonable risk to consumers. ¹⁷⁷ As a result, the FDA only has the power to act reactively in its attempts to protect consumers

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

174. As discussed *supra* Part II.B.1, DSHEA also regulates the content of dietary supplement labels as well as statements of nutritional support. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, §§ 5-7, 108 Stat. 4325, 4328-31 (codified as amended at 21 U.S.C. §§ 341-350 (2006)). These issues are outside the scope of this Note as I argue that a proactive approach is necessary to protect consumers from unsafe dietary supplements. Many of the labeling and advertising issues deal with claims related to the effectiveness of the supplement and not to their safety. Furthermore, the Federal Trade Commission as well as the FDA play a role in this type of regulation. See Eric S. Nguyen, *Weight Loss Testimonials: A Critique of Potential FTC Restrictions on Diet Advertising*, 63 FOOD & DRUG L.J. 493, 495 (2008).

175. § 4, 108 Stat. at 4328 (codified as amended at 21 U.S.C. § 342(f)).

176. See *id.* § 2; see also S. REP. NO. 103-410, at 2.

177. 21 U.S.C. § 342(f); *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033, 1038, 1040 n.6 (10th Cir. 2006). This standard requires the FDA to support its position with the greater weight of the evidence. See *Metropolitan Stevedore Co. v. Rambo*, 521 U.S. 121, 137-38 n.9 (1997).

from unsafe dietary supplements that have already been marketed.¹⁷⁸ As the Committee on Labor and Human Resources stated, “Under present law, a dietary supplement, as with any food, is presumed to be safe. It therefore may be lawfully marketed, unless and until the FDA, by a preponderance of the evidence, shows that the supplement is ‘injurious to health.’”¹⁷⁹ In other words, until the FDA can accumulate sufficient evidence demonstrating that a given dietary supplement presents a significant or unreasonable risk to consumers, it will remain freely marketable. As if this was not problematic enough, even the FDA’s power to act reactively is limited.

The FDA’s limited reactive authority is demonstrated in four primary areas, which are discussed in the following Sections. The first Section discusses the FDA’s ability to regulate dietary supplements only based on recommended dosages. The second Section continues with a discussion of the lack of a general premarket notification requirement. The third Section then discusses the limited safeguards added by the 2006 Act. Finally, the fourth Section concludes with a discussion of the FDA’s limited ability to implement a postmarket ban.

1. *Regulation of Recommended Dosages*

The FDA’s ability to classify existing dietary supplements as adulterated is based on the dosages or uses recommended by the manufacturer.¹⁸⁰ This is significant because there is a difference between demonstrating the harmful effects caused by recommended dosages and all dosages. If the FDA could consider dosages beyond the recommended ones, this would clearly strengthen its ability to remove harmful dietary supplement products from the market. Like over-the-counter drugs, some dietary supplements are safe when taken as recommended, but can be extremely harmful in large doses.¹⁸¹ Nevertheless, the FDA’s narrow ability to regulate based on the recommended dosages seems to imply one of two things. Either Congress believes the average U.S. consumer actually complies with recommended dosages, or it decided the benefits

178. As discussed throughout Part II, Congress intended to limit the FDA’s ability to proactively regulate dietary supplements in order to increase consumer access and in response to public outcry to heightened restrictions. *See supra* Part II.A–B.

179. S. REP. NO. 103-410, at 21 (1994).

180. § 4, 108 Stat. at 4328 (codified as amended at 21 U.S.C. § 342(f)). While DSHEA provides that the U.S. Secretary of Health and Human Services may also declare that the dietary supplement at issue poses an imminent hazard to public health and safety, I disregard this because as of 2004, it has never happened. *See* 150 CONG. REC. S86, 7081 (daily ed. June 21, 2004) (statement of Sen. Hatch). Furthermore, if a dietary supplement label does not contain suggested or recommended conditions of use, the FDA must show that it presents a significant or unreasonable risk of illness or injury under “ordinary conditions of use.” § 4, 108 Stat. at 4328 (codified as amended at 21 U.S.C. § 342(f)). Congress chose not to define “ordinary conditions of use” in DSHEA, yet the burden remains on the FDA to meet this standard. *See id.*

181. Ephedra is a perfect example of this phenomenon. *See supra* Part II.C.

of consumer access outweigh the harmful effects of consumers taking higher than recommended dosages.

Although a congressional belief that consumers follow recommended dosages would justify its statement that “dietary supplements are safe within a broad range of intake,” the belief is misplaced.¹⁸² U.S. consumers often do not follow recommended dosages. In 2003, the National Consumers League reported that over one-third of consumers take more than the recommended dosage of over-the-counter drugs because they believed that doing so would increase the drug’s effectiveness or response time.¹⁸³ This, combined with the finding that certain population groups, especially the young and the economically disadvantaged, “excessively underestimate the relevant risks of dietary supplement consumption,” makes overdosing a common occurrence.¹⁸⁴ Although dietary supplements and over-the-counter medications are classified differently,¹⁸⁵ incorrect dosages of either can result in severe health consequences.¹⁸⁶ For example, high doses of vitamin A can lead to birth defects in pregnant women, and high doses of the dietary supplement herb yohimbe can cause kidney failure, seizures, and even death.¹⁸⁷ The FDA should be given flexibility to regulate dosages beyond those recommended by manufacturers because Congress should take into account that consumers do not always follow recommendations.

