

Dietary Supplements: The Return of Snake Oil?

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Introduction:

Miracle cures have been around forever. No matter what ailment one suffers, there was always a witch doctor, alchemist or snake oil sales man there to cure it. However, after the birth of modern medicine, it is a bit disheartening that snake oil-type products are still being sold to the public without proper regulation or oversight from government authorities. Many promoters of dietary supplements claim to be able to cure cancer, obesity, depression, stress, insomnia and sexual dysfunction, among other ailments, with their various "natural" pills and elixirs. It would appear that many promoters of dietary supplements join that long list of witch doctors that claim to cure real ailments with "natural" cures.

Dietary supplements are commonly thought of as nutrients or other supposed "natural" ingredients intended to supplement a person's daily diet. They can take the form of tablets, capsules, elixirs or lotions that provide vitamins, minerals, or herbs to consumers.¹ Some current dietary supplements include bottled herbs such as “cats claw,” and “dandelion root,” and garlic

¹ Trisha L. Beckstead, Caveat Emptor, Buyer Beware: Deregulation of Dietary Supplements Upon Enactment of the Dietary Supplement Health and Education Act of 1994, 11 San. J. ALR 107 (2001).

pills, as well as vitamins and minerals in various doses.² In today's market, dietary supplements are constantly evolving and changing form. So called "nutraceuticals," describe foods that contain some kind of enhancement, such as a combination of herbs and vitamins in a capsule that the manufacturer claims increases energy levels.³ Also, a "functional food" applies to conventional food products that are enhanced to provide certain health benefits. For example, a "calcium enriched" yogurt that is designed to help prevent osteoporosis.⁴ The FDA is struggling to keep up with regulating these different forms of dietary supplements.

Currently, the federal government regulates dietary supplements under the *Dietary Supplement Health and Education Act of 1994* (DSHEA). DSHEA changed the existing regulatory framework for dietary supplements by: 1) broadening the definition of dietary supplements and 2) decreasing the Food and Drug Administration's (FDA) ability to regulate dietary supplements.⁵ The FDA has more difficulty regulating dietary supplements because under the new law, dietary supplements were given a presumption of safety, which shifted the burden to the FDA to prove that the supplements were not safe.⁶ By increasing the number of substances considered to be dietary supplements and by decreasing the FDA's regulatory ability, the DSHEA has caused the dramatic increase of the distribution of dietary supplements.⁷ Since these substances do not require pre-market approval, some of them could pose a risk to consumer's health, and many more do absolutely nothing positive for a person's health.

² Paula Kertzeil, An FDA Guide to Dietary Supplements, FDA Consumer, (September – October, 1998).

³ Neal D. Fortin, Food & Drug Regulation: Law, Science, Policy, and Practice, X-2 (2005) (electronic casebook, on file with the author and the Institute for Food Laws and Regulations, Michigan State University).

⁴ Neal D. Fortin, Food & Drug Regulation: Law, Science, Policy, and Practice, X-2 (2005) (electronic casebook, on file with the author and the Institute for Food Laws and Regulations, Michigan State University).

⁵ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 662 (Winter 2004).

⁶ Lauren J. Sloane, Herbal Garden of Good and Evil: The Ongoing Struggles of Dietary Supplement Regulation, 51 Admin. L. Rev. 323 (Winter, 1999).

⁷ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 662 (Winter 2004).

This paper explores the problems related to the existing dietary supplement regulatory regime. Part I discusses the evolution of the regulation of dietary supplements, culminating in the passage of the DSHEA, Part II explains what the DSHEA was intended to do and what it does, Part III discusses the social costs of the DSHEA, and Part IV suggests reforms to the DSHEA. Specifically, the paper focuses on *how DSHEA weakened the regulatory authority of the Food and Drug Administration (FDA) and the need to adopt a more aggressive approach when it comes to regulating dietary supplements*. The reforms suggested, will involve clarifying the definition of dietary supplements and increasing the power of the FDA to regulate dietary supplements. *The key suggested reforms involve applying appropriate pre-market safety standards and applying a pre-market "health claim" standard of review to most dietary supplements*. In the end the goal is to balance the constitutional rights of the dietary industry and its supporters with the responsibility of the government to protect the public from snake oil cures, which means balancing freedom with public health.

