

Stomaching the Burden of Dietary Supplement Safety: The Need to Shift the Burden of Proof Under the Dietary Supplement Health and Education Act of 1994

*Morgan J. Wais**

There are some in the industry that would have us accept the notion that ephedra is only an outlier. That the law is sound and only this single substance needs to be banned. I do not believe that that is the truth, and I believe they know better.¹

—Rep. John D. Dingell

I. INTRODUCTION

In the United States, more than half of all Americans consume dietary supplements in some form, be it in a pill, bar, powder, or liquid.² Americans consume dietary supplements for various reasons—to lose weight, to build muscle, to have more energy, to treat colds, or simply to live a healthier life.³ In the latter half of the twentieth century, “[s]kyrocketing healthcare costs, longer life expectancy, perceived fail-

*J.D. Candidate, Seattle University School of Law, 2005; B.A., University of Washington, 2002. The author served as the Business Editor for the Seattle University Law Review. He would like to thank his wife, Lindsay, for her support and encouragement throughout the writing of this article and throughout the rest of law school and life. The author would also like to thank his parents for setting an example to which he can only aspire. Finally, the author would like to sincerely thank the entire crew of student editors at the Seattle University Law Review for their assistance with this article.

1. *Issues Relating to Ephedra-Containing Dietary Supplements, Hearings before the Subcommittee on Oversight and Investigations and the Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy and Commerce*, 108th Cong. 4 (2003) [hereinafter *Ephedra Hearings*] (opening statements of Rep. John D. Dingell, ranking member of the Committee on Energy and Commerce), available at <http://energycommerce.house.gov/108/action/108-43.pdf> (last visited Mar. 13, 2005).

2. *Id.* (testimony of Mark B. McClellan M.D., Ph.D.).

3. Lauren J. Sloane, *Herbal Garden of Good and Evil: The Ongoing Struggles of Dietary Supplement Regulation*, 51 ADMIN. L. REV. 323, 324 (1999); see also Jeffery A. Crossman, Mark McGwire Does It, So Why Can't I? *High School Student Use of Dietary Supplements and the Failure of DSHEA*, 28 CAP. U. L. REV. 617, 623–24 (2000).

ure of Western trained doctors to practice preventative medicine, lack of effective communication with patients, and new diseases all contributed" to Americans seeking alternative medical treatments.⁴ Not wanting the sales of dietary supplements to be wholly unregulated, Congress passed the Dietary Supplement Health and Education Act of 1994 ("DSHEA").⁵ Although DSHEA made several substantial changes to dietary supplement regulation, it also created a great deal of uncertainty about the scope of the Food and Drug Administration's ("FDA") regulatory power over dietary supplements. Such uncertainty is due in large part to three characteristics: (1) DSHEA contains ambiguous verbiage; (2) DSHEA divested the United States government of a large portion of its regulatory power, and, above all; (3) DSHEA placed the burden of proving dietary supplement safety on the FDA, rather than on the dietary supplement industry.⁶

Although this Comment concerns dietary supplements in general, it focuses on ephedra because of its recent rise in popularity and its subsequent fall due to safety concerns.⁷ Ephedra regulation illustrates many of the deficiencies of supplement regulation under DSHEA. However, simply addressing a single dangerous dietary supplement does not provide a long-term solution for the underlying problems endemic in current supplement regulation.⁸ Accordingly, changes made to provisions of DSHEA have to be broad and sweeping rather than narrow and limited to ephedra.

In order to best protect consumers, Congress should amend DSHEA so that the burden of proving the safety of dietary supplements rests solely on the dietary supplement industry, rather than on the FDA. Despite countless injuries to supplement users, the current regulatory scheme under DSHEA has not encouraged the FDA to make the safety determinations necessary to meet its burden and properly regulate the

4. Teresa Schroeder, *Chinese Regulation of Traditional Chinese Medicine in the Modern World: Can the Chinese Effectively Profit from One of Their Most Valuable Cultural Resources?* 11 PAC. RIM L. & POL'Y J. 687, 692 (2002).

5. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, §§ 301 et seq., 108 Stat. 4325 (1994).

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

7. See Jennifer Sardina, *Misconceptions and Misleading Information Prevail—Less Regulation Does Not Mean Less Danger to Consumers: Dangerous Herbal Weight Loss Products*, 14 J.L. & HEALTH 107, 117 (1999–2000).

8. Before ephedra, the dietary supplement of choice was fen-phen. Fen-phen has since been voluntarily pulled from the market by manufacturers because of its numerous dangerous side effects, which are similar to those of ephedra. See *id.* at 125–26.

dietary supplement industry.⁹ It has, therefore, become the injured public who has held dietary supplement manufacturers accountable when they produce an unsafe product.¹⁰ And it will be the public that will continue to be injured until pre-market approval is required of dietary supplements.

If Congress amends DSHEA and places the burden of proving the safety of dietary supplements on the industry, supplement manufacturers of products that are truly safe will be little more than inconvenienced. To illustrate, manufacturers of vitamin C have little to be concerned about, as there is undeniable evidence proving not only vitamin C's safety, but also its benefits.¹¹ However, ephedra and other dangerous dietary supplements not only lack proven benefits, but have several known deleterious effects. Manufacturers of ephedra would have to establish its safety before marketing their products. As the law currently stands, even products like ephedra that are ultimately banned¹² are allowed to remain on the market far too long once their deleterious effects are known, resulting in innumerable unnecessary injuries.¹³

Part II of this Comment will give a brief historical perspective on dietary supplement regulation and discuss the evolution of drug regulation by the FDA. Part II will conclude with a discussion of the political environment in which these regulations occur. Part III will give examples and show how the current system has caused injury and harm to consumers of dietary supplements. Part IV will discuss the current burden of proof and how it was applied in the case of ephedra. Part V will discuss how, under the current regulatory structure, consumers cannot be adequately protected, either by the FDA or the tort system. Part VI discusses

9. H.R. Res. 435, 108th Cong. (2003) (stating that "approximately 30 members of the United States Army have died after taking dietary supplement containing ephedrine alkaloid").

10. Eric M. Kraus & Caroline E. Oh, *Herbal Remedies and Dietary Supplements: Surveying the Landscape of Litigation Trends*, 4 No. 9 ANDREWS DRUG RECALL LITIG. REP. 11, at 1 (2001) ("As complaints mount, even seemingly modest problems can trigger the appetite of an ever-hungry plaintiffs' bar for new and relatively untapped litigation targets.").

11. See News Release, Nat'l Inst. of Health, NIH Study Suggests Women May Need More Vitamin C (Aug. 13, 2001), at <http://www.nih.gov/news/pr/aug2001/niddk-13.htm> (last visited Nov. 13, 2004) [hereinafter *NIH News Release*]; see also Randy Dotinga, *Vitamin C May Screen Second-hand Smoke*, HEALTH DAY REP., August 6, 2003, available at <http://www.hon.ch/News/HSN/514516.html> (last visited Nov. 13, 2004); *Prominent Nutrition Experts Convene to Examine New Benefits of Antioxidant Vitamins C and E*, PR NEWswire, May 29, 2003, available at http://archives.foodsafetynetwork.ca/ffnet/2003/5-2003/functional_foodnet_may_29.htm#PROMINENT (last visited Nov. 18, 2004) ("[S]cientific evidence already indicates that vitamins C and E can provide a benefit for people affected by conditions like diabetes and cardiovascular disease . . .").

12. FDA Rule Declaring Dietary Supplements Containing Ephedra Alkaloids Adulterated Because They Present an Unreasonable Risk, 69 Fed. Reg. 6788 (Feb. 11, 2004) (to be codified at 21 C.F.R. pt. 119) [hereinafter *FDA Rule Banning Ephedra*].

13. See Bruce H. Schindler, *Where There's Smoke There's Fire: The Dangers of the Unregulated Dietary Supplement Industry*, 42 N.Y.L. SCH. L. REV. 261, 278 (1998).

the benefits that would likely be derived from shifting the burden of proving safety onto the dietary supplement industry. Finally, Part VII concludes this Comment.

II. HISTORY OF DSHEA, DRUG REGULATION, MONEY, AND POLITICS

A. Historical Basis and Formation of the Act

DSHEA was signed into law on October 25, 1994, by President Clinton,¹⁴ but the history of regulating dietary supplements extends back much farther.¹⁵ Regulation of supplements began when the FDA was created in 1906 by the passage of the Pure Food Act ("PFA").¹⁶ The initial goals of Congress were to protect the public and to guard against deceptive labeling practices regarding claims made by the manufacturers.¹⁷ PFA was deficient because it gave the FDA only the power to remove dangerous products from the market but did not give it the power to prevent the products from entering the market in the first place.¹⁸

In 1938, Congress amended PFA and enacted the Food, Drug and Cosmetic Act ("FDCA"),¹⁹ which gave the FDA the power to not only remove dangerous products from the market, but also to require pre-market approval from the FDA before certain products were placed on the market.²⁰ The FDCA also made the distinction between dietary foods, which were to be regulated as food, and dietary ingredients, which were to be regulated as drugs.²¹ Dietary foods were presumed safe and the FDA had the burden of proving that the product was not safe, but the burden of proving the safety of dietary ingredients rested upon the manufacturers.²² At that time, most modern dietary supplements were classified as dietary ingredients,²³ and thus, like drugs, the burden of proving product safety rested on the manufacturers.²⁴

14. Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended at 21 U.S.C. § 301 (2004)).

15. See Schindler, *supra* note 13, at 262-72.

16. Pure Food Act, ch. 3915, 34 Stat. 768 (1906) (repealed 1938).

17. Crossman, *supra* note 3, at 639.

18. *Id.*

19. See Food, Drug and Cosmetic Act, Pub. L. No. 75-717, ch. 675, 52 Stat. 1040 (codified at 21 U.S.C. § 301) (1938).

20. See *id.*; see also Pinco & Rubin, *supra* note 6, at 385 ("The FDA historically has used its food additive jurisdiction to prohibit marketing multiple ingredient dietary supplement products. Because the FDA has pre-market approval authority over food additives, the characterization of a dietary supplement ingredient as an unapproved food additive has enabled the agency to lawfully challenge the marketing of a supplement that contains such an ingredient.").

