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Misconceptions and Misleading Information Prevail - Less Regulation Does Not Mean Less Danger to Consumers: Dangerous Herbal Weight Loss Products

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MISCONCEPTIONS AND MISLEADING INFORMATION
PREVAIL—LESS REGULATION DOES NOT MEAN LESS
DANGER TO CONSUMERS: DANGEROUS HERBAL WEIGHT
LOSS PRODUCTS

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I. INTRODUCTION

"Instead of walking down the aisle before a bride. I walked behind a casket," wept Mary Jo Linnen, mother of a thirty-year-old woman who died in February 1997 of a heart and lung disorder after taking the prescription "drug cocktail," fen-phen to lose a few pounds before her wedding.¹

Unfortunately, dieters experienced an array of negative side effects from taking fen-phen before the diet drug pair, a combination of fenfluramine (brand name Pondimin) and phentermine (brand name Redux), was voluntarily removed from the market upon the Food and Drug Administration's (FDA) request.² Although the FDA did not approve this simultaneous, off-label use³ of these two drugs, doctors prescribed the mixture millions of times each year.⁴

Weight conscious consumers have flocked to various brands of "herbal fen-phen" since the withdrawal of prescription fen-phen.⁵ These herbal alternatives do not contain the prescription drugs fenfluramine or phentermine;⁶ consequently, consumers can browse the aisles of a health food store and choose from numerous versions of herbal fen-phen type products that all promise the same results.⁷ However, the dangerous reality is that these products have not been proven safe and effective.⁸ Legislation currently governing dietary supplements is dangerously inadequate. Specifically, the Dietary Supplement Health and Education Act of 1994

¹*Woman's Death Raises Questions About Fen-Phen Diet*, NANDO NET (May 6, 1997) <http://pharminfo.com/drugdb/dbgn_mnuu.html>. Mary Linnen certainly was not obese at 5'6" and 185-190 pounds. *Id.* Before her untimely death, drug manufacturers warned doctors that the off-label combination of the two fen-phen drugs was neither safe nor recommended for her weight loss goals; therefore, her physician should not have prescribed fen-phen in this instance. *Id.*

²*Id.*; FOOD AND DRUG ADMINISTRATION, *FDA Warns Against Drug Promotion of "Herbal Fen-Phen,"* FDA TALK PAPER (Nov. 6, 1997) <<http://www.fda.gov/bbs/topics/ANSWERS/ANS00832.html>> [hereinafter *FDA Warns*]. Fenfluramine is a European weight loss drug that acts on both serotonin and dopamine levels in the human body. Michael D. LeMonick et al., *Medicine: The Mood Molecule Serotonin Drugs Treat Everything from Depression to Overeating, But as We Learned Last Week, Tinkering with the Chemistry of the Brain Can Be Risky*, TIME MAG., Sept. 29, 1997, available in 1997 WL 13375884. Because it also put dieters to sleep, it was linked with phentermine. *Id.* Phentermine is an amphetamine like drug, boosting alertness and the metabolism. *Id.*

³LeMonick et al., *supra* note 2.

⁴*See Woman's Death Raises Questions About Fen-Phen Diet*, *supra* note 1.

⁵*See FDA Warns*, *supra* note 2.

⁶*TrendMark Thin-Thin Diet Program Weight Loss Claims Lack Substantiation*, TAN SHEET, June 29, 1998, available in 1998 WL 8449577.

⁷FOOD AND DRUG ADMINISTRATION, *Warning About Herbal Fen-Phen*, FDA CONSUMER MAG., (Jan.-Feb. 1998) <<http://vm.cfsan.fda.gov/~dms/fdsupp.html>> [hereinafter *Warning About Herbal Fen-Phen*].

⁸*Id.*; *U.S. Government Warns Consumers About 'Fen-Phen' Substitutes*, DOW JONES NEWS SERVICE, Nov. 7, 1997, available in 11/7/97 WL-DJNS.

(DSHEA)⁹ reaffirms that dietary supplements are to be classified as foods.¹⁰ This classification does not provide enough protection for consumers in relation to herbal fen-phen products.

Furthermore under the DSHEA, the FDA cannot even require manufacturers to test herbal products before sold for safety or efficacy,¹¹ rather individual manufacturers may decide what is necessary to provide “reasonable assurance” of a products’ safety.¹² The FDA Secretary, based on limited powers granted by the DSHEA, may remove a dangerous or adulterated supplement only when it poses an “imminent hazard to public health or safety.”¹³ Such action is simply too little too late in most instances.

This Note will examine the dangers associated with current dietary supplement regulation under the DSHEA¹⁴ and the problem of ill-informed consumers.¹⁵ As reflected in the title of this Note, misconceptions about dietary supplement regulation are abundant; consequently, section II of this Note will further discuss and offer illustrations in support of this position. Part III gives an overview of current regulation under the Dietary Supplement Health and Education Act of 1994. Also a brief discussion of the legislation that preceded the DSHEA is offered in section VI.

Part V of this Note analyzes and defines the dietary ingredients that are often found in herbal fen-phen products. Specifically, this section discusses the dangerous and unsubstantiated claims associated with these supplements.

Part V concludes by contrasting prescription fen-phen with herbal fen-phen to explain the dangers associated with both and the dire need for prompt action to protect consumers from “herbal” substitutes.

Part VI offers concrete proposals for dealing with inadequate regulations, which this Note maintains are threatening consumers’ health. Finally, remedies such as legislative amendment and increased funding for training, research, and consumer awareness efforts will be further explored.

In the Fall of 1997, the FDA did warn consumers about the dangers related to herbal fen-phen;¹⁶ however, since then nothing concrete has been done to put a stop to the sale of these menacing supplements. The FDA noted that products, which are

⁹Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994) (codified at 21 U.S.C. § 342).

¹⁰*Id.* § 3, 108 Stat. at 4327-28 (codified at 21 U.S.C. § 321(ff)).

¹¹*Herbal Hope or Herbal Hype?*, CURRENT HEALTH 2, Oct. 1, 1998, available in 1998 WL 9587086.

¹²§ 4, 108 Stat. at 4328 (codified at 21 U.S.C. § 342(f)(1)(B)); *Herbal Hope or Herbal Hype?*, *supra* note 11; Pat Kendall, Ph.D., R.D., *Herbal Fen-Phen: Buyer Beware*, (Oct. 15, 1997) <<http://www.colostate.edu/depts/CoopExt/PUBS/COLUMNNN/nn971015.htm>>.

¹³Pub. L. No. 103-417, § 4, 108 Stat. at 4328 (codified at 21 U.S.C. § 321(f)(1)(C)).

¹⁴Pub. L. No. 103-417, 108 Stat. 4325; Mark A. Kassel, *From a History of Near Misses: The Future of Dietary Supplement Regulation*, 49 FOOD & DRUG L.J. 237, 239 (1994). See discussion *infra* Part III.

¹⁵See discussion *infra* Parts II, VI.B.

¹⁶*Warning About Herbal Fen-Phen*, *supra* note 7.

intended to be used as alternatives to prescription drugs, require FDA approval before being made available to consumers.¹⁷ The FDA stated that herbal fen-phen products are *indeed* marketed as drug alternatives to prescription anti-obesity drugs.¹⁸ Companies that market or imply weight-loss benefits by imitating prescription drug names are violating federal law and must be stopped.¹⁹

Ultimately, products like these run the risk of being classified as new drugs, requiring FDA approval before sale.²⁰ The FDA, using the powers earlier mentioned that are designated by the DSHEA to its Secretary, should promptly act to change the current availability of such products to avoid catastrophic health problems.²¹

Because of the leniency fostered by the DSHEA, some available herbal alternatives contain various dietary ingredients that are dangerous and even deadly.²² Many herbal fen-phen products contain ephedrine (also known as ephedra or ma huang) and St. John's Wort (also known as hypericum perforatum or "herbal Prozac").²³ In addition to a lack of evidence supporting manufacturer's claims, these dietary ingredients combined may also pose a serious health threat to many uninformed or careless consumers.²⁴

II. MISCONCEPTIONS ABOUT DIETARY SUPPLEMENT REGULATION

The \$6.5 billion dietary supplement market evidences American's concern with maintaining and improving their overall health.²⁵ A significant and growing portion of that figure can be attributed to herbal weight-loss products, such as herbal fen-phen products.²⁶ These herbal weight-loss products have become more popular since

¹⁷*Id.* "While the FDA has maintained and progressively tightened its hold over the regulation of drugs throughout this century, the same cannot be said of the FDA's supervision of dietary supplements. Dietary supplements have never had a consistent classification, bouncing around from a drug to a food additive to their present classification as a dietary supplement. Due to Congress's reluctance to recognize dietary supplements as potentially dangerous or to give the FDA the power to ensure the safety of these products, manufacturers are more likely to engage in unscrupulous and hazardous practices." Bruce H. Schendler, *Note, Where There's Smoke There's Fire: The Dangers of the Unregulated Dietary Supplement Industry*, 42 N.Y.L. SCH. L. REV. 261, 266 nn.65-72 (1998).

