

DIETARY SUPPLEMENTS: IS AVAILABILITY WORTH THE RISKS? PROPOSED ALTERNATIVES TO THE PRESENT DSHEA SCHEME

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INTRODUCTION

Today in the United States there is a high demand and correspondingly a huge market for dietary supplements.¹ Accordingly, any regulatory policy in the area of dietary supplements has the potential to affect a large portion of the population.² About sixty percent of Americans take dietary supplements in one form or another.³ The results of a recent American Dietetic Association survey indicate that approximately forty percent of adults take herbal remedies and over eighty percent use vitamin and mineral supplements.⁴ Yet, herbal supplements are potentially dangerous when taken alone, or in combination with prescription drugs.⁵ For example, ginkgo biloba has been linked to excessive bleeding and stroke.⁶ A recent survey found that twelve percent of herbal

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¹ See Arthur A Levin, *RX News: Dietary Supplement Safety Concerns*, HEALTHFACTS, June 2001, available at http://www.findarticles.com/cf_0/m0815/2001_June/75286633/print.jhtml (on file with author).

² Department of Health and Human Services, Office of the Inspector General, *Adverse Event Reporting for Dietary Supplements: An Inadequate Safety Valve* (Apr. 2001), available at <http://oig.hhs.gov/oei/reports/oei-01-00-00180.pdf> (on file with author) [hereinafter HHS Report].

³ *Id.*

⁴ Jacqueline Stenson, *The Herbal Frontier: The Promise and Peril of Supplements*, at <http://www.msnbc.com/news/522365.asp> (last visited Apr. 7, 2002) (on file with author).

⁵ See *infra* note 46.

⁶ See HHS Report, *supra* note 2. The HHS Report noted that the FDA commissioner stated, “[a] small but disturbing number of these products have a potential for harm or bear unsupported claims. In this context, a rapidly expanding industry and a changing demographic of consumers eager to manage their own health care needs provide a significant regulatory challenge.” *Id.* at 7.

supplement consumers experience side effects from these products.⁷

Prior to the passage of the Dietary Supplement Health and Education Act (“DSHEA”),⁸ the Food and Drug Administration (“FDA”) had significantly more control over dietary supplements.⁹ At that time, the FDA categorized dietary supplements as either drugs or food additives, both of which require approval before marketing.¹⁰ The DSHEA altered this scheme by taking dietary supplements out of the food additive category.¹¹ The DSHEA categorized dietary supplements as foods, a category over which the FDA has no power to require clearance prior to marketing.¹²

⁷ *Id.*

⁸ Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended in scattered sections of 21 U.S.C.).

⁹ Lauren J. Sloane, *Herbal Garden of Good and Evil: The Ongoing Struggles of Dietary Supplement Regulation*, 51 ADMIN. L. REV. 323, 324 (1999).

¹⁰ Robert G. Pinco & Todd H. Halpern, *Guidelines for the Promotion of Dietary Supplements: Examining Government Regulation Five Years After Enactment of the Dietary Health and Education Act of 1994*, 54 FOOD & DRUG L.J. 567, 568-69 (1999).

¹¹ *Id.*

¹² Pinco & Halpern, *supra* note 10, at 569. The FDA requires premarket approval of food additives and for new drug application. HHS Report, *supra* note 2, at 6. The FDA “is a scientific regulatory agency responsible for the safety of the nation’s domestically produced and imported foods, cosmetics, drugs, biologics, medical devices, and radiological products.” U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, *Center for Food Safety and Applied Nutrition Overview*, at <http://www.cfsan.fda.gov/~lrd/cfsan4.html> (last updated Aug. 15, 2001) (on file with author). The FDA’s principal function is consumer protection. *Id.* The FDA is the “leading food and drug regulatory agency in the world,” and “is part of the Executive Branch of the United States Government within the Department of Health and Human Services (DHHS) and the Public Health Service (PHS).” *Id.* The following table illustrates the differences between regulatory mechanisms for different product classes as contained in the HHS Report:

Product Class	Product Registration	Manufacturer Registration	Pre-market Approval	Specific Good Manufacturing Practices	Voluntary Postmarket Adverse Event Reporting System	Mandatory Postmarket Adverse Event Reporting System	Safety Related Labeling Requirements
Dietary Supplement				Under Development	X*		Some
Conventional Foods				X	X		Some
Food Additive			X	X	X	Some	X

The DSHEA was passed in 1994, “largely in response to industry pressure.”¹³ The act amended the Food Drug & Cosmetic Act (“FDCA”).¹⁴ Following the enactment of the DSHEA in 1994, which decreased the FDA’s control over dietary supplement manufacturers, the dietary supplement market increased tremendously.¹⁵ Since 1994, dietary supplement sales have nearly doubled—from \$8.6 billion to \$16 billion.¹⁶ This boom is due “in no small part” to the DSHEA.¹⁷

The FDA Commissioner, Jane E. Henney, M.D., stated that the purpose of the DSHEA was to grant the FDA power over dangerous supplements without interfering with consumers’ ability to access dietary supplements in general.¹⁸ The congressional findings relating to the DSHEA are illustrative of the reasoning behind the enactment

Mono-graph Drugs**	X	X		X	X		X
New Drug Application Drugs***	X	X	X	X	X	X	X
<p>*FDA does not collect or evaluate all adverse events on all conventional food. Excluded in this system are the investigations FDA conducts following food-borne illness outbreaks.</p> <p>**Monograph drugs are typically over-the-counter drugs that must adhere to specific safety standards set out for each ingredient and do not undergo clinical testing.</p> <p>***NDA is a new drug application that all prescription drugs and some over-the-counter drugs must submit to FDA prior to market. This application must include data that demonstrates the safety and efficacy of the product.</p>							

HHS Report, *supra* note 2, at 6.

¹³ Roseann B. Termini, *Pharmanex, Inc. v. Shalala: A Wake Up Call For Congress and a Not So Bitter Pill For the FDA*, 26 OHIO N.U. L. REV. 269, 277 (2000).

¹⁴ 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, 270 (1998). “The Federal Food, Drug, and Cosmetic Act (FFDCA) authorizes the Food and Drug Administration (FDA) to regulate foods, cosmetics, drugs and medical devices.” Michigan State University, Institute for Environmental Toxicology, *The Federal Food, Drug, and Cosmetic Act*, at <http://www.iet.msu.edu/Regs/fedfoodact.htm> (last modified July 24, 1999) (on file with author). The purpose of the FDCA is to ensure “that foods are pure and wholesome, safe to eat, and produced under sanitary conditions; that cosmetics are safe and made from appropriate ingredients; that drugs and devices are safe and effective for their intended uses; and, that all labeling and packaging is truthful, informative, and not deceptive.” *Id.*

¹⁵ Iona N. Kaiser, *Dietary Supplements: Can the Law Control the Hype?*, 37 HOUS. L. REV. 1249, 1250 (2000).

¹⁶ Stenson, *supra* note 4.

¹⁷ Pinco & Halpern, *supra* note 10, at 567.

¹⁸ Termini, *supra* note 13, at 281.

of the DSHEA in its present form.¹⁹ Among other things, the congressional findings emphasized the enormity of the dietary supplement industry.²⁰ The findings further noted that although the government should act against unsafe or adulterated products, the government should not impose “unreasonable regulatory barriers” for dietary supplements that are “safe within a broad range of intake.”²¹ By removing some regulatory barriers, the DSHEA has made dietary supplements of all qualities widely available to consumers.²² Thus, consumers face a larger risk of harm, perhaps serious harm, from the effects of these dietary supplements.²³ In allowing dietary supplements to enter the market without first requiring some regulatory review, such as testing for the safety and efficacy of the product, the consumer is, in all probability, subjected to unknown health risks and effects.

This Comment will address the DSHEA, the risks its laxity imposes on consumers, proposals to improve the current system and reduce these risks, and will ultimately recommend a change in the current scheme to protect consumers from these potentially

¹⁹ Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, sec. 2, 108 Stat. 4325, 4326 (Congressional Findings).

²⁰ *Id.* Regarding the enormity of the dietary supplement industry, the congressional findings noted, in pertinent part:

. . . (9) national surveys have revealed that almost 50 percent of the 260,000,000 Americans regularly consume dietary supplements of vitamins, minerals, or herbs as a means of improving their nutrition; (10) studies indicate that consumers are placing increased reliance on the use of nontraditional health care providers to avoid the excessive costs of traditional medical services and to obtain more holistic consideration of their needs; . . . ; (12)(A) the nutritional supplement industry is an integral part of the economy of the United States; (12)(B) the industry consistently projects a positive trade balance; and (12)(C) the estimated 600 dietary supplement manufacturers in the United States produce approximately 4,000 products, with total annual sales of such products alone reaching at least \$4,000,000,000 . . .

Id.

²¹ *Id.* The Congressional Findings provided, in pertinent part, that:
. . . (13) although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers; (14) dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare; and (15)(A) legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness . . .

Id.

²² Pinco & Halpern, *supra* note 10, at 568.

²³ *See id.*

dangerous and highly available dietary supplements. In Part I, this Comment discusses the DSHEA as it operates today and the FDA's power under the present regulatory scheme. Part II addresses special cases in which the courts have accepted FDA's efforts to exclude street drugs, certain ingredients and other products from being considered dietary supplements. Part III describes some of the legislative actions taken by the states in reaction to the lax federal scheme. The Comment concludes in Part IV, analyzing a range of possible alternatives and changes to the DSHEA, and proposing a solution to help remedy the dangers created by the current DSHEA scheme without requiring pre-market clearance. This solution involves the utilization and expansion of present efforts, in addition to three changes which would require legislative action: shifting the burden of proving a product's safety onto the manufacturer, granting the FDA power to act against dietary supplements as a class rather than individually, and granting prescription status to supplements that are dangerous when taken in excess of the amount suggested on the label, when likely to be used in this manner.

I. THE DSHEA

A. *General Provisions*

The DSHEA created a new definition for "dietary supplement."²⁴ This broad definition includes a wide range of products.²⁵ A "dietary supplement," as explained by the FDA's official website,

- is a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients
- is intended for ingestion in pill, capsule, tablet, or liquid form.
- is not represented for use as a conventional food or as the sole item of a meal or diet.
- is labeled as a "dietary supplement."
- includes products such as an approved new drug, certified

²⁴ Sloane, *supra* note 9, at 326.