21. Pinco & Rubin, *supra* note 6, at 385.

22. *Id.*

23. See generally Crossman, *supra* note 3, at 639-40; Schindler, *supra* note 13, at 268.

24. See Food, Drug and Cosmetic Act, ch. 675.

Throughout the 1960s and until the early 1990s, there were frequent discussions regarding the regulation and classification of dietary ingredients to allow them to be more easily brought to market.²⁵ Both sides were strong advocates for their positions: One side sought tighter control of dietary ingredients while the other sought a less burdensome approval process.²⁶ Despite the urging of both dietary supplement manufacturers and the public, the classification remained, and the burden of proving the safety of the dietary ingredients remained on the manufacturers.²⁷

This complex framework—what product falls into which category for the sake of proving its safety—was reworked in 1994 when the FDCA was amended with the passage of DSHEA.²⁸ In passing DSHEA, Congress sought “to supersede the current ad hoc, patch work regulatory policy on dietary supplements.”²⁹ In doing so Congress made several findings, including the following: (1) the availability of dietary supplements improves “the health status of United States citizens[,]”³⁰ (2) the availability of dietary supplements allows consumers to be “empowered to make choices about preventative health care programs based on data from scientific studies of health benefits related to particular dietary supplements,”³¹ and (3) “the nutritional supplement industry is an integral part of the economy of the United States.”³² Most significant was Congress’ finding that “although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers.”³³

DSHEA changed the regulation of dietary supplements in four main ways. First, the Act defined dietary supplements as products supplementing the diet that contain a vitamin, mineral, herb or other botanical, amino acid, “dietary substance for use by man to supplement the diet by increasing the total dietary intake,” or “a concentrate, metabolite, constituent, extract, or combination of any ingredient” described above.³⁴

25. Crossman, *supra* note 3, at 640.

26. *Id.*

27. *Id.*

28. *See generally* 21 U.S.C. § 301 (2004).

29. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 2(15)(B), 108 Stat. 4325 (1994).

30. *Id.* at § 2(1).

31. *Id.* at § 2(8).

32. *Id.* at § 2(12)(A).

33. *Id.* at § 2(13).

34. 21 U.S.C. § 321(ff)(1) (2004).

The new definition was an attempt to clarify the blurry line between foods, dietary supplements, and pharmaceuticals.³⁵

Not only did the redefinition of dietary ingredients to dietary supplements place supplements in the same regulatory framework as food, but the new framework did not require supplement manufacturers to keep accurate records of all adverse reactions reported to them from use of a specific supplement.³⁶ Under the new definition, dietary supplement manufacturers could put the product on the market and disregard any complaints or questions regarding the safety of their product.³⁷ Compare this framework to that of pharmaceuticals, where, among other things, companies must keep accurate records of all adverse reactions reported to them.³⁸

The second primary way in which DSHEA changed regulation of dietary supplements was that DSHEA created the Office of Dietary Supplements (“ODS”) within the National Institute of Health,³⁹ a sub-agency of the FDA. The ODS was created, in part, to make determinations about the safety of certain dietary supplements. The stated purpose of ODS in DSHEA was “to explore more fully the potential role of dietary supplement as a significant part of the efforts of the United States to improve health care”⁴⁰ and “to promote scientific study of the benefits of dietary supplements in maintaining health”⁴¹ To effectuate this purpose, ODS’s role was narrowed to researching and substantiating claims made by dietary supplement companies.⁴² However, from its very inception, ODS has not had the staffing and the funding to sufficiently research products whose safety may be questionable, as discussed below.⁴³

35. Many pharmaceuticals on the market today were originally derived from some kind of food or plant. The same is true of dietary supplements. The difference between the two is merely how well-refined the food or plant is. For instance, ephedra is derived from the ma huang plant, which has been used in Chinese medicine for centuries. Its synthetic alternative, ephedrine, from which pseudophedrine and norpseudoephedrine are derived, differs very little from ephedra other than that it is an approved pharmaceutical. Despite their different origins, both ephedrine and ephedra are classified as ephedrine alkaloids. See Press Release, U.S. Food & Drug Admin., HHS Acts to Reduce Potential Risks of Dietary Supplements Containing Ephedra (Feb. 28, 2003), available at <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00875.html> (last visited Nov. 13, 2004) [hereinafter *FDA Press Release*].

36. 21 U.S.C. § 321.

37. See *id.*

38. Steven M. Kohn & Courtney E. Quinn, *Dietary Supplements and the Playing Field*, 69 DEF. COUNS. J. 517, 520 (2002).

39. 42 U.S.C. § 287c-11(a) (2004).

40. § 287c-11(b)(1).

41. § 287c-11(b)(2).

42. § 287c-11(c).

43. See *infra* Part V.A. See also Sloane, *supra* note 3, at 329.

Third, DSHEA changed the way dietary supplements could be labeled and marketed.⁴⁴ Under DSHEA, dietary supplement manufacturers could only make a statement that has “substantiation that such statement is truthful and not misleading”⁴⁵ Although the Act allows dietary supplement manufacturers to make claims as to a likely benefit that could be derived from the consumption of a particular supplement, the Act does not allow claims that a supplement was supposed “to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.”⁴⁶ The FDA shares its labeling regulatory authority with the Federal Trade Commission (“FTC”).⁴⁷ Thus, many of the concerns about FDA regulation also apply to the FTC; most notably, that the burden remains on the FDA and the FTC to prove certain claims rather than on the supplement companies to prove the safety of their products.⁴⁸

Finally, and the primary focus of this Comment, DSHEA placed the burden of proving the safety of the dietary supplements on the FDA.⁴⁹ Indeed, the first and the last ways in which DSHEA changed regulation of supplements have a corollary relationship: The way in which a dietary supplement was defined was directly connected to whether or not the supplement manufacturer had the burden of proving the product’s safety.

B. Pharmaceutical Regulation

While the history of pharmaceutical regulation does somewhat resemble the history of dietary supplement regulation, pharmaceutical regulation evolved much more in response to pointed shortcomings in the

44. See generally 21 U.S.C. § 301 (2004).

45. § 343(r)(6)(B).

46. § 343(r)(6)(c).

47. See Crossman, *supra* note 3, at 644–45.

The FDA is not the only government entity charged with monitoring the dietary supplement industry. Using its general authority to monitor “unfair or deceptive . . . [trade] acts or practices,” the Federal Trade Commission . . . attempts to reign in the industry by monitoring the health claims manufacturers and retailers are making in the advertising of their dietary supplements The FTC requires that advertisers and advertising agencies have a “reasonable basis” for claims they make before they are published.

Id.; see also *Ephedra Hearings*, *supra* note 1, at 236 (testimony of Mark B. McClellan M.D., Ph.D.) (“With a mutual goal of consumer protection, FDA and FTC formed a Dietary Supplement Enforcement Group to closely coordinate their enforcement efforts against health care fraud.”).

48. See *Ephedra Hearings*, *supra* note 1, at 236; see also 21 U.S.C. § 342(f). It is a lesser burden to prove that the labeling claims are not substantiated than the burden of proving that a specific dietary supplement presents a “significant or unreasonable risk.” Not coincidentally, attorneys have used these same mislabeling claims in civil actions against dietary supplement manufacturers, as discussed *infra* part V.B.

49. 21 U.S.C. § 342(f)(1). In the instance of “new dietary ingredients,” the burden of proving the safety of a dietary supplement was on the manufacturer only in the instances of a new dietary ingredient. A new dietary ingredient was defined as “a dietary ingredient that was not marketed in the United States before October 15, 1994.” *Id.* § 350b(c).

law—shortcomings that lead to the injuries and deaths of numerous pharmaceutical consumers.⁵⁰ Like supplements, pharmaceuticals were classified and loosely regulated by the FDA following the passage of the Pure Food Act of 1906.⁵¹ At the time, PFA did many of the same things for pharmaceutical regulation as DSHEA now does for dietary supplement regulation.⁵² Namely, PFA mandated that drug labeling be “truthful,” that drug manufacturers monitor product potency and quality, and that the FDA be required to show “that a drug’s labeling was false and fraudulent before it could be taken off the market.”⁵³ However, this regulatory framework soon proved insufficient.

“Elixir Sulfanilamide” entered the market in 1937 as an untested tonic that was supposed to treat the common sore throat.⁵⁴ However, when consumers ingested the solution their bodies converted it into a deadly poison that destroyed their kidneys.⁵⁵ Shortly after the tragic deaths of 107 individuals, most of whom were children, Congress passed the FDCA.⁵⁶

Prior to passage of the FDCA, drugs like Elixir Sulfanilamide entered the market in precisely the same way as modern dietary supplements, without pre-market approval from the FDA.⁵⁷ The FDCA changed this by requiring drug manufacturers to obtain approval from the FDA before marketing any drugs or pharmaceuticals.⁵⁸ The FDCA also required drug manufacturers to submit a New Drug Application (“NDA”) to the FDA, in which the FDA would determine whether the benefits of

50. See Schindler, *supra* note 13, at 262–67.

51. See Pure Food Act, ch. 3915, 34 Stat. 768 (1906) (repealed 1938).

52. See Schindler, *supra* note 13, at 263; see also Sidney M. Wolfe, OFFICE OF INSPECTOR GENERAL, DEP’T OF HEALTH & HUMAN SERVS., COMMENTS ON THE HHS INSPECTOR GENERAL’S STUDY OF ADVERSE EVENT REPORTING FOR DIETARY SUPPLEMENTS 86–87 (2001), available at <http://oig.hhs.gov/oei/reports/oei-01-00-00180.pdf> (last visited Nov. 18, 2004).

[T]he FDA relies on DSHEA authority to declare ingredients adulterated if they present “a significant or unreasonable risk of illness or injury.” This after-the-fact form of regulation is painfully reminiscent of the situation for prescription drugs before 1938. In that earlier era FDA authority to take action against a drug could only occur after the agency bore the burden of showing, based on marketing experience, that the drug’s risks were unacceptable rather than the post-1938 requirement of placing the burden for establishing safety on the manufacturer.

Id.

53. See Pure Food Act, ch. 3915.

54. Nancy E. Pirt, *Regulation of the Export of Pharmaceuticals to Developing Countries*, 25 DUQ. L. REV. 255, 259–60 (1987).

55. *Id.*

56. See BENEFIT VS. RISK: HOW CDER APPROVES NEW DRUGS 2, available at <http://www.fda.gov/cder/about/whatwedo/testtube-5.pdf> (last visited Nov. 18, 2004).

