

CAVEAT EMPTOR, BUYER BEWARE: DEREGULATION OF DIETARY SUPPLEMENTS UPON ENACTMENT OF THE DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994

INTRODUCTION

No matter what ailment one might be suffering, there seems to be an herbal supplement claiming to have the cure. Posing in the form of pills, capsules, elixirs and lotions, dietary supplements boast of their many abilities. They claim to treat, among other things, obesity, depression, stress, insomnia, and sexual dysfunction.¹ The \$15 billion a year industry would have us believe such supplements actually work.²

In the early 1990s, Congress focused its attention on strengthening federal agencies' abilities to better deal with health fraud.³ At the same time, the Food and Drug Administration (FDA) was considering more regulations for dietary supplements.⁴ The dietary supplement industry put pressure on Congress by using funds, attorneys, and lobbyists to enact legislation to reduce regulations of dietary supplements.⁵ This

¹ See Lawrence Lindner, 'This is Not a Scam' - and Other Lies, WASH. POST, Apr. 25, 2000, at Z10; U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, *Illnesses and Injuries Associated with the Use of Selected Dietary Supplements*, at <http://vm.cfsan.fda.gov/~dms/ds-ill.html> (last visited Aug. 10, 2000) [hereinafter FDA, *Illnesses and Injuries*]; Guy Gugliotta, *Diet Supplement Marketers Target Kids*, WASH. POST, June 18, 2000, at A01 [hereinafter Gugliotta, *Marketers Target Kids*].

² David A. Kessler, M.D., *Cancer and Herbs*, 342 NEW ENG. J. MED. 1742, 1742 (2000).

³ Stephen Barrett, M.D., *How the Dietary Supplement Health and Education Act of 1994 Weakened the FDA*, at <http://www.quackwatch.com/02ConsumerProtection/dshea.html> (last visited July 17, 2000).

⁴ *Id.*

⁵ *NBC Newsweek: How Safe Is Ephedrine?* (NBC television broadcast, May 18,

pressure was fueled by the fact that some of the legislators were selling dietary supplements.⁶ This fight from the dietary supplement industry led to the enactment of the Dietary Supplement Health and Education Act of 1994 (DSHEA).⁷ Congress appeared to have changed its viewpoint from one of mistrust over the industry and desiring more precautions to complete trust of the industry and requiring almost no precautions.⁸ In DSHEA,

Congress finds that - (1) improving the health status of United States citizens ranks at the top of the national priorities of the Federal Government; (2) the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies; (3)(A) there is a link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases[;] (8) consumers should be empowered to make choices based on data from scientific studies of health benefits related to particular dietary supplements[;] (14) dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare; and (15) legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness⁹

As a result, the American consumer is allowed to purchase dietary supplements in the absence of pre-market scrutiny or approval.¹⁰ This comment will address the following questions: What good is a label that lists ingredients and serving suggestions when it has not passed any safety or regulatory standards to ensure its accuracy? How can health claims on a dietary supplement label promote health when the manufacturer is allowed to make structure/function claims without FDA approval? Should the manufacturers of supplements have to warn of recorded side effects? What is the extent of the FDA's authority over the dietary supplement industry?

Passage of DSHEA resulted in several changes in the regulation of dietary supplements.¹¹ By redefining dietary supplements, DSHEA has

1999) [hereinafter *NBC Newsweek*].

⁶ *Id.*

⁷ 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.); Barrett, *supra* note 3.

⁸ See Barrett, *supra* note 3.

⁹ Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 321 (2000).

¹⁰ U.S. Food and Drug Administration, Center for Food and Applied Nutrition, *Dietary Supplement Health and Education Act of 1994*, at <http://vm.cfsan.fda.gov/~dms/dietsupp.html> (last visited July 17, 2000) [hereinafter FDA, *Dietary Supplement*].

¹¹ Sally Squires, *High Irony: New Labels Are Short on Facts*, WASH. POST, Mar. 7, 2000, at H14 [hereinafter Squires, *High Irony*].

allowed products that were once prescription drugs to be considered dietary supplements free from pre-market approval.¹² Instead of requiring scientific research to show the product is reasonably safe to consumers, DSHEA presumes the product is safe for the public.¹³ The burden of proof is shifted to the FDA to show the product is unreasonably dangerous to consumers.¹⁴ DSHEA also broadens the category of dietary supplement to allow more products to be classified as dietary supplements and bypass pre-market scrutiny. Products that were once regulated as drugs are classified as dietary supplements, protected from the burdening “drug” status.¹⁵ The definition of a dietary supplement was vitamins and minerals, but is now

product[s] (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)¹⁶

The FDA claims that dietary supplements are regulated by requiring labels to be “truthful and not misleading” and thus ensure safety to American consumers.¹⁷ However, the FDA does not have the resources to enforce label accuracy or label content.¹⁸ The scientific community has its concerns regarding the enactment of DSHEA, its resulting effect on the public, and its potential injuries to people.¹⁹ One concern is

¹² Jennifer J. Spokes, Note, *Confusion in Dietary Supplement Regulation: The Sports Products Irony*, 77 B.U. L. REV. 181, 192 (1997).

¹³ See Barrett, *supra* note 3; Laura A. W. Khatcheressian, *Regulation of Dietary Supplements: Five Years of DSHEA*, 54 FOOD DRUG L.J. 623, 628 (1999).

¹⁴ Barrett, *supra* note 3.

¹⁵ Spokes, *supra* note 12.

¹⁶ 21 U.S.C. § 321(ff)(1)(A)-(F) (2000).

¹⁷ Food and Drug Administration, U.S. Dep’t. of Health and Admin., *FDA Finalizes Rules for Claims on Dietary Supplements*, FDA TALK PAPER, Jan. 5, 2000 [hereinafter *FDA Finalizes Rules*].

¹⁸ Barrett, *supra* note 3.

¹⁹ See *id.*; Guy Gugliotta, *Woman Using Herbal Aid Has Stroke*, WASH. POST, Apr. 20, 2000, at A02 [hereinafter Gugliotta, *Woman Using Herbal Aid*] (stating “consumers often have no idea what they’re consuming, and you can’t rely on the labels”); Squires, *High Irony*, *supra* note 11 (stating there is “inaccurate information out there about supplements[;]” supplement information is out-dated or misleading; and not even nutritionists can interpret supplement labels); Marcia Angell, M.D. & Jerome P. Kassirer, M.D., *Alternative Medicine - The Risks of Untested and Unregulated Remedies*, 339 NEW ENG. J. MED. 839, 841 (1998) (reporting adulteration in several supplements); Sally Squires, *The Risks of Fat Busters*, WASH. POST, Mar. 28, 2000, at HE14

that there are usually no warnings on the labels of dietary supplements, even though scientific research is available documenting side effects linked to particular supplements.²⁰ Further, labels fail to mention the dangerous chemical interactions between certain supplement ingredients.²¹ Information as to tolerable upper limits of certain vitamins and minerals that will be toxic to humans is not required to be on labels.²² Lack of pre-market scrutiny has rendered nutrition information on supplement labels meaningless.²³ According to research, dietary supplement contents do not match label descriptions.²⁴ This problem includes mislabeled ingredients, omitted ingredients, contaminated products, and varied contents in bottles of the same product.²⁵ DSHEA has extensively debilitated the FDA, practically stripping it of all authority concerning dietary supplements.²⁶ The FDA has only a few inadequate channels for exercising any form of control in this area.²⁷

[hereinafter Squires, *Risks of Fat Busters*] (discussing lack of knowledge on supplements and their effects); *From Ginseng to St. John's Wort: Minimal Regulation of Dietary Supplements Compromises Consumers and their Health Care Providers*, at <http://www.aphanet.org/govt/policycomm2000/dietarysuppsbackground.html> (last visited Aug. 10, 2000) [hereinafter *From Ginseng to St. John's Wort*].

²⁰ See FDA, *Illnesses and Injuries*, *supra* note 1.