²⁵ Laura A. Khatcheressian, *Regulation of Dietary Supplements: Five Years of DSHEA*, 54 FOOD & DRUG L.J. 623, 626 (1999).

antibiotic, or licensed biologic that was marketed as a dietary supplement or food before approval, certification, or license (unless the Secretary of Health and Human Services waives this provision).²⁶

Under the DSHEA, a dietary supplement is “adulterated” if it falls under any one of three new standards.²⁷ First, the DSHEA deems a dietary supplement “adulterated” if any of its ingredients or the supplement itself present “a significant or unreasonable risk of illness or injury” when taken according to the directions on the label or under normal use when no directions are provided.²⁸ Second, if a dietary supplement “pose[s] an imminent hazard to public health or safety,” the DSHEA deems this product adulterated and allows the Secretary of Health and Human Services (“Secretary”) to remove the supplement from the market.²⁹ Lastly, if a dietary supplement contains a “new dietary ingredient,”³⁰ it is considered adulterated if there exists insufficient information to reasonably assure the absence of a “significant or unreasonable risk.”³¹

The DSHEA defines a “new dietary ingredient” as an “ingredient that was not marketed in the United States before October 15, 1994.”³² The DSHEA’s definition of “new” suggests that it excludes dietary ingredients sold before October 15, 1994, even if marketed for a different use.³³ If a manufacturer plans to sell a product containing a “new dietary ingredient,” it must give the FDA seventy-five days notice and include information demonstrating that the

²⁶ U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition, *Dietary Supplement Health and Education Act of 1994*, at <http://vm.cfsan.fda.gov/~dms/dietsupp.html> (Dec. 1, 1995) (on file with author) [hereinafter DSHEA Website]. The exact statutory language is found in 21 U.S.C. section 321(ff). See 21 U.S.C. § 321(ff) (2002).

²⁷ Meghan Colloton, *Dietary Supplements: A Challenge Facing the FDA in Mad Cow Disease Prevention*, 51 AM. U. L. REV. 495, 526 (2002) (citing Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, sec. 4, § 402(f), 108 Stat. 4325, 4328 (1994)); see also 21 U.S.C. § 342(f) (2002).

²⁸ DSHEA Website, *supra* note 26; see also 21 U.S.C. § 342(f)(1)(A) (2002).

²⁹ Colloton, *supra* note 27, at 526 (quoting Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, sec. 4, § 402(f)(1)(C), 108 Stat. 4325, 4328 (1994)); see also 21 U.S.C. § 342(f)(1)(C) (2002).

³⁰ 21 U.S.C. § 350b(c) (1999). A “new dietary ingredient” is an ingredient that was not present in a dietary supplement prior to October 15, 1994. *Id.*

³¹ Colloton, *supra* note 27, at 526; see also 21 U.S.C. § 342(f)(1)(B) (2002).

³² Stephen H. McNamara & A. Wes Seigner, Jr., *FDA has Substantial and Sufficient Authority to Regulate Dietary Supplements*, 57 FOOD & DRUG L.J. 15, 20 (2002) (quoting 21 U.S.C. § 350b(c) (1999) (F.D.C.A. Subchapter IV)).

³³ Margaret Gilhooley, *Deregulation and the Administrative Role: Looking at Dietary Supplements*, 62 MONT. L. REV. 85, 119 (2001).

ingredient can “reasonably be expected to be safe.”³⁴ The law does not, however, require FDA approval.³⁵ Because there is no official record of ingredients that were sold before October 15, 1994, the manufacturer must determine whether a particular ingredient is “new.”³⁶ In addition, a dietary supplement is deemed adulterated if it “is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.”³⁷

The FDA only has the power to limit the use of a specific dietary supplement (provided there is no “new” ingredient) if the FDA proves the supplement creates a “significant or unreasonable risk” under the dosage specified on the label.³⁸ Therefore, provided the supplement does not contain a new ingredient, the FDA has no power to stop a dietary supplement from placement on the market.³⁹ These supplements will be available to consumers until the FDA shows that the supplement is a “significant or unreasonable risk,” typically established by adverse event reports.⁴⁰

An adverse event is an event that may be linked to a product or ingredient.⁴¹ The FDA has a system in effect to collect and review adverse event reports linked to dietary supplements.⁴² Reporting these adverse events is completely voluntary, and these adverse events are reported by “consumers, health professionals, and manufacturers through a variety of sources, including State health departments, Poison Control Centers, direct communication with individuals, and MedWatch, a computerized reporting system used to monitor a variety of FDA-regulated products.”⁴³ In effect, the statute provides little protection to consumers until actual instances of harm have

³⁴ DSHEA Website, *supra* note 26.

³⁵ Ilene Ringel Heller, *Functional Foods, Regulatory and Marketing Developments*, 56 FOOD & DRUG L.J. 197, 198-99 (2001).

³⁶ *See id.*

³⁷ 21 U.S.C. § 342(f)(1)(D) (2002). 21 U.S.C. section 342(a)(1) addresses particular circumstances in which a food will be deemed adulterated. *See* 21 U.S.C. § 342(a)(1) (2002). For example, it states that a food is deemed adulterated if it “bears or contains any poisonous or deleterious substance which may render it injurious to health” or if it “consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food.” *Id.*

³⁸ 21 U.S.C. § 342(f) (2002).

³⁹ *See id.*

⁴⁰ Colloton, *supra* note 27, at 529-30.

⁴¹ HHS Report, *supra* note 2, at 1.

⁴² *Id.*

⁴³ *Id.*

occurred or until a basis exists to project that actual instances of harm will occur.⁴⁴ Additionally, the DSHEA placed the burden of proving a supplement unsafe or adulterated on the FDA.⁴⁵ With this lax statutory regime, potentially dangerous supplements are widely available to the public.⁴⁶ These supplements may have serious side effects and may interact with other medications.⁴⁷ For example, ginkgo biloba, a dietary supplement, is a blood thinner that may cause excessive bleeding, and may lead to stroke.⁴⁸

⁴⁴ 21 U.S.C. § 342(f) (2002); *see also* Colloton, *supra* note 27, at 528-34.

⁴⁵ Colloton, *supra* note 27, at 527.

⁴⁶ *See* Colloton, *supra* note 27, at 497. Some of the potential dangers of dietary supplements are worth noting to demonstrate the need for stricter regulation. Ginkgo biloba, a popular herbal supplement, can cause excessive bleeding. Levin, *supra* note 1. Ginkgo biloba is sold in varying contents and amounts of active ingredients; to date, there is no specific daily amount established as safe. NIH News Release, *NIH Awards Multicenter Study on Ginkgo Biloba for Dementia*, at <http://www.nih.gov/news/pr/sept99/nccam-30.htm> (Sept. 30, 1999) (on file with author). "Some recent cases imply that daily use of ginkgo biloba extracts may cause side effects, such as excessive bleeding, especially when combined with daily use of aspirin." *Id.* There is an additional risk in taking ginkgo biloba with anticoagulants and antiplatelet medications. Melanie Johns Cupp, *Herbal Remedies: Adverse Effects and Drug Interactions*, AM. FAM. PHYSICIAN (Mar. 1, 1999), available at <http://www.aafp.org/afp/990301ap/1239.html> (on file with author).

There are dangers even in conventional dietary supplements such as vitamin A. *See* Levin, *supra* note 1; *see also* Associated Press, *Vitamin A linked to hip fracture*, available at <http://www.msnbc.com/news/680496.asp> (Jan. 1, 1999) (on file with author). High doses of vitamin A have been linked to birth defects, and recently have been associated with hip fractures. *Id.* Garlic may dangerously interfere with AIDS drugs. Associated Press, *Garlic Pills may block AIDS drugs*, available at www.msnbc.com/news/668796.asp (Dec. 6, 2001) (on file with author).

Ephedra is a popular dietary supplement that is taken by approximately 12 million Americans. Stenson, *supra* note 4. Ephedra is associated with cardiovascular problems such as high blood pressure, strokes, and heart attacks, in addition to being associated with seizures. *Id.* Furthermore, Ephedra has caused 20-30 deaths. Levin, *supra* note 1.

St. John's Wort should be avoided by individuals taking antidepressants. Cupp, *supra* note 46. Additionally, St. John's Wort can interfere with oral birth control pills, AIDS drugs, cancer drugs, and treatments to help with organ transplants. Stenson, *supra* note 4.

Taking ginseng can cause a decreased response to warfarin, commonly known by its brand name, Coumadin. Cupp, *supra* note 46. Warfarin is generally prescribed to prevent the formation or movement of blood clots. *See* <http://www.fyipharmacist.com/monographs/coumadin.html> (last visited Apr. 9, 2002) (on file with author).

It has not yet been proven, but doctors caution that Androstendione may cause side effects similar to those of steroids, such as liver cancer. Crossman, *infra* note 196, at 632. Creatine, when taken regularly, is presumed by some physicians to cause renal failure. *Id.* The preceding is just an abbreviated list of the potential hazards of dietary supplements.

⁴⁷ *See supra* note 46 (describing potential side effects of dietary supplements).

⁴⁸ HHS Report, *supra* note 2, at 7.

With the exception of new dietary ingredients, manufacturers have no obligation to provide the FDA with any evidence to prove the safety or efficacy of their product.⁴⁹ Additionally, manufacturers are not required to register their product or company information with the FDA.⁵⁰

Presently, there are no FDA regulations that govern the manufacture of dietary supplements.⁵¹ The nature of some herbs makes the absence of FDA regulation especially dangerous.⁵² The potency of an herb depends on many different factors, such as soil, sunlight, temperature, season, age and structure of the plant, and the post-harvesting method used.⁵³ Because of these factors, herbal remedies can differ significantly in quality and strength of ingredients.⁵⁴ Herbal remedies frequently contain amounts of ingredients that differ, sometimes significantly, from the amount listed on the label.⁵⁵

The DSHEA gave the Secretary power to enact regulations that impose good manufacturing practices on dietary supplement manufacturers.⁵⁶ The FDA plans to create these “good manufacturing practices” (“GMPs”) regulations for the dietary supplement industry.⁵⁷ These regulations would work to ensure the “identity, purity, quality, strength and composition of dietary supplements.”⁵⁸ Accordingly, the regulations should help prevent some of the dangers associated with dietary supplements, such as when prescription medications are illegally added into the supplements, or when supplements are contaminated with metals and pesticides.⁵⁹ Additionally, GMPs would allow the FDA to confirm ingredient amounts contained in the product.⁶⁰ Until the FDA issues

⁴⁹ U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition, *Overview of Dietary Supplements*, at <http://vm.cfsan.fda.gov/~dms/ds-overview.html#what> (Jan. 3, 2001) (on file with author) [hereinafter FDA Overview Website].

⁵⁰ *Id.*

⁵¹ FDA Overview Website, *supra* note 49.

⁵² See Linda G. Tolstoi, *Herbal Remedies: Buyer Beware*, NUTRITION TODAY, July 2001, available at http://www.findarticles.com/cf_0/m0841/4_36/77841951/p1/article.jhtml?trm=Tolstoi (on file with author).

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ Stenson, *supra* note 4.

⁵⁶ 21 U.S.C. § 342 (g)(2) (2002).

⁵⁷ FDA Overview Website, *supra* note 49.

⁵⁸ *Id.*

⁵⁹ See Stenson, *supra* note 4; see also HHS Report, *supra* note 2, at 23.