I. Evolution of Dietary Supplement Regulation

A. Pure Food Act of 1906

Back in 1906, the United States Congress passed the Pure Food Act in an attempt to ensure the safety and quality of food and drugs.⁸ This Act differentiated between a substance that was a food, and one that was a drug, and prohibited the sale, shipment or receiving of adulterated or misbranded foods or drugs through interstate commerce.⁹ Then the role of the appropriate federal regulatory body was to investigate and examine questionable food and drugs to determine whether they were adulterated or misbranded. The 1906 Act empowered the FDA

⁸ Peter Barton, FDA Statutory Authority to Regulate the Safety of Dietary Supplements, 31 Am J.L. & Med. 155 (2005).

⁹ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 665 (Winter 2004).

to take action against quack health claims and the FDA used these powers to regulate health claims on powders pills and liquid dietary supplements.¹⁰ The major limitation of the early legislation was that it did not require new dietary supplements to obtain pre-market approval.¹¹

B. Food, Drug and Cosmetic Act of 1938

In 1937, over a hundred people died from the consumption of a new drug called Elixir Sulfanilamide.¹² These deaths heightened the public's awareness of problems with food and drug regulation. Had the Elixir been subject to pre-market testing it is probable that the government would have discovered the toxic substance found in the drug.¹³ As a result of this tragedy, the United States Congress passed the Federal Food, Drug and Cosmetic Act of 1938 (FDCA) and repealed the old 1906 version of food and drug regulation.¹⁴ The new legislation mandated that any new drug obtain pre-market approval.¹⁵ Thus, the burden to prove the safety of the new drug was on the manufacturer, who must apply to the federal government for market approval. The FDA continued to wrestle with the difficulties in trying to regulate dietary supplements as foods or drugs.

¹⁰ Neal D. Fortin, Food & Drug Regulation: Law, Science, Policy, and Practice, X-5 (2005) (electronic casebook, on file with the author and the Institute for Food Laws and Regulations, Michigan State University).

¹¹ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 667 (Winter 2004).

¹² Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 666 (Winter 2004).

¹³ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 667 (Winter 2004).

¹⁴ Trisha L. Beckstead, Caveat Emptor. Buyer Beware: Deregulation of Dietary Supplements Upon Enactment of the Dietary Supplement Health and Education Act of 1994, 11 SANJALR 107, 111 (2001).

¹⁵ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 667 (Winter 2004).

C. FDA Regulations of 1941

In 1941, the FDA promulgated regulations for dietary supplements based on the statutory authority provided in the Food, Drug and Cosmetic Act of 1938.¹⁶ The regulations were for foods which had a “special dietary use” because of the vitamin or mineral content of the food.¹⁷ Food product labels were required to list the percentage of minimum daily requirements for the specified vitamin or mineral, and if the product contained a vitamin or mineral not recognized by the rule, then the label must contain a disclaimer noting that the need for the listed vitamin or mineral had not been determined.¹⁸

D. Food Additives Amendment of 1958

In 1958 the United States Congress passed the Food Additives Amendment of 1958 in order to regulate the substances which legally could be added to food.¹⁹ This Act was passed to close a loophole in existing regulatory law that allowed substances defined as “food additives” to be added to food without pre-market approval.²⁰ The new legislation initiated pre-market approval for all food additives and assigned the burden of proof to the food manufacturer and processor.²¹ So the FDA was somewhat successful in applying pre-market approval standards to dietary supplements. The FDA continued its struggle to regulate dietary supplements until it began to receive a great deal of push back in the 1970’s and beyond.

¹⁶ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 668 (Winter 2004).

¹⁷ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 668 (Winter 2004).

¹⁸ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 668 (Winter 2004).

¹⁹ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 668 (Winter 2004).

²⁰ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 669 (Winter 2004).

²¹ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 669 (Winter 2004).