¹⁸Warning About Herbal Fen-Phen, *supra* note 7.

¹⁹U.S. Government Warns Consumers About 'Fen-Phen' Substitutes, *supra* note 8.

²⁰*Id.*

²¹Pub. L. No. 103-417, § 4, 108 Stat. at 4328 (codified at 21 U.S.C. § 342 (f)(1), (2)).

²²LeMonick et al., *supra* note 2.

²³*Id.*

²⁴FDA Warns, *supra* note 2.

²⁵Kristine Brenneman, *Adding a Dose of Concern: Safety of Herbal Supplements Questioned*, PATRIOT LEDGER, Jan. 15, 1999, available in 1999 WL 8449241; Paula Kurtzweil, *An FDA Guide to Dietary Supplements*, FDA CONSUMER MAG. (Sept.-Oct. 1998) <<http://vm.cfsan.fda.gov/~dms/fdsupp.html>>.

²⁶U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *FDA Announces Withdrawal of Fenfluramine and Dexfenfluramine*, HHS NEWS, (Sept. 15, 1997)

drug manufacturers followed the FDA's admonition in 1997 and removed these prescription diet drugs from the market.²⁷ Although dieters are eager to shed pounds and continue to rely on promises of quick results from herbal diet remedies, the FDA and nutritionists maintain that there is no evidence that these herbal dietary supplements are effective weight-loss aids.²⁸ Nutritionists "fret that Americans regard herbs as harmless, no matter what the dose."²⁹

Due to a lack of consumer education and/or misleading advertising, many Americans using dietary supplements falsely believe that the FDA, Federal Trade Commission (FTC),³⁰ or some other governmental agency will be their watchdog, disallowing any harmful supplements or ingredients.³¹ This is simply not true. Dietary supplements do not go through the strict screening that drugs must go through.³² Prescription and over-the-counter drug manufacturers must conduct studies on safety and effectiveness before the FDA approves a new drug for sale.³³ Dietary supplement manufacturers only need to demonstrate that a product is safe when taken according to the recommended dosage.³⁴ In fact, the FDA does not have the power to intervene to stop the sale of a supplement unless it poses an unreasonable risk to health or is marketed as a drug.³⁵

The Federal Food, Drug, and Cosmetic Act (FDCA)³⁶ defines drugs as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or any other animals" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals."³⁷ Furthermore, the

<<http://www.fda.gov/bbs/topics/NEWS/NEW00591.html>>; MAYO CLINIC, *FDA Warns Against "Herbal Fen-Phen,"* (Nov. 13, 1997) <<http://www.mayohealth.org/mayo/9711/htm/fen-phen.htm>>.

²⁷*FDA Cracks Down on 'Herbal Fen-Phen' and Warns Consumers*, WALL ST. J., Nov. 7, 1997, available in 1997 WL-WSJ 14173035.

²⁸Bob Condor, *It's a Jungle: Herbal Weight-Loss Concoctions Have Risks, But No Guarantees*, CHI. TRIB., Feb. 25, 1998, available in 1998 WL 2829053.

²⁹*Id.*

³⁰See generally Douglas W. Hyman, Esq., *The Regulation of Health Claims in Food Advertising: Have the FTC and the FDA Finally Reached a Common Ground?*, 51 FOOD AND DRUG L.J. 191 (1996).

³¹Condor, *supra* note 28.

³²Pub. L. No. 103-417, § 6, 108 Stat. at 4329 (codified at 21 U.S.C. § 343(r)(6) (guidelines for making supplements available only assert requirements about statements of nutritional support)).

³³FDCA, 21 U.S.C. § 321(p); *Herbal Hope or Herbal Hype?*, *supra* note 11.

³⁴DSHEA § 4(f)(1)(A), (B); Martha Schindler, *Navigating the Natural Sports Supplements*, NAT. HEALTH, May 15, 1998, available in 1998 WL 9870616.

³⁵DSHEA, § 4(f)(1)(A); *Herbal Hope or Herbal Hype?*, *supra* note 11.

³⁶Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. § 301 et seq.).

³⁷*Id.* (codified at 21 U.S.C. § 321(g)(1)(B),(C)).

FDCA, as amended by the DSHEA, regulates supplements as “foods” and not “drugs,” specifically prohibiting dietary supplements from making drug claims.³⁸

Moreover, critics warn that supplements are regulated as foods but used as drugs.³⁹ Companies that market or imply weight-loss benefits by imitating prescription drug names are violating federal law and must be stopped.⁴⁰ Products like these may run the risk of being classified as new drugs, requiring FDA approval before sale.⁴¹ The FDA, using the powers designated by the DSHEA to its Secretary, should promptly act to change the current availability of such products to avoid catastrophic health problems.⁴²

Another governmental agency, the FTC, has a regulating hand in the supplement industry and this agency works closely with the FDA and monitoring advertising for supplements.⁴³ One example of the FTC's exercise of regulatory dominion occurred in 1997 after the FTC launched a consumer education and regulatory campaign, “operation waistline.”⁴⁴ Because of this campaign, the FTC engaged in settlement agreements with some supplement manufacturers, prohibiting future advertising that lacks appropriate claim substantiation and trustworthy scientific data.⁴⁵ The disingenuous claims made in several products' ads included:

- (1) NEW ALL-NATURAL WEIGHT LOSS PRODUCT, NOW ON THE MARKET! If you've heard about the new 'Phen/Fen' Diet, and thought about trying it . . . Don't! With the ALL NATURAL 'Thin-Thin Diet,' you can achieve the same results, without the dangerous side-effect of Drugs! Eat the foods you want, and STILL lose 10-12 pounds per month!;
- (2) Neuro-Thin turns your 'hunger switch' off; and
- (3) Neuro-Thin help[s] balance the levels of serotonin and dopamine in your brain. The result? Food cravings and hunger pangs are eliminated . . . and . . . you'll be on your way to achieving your goal.⁴⁶

Because these advertisements make claims based on studies that were not performed on humans, they seem insufficient according to the DSHEA's standard that requires

³⁸Pub. L. No. 103-417, § 3, 108 Stat. at 4327 (codified at 21 U.S.C. § 321 (ff)(1)). Robert G. Pinco & Paul D. Rubin, *Ambiguities of the Dietary Supplement Health and Education Act of 1994*, 51 FOOD & DRUG L.J. 383, 390 (1996).

³⁹Kassel, *supra* note 14, at 268.

⁴⁰U.S. Government Warns Consumers About 'Fen-Phen' Substitutes, *supra* note 8.

⁴¹*Id.*

⁴²Pub. L. No. 103-417, § 4, 108 Stat. at 4328 (codified at 21 U.S.C. § 342(f)(1), (2)).

⁴³*See generally* Hyman, *supra* note 31.

⁴⁴*TrendMark Thin-Thin Diet Program Weight Loss Claims Lack Substantiation*, *supra* note 6.

⁴⁵*Id.*

⁴⁶*Id.* (emphasis in original) (the only substantiation offered for these powerful claims was based on studies performed on rats and in test tubes).

“reasonable assurances” of a new product's safety.⁴⁷ According to Food Science and Human Nutrition Specialist, Pat Kendall, Ph.D., R.D., at Colorado State University, another alarming truth associated with inadequate regulation is that unrestricted “[f]actors, such as variations in growth, product preparation, and storage length and conditions, affect the quality and potency of a product. In addition, plants are sometimes improperly identified by manufacturers.”⁴⁸ Consequently, illustrations of the need for regulatory changes are plentiful; a look at FDA records revealed over 2,500 reports of side effects and 79 deaths associated with dietary supplement use.⁴⁹

Primarily due to a lack of consumer education and reliance upon government for proactive intervention, the FDA is working to regain more power to protect the public's health.⁵⁰ On April 29, 1998, the FDA proposed changes to the current regulatory scheme, hoping to better protect the health of Americans.⁵¹ Until these proposals are approved, the FDA can only regulate with minimal effect under the DSHEA.⁵²

III. CURRENT REGULATIONS UNDER THE DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994

In response to tremendous quantities of mail, phone calls, and constituent pressure, Congress enacted the Dietary Supplement Health and Education Act (DSHEA), “reduc[ing] the regulatory burdens on dietary supplement manufacturers.”⁵³ Some call the DSHEA “a compromise” because neither the supplement manufacturers nor increased regulation advocates, like the FDA, gained more coveted reformations than the other.⁵⁴ In practice, the DSHEA has proven to be problematic and has allowed dangerous supplements to remain on the market.⁵⁵

⁴⁷Pub. L. No. 103-417, § 4, 108 Stat. at 4328 (codified at 21 U.S.C. § 342(f)(1)(B)).

⁴⁸Kendall, *supra* note 12.

⁴⁹Rebecca Porter, *Supplements Supply Dietary Danger, as FDA Looks on*, 34 TRIAL 12, 12 (1998).