⁶⁰ HHS Report, *supra* note 2, at 23.

these regulations, the manufacturer will continue to have power over its own production of dietary supplements.⁶¹

B. FDA's Supervision of the Dietary Supplement Industry

The DSHEA places dietary supplements within the food category and the FDA's Center for Food Safety and Applied Nutrition ("CFSA") is responsible for the oversight of dietary supplements.⁶² To police the dietary supplement market for illegal products, the FDA utilizes the Internet, results from inspections conducted on the manufacturers and distributors, complaints and adverse events reported to the FDA, and the occasional product laboratory test.⁶³ The FDA considers a product illegal when it exhibits false or misleading claims, or when the product is deemed unsafe.⁶⁴

Because manufacturers are generally not required to get FDA approval, nor are they required to register their products with the FDA, the FDA does not have a record of the supplements presently on the market.⁶⁵ If a consumer desires more information on a particular product on the market, the FDA will not possess it.⁶⁶ To obtain this additional information, the consumer must turn to the product manufacturer.⁶⁷

A recent U.S. Department of Health and Human Services ("HHS") study concluded that the FDA's method of supervision regarding dietary supplements is inadequate.⁶⁸ The report stated that the FDA learns of less than one percent of the adverse events linked to dietary supplement use.⁶⁹ The study opined that this low number

⁶¹ See FDA Overview Website, *supra* note 49. 21 C.F.R., pt. 111 is titled "CURRENT GOOD MANUFACTURING PRACTICE FOR DIETARY SUPPLEMENTS" and states that its authority comes from 21 U.S.C. sections 321, 342 (2002), and 371 (1999). 21 C.F.R., pt. 111 (2002). As of yet, there appears to be only one provision in this part, and it addresses the packaging of iron-containing dietary supplements. See 21 C.F.R. § 111.50 (2002). This section establishes that for certain iron-containing supplements to be in accordance with good manufacturing practices, the supplements must be in unit-dose packaging. *Id.* The provision goes on to define "unit-dose packaging," and to exempt certain classes of iron-containing supplements. *Id.*

⁶² FDA Overview Website, *supra* note 49.

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ EXECUTIVE BRIEFING, BNA'S HEALTH CARE DAILY REPORT (Apr. 24, 2001) [hereinafter EXECUTIVE BRIEFING]; see also HHS Report, *supra* note 2.

⁶⁹ HHS Report, *supra* note 2.

may be due to various factors.⁷⁰ The study noted, for example, that consumers may presume dietary supplements are safe, and, additionally, that consumers often take supplements without medical supervision.⁷¹ The report observed that the FDA was unsuccessful in obtaining the necessary information to properly look into the adverse events reported.⁷² For example, in the period between 1994 and 1999, the FDA failed to obtain medical records for fifty-eight percent of the adverse event reports it was to investigate.⁷³ The report listed other factors that illustrate how the oversight is inadequate, including the FDA's inability to identify the ingredients in thirty-two percent of the supplements involved in the adverse event reports, the FDA's failure to possess labels for seventy-seven percent of the supplements referred to in the reports, and the FDA's failure to obtain sixty-nine percent of the supplement samples it requested from manufacturers.⁷⁴ The report also criticized the use of the FDA's website as its principal means for disseminating information to consumers.⁷⁵ Among the reasons for this criticism was the fact that the FDA seldom updates the website and, therefore, the information contained in the website may be outdated.⁷⁶

C. Overview of Permissible Claims Under DSHEA

The DSHEA also addresses the claims that dietary supplement manufacturers place on their products.⁷⁷ The statute clarifies what types of claims are permissible for dietary supplement labels.⁷⁸ This comment gives only a broad overview of the DSHEA's restrictions on permissible claims; however, it is important to address the permissible claims because the DSHEA arguably allows manufacturers to dangerously lead consumers to believe a certain dietary supplement will, for example, help treat a certain disease.⁷⁹ The DSHEA does permit various statements to be placed on dietary supplement labels,

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² EXECUTIVE BRIEFING, *supra* note 68.

⁷³ HHS Report, *supra* note 2.

⁷⁴ *Id.*

⁷⁵ *Id.* at 17.

⁷⁶ EXECUTIVE BRIEFING, *supra* note 68.

⁷⁷ Khatcheressian, *supra* note 25, at 628. Claims are the statements manufacturers place on the labels of dietary supplements. See DSHEA Website, *supra* note 26.

⁷⁸ Kelly Ann Kaczka, *From Herbal Prozac to Mark McGwire's Tonic: How the Dietary Supplement Health and Education Act Changed the Regulatory Landscape for Health Products*, 16 J. CONTEMP. HEALTH L. & POL'Y 463, 477-78 (2000).

⁷⁹ Khatcheressian, *supra* note 25, at 637-38.

however, it does not allow these claims to state that the dietary supplement will “diagnose, prevent, mitigate, treat, or cure a specific disease (unless approved under the new drug provisions of the [Federal Food, Drug, and Cosmetic] Act).”⁸⁰ There are three basic types of claims that are legally permissible: “health claims, structure/function claims, and nutrient content claims.”⁸¹ Different claims have different requirements.⁸² Prior regulations allowed health claims and nutrient content claims; the DSHEA added the category of structure/function claims.⁸³

The DSHEA permits claims asserting that a “dietary ingredient” impacts “the structure or function of the body” (“structure/function claims”).⁸⁴ A permissible type of structure/function claim describes the “general well-being from consumption of a nutrient or dietary ingredient.”⁸⁵ Another generally acceptable type of structure/function claim involves assertions that dietary supplement use is beneficial to a nutrient deficiency disease.⁸⁶ Manufacturers have the responsibility of substantiating these structure/function claims; however, prior approval by the FDA is not required.⁸⁷ The DSHEA does not define “substantiation,” and does not require submission to the FDA.⁸⁸ When making structure/function claims, manufacturers need only include the following disclaimer on the

⁸⁰ DSHEA Website, *supra* note 26.

⁸¹ U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling, and Dietary Supplements, *Claims that Can be Made for Conventional Foods and Dietary Supplements*, at <http://www.cfsan.fda.gov/~dms/hclaims.html> (last revised Oct. 2001) (on file with author) [hereinafter FDA Claims Website].

⁸² FDA Overview Website, *supra* note 49.

⁸³ See FDA Claims Website, *supra* note 81.

⁸⁴ Gilhooley, *supra* note 33, at 95-96 (citing 21 U.S.C. § 343(r)(6)(A) (2002)); see also 21 C.F.R. § 101.93 (2001). 21 C.F.R. section 101.93(f) states that dietary supplement labels may contain statements that “describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function.” 21 C.F.R. § 101.93(f) (2001). This provision specifies that dietary supplement labels cannot make disease claims, as defined by 21 C.F.R. section 101.93(g), and if such claims are made, the product will be regulated as a drug. *Id.*

⁸⁵ Khatcheressian, *supra* note 25, at 628 (citing 21 U.S.C. § 343(r)(6) (2002)); see also FDA Claims Website, *supra* note 81 (listing this type of claim as allowed under the category of structure/function claims).

⁸⁶ Khatcheressian, *supra* note 25, at 628; see also FDA Claims Website, *supra* note 81. If making such a claim, however, a manufacturer must include information on how prevalent this deficiency disease is in the United States. FDA Claims Website, *supra* note 81.

⁸⁷ Gilhooley, *supra* note 33, at 95; see also FDA Claims Website, *supra* note 81.

⁸⁸ Khatcheressian, *supra* note 25, at 628.

label of the dietary supplement: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”⁸⁹ However, “[t]his system allows manufacturers of dietary supplements to hint that a product will help a disease without actually saying so (e.g., ‘lowers cholesterol’ is reasonably understood by consumers to mean that the product treats the illness of high cholesterol).”⁹⁰

Health claims are also permissible.⁹¹ These claims “describe a relationship between a food substance and a disease or health-related condition.”⁹² There are two different avenues under which the FDA evaluates these claims to determine whether they are permissible.⁹³ Under the first avenue, the FDA reviews scientific literature.⁹⁴ Here, if the FDA finds “significant scientific agreement” as to the particular nutrient/disease relationship, the claim is allowed.⁹⁵ If there is insufficient scientific evidence to obtain permission through the first avenue, a second avenue is available to obtain this permission.⁹⁶ The second avenue requires the FDA to “allow appropriately qualified health claims that would be misleading without such qualifications.”⁹⁷ These claims need only have sufficient scientific evidence such that there is more proof for the relationship than against it.⁹⁸ The United States Circuit Court for the District of Columbia approved this second means of evaluating a claim in *Pierson v. Shalala*,⁹⁹ in a decision “relating to supplements on constitutional grounds based on commercial free speech.”¹⁰⁰

D. Research Efforts

The DSHEA provided that the HHS Secretary should create an Office of Dietary Supplements (“ODS”).¹⁰¹ The DSHEA mandated the formation of the ODS to establish a body in charge of obtaining

⁸⁹ *Id.* (quoting 21 U.S.C. § 343(r)(6)(C)); see also FDA Claims Website, *supra* note 81.

⁹⁰ Khatcheressian, *supra* note 25, at 637-38.

⁹¹ FDA Claims Website, *supra* note 81.

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ FDA Claims Website, *supra* note 81.

⁹⁸ *Id.*

⁹⁹ 164 F.3d 650, 657 (D.C. Cir. 1999).

¹⁰⁰ Gilhooley, *supra* note 33, at 110.

¹⁰¹ Sloane, *supra* note 9, at 328.

information on dietary supplements through scientific research and to subsequently distribute the information.¹⁰² On November 27, 1995, the ODS was formally established within the National Institutes of Health (“NIH”).¹⁰³ The two primary goals of the ODS are: “(1) to research how dietary supplements can improve our nation’s healthcare system; and (2) to encourage the study of dietary supplements.”¹⁰⁴ The ODS is also responsible for advising federal agencies on dietary supplement matters.¹⁰⁵ The ODS, however, has no role in the regulation of dietary supplements.¹⁰⁶

At the start of 2000, the FDA announced its Ten Year Plan setting forth the CFSAN’s “overall dietary supplement strategy.”¹⁰⁷ Section V of this Ten Year Plan set forth CFSAN’s goals in science and research.¹⁰⁸ In an effort to initiate these objectives, the FDA presented a two-year, \$1 million grant to the National Academy of Sciences for the purpose of creating a framework for evaluating

¹⁰² *Id.* at 328, 337.

¹⁰³ National Institutes of Health Office of Dietary Supplements, *About ODS*, at <http://ods.od.nih.gov/about/started.html> (last visited Oct. 20, 2002) (on file with author). Specifically, the ODS was established “within the Office of Disease Prevention, Office of the Director, at the National Institutes of Health. Bernadette M. Marriott, Ph.D. was appointed Director of the ODS. The current Director is Paul M. Coates, Ph.D.” *Id.*

¹⁰⁴ Sloane, *supra* note 9, at 328.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.* at 337.