²¹ See Squires, *High Irony*, *supra* note 11 (explaining interactions between supplements with other supplements or with drugs); U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *Risk of Drug Interactions with St. John's Wort and Indinavir and Other Drugs*, FDA PUB HEALTH ADVISORY, Feb. 10, 2000, at <http://www.fda.gov/cder/drug/advisory/stjwort.html> (last visited Aug. 10, 2000) [hereinafter FDA, *Risk of Drug*].

²² Squires, *High Irony*, *supra* note 11.

²³ See Spokes, *supra* note 12, at 192-93 (stating "very lenient standards . . . did not require pre-market approval . . . [and] has infused a great deal of uncertainty into the industry."); FDA, *Dietary Supplement*, *supra* note 10 (stating "dietary supplements are no longer subject to the pre-market safety evaluations required of other new food ingredients"); Kessler, *supra* note 2, at 1743.

²⁴ See Bill J. Gurley et al., *Content Versus Label Claims in Ephedra-Containing Dietary Supplements*, 57 AM. J. HEALTH-SYS. PHARMACOLOGY 963, 965-67 (2000); *NBC Newsweek*, *supra* note 5.

²⁵ See Gurley, *supra* note 24, at 964.

²⁶ Cf. 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> (last visited July 17, 2000) [hereinafter FDA, *Overview*] (reporting that "Manufacturers and distributors do not need to register with FDA or get FDA approval before producing or selling dietary supplements The manufacturer is responsible for ensuring that these statements are accurate and truthful").

²⁷ See *id.*

I. BACKGROUND ON DSHEA

Before the enactment of DSHEA, the Government's earlier concerns over dietary supplements were already decreasing.²⁸ Dating back to 1938, the FDA became concerned with dietary supplements and passed the Federal Food, Drug and Cosmetic Act (FDCA).²⁹ The "FDA established detailed labeling requirements for foods marketed for 'special dietary uses.'" ³⁰ The FDA's focus and concern over dietary supplements has varied over the years. In the early 1960s, the FDA published proposed regulations for setting "minimum and maximum levels for dietary supplements," but was forced to withdraw them after much "consumer protest."³¹ Congress later "foreclosed" on the FDA's attempt "to regulate excessive dosages of vitamins as drugs through adjudication."³² "In the late 1970s, the FDA again attempted to regulate high-level dosage vitamins as drugs through adjudication, this time focusing on the toxic impacts of the products."³³ Neither Congress nor the courts were receptive to the FDA's attempt to regulate the vitamins as "food additives" under the FDCA.³⁴

"In 1990 Congress enacted the Nutrition Labeling and Education Act of 1990 ("NLEA"), which requires standardized labeling for conventional foods and prohibits manufacturers from making unsubstantiated health claims about their products."³⁵ Acting in compliance with the NLEA, the FDA established the same standards for dietary supplements.³⁶ In response, "Congress enacted the Dietary Supplement Act of 1992,³⁷ which placed a moratorium on the FDA's application" of these standards to dietary supplements.³⁸ This Act also forced the FDA to "promulgate rules . . . reiterating that the FDA would treat dietary supplements as conventional foods."³⁹ After the FDA created its pro-

²⁸ Khatcheressian, *supra* note 13, at 623.

²⁹ *Id.*; see Federal Food, Drug and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. § 321).

³⁰ Khatcheressian, *supra* note 13, at 624.

³¹ *Id.*

³² *Id.*

³³ *Id.*

³⁴ *Id.* at 624, 627.

³⁵ Spokes, *supra* note 12, at 189; see Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended at 21 U.S.C. § 343).

³⁶ Spokes, *supra* note 12, at 189.

³⁷ Dietary Supplement Act of 1992, Pub. L. No. 102-571, Title II, 106 Stat. 4491, 4500 (codified as amended in scattered sections of 21 U.S.C.).

³⁸ Spokes, *supra* note 12, at 189.

³⁹ *Id.* at 190.

posed rules under the Dietary Supplement Act, Congress passed DSHEA.⁴⁰ This Act preempts proposed rules set by the FDA, codifies Congress' "desire for reduced regulation of dietary supplements," and sets regulation of dietary supplements at a lower standard than it had for "conventional foods, food additives, or drugs."⁴¹

II. BUYER BEWARE

Congress enacted DSHEA because it believes that dietary supplements are linked to the promotion of health and well being. However, Congress must have overlooked the fact that dietary supplements are also linked to kidney disease, liver disease, heart attacks, strokes, and other health problems.⁴² Making an informed decision about purchasing dietary supplements includes having knowledge of their beneficial and harmful qualities.⁴³ Instead of placing the responsibility on the FDA to ensure manufacturers disclose all risks involved in a supplement, DSHEA places that responsibility on consumers.⁴⁴

A. Label Requirements for Dietary Supplements

DSHEA provides for certain things to be on a dietary supplement label. First, there must be "ingredient labeling," which "must include the name and quantity of each dietary ingredient or . . . the total quantity of all dietary ingredients" in the product as blended.⁴⁵ Second, there must be identification on the label that states the product is a dietary supplement. Third, if the dietary supplement contains an herb or botanical, the label must indicate "the part of the plant from which the ingredient is derived."⁴⁶ Dietary supplement manufacturers may, but need not, disclose "the source of a dietary ingredient"⁴⁷ even though its source can make a difference in its properties or potency.⁴⁸ Fourth,

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² See Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended at scattered sections of 21 U.S.C.); FDA, *Illnesses and Injuries*, *supra* note 1.

⁴³ See Squires, *High Irony*, *supra* note 11.

⁴⁴ See *id.* (suggesting that since labels are out of date and inaccurate, the consumer must be the one to research the negative effects).

⁴⁵ FDA, *Dietary Supplement*, *supra* note 10.

⁴⁶ *Id.*

⁴⁷ *Id.* (providing the example of "calcium from calcium gluconate" as a source of an ingredient).

⁴⁸ Squires, *Risks of Fat Busters*, *supra* note 19 (stating that the "composition of the chitin can vary depending on the seawater, the time of year and the animal it is ex-

if the label indicates that a supplement falls within the coverage of an official compendium,⁴⁹ such as the U.S. Pharmacopoeia or the Homeopathic Pharmacopoeia of the United States, the supplement must conform to that compendium's specifications.⁵⁰ Last, the dietary supplement label must include "nutrition labeling."⁵¹ "This labeling must first list dietary ingredients present in 'significant amounts' for which FDA has established" a recommended daily allowance.⁵² Ingredients present in significant amounts must be listed if the FDA has not established such a recommended allowance. Ingredients that are not present in the supplement in a significant quantity need not be listed at all. "If an ingredient is listed in the nutrition labeling, it need not appear in the statement of ingredients."⁵³

The FDA allows the manufacturers to place "structure/function" claims on dietary supplement labels.⁵⁴ These are claims stating how the product will affect the structure or function of the body.⁵⁵ Some examples are: "promotes a healthy circulatory system" or "for muscle enhancement."⁵⁶ DSHEA requires that the manufacturer be able to substantiate any and all structure/function claims that are made.⁵⁷ "[DSHEA] does not define substantiation."⁵⁸ If the manufacturer is making a structure/function claim, it need not pass any pre-market approval.⁵⁹ The FDA "precludes express disease claims . . . and implied disease claims . . . without prior FDA review."⁶⁰ A disease claim states the product is able to "prevent, treat, cure, mitigate or diagnose disease"⁶¹ Examples of disease claims are: "prevents osteoporosis," "treats cancer," or a name such as "CircuCure."⁶² Manufac-

tracted from").

⁴⁹ FDA, *Dietary Supplement*, *supra* note 10 (stating that a compendium provides specifications that must be met for certain supplements). A compendium is "a brief summary of a larger work or of a field of knowledge." NEW MERRIAM-WEBSTER DICTIONARY 163 (1989).

⁵⁰ FDA, *Dietary Supplement*, *supra* note 10.

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

⁵⁴ FDA *Finalizes Rules*, *supra* note 17.

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ Barrett, *supra* note 3.

⁵⁹ FDA *Finalizes Rules*, *supra* note 17.