E. FDA Regulations in the 1970's

Throughout the 1960's and 1970's, the FDA repeatedly failed to update and replace the 1941 regulations for dietary supplements, so they eventually had to rely on this food additives legislation to regulate dietary supplements.²² By labeling dietary supplements as "food additives" the FDA was able to provide some oversight on dietary supplements.²³ However, in the 1970's the FDA found increasing resistance from the dietary supplement industry. In 1976, the supplement industry waged a lobbying effort which culminated in the passage of the Proxmire Vitamin and Mineral Amendment of 1976, which expressly prohibited the FDA from establishing maximum limits on the potency of vitamin or mineral.²⁴

F. FDA Setbacks in 1990s and Beyond

Throughout the 1990's the FDA attempted to more effectively regulate dietary supplements, only to be thwarted by the United States Congress, which was being heavily lobbied by dietary supplement interest groups.²⁵ In 1990, Congress passed the Nutrition Labeling and Education Act (NLEA), which set standards for health claims for all foods and instructed the FDA to create similar standards for dietary supplements.²⁶ The FDA responded by proposing to subject dietary supplements to the same labeling regulations as food.²⁷ The United States Congress did not like the sounds of these regulations so they responded by passing the Dietary Supplement Act of 1992, which placed a one-year moratorium on the FDA to prevent it from implementing its

²² Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 670 (Winter 2004).

²³ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 670 (Winter 2004).

²⁴ Neal D. Fortin, Food & Drug Regulation: Law, Science, Policy, and Practice, X-5 (2005) (electronic casebook, on file with the author and the Institute for Food Laws and Regulations, Michigan State University).

²⁵ Lauren J. Sloane, Herbal Garden of Good and Evil: The Ongoing Struggles of Dietary Supplement Regulation, 51 Admin. L. Rev. 323, 325 (Winter, 1999).

²⁶ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 676 (Winter 2004).

²⁷ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 676 (Winter 2004).

dietary supplement regulations.²⁸ After the moratorium the FDA once again proposed new dietary supplement regulations, arguing that dietary supplements should be regulated as “food” or “drug” depending upon the use of the dietary supplement product.²⁹ Specifically, regulating dietary supplements as drugs when they are used as anything other than food additives, such as when medicinal claims are made.³⁰ Congress viewed this as over-regulating dietary supplements and responded by passing the Dietary Supplement Health and Education Act (DSHEA) of 1994 which declared the FDA’s dietary supplement rules to be null and void.³¹

G. Summary

So time and again the FDA tried to more effectively regulate dietary supplements and limit the promotion and distribution of dietary supplements, only to be thwarted by Congress. The FDA proposed regulating dietary supplements as either food or drugs, depending on the claims being made and the form of the dietary supplement. This is also the method of regulation advocated by this paper. Unfortunately, Congress interfered with the FDA regulatory scheme by enacting DSHEA. Now DSHEA provides the regulatory scheme the FDA must use when regulating dietary supplements.

III. DSHEA: Explanations & Criticisms

A. What is DSHEA?

The Dietary Supplement Health and Education Act of 1994 was signed into law by President William Clinton on October 15, 1994, and it created a new framework for the regulation of

²⁸ Peter A. Vignuolo, The Herbal Street Drug Crisis: An Examination of the Dietary Supplement Health and Education Act of 1994, 21 Seton Hall Legis. J. 200, 204 (1997).

²⁹ Peter A. Vignuolo, The Herbal Street Drug Crisis: An Examination of the Dietary Supplement Health and Education Act of 1994, 21 Seton Hall Legis. J. 200, 206 (1997).

³⁰ Neal D. Fortin, Food & Drug Regulation: Law, Science, Policy, and Practice, X-6 (2005) (electronic casebook, on file with the author and the Institute for Food Laws and Regulations, Michigan State University).

³¹ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 678 (Winter 2004).

dietary supplements.³² It amended the Federal Food, Drug and Cosmetic Act (FDCA). Supporters of dietary supplements argue that the intent of the United States Congress in passing DSHEA was to reject the FDA's attempts to limit the access to dietary supplements and to provide consumers with greater information and access to dietary supplements.³³ DSHEA added the following to FDCA: a) a definition of dietary supplement, b) a number of safety provisions designed to protect consumers, such as requiring companies to submit information about the safety of a new dietary ingredient, c) the requirement that dietary supplements bear nutrition labeling as well as the name and quantity of each dietary ingredient or proprietary blend in the product, among other provisions.³⁴

While certain consumer protection provisions such as disclosure of information about new ingredients and requiring labeling are important consumer safety provisions, the far more impacting and possibly dangerous aspect of this legislation involves the change in the existing regulatory framework of dietary supplement regulation. DSHEA changed the existing regulatory framework for dietary supplements by: 1) broadening the definition of dietary supplements and 2) decreasing the Food and Drug Administration's (FDA) ability to regulate dietary supplements.³⁵ Under the new law, dietary supplements are given a presumption of safety, which shifted the burden to the FDA to prove that the supplements were not safe.³⁶

A dietary supplement is defined in section 3(a) of DSHEA as a product "intended to supplement the diet" (which means, not intended to be a drug or conventional food) that contains

³² Lauren J. Sloane, Herbal Garden of Good and Evil: The Ongoing Struggles of Dietary Supplement Regulation, 51 Admin. L. Rev. 323 (Winter, 1999).