¹⁰⁷ LETTER FROM DIRECTOR, U.S. FOOD AND DRUG ADMINISTRATION, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, DIETARY SUPPLEMENT STRATEGY (TEN YEAR PLAN) (Jan. 2000), *available at* <http://vm.cfsan.fda.gov/~dms/ds-strat.html> (on file with author) [hereinafter TEN YEAR PLAN]. “The Center for Food Safety and Applied Nutrition, known as CFSAN, is one of six product-oriented centers, in addition to a nationwide field force, that carry out the mission of the Food and Drug Administration (FDA).” U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, *Center for Food Safety and Applied Nutrition Overview*, at <http://www.cfsan.fda.gov/~lrd/cfsan.html> (last updated Aug. 15, 2001) (on file with author). “CFSAN, in conjunction with the Agency’s field staff, is responsible for promoting and protecting the public’s health by ensuring that the nation’s food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled.” *Id.*

¹⁰⁸ *Id.* One of the goals set out by Section V is to “enhance research/science capabilities,” including strengthening the science base by ensuing “sound science-based program for all dietary supplement review and develop a core of well-trained, multidisciplinary scientists in support of supplement review and research.” *Id.* Another goal mentioned in Section V is strengthening research efforts by working with the “assistance of a nationally recognized organization” to create a “broad research agenda and needs assessment framework to implement priority-based research for dietary supplement issues.” *Id.* Section V additionally sets out the goals related to, among other things, dietary supplement ingredient reviews, consumer research, marketplace research, and the adverse event monitoring system. *Id.*

herbs.¹⁰⁹

More recently, on July 25, 2002, the National Institute of Environmental Health Sciences (“NIEHS”) and the ODS, both part of the NIH, announced a \$6 million, five-year grant to create a research center to study Echinacea and Hypericum, known as St. John’s Wort.¹¹⁰ Echinacea and Hypericum are botanical dietary supplements.¹¹¹ This new center, along with established NIH centers located at universities around the country, “[is] expected to greatly advance the scientific base of knowledge on botanicals, including issues of their effectiveness, safety, and biological action.”¹¹²

II. SPECIAL SITUATIONS LIMITING SCOPE OF DIETARY SUPPLEMENTS

This section will focus on two recent court decisions: *United States v. Undetermined Quantities of Articles of Drug*¹¹³ and *Pharmanex v. Shalala*.¹¹⁴ In both of these cases, the courts had the power to evaluate the FDA’s interpretation and application of law, with the potential to either reduce or increase the FDA’s authority.¹¹⁵ Both courts ruled in favor of the FDA.¹¹⁶ These cases expanded the FDA’s power by allowing increased control, at least in these special circumstances, over dietary supplements.¹¹⁷ In these special cases, the court accepted an FDA position narrowing the meaning of “dietary supplement,” thereby promoting safety.¹¹⁸

There is a great deal of controversy concerning products that claim to be dietary supplements while advertising that they act as natural alternatives to illicit drugs.¹¹⁹ In *Undetermined Quantities*,¹²⁰ for example, some of the products at issue were called “Rave X,”

¹⁰⁹ Stenson, *supra* note 4.

¹¹⁰ NIH News Release, *NIH Funds Botanical Center in Iowa to Study Health Effects of Echinacea and St. John’s Wort*, at <http://www.nih.gov/news/pr/jul2002/niehs-25.htm> (July 25, 2002) (on file with author).

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ 145 F. Supp. 2d 692 (D. Md. 2001).

¹¹⁴ 221 F.3d 1151 (10th Cir. 2000).

¹¹⁵ See *Undetermined Quantities*, 145 F. Supp. 2d 692; *Pharmanex*, 221 F.3d 1151.

¹¹⁶ See *Undetermined Quantities*, 145 F. Supp. 2d 692; *Pharmanex*, 221 F.3d 1151.

¹¹⁷ See *Undetermined Quantities*, 145 F. Supp. 2d 692; *Pharmanex*, 221 F.3d 1151.

¹¹⁸ See *Undetermined Quantities*, 145 F. Supp. 2d 692; *Pharmanex*, 221 F.3d at 1151.

¹¹⁹ See, e.g., Cary Elizabeth Zuk, *Herbal Remedies are Not Dietary Supplements: A Proposal for Regulatory Reform*, 11 HASTINGS WOMEN’S L.J. 29, 43-46 (2000) (describing the marketing of, and the FDA’s reaction to, a product called “Herbal Ecstasy,” and its claims of, among other things, “euphoria, increased sexual sensations, [and] heightened awareness”).

¹²⁰ *Undetermined Quantities*, 145 F. Supp. 2d at 696.

“Hashanna Oil,” “Herbal Hash,” and “Herbal Opium.”¹²¹ The defendants claimed these products were dietary supplements.¹²² The FDA disagreed, categorizing these products as “street drug alternatives,” and concluded that they were misbranded and unapproved drugs.¹²³ This characterization meant the products were illegal as violative of the Food, Drug, & Cosmetic Act (“FDCA”).¹²⁴ The FDA seized the products and the United States brought action to seek an order of condemnation as well as permanent injunctive relief.¹²⁵ The FDA relied on its own “Guidance for Industry on Street Drug Alternatives” (“the Guidance”)¹²⁶ in making its determination.¹²⁷ The Guidance declared that these street drug alternatives were not dietary supplements, but instead were unapproved new and misbranded drugs.¹²⁸ The *Undetermined Quantities* court agreed with the defendants that the Guidance was not binding because it was not a substantive rule, but rather an interpretive statement of the FDA’s position.¹²⁹ Yet, the court did acknowledge that the Guidance was to be accorded some deference.¹³⁰ The court noted that interpretations are entitled to some deference in the respect that they have the “power to persuade.”¹³¹ The court found that the Guidance was “highly persuasive in light of the text and purposes of the FDCA.”¹³² The court refused “to carve out a statutory loophole for drug manufacturers attempting to profit from the illegal drug epidemic by

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ Guidance for Industry on Street Drug Alternatives; Availability, 65 Fed. Reg. 17, 512 (Dep’t of Health and Human Servs., FDA Apr. 3, 2000). This guidance, in pertinent part, stated the following:

[t]his guidance is intended to inform industry and the public that FDA considers any product that is promoted as a street drug alternative to be an unapproved new drug and a misbranded drug in violation of sections 505 and 502 of the act (21 U.S.C. §§ 355, 352). Such violations may result in regulatory action, including seizure and injunction. Moreover, FDA is also aware that some of these street drug alternatives are being promoted as dietary supplements. FDA does not consider street drug alternatives to be dietary supplements because they are not intended to supplement the diet.

Id.

¹²⁷ *Id.*

¹²⁸ *Undetermined Quantities*, 145 F. Supp. 2d at 697.

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² *Id.*

masquerading potentially dangerous substances as legitimate dietary supplements.¹³³ The court noted that the definition of “dietary supplement” requires that the product be labeled as a dietary supplement.¹³⁴ Because many of the defendants’ products at issue were not labeled as dietary supplements, they could not be regarded as dietary supplements.¹³⁵ The court continued its analysis, however, to determine whether both these supplements, as well as those labeled as dietary supplements, fit within the definition of “drug.”¹³⁶ The court found that the term “drug” is defined by the FDCA as “articles (other than food) intended to affect the structure or any function of the body of man or other animals.”¹³⁷ Therefore, the court posited, to be a “drug,” the product must both actually and intentionally “affect the structure or any function of the body.”¹³⁸ In determining whether a product intends to have such an effect, the court emphasized that it is crucial to look at the claims and labeling made by the manufacturer.¹³⁹ The court asserted that the products in question did purport to affect the mind.¹⁴⁰ Concluding that the products intended “to affect the function and structure of the mind by elevating the psychological condition of users and therefore the products were ‘drugs,’”¹⁴¹ the court granted summary judgment to the government and ruled that these “street drug alternatives” were in fact new drugs in violation of the FDCA.¹⁴² The court recognized the danger of manufacturers attempting to classify products as dietary supplements.¹⁴³ Manufacturers would presumably want their products to be classified as dietary supplements, as in the present case, because of the relaxed regulations.¹⁴⁴ Fortunately, the court stepped in and disallowed the manufacturers from taking advantage of the DSHEA’s loose requirements.¹⁴⁵

¹³³ *Id.*

¹³⁴ *Undetermined Quantities*, 145 F. Supp. 2d at 698.

¹³⁵ *Id.*

¹³⁶ *See id.* In *United States v. Ten Cartons*, the court ruled that a particular product can qualify both as a “dietary supplement” and as a “drug.” 72 F.3d 285 (2d Cir. 1995).

¹³⁷ *Undetermined Quantities*, 145 F. Supp. 2d at 698 (citing 21 U.S.C. § 321(g)(1)(C)).

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ *Id.* at 700.

¹⁴² *Id.* at 692.

¹⁴³ *See Undetermined Quantities*, 145 F. Supp. 2d at 692.

¹⁴⁴ *Id.* at 696-97.

¹⁴⁵ *See id.* at 692.

This case demonstrates how courts can help to increase the FDA's current power over dietary supplements.¹⁴⁶ Interpretations can significantly affect regulatory policy,¹⁴⁷ and in deferring to the FDA regarding their more expansive interpretations, courts may be able to assist in expanding power over the dietary supplement industry. The court recognized the danger inherent in the defendants' attempt to circumvent anti-drug laws and the FDCA, and appears to have reached its conclusion in part to prevent these potential dangers.¹⁴⁸

In *Pharmanex*,¹⁴⁹ the plaintiff challenged the FDA's interpretation of 21 U.S.C. §321(ff)(3)(B)—part of the FDCA as amended by the DSHEA—which defines the term “dietary supplement.”¹⁵⁰ This statute states that the term “dietary supplement” does not include articles approved as new drugs.¹⁵¹ The FDA's argument was that the statutory language stating, “an article that is approved as a new drug,” applies to both finished products and active ingredients.¹⁵² After analyzing *Pharmanex*'s argument that the plain meaning cannot support such an interpretation, looking at the legislative history, and examining the policies of the DSHEA and the FDCA, the court concluded that the language was “sufficiently ambiguous to merit Chevron deference.”¹⁵³ The court, therefore, held that the FDA's interpretation as applying to both active ingredients and to finished products was not “arbitrary, capricious, or manifestly contrary to the statute.”¹⁵⁴

This holding allowed the FDA to prevent *Pharmanex* from

¹⁴⁶ See *id.*

¹⁴⁷ Daniel B. Rodriguez, *The Presumption of Reviewability: A Study in Canonical Construction and Its Consequences*, 45 VAND. L. REV. 743, 766-67 (1992) (stating that “[b]y developing and applying the canons of construction, courts can recover from the political branches a certain amount of power over the process of interpretation and, as a consequence, preserve their role in implementing and making regulatory policy”).

¹⁴⁸ See *Undetermined Quantities*, 145 F. Supp. 2d at 697.

¹⁴⁹ *Pharmanex v. Shalala*, 221 F.3d 1151 (10th Cir. 2000).

¹⁵⁰ *Id.* at 1153.

¹⁵¹ *Id.* at 1154.