⁵⁰Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,623 (1998) (to be codified at 21 C.F.R. pt. 101) (the FDA proposed regulations that will define the types of statements that may be made on supplements. This initiative was in response to the Commission on Dietary Supplement Labels' report and to offer guidance for the industry as a whole).

⁵¹*Id.*; *see generally* Dietary Supplements Containing Ephedrine Alkaloids.

⁵²*See* discussion *infra* Parts III, IV.B.

⁵³Steven H. McNamara, *FDA Regulation of Ingredients in Dietary Supplements After Passage of the Dietary Supplement Health and Education Act of 1994: An Update*, 51 FOOD & DRUG L.J. 313 (1996). Within a three-year period, Congress experienced more pressure on this issue than health care reform, abortion, or the deficit. *Id.*; *see also* *FDA Take on Vitamins Raises Concerns*, PLAIN DEALER (Cleveland), Nov. 28, 1993, available in 1993 WL 5103381.

⁵⁴McNamara, *supra* note 57, at 313; Michael F. Conlan, *Supplement Settlement: Both Sides Hail Compromise in a Vitamin Duel as Victory*, DRUG TOPICS, Nov. 7, 1994, available in 1994 WL 2886154.

⁵⁵*See supra* notes 46-50 and accompanying text.

Signed by the President in October of 1994, the DSHEA amended the Federal Food, Drug, and Cosmetic Act (FDCA), primarily affecting dietary supplements and their dietary ingredients.⁵⁶ Public health and welfare were at the forefront of Congress' intentions with the enactment of the DSHEA.⁵⁷ Additionally, Congress recognized that, "millions of consumers believe dietary supplements may help to augment daily diets and provide health benefits."⁵⁸ To advance these goals, the DSHEA was designed to satisfy both consumers and manufactures by keeping safe, properly labeled products available to those seeking them.⁵⁹ Among the findings made in relation to the DSHEA, Congress confirmed that "there may be a positive relationship between sound dietary practice and good health, and that, although further scientific research is needed there may be a connection between dietary supplement use, reduced health-care expenses, and disease prevention."⁶⁰

Before the passage of the DSHEA, pre-market safety evaluations, required by the FDCA, ensured that dietary supplements available to consumers were safe, providing labels that were direct, not misleading, for consumers to readily understand.⁶¹ The DSHEA changed all this, allowing dietary supplement manufacturers to introduce new supplements without the FDA's prior approval.⁶² Manufacturers are no longer required to submit safety and efficacy reports to the FDA for prior approval and herbal products may be introduced without standardized dosages or strengths.⁶³

Section 4 of the DSHEA discusses dietary supplement safety requirements.⁶⁴ While preserving adulteration standards set out by the FDCA, the DSHEA does create two additional standards.⁶⁵ A supplement or dietary ingredient is adulterated if it "presents a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use."⁶⁶

⁵⁶Pub. L. No. 103-417, § 3, 108 Stat. at 4327 (codified at 21 U.S.C. § 321(a),(ff)); FOOD AND DRUG ADMINISTRATION, *Dietary Supplement Health and Education Act of 1994*, (Dec. 1, 1995) <<http://vm.cfsan.fda.gov/~dms/dietsupp.html>> [hereinafter FDA, *DSHEA*].

⁵⁷§ 2, 108 Stat. at 4325 (codified at 21 U.S.C. § 321 NOTE (1)).

⁵⁸FDA, *DSHEA*, *supra* note 56.

⁵⁹Pub. L. No. 103-417, § 2, 108 Stat. at 4325 (codified at 21 U.S.C. § 321 NOTE (2)); FDA, *DSHEA*, *supra* note 56.

⁶⁰FDA, *DSHEA*, *supra* note 56.

⁶¹Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321 (1993); FDA, *DSHEA*, *supra* note 56.

⁶²Pub. L. No. 103-417, §§ 6, 7, 108 Stat. at 4329 (codified at 21 U.S.C. § 343(r)(s)); FDA, *DSHEA*, *supra* note 60.

⁶³*Herbal Hope or Herbal Hype?*, *supra* note 11. *But cf. infra* notes 72-74 and accompanying text; Pub. L. No. 103-417, § 4, 108 Stat. at 4328 (codified at 21 U.S.C. § 342(f)(1)(A)) (showing that limited safeguards still exist).

⁶⁴DSHEA, Pub. L. No. 103-417, § 4, 108 Stat. 4325, 4328 (codified at 21 U.S.C. 342).

⁶⁵*Id.* at 4328 (codified at 21 U.S.C. 342(f)(1)(A)).

⁶⁶*Id.*

Under either of the above stated conditions, the Secretary may conclude that the supplement poses an imminent hazard to health and/or safety of the public.⁶⁷

Additionally, the DSHEA created a new category, separate from food or drugs, to include any “dietary supplement for use by man to supplement the diet,”⁶⁸ it redefines a “dietary supplement” as a product (excluding tobacco) meant to fortify the diet.⁶⁹ According to the Act, a supplement also includes a product 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 dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any ingredient[s listed above.]⁷⁰

A dietary supplement intended for ingestion may come in various forms, including a pill, capsule, tablet, or liquid form.⁷¹ Consequently, the definition of a dietary supplement has been expanded. These relaxed standards enabled manufacturers to market various supplements that have proven to be less than safe.⁷² Although Congress' intent with the passage of the DSHEA was noble,⁷³ the ramifications following its passage render the DSHEA less than commendable.⁷⁴

IV. VITAL REGULATORY LEGISLATION PRECEDING THE DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994

A. *Federal Food, Drug, and Cosmetic Act of 1938*

Since its introduction in 1938, the Federal Food, Drug, and Cosmetic Act has had a significant effect upon the vitamin and dietary supplement industry.⁷⁵ Through this Act, the FDA received authorization to proctor foods and dietary supplements, monitoring safety and truthfulness in labeling.⁷⁶ Currently, the FDCA is still in effect as amended by the DSHEA and it remains the leading legislative tool for regulating foods, drugs, and dietary supplements.

⁶⁷*Id.* (codified at 21 U.S.C. § 342 (f)(1)(C)).

⁶⁸Pub. L. No. 103-417, § 3, 108 Stat. at 4327 (codified at 21 U.S.C. § 321(ff)(1)).

⁶⁹*Id.*

⁷⁰*Id.*

⁷¹*Id.*; FDA, *DSHEA*, *supra* note 56.

⁷²*See supra* note 46 and accompanying text and *infra* note 106 and accompanying text.

⁷³Pub. L. No. 103-417, § 2, 108 Stat. 4325 (codified at 21 U.S.C. § 341 NOTE (1),(2)).

⁷⁴*See supra* Part III.

⁷⁵*See generally* Kathi Gannon, *Vitamin Showdown: Who Should Control Dietary Supplements?*, DRUG TOPICS, Jan. 24, 1994, available in 1994 WL 2886032.

⁷⁶*Id.* The FDA, under the FDCA, commenced actions against many dietary supplement ingredients, including St. John's Wort, to confirm whether the ingredients were illegal because they failed to meet “food additive” standards. McNamara, *supra* note 53, at 315-16.

B. Nutrition Labeling and Education Act of 1990

By enacting the Nutrition Labeling and Education Act of 1990,⁷⁷ Congress amended the FDCA and gave the FDA the power to require that foods and, later through amendment, supplement labels making nutritional or disease-related claims must be backed by sound scientific data.⁷⁸ This Act brought herbs and similar nutritional substances within the scope of the dietary supplement definition.⁷⁹

After this Act was passed, consumers flooded the FDA and Congress with letters fearing the implementation of this law.⁸⁰ Others voiced concern that supplements would be removed from stores or only available with a doctor's prescription.⁸¹ FDA officials tried to dispel these false beliefs and reassure consumers that products would not be removed but relabeled if necessary.⁸²

C. Dietary Supplement Act of 1992

Opposition to the Nutrition Labeling and Education Act of 1990 (NLEA) gave rise to the Dietary Supplement Act of 1992, which made a one-year moratorium possible.⁸³ Consumer groups and the supplement industry put forth a strong effort to influence Congress to stop the NLEA's implementation.⁸⁴ The moratorium temporarily halted the FDA's regulation of dietary supplements under the NLEA.⁸⁵ Soon after, the lenient DSHEA was enacted, which continued to limit the FDA's protective powers because it was too easy on supplement standards.

V. DEADLY AND INEFFECTIVE DIETARY INGREDIENTS IN
"HERBAL FEN-PHEN" PRODUCTS

Herbal fen-phen products primarily combine dietary ingredients including: Ephedrine, St. John's Wort, and sometimes 5-hydroxy tryptophan or caffeine.⁸⁶ As repeatedly proven by adverse medical reactions, these are unsafe mixtures.⁸⁷

⁷⁷Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified at 21 U.S.C. 343 § 403).

⁷⁸*Id.*; see also Gannon, *supra* note 75.

⁷⁹Pub. L. No. 101-535, 104 Stat. 2353; see also FDA, *DSHEA*, *supra* note 56.