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.*

turers are required to substantiate their claims with evidence. However, since there is no pre-market regulation or scrutiny, they face no accountability before marketing the product.⁶³ Subsequently, the FDA expanded what is considered to be a structure/function claim. It now includes health maintenance claims, such as “helps you relax,” as well as “claims for common, minor symptoms associated with life stages,” such as “for hot flashes” or “for common symptoms of PMS.”⁶⁴

A health claim that associates a supplement with a disease can only be on the label if the FDA has reviewed it.⁶⁵ Manufacturers need only show “significant scientific agreement” to get approval of a health claim. However, the FDA has never explained how it measures “significant.”⁶⁶ If the FDA has not approved the health claim the manufacturer wishes to use, the manufacturer may still use that claim if it adds a disclaimer to the label.⁶⁷ The disclaimer need only state that “the FDA has not evaluated the statement.”⁶⁸ Further, DSHEA allows manufacturers to use unapproved health claims without the disclaimer, as long as they are displayed separate from the supplement.⁶⁹ Essentially, the manufacturer is free to make any health claims it wishes.⁷⁰

Moreover, the manufacturer must notify the FDA of claims made on the label within thirty days of marketing the dietary supplement product.⁷¹ The purpose behind this requirement is to have some minimal policing of dietary supplements.⁷² The FDA believes this rule will ultimately provide the consumer with “a high level of confidence in the safety, composition, and labeling of dietary supplements.”⁷³ The rule may build confidence in the American consumer in the safety of these products, but the information is one-sided. The FDA has “increase[d] the amount of misinformation that can be directly transmitted to prospective customers.”⁷⁴ Thus, consumers are “virtually unprotected

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Pearson v. Shalala*, 164 F.3d 650, 653 (D.C. Cir. 1999).

⁶⁷ FDA, *Overview*, *supra* note 26.

⁶⁸ FDA *Finalizes Rules*, *supra* note 17.

⁶⁹ *See* FDA, *Dietary Supplement*, *supra* note 10.

⁷⁰ FDA, *Overview*, *supra* note 26.

⁷¹ FDA *Finalizes Rules*, *supra* note 17; *see* *Nutritional Health Alliance v. Shalala*, 144 F.3d 220, 225 (2nd Cir. 1998) (discussing the procedure for placing new claims on supplement products).

⁷² FDA *Finalizes Rules*, *supra* note 17.

⁷³ Barrett, *supra* note 3.

⁷⁴ *Id.*

against supplements and herbs that are unsafe.”⁷⁵

B. Side Effects and Health Concerns of Dietary Supplements

The FDA states that the use of health claims has provided more information to consumers, allowing them to “make informed choices.”⁷⁶ The purpose of a warning is “to inform a party of the existence of a potential danger of which he may not be aware, enabling the consumer to protect himself against it.”⁷⁷ Generally, product manufacturers must warn of all known dangers,⁷⁸ but DSHEA created an exception for dietary supplement manufacturers. Research has more than proven that there are disagreeable consequences and dangers associated with several of the dietary supplements.⁷⁹ In order for consumers to make a truly informed decision, they must be aware of the health benefits as well as the health risks.⁸⁰

1. Side Effects

Several side effects are scientifically linked to various dietary and herbal supplements. A few of the common herbal supplements that have known side effects include chaparral, comfrey, jim bu huan, germander, yohimbine, and stephania. Continued use of any of these herbal supplements results in damage to liver and kidney functions.⁸¹ Ephedrine-containing supplements are linked to very serious side effects, such as strokes and dangerously high blood pressure.⁸² Other serious effects of ephedra include hypertension, palpitation, memory loss, neuropathy (nerve damage), myopathy (muscle injury), psychosis, and death.⁸³ Between 1993 and 1996, the FDA recorded about seven

⁷⁵ *Id.*

⁷⁶ FDA, *Overview*, *supra* note 26.

⁷⁷ BLACK'S LAW DICTIONARY 1584 (6th ed. 1990); *see* NEW MERRIAM-WEBSTER DICTIONARY 822 (1989) (defining warning as “to put on guard; caution; also admonish, counsel; to notify especially in advance; inform”).

⁷⁸ W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 102, at 710 (5th ed. 1984).

⁷⁹ FDA, *Illnesses and Injuries*, *supra* note 1; Kessler, *supra* note 2; Squires, *High Irony*, *supra* note 11.

⁸⁰ *See* Squires, *High Irony*, *supra* note 11.

⁸¹ FDA, *Illnesses and Injuries*, *supra* note 1; Kessler, *supra* note 2; Squires, *High Irony*, *supra* note 11.

⁸² Gugliotta, *Woman Using Herbal Aid*, *supra* note 19.

⁸³ Keith Epstein, *In Fact: Ephedra*, WASH. POST, May 2, 2000, at HE8; Guy Gugliotta, *FDA Takes Aim at Ephedra*, WASH. POST, Mar. 19, 2000, at A22 [hereinafter Gugliotta, *FDA Takes Aim*].

hundred adverse reactions and thirty-nine deaths from taking ephedra.⁸⁴ In one case, a twenty-four year-old girl tried to lose a few pounds before her wedding, took an ephedrine-containing diet pill according to directions, and suffered a stroke.⁸⁵ In another case, a twenty-nine year-old soldier suffered “a massive brain hemorrhage” on a treadmill after taking the ephedra-containing nutrition mix called “Ultimate Orange.”⁸⁶

Millions of Americans purchase St. John's Wort, which purports to treat depression.⁸⁷ A study performed by students at the University of Maryland School of Pharmacy reveals that 47% of the people in the survey experienced negative side effects, and one had to seek emergency care.⁸⁸ The study also suggests that 12.5% of the group suffered serious interactions with food, prescription drugs, and alcohol.⁸⁹ Dr. Piscitelli, of the University of Maryland, performed research which suggests the effectiveness of birth control pills is cut in half when taking St. John's Wort.⁹⁰ Indinavir, a drug used to fight HIV, was administered to a group of volunteers. After a few days, St. John's Wort was added to their treatment. Once St. John's Wort was added, the concentration of Indinavir in their system was reduced by 80%. There was a 57% decrease in the concentration of total HIV drugs in their system when taken with St. John's Wort.⁹¹ “There is a misconception that herbal supplements are safe.”⁹² The truth about these interactions is even more alarming when studies show that more often than not, people use herbal supplements without informing their physicians. Studies show an extremely high possibility of other drug interactions with St. John's Wort. St. John's Wort is an inducer of cytochrome P450, an important metabolic pathway of prescription drugs for heart disease, depression, seizures, certain cancers, prevention of pregnancy, or preven-

⁸⁴ Gugliotta, *FDA Takes Aim*, *supra* note 83.

⁸⁵ Gugliotta, *Woman Using Herbal Aid*, *supra* note 19.

⁸⁶ Gugliotta, *FDA Takes Aim*, *supra* note 83.

⁸⁷ American College of Clinical Pharmacy, *St. John's Wort May Cause Adverse Effects and Drug Interactions*, at <http://www.accp.com/news> (last visited July 17, 2000) (reporting on a survey which revealed that 84% of the persons contacted experienced beneficial results from St. John's Wort); MSNBC Health, *Popular Herb May Weaken the Pill*, at <http://www.msnbc.com/news/368672.asp?cp1=1> (visited July 17, 2000) [hereinafter MSNBC Health].

⁸⁸ American College of Clinical Pharmacy, *supra* note 87.

⁸⁹ *Id.*

⁹⁰ MSNBC Health, *supra* note 87.