¹⁵² *Id.*

¹⁵³ *Id.* The U.S. Supreme Court first articulated the Chevron deference test in *Chevron U.S.A., Inc. v. Nat'l Res. Def. Council*, 467 U.S. 837 (1984). The *Chevron* Court set forth the standard to review an agency's construction of a statute. *Id.* The first inquiry, in reviewing an agency's construction of a statute, is whether “Congress has directly spoken to the precise question at issue.” *Id.* If the answer to this inquiry is yes, then Congress's intent must prevail. *Id.* If, however, the answer to that inquiry is no, then the court must evaluate only whether “the agency's answer is based on a permissible construction of the statute” in order to allow the agency's interpretation to stand. *Id.*

¹⁵⁴ *Pharmanex*, 221 F.3d at 1160.

marketing its product as a dietary supplement without FDA approval because the supplement contained an active ingredient, mevinolin, which the FDA deemed to be a drug.¹⁵⁵ This case illustrates the realistic danger that dietary supplement manufacturers may formulate products that are categorized as dietary supplements, yet imitate drugs—allowing manufacturers to avoid the stricter regulatory framework that applies to drugs.¹⁵⁶ The FDA, as a result of this case, can look not only at finished products as a whole to determine their status as a dietary supplement, but also at individual ingredients within a product to see if any ingredients are properly characterized as drugs.¹⁵⁷ This decision gives the FDA the authority to prevent manufacturers from placing substances that would be characterized as drugs if taken alone into a formula of other ingredients to gain the status and looser regulations of dietary supplements.¹⁵⁸

III. THE ROLE OF THE STATES

A. *State attempts to increase control over dietary supplements within their borders*

Some states have enacted statutes to increase control over a certain dietary supplement—ephedrine.¹⁵⁹ This Comment addresses various legislative steps states have taken to protect their citizens from the harms presented by ephedrine. These legislative steps include

¹⁵⁵ *Id.* at 1153.

¹⁵⁶ See Termini, *supra* note 13, at 287.

¹⁵⁷ *Pharmanex*, 221 F.3d at 1153.

¹⁵⁸ *Id.*

¹⁵⁹ HHS Report, *supra* note 2, at 28. A description of ephedra was given in the HHS Report, and stated that

[e]phedrine alkaloids may be derived from plants (botanicals) or synthesized chemically. The botanical form is generally derived from *Ephedra sinica*, also known as ma huang, but it may come from other botanical sources. The most common uses for supplements containing botanical ephedrine alkaloids are for losing weight and boosting energy. . . . According to the FDA, between 1993, when it began a new system to collect dietary supplement adverse event reports, and March, 2000, it received 1,173 adverse event reports associated with the use of products that contain, or were suspected to contain, ephedrine alkaloids. Many of these reports involved serious events, including some deaths. . . . As of September 2000, FDA had not taken any action to regulate ephedrine alkaloids, although during this time period many States and industry groups have taken safety measures related to these supplements.

Id.

making ephedrine available only by prescription, prohibiting any individual who is not a pharmacist from dispensing ephedrine, and making it a criminal offense to sell ephedrine-containing products to minors or individuals under seventeen years of age.¹⁶⁰ For example, in Texas, a “person commits an offense if the person knowingly sells, transfers, or otherwise furnishes a product containing ephedrine to a person under 17 years of age,” with certain exceptions.¹⁶¹ Florida makes it necessary to obtain a prescription for products containing ephedrine.¹⁶² Tennessee, Louisiana, and Minnesota have statutes, which provide that ephedrine-based products “may be dispensed only upon prescription of a duly licensed practitioner authorized by the laws of the state to prescribe prescription drugs.”¹⁶³ Ohio mandates that consumers obtain ephedrine substances from pharmacists only, with certain exceptions, and that consumers must be at least eighteen years of age.¹⁶⁴ Virginia has a statute that makes it a Class 1 misdemeanor to “knowingly sell or otherwise distribute (without prescription), to a minor, any pill, capsule, or tablet containing any combination of caffeine and ephedrine sulfate.”¹⁶⁵ Nebraska statutory law imposes certain requirements for labeling on ephedrine containing food and dietary supplements, and requires that a

¹⁶⁰ See, e.g., TENN. CODE ANN. § 39-17-431 (1995); LA. REV. STAT. ANN. § 40:962.1 (West 1995); MINN. STAT. ANN. § 152.135 (West 1998); TEX. HEALTH & SAFETY CODE ANN. § 431.022 (Vernon 2001); OHIO REV. CODE ANN. §§ 3719.41 (West 1999), 3719.44(K)(1) (West 2002); VA. CODE ANN. §§ 18.2 – 248.5(B) (Michie 2000); NEB. REV. STAT. § 28-448 (2001).

¹⁶¹ TEX. HEALTH & SAFETY CODE ANN. § 431.022 (Vernon 2001). The prohibition made in this statute does not apply if:

- (1) the actor is: (A) a practitioner or other health care provider licensed by this state who has obtained, as required by law, consent to the treatment of the person to whom the product is furnished; or (B) the parent, guardian, or managing conservator of the person to whom the product is furnished; (2) the person to whom the product is furnished has had the disabilities of minority removed for general purposes under Chapter 31, Family Code; or (3) the product is a drug.

TEX. HEALTH & SAFETY CODE ANN. § 431.022 (Vernon 2001).

¹⁶² Jennifer Sardina, Note, *Misconceptions and Misleading Information Prevail—Less Regulation Does Not Mean Less Danger to Consumers: Dangerous Herbal Weight Loss Products*, 14 J.L. & HEALTH 107, 123-24 (2000).

¹⁶³ TENN. CODE ANN. § 39-17-431 (1995); LA. REV. STAT. ANN. § 40:962.1 (West 1995); MINN. STAT. ANN. § 152.135 (West 1998).

¹⁶⁴ Kaiser, *supra* note 15, at 1269; see also OHIO REV. CODE ANN. §§ 3719.41 (West 1999), 3719.44(K)(1) (West 2002). Ohio state law classifies ephedrine as a Schedule V drug, which requires a prescription, except as provided by § 3719.44(K)(1). OHIO REV. CODE ANN. § 3719.41 (West 1999). Section 3719.44(K)(1) lists specific products that are not to be considered schedule V drugs, such as amesec capsules, Primatene “M” and “P” formula tablets, and Vatrolol nose drops. *Id.*

¹⁶⁵ VA. CODE ANN. §§ 18.2 – 248.5(B) (Michie 2000).

“prominent label securely affixed to each package” include certain specific information such as the amount of ephedrine in milligrams and a maximum dosage.¹⁶⁶ Importantly, the statute also requires that this label contain a specific warning.¹⁶⁷

B. Preemption

In *Jones v. Rath Packing Co.*,¹⁶⁸ the United States Supreme Court described preemption law as occurring:

when Congress has “unmistakably . . . ordained,” that its enactments alone are to regulate a part of commerce, state laws regulating that aspect of commerce must fall. This result is compelled whether Congress’ command is explicitly stated in the statute’s language or implicitly contained in its structure and purpose.¹⁶⁹

Therefore, preemption may be either express or implied.¹⁷⁰ One type

¹⁶⁶ NEB. REV. STAT. § 28-448 (2001).

¹⁶⁷ *Id.* The warning must state:

WARNING: Not intended for use by anyone under the age of 18. Do not use this product if you are pregnant or nursing. Consult a health care professional before using this product if you have heart disease, thyroid disease, diabetes, high blood pressure, depression or other psychiatric condition, glaucoma, difficulty in urinating, prostate enlargement, or seizure disorder, if you are using a monoamine oxidase inhibitor (MAOI) or any other prescription drug, or if you are using an over-the-counter drug containing ephedrine, pseudoephedrine, or phenylpropanolamine (ingredients found in certain allergy, asthma, cough/cold, and weight control products). Discontinue use and call a health care professional immediately if you experience rapid heartbeat, dizziness, severe headache, shortness of breath, or other similar symptoms.

Id.

¹⁶⁸ 430 U.S. 519 (1977).

¹⁶⁹ *Id.* at 525.

¹⁷⁰ *Id.* A case on the October 2002 United States Supreme Court docket was expected to clarify the implied preemption doctrine. Binh Ha Hong, Sprietsma, *Rex v. Mercury Marine*, at <http://www.medill.nwu.edu/cases.srch?-database=docket&-layout=lasso&-response=/docket/detail.srch&-search&-docket=01-0706> (last visited Oct. 21, 2002) (on file with author). The case, *Sprietsma v. Mercury Maine*, was decided on December 3, 2002. 123 S. Ct. 518 (2002). The question at issue was “whether a state common-law tort action seeking damages from the manufacturer of an out-board motor is [preempted] either by the enactment of the Federal Boat Safety Act of 1971 [FBSA]” or by a 1990 Secretary of Transportation decision “not to promulgate a regulation requiring propeller guards on motor boats.” *Id.* at 522. The United States Supreme Court rejected the argument that “a need for regulatory uniformity mandated a finding of federal preemption.” Trial Lawyers for Public Justice, *Supreme Court Holds that Injury Victims May Sue Boat Engine Manufacturers for Failure to Install Propeller Guards*, at http://www.tlpj.org/pressreleases/sprietsma_12-03-02.htm (last visited Jan. 26, 2003) (on file with author). The Court, noting that the express preemption clause in the FBSA did not include common-law claims,

of implied preemption is field preemption.¹⁷¹ Field preemption exists where the federal regulation in an area is “so pervasive as to make reasonable the inference that Congress left no room for the states to supplement it.”¹⁷² The second type of implied pre-emption is conflict pre-emption.¹⁷³ Conflict pre-emption is present when a state’s law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”¹⁷⁴

The DSHEA does not contain a general preemption clause, and therefore, there is no express preemption.¹⁷⁵ When analyzing the purposes of the enactment of the DSHEA, however, it is clear that the federal government wanted to make dietary supplements more accessible to consumers, and that Congress wanted the FDA to have the power to act against dangerous dietary supplements.¹⁷⁶ State action that hinders consumers’ ability to access these supplements may be in opposition to the congressional objectives of availability, and accordingly, it may be possible that these actions are subject to preemption.¹⁷⁷

found that it “made sense for Congress not to [preempt] common-law claims, which necessarily perform an important remedial role in compensating accident victims.” Binh Ha Hong, *Sprietsma Rex v. Mercury Maine*, at <http://journalism.medill.northwestern.edu/docket/action.lasso?-database=docket&-layout=lasso&-response=%2Fdocket%2Fdetail.srch&-recordID=33049&-search> (last visited Jan. 26, 2003) (on file with author).

¹⁷¹ *Gade v. Nat’l Solid Waste Mgmt. Ass’n*, 505 U.S. 88 (1992).

¹⁷² *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

¹⁷³ *Gade*, 505 U.S. 88.

¹⁷⁴ *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963).

¹⁷⁵ Pinco & Rubin, *Ambiguities of the Dietary Supplement Health and Education Act of 1994*, 51 FOOD & DRUG L. J. 383, 397 (1996).

¹⁷⁶ *Id.*; see also Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, sec. 2, 108 Stat. 4325, 4326 (Congressional Findings).