57. See *id.*

58. See 21 U.S.C. § 301 (2004).

the drug outweighed any potential risks.⁵⁹ At this point, however, drug manufacturers still did not have to prove that their product was effective for its intended use upon undertaking clinical testing on humans.⁶⁰

The regulatory shortcomings of the FDCA became apparent when, in the early 1960s, thousands of malformed babies were born after their mothers consumed the experimental drug Thalidomide.⁶¹ The drug was developed to quell nausea during pregnancy, though its effect on the developing child could not be determined until it was too late.⁶²

Responding to the Thalidomide tragedy, in 1962 Congress passed the Kefauver-Harris Amendments to the FDCA, which required far more extensive pre-market testing requirements.⁶³ Among the requirements of the Kefauver-Harris Amendments was the requirement that drug manufacturers conduct "adequate and well-controlled" clinical testing on humans.⁶⁴ Moreover, the Kefauver-Harris Amendments required that manufacturers submit an application to begin clinical testing whenever they test an Investigational New Drug ("IND") on humans.⁶⁵ Notably, the Kefauver-Harris Amendments also required drug manufacturers to send all adverse reaction reports to the FDA.⁶⁶

Currently, the procedure for obtaining pre-market approval for a drug is extremely burdensome for pharmaceutical manufacturers.⁶⁷ Even before manufacturers submit an IND, the drug must undergo extensive laboratory and animal testing.⁶⁸ Looking at all the available information on the drug, an FDA review board must authorize the drug for human testing.⁶⁹ Once approved for human testing, the drug manufacturer must complete three phases of research on the IND.⁷⁰ Phase I is conducted on a small sample of individuals to determine what dosage, if any, of the

59. See *BENEFIT VS. RISK: HOW CDER APPROVES NEW DRUGS*, *supra* note 56, at 3.

60. See Schindler, *supra* note 13, at 263–64.

61. *BENEFIT VS. RISK: HOW CDER APPROVES NEW DRUGS*, *supra* note 56, at 5.

62. Pirt, *supra* note 54, at 260–61.

63. Drug Amendments of 1962 (Kefauver-Harris Act), Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified at 21 U.S.C. §§ 321, 331, 332, 348, 351–353, 355, 357, 358–360, 372, 374, 376, 381 (2004)).

64. *Id.*

65. See *id.*

66. *Id.* See also *BENEFIT VS. RISK: HOW CDER APPROVES NEW DRUGS*, *supra* note 56, at 5. It should again be noted that DSHEA does not require dietary supplement manufacturers to report adverse reactions to the FDA. Accordingly, the FDA is not able to gather information in an efficient and timely manner as it is able to with drugs. This, in turn, has led to a slower process in removing dangerous dietary supplements from the market because the nature and scope of their danger is not recorded or reported by any party.

67. See Schindler, *supra* note 13, at 267.

68. See *BENEFIT VS. RISK: HOW CDER APPROVES NEW DRUGS*, *supra* note 56, at 7.

69. Schindler, *supra* note 13, at 265.

70. *Id.* at 265–66.

drug is safe.⁷¹ Phase II is conducted on a larger group of people, usually several hundred, and its purpose is to determine the effectiveness of the drug on the particular condition it was intended to treat.⁷² Phase III usually involves several hundred to several thousand people and can last one to four years.⁷³ During phase III, safety, proper dosage, and effectiveness of the IND are all scrutinized.⁷⁴ The NDA will be approved only if it satisfies the FDA at every step along the way.⁷⁵ But even after the drug is placed on the market, the FDA continues to closely scrutinize the drug until the FDA is absolutely satisfied of its safety; if it becomes concerned about the safety of the drug, the FDA may immediately remove the drug from the market.⁷⁶ The drug approval process often takes well over ten years, with the average cost to develop a new drug ranging from \$300 million to \$800 million.⁷⁷

While it is true that when Congress enacted DSHEA, it did not intend to put such a costly and time-consuming burden upon the dietary supplement industry, the potential of injury from dangerous dietary supplements may now necessitate it.⁷⁸ Like Elixir Sulfanilamide and Thalidomide, the problems caused by ephedra should signal to Congress that a significant change is needed.

C. Ephedra Is Not the Only Dangerous Dietary Supplement

Ephedra is not the only dietary supplement that should give both Congress and the FDA cause for concern. Prior to the explosive growth of dietary supplements containing ephedra there was Gamma-Hydroxy Butyrate ("GHB"), and prior to that there was L-tryptophan.⁷⁹ Thus, ephedra is not a unique phenomenon and the underlying problem will not

71. *Id.*

72. *Id.* at 266.

73. *Id.*

74. *Id.*

75. *Id.*

76. *Id.*

77. *See id.* at 66–67; *see also* How Much Should Medicare Pay for Drugs?, http://www.medscape.com/content/2004/00/46/62/466262/466262_ref.html (last visited Nov. 18, 2004) (indicating that developing a new drug can cost a manufacturer as much as \$800 million); M. June Casalmir & Bernard Rhee, *Pfizer/Pharmacia Merger—The Biggest Just Got Bigger*, available at <http://articles.corporate.findlaw.com/articles/file/00968/008887> (last visited Nov. 18, 2004).

78. *FDA Rule Banning Ephedra*, *supra* note 12.

79. Joshua Beisler, Note, *Dietary Supplements and Their Discontents: FDA Regulation and the Dietary Supplement Health and Education Act of 1994*, 31 RUTGERS L.J. 511, 527–42 (2000). The FDA recalled L-tryptophan in the fall of 1989, but waited more than five months, until March 22, 1990, before it completely banned the public sale of L-tryptophan. *Id.* GHB, on the other hand, was banned from sale as a dietary supplement in a much more abrupt fashion. *Id.* In November of 1990, the FDA made GHB an illegal "drug [w]ithout offering any evidence that GHB caused long-term health problems, and without offering a shred of scientific proof that GHB was dangerous" *Id.*

be dissipated by the mere banning of one particular supplement. The trend of dangerous dietary supplements demonstrates that reactive "ad hoc" determinations are insufficient to protect consumers.⁸⁰

In 1989, more than 1500 people became afflicted with the Eosinophilia-Myalgia Syndrome ("EMS")⁸¹ after consuming the dietary supplement, L-tryptophan.⁸² Of those affected, at least thirty-eight died from the debilitating illness.⁸³ L-tryptophan, a synthetically-produced amino acid,⁸⁴ was widely presumed to be safe and was taken as a natural way to aid in sleep and to help depression and premenstrual syndrome.⁸⁵ The presumption of safety on the part of consumers was due in large part to L-tryptophan's wide availability in the market, with consumers believing that the FDA would not allow dangerous products to enter the market.⁸⁶ Responding to the epidemic, the FDA recalled and banned the sale of all L-tryptophan.⁸⁷ After the ban, the FDA discovered that all of the injured consumers had ingested L-tryptophan from a batch prepared by a single manufacturer.⁸⁸

Although the cause of the EMS outbreak was apparently linked to a single contaminated batch, serious doubts remain today about the safety of L-tryptophan and its use as a dietary supplement.⁸⁹ Further, while the FDA should be commended for its quick response to the safety concerns about L-tryptophan, the response to the EMS outbreak was prior to the enactment of DSHEA, which divested the FDA of its power to quickly ban supplements that appear to present an immediate danger.⁹⁰

GHB was another dietary supplement of questionable safety.⁹¹ Although GHB is generally chemically synthesized, GHB occurs naturally in the human body and is present in meat, thus allowing it to fit the existing definition of a dietary ingredient.⁹² GHB was marketed for a wide

80. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 2(15)(B), 108 Stat. 4325 (1994).

81. EMS is a rare disease that causes severe muscle and joint pain, swelling in the limbs, and fever and shortness of breath. Beisler, *supra* note 79, at 528.

82. Schindler, *supra* note 13, at 276; *see also* Beisler, *supra* note 79, at 528.

83. Schindler, *supra* note 13, at 276.

84. Though L-tryptophan was synthetically produced, it was regulated as a dietary ingredient because it was an amino acid. Though it was introduced prior to DSHEA, it would have been regulated as a dietary supplement under DSHEA for that same reason.

85. Beisler, *supra* note 79, at 528.

86. *See generally id.*

87. *Id.* at 528.

88. *Id.*

89. *Id.* at 528 ("This ban is still in effect today, and the FDA continues to allege that L-tryptophan might cause EMS.").

90. *Id.*

91. *Id.* at 538-48.

92. *Id.* at 536-37.

variety of uses, from use as a sleep aid to a muscle builder.⁹³ However, GHB was also being used as a “date rape drug” and, when mixed with alcohol, caused a person to become sedentary or fall asleep.⁹⁴ Other adverse reactions tied to GHB use included vomiting, dizziness, tremors, and death.⁹⁵ In late 1990, the FDA took swift action to remove GHB from the market;⁹⁶ however, this prompt removal was also prior to the enactment of DSHEA.⁹⁷

Although few dietary supplements of questionable safety have appeared since the passage of DSHEA, dangerous new supplements will appear.⁹⁸ The money to be made in the industry and the lessons of history assure that more products will be developed, many of which will be beneficial. Some of those supplements, however, will likely cause agony and grief to countless individuals long before the FDA can respond—unless such supplements are prevented from entering the market.

III. THE STATUS QUO AND THE RESULTING INJURIES TO CONSUMERS

A. Ephedra's Harms

While there are other uses for ephedra,⁹⁹ it was most commonly found in dietary supplements that were marketed to encourage weight-loss or enhance athletic performance.¹⁰⁰ Although ephedra is a naturally

93. *Id.* at 539–40.

94. *Id.* at 540.

95. *Id.* at 541.

96. Despite its potential for side effects, GHB has found its place among regulated drugs and is quite beneficial when used under the supervision of a physician. See 27 P&T J. 427, 427 (2002), available at <http://www.ptcommunity.com/ptjournal/fulltext/27/9/PTJ2709427.pdf> (last visited Nov. 18, 2004).

Xyrem, manufactured by Orphan Medical, has been approved for treating patients with narcolepsy who have episodes of cataplexy, a sudden loss of muscular control and weakness, usually triggered by emotions. The drug's active ingredient is sodium oxybate, also known as gamma hydroxybutyrate (GHB). Because of the abuse of GHB—it is used recreationally and in date rapes—distribution will be tightly controlled.

Id.

97. Beisler, *supra* note 79, at 536–42. There remains a substantial amount of controversy as to whether the FDA's decision to ban GHB was based on adequate scientific data. Many in the medical field consider GHB to be one of the most versatile ingredients in treating many different ailments. It is also considered to be safe and free from any significant side effects by a majority of researchers.

98. Schindler, *supra* note 13, at 272 (“The FDA's haphazard regulation of dietary supplements has left an open door through which manufacturers can send untested products. With dietary supplements such as melatonin, which claims to help you sleep, and DHEA, which claims to restore youth, product introduction without any assurance of safety, not to mention efficacy, is sharply on the rise.” (internal citations omitted)).

99. Jody L. Aaron, *Death Over-the-Counter: Dangers of Ephedrine*, 33 DEC. TRIAL 61, 61 (1997) (ephedra used in traditional Chinese medicine as a cough suppressant, an arthritis treatment, and for many other uses).