⁸⁰Gannon, *supra* note 75.

⁸¹*Id.* These fears were "spurred on by some makers of dietary supplements who are waging an all-out campaign, with brochures and handouts, telling consumers they can 'kiss their supplements good-bye' if the FDA is given jurisdiction over them." *Id.*

⁸²*Id.* (according to an FDA spokesperson).

⁸³Pub. L. No. 102-571, 106 Stat. 4500 (1992) (codified at 21 U.S.C. § 343).

⁸⁴Gannon, *supra* note 75.

⁸⁵Pub. L. No. 102-571, 106 Stat. 4500 (1992) (codified at 21 U.S.C. § 343).

⁸⁶Scientific Evidence Suggests the Use of Supplements Such as Phen-Free May Help Reinforce the Metabolic Rate, (visited Jan. 19, 1999) <<http://eas.com/q-a/index.html>>.

⁸⁷See *infra* text accompanying note 106; see also Schlendorf v. Alternative Health Research, Inc., No. 3:97-CV. 104 RV (SMA N.D. Fla. settled May 20, 1998) (herbal containing ephedra caused a fatal cardiac arrhythmia in a college student).

Ephedra, also popularly known as ephedrine and ma huang, is notorious for its dangerous side effects which include high blood pressure, insomnia, stroke, and even death.⁸⁸ Metabolic stimulants, like ephedrine, are fast acting but risky; they suppress appetite and burn calories by causing an “adrenaline-like effect” on the nervous system.⁸⁹ Admittedly, the FDA has acknowledged that it has no reports of side effects from St. John's Wort.⁹⁰ However, it strongly cautions consumers that neither St. John's Wort nor 5-hydroxy tryptophan has been properly studied, and warns that 5-hydroxy tryptophan was related to a supplement banned in the 1990s after it was linked to a fatal blood disorder.⁹¹

A. Ephedra or Ephedrine

“Primarily a bronchial decongestant, ephedra is one of the oldest-known medicinal herbs.”⁹² In the 1940s, Ephedrine, the active ingredient in ephedra, began to be used in the treatment of asthma.⁹³ As the uses of the supplement expanded, serious side effects were discovered.⁹⁴ While ephedrine expands breathing passages, it also constricts blood vessels (vasoconstriction) and increases arterial blood pressure, leading to severe hypertension, heart attack, or stroke.⁹⁵ Because of these side effects, many doctors and pharmacists frowned upon its “single-component” use⁹⁶ and refrained from prescribing or recommending it.⁹⁷ Ephedrine's revival came with dietary supplement manufacturers' claims of curbed appetite, increased energy, and a faster metabolism.⁹⁸ Research has proven that ephedra contains the alkaloid ephedrine, a natural central nervous system stimulant.⁹⁹

⁸⁸U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *FDA Proposes Safety Measures for Ephedrine Dietary Supplements*, HHS NEWS, (June 2, 1997) <<http://www.fda.gov/bbs/topics/NEWS/NEW00568.html>>; see also *Dietary Supplements Containing Ephedrine Alkaloids*, 62 Fed. Reg. 30, 667, 30, 678 (1997) (to be codified at 21 C.F.R. pt. 111).

⁸⁹Laurie Berger, *The Lowdown on Natural Fat Fighters*, VEGETARIAN TIMES, Jan. 1, 1998, available in 1998 WL 10570594.

⁹⁰*FDA Cracks Down on 'Herbal Fen-Phen' and Warns Consumers*, *supra* note 27.

⁹¹*Id.*; *Sayre v. General Nutrition Corp.*, 867 F. Supp 431, 435 (S.D.W. Va. 1994) *aff'd*, 67 F.3d 296 (4th Cir. 1995).

⁹²Berger, *supra* note 89.

⁹³Jody L. Aaron, *Death Over-the-Counter: Dangers of Ephedrine*, 33 TRIAL 61, 61-62 (1997).

⁹⁴*Id.* at 62.

⁹⁵*Id.*

⁹⁶*Id.* at 62.

⁹⁷*Id.*

⁹⁸Aaron, *supra* note 95, at 62; Schindler, *supra* note 34.

⁹⁹Schindler, *supra* note 34.

Since 1993, the FDA has received nearly 1000 complaints about herbal and synthetic ephedrine products.¹⁰⁰ As even more cause for alarm, forty-two deaths reported to the FDA were connected to ephedrine use.¹⁰¹ The FDA has issued warnings about the use of ephedra-containing and herbal fen-phen products.¹⁰² Sales of the product have greatly risen in the past ten years, due to the herb's vast availability because manufacturers have inundated the market with countless products containing the herb.¹⁰³ An FDA spokesperson remarked that these were the most complaints received about any dietary supplement on the market.¹⁰⁴ Very few people using this supplement are aware of its dangers.¹⁰⁵ Consider the following examples of people harmed and even killed from ephedrine products:

(1) A 19-year-old college student begins to take an over-the-counter ephedrine product he bought as a stay-awake aid from the gas station where he works. After taking four caplets over a 24-hour period, he dies while pumping gas. The death, according to the autopsy, was caused by a massive heart attack triggered by ephedrine toxicity[;]

(2) A 17-year-old high school football player suffers a fatal heart attack just before going to sleep one evening. According to the autopsy, the cause was ephedrine toxicity. His use of the product never exceeded the recommended dosage[; and]

(3) A 16-year-old high school student begins using an ephedrine-based product as a diuretic. Shortly after taking the pills, she suffers severe heart palpitations and collapses during a school sporting event. She continues to require treatment for irregular heartbeat years after the incident.¹⁰⁶

Clearly illustrated by the incidents above, serious health consequences may occur from ephedrine use, especially if the supplement is misused.¹⁰⁷ Additionally, ephedrine has a half-life between six to ten hours and with repeated use, it can build to toxic levels in the body.¹⁰⁸ Therefore, combining it with other caffeine-containing products like "coffee, chocolate, or [over-the-counter] pain relief drugs such as

¹⁰⁰Berger, *supra* note 89.

¹⁰¹*Id.*

¹⁰²*FDA Warns, supra* note 2.

¹⁰³Aaron, *supra* note 93, at 62.

¹⁰⁴Berger, *supra* note 89.

¹⁰⁵Aaron, *supra* note 93, at 61.

¹⁰⁶*Id.* (quotations omitted).

¹⁰⁷Schindler, *supra* note 34. ("Many consumers take a handful of supplements at a time, yet no one knows how these supplements interact with one another or how they affect the body's production of substances such as hormones.").

¹⁰⁸Aaron, *supra* note 93, at 62.

Excedrin can further amplify the [herb's] effect."¹⁰⁹ Some herbal fen-phen products contain caffeine in addition to ephedrine, increasing the hazard for dieters.¹¹⁰ Naturopathic physician and licensed acupuncturist, Ian D. Bier, N.D., L.Ac. does not recommend this matching of stimulant with stimulant.¹¹¹ Furthermore, Bier refrains from recommending or approving the use of either caffeine or ephedra to those looking to lose weight.¹¹²

Adverse reports from consumers and health care providers, and scientific literature prompted the FDA to propose regulations to provide maximum dosages for the herb.¹¹³ The proposed regulation recommends that ephedrine containing products be: (1) limited to twenty-four mg per day; (2) banned if combined with stimulants or caffeine; (3) labeled with the warning, "taking more than the recommended serving may result in heart attack, stroke, seizure, or death;" and (4) prohibited from being marketed for weight-loss or bodybuilding ephedrine supplements.¹¹⁴ Currently some herbal fen-phen products exceed twenty-four milligrams of ephedrine (some contain much more).¹¹⁵

These efforts are much needed to protect consumers, often times from their own actions.¹¹⁶ Although many patients do not take their prescription medications for the entire time recommended, herbal supplement users are taking these products for long periods.¹¹⁷ This is a major cause for concern by health care professionals because this may certainly prove detrimental to individuals' health.¹¹⁸

B. *St. John's Wort*

In addition to dangerous ephedrine, many herbal fen-phen products also contain *St. John's Wort*.¹¹⁹ This ingredient's herbal name is "hypericum perforatum"¹²⁰ and it is commonly called "herbal Prozac."¹²¹ Although the herb has been used in many

¹⁰⁹*Id.*

¹¹⁰*See generally id.*

¹¹¹Schindler, *supra* note 34.

¹¹²*Id.*

¹¹³Porter, *supra* note 49, at 12; Brenneman, *supra* note 25.

¹¹⁴Porter, *supra* note 49, at 12; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *supra* note 88; *Dietary Supplements Containing Ephedrine Alkaloids*, 62 Fed. Reg. 30,667, 30,678 (1997) (to be codified at 21 C.F.R. pt. 111); *see* Kendall, *supra* note 12.

¹¹⁵Kendall, *supra* note 12.

¹¹⁶*See* discussion *supra* note 107 and accompanying text.

¹¹⁷Brenneman, *supra* note 25.