⁹¹ *Id.*

⁹² *Id.*

tion of organ rejection.⁹³

Another dietary supplement of concern is dehydroepiandrosterone (DHEA), which is referred to as “the mother of all hormones,” “the fountain of youth hormone,” or “superhormone.”⁹⁴ DHEA is a steroid hormone that supposedly helps people live longer, lose or gain weight, and prevent cancer and several diseases.⁹⁵ However, scientific studies show that it increases body fat in women.⁹⁶ Further side effects include body or facial hair stimulation, irregular menstruation, decreases in levels of high density lipoproteins (the good cholesterol), and increases in risk of heart disease in women.⁹⁷ DHEA also increases testosterone in men to levels that would stimulate growth of any tiny, dormant tumors.⁹⁸ Other side effects include acne, heart rhythm disturbances, irritability, aggression, and hair loss.⁹⁹ Several physicians agree that they would not recommend DHEA supplements to patients without careful supervision by a physician and are troubled over its availability.¹⁰⁰ Their concern stems from the little research on the supplement and the lack of FDA requirements. Thus, the full extent and occurrence of its side effects are still unknown.¹⁰¹

Several other hormone-based supplements are reportedly linked to negative side effects.¹⁰² Gamma butyrolactone (GBL) has had at least fifty-five adverse health effects and one death reported.¹⁰³ In nineteen cases, victims became unconscious, and several required intubation.¹⁰⁴ There are other reports linking GBL intake to seizures, vomiting, slowed breathing, and slowed heart rate.¹⁰⁵ Tiratricol (TRIAX), another

⁹³ *Id.*; FDA, *Risk of Drug*, *supra* note 21; Jane E. Henney, M.D., *Risk of Drug Interactions with St. John's Wort*, 283 JAMA 1679, 1679 (2000).

⁹⁴ P. J. Skerret, *DHEA: Ignore the Hype*, at <http://www.quackwatch.com/01quackrelatedtopics/dhea.html> (last visited July 17, 2000).

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² U.S. Food and Drug Administration, *FDA Warns About Products Containing Gamma Butyrolactone or GBL and Asks Companies to Issue a Recall*, FDA TALK PAPER, Jan. 21, 1999 [hereinafter *FDA Warns About GBL*]; U.S. Food and Drug Administration, *FDA Warns Against Consuming TRIAX Metabolic Accelerator*, FDA TALK PAPER, Nov. 11, 1999 [hereinafter *FDA Warns Against TRIAX*].

¹⁰³ *FDA Warns About GBL*, *supra* note 102.

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

commonly used hormone-based supplement, causes side effects such as abnormal thyroid function, severe diarrhea, fatigue, lethargy, profound weight loss, insomnia, nervousness, and sweating.¹⁰⁶

These and many other supplements pose serious and genuine side effects.¹⁰⁷ Material information concerning these side effects is not readily available and is difficult to find.¹⁰⁸ The FDA has published reports on the side effects of over twenty of the most popular supplements.¹⁰⁹ These reports, unfortunately, are not circulated to the average consumer and can be found only after active research.¹¹⁰

2. Tolerable Upper Intake Levels

With the rise in popularity of multivitamins, the National Academy of Science (NAS) had its Food and Nutrition Board begin looking into the toxicity levels of certain vitamins and minerals.¹¹¹ In 1997, NAS "began setting the first tolerable upper intake levels (TUI)."¹¹² The TUI is not the recommended level.¹¹³ Instead, it is the maximum dosage level that the average human can tolerate biologically before it becomes toxic.¹¹⁴ The NAS set forth the following daily TUIs: Calcium at 2,500 milligrams (mg); Vitamin K at 80 micrograms (mcg); Vitamin A at 25,000 IU;¹¹⁵ Vitamin B6 at 100 mg, with recurrence of toxicity thereafter at 50 mg; Niacin at 20 mg; and Selenium between 800 to 1,000 mcg.¹¹⁶ Although science has proven that certain levels of vitamins and minerals are toxic to humans, manufacturers are not required to post TUIs. Thus, TUIs are rarely found on a supplement label.¹¹⁷ Not only does DSHEA not require TUIs, it also prohibits the FDA from establishing maximum limits on potency of any synthetic or nat-

¹⁰⁶ *FDA Warns Against TRIAX*, *supra* note 102.

¹⁰⁷ *See FDA, Illnesses and Injuries*, *supra* note 1; Kessler, *supra* note 2.

¹⁰⁸ Squires, *High Irony*, *supra* note 11; *see* Kessler, *supra* note 2, at 1743.

¹⁰⁹ FDA, *Illnesses and Injuries*, *supra* note 1 (publishing reports on chaparral, comfrey, yohimbe, lobelia, germander, willow bark, jin bu huan, stephania, aristolochic acid (*A. fangchi*), St. John's wort, gamma-butyrolactone (GBL), tiratricol, ma huang, L-tryptophan, phenylalanine, vitamin A, vitamin B6, niacin, selenium, and germanium).

¹¹⁰ *See* Squires, *High Irony*, *supra* note 11.

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Id.* (stating that IU is an international and standard unit of measurement).

¹¹⁶ *Id.*

¹¹⁷ *Id.* (stating that TUIs are not required to be on labels and are rarely disclosed).

ural vitamin or mineral.¹¹⁸ Thus, the consumer is left unaware by the manufacturer and unprotected by the FDA.¹¹⁹

3. Minimum Warnings on Labels

In America, it is common, and probably expected, to see warning labels on consumer products. Under tort law and product liability, a manufacturer must warn not only of foreseeable dangers from its use, but also from its misuse.¹²⁰ However, DSHEA does not specifically require label warnings, only that claims on labels be "truthful and not misleading."¹²¹

The warnings that manufacturers offer on today's herbal and dietary supplements are incomplete.¹²² For example, Long's Brand and Your-life iron supplements warn of iron poisoning for children under six.¹²³ However, the label fails to mention that 12% of the adult population has a gene in its DNA that causes it to over absorb iron by as much as 50%, putting it at an equal risk of iron poisoning.¹²⁴ Long's Niacin warns that it may cause nausea, flushing, itchiness, or dizziness. However, it fails to warn that its dosage of 100 mg exceeds the TUI set at 20 mg.¹²⁵ The label also fails to warn of other reported adverse reactions, including gastrointestinal distress and mild to severe liver damage.¹²⁶ One tablet of Rite-Aid's Daily Vitamin Supplement contains approximately 5,000 IU of vitamin A. Ninety-five percent of vitamin A in that tablet is of the type called retinyl acetate. If two tablets are taken, the retinyl acetate level is high enough to cause birth defects.¹²⁷ Lastly, Yourlife and NatureMade St. John's Wort products warn that the product may cause photosensitivity.¹²⁸ However, photosensitivity

¹¹⁸ FDA, *Overview*, *supra* note 26; *see* National Counsel v. Shalala, 893 F. Supp. 1512, 1521 (D. Utah 1995).

¹¹⁹ *See* Squires, *High Irony*, *supra* note 11.

¹²⁰ *See* KEETON ET AL., *supra* note 78, § 102, at 710.

¹²¹ Squires, *High Irony*, *supra* note 11; *see* Spokes, *supra* note 12.

¹²² Squires, *Risks of Fat Busters*, *supra* note 19.

¹²³ *See* Squires, *High Irony*, *supra* note 11.

¹²⁴ *Id.*

¹²⁵ FDA, *Dietary Supplement*, *supra* note 10.

¹²⁶ *Id.*

¹²⁷ Squires, *High Irony*, *supra* note 11.

¹²⁸ Photosensitivity is (1) Sensitivity or responsiveness to light. (2) *Medicine*. An abnormally heightened response, especially of the skin, to sunlight or ultraviolet radiation, caused by certain disorders or chemicals and characterized by a toxic or allergic reaction. MICROSOFT BOOKSHELF (1999); Some people develop a rash because their skin is sensitive to sunlight; this is known as Photosensitivity. New Zealand DermNet, *Photosensitivity*, at <http://www.dermnet.org.nz/index.html> (last visited Oct. 15, 2000).

pales in comparison to the unmentioned reported side effects of drug interactions with Indinavir, birth control pills, and other prescription drugs using the cytochrome P450 metabolic pathway.¹²⁹

Many experts fear for the health and safety of consumers today, especially when the truth about dietary supplements is practically non-existent.¹³⁰ Nutrition specialists know the labels do not reveal the truth about vitamins and minerals they should be taking.¹³¹ One such specialist advises, “You can’t just go by the label, it provides a really limited amount of information, which is why you need to be armed with a [nutrition] book or other information.”¹³²

Professionals are also concerned over the advertising techniques of the dietary supplement industry.¹³³ A major concern is that dietary supplements are often marketed to children and young adults who are the least likely to research the supplement before purchasing.¹³⁴ Advertising of supplements seems to target citizens with a lower educational background and lower income.¹³⁵ Supplement marketers assume that persons with lower levels of education are less likely to research dietary supplements before their purchase.¹³⁶ Further, the dietary supplement industry runs advertisements that feed off the hopelessness and frustration of consumers with questions such as “are you tired of being overweight?” and “want to look sexy and feel great?”¹³⁷ There are a lot of overweight people who are tired of feeling uncomfortable and fatigued, and who become more frustrated with each passing year. Experts believe that many people find themselves so desperate that they are willing to try anything, regardless of the consequences. A person who feels “anything is better than nothing” is less likely to bother investigating all possible negative side effects.¹³⁸ For consumer safety, the FDA must mandate adequate and truthful warnings on the supplement labels.