100. *Id.*

occurring substance found in the ma huang plant, it is refined by supplement manufacturers to levels that could never be found in nature.¹⁰¹ Ephedra is, pharmacologically, very similar to ephedrine, which is the active ingredient in many prescription and over-the-counter decongestants and cold suppressants.¹⁰² Ephedrine is also the ingredient that is extracted from cold medicines in order to make methamphetamine.¹⁰³ Both ephedra and ephedrine are vasoconstrictors, which means that they constrict blood vessels in most consumers of the products. When blood vessels are constricted, blood pressure rises, and the likelihood of a stroke or heart attack increases.¹⁰⁴

On February 17, 2003, the dangers of a loosely regulated supplement industry became clearer to the public than ever before when a 23-year-old pitcher for the Baltimore Orioles, Steve Bechler, died at spring training.¹⁰⁵ Bechler died on top of the pitcher's mound; his cause of death was heatstroke linked to the use of ephedra.¹⁰⁶ The Bechler tragedy caught the public's attention, not only because Bechler was an athlete and a public figure in his physical prime dying in a suspicious way, but because another top athlete died under similar circumstances just a year and a half earlier.¹⁰⁷ In August 2001, Korey Stringer, a Minnesota Vikings football player, also died of heatstroke in training camp.¹⁰⁸ Although a bottle of Ripped Fuel, a dietary supplement containing ephedra, was found in his locker, it was not known with certainty whether he had actually consumed any ephedra.¹⁰⁹ In Bechler's case it was known with certainty that he had consumed ephedra.¹¹⁰ With two high profile deaths in the professional sports world linked to ephedra, this appeared to be much more than an isolated problem.¹¹¹

101. See Tod L. Stewart, *Getting High With a Little Help From the Feds: Federal Regulation of Herbal Stimulants*, 6 J. PHARMACY & L. 101, 101-03 (1997).

102. *Id.* at 102.

103. *Id.*

104. *Id.* at 103.

105. Paul G. Shekelle et al., *Preponderance of Evidence: Judging What to Do About Ephedra*, 27 RAND REVIEW 16 (2003), available at <http://rand.org/publications/randreview/issues/spring2003/evidence.html> (last visited Nov. 13, 2004).

106. *Id.*

107. See Donald T. Meier, Note, *Primary Assumption of Risk and Duty in Football Indirect Injury Cases: A Legal Workout from the Tragedies on the Training Ground for American Values*, 2 VA. SPORTS & ENT. L.J. 80, 92 (2002) (discussing the speculation that intensive efforts and the use of supplements caused Stringer's death).

108. *Id.* at 91.

109. *Id.* (stating "[a]n empty bottle of the supplement Ripped Fuel and an unopened bottle of the weight-loss product Xenadrine, both of which contain ephedrine, were found in Korey Stringer's locker according to The Vikings, although Stringer's representatives say no traces of the drug were found in his system.").

110. Shekelle et al., *supra* note 105, at 16-17.

111. *Id.*

The deaths of these athletes were neither the beginning of the problem nor the end.¹¹² Less than two weeks after Steve Bechler's death, the RAND Corporation completed a study reviewing more than 16,000 adverse event reports.¹¹³ The event reports revealed "two deaths, four heart attacks, nine strokes, one seizure, and five psychiatric cases involving ephedra in which the records appeared thorough and no other contributing factors were identified."¹¹⁴ Although these numbers are not staggering, they grossly underrepresent the truth.¹¹⁵

The FDA estimates that it "receives reports of less than 1 percent of all adverse events associated with dietary supplements."¹¹⁶ The report stated, "[a]mong the factors that may contribute to the under-reporting are that many consumers presume supplements to be safe, use these products without the supervision of a health care professional, and may be unaware that the FDA regulates them."¹¹⁷ Despite underreports of ephedra-related injuries in the general population, injury reports by those serving in the United States military have been much more precise.¹¹⁸ Between 1997 and 2001, thirty-three military personnel died as a result of using ephedra.¹¹⁹

When the public and governmental officials closely examined these event reports and other scientific information, they saw an abstract yet cognizable trend toward injury among those consuming ephedra.¹²⁰ Many of those using ephedra ended up in the hospital with side effects ranging from upset stomach to elevated blood pressure and death.¹²¹ By

112. RAND CORPORATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVS., EPHEDRA AND EPHEDRINE FOR WEIGHT LOSS AND ATHLETIC PERFORMANCE ENHANCEMENT: CLINICAL EFFICACY & SIDE EFFECTS (Feb. 28, 2003), available at <http://www.ahrq.gov/downloads/pub/evidence/pdf/ephedra/ephedrapdf.zip> (last visited Mar. 13, 2005) [hereinafter *RAND Study*]. The RAND Corporation is a non-profit institution that conducts research and analysis for use in policy making. RAND is a contraction of the phrase "research and development." See <http://www.rand.org/about/index.html> (last visited Nov. 13, 2004).

113. See *id.*

114. See *FDA Press Release*, *supra* note 35. See also *FDA Rule Banning Ephedra*, *supra* note 12, at 6790 (noting that reports of deaths associated with use of ephedra was a motivating factor behind the rule).

115. U.S. DEPARTMENT OF HEALTH & HUMAN SERVS., ADVERSE EVENT REPORTING FOR DIETARY SUPPLEMENTS; AN INADEQUATE SAFETY VALVE (REPORT) (Apr. 2001), available at <http://oig.hhs.gov/oei/reports/oei-01-00-00180.pdf> (last visited Mar. 20, 2005).

116. *Id.*

117. *Id.*

118. See Rebecca Porter, *Government, Health Advocates, Lawyers Challenge Safety of Weight-Loss Supplement*, 39 TRIAL 12, 16 (Jan. 2003).

119. *Id.* at 16.

120. *Id.*

121. *FDA Rule Banning Ephedra*, *supra* note 12, at 6791.

the end of 2003, when the FDA announced a ban on the drug, it could show that ephedra had killed 155 people.¹²²

B. The Harms of Ephedra are Evidenced by Numerous Lawsuits

As consumers identify companies in the supplement industry who produce harmful products, it is not surprising that many lawsuits have been filed.¹²³ Such lawsuits are, under the current regulatory scheme, an injured consumer's only redress against manufacturers that produce dangerous dietary supplements.¹²⁴ These lawsuits will continue unless Congress overhauls DSHEA and requires companies to prove the safety of their products before offering them for sale.¹²⁵

Many of these lawsuits do not attack the safety of the dietary ingredient itself; rather, injured consumers assert claims sounding in misrepresentation, fraud, and inadequate warning.¹²⁶ Plaintiffs bring these claims because, unlike products liability claims, plaintiffs need not show a physical injury was actually caused by a dangerous dietary supplement in order to win on misrepresentation or fraud grounds.¹²⁷ Instead, plaintiffs need only show that the product information on the label does not correlate with the contents of the product. Thus, fraud and misrepresentation claims based on labeling are easier to prove than the products liability claims.¹²⁸ Even so, such claims do not typically have the same financial impact on the supplement companies as claims sounding in products liability.

For example, in *Delehunt v. Cytodyne Technologies*, a consumer who purchased Xenadrine RFA-1, a dietary supplement containing ephedra, suffered an "acute psychotic break" and a seizure upon being admitted to the hospital.¹²⁹ Shortly thereafter, the plaintiff filed suit in United States District Court in Ohio on behalf of herself and as a putative class of plaintiffs.¹³⁰

Delehunt appears to be representative of the growing number of cases in which plaintiffs assert narrowly construed products liability claims, in conjunction with much broader fraud and misrepresentation

122. See *id.* See also H.R. 435, *supra* note 9; see also *U.S. to Ban Ephedra Diet Supplement over Heart Risk*, N.Y. TIMES, Dec. 31, 2003, at A1.

123. Kraus & Oh, *supra* note 10, at *3.

124. *Id.* at *1.

125. *Id.* at *8.

126. *Id.* at *3-5. See generally *Delehunt v. Cytodyne Tech.*, 241 F. Supp.2d 827 (S.D. Ohio 2003); *McClain v. Metabolife Int'l, Inc.*, 193 F. Supp. 2d 1252 (N.D. Ala. 2002).

127. Kraus & Oh, *supra* note 10, at *3-5.

128. *Id.* at *4.

129. *Delehunt*, 241 F. Supp. 2d at 831.

130. *Id.*

claims against dietary supplement manufacturers.¹³¹ When such products liability claims are made, they are generally made under the guise of a failure to warn claim.¹³² Plaintiffs tend to assert failure to warn claims to avoid having to meet the burden of proof when showing that the product was defectively designed or manufactured.¹³³ Instead of a products liability claim, the plaintiff in *Delehunt* asserted the following in her complaint:

Defendant Cytodyne Technologies knew, or, in the exercise of reasonable care, should have known about the risks associated with ephedrine, but failed to provide the warning that a manufacturer exercising reasonable care would have provided concerning the risk, in light of the likelihood that the product would cause harm of the type suffered by Plaintiff and in light of the likely seriousness of that harm.¹³⁴

Based on this claim, the plaintiff merely has to show that the defendant knew or reasonably should have known about the risk associated with ephedra.¹³⁵

In *McClain v. Metabolife International, Inc.*, four consumers of "Metabolife 356," a dietary supplement containing ephedra, sued the manufacturer after sustaining several strokes and a heart attack.¹³⁶ Plaintiff's first amended complaint alleged six counts, including a claim for the manufacturer's "negligent, reckless or wanton failure to warn of the dangers of Metabolife 356."¹³⁷ After Metabolife's motion for summary judgment was granted on four of the six counts, it was ultimately found liable for products liability claims based on failure to warn and was ordered to pay several million dollars in actual and punitive damages to the plaintiffs.¹³⁸

131. See TREATISE ON AMERICAN LAW OF PRODUCTS LIABILITY § 89:97 (Timothy E. Travers et al. eds., 3d ed. 2003).

132. *Id.* See generally Kraus & Oh, *supra* note 10.

133. See generally Kraus & Oh, *supra* note 10, at 2–3.

134. *Delehunt*, 241 F. Supp. 2d at 844.

135. *Id.*

136. 193 F. Supp. 2d 1252, 1258 (N.D. Ala. 2002).

137. *Id.*

138. *Id.* Following jury verdicts for the plaintiffs, the defendant moved for a remittitur of the six separate jury verdicts on account of their excessiveness. *Id.* The court reduced each award to the maximum amount constitutionally permissible. *Id.* Accordingly, each plaintiff could only recover nine times their pecuniary damages in punitive damages. *Id.* The respective spouses of the injured plaintiffs also sued Metabolife International, Inc., based on loss of consortium claims. See also Arlene Weintraub & John Carey, *Commentary: Diet Pills and Polls: A Dangerous Mix*, BUS.WEEK, Sept. 2, 2002, at 40 (noting that in September of 2002 more than 85 consumer lawsuits were pending against Metabolife).