Congress might also believe that the benefits of consumer access outweigh the potential harms associated with consumers taking incorrect dosages of dietary supplements. Admittedly, the risks associated with high dosages are preventable, and Congress cannot protect consumers from every possible mishap. Nevertheless, Congress takes the opposite approach with both over-the-counter and prescription drugs, which require premarket notification.¹⁸⁸ Although drugs may have a higher propensity for causing harm, the serious harms caused by dietary supplements emphasize the need for a similar approach. Ephedra, L-tryptophan, Hydroxycut, and the documented effects of high doses of certain vitamins all demonstrate the potential harm of dietary supplements.

182. § 2(14), 108 Stat. at 4326 (codified as amended at 21 U.S.C. § 321).

183. National Consumers League, Health: Answers to Your Questions About OTC Painkillers, <http://www.nclnet.org/health/100-over-the-counter-medicines/272-answers-to-your-questions-about-otc-painkillers> (last visited Mar. 14, 2010).

184. Michael A. McCann, *Dietary Supplement Labeling: Cognitive Biases, Market Manipulation & Consumer Choice*, 31 AM. J.L. & MED. 215, 258 (2005). For clarity, I am using the word overdose to mean taking more than the recommended dosage and not as a cause of death.

185. Over-the-counter medications are considered to be drugs because they satisfy the Code definition of drug. See 21 U.S.C. § 321(g)(1).

186. See JULIE GARDEN-ROBINSON, N.D. STATE UNIV. EXTENSION SER., Q & A ABOUT DIETARY SUPPLEMENTS 1 (1997), <http://www.ag.ndsu.edu/pubs/yf/foods/fn574.pdf>.

187. *Id.*

188. See 21 U.S.C. § 360e.

2. *No Premarket Approval for Most Dietary Supplements*

DSHEA, as its drafters admit,¹⁸⁹ generally enables manufacturers to market dietary supplements without “approval from FDA.”¹⁹⁰ Under DSHEA, dietary supplements not containing new dietary ingredients are not subject to any premarket notification requirements.¹⁹¹ It was because of this that ephedra remained on the market for years following DSHEA’s enactment.¹⁹² Different ephedrine-alkaloid formulas were available to consumers prior to 1994 so the majority of new formulations did not contain any new dietary ingredients.¹⁹³ Therefore, despite the ongoing health crisis, the FDA was limited to a slow and burdensome reactive evaluation of ephedra.

Conversely, DSHEA does require manufacturers to submit information regarding the safety and efficacy of dietary supplements containing new dietary ingredients.¹⁹⁴ Though a beneficial step, consumers are still at risk. First, neither Congress nor the FDA maintains a list of dietary ingredients marketed prior to DSHEA’s enactment.¹⁹⁵ Accordingly, the FDA recommends that manufacturers submit a notification to the FDA if they are unsure whether a new dietary supplement contains a new dietary ingredient.¹⁹⁶ Otherwise, the FDA warns that the dietary supplement may be “adulterated as a matter of law.”¹⁹⁷ This is merely a warning, however, because in these situations the burden of proof remains on the FDA.¹⁹⁸ The FDA would still have to demonstrate, by a preponderance of the evidence, that the dietary ingredient at issue was not marketed before DSHEA.¹⁹⁹ Furthermore, in cases involving actual new dietary ingredients, as long as the manufacturer submits the requisite information to the FDA, the dietary supplement may be marketed

189. See S. REP. NO. 103-410, at 20 (1994).

190. Press Release, U.S. Food & Drug Admin., FDA Announces Major Initiatives for Dietary Supplements (Nov. 4, 2004), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108369.htm> [hereinafter FDA Initiative].

191. See *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033, 1039 n.35 (10th Cir. 2006).

192. See *id.*

193. Ephedrine and ephedrine alkaloids were first isolated in 1887 and were introduced to the United States in 1924 as decongestants and bronchodilators for asthma. See UNIV. OF WASH., EPHEDRA 17 (n.d.), www.fammed.washington.edu/predoctoral/CAM/images/ephedra.pdf. As a result, neither fell within the definition of new dietary ingredient, or one that was “not marketed in the United States before [DSHEA].” Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 8, 108 Stat. 4325, 4331 (codified as amended at 21 U.S.C. § 350b).

194. § 8, 108 Stat. at 4331 (codified as amended at 21 U.S.C. § 350b); 21 C.F.R. § 190.6(a) (2009); see also FDA Initiative, *supra* note 190.

195. U.S. Food & Drug Administration, New Dietary Ingredients in Dietary Supplements—Background for Industry, <http://www.cfsan.fda.gov/~DMS/ds-ingrd.html> (last visited Mar. 14, 2010) [hereinafter DSHEA New Dietary Ingredients].