¹¹⁸*Id.*

¹¹⁹*FDA Warns*, *supra* note 2; MAYO CLINIC, *supra* note 26; Kendall, *supra* note 12.

¹²⁰This plant, growing in the wild, enhances serotonin, norepinephrine, and dopamine. LeMonick et al., *supra* note 2.

¹²¹*FDA Warns*, *supra* note 2.

countries to treat mild depression or mood disorders,¹²² it has not been carefully studied individually or in combination with ephedrine.¹²³ The Mayo Clinic reported that the National Institute of Health will study St. John's Wort for the first time in the United States; however, the study will focus on its use for the possible treatment of depression, not obesity.¹²⁴

Some experts maintain that St. John's Wort "mimics the metabolic effects of ephedra."¹²⁵ Consequently, the herb is also used in some ephedra-free diet products.¹²⁶ Furthermore, many herbal fen-phen products have both dietary ingredients; such a composition may equate to the stimulant matching cautioned against earlier in this Note.¹²⁷ Scientific studies and research have not proven St. John's Wort to be an effective diet aid.¹²⁸ Moreover, one expert on herbs contends that "hypericin" has been proven to cause photosensitivity, including dermatitis and inflammation of mucous membranes when directly exposed to the sun.¹²⁹

C. 5-Hydroxy Tryptophan

Other herbal fen-phen products include 5-hydroxy-tryptophan among their dietary ingredients.¹³⁰ This ingredient also has not been proven effective in controlled studies.¹³¹ In fact, FDA and Mayo Clinic scientists recently confirmed that the supplement contains impurities.¹³²

Moreover, 5-hydroxy-tryptophan has frequently been associated with L-tryptophan.¹³³ L-tryptophan was removed from the market after a contaminated batch may have caused eosinophilia-myalgia syndrome (EMS), a rare blood disorder.¹³⁴ In more than 1,500 instances L-tryptophan use (as a sleep aid, appetite suppressant, or menstrual cramp reliever) was linked to EMS.¹³⁵ In addition, as

¹²²MAYO CLINIC, *supra* note 26.

¹²³FDA Warns, *supra* note 2.

¹²⁴MAYO CLINIC, *supra* note 26.

¹²⁵Berger, *supra* note 89.

¹²⁶*Id.*

¹²⁷*See supra* notes 111-12 and accompanying text.

¹²⁸Berger, *supra* note 89.

¹²⁹Kendall, *supra* note 12 (citing Varro Tyler, *The Honest Herbal*).

¹³⁰FDA Warns, *supra* note 2.

¹³¹FDA Cracks Down on 'Herbal Fen-Phen' and Warns Consumers, *supra* note 15.

¹³²FOOD AND DRUG ADMINISTRATION, *Impurities Confirmed in Dietary Supplement 5-Hydroxy-L-Tryptophan*, FDA TALK PAPER, (Aug. 31, 1998) <<http://fda.gov/bbs/topics/ANSWERS/ANS00891.html>>. The specific impurity, formerly linked to dangers of L-tryptophan use, is "peak x." *Id.*

¹³³*Id.*

¹³⁴FDA Warns, *supra* note 2.

¹³⁵*Id.*; Kassel, *supra* note 14, at 241-42.

many as thirty-eight deaths were related to EMS and L-tryptophan.¹³⁶ The L-tryptophan scandal revealed, via victim testimony before Congress, that consumers assumed that the FDA monitored this product.¹³⁷

D. PRESCRIPTION “FEN PHEN” V. “HERBAL FEN-PHEN”

As recent as 1997, those who did visit their doctors to obtain weight-loss advice may have been introduced to this diet miracle in a prescription bottle,¹³⁸ the now-banned combination of fenfluramine¹³⁹ and phentermine,¹⁴⁰ commonly known a “fen-phen.”¹⁴¹ Separately, the drugs were approved for short-term use by obese individuals.¹⁴² Reports reveal that eighteen million people used the combination before it was removed from the market.¹⁴³ “Alone, neither drug (available for nearly three decades) was doing much to satisfy dieters. The ‘magic’ came as a pairing.”¹⁴⁴ One dieter was delighted to experience this “magic” because after years of unsuccessful dieting, Beth Herwig, 5’4,” weighed more than 500 pounds at the age of twenty-nine.¹⁴⁵ Fen-Phen was prescribed for Beth and she saw great results as her weight dropped to 265 pounds.¹⁴⁶

A combination of two separately approved prescription drugs equates to an off-label use.¹⁴⁷ The FDA does not approve such usage.¹⁴⁸ Critics note that “many

¹³⁶*FDA Warns, supra note 2.*

¹³⁷H.R. Doc. No. 25 (1991). In *Sayre*, the plaintiff continually used L-tryptophan to help her sleep, despite her adverse symptoms and warnings in television and magazine news reports urging consumers to stop taking the supplements. *Sayre v. General Nutrition Corp.* 867 F. Supp. 431, 435, 432-33 (S.D.W.V. 1994) *aff’d* 67 F.3d 296 (4th Cir. 1995). She continued to self-medicate before consulting a doctor, at which time she was told that her L-tryptophan use was causing her symptoms. *Id.* at 434 (the court upheld summary judgment for Defendant because Plaintiff should have known of dangers of harmful product due to sufficient warnings and information disseminated.). This suit further evidences the lack of caution consumers’ express regarding dietary supplement use. *Id.*

¹³⁸A European weight-loss drug that affects serotonin and dopamine levels. LeMonick et al., *supra note 2.*

¹³⁹An amphetamine-like drug that increases alertness and helps burn calories faster by boosting the metabolic rate. LeMonick et al., *supra note 2.*

¹⁴⁰Doctors combined fenfluramine and phentermine to speed up the metabolism and provide energy because fenfluramine alone caused drowsiness. LeMonick et al., *supra note 2.*

¹⁴¹FOOD AND DRUG ADMINISTRATION, *Mixing Diet Drugs Calls for Caution*, FDA CONSUMER MAG., (Sept.-Oct. 1997) <<http://vm.cfsan.fda.gov/~dms/fdsupp.html>>.

¹⁴²Berger, *supra note 89.*

¹⁴³*Id.*

¹⁴⁴Condor, *supra note 28.*

¹⁴⁵*Id.*

¹⁴⁶*Id.* (Beth implies that fen-phen helped her lose weight and change her attitude towards food: “It’s not that I don’t want that Twinkie still. . . [b]ut before, I would see it, and there was almost nothing that could stop me.”).

¹⁴⁷*Id.*

doctors went overboard, giving Redux and fen/phén to patients who were merely overweight, not obese, a violation of the FDA and drug-company prescription criteria."¹⁴⁹

Before numerous reports documenting heart valve abnormalities potentially leading to cardiac weakness and even death,¹⁵⁰ consumers experienced "short-term diet miracles" from taking the combination; however, the long-term expense to users was tremendous.¹⁵¹ Doctors performed echocardiograms¹⁵² on patients using the two drugs simultaneously and found abnormalities in about thirty percent of patients.¹⁵³ Ironically, patients tested exhibited no other symptoms of heart abnormalities.¹⁵⁴ Such substantial reports of heart valve damage and weakened heart muscle from the drug combination prompted the FDA to recommend removal of the products from the market.¹⁵⁵

In October of 1999, attorneys for the diet-drug users achieved a proposed settlement with the drug manufacturer for \$3.75 billion.¹⁵⁶ This products liability, class action was settled on behalf of people who claimed injuries associated with fen-

¹⁴⁸*Id.* (see for a discussion, strongly criticizing the two component drugs individually. Furthermore, research prior to fen-phén's combination, showed that the FDA and drug manufacturers know of other serious side effects; however, justifications offered by fen-phén proponents stressed that disadvantages were outweighed by the benefits); see *supra* text accompanying note 1.

¹⁴⁹LeMonick et al., *supra* note 2 and accompanying text.

¹⁵⁰Condor, *supra* note 28.

¹⁵¹A diagnostic procedure to test the functioning of the heart valves. U.S DEPARTMENT OF HEALTH AND HUMAN SERVICES, *supra* note 26.

¹⁵²U.S DEPARTMENT OF HEALTH AND HUMAN SERVICES, *supra* note 26.

¹⁵³*Id.*

¹⁵⁴*Id.* (Mayo Clinic and Mayo Foundation researchers reported 24 cases of rare valvular disease found in women who took the fen-phén combination therapy.); see generally U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Interim Recommendations Issued for Patients Exposed to Fenfluramine and Dexfenfluramine*, HHS NEWS, (Nov. 13 1997) <<http://www.fda.gov/bbs/topics/NEWS/NEW00598.html>>.