¹²⁹ Squires, *High Irony*, *supra* note 11; FDA, *Risk of Drug*, *supra* note 21.

¹³⁰ Squires, *High Irony*, *supra* note 11.

¹³¹ *Id.*

¹³² *Id.*

¹³³ Gugliotta, *Marketers Target Kids*, *supra* note 1; Lindner, *supra* note 1.

¹³⁴ Gugliotta, *Marketers Target Kids*, *supra* note 1.

¹³⁵ *Id.*

¹³⁶ *United States v. Vitasafe Formula One*, 226 F. Supp. 266, 271 (D. N.J. 1964).

¹³⁷ Lindner, *supra* note 1.

¹³⁸ *Id.*; see Michael Higgins, *Hard to Swallow*, 85 A.B.A. J. 60, 63 (1999).

III. YOU CAN'T JUDGE A DIETARY SUPPLEMENT BY ITS COVER

Before the 20th Century, medicine basically consisted of botanicals, which were used to treat certain ailments, usually by trial and error. Often the botanicals did not work, were contaminated, or were harmful and deadly.¹³⁹ Today, we are a modern society requiring scientific proof of a drug's safety before the FDA will allow it to be marketed.¹⁴⁰ However, since the passage of DSHEA, dietary supplements have been isolated from the benefits of our modern technology and science and resumed the archaic trial by error approach to medicine.¹⁴¹ The FDA can only intervene when a product has shown itself harmful after a significant number of persons are injured.¹⁴²

The FDA states that it is up to the manufacturer to make sure its supplement labels accurately represent the product.¹⁴³ If all manufacturers were of the highest moral character and ran perfect operations without error, this strategy would work. However, beyond mere human error, scientific studies show major discrepancies between supplement content and that which is represented on the label.¹⁴⁴ These discrepancies appear in popular dietary supplements such as melatonin, ginseng, kava kava, and ephedrine.¹⁴⁵ Common mistakes in supplement production are varied ingredient content from label, misnamed ingredients, omitted ingredients, and added ingredients not on the label.¹⁴⁶ Further, there are incidents of contamination and adulteration where manufacturers add "undeclared conventional pharmaceuticals or heavy metals" to their supplements.¹⁴⁷ It is evident that manufacturers of dietary supplements are either not capable of the responsibility that has been given to them under DSHEA or not interested in consumer health and safety.¹⁴⁸

A. Daily Values on Labels are Deceptive

Most dietary supplements containing vitamins and minerals will place Daily Values (DVs) in the nutrition labeling section of the la-

¹³⁹ Angell & Kassirer, *supra* note 19, at 839.

¹⁴⁰ *Id.* at 840.

¹⁴¹ *Id.*

¹⁴² *Id.* at 841.

¹⁴³ FDA, *Overview*, *supra* note 26.

¹⁴⁴ Gurley, *supra* note 24, at 964-68.

¹⁴⁵ *Id.* at 964.

¹⁴⁶ *Id.* at 964-68; *NBC Newsweek*, *supra* note 5.

¹⁴⁷ Gurley, *supra* note 24, at 964.

¹⁴⁸ *See id.*

bel.¹⁴⁹ DVs are calculated by dividing the product content by the Recommended Daily Allowance (RDA) of that product. The NAS establishes the RDAs.¹⁵⁰ The RDAs set by the NAS have fluctuated over time because they are modified with new scientific studies. Most RDA standards have lowered through the years as scientists learned of TUIs.¹⁵¹ The significance of the changes in RDAs is great in light of the fact that DVs need only rely upon any RDA standard published. In other words, the DVs on dietary supplements may be calculated using out-dated information.¹⁵² The oldest dated RDA standard was published in 1968, and it has been reformed and updated by the NAS several times since. Therefore, labels claiming one hundred percent DV could be based on thirty-three year-old data, which current research might qualify as below the RDA standard or at a toxic level.¹⁵³ This allows the dietary supplement industry to place data on its product that suits the best interest of the manufacturer, not the consumer.¹⁵⁴ The supplement industry's comment is that "[e]ach consumer should take the responsibility to make themselves as well informed as they can be to be sure that these Daily Values really apply."¹⁵⁵

B. *Playing Russian Roulette with Dietary Supplements*

Since DSHEA loosened the regulations over dietary supplements, three major problem areas have arisen.¹⁵⁶ The first problem is that the labels are inaccurate and no longer dictate or predict what will be inside. Sometimes an ingredient is listed on the label but omitted from the product. Other times, an ingredient is added to the product but omitted from the label. Further, the ingredient amount stated on the label does not necessarily reflect the actual amount of the ingredient inside the product.¹⁵⁷ Second, there are many incidents of contamination in dietary supplements.¹⁵⁸ Third, there are incidents of adulteration discovered in dietary supplements, meaning that they contain a poisonous or deleterious substance that renders them injurious to the consumer's

¹⁴⁹ Squires, *High Irony*, *supra* note 11.

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ Squires, *High Irony*, *supra* note 11.

¹⁵⁶ See Gurley, *supra* note 24, at 964; NBC *Newsweek*, *supra* note 5.

¹⁵⁷ Gurley, *supra* note 24, at 964-68; NBC *Newsweek*, *supra* note 5.

¹⁵⁸ Gurley, *supra* note 24, at 964.

health.¹⁵⁹

1. Lack of Consistency Between Product Label and Content

Inconsistencies between labels of dietary supplements and their contents have grabbed the attention of the media on more than one occasion.¹⁶⁰ On May 18, 1999, Newsweek ran a story on the serious side effects of ephedrine after a twenty-one year-old male collapsed and died while running a short agility course at a New Jersey police academy. His parents and police discovered he had been taking an herbal supplement, Hydroxycut, which contained ephedrine.¹⁶¹ The young man only took two tablets, which was half the recommended dosage.¹⁶² Dr. Bill Gurley, a scientist interviewed by Newsweek, stated, "The consumer literally has no idea what it is they're [sic] ingesting What's inside these bottles often doesn't match what's listed on the outside."¹⁶³

Dr. Gurley conducted his own research on twenty of the most popular selling dietary supplements.¹⁶⁴ Experts consider the results frightening.¹⁶⁵ The most common ephedrine found in dietary supplements is (-)-Ephedrine.¹⁶⁶ Of these twenty products, 55% "either failed to make a label claim for [ephedrine] content or exceeded 20% difference between [ephedrine] content and label claim."¹⁶⁷ Dr. Gurley's study reveals a range from having only 53% to having 260% ephedrine content variance from the label claim.¹⁶⁸ Therefore, when taking a normal dosage of one of these supplements, one could be taking double the amount without knowing it.¹⁶⁹ This is troubling, especially when ephedrine has already been linked to approximately seven hundred Adverse

¹⁵⁹ *Id.*

¹⁶⁰ See *NBC Newsweek*, *supra* note 5; Lindner, *supra* note 1; Gugliotta, *Woman Using Herbal Aid*, *supra* note 19; Gugliotta, *Marketers Target Kids*, *supra* note 1.

¹⁶¹ *NBC Newsweek*, *supra* note 5 (describing ephedra (ephedrine) as a chemical stimulant, extracted from a Chinese herb called ma huang, which is used in products for weight loss and boosting energy).

¹⁶² *Id.*

¹⁶³ *Id.*

¹⁶⁴ Gurley, *supra* note 24, at 965.

¹⁶⁵ *NBC Newsweek*, *supra* note 5.

¹⁶⁶ Gurley, *supra* note 24, at 965. (reporting there are five ephedrine alkaloids derived from ephedra, which is derived from the Chinese herb, ma huang. "Of the 20 products, 19 contained (-)-Ephedrine" Therefore, it was separated and further analyzed).