196. *Id.*

197. *Id.*

198. § 4, 108 Stat. at 4328 (codified as amended at 21 U.S.C. § 342(f)).

199. See *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033, 1040 n.6 (10th Cir. 2006). The FDA would have to demonstrate that the evidence does not establish that the dietary supplement would not reasonably be expected to be safe under the conditions recommended or suggested in the dietary supplement label. § 8, 108 Stat. at 4331 (codified as amended at 21 U.S.C. § 350b(a)(2)).

once the seventy-five day period expires.²⁰⁰ This seventy-five day period gives the FDA the ability to respond to the notification if the manufacturer did not provide the requisite information, the information is inadequate to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk, or if there are questions or concerns about the information in the notification.²⁰¹ If the FDA does not respond during the seventy-five day period, its authority reverts back to requiring a showing that the dietary supplement presents a significant or unreasonable risk of illness or injury to consumers to be taken off the market.²⁰²

In all, the FDA's limited ability to regulate dietary supplements emphasizes that despite Congress's assurances to protect consumers from unsafe dietary supplements, it will stand by a reactive regulatory approach. As a result, the consumer market could potentially be littered with dietary supplements that are untested and potentially dangerous. Congress recognized the problems with DSHEA and sought to remedy the situation with the 2006 Act.²⁰³ The changes, however, were merely additional reactive provisions that do not adequately address DSHEA's shortcomings.²⁰⁴

3. *The Limited Effect of the 2006 Act*

The 2006 Act primarily added the requirement that manufacturers submit to the FDA any reports they receive that a dietary supplement was related to a *serious* adverse event.²⁰⁵ When this requirement is analyzed, several observations emerge. First, manufacturers are required to submit only reports involving *serious* adverse events, and not merely moderately adverse events. This is noteworthy because serious adverse events only involve situations resulting in death, life-threatening experiences, inpatient hospitalization, or other equally severe conse-

200. DSHEA New Dietary Ingredients, *supra* note 195.

201. *Id.* For example, the FDA provided such a response to the manufacturer of a dietary supplement containing manganese glucosamine gluconate in 2005. See Letter from Dr. Susan J. Walker, Dir., Div. of Dietary Supplement Programs, U.S. Food & Drug Admin., to Brent M. Burningham, Gen. Counsel, Albion Laboratories, Inc. (Nov. 10, 2005), <http://www.fda.gov/ohrms/dockets/DOCKETS/95s0316/95s-0316-rpt0298-02-vol233.pdf>.

202. See Letter, *supra* note 201.

203. See Dietary Supplement and Nonprescription Drug Consumer Protection Act, Pub. L. No. 109-462, 120 Stat. 3469 (2006) (codified as amended at 21 U.S.C. § 371).

204. In fact, the Senate Committee on Health, Education, Labor, and Pensions affirmed this fact by stating:

Critics of the regulatory scheme laid out by DSHEA argue that all, or at least some, dietary supplement products or ingredients (such as stimulants) should be subject to premarketing approval by the government. When approving DSHEA, this committee and later the Congress rejected such a regulatory system given the history of safe use of the majority of supplement products and the inherent cost of any preapproval marketing requirement. The committee is not reconsidering that decision with this legislation.

S. REP. NO. 109-324, at 2 (2006).

205. § 760, 120 Stat. at 3469 (codified as amended at 21 U.S.C. § 379aa).

quences.²⁰⁶ Most harmful effects do not rise to this level and would be considered adverse events, which are not subject to the reporting requirement.²⁰⁷

Second, the 2006 Act does not require the manufacturer²⁰⁸ to report any serious adverse effects which it did not itself receive.²⁰⁹ Therefore, unless the manufacturer actually receives a report that one of its dietary supplements was involved in a serious adverse event, the FDA does not need to be notified.²¹⁰ Furthermore, the manufacturer does not need to report any events it may have merely heard about through some other means.²¹¹ Finally, as the Senate Committee acknowledged, the 2006 Act does not remedy the most problematic aspect of DSHEA, its reactive approach.²¹² Instead, it merely enables the FDA to respond more quickly to harmful dietary supplements by increasing communications regarding serious adverse events. The result: harmful dietary supplements may still be marketed and it will still take significant harm for the FDA to ban them.

4. *Removing Unsafe Dietary Supplements from the Market*

The final major problem with DSHEA is that even when a dietary supplement is by all accounts harmful, the FDA struggles to implement an effective ban. This is demonstrated by it taking the FDA over ten years to ban ephedra after it became aware of the dietary supplement's harmful effects. Although the FDA first issued a warning about ephedra a month before DSHEA was enacted, it still took years, overt test results, organizational bans, and statewide bans before the ephedra ban was finally promulgated.²¹³ With over 16,000 adverse events and 150

206. *Id.* § 760 (codified at 21 U.S.C. § 379aa(a)(3)(A)).