¹⁵⁵U.S DEPARTMENT OF HEALTH AND HUMAN SERVICES, *supra* note 154. After the drugs were pulled from the market, many dieters who had been using fen-phén gained the weight back. *Id.* The justification for this is simple, the drugs did not cure the underlying cause of the excess weight. Berger, *supra* note 89. Aside from over eating, weight gain may be attributed to underactive thyroids, toxic livers, poor immune systems, or even psychological afflictions. *Id.* ("According to the Caloric Control Council, 60 million consumers—or one in four Americans—are trying to lose weight at any given time. And each year, impatient dieters ignore doctors' orders to change their eating habits, preferring to shell out nearly \$33 billion on 'wonder drugs' and diet products."). For all the preceding reasons, herbal weight-loss remedies are also not the answer or quick-fix which consumers demand. MAYO CLINIC, *supra* note 26 ("Beware of *any* pill that claims it will lead to fast, easy or permanent weight loss." (emph. added)).

¹⁵⁶Alicia Mundy, *A Big Fat Settlement*, U.S. NEWS ONLINE, (Oct. 18, 1999) <<http://www.usnews.com/usnews/issue/991018/fen.htm>>.

phen use.¹⁵⁷ The settlement proposal is unique in that it provides for long-term medical monitoring of people who currently have no symptoms of valvular or lung disorders but did use the drug pair.¹⁵⁸

VI. DISCUSSION AND PROPOSALS

A. Remove Current Herbal Fen-Phen Products Containing Ephedrine from the Market: Federal & State Actions

The FDA must exercise its power to remove the herbal fen-phen products from the market;¹⁵⁹ however, it has only issued warnings at this point.¹⁶⁰ The products, due to their hazardous ingredient composition, do pose an unreasonable health risk and may, therefore, be removed promptly.¹⁶¹ Based on drug-like claims¹⁶² and the dangers associated with ephedrine and 5-hydroxy tryptophan,¹⁶³ the Secretary must exercise the power to remove these products.¹⁶⁴ Also, these products are in violation of FTC and FDA marketing mandates because the products infer that they are substitutes for prescription drugs.¹⁶⁵ For example, calling St. John's Wort, "herbal Prozac," or anti-obesity supplements, "herbal fen-phen" falsely and dangerously imply that these products will deliver the same results as prescription drugs.¹⁶⁶

Aside from the FDA, individual states may ban or restrict the sale of harmful herbal fen-phen supplements.¹⁶⁷ Approximately fourteen states, including Florida,¹⁶⁸ Illinois,¹⁶⁹ and Ohio,¹⁷⁰ have passed laws to ban or restrict the sale and use of some

¹⁵⁷*Id.* (the settlement is pending approval by the court and many lawyers have advised their clients to decline the offered settlement).

¹⁵⁸*Id.*

¹⁵⁹Porter, *supra* note 49, at 14.

¹⁶⁰*FDA Warns, supra* note 2.

¹⁶¹Pub. L. No. 103-417, § 4, 108 Stat. at 4327 (codified at 21 U.S.C. § 321(f)(1)(B)).

¹⁶²*FDA Warns, supra* note 2.

¹⁶³*See supra* Part V.A.C.

¹⁶⁴Pub. L. No. 103-417, § 2, 108 Stat. at 4326 (codified at 21 U.S.C. § 321 NOTE (12)).

¹⁶⁵Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. at 23,623; *FDA Warns, supra* note 2; FOOD AND DRUG ADMINISTRATION, *FDA's Dietary Supplement Proposal* (last modified Apr. 27 1998) <http://www.fda.gov/bbs/topics/FACTSHEETS/fs_diet1.html>.

¹⁶⁶Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,623; *FDA Warns, supra* note 2; FOOD AND DRUG ADMINISTRATION, *FDA's Dietary Supplement Proposal* (last modified Apr. 27 1998) <http://www.fda.gov/bbs/topics/FACTSHEETS/fs_diet1.html>.

¹⁶⁷39 AM. JUR. 2D, *Health* § 1 (1968); Kurtzweil, *supra* note 25.

¹⁶⁸Fla. Stat. ch. 499.0054 (1998).

¹⁶⁹720 Ill. Comp. Stat. 570/210 (g)(1) (West 1999).

¹⁷⁰OHIO REV. CODE. ANN. § 3719.41 (West 1998).

products containing ephedrine due to their proven hazards.¹⁷¹ Florida, for instance, has banned all ephedrine-containing products unless dispensed by prescription;¹⁷² furthermore, individuals found to be “trafficking” ephedrine are charged with a first-degree felony.¹⁷³ Illinois has similarly cracked down on ephedrine use, especially by adolescents.¹⁷⁴ In *Wilson v. Collinsville Community School District*, the court upheld the school board's expulsion of a student possessing pills combining ephedrine and caffeine.¹⁷⁵ Ohio also classifies Ephedrine as a “Schedule IV” controlled substance which includes: “any material, compound, mixture, or preparation that contains any quantity of the . . . substance[] having a stimulant effect on the central nervous system.”¹⁷⁶ Unfortunately, many other states have not acted thus far.¹⁷⁷

B. Legislative Changes: DSHEA Reforms Are Needed

1. Overview

Even a principal sponsor of the DSHEA, Congressman Bill Richardson, admitted there was a need to reform the DSHEA.¹⁷⁸ Consequently, Richardson proposed to clarify and possibly repeal the DSHEA.¹⁷⁹ Members of the supplement industry were divided over whether to support Richardson's proposals.¹⁸⁰

By enacting new or amending current laws, the Government can provide greater protection to all dietary supplement consumers,¹⁸¹ especially for those who fail to sufficiently educate themselves prior to the purchase or ingestion of a supplement such as herbal fen-phen.¹⁸² This Note does not imply that supplements should be regulated as drugs, requiring a prescription from a physician.¹⁸³ Instead, supplements should have to meet more rigorous safety and efficacy standards before being

¹⁷¹Kurtzweil, *supra* note 25; Bruce A. Silverglade, Regulating Dietary Supplements Safety Under the Dietary Supplement Health and Education Act: Brave New World or Pyrrhic Victory?, 51 FOOD & DRUG L.J. 319 (1996); Aaron, *supra* note 93, at 62.

¹⁷²Fla. Stat. ch. 490.033(1) (1998).

¹⁷³*Id.* at ch. 893.135(f)(1).

¹⁷⁴*See generally* *Wilson v. Collinsville Community Unit Sch. Dist.*, 451 N.E.2d 939 (5th Cir. Ill. 1983).

¹⁷⁵*Id.*

¹⁷⁶OHIO REV. CODE. ANN. § 3719.41 Schedule IV (C)(1).

¹⁷⁷*See* Tod L. Stewart, Case Note, *Getting High with a Little Help from the Feds: Federal Regulation of Herbal Stimulants*, 6 J. PHARMACY & L. 101, 109-113 (1997).

¹⁷⁸Silverglade, *supra* note 171, at 320.

¹⁷⁹*Id.* at 319 n.3. (citing H.R. 1951, 104th Cong. (1995)).

¹⁸⁰*Id.* at 319.

¹⁸¹39 AM. JUR 2D, *Health* § 1 (1968).

¹⁸²Pub. L. No. 103-417, § 2, 108 Stat. at 4326 (codified at 21 U.S.C. § 321 NOTE (8),(10)).

¹⁸³Silverglade, *supra* note 171, at 319.

released. Before the deregulation under the DSHEA, manufacturers were required to make such showings under the FDCA.¹⁸⁴

Additionally, an improved regulatory scheme should require the establishment of purity levels for ingredients to guarantee consistency and improve safety in supplements because they are not regulated for potency or quality.¹⁸⁵ Essentially, “[h]erbal remedies have a place in wellness and healthcare. They also need to be regulated to ensure safety, quality, potency and appropriate use.”¹⁸⁶ One example of these inconsistent factors may be found in St. John’s Wort.¹⁸⁷ One manufacturer’s product may contain dried flowers from the herb, while another may use a liquid extract.¹⁸⁸ The problem is that we cannot tell how much of the “active ingredient, if any” we are ingesting.¹⁸⁹

The problem is exacerbated by the fact that herbal supplements are no longer confined to small, remotely located health food stores.¹⁹⁰ Supplements are now frequently found in supermarket aisles and pharmacies,¹⁹¹ retail outlets in malls and plazas, on television, in catalogs, and on-line.¹⁹²

2. Restore FDA's Power to Serve and Protect: Increase Funding

Because the FDA has limited resources, it focuses on public health emergencies and products that have caused injury and/or illness receive analytical attention before fraudulent or illegal products.¹⁹³ Currently, funding of the FDA is inadequate to allow necessary practices of protecting consumers to expand.¹⁹⁴ For example, if a concerned consumer contacts the FDA for information about the concentration or amount of a dietary ingredient per serving, their request is denied due to a lack of

¹⁸⁴21 U.S.C. § 321(g) (defining a “drug”).

¹⁸⁵Porter, *supra* note 49, at 12.

¹⁸⁶Kendall, *supra* note 12.

¹⁸⁷Herbal Hope or Herbal Hype?, *supra* note 11.

¹⁸⁸*Id.*

¹⁸⁹*Id.*

¹⁹⁰Brenneman, *supra* note 25.