¹⁶⁷ *Id.* at 967.

¹⁶⁸ *Id.* at 966.

¹⁶⁹ See *id.*

Event Reports of the FDA.¹⁷⁰

(-)-Ephedrine is not the only ingredient that shows significant variance. There are reported variations in (-)-Methylephedrine content between the bottle label and content in excess of 100%. One product, called Ripped Fuel, shows a variance in the content of (+)-pseudoephedrine and label claim of 188%. Another product claims that it contains 12.5 mg of norephedrine, but the study reveals no evidence of any ephedrine.¹⁷¹ Dr. Gurley's test reveals that five of the products contain (+)-norpseudoephedrine. He is concerned over this finding since (+)-norpseudoephedrine is classified as a Schedule IV controlled substance.¹⁷² Dr. Gurley's study demonstrates that because labels can be inaccurate, the consumer should not rely upon them.¹⁷³

Of further importance, Dr. Gurley's study reveals considerable lot-to-lot variation, meaning variance between bottles of the same product. Dr. Gurley states that "conventional pharmaceuticals exhibiting lot-to-lot differences for (-)-ephedrine in excess of 100% would never be released for public consumption, yet ephedra-containing dietary supplements with such variability fill the shelf."¹⁷⁴ One of the products, called Herbal Ecstasy, varies as much as 132% between lots of the same product. Metabolife, another popular product, has a 106% lot-to-lot variance. There is a 104% variation between lots of Ripped Fuel, and Trim Fast has 145% lot-to-lot variance. Hence, all four products tested specifically for lot-to-lot variance demonstrate significant variation.¹⁷⁵

¹⁷⁰ Gugliotta, *FDA Takes Aim*, *supra* note 83; see U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, *The Special Nutritional Adverse Event Monitoring System*, at <http://vm.cfsan.fda.gov/~dms/aems.html> (last visited Oct. 15, 2000) (associating adverse events of illnesses or injuries with the use of a special nutritional product, such as a dietary supplement); Food and Drug Administration, *FDA Announces the Availability of New Ephedrine and "Street drug alternative,"* FDA TALK PAPER, Mar. 31, 2000 [hereinafter *FDA Announces the Availability*].

¹⁷¹ Gurley, *supra* note 24, at 967.

¹⁷² *Id.* at 964; see *Controlled Substance Act*, at <http://www.dos.vt.edu/upslfiles/csa2.htm> (last visited Oct. 16, 2000) (stating that Schedule IV drugs have a low potential for abuse relative to the drugs in Schedule III. The drug "has a currently accepted medical use in treatment in the United States. Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III. Included in Schedule IV are Darvon, Talwin, Equanil, Valium, and Xanax"); see also, DEA, *Publications: Drugs of Abuse*, at <http://www.usdoj.gov/dea/concern/abuse/chap1/control/sched4.htm> (last visited Oct. 16, 2000).

¹⁷³ See Gurley, *supra* note 24, at 967-68.

¹⁷⁴ *Id.* at 968.

¹⁷⁵ See *id.* at 966.

A similar study was performed on Ginseng in an effort to study its lot-to-lot variance.¹⁷⁶ All of the brands of Ginseng tested claimed the same amount of Ginseng. The study reveals as much as a ten-fold variance between the products, and some products have no Ginseng at all.¹⁷⁷

2. Contamination

Most experts attribute the contamination in dietary supplements to insufficient regulations of dietary supplements.¹⁷⁸ Many experts feel the occurrence of contamination is linked to the lack of Good Manufacturing Practices (GMPs) that the FDA establishes in other areas of regulation. "To support product safety and decrease risk of contamination, the FDA should establish GMPs specific to dietary supplements. Dietary supplement GMPs should borrow applicable provisions from food and drug GMPs to assure quality, safe, contaminant-free products."¹⁷⁹ The FDA has the authority under DSHEA to establish GMPs for dietary supplements, but has yet to do so.¹⁸⁰

In August 1998, the FDA discovered the presence of impurities in 5-hydroxy-L-tryptophan (5HTP)-containing products.¹⁸¹ Products with 5HTP are widely marketed as dietary supplements to treat insomnia, depression, obesity, and attention deficit disorder in children.¹⁸² One of the impurities found, "peak X," is associated with a previous outbreak of eosinophilia-myalgia syndrome (EMS) in 1989 and 1991.¹⁸³

Physicians have detected a few other minor and random incidents of contamination.¹⁸⁴ A young woman developed digitalis toxicity after taking an herbal supplement contaminated with digitalis.¹⁸⁵ One person suffered central nervous system depression after ingesting a growth

¹⁷⁶ Angell & Kassirer, *supra* note 19, at 840.

¹⁷⁷ *Id.*

¹⁷⁸ *See id.*

¹⁷⁹ *From Ginseng to St. John's Wort*, *supra* note 19.

¹⁸⁰ *Id.*

¹⁸¹ Food and Drug Administration, *Impurities Confirmed in Dietary Supplement 5-Hydroxy-L-Tryptophan*, FDA TALK PAPER, Aug. 31, 1998.

¹⁸² *Id.*

¹⁸³ *Id.* (stating that EMS is characterized by an elevation in white blood cell count and severe muscle pain).

¹⁸⁴ *Id.*

¹⁸⁵ Angell & Kassirer, *supra* note 19, at 840; *see also* MICROSOFT BOOKSHELF (1999) (stating that digitalis is "(1) a plant of the genus *Digitalis*, which includes fox-gloves; and (2) a drug prepared from the seeds and dried leaves of this plant, used in medicine as a cardiac stimulant").

hormone supplement from a health food store, and his physician believes it was due to some contaminant in the supplement.¹⁸⁶ Another person suffered lead poisoning after taking an herbal supplement to treat his diabetes.¹⁸⁷ Studies also indicate a general “widespread inconsistencies and adulterations” in medicines and supplements from Asia.¹⁸⁸

Another dietary supplement posing risks of contamination is chitin and chitin products, which are sold as diet pills. The manufacturers of chitin claim to have pure chitin. However, experts agree that pure chitin does not exist in a supplement.¹⁸⁹ Chitin is extracted from the shell of shellfish. The chitin molecules, by a process called chelation, latch onto any heavy metal, amino acid, or fatty acid that it comes into contact with.¹⁹⁰ This means that the location where the chitin is harvested and the specific shellfish from which it is extracted makes a large difference in the chitin product.¹⁹¹ However, under DSHEA, manufacturers of dietary supplements do not have to divulge where their products are obtained.¹⁹² Many physicians will not recommend chitin to their patients without constant physician supervision. One physician stated that he is “afraid of its use as a biomedical product.”¹⁹³

Since the enactment of DSHEA, our courts have been burdened with cases on contamination in dietary supplements. In 1996, the California Court of Appeal denied relief to a woman who suffers from EMS as a result of contaminated L-tryptophan dietary supplements.¹⁹⁴ L-tryptophan is an essential amino acid for our bodies.¹⁹⁵ In this case, the plaintiff had not paid attention to a recall on the product after an entire batch of the product was contaminated and several people contracted EMS.¹⁹⁶

¹⁸⁶ Angell & Kassirer, *supra* note 19, at 840.

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

¹⁸⁹ Squires, *Risks of Fat Busters*, *supra* note 19.

¹⁹⁰ *Id.* (stating that chitin products are used for weight loss because of the chelation process. In theory, chitin latches onto fatty acids and carries them out of the body, keeping them from being metabolized and stored in fat cells).

¹⁹¹ *Id.*

¹⁹² *Id.*

¹⁹³ *Id.*

¹⁹⁴ DiRosa v. Showa Denko, 44 Cal. App. 4th 799, 802-04 (1996) (reporting plaintiff contracted EMS, and suffers from severe muscle pains and progressive skin discoloration by texture and rashes).

¹⁹⁵ *Id.* at 802.

¹⁹⁶ *Id.* at 804.