207. *See id.* § 760 (codified at 21 U.S.C. § 379aa). An adverse event, for purposes of dietary supplements, is simply defined as an event "that is adverse." *Id.* § 760 (codified at 21 U.S.C. § 379aa(a)(1)). As discussed in Part II.B.2, this definition is circular but its interpretation as meaning to cause harm is pretty clear.

208. The 2006 Act requires a "responsible person" to submit the information. *Id.* § 760 (codified at § 379aa(b)(1)). The responsible person includes the manufacturer, packer, or distributor whose name appears on the dietary supplement label. *Id.* For the purposes of this Note and for simplicity's sake, I refer to the responsible person collectively as the manufacturer.

209. *Id.*

210. The Senate Committee's explanation of the 2006 Act affirms this interpretation as it specifically states in the Senate Report that "[t]he manufacturer . . . of the supplement . . . must submit through the MedWatch form any serious adverse event report *it receives* and a copy of the labeling for the product to the [FDA] within 15 business days after the report is received." S. REP. NO. 109-324, at 5 (2006) (emphasis added).

211. *See id.*; *see also* § 760, 120 Stat. at 3469 (codified as amended at 21 U.S.C. § 379aa). The limited reporting requirement also suggests that adverse events are underreported to the FDA. For example, Metabolife, the manufacturer of an ephedra-containing weight loss product, in a letter to the FDA explained it had never received consumer notice of a serious adverse health event when it had received over fifteen thousand reports of adverse events from consumers. Edwards, *supra* note 139, at 54.

212. *See supra* note 204 and footnote text.

213. Dunne, *supra* note 69, at 351–52.

deaths taking place during that period,²¹⁴ the delay was simply inexcusable. What makes matters worse is that the delay was not a result of mismanagement by the FDA,²¹⁵ but an intentional policy implemented by Congress with DSHEA.

The Tenth Circuit's decision in *Nutraceutical Corp. v. Von Eschenbach*,²¹⁶ exemplifies the FDA's uphill battle in banning dietary supplements.²¹⁷ In *Nutraceutical*, a dietary supplement manufacturer challenged the validity of the ephedra ban after it was promulgated in 2004.²¹⁸ The manufacturer, which produced a dietary supplement containing small amounts of ephedrine alkaloids, argued the ban was unlawful because the FDA could not demonstrate that dietary supplements containing less than 10 mg of ephedrine alkaloids qualified as adulterated.²¹⁹ The district court granted summary judgment for the manufacturer, holding that the FDA's use of a risk-benefit analysis was improper and that the FDA had failed to meet its burden of showing that 10 mg dosages of ephedrine alkaloids presented a significant or unreasonable risk of injury.²²⁰ After the district court ruling and while the appeal was pending, the ban was effectively repealed. Eventually, fourteen months later, the Tenth Circuit reversed the district court's decision²²¹ and the ephedra ban was finally complete after the Supreme Court refused to grant certiorari.²²²

According to the Tenth Circuit panel, the FDA properly conducted a risk-benefit analysis because it understood "[t]he plain meaning of 'unreasonable' . . . [to] connote . . . comparison of the risks and benefits of the product."²²³ To satisfy its burden of proof,²²⁴ the FDA necessarily hired an expert to conduct pharmacokinetics research on the effects of

214. *Id.* at 352.

215. In fact, the FDA wanted to implement the ban much sooner. See Dietary Supplements Containing Ephedrine Alkaloids, 62 Fed. Reg. 30,678 (proposed June 4, 1997) (to be codified at 21 C.F.R. pt. 111).

216. 459 F.3d 1033 (10th Cir. 2006), *rev'g sub nom.* *Nutraceutical Corp. v. Crawford*, 364 F. Supp. 2d 1310 (D. Utah 2005), *cert. denied*, 550 U.S. 933 (2007). What makes this case noteworthy is that such a challenge is incredibly rare because dietary supplements containing ephedrine alkaloids are the *only* dietary supplements banned for presenting a significant or unreasonable risk. See 21 C.F.R. § 119.1 (2009) (listing only supplements containing ephedrine alkaloids among "Dietary Supplements that Present a Significant or Unreasonable Risk").

217. Several other cases did arise out of the ephedra ban following *Nutraceutical*, but these were often dismissed at the summary judgment stage. See, e.g., *Hi-Tech Pharm., Inc. v. Crawford*, 505 F. Supp. 2d 1341, 1358 (N.D. Ga. 2007).

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

219. *Nutraceutical*, 459 F.3d at 1035.

220. *Crawford*, 364 F. Supp. 2d at 1319, 1321.

221. *Nutraceutical*, 459 F.3d at 1044.

222. *Nutraceutical Corp. v. Von Eschenbach*, 550 U.S. 933 (2007).

223. *Nutraceutical*, 459 F.3d at 1038 (quoting Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk, 69 Fed. Reg. at 6823).