So long as dangerous dietary supplements like ephedra are marketed to consumers, lawsuits such as these will continue to be quite common.¹³⁹ Unless Congress compels dietary supplement manufacturers to produce safe products, consumers' only form of redress for serious physical injuries will be the assertion of legal claims.¹⁴⁰ However, it appears that Congress will not change the law until there is enough political or financial pressure to do so.

C. Money, Lobbying, and Getting the Supplement Industry Its Act

To better understand DSHEA and the policy that went into creating and maintaining its present form, we should examine the politics involved. Given the nature of politics, generally, there are almost always competing interests on both sides of any given resolution. Enactment of DSHEA was no different because politicians had, and continue to have, a hefty monetary incentive to cooperate with the dietary supplement industry.¹⁴¹

On one side of the present controversy stands the injured consumer, as well as the countless others who may join that group of injured consumers.¹⁴² On the other side of the issue is the dietary supplement industry. The industry employs tens of thousands of people, both directly and indirectly.¹⁴³ Moreover, in the year that DSHEA was enacted, total annual sales of supplements, vitamins, minerals, and herbs exceeded \$4 billion.¹⁴⁴ Since DSHEA was passed, those sales have grown to more than \$27 billion per year.¹⁴⁵ Not surprisingly, those dollar figures are only expected to grow larger in the future as the baby boomers age and perhaps search for alternatives to Western medicine.¹⁴⁶

When an industry stands to expand and become more profitable, legislation often accompanies the expansion to assist and maintain that industry not only for the public's benefit, but also for the politicians' benefit.¹⁴⁷ The public pays a heavy price for such "favorable" legisla-

139. Kraus & Oh, *supra* note 10, at *4-5.

140. *See generally id.*

141. *See* Weintraub & Carey, *supra* note 138, at 40.

142. *See id.*

143. *See* CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., ECONOMIC CHARACTERIZATION OF THE DIETARY SUPPLEMENT INDUSTRY FINAL REPORT (1999), available at <http://vm.cfsan.fda.gov/~comm/ds-econ5.html> (last visited Nov. 13, 2004).

144. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 2(12)(c), 108 Stat. 4325 (1994).

145. *Senate Grills Dietary Supplement Sellers*, Sept. 11, 2001, available at <http://usgovinfo.about.com/library/weekly/aa091101b.htm> (last visited Nov. 13, 2004).

146. *See* Schroeder, *supra* note 4, at 693.

147. DSHEA itself is an example of favorable legislation enacted as a result of special interest pressure.

tion.¹⁴⁸ Consumers do not have the same confidence that they once had that the FDA is protecting them from dangerous products.¹⁴⁹ When Congress passed DSHEA, lawmakers were willing to lose the confidence of some consumers because of the size of the industry and the money it generates.¹⁵⁰ The economic benefit to society creates a strong incentive for public officials to sustain the dietary supplement industry.¹⁵¹ Although the money generated by the industry does help support the national economy, not all the money generated is paid out for raw materials and labor.¹⁵² The dietary supplement industry has been consistently among the top campaign contributors to lawmakers.¹⁵³ In 2000, the dietary supplement industry donated more than \$2.3 million to various representatives to work in their favor.¹⁵⁴

A notorious example of a politician who received money from a dietary supplement company was California Governor Gray Davis. In 2000, he received a \$150,000 contribution from Metabolife International Inc.¹⁵⁵ The San Diego-based company was one of the largest producers of ephedra-based dietary supplements.¹⁵⁶ Shortly after receiving the contribution, Governor Davis vetoed state legislation that would have required better and more labeling of dietary supplement ingredients.¹⁵⁷

Governor Davis, however, is not alone in receiving supplement industry money. Republican Senator Orrin G. Hatch from Utah has also received substantial contributions from dietary supplement companies.¹⁵⁸ Despite having personal and financial ties with the supplement industry, Senator Hatch has insisted that there is no conflict between his duties to

148. See Weintraub & Carey, *supra* note 138, at 40.

149. *Id.*

150. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 2(12)(A), 108 Stat. 4325 (1994) (stating that part of Congress' justification for DSHEA was that the "nutritional supplement industry is an integral part of the economy of the United States"). See also Weintraub & Carey, *supra* note 138, at 40.

151. Weintraub & Carey, *supra* note 138, at 40.

152. See *id.*

153. CENTER FOR RESPONSIVE POLITICS, NUTRITIONAL & DIETARY SUPPLEMENTS: LONG-TERM CONTRIBUTION TRENDS, at <http://www.opensecrets.org/industries/indus.asp?Ind=H4600> (last visited Nov. 17, 2004).

154. See CENTER FOR RESPONSIVE POLITICS, TOP INDUSTRIES GIVING TO MEMBERS OF CONGRESS 2004 CYCLE (2004), at <http://www.opensecrets.org/industries/mems.asp> (last visited Nov. 17, 2004).

155. See Weintraub & Carey, *supra* note 138, at 40.

156. See *id.*

157. See *id.*

158. *Id.* See also Chuck Neubauer et al., *Senator, His Son Get Boosts from Makers of Ephedra*, L.A. TIMES, Mar. 5, 2003, at A1. More money was paid to lobbying firms that employed Senator Hatch's son Scott than was paid to Senator Hatch. *Id.* These lobbying firms received \$1.96 million between 1998 and 2001; of that money, more than \$1 million came from clients involved with ephedra manufacturing. *Id.*

the public and his aiding the dietary supplement industry.¹⁵⁹ Not surprisingly, it was Senator Hatch who pushed for and co-authored DSHEA with Senator Tom Harkin of Iowa, who also received \$119,242 from the supplement industry between 1993 and 2002. Yet it was Senator Hatch who pushed for and co-authored DSHEA,¹⁶⁰ along with Senator Tom Harkin of Iowa, who also received \$119,242 from the supplement industry from 1993 to 2002.¹⁶¹

Because of this flow of money from the supplement industry to lawmakers, lawmakers have strong incentive to give the supplement industry what it wants.¹⁶² If lawmakers stopped taking such contributions, the pressure from public interest groups would then likely become too great for Congress to ignore.¹⁶³ But even if lawmakers continue taking contributions, public pressure itself may compel Congress to amend DSHEA as needed to prevent dangerous dietary supplements from reaching the market.¹⁶⁴ In the meantime, political contributions continue to pour into the bank accounts of those with the power to regulate the dietary supplement industry.¹⁶⁵

IV. WHERE THE BURDEN RESTS AND WHERE IT SHOULD REST

A. The Current Burden

As the system currently stands, the FDA can shift the burden onto the dietary supplement industry only after the FDA has met its own burden.¹⁶⁶ The FDA can carry its burden of proof for “unreasonable risk . . .

159. *See id.*

160. *See id.* DSHEA did help bolster the lagging economy of Senator Hatch’s home state of Utah, which is home to many dietary supplement manufacturers and describes itself as “the Silicon Valley of the supplements industry.” *Id.*

161. *See id.* DSHEA is also sometimes referred to as the “Hatch-Harkin Act.” *Id.*

162. *See* Weintraub & Carey, *supra* note 138, at 40.

[W]henver the FDA has requested additional funding to beef up its own system for tracking complaints, Congress has said no. The FDA has been trying for years to obtain safety information on Metabolife, only to be told by members of Congress to back off. “This is a company that has a lot of friends,” reports an FDA official.

Id. at 40.

163. *U.S. to Ban Ephedra Diet Supplement over Heart Risk*, *supra* note 122, at A1.

164. *See* Weintraub & Carey, *supra* note 138, at 40.

165. *See* Neubauer, *supra* note 158, at A1.

166. *FDA Rule Banning Ephedra*, *supra* note 12, at 6799, notes the following:

[B]ecause of the nature of these risks, we do not believe it appropriate to delay action until further clinical studies can be conducted to evaluate the safety of dietary supplements containing ephedrine alkaloids in the general population. We would, however, support the conduct of clinical investigations carried out under the Investigational New Drug . . . regulations with careful screening to exclude subjects at risk and careful safety monitoring during the trials that examine the safety and efficacy of ephedrine alkaloids, with or without caffeine, as drugs such as for the treatment of obesity . . .

when a product's risks outweigh its benefits in light of the claims and directions for use in the product's labeling or, if the labeling is silent, under ordinary conditions of use."¹⁶⁷ This test balances the known risk that a supplement will harm the public against the likely benefit that the public would receive from the supplement's availability.¹⁶⁸ Only when this balancing test shows a significant or unreasonable risk to the public may the FDA ban the supplement from the market.¹⁶⁹ Once its supplement has been banned, the manufacturer can rebut the FDA findings by coming forward with evidence of safety.¹⁷⁰

Unfortunately, the FDA must assess the risk of a particular dietary supplement without having the benefit of clinical studies about the dietary supplement's safety or efficacy performed by the supplement's manufacturer.¹⁷¹ Moreover, it is not clear how dangerous a supplement has to be in order to justify a ban on the supplement.¹⁷² While DSHEA seems to grant a large amount of discretion to the FDA, the extent of that discretion is not clear.

Although few dietary supplements on the market have required FDA attention since the passage of DSHEA, dangerous supplements can still reach the market easily.¹⁷³ Because virtually any supplement can get to the market, the likelihood increases that consumers will be faced with dangerous supplements.¹⁷⁴ Yet because the FDA cannot ban a product until the FDA can meet the "significant or unreasonable risk" burden, it has little choice but to wait until the danger is apparent and only then react.¹⁷⁵ Accordingly, dangerous supplements like ephedra penetrate the market enough to kill people because the FDA's regulatory power has been hobbled by the burden of proof placed on it by DSHEA.

B. Application of the Current Burden of Proof on Ephedra

Although many injuries have been attributed to the use of ephedra, the scales tipped enough only recently to allow the FDA to remove ephedra from the market.¹⁷⁶ The FDA took its first significant steps toward a complete ban on ephedra by seeking public comment for a thirty-

167. *Id.*

168. *Id.*

169. *Id.*

170. *See id.*

171. Shekelle et al., *supra* note 105, at 17–18.

172. *See generally id.*; *FDA Rule Banning Ephedra*, *supra* note 12, at 6788.

173. *See generally* Schindler, *supra* note 13.

174. *Id.* at 262.

175. *Id.* at 278 ("As the system stands now, the FDA must wait for a tragedy to occur and then shoulder the burden of proving that the hazard is real.").