³³ Scott Bass and Emily Marden, The New Dietary Ingredient Safety Provision of DSHEA: A Return to Congressional Intent, 31 Am. J. L. Med. 285, 287 (2005).

³⁴ Scott Bass and Emily Marden, The New Dietary Ingredient Safety Provision of DSHEA: A Return to Congressional Intent, 31 Am. J. L. Med. 285, 287 (2005).

³⁵ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 662 (Winter 2004).

³⁶ Lauren J. Sloane, Herbal Garden of Good and Evil: The Ongoing Struggles of Dietary Supplement Regulation, 51 Admin. L. Rev. 323 (Winter, 1999).

one or more of the following ingredients: a) a vitamin; b) mineral; c) 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.³⁷ Also, to be a dietary supplement the item must be “ingested,” in capsule, tablet, liquid, powder, softgel, or gelcap form, or into products that are conventional food form and must not be represented as a conventional food nor as a sole item of a meal or diet.³⁸ Also, the dietary supplement definition in DSHEA excludes new drugs unless sold as a dietary supplement before 1994, or tobacco.³⁹ This definition is quite broad, as is demonstrated by the subsection that discusses supplementing the diet by “increasing the total dietary intake.”⁴⁰ This broad definition makes it difficult for the FDA to regulate certain products that companies are able to market as dietary supplements.

B. How DSHEA Weakened FDA Oversight of Dietary Supplements

The DSHEA’s broadening of the definition of dietary supplements created a major change in the way government regulated dietary supplements. The Act took a category of product traditionally regulated by the FDA as either a food or a drug, depending on the product claims and formulation, and created a new regulatory category called “dietary supplement” that was placed within the food definition.⁴¹ Products meeting the “dietary supplement” definition benefited in two ways: 1) dietary supplements could make “structure/function” claims traditionally within the realm of drug products, and 2) unlike food ingredients, dietary ingredients could be used in dietary supplements without being either approved food additives or

³⁷ Neal D. Fortin, *Food & Drug Regulation: Law, Science, Policy, and Practice*, X-8 (2005) (electronic casebook, on file with the author and the Institute for Food Laws and Regulations, Michigan State University).

³⁸ Suzan Onel, *Dietary Supplements: A Definition That is Black, White, and Gray*, 31 *Am. J. L. & Med.* 341, 342 (2005).

³⁹ Neal D. Fortin, *Food & Drug Regulation: Law, Science, Policy, and Practice*, X-8 (2005) (electronic casebook, on file with the author and the Institute for Food Laws and Regulations, Michigan State University).

⁴⁰ Neal D. Fortin, *Food & Drug Regulation: Law, Science, Policy, and Practice*, X-9 (2005) (electronic casebook, on file with the author and the Institute for Food Laws and Regulations, Michigan State University).

⁴¹ Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994).

“generally recognized as safe ingredients.”⁴² These two benefits allowed dietary supplements to enter the marketplace with broad-based claims and without FDA pre-market review of the ingredients, formulation, or product claims.⁴³

1. Health Claims vs. Structure/Function Claims

Under the FDCA, both health claims and structure/function claims can be used on the labels of dietary supplements. The FDA has strict evidentiary claims for health claims, but its standards for structure/function are not clearly defined.⁴⁴ Health claims state that an ingredient or product may reduce the risk of a disease.⁴⁵ Before a health claim for an ingredient or product can be used, it must go through a rigorous FDA review of the scientific evidence supporting the claim.⁴⁶ An example of a health claim is, that a product "may reduce risk of heart disease," or "may reduce the risk of some cancers."⁴⁷

Structure/function claims describe how consuming the product will affect a structure, such as the skeletal system, or a function, such as the circulatory system.⁴⁸ The structure/function claim can describe how a product will improve a person's general health but cannot claim to reduce the risk of or treat a disease. For example, structure/function claims can state that the product "supports the immune system" or "supports joint function."⁴⁹

⁴² Suzan Onel, Dietary Supplements: A Definition That is Black, White, and Gray, 31 Am. J. L. & Med. 341 (2005).