3. Adulteration

A dietary supplement, or any article intended for consumption, is deemed adulterated when it contains poisonous, unsanitary, or deleterious ingredients.¹⁹⁷ An article of food is also considered adulterated if it contains an unsafe food additive, consists of filthy, putrid, or decomposed substances, or is prepared or held under unsanitary conditions.¹⁹⁸ Under DSHEA, supplements containing a “new drug” not approved by the FDA will be considered adulterated until it meets FDA approval.¹⁹⁹ While this requirement appears to protect the consumers, the FDA has the burden of proving the product is adulterated, which has been made difficult by the courts.²⁰⁰

The FDA has responded to adulteration in supplements containing GBL by issuing warnings and reports.²⁰¹ GBL is found in products that claim to build muscles, improve physical performance, enhance sexual performance, reduce stress, and induce sleep.²⁰² Several persons have developed health problems after taking supplements that contain this product, including life-threatening side effects.²⁰³ When taken orally, GBL is converted in the body to Gamma Hydroxybutyrate (GHB). GHB is a drug that is currently undergoing investigation for drug approval status. Thus, GBL is considered to be an unapproved drug at this time.²⁰⁴ Since it has made its way into dietary supplements, products with GBL are considered to be adulterated.²⁰⁵

The FDA has also warned against products that contain TRIAC.²⁰⁶ The FDA has determined that at least one product, Triax Metabolic Accelerator, contains TRIAC.²⁰⁷ TRIAC is not approved by the FDA

¹⁹⁷ See 21 U.S.C. § 342(a)(1) (2000) (stating that the ingredient must render the supplement injurious to health. When the substance is the supplement itself, then it is not deemed adulterated as long as it is not injurious).

¹⁹⁸ See 21 U.S.C. §§ 342(a)(2)(C)(i), 342(a)(3)-(4) (2000).

¹⁹⁹ See 21 U.S.C. § 342(f)(1)(B) (2000).

²⁰⁰ See 21 U.S.C. § 342(f)(1)(D) (2000); *United States v. Two Plastic Drums*, 791 F. Supp. 751, 755 (D. Ill. 1991) (rejecting the FDA’s argument that BCO was adulterated by looking to the intent of Congress that all supplements be treated as relatively safe); *United States v. Nutri-cology, Inc.*, 982 F.2d 394, 395 (9th Cir. 1992) (rejecting the FDA’s claim that the supplement was a “new drug” because the FDA failed to prove any harm to consumers).

²⁰¹ *FDA Warns About GBL*, *supra* note 102.

²⁰² *Id.*

²⁰³ *Id.*

²⁰⁴ *Id.*

²⁰⁵ *Id.*

²⁰⁶ *FDA Warns Against TRIAX*, *supra* note 102.

²⁰⁷ *Id.*

and is considered to be “an unapproved new drug containing a potent thyroid hormone which may cause serious health consequences including heart attacks and strokes.”²⁰⁸ Therefore, products that contain TRIAC are adulterated.²⁰⁹ Additional serious side effects caused by TRIAC include thyroid damage, insomnia, severe diarrhea, fatigue, lethargy, and profound weight loss.²¹⁰

Adulteration also occurs by mistake. Aristolochic Acid (A. acid), from the herb *Aristolochia fang chi* (or *A. fang chi*), is often mistaken for *stephania fang ji*, another herb, because the names sound the same in the Chinese language.²¹¹ A. acid is a potent carcinogen and nephrotoxin (toxic to kidneys), causing rapid onset of renal failure with continued consumption.²¹² The FDA issued alerts because several persons have been injured as a result of A. acid in dietary supplements.²¹³ This adulteration was first discovered when persons were suffering renal damage caused by A. acid, which was not listed on any of the patients’ supplement labels.²¹⁴ According to at least one medical professional, since FDA control over product quality is virtually non-existent, it is not surprising that this type of mistaken adulteration occurs.²¹⁵

Even though there is contamination and adulteration in dietary supplements, they are still considered safe until proven otherwise by the FDA.²¹⁶ The burden of proof still rests on the FDA to show a dietary supplement is unreasonably dangerous. Despite the variations between product content and label information no pre-market approval is

²⁰⁸ *Id.*

²⁰⁹ *See id.*

²¹⁰ *Id.*

²¹¹ Kessler, *supra* note 2.

²¹² *Id.*

²¹³ Food and Drug Administration, *Import Alert #54-10, Detention Without Physical Examination of Bulk or Finished Dietary Supplements and Other Products That May Contain Aristolochic Acid*, at http://www.fda.gov/ora/fiars/ora_import_ia5408.html (last visited July 6, 2000) (calling for the detention of products that may contain A. acid, which the FDA labeled as a poison and unapproved drug. *A. fang chi* has been also been found in herbal supplements in the place of other herbs such as *stephania tetrandra*, *clematis* sp., *cocculus* sp., *asarum* sp., *bragantia* sp., *diploclisia* sp., *menispermum* sp., *sinomenium* sp., and *magnolia officinalis*, all of which are popular supplements and readily found in health stores. These Chinese names sound similar and are easily confused and misidentified).

²¹⁴ Kessler, *supra* note 2.

²¹⁵ *Id.*

²¹⁶ *See United States v. Nutri-cology, Inc.*, 982 F.2d 394, 395 (9th Cir. 1992).

required.²¹⁷

IV. DIETARY SUPPLEMENTS HAVE FOUND A SAFE HARBOR FROM THE FDA²¹⁸

As this comment has communicated, some dietary and herbal supplements are proven to be harmful.²¹⁹ The FDA has a system of tracking problems with dietary supplements by collecting Adverse Event Reports (AERs) and filing them with the Special Nutritional's Adverse Event Monitoring System.²²⁰ The flaw in this system is that only physicians can file AERs, and their filing is not mandatory.²²¹ These reports are collected, compiled, and where a pattern lies, the FDA reports warnings about the supplement. The FDA itself considers the patterns unreliable, but they are the only evidence the FDA has to challenge products as unsafe or adulterated.²²²

The FDA only has a few weapons against the dietary supplement industry. The FDA can either try to classify the product as adulterated, as a "new drug," or penalize the manufacturer for failing to meet GMPs.²²³ However, as previously discussed, GMPs are not currently available because they have not been established for dietary supplements.²²⁴

The FDA confesses it has limited abilities to monitor dietary supplements.²²⁵ The FDA says it first focuses on public health emergencies and products thought to have caused illnesses or injuries. Next, the FDA analyzes the products thought to be fraudulent or in violation of the law.²²⁶ The FDA does not analyze supplement products before sale to consumers. Responsibility is on the manufacturer to ensure the "ingredient list is accurate and that the ingredients are safe," as well as to make sure the "content matches the amount declared on the label."²²⁷ The FDA does not keep a record of dietary supplement products entering the market nor does it keep a record of the dietary sup-

²¹⁷ Gurley, *supra* note 24, at 964-68.

²¹⁸ Pearson v. Shalala, 172 F.3d 72, 73 (D.C. Cir. 1999).

²¹⁹ See FDA, *Illnesses and Injuries*, *supra* note 1; Squires, *High Irony*, *supra* note 11.

²²⁰ FDA, *Overview*, *supra* note 26.

²²¹ *Id.*

²²² *Id.*

²²³ *From Ginseng to St. John's Wort*, *supra* note 19.

²²⁴ *Id.*

²²⁵ FDA, *Overview*, *supra* note 26.

²²⁶ *Id.*

²²⁷ *Id.*

plement manufacturers. Therefore, to find out if supplements are safe, a consumer's only resource is to ask the manufacturer directly.²²⁸

Under DSHEA, the FDA has the initial burden of proving a product is unreasonably dangerous to consumers.²²⁹ "[T]he FDA hasn't been able to prove 'harm' in a single case [since the passage of DSHEA], despite reports of illness and even death from supplements."²³⁰ Since the FDA has greater regulatory power over food and drugs, at times it attempts to re-classify supplements as drugs or food additives in order to bring harmful supplements under regulation.²³¹

In attempting to re-classify supplements as drugs, the FDA has faced much opposition from the courts.²³² Courts state that the test for classification as a drug is how the product is being sold.²³³ Courts look to whether the supplement, vitamin, or mineral is sold as a food or as a treatment, cure, mitigation or prevention of disease.²³⁴ If the FDA can get the supplement re-classified as a drug, the manufacturer is subject to a number of violations: (1) introduction of an unapproved drug into interstate commerce; (2) failure to register with the Secretary of Health and Welfare; and (3) engaging in manufacture, preparation, propagation, compounding or processing of a drug.²³⁵

Evening Primrose Oil (EPO) was distributed with literature stating EPO "helps to prevent, treat, or cure a broad array of maladies ranging from atopic dermatitis to cancer, obesity, and schizophrenia."²³⁶ One court determined that EPO was manufactured and intended for use as a dietary supplement and not as a food or drug, despite its

²²⁸ *Id.*

²²⁹ *Buyer Beware - There's No Guarantee Dietary Supplements are Safe*, at http://www.mayohealth.org/mayo/9707/htm/me_5sb.htm (last visited July 17, 2000) (originally published as Medical Essay, a supplement to Mayo Clinic Health Letter, June 1997).