224. To meet its preponderance burden, the FDA had to support its position with the greater weight of the evidence. *Nutraceutical*, 459 F.3d at 1040.

ephedra on the cardiovascular system.²²⁵ The FDA also considered findings by the National Institute of Health, the GAO, and the 1996 Food Advisory Committee.²²⁶ The FDA submitted all of its research to the court, which ultimately determined that the majority of data in the record suggested that ephedra posed an “unreasonable threat to the public’s health.”²²⁷ Considering the large amount of information the FDA compiled in support of the ephedra ban, and that the district court still invalidated it, the FDA’s ability to enact additional dietary supplement bans is an uncertain proposition. Perhaps lamenting the reactive nature of DSHEA, Judge Eagan wrote for the Tenth Circuit panel that ephedra supplements “were allowed to enter the market without findings of safety or effectiveness.”²²⁸

Overall, DSHEA is ineffective because it limits the FDA’s ability to remove unsafe dietary supplements from the market until significant damage has been done.²²⁹ Dr. Richard Friedman, the current Director of the Psychopharmacology Clinic at Weill Cornell Medical College, commented that the FDA “couldn’t stop [anyone] from selling hemlock tea until the bodies piled up.”²³⁰ Instead the FDA must issue frequent public warnings about the dangers of certain dietary supplements as the only way to protect consumers.²³¹ Replacing DSHEA with a more proactive regulatory approach would alleviate these concerns and dramatically increase the FDA’s ability to ensure consumer safety. Congress should emulate the European Commission, which was not willing to adopt DSHEA’s reactive approach. Instead it favored a proactive and exclusionary approach—the result being the Food Supplements Directive.²³²

B. Comparing DSHEA and the Food Supplements Directive

Congress enacted DSHEA with the purported belief that dietary supplements are safe, adverse reactions are rare, and the American consumer should have wide access to them.²³³ It is more likely, however, that Congress believed that the dietary supplement industry, which has significant lobbying power, should not be hampered by unnecessary legislation

225. See *id.* at 1041–42.

226. *Id.* at 1042–43.

227. *Id.* at 1043.

228. *Id.* at 1039.

229. LeCong, *supra* note 163, at 117.

230. *Id.* at 117 (quoting Gina Kolata, *The Unwholesome Tale of the Herb Market*, N.Y. TIMES, Apr. 21, 1996, at E6).

231. Dunne, *supra* note 69, at 357. The effectiveness of these public warnings, however, is questionable as these warnings by themselves do not result in the removal of the product from the market. *Id.*

232. See *supra* Part II.D.

233. See Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 2(9), 2(12), 2(14), 108 Stat. 4325, 4325–26 (codified as amended at 21 U.S.C. § 321 (2006)).

and prohibitions.²³⁴ Additional restrictions or a proactive regulatory approach would likely require manufacturers to spend more time and money on efforts to market dietary supplements. The European Commission decided that consumer safety was worth additional manufacturer expense and enacted the Food Supplements Directive.

Congress's reactive approach is justified if we assume that all dietary supplements are actually safe. Comparing DSHEA with the Food Supplements Directive makes it obvious that the European Commission did not hold this assumption. Whereas Congress took the approach of not "tak[ing] any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers,"²³⁵ the European Commission prohibited the sale of all dietary supplements containing ingredients not on the positive list.²³⁶

Under DSHEA, dietary supplement manufacturers are not required to obtain premarket approval unless the dietary supplement contains a new dietary ingredient. Even then, the manufacturer need only submit a report demonstrating a "history of use or other evidence of safety establishing that the dietary ingredient when used . . . [as recommended] will reasonably be expected to be safe," and the "basis" for establishing that history.²³⁷

The Food Supplements Directive takes the opposite approach and requires manufacturers to have each dietary supplement they seek to market evaluated and approved by the Scientific Committee on Food (SCF).²³⁸ Only those vitamins and minerals explicitly approved by the SCF and placed on the positive list are permitted to be used in the manufacture of food.²³⁹ Nevertheless, having a dietary ingredient added to the positive list is not the end of the story. Even then, maximum amounts of vitamins and minerals present in food supplements per daily portion as recommended by the manufacturer are established.²⁴⁰ Therefore, unlike Congress, the European Commission ensured that consumers would be protected from unsafe dietary supplements.²⁴¹

This is not to say that the Food Supplements Directive is not without its critics or flaws. Attempts to add a dietary ingredient to the positive lists takes significant amounts of time and money.²⁴² These costs are inherent in a system that places the burden on the manufacturer instead

234. See, e.g., Grossman, *supra* note 9, at 1139 (discussing how the herbal supplement industry grew from a market of "small niche companies" to a corporation-dominated industry capable of defending itself against the FDA).

235. § 2(13), 108 Stat. at 4326.

236. Food Supplements Directive, *supra* note 19, art. 4.

237. § 8, 108 Stat. at 4331 (codified as amended at 21 U.S.C. § 350b(a)(2)).

238. LeCong, *supra* note 163, at 115.

239. Food Supplements Directive, *supra* note 19, art. 4.

240. *Id.* art. 5. Once this maximum dosage is established, the manufacturer must include a warning not to exceed the state recommended daily dose on the label. *Id.* art. 6(1)–(3)(c).