176. *Id.*

day period in the summer of 2003.¹⁷⁷ The agency sought comments from health professionals, the supplement industry, and the public for any additional data on ephedra's safety so that it could assemble the most complete picture possible of the product's potential risks as a basis for further regulatory action.¹⁷⁸

Although a public comment period is required of virtually all government agencies when a new rule is proposed,¹⁷⁹ a comment period partially shifts the burden onto the public to gather information.¹⁸⁰ But at the end of the comment period the FDA believed it had finally gathered enough empirical evidence to meet its "significant or unreasonable risk" burden and was able to justify removing products containing ephedra from the market.¹⁸¹

The final rule banning the sale of ephedra went into effect on February 11, 2004, six months after Steve Bechler's death.¹⁸² This was the first time since the passage of DSHEA that the FDA determined that a dietary supplement presented a "significant or unreasonable risk."¹⁸³ Yet well before this drawn-out decision to ban ephedra, users reacted adversely to ephedra frequently enough to put health officials on notice that the supplement posed a risk of serious injury.¹⁸⁴

Now that the FDA's burden has been tested, it is clear that this burden is too unmanageable to ensure the safety of dietary supplements on a

177. *FDA Press Release*, *supra* note 35.

178. *See also Ephedra Hearings*, *supra* note 1, at 235 (testimony of Mark B. McClellan M.D., Ph.D.) ("By undertaking these regulatory actions and seeking public comments on these issues, our intent is to give DSHEA the meaning in practice that many of its supporters say it should have, by clarifying that public health authorities can use the standard in the law to determine whether a product poses unreasonable, albeit uncertain, safety risks and then take appropriate regulatory or enforcement action."); *see also* Letter from W.J. "Billy Tauzin," Chairman of the House Committee on Energy and Commerce, to Steven M. Goldberg, President, Starlight Int'l (Mar. 13, 2003), *available at* http://energycommerce.house.gov/108/Letters/03132003_845.htm (last visited Nov. 13, 2004):

[The FDA] sought expedited public comment on: (1) new evidence on health risks associated with ephedra to establish an up-to-date record as quickly as possible to support new restrictions on ephedra-containing products; (2) whether the currently available evidence and medical literature indicate a "significant or unreasonable risk of illness or injury" from dietary supplements containing ephedra; and (3) a new warning label on any ephedra supplements that continue to be marketed.

Id.

179. *See* Administrative Procedure Act § 1, 5 U.S.C. § 552 (1994).

180. *See FDA Rule Banning Ephedra*, *supra* note 12, at 6792. Of the more than 48,000 comments received in the comment period, most opposed a ban on dietary supplements containing ephedra. *Id.*

181. *See id.* *See also RAND Study*, *supra* note 112.

182. *FDA Rule Banning Ephedra*, *supra* note 12.

183. *Id.*

184. *U.S. to Ban Ephedra Diet Supplement Over Heart Risk*, *supra* note 122, at A1. By the time the final rule banning ephedra was announced, the FDA had reports of 155 deaths of people who took ephedra and more than 16,500 complaints. *Id.*

case-by-case basis. This case-by-case approach is a retrenchment to the “ad hoc” determinations that Congress sought to do away with when it enacted DSHEA.¹⁸⁵ But at least the pre-DSHEA “ad hoc” determinations were made *before* the product hit the market.¹⁸⁶ To rectify this problem, Congress should amend DSHEA and place the burden of proving dietary supplement safety onto the dietary supplement industry.

C. Shifting the Burden Will Save Lives

The best way to protect consumers from dangerous dietary supplements is for Congress to amend DSHEA by including a provision that shifts the burden of proof onto the dietary supplement industry to prove the safety of its dietary supplements. Only when the industry can show that every dietary supplement on the market does not present a “significant or unreasonable risk” can consumers rely on dietary supplements to improve their health and well-being.

Although the FDA’s current regulatory framework may, over time, eventually pull unreasonably dangerous dietary supplements from the market, that method is too reactive and too slow to respond to an imminent crisis, given the danger involved.¹⁸⁷ Instead of a slow reaction from the FDA, Congress should require the industry to obtain advance approval for its products, just as it requires drug manufacturers to obtain premarket approval for its products. After certain supplements gain approval, the FDA will still have power to remove any products that it later finds to present a “significant or unreasonable risk.” By shifting the burden of proof onto manufacturers, dangerous dietary supplements will not reach the market in the first place and countless lives will be saved.

V. THE STATUS QUO CANNOT ADEQUATELY PROTECT CONSUMERS

A. The FDA Cannot Guard Against Dangerous Dietary Supplements

The FDA cannot adequately protect the public against the dangers of dietary supplements for a number of reasons. The main reason is that the FDA is a political entity with a complex bureaucratic process that must balance the interests of both consumers and manufacturers. But to achieve this balance, the FDA’s rulemaking process, which often encounters political and procedural delays, does not allow the FDA to protect the public from imminent threats. Lack of funding is another reason.

185. See *FDA Rule Banning Ephedra*, *supra* note 12, at 6792.

186. Press Release, U.S. Food & Drug ADMIN., FDA Statement on Street Drugs Containing Botanical Ephedrine (Apr. 10, 1996), available at <http://vm.cfsan.fda.gov/~lrd/hhsephe1.html> (last visited Nov. 18, 2004).

187. See Schindler, *supra* note 13, at 278.

The Office of Dietary Supplements, the subagency charged with making supplement safety determinations, simply does not receive the funding to research the safety of each and every dietary supplement.¹⁸⁸

Although the FDA found that ephedra presented a “significant or unreasonable risk,” this finding probably would not have occurred without pressure from Congress.¹⁸⁹ On November 6, 2003, Congress entered a resolution stating that “the Secretary of Health and Human Services should take immediate action to remove dietary supplements containing ephedrine alkaloids from the market.”¹⁹⁰ Thus, unless Congress applies significant pressure to the FDA to restrict a particular dietary supplement, the FDA will not be able to meet its burden to ban a particular dietary supplement.¹⁹¹ But if the burden of proving supplement safety were on the manufacturers, then Congress’ political considerations would not be involved when determining product safety.¹⁹² Unfortunately, instead of directly addressing the problems of supplements, the FDA takes only incremental action towards a solution.

One example of incremental FDA action is the issuing of “strong statements cautioning about the use of” a particular dietary supplement.¹⁹³ Warnings such as these are more like soft disclaimers and are not geared to protect the public. For example, a warning may be contained in a press release, mentioned for ten seconds on the nightly news, or simply affixed to the side of the product. Few consumers actually read the multiple warnings that come in or on the bottles of many dietary supplements.

The most prominent form of FDA foot-dragging is the failure to conduct the necessary safety studies on suspect dietary supplements.¹⁹⁴

188. See COMM’N ON DIETARY SUPPLEMENT LABELS, REPORT OF THE COMM’N ON DIETARY SUPPLEMENT LABELS app. B at B-2 (Nov. 1997), available at <http://mentalhealth.about.com/gi/dynamic/offsite.htm?site=http://web.health.gov/dietsupp> (last visited Nov. 18, 2004).

189. See generally Weintraub & Carey, *supra* note 138, at 40; see also H.R. 435, *supra* note 9.

190. See H.R. 435, *supra* note 9.

It is the sense of the House of Representatives that—(1) the Secretary of Health and Human Services has authority under subsections (a) and (f) of section 402 of the Federal Food, Drug, and Cosmetic Act . . . to determine that dietary supplements containing ephedrine alkaloids—(A) present a significant or unreasonable risk of illness or injury; (B) pose an imminent hazard to public health or safety; or (C) contain poisonous or deleterious substances that may render dietary supplement injurious to health; (2) there is sufficient evidence to make such a determination; and the Secretary should take immediate action to remove dietary supplements containing ephedrine alkaloids from the marketplace.

Id.

191. See *id.*

192. *Id.*

193. FDA Press Release, *supra* note 35.

194. 21 U.S.C. § 342(f) (2004). The statutory language makes it discretionary for the FDA to actually conduct the studies because there is no standard declaring when it is appropriate to scruti-

DSHEA puts the burden of proving the safety of dietary supplement products on the government, stating, "the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated."¹⁹⁵ As such, the easiest way for the FDA to avoid regulating a product is to claim that there is no compelling need for a study.¹⁹⁶ Although DSHEA states that the FDA can remove supplements from the market when they present "a significant or unreasonable risk[.]"¹⁹⁷ it is unclear whether this risk is after one heart palpitation or 1000 consumer deaths. Studies would help shrink this vast and uncertain middle ground.¹⁹⁸

Since its inception, congressional leaders have proposed many changes to DSHEA that could improve the safety of dietary supplements.¹⁹⁹ However, those ideas and proposed rules usually take many years before becoming reality.²⁰⁰ There should be no room for delay when it comes to regulating the consumption of potentially dangerous substances. Thus, the FDA needs discretion to promptly issue safeguarding rules or force the industry to prove the safety of its products before the products reach consumers.

The FDA works slowly. Although safeguards against the suspected dangers of ephedra were first proposed in 1997,²⁰¹ it was not until the end of 2003 that the FDA announced that it would ban all dietary supplements containing ephedra.²⁰² In fact, ephedra was banned only after several states²⁰³ and many athletic organizations, including the NFL, the

nize a specific dietary supplement. Indeed, some would argue that it is the FDA's failure to exercise its discretion that is at the basis of the problem of regulating dietary supplements. *See also* Stephen H. McNamara & A. Wes Siegner, Jr., *FDA Has Substantial and Sufficient Authority to Regulate Dietary Supplements*, 57 *FOOD & DRUG L.J.* 15, 23 (2002) ("[The] FDA has ample authority to act against supplements that do not provide the full amounts of nutrients they are labeled as providing; yet the agency has done almost nothing to use this authority.").

195. § 342(f)(1)(d).

196. *Id.*

197. *Id.*

198. *FDA Press Release*, *supra* note 35 (comments of FDA Commissioner Mark B. McClellan, M.D., Ph.D.) ("The standard for regulating the safety of dietary supplements is largely untested. . . .").

199. *Ephedra Hearings*, *supra* note 1, at 233 (testimony of Mark B. McClellan M.D., Ph.D.).

200. *See id.* at 237.

201. Proposed Rules, 62 Fed. Reg. 30678-01 (June 4, 1997).

202. News Release, U.S. Food & Drug ADMIN., FDA Announces Plans to Prohibit Sales of Dietary Supplements Containing Ephedra (December 30, 2003), *available at* <http://www.fda.gov/oc/initiatives/ephedra/december2003/> (last visited Nov. 13, 2004).