¹⁷⁷ Pinco & Rubin, *supra* note 175, at 397; see also Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, sec. 2, 108 Stat. 4325, 4326 (Congressional Findings). It is important to note that the federal government plans to mandate its own particular warning labels for ephedra products, thereby creating an even stronger preemption argument against state warning label legislation. *Ephedra: Government Urges Strongest Possible Warning Labels for Ephedra Products*, 6 No. 4 ANDREWS DRUG RECALL LITIG. REP. 8 (Nov. 2002). “Following a flurry of lawsuits against manufacturers of ephedra-based diet remedies and calls by consumer groups for tighter regulation of such products, the [HHS] has ordered the [FDA] to generate the ‘strongest possible mandatory warning label for ephedra products.’” *Id.* “Ephedrine, an adrenaline-like neurostimulator, is the active ingredient in ephedra.” *Ephedra: Legal Troubles Mount for Maker of Ephedra Supplements*, 18 No. 5 ANDREWS PHARMACEUTICAL LITIG. REP. 7 (Sept. 2002).

At present, there appear to be no federal regulations in direct conflict with the state provisions discussed in Part III.A. There have been, however, attempts by the federal government to regulate ephedrine products. See, e.g., Dietary Supplements

C. Commerce Clause

The Commerce Clause may prohibit state regulation.¹⁷⁸ States, under their police powers, have the power to regulate intrastate commerce, even in a manner that will affect interstate commerce.¹⁷⁹ State legislation in this area must not, however, be protectionist in nature.¹⁸⁰ When state legislation is aimed against interstate commerce, the court will apply a two-part test to determine whether

Containing Ephedrine Alkaloids from Department of Health and Human Services, Food and Drug Administration, 65 Fed. Reg. 17474 (withdrawal in part April 3, 2000). On April 3, 2000, the FDA announced that it was withdrawing specific provisions of its proposed June 4, 1997 rule regarding dietary supplements that contain ephedrine alkaloids. *Id.* This action was prompted by the Government Accounting Office's (GAO) concerns regarding the FDA's basis for establishing the proposed dietary ingredient level and the limit on duration of use. *Id.* The June 4, 1997 FDA proposed rule sought to establish when an ephedrine alkaloid containing a dietary supplement would be deemed adulterated. *Id.* The proposed FDA regulations were initiated "in response to reports of serious illnesses and injuries, including a number of deaths, associated with the use of dietary supplement products containing ephedrine alkaloids and the agency's investigations and assessment of these illnesses and injuries." *Id.* The GAO agreed with the FDA that attention and action against dietary supplements containing ephedrine alkaloids was appropriate. *Id.* The GAO, however, "expressed concerns about the use of the reported adverse events in supporting the proposed dosing level and duration of use limit, and concluded that the agency needed additional evidence to support these restrictions." *Id.* The "GAO recommended that FDA 'provide stronger evidence on the relationship between the intake of dietary supplements containing ephedrine alkaloids and the occurrence of adverse reactions that support the proposed dosing level and duration of use limits.' In addition, GAO recommended that FDA improve the transparency of its cost-benefit analysis in its final rulemaking." *Id.* These conclusions, in addition to other comments on the proposed rules, prompted the FDA to announce that certain aspects of the proposed rule should be reassessed. *Id.* Therefore, the FDA withdrew the provisions of the proposed rule regarding the ingredient level and duration of use limits. *Id.* The FDA plans to reevaluate whether ingredient level and/or duration of use limits are appropriate, and will use public input to assist in these determinations. *Id.* The FDA did not withdraw the provisions concerning the "prohibition on the use of ingredients with stimulant effects with dietary supplements containing ephedrine alkaloids (§111.100(d)) and the proposed warning statement (§111.100(g))." *Id.* The FDA did not at the time of this announcement conclude whether it will finalize these two provisions.

¹⁷⁸ U.S. CONST. art. I, § 8, cl. 3 (Commerce Clause). The Commerce Clause states that Congress has the power "to regulate commerce with foreign nations, and among the several States, and with the Indian tribes." *Id.*

¹⁷⁹ See *United Nuclear Corp. v. Gen. Atomic Co.*, 629 P.2d 231, 270 (N.M. 1980) (citing *Merrill Lynch, Pierce, Fenner & Smith v. Ware*, 414 U.S. 117, 140 (1973)); see also *Cities Serv. Co. v. Peerless Co.*, 340 U.S. 179, 186 (1950); *Southern Pac. Co. v. Arizona*, 325 U.S. 761, 766-67 (1945); *K.S.B. Tech. Sales v. North Jersey*, 75 N.J. 272, 381 A.2d 774 (N.J. 1977)).

¹⁸⁰ *Philadelphia v. New Jersey*, 437 U.S. 617, 626-27 (1978). The Court stated that if a state enacted a "law that overtly blocks the flow of interstate commerce at a State's borders," it would clearly be an example of economic protectionism. *Id.* at 624.

such legislation may be upheld.¹⁸¹ This test requires the court first to determine whether regulation's "effects on interstate commerce are only incidental."¹⁸² If the court determines that the effects are only incidental, the regulation will be valid as long as the burden it creates on interstate commerce is not "clearly excessive in relation to the putative local benefits."¹⁸³

State imposition of prescription status for particular products may potentially create a burden on interstate commerce. For example, granting products containing ephedrine prescription status would restrict the ability of manufacturers to legally sell those products to certain entities.¹⁸⁴ A state's interest in protecting the health of its citizens is a legitimate state interest.¹⁸⁵ If a court finds the burdens imposed on interstate commerce are more than incidental, it will disallow the regulation.¹⁸⁶ Conversely, the court applies the two-

¹⁸¹ See On petition for Review of Opinion 475 of the Advisory Committee on Professional Ethics and DR 2102(C), 89 N.J. 74, 91,444 A.2d 1092, 1100 (N.J. 1982) (upholding "regulations whenever (1) they are rationally to legitimate state concerns, and (2) the resulting discrimination is outweighed by the state interest in enforcing the regulation").

¹⁸² *United Nuclear*, 629 P.2d 270 (citing *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970)).

¹⁸³ *Id.*

¹⁸⁴ For example, in New Jersey,

[n]o person, who is not a registered pharmacist or an apprentice employed in a pharmacy or drug store under the immediate personal supervision of a registered pharmacist, or who is not a duly licensed physician, dentist, veterinarian or other person licensed to prescribe drugs shall sell, dispense, or furnish any drug the label of which by law or regulations of the State Department of Health or Federal Food and Drug Administration is required to bear a statement that it is to be dispensed only by or on the prescription of a physician, dentist, veterinarian or other person licensed to prescribe drugs, or words of similar or like import; nor shall any registered pharmacist, or any apprentice employed in a pharmacy or drug store under the immediate personal supervision of a registered pharmacist, sell, dispense, or furnish any such drug except upon the prescription of a duly licensed physician, dentist, veterinarian or other person licensed to prescribe such drug.

.....

The provisions of this act shall not apply to the sale of any such drug by a manufacturer or wholesaler or pharmacy to each other or to or by a physician, dentist, veterinarian or other person licensed to prescribe such drug in their professional practice.

N.J. STAT. ANN. § 45:14-26.1 (West 1995).

¹⁸⁵ See *Hughes v. Oklahoma*, 441 U.S. 322, 337 (1979) ("We consider the States' interests in conservation and protection of wild animals as legitimate local purposes similar to the States' interests in protecting the health and safety of their citizens.").

¹⁸⁶ See *United Nuclear*, 629 P.2d at 270 (citing *Pike*, 397 U.S. at 142).

step balancing test if the burden is only incidental.¹⁸⁷

Additionally, other state actions, such as Nebraska's statute that requires specific warnings be affixed to labels, could be Commerce Clause violations.¹⁸⁸ Separate labeling requirements imposed by individual states may effect interstate commerce in a way that is not merely incidental. It potentially could be too costly and burdensome for manufacturers to meet each separate state's labeling requirements. Even if the court finds the burdens incidental, the balancing test must be applied and the possibility exists that the burdens would be found to outweigh the benefits of such regulations.¹⁸⁹

As addressed above, state regulation of dietary supplements may potentially create many problems.¹⁹⁰ There may be preemption issues as well as possible Commerce Clause violations.¹⁹¹ Inconsistent standards across the country can interfere with a manufacturer's ability to comply with all of them.

IV. ALTERNATIVES TO THE CURRENT DSHEA METHOD OF REGULATION

The main problem with the current regulatory system is that dietary supplements that are not approved prior to marketing are readily available to consumers of all ages, despite the fact that they pose potential health risks. Commentators have proposed numerous solutions to this problem, ranging from congressional action to stricter enforcement of the FDA's goals and statutory regime.¹⁹² This section will address the strengths and weaknesses of some of those proposals, and will evaluate other possible solutions not yet proposed. Additionally, the FDA and other organizations are presently taking actions to fill some of the gaps that exist in dietary supplement regulation; this section will address those actions and assess their sufficiency.

A. *Leaving the Present Scheme Unaltered*

One possibility is to leave the scheme as it presently stands, thereby encouraging states to continue to enact statutory law restricting the availability of certain dietary supplements within their

¹⁸⁷ See *id.*

¹⁸⁸ See NEB. REV. STAT. § 28-448 (2001).

¹⁸⁹ See *United Nuclear*, 629 P.2d at 270.

¹⁹⁰ See *supra* PART III.B-C.

¹⁹¹ See *id.*

¹⁹² See, e.g., *infra* notes 196, 207, and 218.

borders, if they desire a stricter scheme. As of now, state action has been centered around restriction of, or total bans on, ephedrine and ephedrine products.¹⁹³ Greater state regulation of dietary supplements, however, threatens to impinge on at least one of Congress's goals in enacting the DSHEA—expanding availability.¹⁹⁴ States that choose to increase regulation in a manner that frustrates Congressional goals may face a preemption challenge.¹⁹⁵

B. Pre-market Approval

A second possible solution is to require pre-market approval of dietary supplements by requiring all manufacturers to submit evidence of the safety and efficacy of the product to the FDA prior to introducing it to the market, regardless of whether it has a “new ingredient.”¹⁹⁶ This solution would require legislative changes to the present statute.¹⁹⁷ This approach ensures the safety of dietary supplements by requiring proof of safety before marketing.¹⁹⁸ The FDA would then have the opportunity to reject potentially dangerous supplements before consumers can ingest them, and manufacturers who know their products are unsafe would likely be reluctant to spend time and money to attempt to obtain FDA approval when such approval is unlikely.¹⁹⁹ This approach, however, may run in direct opposition to the congressional goal of availability by imposing a regulatory barrier prior to marketing.²⁰⁰

Requiring dietary supplement manufacturers to test products prior to marketing may create economic disincentives that discourage manufacturers from producing supplements.²⁰¹ The testing and approval process is expensive, and FDA approval is a time consuming

¹⁹³ See generally PART III.A.

¹⁹⁴ See Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, sec. 2, 108 Stat. 4325, 4326 (Congressional Findings).

¹⁹⁵ See PART III.B.