241. See Coutrelis, *supra* note 160, at 36.

242. See *supra* note 167 and accompanying text.

of the government. It is also likely that this burden may result in fewer new dietary supplements marketed to consumers.²⁴³ Nevertheless, the benefits of the proactive approach outweigh the negatives. If Congress had adopted the Food Supplements Directive twenty years ago, the ephedra and L-tryptophan crises would have been avoided²⁴⁴ because the inherent risks in taking those dietary supplements would have been discovered before they reached the market.²⁴⁵

As a whole, the Food Supplements Directive protects consumers more effectively than DSHEA because it uses a proactive regulatory scheme. This proactive approach has been quite effective, and its effects have been noticed. For example, Canada adopted a similar approach in 2004 with the National Health Products Regulations.²⁴⁶ Nevertheless, Congress's hesitation to overly burden manufacturers and limit consumer access to dietary supplements does have some merit. Therefore, the optimal approach to dietary supplement regulation, which Congress should hereinafter adopt, is an intermediate approach that proactively regulates new dietary supplements while not overly inhibiting those dietary supplements previously marketed.

IV. RECOMMENDATION

Parts II and III discussed DSHEA's limitations and emphasized the need for additional legislation to prevent future health crises like those involving ephedra and L-tryptophan. The European Commission was not willing to settle for DSHEA's reactive approach and enacted the proactive Food Supplements Directive. Though an improvement, the Food Supplements Directive has its own drawbacks and potentially overly restricts consumer access to dietary supplements. In order to properly balance safety and consumer access, Congress should adopt an intermediate approach implementing premarketing requirements based on a three-tier regulatory scheme. These tiers would regulate dietary supplements based on their marketing date and potential risk of consumer harm.

Tier I would be the least restrictive category and would encompass dietary supplements containing only ingredients marketed prior to DSHEA's enactment. Tier II would include all dietary supplements marketed in the time since DSHEA. Finally, Tier III would include future dietary supplements with ingredients not currently marketed in the United States at the time the tier system is implemented. The tier system would represent a sliding-scale approach in which most dietary supple-

243. Jungbeck, *supra* note 167.

244. See LeCong, *supra* note 163, at 117–18.

245. *Id.*

246. Natural Health Products Regulations (Food and Drugs Act) SOR/2003-196 (Can.); see also Health Canada, Compliance Policies for Natural Health Products, http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/pol/complian-conform_pol-eng.php#toc1 (last visited Mar. 14, 2010).

ments, including those currently marketed, would remain marketable. At the same time, the tier system would increase the burden on manufacturers seeking to market new ingredients that have the largest potential risk. The overall goal of the tier system is to take a more proactive regulatory approach to dietary supplements while still balancing the competing interests of consumer safety and access.

A. Tier I: Pre-DSHEA Dietary Supplements

Tier I would include dietary supplements containing only ingredients marketed prior to DSHEA's enactment. Unlike the current new dietary ingredient requirements, the FDA would establish a list of Tier I dietary ingredients, similar to the Food Supplements Directive's positive list.²⁴⁷ The FDA list, however, would not be as exclusive as the positive list and would include all dietary ingredients available before DSHEA, except in extreme circumstances. This would basically enable all pre-DSHEA dietary supplements to remain on the market without inhibition. To be added to the list, the manufacturer would bear the burden of demonstrating that a specific dietary supplement and its ingredients were marketed before DSHEA. For the large majority of dietary supplements this should only be a minor inconvenience as manufacturers should have readily accessible business records.²⁴⁸ Placing the burden on the manufacturers would also speed up the process of compiling the FDA list and would relieve the FDA of a significant administrative burden.²⁴⁹

Once an ingredient is added to the FDA list, it would be freely marketable and only subject to the DSHEA's current reactive provisions. As the ingredients on this list will have been marketed for over fifteen years when the list is compiled, any related health concerns will likely have been alleviated. Only in extreme circumstances in which harmful scientific data and serious adverse events have been reported should a dietary ingredient not gain automatic entry. In these cases, the FDA would evaluate the dietary supplement and decide between seeking an adulteration ban of the supplement and allowing it list entry.

It is likely that the overwhelming majority of dietary supplements available since before DHSEA are safe and Congress's finding that "dietary supplements are safe within a broad range of intake, and safety

247. See *supra* Part III.B.

248. For the purposes of this Note, it is not necessary to fully lay out specific requirements the dietary supplement manufacturers must satisfy to have their supplements placed on the list of permitted supplements. Newer manufacturers of dietary supplements would also not be harmed under this standard because they would be allowed to use ingredients shown by other manufacturers to have marketed pre-DSHEA. For example, if Company A effectively demonstrates that a certain type of vitamin A was available prior to 1994, then Company B may market its vitamin A as well, so long as it does not contain any additional ingredients that do not satisfy the pre-1994 requirements.