203. *See* Pinco & Rubin, *supra* note 6, at 397. Because DSHEA does not specifically preempt state law regulating supplements, several states, including Illinois, Louisiana, and Florida, have banned products containing ephedra.

As with the FDCA, DSHEA also does not contain any explicit preemption language. [However], DSHEA was enacted to protect the right of access of consumers to safe dietary supplements. State action that limits the availability of these products runs counter to

NCAA, and the International Olympic Committee, had already banned the product.²⁰⁴ The Department of Defense had already banned ephedrine supplements from military commissaries worldwide because of safety concerns.²⁰⁵ Ephedra's complete ban in 2003 would not have occurred without the intense public scrutiny and subsequent congressional pressure that resulted from the deaths of prominent athletes.

Aside from the six-year delay in the ban of ephedra, there are other examples of rules that have been caught up in the FDA's regulatory matrix. The Department of Health and Human Services has proposed that dietary supplement manufacturers adhere to Good Manufacturing Practices ("GMP") to ensure that products meet minimum compliance standards before being released to the market.²⁰⁶ While proposed adherence to the GMP is a step in the right direction, it is, at this point, still just a proposal.²⁰⁷ The FDA has not fully utilized its existing power by pushing these proposed rules through the rulemaking process.²⁰⁸

Another reason the FDA cannot adequately protect consumers is because of underfunding. Because lack of funding from Congress keeps the FDA from conducting the necessary studies, Congress might also share the blame for the FDA's inability to protect consumers.²⁰⁹ Although the current state of the federal budget is problematic, Congress should still fund such important research.

From the inception of DSHEA, Congress did not appropriate enough funds to the newly created Office of Dietary Supplements.²¹⁰ DSHEA provided only \$5 million in funding,²¹¹ which is insufficient for a task involving hundreds of individual research projects. Congress actually allocated even less money to the ODS in the first few years follow-

congressional goals, and may result in the grant of preemption. In addition, such state action also may run counter to the congressional intent of reducing regulatory barriers and eliminating the patchwork regulatory policy for dietary substances.

Id.

204. 720 ILL. COMP. STAT. 602/5 (2004).

205. H.R. Res. 435, *supra* note 9.

206. See Proposed Rules, 68 Fed. Reg. 12158 (Mar. 13, 2003). The Good Manufacturing Practices are designed to prevent inaccurate potency of the claimed ingredient, wrong ingredient, drug contamination, variations in tablet size and color and mislabeling, among other things. The effect of the Good Manufacturing Practices would be to establish industry-wide standards in the manufacture and sale of dietary supplements at the manufacturing level.

207. See *id.*

208. McNamara & Siegner, Jr., *supra* note 194, at 23.

209. U.S. FOOD & DRUG ADMIN., CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, OVERVIEW OF DIETARY SUPPLEMENTS (Jan. 2001), available at <http://www.cfsan.fda.gov/~dms/ds-oview.html> (last visited Nov. 13, 2004) ("In that FDA has limited resources to analyze the composition of food products, including dietary supplements, it focuses these resources first on public health emergencies and products that may have caused injury or illness.").

210. See COMM'N ON DIETARY SUPPLEMENT LABELS, *supra* note 188, at 66.

211. 42 U.S.C. § 287c-11(e) (2004).

ing the subagency's creation.²¹² However, in the new millennium, the budget of the ODS has gone up significantly: In 2003 Congress allocated it just under \$20 million.²¹³

Although such an increase helps conduct research on dietary supplements, it is far from enough. If the ODS is to try to make the same kinds of safety determinations for supplements that drug giants make for their products, the ODS will need far more resources than Congress is currently willing to give.²¹⁴

Dangerous supplements will continue to enter the marketplace unless either the supplement industry stops giving political contributions to public officials or the public puts enough pressure on Congress to amend DSHEA to let the FDA effectively regulate the supplement industry.

B. Tort Law Cannot Guard Against Dangerous Dietary Supplements

Because the FDA is not able to conduct safety tests on many dietary supplements, unsafe products will not be removed from the market until someone other than the government proves them dangerous. Most of the public has no incentive to prove the danger of a particular supplement. For injured consumers and the plaintiffs' personal injury bar, however, such an incentive does exist.²¹⁵ The injured consumer's incentive is compensation for past injuries; for the plaintiff's attorney, it is a fair share of the damages and a chance at a punitive award.

When consumers get injured, not only is there an incentive to prove the danger of a particular supplement, but a lightened burden of proof, as compared to the FDA's burden. The FDA must prove that a dietary supplement presents an "unreasonable risk" to the public,²¹⁶ but an injured plaintiff need only prove by a "preponderance of the evidence" that the

212. *The Food and Drug Law Institute's 45th Annual Educational Conference*, 57 FOOD & DRUG L.J. 227, 229 (2002) (Senator Hatch described the FDA as "woefully underfunded").

213. OFFICE OF DIETARY SUPPLEMENTS, DEPT. OF HEALTH & HUMAN SERVS., A STRATEGIC PLAN FOR THE OFFICE OF DIETARY SUPPLEMENTS: 2004-2009 (Jan. 28, 2004), available at <http://ods.od.nih.gov/pubs/SP10B.Web.pdf> (last visited Nov. 13, 2004).

214. Shifting the burden onto the supplement manufacturers would prove to be very costly for them. Although it is still difficult to discern the exact costs, studies on the safety and efficacy of dietary supplements would likely involve several years, thousands of people, and millions of dollars. Even so, the safety and efficacy of many dietary supplements has already been researched and proven and would not need to be repeated. Therefore, it does not seem likely that average cost of researching the safety of dietary supplements would even approach the costs associated with bringing a drug to market.

215. Kraus & Oh, *supra* note 10, at *1 ("As complaints mount, even seemingly modest problems can trigger the appetite of the ever-hungry plaintiffs' bar for new and relatively untapped litigation targets.").

216. 21 U.S.C. § 342(f)(1) (2004).

product caused a specific injury. Nor does the plaintiff need to factor in large-scale statistics gathered from a heterogeneous sample.²¹⁷ Accordingly, with a lighter burden,²¹⁸ many plaintiffs have been recovering damages for injuries sustained as a result of harmful dietary supplements.²¹⁹

While plaintiffs have an easier task in proving their cases, they still face the challenge of a lack of empirical proof of the danger of particular dietary supplements, as discussed above.²²⁰ However, such a lack of proof does not present the same obstacle that it does to the FDA.²²¹ In plaintiffs' cases, proving that a particular supplement was the cause of harm is not an insurmountable task²²² because physicians, coroners and other experts are generally able to make a determination that consumption of a specific dietary supplement caused an injury.²²³ As the court in *McClain v. Metabolife International, Inc.* noted, "an expert is required to prove causation in this case, as the interplay between ephedrine, caffeine, and the other ingredients in Metabolife 356, the varying states of pre-existing ill-health of Plaintiffs, and their various ultimate injuries is 'complex and technical in nature.'"²²⁴ Because experts often have such intricate and specific knowledge that can be used to show causation,²²⁵ plaintiffs prevail more easily than the FDA can.

The FDA, on the other hand, must prove the danger of a particular dietary supplement where the danger is not readily apparent, and where experts may not be able to establish causation between the dietary sup-

217. *Id.*

218. See Kraus & Oh, *supra* note 10, at *3.

219. *Id.* More often than not, lawsuits against dietary supplement manufactures are settled long before a jury is even selected. *Id.* Because settlements are generally not made public, little information is available about how such claims are resolved. *Id.*

220. See *supra* Part III.B. See also Kraus & Oh, *supra* note 10, at *4-5 ("[E]ven complete compliance with all applicable FDA regulations does not necessarily insulate manufacturers from plaintiffs' claims. Recent cases suggest that FDA regulations set minimum standards; while regulatory compliance is admissible, it is not conclusive of the issue of due care. Although jurisdictional trends differ, dietary supplement manufacturers should be aware that there is room for common-law claims despite compliance with FDA regulations." (internal citations omitted)).

221. See generally *id.*

222. *Id.* at *3.

223. See generally *id.*

224. *McClain v. Metabolife Int'l, Inc.*, 193 F. Supp. 2d 1252, 1258 (quoting *McPhail v. Mitsubishi Motor Mfg. of Am., Inc.*, 80 F. Supp. 2d 1309, 1313 (S.D. Ala. 1997)).

225. See Kraus & Oh, *supra* note 10, at *3.

Because exclusion of an expert may mean the end of a plaintiff's claims, *Daubert* hearings can be the forum for the real "trial," and drug manufacturer defendants have taken advantage of this whenever possible. Supplement manufacturers should do so as well. Since the data on herbal remedies in peer-reviewed medical journals is far less available than for traditional pharmaceutical products, plaintiffs have a large hurdle when it comes to meeting the criteria under *Daubert*.

Id. (citations omitted)

plement and the resulting injury.²²⁶ Doctors and statisticians working for the FDA can look at data of documented injuries, yet still not be able to demonstrate an “unreasonable risk.”²²⁷ Those same doctors and statisticians, if working for plaintiffs, would only have to show that a plaintiff’s harm was caused by a specific supplement in order for the plaintiff to win the case.²²⁸ Thus, it is far more difficult for the FDA to prove causation than it is for a plaintiff.²²⁹

The difference between the plaintiff’s burden of proving specific causation and the FDA’s burden of proving general causation is illustrated in *Kemp v. Metabolife*.²³⁰ In that case, a group of injured plaintiffs charged the supplement company with having “violated the Louisiana Products Liability Act by failing to warn the plaintiffs of an unreasonably dangerous condition of their product, Metabolife 356—namely, the presence of ephedra in Metabolife 356.”²³¹ Rather than trying to show specific causation between their ingestion of the dietary supplement and the subsequent injuries,²³² the plaintiffs instead asserted that Metabolife 356 was dangerous *per se* because the Louisiana Products Liability Act bans the sale of such products in Louisiana.²³³ The court rejected the plaintiffs’ claims, stating that although “[a] violation of a statute may give rise to negligence *per se* . . . it cannot serve to establish causation.”²³⁴ The court further clarified by stating the following:

Proof of causation has two components, general and specific. General causation deals with whether the substance at issue can cause diseases or disorders in people in general. Specific causation focuses upon whether the substance was in fact the cause of the ailments or symptoms in the particular patient. An inability to establish specific causation is fatal to Plaintiff’s claim.²³⁵

Thus, the difference between the causation standard borne by the FDA and that borne by plaintiffs is that the FDA must prove general causation, whereas plaintiffs only need to prove specific causation.²³⁶

226. See generally *id.*

227. *Id.*

228. *Id.*

229. *Id.*

230. Civ.A 00-3513, 2003 WL 22326560, at *1 (E.D. La. Oct. 7, 2003).

231. *Id.*

232. *Id.* at *2.