¹⁹⁶ See Jeffrey A. Crossman, Note, “Sparing Cain: Executive Clemency in Capital Cases”: Mark McGwire Does It, So Why Can't I? High School Student Use of Dietary Supplements and the Failure of the DSHEA, 28 CAP. U. L. REV. 617, 656 (2000) (suggesting that the FDA should have the power to subject dietary supplements to the same standards and requirements as are imposed on foods and drugs). For an explanation of these requirements, see Crossman, *supra*, at 643-44.

¹⁹⁷ See generally Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended in scattered sections of 21 U.S.C.).

¹⁹⁸ See Crossman, *supra* note 196, at 643-44, 656.

¹⁹⁹ See *id.*

²⁰⁰ See Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, sec. 2, 108 Stat. 4325, 4326 (Congressional Findings).

²⁰¹ See Kaiser, *supra* note 15, at 1260.

process.²⁰² Drug manufacturers are economically capable of complying with pre-market clearance requirements because by patenting their drug they can secure income for profits and research.²⁰³ Herbal supplement manufacturers do not have the economic protection that a patenting system would afford, and accordingly, do not have the same financial capabilities to comply with pre-market clearance requirements as do drug manufacturers.²⁰⁴ If a system of patenting could be fashioned for dietary supplements, it would give manufacturers an opportunity to recover the funds expended in initial testing for safety.²⁰⁵

C. Creating “New” Ingredient Lists

One means by which the FDA could regain some control over what enters the market involves compiling a list of dietary ingredients that are not “new” within the relevant definition of the word. It arguably should not be the manufacturer’s responsibility to determine whether its product contains a “new” ingredient, because the manufacturer has an interest in determining that the ingredients in their supplement are not in fact “new.”²⁰⁶ The FDA could compile this list and include all ingredients that the FDA would not consider “new,” thereby eliminating the manufacturer’s power to determine whether or not its product contains a “new” ingredient. The FDA, however, may be better served expending its resources trying to find dangerous supplements, rather than by relieving manufacturers from the burden of making this determination.

D. Increasing Manufacturer Responsibilities

An alternative solution involves a change in the reporting system that requires all dietary supplement manufacturers report to the FDA any side effects or adverse events linked to the use of a supplement.²⁰⁷ If manufacturers informed the FDA of side effects and adverse events,

²⁰² *Id.* Manufacturers can expect to spend \$2,000,000 on the process, and subsequently will have to wait two to six years to gain approval from the FDA. *Id.*

²⁰³ Sonia Sequeira, *Drug Rules Under Spotlight at WTO*, at <http://www.cnn.com/2001/WORLD/europe/11/08/wto.trips/> (Nov. 8, 2001) (on file with author).

²⁰⁴ Zuk, *supra* note 119, at 38.

²⁰⁵ Schindler, *supra* note 14, at 279-80.

²⁰⁶ See DSHEA Website, *supra* note 26 (describing the additional requirements when introducing a “new dietary ingredient” to the market).

²⁰⁷ Robert Hager, *Unsafe Supplements?*, at <http://www.msnbc.com/news/557618.asp> (Apr. 10, 2001) (on file with author). In Appendix C of the HHS Report, the FDA noted that it is “evaluating whether or not such a reporting could be required under current law.” HHS Report, *supra* note 2, at 41.

the FDA could evaluate the risks and alert consumers when necessary.²⁰⁸ This procedure is already required of pharmaceutical manufacturers; adverse events for prescription drugs and for some over-the-counter drugs must be reported.²⁰⁹ This would allow the FDA access to more information, and accordingly, would help the FDA inform consumers and act against unsafe supplements.²¹⁰ It may be difficult, however, for the FDA to ensure manufacturers are complying with this reporting requirement.²¹¹

Alternatively, the FDA could compel manufacturers to register the dietary supplements they place on the market.²¹² The implementation of such a registration requirement would necessitate a legislative change in the DSHEA, and the commitment of additional resources.²¹³ Presently, the FDA has difficulty determining what ingredients are in each supplement,²¹⁴ therefore, along with this registration, the manufacturer should be compelled to provide a list of all of the ingredients in the supplement.²¹⁵ This could assist the FDA in following up on adverse reports. When the FDA receives adverse reports, it would have the manufacturer's name and contact information, along with the supplements it sells and the ingredients in each supplement.²¹⁶ A registration system would give the FDA sufficient information to act quickly on adverse event reports.²¹⁷

E. Germany's Approval System

At least one commentator has suggested establishing a system similar to that used in Germany.²¹⁸ In Germany, prior to marketing an herbal remedy, safety and "reasonable proof" of efficacy of the

²⁰⁸ *Id.*

²⁰⁹ HHS Report, *supra* note 2, at 19.

²¹⁰ *See id.* (suggesting a requirement that manufacturers report adverse events in order to "facilitate greater detection of adverse events").

²¹¹ *Id.* The HHS report goes on to suggest the FDA should convince manufacturers of the importance and adequacy of such a system in order to promote compliance. *Id.*

²¹² *Id.*

²¹³ *Id.* at 25.

²¹⁴ EXECUTIVE BRIEFING, *supra* note 68.

²¹⁵ Hager, *supra* note 207.

²¹⁶ HHS Report, *supra* note 2, at 20-21.

²¹⁷ *See id.* at 20 (noting that requiring "dietary supplement manufacturers to register their products with the FDA" would "improve the quality and quantity of . . . product information" and therefore "generate stronger signals of public health concerns").

²¹⁸ Stenson, *supra* note 4.

product must be established.²¹⁹ Germany has an independent panel of medical experts with the responsibility of reviewing different herbal remedies and evaluating their efficacy and safety.²²⁰ This panel also has the responsibility of creating monographs for some of these herbal remedies.²²¹ A product meets its burden of proof when the panel gives an indication in a monograph.²²² This standard is not as stringent as the FDA's standard for the entrance of drugs and food additives into the market.²²³ It does, however, impose some entrance requirements prior to marketing, unlike the current DSHEA regime.²²⁴

F. Changes in Enforcement

Yet another improvement to the current system involves a change in enforcement. As mentioned in Part I, the FDA often requests samples from manufacturers when investigating an adverse event report, and more often than not, manufacturers fail to comply.²²⁵ FDA sanctions for noncompliance would possibly enable the FDA to follow up on adverse event reports more efficiently and thoroughly. This method would also give the FDA a greater ability to warn consumers of potentially harmful supplements on the market. Without imposing sanctions, the trend of manufacturers failing to comply with these requests may be difficult to change.

G. Additional Research

Additional safety research on dietary supplements would likely help to improve the current system.²²⁶ If the FDA conducted its own studies, or funded independent studies, the results would increase the FDA's access to information.²²⁷ This information could be used to "adequately assess signals generated by the adverse event reporting

²¹⁹ Tolstoi, *supra* note 52.

²²⁰ Stenson, *supra* note 4; *see also* Tolstoi, *supra* note 52.

²²¹ Tolstoi, *supra* note 52. "Monographs are point papers on particular products or ingredients that contain safety and efficacy information." HHS Report, *supra* note 2, at 22.

²²² Tolstoi, *supra* note 52.

²²³ *Id.*

²²⁴ *Id.*

²²⁵ EXECUTIVE BRIEFING, *supra* note 68.

²²⁶ HHS Report, *supra* note 2, at 22. The HHS Report recommends a collaboration with the NIH in "setting a research agenda addressing safety issues" in order to "increase the quality and quantity of clinical data" in order to "obtain vital information to adequately assess signals generated by the adverse event reporting system." *Id.*

²²⁷ *Id.*

system.”²²⁸ There are currently some federally funded studies on dietary supplements in progress.²²⁹ The process of researching and analyzing results, however, is a time consuming and costly project, and it may not be feasible for the FDA or the government to fund this alone. Commentators have suggested the creation of a compulsory system where supplement manufacturers contribute money, based on their market share, to a fund to pay for clinical trials.²³⁰ This would benefit consumers because studies would be conducted, and would benefit manufacturers because they would not carry the burden of paying for individual studies.²³¹ Requiring manufacturers to contribute money for use in clinical trials, however, may discourage manufacturers from producing these products.²³² Without a patent process for herbal supplements, these research costs would be imposed upon manufacturers without providing economic safeguards to make such investments less financially risky.²³³

The DSHEA originally allotted \$5 million annually for the ODS; however, the ODS is consistently underfunded, receiving approximately one-fifth of the allotted amount.²³⁴ The absence of sufficient funding has prevented the ODS from being able to address individual inquiries and has limited its research abilities.²³⁵ One commentator argues that the ODS can increase consumer protection by distributing information, but only if the ODS is given adequate funding and staffing.²³⁶ If the ODS were adequately funded, it would have the ability to obtain information on the beneficial and dangerous aspects of dietary supplements and inform consumers of these aspects.²³⁷

Although research on different fronts is arguably helpful in attaining supplement information, there is a sound argument that the manufacturer, and not the taxpayer, should be responsible for all of the costs of research because it is the manufacturer who ultimately profits from the sale of these supplements. The research and evaluation of the results would provide vital information regarding

²²⁸ *Id.*

²²⁹ Stenson, *supra* note 4.

²³⁰ Termini, *supra* note 13, at 286.

²³¹ *Id.*

²³² See *supra* notes 202-05.

²³³ *Id.*

²³⁴ Sloane, *supra* note 9, at 337.

²³⁵ *Id.*

²³⁶ *Id.* at 339.

²³⁷ *Id.*

these dietary supplements.²³⁸ If there is sufficient information to educate manufacturers, the FDA, and consumers, there may be no need to create a stricter scheme for dietary supplements.²³⁹ Part of the problem is that not enough is known about the dangers of these products.²⁴⁰ If such dangers were identified, the FDA would arguably be better equipped to determine whether a dietary supplement is “adulterated,” and could then react within their present DSHEA powers.²⁴¹

H. Current Efforts

One goal of the Ten Year Plan involves establishing GMPs for dietary supplements.²⁴² The FDA is working to establish GMPs for dietary supplements, which will help to both standardize dietary supplements and improve their quality.²⁴³ HHS has recommended the creation of GMPs to help prevent contamination of supplements.²⁴⁴ GMPs would lessen some of the dangers of dietary supplements, such as contamination and differences in strength.²⁴⁵ The GMPs alone, however, would not be an effective remedy because they do not test the safety of the supplement.²⁴⁶ Supplements may have inherently dangerous side effects or interactions with other drugs, and GMPs would not address this problem.²⁴⁷ Yet, GMPs would be a valuable tool, especially if used in combination with other methods aimed at the inherent dangers of supplements.

A national certification system designed for dietary supplements is another alternative.²⁴⁸ The United States Pharmacopeia (“USP”) is initiating a pilot program for such a certification system.²⁴⁹ The USP presently sets standards for prescription and over-the-counter

²³⁸ See HHS Report, *supra* note 2, at 22-23.

²³⁹ See *id.* at 22 (noting that “[p]erhaps the largest problem the FDA faces is the paucity of scientifically robust research on dietary supplements that is available in the event that a particular supplement product or ingredient generates a signal of possible public health concern”).