249. A manufacturer would have a larger incentive to act quickly because it would likely still be manufacturing the dietary supplements at issue and failure could result in lost profits.

problems with the supplements are relatively rare” is accurate.²⁵⁰ Since DSHEA, however, scientific advances have led to a significant increase in the number of dietary supplements on the market.²⁵¹ These dietary supplements do not have the same safety assurances as the Tier I supplements and require additional safeguards.

B. Tier II: Dietary Supplements Marketed Since DSHEA’s Enactment

In the years since DSHEA, thousands of new dietary supplements have been marketed,²⁵² and the majority of consumers believe that these dietary supplements are safe.²⁵³ For Tier II supplements, DSHEA currently requires manufacturers to submit to the FDA premarket information regarding their safety.²⁵⁴ Though not an overly effective consumer safety measure, the FDA is given notice of the new ingredient and is then able to reactively evaluate it. Tier II supplements do not have the safety assurances of Tier I supplements, but there has been time to evaluate them, which makes them less risky than Tier III supplements. The adequacy of the evaluation period does depend on how long a dietary supplement has been marketed, but the additional event reporting requirements of the 2006 Act help compensate for this.²⁵⁵

Unlike Tier I, the FDA would evaluate Tier II dietary supplements based on all the available relevant information. This would include any scientific studies, tests, adverse event reports, and professional opinions. If the FDA concludes there have been no serious adverse event reports and less than a significant number of adverse event reports, the dietary supplement may continue to be marketed. If the FDA has received serious adverse event reports or a significant number of adverse event reports, however, then it would evaluate the dietary supplement by closely analyzing all the available information. This first step would allow dietary supplements not raising any red flags to remain on the market, but would also protect consumers by forcing the others to be evaluated more thoroughly.

If a dietary supplement requires an FDA evaluation, the FDA must find that the evidence demonstrates that the dietary supplement would reasonably be expected to be safe. This standard mirrors the current

250. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 2(14), 108 Stat. 4325, 4326 (codified as amended at 21 U.S.C. § 321 (2006)). Admittedly, both L-tryptophan and ephedra were dangerous dietary supplements marketed before DSHEA. Both are no longer allowed to be sold in the United States, however, alleviating the problems associated with them.

251. Throughout the 1990s, the dietary supplement industry experienced growth of over ten percent each year. TALBOTT, *supra* note 56, at 2.

252. KAREN EICH DRUMMOND & LISA M. BREFERE, NUTRITION FOR FOODSERVICE AND CULINARY PROFESSIONALS 291 (6th ed. 2007).

253. *Id.* This is despite the fact that dietary supplement labels must contain disclaimers stating that any claims they make regarding their effect on the structure or function of the body have not been evaluated by the FDA. See U.S. Food & Drug Administration, *supra* note 10.

254. See *supra* notes 194–200 and accompanying text.

255. See *supra* Part III.A.3.

new dietary ingredient standard, but the FDA would actually evaluate the dietary supplement and make a marketability finding. If the FDA finds the evidence does not establish the dietary supplement to be safe, then the dietary supplement would no longer be marketable. This, however, would not be a finding of adulteration and would merely be a temporary ban, enabling the manufacturer to submit additional information supporting its position that the dietary supplement is safe.²⁵⁶

Though the burden on manufacturers under Tier II is greater than Tier I, the majority of dietary supplements would remain marketable as long as manufacturers actually performed adequate scientific tests or the dietary supplement was not the subject of adverse reports. Unlike Tier I and II, future dietary supplements falling into Tier III do not have similar safety assurances because they have not yet been marketed and shown to be safe, and there has likely not been significant scientific test data.

C. Tier III: Future Dietary Supplements

Considering the number of new dietary supplements currently marketed each year, the growth trend of the supplements industry will likely continue in the foreseeable future. In less than a century, a market consisting of single vitamin tablets has evolved into a market of thousands of dietary supplements. With the speed that technology develops, the future of dietary supplements is difficult to comprehend. For this reason, a proactive regulatory scheme is needed because new technology often comes with unforeseen consequences. For example, when ephedra was first marketed, it was publicized as being a wonderful weight loss product, but as time went on, its harmful effects became highly publicized. To avoid this type of situation from repeating, a more stringent Tier III scheme is necessary.

The current premarket notification requirement for new dietary ingredients is a good start, but enhancements are needed. For Tier III supplements, manufacturers would be required to demonstrate that there is substantial evidence showing the dietary supplement to be safe. Similar to Tier II supplements, the manufacturer could submit any relevant information including scientific test results, studies, and professional opinions. But because the dietary supplements have not been marketed and the number of valid scientific tests is likely limited, the manufacturer would have an increased burden to satisfy the Tier III standard of review.

256. This may seem like a harsh result as these dietary supplements will have already been marketed to consumers at the time this approach is enacted. The burden, however, is only heightened for manufacturers of dietary supplements that were first marketed only since the DSHEA's passage or those for whom serious adverse event reports or a significant number of adverse events have been reported.