¹⁹¹According to Hunter Pelley, R.Ph., Pharm.D: “Weight-loss aids are among our best sellers and herbal fen-phen is the best selling natural weight-loss product we stock. The St. John’s wort and ephedra combination is popular.” Judith Eaten, M.S., R.D., C.N.D., *Beyond Fen-Phen: What’s Safe in Weight Loss Products*, NAT. PHARMACY, (Feb. 1998) <http://www.healthshoppe.com/hl_womenshealth_diet.htm> (quoting Hunter Pelley, R.Ph., Pharm.D.).

¹⁹²Brenneman, *supra* note 25; *Supermarkets Experience Fastest Rate of Growth in Mainstream Dietary Supplement Market*, NAT. BUS., (Oct. 1998) reprinted in Herb World News Online <<http://www.herbnet.com>>.

¹⁹³FOOD AND DRUG ADMINISTRATION, *Overview of Dietary Supplements*, (May 1997) <<http://www.vm.cfsan.fda.gov/~dsm/ds-oview.html>> [hereinafter *Overview of Dietary Supplements*].

¹⁹⁴*Id.*

monetary resources.¹⁹⁵ Instead consumers must rely either on biased manufacturers for detailed information beyond ads and labels, or hire an independent laboratory for a costly analysis.¹⁹⁶ These are simple, yet effective, practices that the FDA could adopt to better serve Americans if Congress would authorize increased, necessary funding.¹⁹⁷

Increasing funding for committees appointed by legislative enactment would allow such groups to do work that is more effective.¹⁹⁸ Currently, the Office of Dietary Supplements only receives \$5,000,000 to run an entire division charged with the monumental task of improving the way supplements are regulated and provided to the public.¹⁹⁹ Funding for such vital groups should be in proportion to the huge success of this booming industry.²⁰⁰ In Germany, a special governmental committee, "Commission E," is maintained for the sole purpose of regulating herbal products.²⁰¹ Germany provides a model that the government should use as a guide for future reformations.

3. Manufactures' Contributions

Along with stronger legislation, manufactures should be responsible to provide an abundant amount of clear and accurate information to consumers with the sale of

¹⁹⁵*Id.*

¹⁹⁶*Id.*

¹⁹⁷*See generally id.*

¹⁹⁸*See generally* Kurtzweil, *supra* note 25.

¹⁹⁹Pub. L. No. 103-417, § 485C, 108 Stat. at 4334 (codified at 42 U.S.C. § 287C-11). Additionally, groups like the Council for Responsible Nutrition, made up of manufactures, should also increase its monetary contribution to improve American's health. Pub. L. No. 103-417, § 2, 108 Stat. at 4326 (codified at 21 U.S.C. § 321 NOTE (12) (Congress found that an estimated 600 supplement manufacturers sold 4,000 products and realized sales of \$4,000,000,000.). This group and others like the Corporate Alliance for Integrative Medicine, sponsor consumer education efforts to better service consumers. *Industry Alliance Formed to Increase Research and Education on Supplements*, BUS. WIRE, (Oct. 8, 1998) reprinted in Herb World News Online <<http://www.herbnet.com>>. Manufacturers need to act more responsibly, avoiding deceptive and dangerous tactics to increase sales. "Since the federal Food and Drug administration issued warnings on [ephedra, Chaparral and DHEA] in the past three years, they're 'being snuck into' more than 90 other products in the weight loss, sports and energy supplement sections." Brenneman, *supra* note 25 (quoting nutritionist Mark Mincolla).

²⁰⁰Pub. L. No. 103-417, § 2, 108 Stat. at 4326 (codified at 21 U.S.C. § 321 NOTE (12)(C)).

²⁰¹Edgar R. Cataxinos, Note, Regulation of Herbal Medications in the United States: Germany Provides a Model for Reform, 1995 UTAH L. REV. 561, 579-589 (Cataxinos' use of the phrase "herbal medications," for purposes of this comparison, should be construed to mean the same as "dietary supplements" referred to in this Note). Germany has enjoyed support from both the medical and pharmaceutical/supplement companies with regard to safety and efficacy of supplements. *Id.* at 578. A good portion of a product's research is contracted for or achieved through grants with educational institutions. *Id.*

each product.²⁰² This point is especially crucial because "[t]here are no significant studies to prove the success rate of herbal fen-phen products."²⁰³ Experts suggest that consumers should request and manufacturers should provide data evidencing scientific results from product tests.²⁰⁴ Even FDA critics, like Senator Orrin Hatch and Representative Bill Richardson, "encourage greater consumer knowledge about preventative medicine."²⁰⁵ The two legislators, in a joint statement, also remarked: "It doesn't make any sense at all to curb the dissemination of information about products that could end up saving this nation billions of dollars in health-care costs."²⁰⁶

Further information should also be made available through toll free phone numbers or web sights, allowing a consumer to make a more informed decision about what supplements to use and which to stay away from.²⁰⁷ The "MedWatch" program, offered by the FDA, enables health care professionals to report harmful effects or illnesses suffered by patients from dietary supplements.²⁰⁸ Incidents may be reported to MedWatch via its website, www.fda.gov/medwatch/report/hcp.htm, or hotline at 1-800-FDA-1088.²⁰⁹ Several manufactures are currently attempting to service this need through the internet;²¹⁰ for example, EAS has a web site which gives information about the company and its products.²¹¹ A simple search of this site will afford consumers facts about a supplement's ingredients, purpose, and dosage.²¹² Another part of the database, "frequently asked questions" gives visitors satisfactory responses to inquiries commonly made about various products.²¹³

²⁰²See Silverglade, *supra* note 171, at 319.

²⁰³Condor, *supra* note 28 (quoting Professor Janet Walberg Rankin, Virginia Tech University).

²⁰⁴*Id.* (citing Professor Janet Walberg Rankin, Virginia Tech University).

²⁰⁵Gannon, *supra* note 75.

²⁰⁶*Id.*

²⁰⁷For example, the National Institute of Health's Office of Dietary Supplements recently announced its plans to create a dietary supplement information database. CNN INTERACTIVE, *NIH Creates Information Database for Dietary Supplements*, (Jan. 6, 1999) <<http://cnn.com/HEALTH/9901/06/dietary.supplement/index.html>>.

²⁰⁸*Overview of Dietary Supplements*, *supra* note 193.

²⁰⁹*Id.* (consumers may call 1-800-FDA-1088 or visit <<http://www.fda.gov/medwatch/report/consumer/consumer.htm>>).

²¹⁰*Scientific Evidence Suggests the Use of Supplements, Such as Fen-Free May Help Reinforce the Metabolic Rate*, (visited Jan. 19, 1999) <<http://eas.com/q-a/index.html>>.

²¹¹*Id.*

²¹²*Id.*

²¹³*Id.*

Several other responsible manufacturers are attempting to reach out to consumers by offering them a considerable amount of information.²¹⁴ For example, Goldine, a supplement manufacturer, tells consumers what is and what is not in their supplements.²¹⁵ They take this "full-disclosure labeling" one step further by giving informational statements on the labels of each product, telling the consumer why that supplement is recommended.²¹⁶ This is a commendable start; however, Americans need to consistently see more supplements on the shelves with such information.²¹⁷

Recently, the Council for Responsible Nutrition, an organization of dietary supplement manufacturers and suppliers, submitted "Good Manufacturing Practices (GMPs)" to the FDA.²¹⁸ The FDA is reviewing these suggested industry practices and considering making GMPs mandatory.²¹⁹ Today about ninety percent of manufacturers use the Council's draft of a warning label for ephedrine alkaloid-containing products.²²⁰ This exemplifies the GMPs fostered by most of the supplement industry; however, any non-compliance remaining must be corrected through governmental mandate.²²¹ The manufacturers that have not adopted the warning, in combination with misuse and misguided recommendations, continue to threaten consumer health.²²²

C. Significantly Increase Dietary Supplement Research

Another issue to be addressed by future, legislative reform concerns dietary supplement research. This change is necessary simply because today's marketing is too far ahead of research.²²³ Because human studies to test how various supplements or ingredients taken simultaneously interact have not been performed for more than a few weeks at a time, we do not know the long-term health effects of supplement usage.²²⁴ This would require scrutiny of a preponderance of data from scientific studies of the health benefits conferred upon individuals through dietary supplement use.²²⁵

²¹⁴Iris Rosendahl, *Vitamins Promote Health and Healthy Sales*, DRUG TOPICS, Apr. 20, 1992, available in 1992 WL 3252679 (companies include Goldine, Centrum, and Hoffman-La Roche Inc.).

²¹⁵*Id.*

²¹⁶*Id.*

²¹⁷*See generally id.*

²¹⁸Porter, *supra* note 49, at 16.

²¹⁹*Id.*

²²⁰Kurtzweil, *supra* note 25.

²²¹*Id.*

²²²*Id.*

²²³Schindler, *supra* note 34.

²²⁴*Id.*

²²⁵Pub. L. No. 103-417, § 2, 108 Stat. at 4325-26 (codified at 21 U.S.C. § 321 NOTE (1), (8)).