²³⁰ *Id.*

²³¹ See *DiRosa v. Denko*, 44 Cal. App. 4th 799, 805-08 (1996); see also 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.).

²³² *United States v. Two Plastic Drums*, 761 F. Supp. 70, 72 (D. Ill. 1991) (concluding that the FDA was wrong in that BCO was not a food additive, but a dietary supplement in itself); *Pharmanex, Inc. v. Shalala*, 35 F. Supp. 2d 1341, 1343 (D. Utah 1999) (scolding the FDA for claiming the supplement was a drug, when clearly the manufacturer intended for it to be a supplement); *United States v. Nutri-cology, Inc.*, 982 F.2d 394, 395 (9th Cir. 1992) (rejecting the FDA's claim that the supplement was a "new drug" because the FDA failed to prove any harm to consumers).

²³³ *United States v. Nutrition Serv.*, 227 F. Supp. 375, 386 (D. Pa. 1964).

²³⁴ *Id.* at 387.

²³⁵ See *id.* at 391.

²³⁶ *United States v. 21 Bulk Metal Drums*, 761 F. Supp. 180, 182 (D. Me. 1991).

claim to treat diseases.²³⁷ The same court then examined whether Black Currant Oil (BCO), another dietary supplement, could be considered an unsafe food additive as urged by the FDA, which would deem the supplement adulterated.²³⁸ An unsafe food additive is any substance where the

intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having being adequately shown through scientific procedures . . . to be safe under the conditions of its intended use.²³⁹

The court held that both EPO and BCO were adulterated as food additives not generally recognized as safe by expert testimony.²⁴⁰ Since the manufacturer had not obtained FDA exemption for use of the food additives in the dietary supplements, the court declared the supplements condemned.²⁴¹ Therefore, by declaring the EPO and BCO products adulterated, the FDA was able to bring the manufacturers of these products under regulation.²⁴²

In *Two Plastic Drums*, the court applied the rule that “food shall be adulterated if it is injurious to health or if it bears or contains any food additive which is unsafe.”²⁴³ “First, the court must find that the undisputed evidence demonstrates that the FDA sustained its burden of showing that the intended use of [the dietary supplement seized] was as a component of food.”²⁴⁴ In this case, BCO was the entire dietary supplement and there were no other components or additives. Therefore, the court held that BCO could not be a food additive.²⁴⁵

Some dietary supplements contain ingredients that are regulated as drugs when not under the guise of dietary supplement.²⁴⁶ One court recently indicated that just because the FDA approves a substance as a drug does not make the dietary supplement containing that same drug lose its status as a dietary supplement.²⁴⁷ The court reasoned that a

²³⁷ *Id.* at 183.

²³⁸ *See id.* at 185.

²³⁹ *Id.* at 183.

²⁴⁰ *See id.* at 184-85.

²⁴¹ *Id.* at 185.

²⁴² *See id.*

²⁴³ *United States v. Two Plastic Drums*, 761 F. Supp. 70, 71-72 (D. Me. 1991).

²⁴⁴ *Id.* at 71.

²⁴⁵ *Id.* at 73-74.

²⁴⁶ *Pharmanex, Inc. v. Shalala*, 35 F. Supp. 2d 1341, 1343 (D. Utah 1999).

²⁴⁷ *Id.* at 1344.

drug is promoted with disease claims and FDA approval, while dietary supplements are restricted to only making health claims and do not need FDA approval.²⁴⁸ The court considered the drugs within dietary supplements safer because supplements do not claim to cure, but only to promote health.²⁴⁹

Additionally, the FDA lacks authority to limit the serving size or amount of nutrients in dietary supplements.²⁵⁰ After so many AERs on ephedrine, the FDA's proposals to limit its dosage have yet to be accepted, even after numerous revisions.²⁵¹ Despite the fact that the FDA has approximately seven hundred AERs on ephedrine, the Government Accounting Office (GAO) asked for additional evidence to support the proposed limits.²⁵²

V. CONCLUSION

It is difficult to believe that Congress had our best interest in mind when it passed DSHEA. Congress states its policy as promoting health and well being by allowing consumers access to supplements and giving them freedom to make their own decisions.²⁵³ Incorrect and missing information on supplement labels makes a truly informed decision impossible. Essential information, such as adverse side effects and potential dangers, is not required to be on supplement labels. Therefore, it does not appear that DSHEA was enacted for the health and safety of American consumers.

No pre-market regulations are required for dietary supplements. The FDA discloses that the manufacturers are responsible for their products' safety and truthful labeling.²⁵⁴ The government has not explained why it has left the health and safety of over half the American population in the hands of supplement manufacturers. These manufacturers are not deserving of such responsibility, especially after repeated instances of contamination and adulteration. Removing scientific testing and safety requirements before product marketing only delays the testing, which is essentially conducted once the supplements are pur-

²⁴⁸ *Id.*

²⁴⁹ *Id.*

²⁵⁰ See FDA, *Overview*, *supra* note 26.

²⁵¹ Gugliotta, *Woman Using Herbal Aid*, *supra* note 19.

²⁵² Gugliotta, *FDA Takes Aim*, *supra* note 83; *FDA Announces the Availability*, *supra* note 170 (reporting that the GAO is responsible for reviewing the FDA's proposed restrictions on dietary supplements and making the decision on whether or not to accept the proposal).

²⁵³ Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 321 (2000).

²⁵⁴ FDA, *Overview*, *supra* note 26.

chased and consumed. The large number of AERs connecting dietary supplements to injuries and illnesses testify to the need for pre-market safety standards.

Pre-market regulation would tighten up the industry and protect the consumers from contamination and unknown, adverse side effects. Rigorous testing of medicine and drugs is what has helped so many Americans' health today. It is important that all medicine, including supplements, be tested and proven reasonably safe before being dispersed to consumers. Health claims, speculations, and testimonials do not substitute for evidence. Dietary supplements need to be subject to the same scientific studies and tests as are required for conventional pharmaceuticals.²⁵⁵ Without protective mechanisms, the real party being protected is the dietary supplement manufacturer.

The only way to correct the injuries and illnesses suffered since DSHEA is to place more regulations on the industry. The dietary supplement industry is a multi-billion dollar a year industry that will not suffer under increased regulations.²⁵⁶ Consumers need to be able to trust that governmental agencies will ensure the safety of their supplements. Consumers need to be able to trust the claims on the supplement labels. They need to be able to read about all known side effects on the labels, not just the ones that the manufacturer feels like disclosing. They also need to know if there are dangerous drug interactions before purchasing the product. Information this vital can no longer be hidden from consumers.

The American consumer deserves accurate representation of the products they purchase. DVs need to be based on the most recent and accurate RDAs. TUIs also need to be placed on the labels of products containing vitamins or minerals that are toxic to humans at certain levels. Regulations are needed that ensure a supplement's contents match its label.

The answer is simple: more information and more regulation. This is the only way to be sure that our government is really protecting America's health, while still enabling the public to make informed decisions. "Improving the health status of United States citizens [should] rank[] at the top of the national priorities of the Federal Government,"²⁵⁷ and it is time that it did.

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²⁵⁵ Angell & Kassirer, *supra* note 19.

²⁵⁶ Kessler, *supra* note 2.

²⁵⁷ Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 321 (2000).