In evaluating Tier III supplements, the FDA should use the *Daubert* reliability standard for expert witness testimony.²⁵⁷ Although the arenas are quite different, the *Daubert* factors lend themselves quite well to the dietary supplement context because of the limited scientific test results likely to be available. The FDA, to make an informed decision, would only evaluate and accept the results of scientific tests and studies conforming to the scientific method. The *Daubert* reliability factors were established for that very purpose and include: empirical testing, peer review, known or potential error rate, and relevant scientific community acceptance.²⁵⁸

Adopting these factors would enable the FDA to evaluate manufacturers' claims under a consistent standard that has been used by the federal courts for over fifteen years. The *Daubert* factors would allow the FDA to efficiently evaluate each claim and do so in a consistent manner.²⁵⁹ The FDA would also be able to avoid the long delays that have been inherent under the Food Supplements Directive. Though this system would have time and monetary constraints as a result of the necessary testing and evaluation period, it would ensure that the new dietary supplements reaching the market are actually safe. It would also accomplish Congress's goal of protecting "the right of access of consumers to safe dietary supplements."²⁶⁰

Admittedly, the flow of safe dietary supplements to consumers would potentially be slowed by the requirement of scientific test evaluation. It may also constrain the development of new dietary supplements. Nevertheless, Tier III would only include dietary supplements containing new ingredients after the tier system is adopted. The large majority of dietary supplements would likely fall into Tier I or II. For the ones that do fall into Tier III, the burden of the heightened testing requirements would be outweighed by the assurances of safety.

As a whole, a tier system would proactively prevent future crises like the ephedra and L-tryptophan episodes, yet still enable widespread consumer access to safe dietary supplements. The three tier approach adopts the beneficial aspects of DSHEA and the Food Supplements Directive, but avoids the drawbacks. With DSHEA, Congress sought to balance consumer access and safety but ultimately access won out. The tier system represents a middle ground of proactively regulating dietary supplements while being less exclusive than the Food Supplements Directive. Congress should continue to promote the great potential of die-

257. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592–94 (1993).

258. *Id.* at 592–95.

259. The FDA could implement such interpretations by publishing Proposed and Final Rules in the *Federal Register* and ultimately codifying them in the *Code of Federal Regulations*. Because the FDA would implement these standards and utilize them in its Tier III evaluations, it would be in the best position to establish the most appropriate working standard.

260. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 2(15)(A), 108 Stat. 4325, 4326 (codified at 21 U.S.C. § 321 (2006)).

tary supplements, but should adopt a tier system to most effectively protect consumers from unsafe dietary supplements.²⁶¹

IV. CONCLUSION

Dietary supplements are an integral part of society. Since their initial development in the early twentieth century, dietary supplements have evolved into an established industry of thousands of products. The benefits of dietary supplements are great and consumer access is important for promoting “good health and healthy lifestyles.”²⁶² At the same time, consumers must be protected from unsafe dietary supplements to avoid repeats of the ephedra and L-tryptophan tragedies. The recent Hydroxycut recall further emphasizes this. DSHEA fails to protect consumers because its reactive approach simply cannot ensure that currently marketed dietary supplements are actually safe. A more proactive approach is needed.

This Note proposes that Congress adopt a three tier system for regulating dietary supplements. This system would proactively regulate new dietary supplements while ensuring consumer access to dietary supplements proven to be safe. This system therefore takes a middle approach between DSHEA and the Food Supplements Directive. Congress's goal in balancing consumer safety and access is important, and the Food Supplements Directive is overly restrictive. The three tier system balances the beneficial aspects of both systems and would ultimately protect the right of consumer access to safe dietary supplements. As a result, innovation would still be fostered without sacrificing the health and safety of the American consumer.

261. Products liability lawsuits also have the potential to deter dietary supplement manufacturers from marketing potentially unsafe products. Although the actual deterrent effect of such suits is beyond the scope of this Note, additional congressional action is needed to adequately protect consumers with one reason being the inherent difficulty for plaintiffs to establish a class action under Federal Rule of Civil Procedure 23(b)(3). This is emphasized by a New York district court's refusal to certify a settlement class against an ephedra manufacturer because the predominance requirements were not satisfied. See *In re Ephedra Prods. Liab. Litig.*, 231 F.R.D. 167, 171 (S.D.N.Y. 2005); FED. R. CIV. P. 23(b)(3) (stating that the court must find that “the questions of law or fact common to class members predominate over any questions affecting only individual members”). “Innumerable questions affecting individual class members would arise,” because the plaintiff class ranged from individuals with no actual injuries to the survivors of those who had died from the product. *In re Ephedra Prods. Liab. Litig.*, 231 F.R.D. at 168–70 (citing *Amchem Prods. v. Windsor*, 521 U.S. 591, 622 (1997)) (“[The] common interest in a fair, reasonable and adequate settlement is not a question to be considered under the predominance test.”). Furthermore, the purpose of the tier system is to prevent unsafe dietary supplements from reaching the market in the first place, whereas a products liability suit is a reactive measure. Coupling lawsuits with a more proactive regulatory scheme would be the most effective way to protect consumers.

262. § 2(6)(A), 108 Stat. at 4326 (codified at 21 U.S.C. § 321).