In addition, “many consumers take a handful of supplements at a time, yet no one knows how these supplements interact with one another,” claims Priscilla M. Clarkson, Ph.D., professor of exercise science at the University of Massachusetts at Amherst and editor of the *International Journal of Sport Nutrition*.²²⁶ Varying doses and dietary ingredients may be deteriorating our health rather than helping to maintain it.²²⁷ We have been warned by the tremendous number of adverse consequences from the use of ephedra; similar or more devastating effects may be what the future hold for the majority of herbal fen-phen users.²²⁸ We cannot wait to see if or what may occur, intensive research project on humans, not animals, must be conducted.²²⁹ Ultimately, Congress and the supplement manufacturers should provide the financial means necessary to conduct such studies.²³⁰

D. Training of Health Care Professionals: Dietary Supplement Education for Physicians

Ideally, “[c]onsumers who use dietary supplements should always read product labels, follow directions, and heed all warnings.”²³¹ Unfortunately, many consumers fail to do so. Doctors and health care professionals, however, can help increase awareness and responsible supplement use.²³²

Medical doctors need to be better informed about dietary supplements and their possible interactions with prescription medications.²³³ Many doctors admit that they are not trained about supplements and patients do not tell their health care providers about supplement usage.²³⁴ Because many patients who consult a doctor fail to mention that they use supplements, physicians need more knowledge about supplements so they may provide better care to patients by asking more informed questions to gather pertinent information.²³⁵

Achieving a broader base of information, through appropriate questions, may enable doctors to better care for patients by uncovering and addressing supplement

²²⁶Schindler, *supra* note 34.

²²⁷See, e.g., Porter, *supra* note 49, at 12.

²²⁸FDA Warns, *supra* note 2.

²²⁹Pub. L. No. 103-417, § 2, 108 Stat. at 4326 (codified at 21 U.S.C. § 321 NOTE (2),(7),(8)).

²³⁰*Id.* (codified at 21 U.S.C. § 321 NOTE (1),(12)(C)).

²³¹Kurtzweil, *supra* note 25.

²³²See generally *id.*

²³³FDA Asked to Set Standards for Dietary Supplement Quality, Labeling, FOOD LABELING NEWS, Mar. 25, 1998, available in 1998 WL 12497578.

²³⁴*Id.*

²³⁵*Id.* Furthermore, health food stores where supplements are purchased should be staffed with registered nutritionists or others similarly trained about supplements, dietary ingredients, and their effects upon the body. *Id.* This proposed action may help to cut down on the number of consumers who endanger their health by exceeding manufacturer-recommended doses because they believe “more is better.” Porter, *supra* note 49, at 12.

usage, attempting to dispel misconceptions, and even reporting suspicions about supplement misuse or interaction to the FDA.²³⁶ Moreover, this action would certainly help combat the present danger of mixing some prescription drugs with supplements.²³⁷

Most importantly, a physician's expert advise that "[l]ong term use of [herbal] stimulants is not advised because they keep the body in a constant 'fight or flight' mode, rapidly depleting its energy reserves and potentially leading to a variety of disorders" certainly may make a strong impression on patients.²³⁸ Altogether, this justification for expanded physician education is logical and necessary with the rapid growth of this industry.²³⁹

E. Responsible Reporting and Public Service Campaigns

Finally, an increase in the frequency of responsible reports by various media outlets and public service campaigns could considerably raise consumer awareness.²⁴⁰ By providing consumers with accurate and scientifically sound information about safety, and the appropriate use, benefits, and risks of supplements, education campaigns can significantly impact and improve consumers' usage and impressions of supplements.²⁴¹ If Americans are repeatedly warned about potential

²³⁶Porter, *supra* note 49, at 16.

²³⁷Brenneman, *supra* note 25.

²³⁸Berger, *supra* note 89.

²³⁹FDA Asked to Set Standards for Dietary Supplement Quality, Labeling, *supra* note 233.

²⁴⁰Still today, countless Americans look at themselves in the mirror each day and cringe at what they see peering back at them. They feel unattractive and unhealthy because they are carrying excess pounds. Adding to and in some cases creating this complex is society's endless focus and promotion of healthy eating, exercise, and generally looking great; altogether, this image conveys one message loud and clear: LOSE WEIGHT AND BE THIN. CENTER FOR DISEASE CONTROL AND PREVENTION, *Statistical Rolodex-Overweight Prevalence* (last modified May 28, 1998) <<http://www.cdc.gov/nchswww/fastats/overwt.htm>> (studies in the United States between 1988-1994 revealed that 35% of the adults are overweight).

Consequently many ask: What is a slightly overweight or obese person to do when they have tried to diet, exercise, and even starve themselves to no avail? *See Woman's Death Raises Questions About Fen-Phen Diet, supra* note 1 (obesity is defined as 20% or more over normal weight; Body mass index of 30 or greater); *see also FDA Warns, supra* note 2. They should seek professional help from a physician or nutritionist. The unfortunate reality is that many individuals can only muster up enough courage to stop into a health food store in the mall or a diet clinic, or buy products advertised on television or the internet from the privacy of their own living rooms. Kassel, *supra* note 14, at 247-48. Emotional appeals by manufacturers encourage people to use supplements for medical treatment instead of consulting their physician. *Id.* These unguided searches for weight-loss shortcuts have proven to be hazardous to our health. Kendall, *supra* note 12. Laura Neergaard, *Government Cracks Down on Diet Supplement*, (Nov. 6, 1997) <http://www.sddt.com/files/librarywire/9...es/11-97/DN97_11_06_fay.html>.

²⁴¹Kassel, *supra* note 14, at 263 n.197.

dangers lurking in certain supplements or through the abuse of supplements, they may begin to use this information to create a more favorable and healthful system.²⁴²

The National Institute of Health (the Institute also maintains the Office of Dietary Supplements) now sponsors an internet site to provide information to the public as well as health care providers.²⁴³ Currently, the site offers credible information on dietary supplements from “published, international, [and] scientific literature.”²⁴⁴ Later, the database will allow users to search for bibliographical data through keyword searches.²⁴⁵ This service is a commendable attempt at dealing with consumer awareness deficiencies; however, much more is needed to properly address this serious hurdle.²⁴⁶

The message must be conveyed effectively: “the best way to lose weight is to do it slowly: [S]witch to a low-fat, sensible diet and get regular exercise.”²⁴⁷ We must take responsibility to teach the public and better shape younger generations’ attitude towards health.²⁴⁸ In doing so, we can effectively discourage Americans from “opt[ing] for the easy way out—fat-free chips, diet soda and a bottle of the latest fat-burning pills.”²⁴⁹

VII. CONCLUSION

Currently, manufacturers and distributors have “free reign in testing and marketing” products as long as they are called a “dietary supplement.”²⁵⁰ Due to powerful lobbying efforts by the supplement industry, regulatory modifications may evolve very slowly.²⁵¹ Nevertheless, we must be optimistic as some supplement makers are attempting to work with the FDA, striving to better serve consumers. Amending the DSHEA or enacting more effective, consumer-oriented legislation would serve to satisfy Congress, consumers, and manufacturers. Moreover, Congress’ goal of protecting and improving Americans’ health can be made possible through the implication of the solutions proposed in this Note, while maintaining consumers’ access to a wide variety of safe dietary supplements. As a result of modifications to current dietary supplement regulatory practices, as proposed and

²⁴²Pub. L. No. 103-417, § 2, 108 Stat. at 4326 (codified at 21 U.S.C. § 321 NOTE (5),(7),(8)).

²⁴³CNN INTERACTIVE, *supra* note 207.

²⁴⁴*Id.* (quoting Bernadette Marriott, director of the Office of Dietary Supplements).

²⁴⁵*Id.*

²⁴⁶*See* discussion *supra* Parts II, VI.B.

²⁴⁷Berger, *supra* note 89.

²⁴⁸MAYO CLINIC, *supra* note 26 (individuals should “emphasize diet, exercise and lifestyle modification,” according to Dr. Pasquale Palumbo, an endocrinologist at Mayo Clinic and member of the American Association of Clinical Endocrinologists task force on obesity).

²⁴⁹Berger, *supra* note 89.

²⁵⁰Porter, *supra* note 49, at 16.

²⁵¹*Id.*

discussed in this part VI of this Note, the supplement industry will enjoy increased credibility and prosperity as consumers gain confidence in the system.

The legislative alterations and proposals contained in this Note are attainable. Because Americans' health and well-being is such a legitimate concern, all parties need to work together and compromise to achieve these goals. We have all heard the reoccurring message from health care professionals who advise consumers to: "[R]ealize that the label term 'natural' doesn't guarantee that a product is safe."²⁵² Take a moment to "[t]hink of poisonous mushrooms," says Elizabeth Yetley, Ph.D., director of FDA's Office of Special Nutritionals. "They're natural."²⁵³

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²⁵²Kurtzweil, *supra* note 25.

²⁵³*Id.*

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