²⁴⁰ *Id.*

²⁴¹ See PART I, for a discussion of the FDA’s present DSHEA powers.

²⁴² TEN YEAR PLAN, *supra* note 107. Section I.B. states that a CFSAN goal is to publish good manufacturing practices, and once issued, to “establish an outreach program to small business manufacturers and an ongoing inspection program.” *Id.*

²⁴³ Stenson, *supra* note 4.

²⁴⁴ Hager, *supra* note 207.

²⁴⁵ See Stenson, *supra* note 4.

²⁴⁶ See *id.*

²⁴⁷ For examples of such dangers, see *supra* note 46.

²⁴⁸ Stenson, *supra* note 4.

²⁴⁹ *Id.*

medications.²⁵⁰ Once the national certification system is established for dietary supplements, manufacturers that meet the necessary requirements would be allowed to place a certification mark on their product labels.²⁵¹ This certification mark would be a sign to the consumer that the products are of a particular quality and that they contain only the ingredients on the label.²⁵² This process would help consumers choose dietary supplements, however, as the HHS Report notes, this system would have limited capability to protect consumers because “it would be voluntary; it would not address botanicals’ health claims or safety issues, and United States Pharmacopeia would not enforce adherence to these standards.”²⁵³

I. Broadening the FDA’s Power to Act Against Supplements

Some argue that the FDA’s power should be broadened in the area of dietary supplement regulation.²⁵⁴ One suggestion is that the FDA could better regulate in this area if given wider powers once a health threat is discovered, without altering the present scheme to require pre-market clearance.²⁵⁵ Under this scheme, once a health threat is found, the FDA should have the power to force ingredient changes, or pull the product from the market completely.²⁵⁶ This differs from the present regulatory scheme, which requires the FDA to bear the burden of proving that the product presents “a significant or unreasonable risk of illness or injury” prior to taking action against it.²⁵⁷

Another suggestion is to empower the FDA to act against an entire supplement class, broadening its current powers which only permit the FDA to act against individual products.²⁵⁸ These broader powers would be highly advantageous because the FDA would have the ability to act simultaneously against many supplements that pose the same risk, instead of going after one at a time.²⁵⁹

²⁵⁰ *Id.*

²⁵¹ *Id.*

²⁵² *Id.*

²⁵³ HHS Report, *supra* note 2, at 23.

²⁵⁴ *See, e.g.*, Kaiser, *supra* note 15, at 1273.

²⁵⁵ *Id.*

²⁵⁶ *Id.*

²⁵⁷ 21 U.S.C. § 342 (f) (1) (A) (2002).

²⁵⁸ Kaiser, *supra* note 15, at 1273.

²⁵⁹ *See id.*

J. Burden Shifting Through Legislative Change

A different proposal is to treat dietary supplements as food additives.²⁶⁰ This would require a change in the law, and would broaden the FDA's power by eliminating its burden of proving a product unsafe.²⁶¹ With this method of regulation, if the FDA determines that a supplement is unsafe, the manufacturer would then bear the burden of proving that the product is safe.²⁶² To gain admission to the market, this system would require proof of safety, but not efficacy.²⁶³ A similar approach would be to change the statute to require manufacturers to "substantiate the safety" of its products.²⁶⁴ This would be helpful to the FDA in its enforcement efforts because the burden of proving a product's safety is shifted to the manufacturer.²⁶⁵ These processes would help protect consumers from dangerous products, however, any proposed change of the statute giving the FDA greater power would possibly face lobby efforts from the powerful supplement industry.²⁶⁶

K. Granting Prescription Status to Particular Supplements

A final solution is to give certain dietary supplements prescription status, as some states are doing with ephedrine.²⁶⁷ Product classes that pose a serious threat when taken as directed, that may be improperly used, or that have serious interactions with medications, could be given prescription status.²⁶⁸ Granting these

²⁶⁰ Schindler, *supra* note 14, at 280.

²⁶¹ *Id.*

²⁶² *Id.*

²⁶³ *Id.*

²⁶⁴ Gilhooley, *supra* note 33, at 128. Professor Gilhooley notes that "[a] major weakness in the DSHEA is that it does not impose on all dietary supplements the burden and obligation to affirmatively substantiate their safety." *Id.* Professor Gilhooley explains that "[i]f manufacturers had to substantiate safety, they would have to perform tests, in accordance with scientific standards, to determine risks and establish a safe level. They would have a responsibility to follow-up on adverse reaction reports, and undertake whatever testing or changes scientists would consider necessary to assure safety." *Id.* at 119.

²⁶⁵ *See id.* at 128.

²⁶⁶ *See* Colloton, *supra* note 27, at 496-97 (noting the enormity of the dietary supplement industry, and stating that "[p]rior to the DSHEA, the dietary supplement industry and consumers struggled for decades with the U.S. Food and Drug Administration ("FDA") in an effort to increase public access to both supplements and information regarding the benefits of supplements").

²⁶⁷ *See, e.g.*, TENN. CODE ANN. § 39-17-431 (1995); LA. REV. STAT. ANN. § 40:962.1 (West 1995); MINN. STAT. ANN. § 152.135 (West 1998).

²⁶⁸ *See, e.g.*, PART III.A. (discussing how some states have made ephedrine available only by prescription).

products prescription status would provide a greater opportunity for consumer education through the prescribing physician, the pharmacist, and the labeling and information provided by the pharmacy.²⁶⁹ When evaluating whether a supplement is adulterated, and therefore whether the FDA has authority to take action against it, the FDA looks at the safety when taken as the label directs, or in the absence of such directions, under normal use.²⁷⁰ Perhaps the FDA, however, should look at the health threat when taken in excess of the specific dosage directions to determine whether additional steps should be taken and whether prescription status should be granted.²⁷¹ This approach might make it more difficult for consumers to access certain supplements, and accordingly would run counter to one of the purposes of the DSHEA—greater availability.²⁷² Requiring a consumer to obtain a prescription, however, is not as restrictive as completely removing a product from the market. Additionally, imposing prescription status when necessary would further Congress's goal of preventing the sale of dangerous supplements.²⁷³

L. Proposed Solution

The solution best suited for this situation would appear to be a combination of changes designed to improve the safety of dietary supplements without unduly hindering Congress's goal of increasing the availability of dietary supplements.²⁷⁴ To achieve this balance, three regulatory changes must be made. First, Congress must shift the burden of proving a product's safety onto the manufacturer, even if pre-market approval is not required.²⁷⁵ When the FDA wants to take

²⁶⁹ For example, a pharmacist may be required to counsel patients on their prescription medications. See, e.g., Arkansas State Board of Pharmacy, *Consumers – Did You Know?*, at <http://www.state.ar.us/asbp/public.html> (last visited Oct. 22, 2002) (on file with author). This website states that the pharmacist “should counsel you regarding your prescription,” “should tell you about any side effects of the drug or any interaction that it might have with other drugs you are taking,” and “should give you instructions regarding when you should take the medicine and if it should be taken with food.” *Id.*

²⁷⁰ DSHEA Website, *supra* note 26.

²⁷¹ Jennifer Spokes, Note, *Confusion in Dietary Supplement Regulation: The Sports Product Irony*, 77 B.U. L. REV. 181 (1997) (pointing out that products that are dangerous in excess of the dosage directions are excluded from the definition of adulteration).

²⁷² See Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, sec. 2, 108 Stat. 4325, 4326 (Congressional Findings).

²⁷³ *Id.*

²⁷⁴ Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, sec. 2, 108 Stat. 4325, 4326 (Congressional Findings).

²⁷⁵ Schindler, *supra* note 14, at 280; see also Gilhooley, *supra* note 33, at 128.

action against a product, it should not first bear the burden of proving it unsafe; instead, the manufacturer should bear the burden of proving that the product at issue is safe.²⁷⁶ The FDA should then examine the data on which the manufacturer relies, and take action if the data is insufficient to demonstrate the product's safety. Second, Congress should amend the DSHEA to grant the FDA power to act against a dietary supplement class, as opposed to against each individual dietary supplement.²⁷⁷ If the FDA is acting against a class of products, it may be appropriate for manufacturers to prove product safety as a class, and divide researching and other costs incurred in making these proofs. Third, supplements that are found to be dangerous in doses larger than that suggested on the label, if these higher doses are likely to be used despite warnings, should be granted prescription status on the federal level.²⁷⁸ Prescription status would help curb dangers of these products without completely withdrawing them from the market.

These regulatory changes would increase the FDA's ability to police the dietary supplement market, and would only interfere with the sale of potentially dangerous supplements. This combination approach does not unduly limit the availability of dietary supplements, while still protecting consumers.

The FDA's present research efforts, along with research efforts of other organizations such as the NIEHS and the ODS, should be continued.²⁷⁹ Research can significantly assist the FDA in determining which dietary supplements are potential risks, thereby enabling the FDA to take appropriate action.²⁸⁰ The ODS should receive funding equivalent to, or greater than, the original amount granted in the DSHEA.²⁸¹ GMPs and USPs are valuable in ensuring the quality, purity and strength of dietary supplements, and should be established.²⁸²

Research, GMPs, and USPs, combined with the suggested regulatory modifications, will help ensure that products on the market are not contaminated and are not misbranded. This will also provide the FDA with a greater opportunity for questioning, limiting

²⁷⁶ See Gilhooley, *supra* note 33, at 128.

²⁷⁷ Kaiser, *supra* note 15, at 1273.

²⁷⁸ As discussed previously, some states are already doing this with ephedrine. See, e.g., TENN. CODE ANN. § 39-17-431 (1995); LA. REV. STAT. ANN. § 40:962.1 (West 1995); MINN. STAT. ANN. § 152.135 (West 1998).

²⁷⁹ See, e.g., PART I.D.

²⁸⁰ HHS Report, *supra* note 2, at 22.

²⁸¹ See Sloane, *supra* note 9, at 337.

²⁸² FDA Overview Website, *supra* note 49; see also Stenson, *supra* note 4.

and removing dangerous products from the market.

CONCLUSION

Dietary supplements are freely available to consumers, and are placed on the market with minimal regulation.²⁸³ Approximately sixty percent of Americans take dietary supplements.²⁸⁴ Some dietary supplements have potentially dangerous side effects, and have been shown to interact with prescription medications.²⁸⁵ These dangerous side effects and interactions are largely discovered after the harm has occurred, because of the manner in which the current system operates.²⁸⁶ Additionally, once the FDA determines a dietary supplement poses a potential threat, the DSHEA limits the FDA's power and assigns burdens in such a way as to hinder the FDA's ability to promptly and effectively eliminate such dangers to consumers. A change in this system is necessary. Allowing the marketing of these potentially dangerous supplements until sufficient harm is reported by consumers, while hindering the FDA's ability to act against potentially dangerous supplements, is unacceptable—consumers need greater protection.

²⁸³ See generally PART I.

²⁸⁴ HHS Report, *supra* note 3.

²⁸⁵ See *supra* note 46 (describing potential side effects of dietary supplements).

²⁸⁶ See generally PART I.B.