233. *Id.*

234. *Id.*

235. *Id.* (citing *Pick v. Am. Med. Sys., Inc.*, 958 F. Supp. 1151, 1164 (E.D. La. 1997)).

236. See *id.* See also *FDA Rule Banning Ephedra*, *supra* note 12, at 6822.

[T]here is no requirement that there be evidence conclusively demonstrating causation of actual harm in specific individuals. In our evaluation of “significant or unreasonable risk,” we can consider any relevant evidence, including scientific data about the toxico-

Despite the lower threshold of causation for plaintiffs, class action suits might not be suited for ephedra litigation because of the difficulty of proving that common circumstances existed across a broad spectrum of injured dietary supplement users.²³⁷ Plaintiffs have thus found it difficult to obtain class status for class action lawsuits against the manufacturers of allegedly unsafe dietary supplements.²³⁸ Nonetheless, the large number of plaintiffs' claims surrounding ephedra probably buttressed the FDA's position that the supplement presented a "significant or unreasonable risk of illness or injury" when, in December of 2003, the FDA announced the ban on sales of ephedra.²³⁹

Ongoing tort reform, particularly reforms that limit or outlaw punitive damages, also hampers using the tort system to keep ephedra from the market.²⁴⁰ Many states have legislated against or limited punitive damages in tort cases as a way to control rising health care costs.²⁴¹ Such a strategy, however, seems to work against the very purpose of punitive damages: Punitive damages were created to deter a party from its egregious conduct.²⁴² With no punitive damages in many states, the ability of the public to regulate the dietary supplement industry through the tort system is seriously crippled. In states with punitive damages, it may be more cost effective for a liable supplement manufacturer to pay the actual damages up front than it would be to battle in court and risk owing punitive damages.²⁴³ This tactic not only allows the manufacturer to continue producing and selling the drug, but also shields the issue from the influential public eye.

Even if the problems of litigating personal injury claims caused by dietary supplements were suddenly to disappear, litigation is still not an effective check on the industry for many of the same reasons that the FDA, with its current framework, is not an effective check on the indus-

logical properties of a dietary ingredient or its mechanisms of action The Government's burden of proof for "significant or unreasonable risk" can be met with any science-based evidence of risk, without the need to prove that the substance has actually caused harm in particular cases.

Id.

237. *Kemp v. Metabolife Int'l, Inc.* Civ.A 00-3513, 2003 WL 22326560, at *1 (E.D. La. Oct. 7, 2003); *see also* Kraus & Oh, *supra* note 10, at *6.

238. *See generally* Kraus & Oh, *supra* note 10.

239. *Id.*

240. *Id.*

241. *See* Note, "Common Sense" Legislation: The Birth of the Neoclassical Tort Reform, 109 Harv. L. Rev. 1765, 1769 (1996).

242. Punitive damages are "damages awarded in addition to actual damages when the defendant acted w/recklessness, malice or deceit; such damages which are intended to punish, and thereby deter blameworthy conduct, are generally not recoverable for breach of conduct." BLACK'S LAW DICTIONARY 390 (8th ed. 2004).

243. Note, *supra* note 241, at 1780.

try.²⁴⁴ Because litigating individual claims only works retrospectively, it is an inefficient means of preventing future harm to the public.²⁴⁵ Thus, while the FDA's action and cases won by injured plaintiffs may eventually move dangerous dietary supplements from the market, these solutions do not protect the public immediately.²⁴⁶ Congress alone wields the power to prospectively protect the public against dangerous dietary supplements.²⁴⁷ Congress alone can amend DSHEA and put the burden of proof on the manufacturers to show that their products are safe.

VI. THE BENEFITS OF SHIFTING THE BURDEN ARE SIGNIFICANTLY GREATER THAN THE COSTS

In enacting DSHEA, Congress sought to avoid spending vast amounts of time and money to prove the safety of what were otherwise safe dietary supplements.²⁴⁸ Research is not always prohibitively expensive. Even if Congress were to shift the burden of proving supplement safety, it is unlikely that researching dietary supplement safety would require the same amount of time and money as pharmaceutical research requires.²⁴⁹ Less time and money is required for supplements because the track records of most dietary supplements are well documented.²⁵⁰ Dietary supplements are simply variations on a few key compounds and once the staple compounds have been researched, the time and tests required for each supplement decline. By contrast, the compositions of pharmaceuticals differ significantly. Shifting the burden of proof back onto the dietary supplement companies is not only smart and sensible, but is also the only way for Congress to remain consistent with the original purpose of DSHEA.²⁵¹ Congress must be held to its vow that "improving the health status of United States citizens ranks at the top of the national priorities of the Federal Government."²⁵²

In addition to maintaining Congress's original purpose, shifting the burden of proof has many other benefits. Primarily, another dangerous dietary supplement will not likely enter the market. By preventing another ephedra, L-tryptophan, or GHB to reach the public, many lives can

244. See Thomas O. McGarity, *Our Science Is Sound Science and Their Science Is Junk Science: Science-Based Strategies for Avoiding Accountability and Responsibility for Risk-Producing Products and Activities*, 52 U. KAN. L. REV. 897, 931-33 (2004).

245. See generally Schindler, *supra* note 13.

246. See generally *id.*

247. See U.S. Const. art. I. See generally 21 U.S.C. §§ 301-399 (2004).

248. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 2(12), (13), 108 Stat. 4325 (1994).

249. See generally Schindler, *supra* note 13.

250. See *NIH News Release*, *supra* note 11.

251. Dietary Supplement Health and Education Act of 1994 § 2(15).

252. *Id.*

be saved.²⁵³ This benefit is not quantifiable and should not be sacrificed for whatever boost the economy receives from the sales of dietary supplements.

Shifting the burden of proof would also reduce the FDA's workload while still allowing the agency to have final approval authority. While this may create new work for the agency, the cost will likely be offset by the reduction in costs from no longer being required to meet the burden of proof in litigation. Instead, the cost of the research would likely be passed on to consumers of dietary supplements.

Although shifting the burden of proof would likely slow the introduction of new supplements, a manufacturer could aid in the establishment of a new supplement's safety by referring to the safety of similar or same dietary supplements. By spreading the cost of testing a particular ingredient across many manufacturers, the price of any given supplement would be only negligibly increased. Moreover, the ODS need not discontinue operations; the ODS could continue to provide information on specific dietary supplement ingredients and their safety.²⁵⁴

Finally, shifting the burden would have the practical effect of eliminating the procedural question of under what circumstances the FDA can implement rulemaking power using the "unreasonable risk" standard.²⁵⁵ The FDA rule banning ephedra is the first time that the standard has been used and it is also the first time that the FDA's power under DSHEA has been tested.²⁵⁶ The FDA's rule banning ephedra has already been challenged by some in the dietary supplement industry.²⁵⁷ The industry's challenge was based on the argument that the FDA did not meet its burden to show that ephedra posed an "unreasonable risk"

253. See Wolfe, *supra* note 52 ("Without the additional legal authority to require evidence of safety and effectiveness for dietary supplements as a condition of continued marketing, the FDA is still in a position of waiting until enough deaths or injuries have been caused by a specific dietary supplement and detected by the agency before pushing for the recall.").

254. The ODS currently maintains a web site with a database of research information for virtually every dietary supplement.

255. See Crossman, *supra* note 3, at 640-41.

256. *FDA Rule Banning Ephedra*, *supra* note 12, at 6794 ("[W]e are articulating a standard for unreasonable risk under [§] 402(f)(1)(A) of the act for the first time and because it is more efficient to declare these products adulterated as a category than to remove them from the market in individual enforcement actions in which we would have to establish, for each individual product, that they present a significant or unreasonable risk.").

257. *Supplement Makers Sue FDA to Allow Sale of Low-Dose Ephedra*, FDA WEEK, Aug. 20, 2004. "[T]he makers of dietary supplements that once contained low levels of the now-banned herbal substance ephedra sued FDA Aug. 17 seeking to partially overturn the agency's ban of the sale of ephedra-containing products to allow the sale of dietary supplements that contain low dosages of ephedra." *Id.* The supplement makers contend that the FDA failed to meet the statutory burden required to prove that dietary supplements containing small amounts of ephedra pose a risk to consumer health. *Id.*

with sufficient evidence.²⁵⁸ However, if Congress amends DSHEA and places the burden of proving supplement safety onto the supplement industry, supplement manufacturers will not have grounds on which to challenge whether or not the FDA has met its burden.

While in other situations the FDA's power is virtually uncontestable, DSHEA provides for *de novo* review when a rule is challenged in order to determine whether or not the FDA carried its "unreasonable risk" burden.²⁵⁹ Because of such plenary review, many argue that any regulations that the FDA issues are not rules but mere guidelines.²⁶⁰ If Congress were instead to require pre-market approval, much of the ambiguity would be eliminated surrounding the scope of the FDA's rule-making power under DSHEA.²⁶¹

Finally, if the "significant or unreasonable risk" burden of proof were shifted, identifiable changes would be minimal. The dietary supplement industry would be held to the same standard as the pharmaceutical industry and it would be the industry's duty to come forward with evidence showing that the introduction of a supplement is in the public good. Furthermore, shifting the burden is reasonable: The drug industry has found success and there is no reason to believe that the supplement industry will not find the same success under an increased burden.

VII. CONCLUSION

Although DSHEA places the burden of proving dietary supplement safety upon the FDA, the burden should be shifted to the dietary supplement industry. With Congress dragging its heels on making any changes to DSHEA, the only check on dietary supplement manufacturers is the tort system. While it is true that in individual cases plaintiffs may have less difficulty overcoming the burden of proof than does the FDA, this does not adequately protect the public from injuries caused by new dietary supplements. The FDA will likely continue to deal with dietary supplement safety on a case-by-case basis, as it did with ephedra, until the burden of proof is shifted. The high burden that the FDA must currently meet to remove a dangerous dietary supplement from the market means that many people must be injured or die before a product can be banned. Finally, the current burden shifting framework and untested "unreason-

258. *Id.*

259. 21 U.S.C. § 342(f)(1)(D) (2004) ("[T]he United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated. The court shall decide any issue under this paragraph on a *de novo* basis.").

260. See McNamara & Siegner, Jr., *supra* note 194, at 23.

261. See *id.*

able risk” standard that the FDA must meet opens the door to expensive industry litigation of FDA decisions.

Congress must amend DSHEA and place the burden back onto the dietary supplement industry to prove the safety of its products. Only when every dietary supplement is proven to be safe before entering the market will consumers know that the FDA is protecting them from dangerous dietary supplements.