⁴³ Suzan Onel, Dietary Supplements: A Definition That is Black, White, and Gray, 31 Am. J. L. & Med. 341 (2005).

⁴⁴ Lawrence J. Dyckman, and Keith W. Oleson, Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and Functional Foods, United States General Accounting Office, at 18 (July 2000).

⁴⁵ Lawrence J. Dyckman, and Keith W. Oleson, Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and Functional Foods, United States General Accounting Office, at 18 (July 2000).

⁴⁶ Lawrence J. Dyckman, and Keith W. Oleson, Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and Functional Foods, United States General Accounting Office, at 18 (July 2000).

⁴⁷ Lawrence J. Dyckman, and Keith W. Oleson, Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and Functional Foods, United States General Accounting Office, at 19 (July 2000).

⁴⁸ Lawrence J. Dyckman, and Keith W. Oleson, Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and Functional Foods, United States General Accounting Office, at 19 (July 2000).

⁴⁹ Lawrence J. Dyckman, and Keith W. Oleson, Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and Functional Foods, United States General Accounting Office, at 19 (July 2000).

FDA has established strict evidentiary requirements for health claims, but it has not done so for structure/function claims. Structure/function claims on dietary supplements are not supposed to be false or misleading, however, the law does not really define the extent of the evidence necessary to adequately support such a claim.⁵⁰ Therefore, many structure function claims are written in such a way as to suggest or hint at a certain health benefit. The extent to which such claims are intentionally misleading depend on the circumstances. Some structure/function claims such as "cleanses the blood" are so vague that they do not have much scientific meaning and cannot really be proven either way.⁵¹

Since a dietary supplement can use the structure/function claim, it can advertise itself as a drug-like product while avoiding the strict pre-market FDA review that real drug products must endure. A dietary supplement can claim to heal the body and even hint at curing certain diseases, while avoiding the strict FDA regulations that would delay similar drug products. Also, under the new definition, the dietary supplement can use the structure/function claim to produce a product that hints at curing a certain disease, while not actually having to prove scientifically that it can cure a consumer of his ailment, or even improve the condition of the consumer. A similar drug product would have to scientifically demonstrate positive results.

2. Breakdown of Safety Standards

The second area of regulation where DSHEA weakens the FDA's oversight of dietary supplements is in the weakening of the GRAS standard. The FDA attempts to ensure that the ingredients making up a food product are safe for their intended use.⁵² When an ingredient is

⁵⁰ Lawrence J. Dyckman, and Keith W. Oleson, Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and Functional Foods, United States General Accounting Office, at 19 (July 2000).

⁵¹ Lawrence J. Dyckman, and Keith W. Oleson, Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and Functional Foods, United States General Accounting Office, at 20 (July 2000).

⁵² Laura A. W. Khatcheressian, Regulation of Dietary Supplements: Five Years of DSHEA, 54 Food & Drug L.J. 623, 628 (1999).

added to a food, the FDA requires that the ingredient either be determined to be "generally recognized as safe" (GRAS) by qualified experts or go through FDA's review and approval process for a food additive.⁵³

The problem arises because FDA regulates the safety of dietary supplements under the provisions set out in DSHEA, which exempted new dietary ingredients in dietary supplements from the safety requirements that apply to food additives.⁵⁴ Companies must have a basis for concluding that a supplement containing a new dietary ingredient is reasonably expected to be safe under the conditions of use recommended or suggested in the product's labeling.⁵⁵ Also, DSHEA requires companies to notify FDA of their evidence for determining the safety of a new dietary ingredient in a supplement 75 days before marketing the supplement.⁵⁶ However, the real problem with DSHEA is that companies do not have to obtain FDA's approval before marketing their product. Also, DSHEA allows dietary supplements to be marketed in conventional food form.⁵⁷ This means that if it is a power bar or granola bar it can be regulated as a dietary supplement as long as it is labeled as a dietary supplement and does not advertise itself as conventional food.

This DSHEA safety standard exemption from the food additive safety requirements could allow dietary supplement products of questionable safety to reach the market and harm consumers. Companies must estimate on their own, how much evidence is adequate to ensure

⁵³ Laura A. W. Khatcheressian, Regulation of Dietary Supplements: Five Years of DSHEA, 54 Food & Drug L.J. 623, 628 (1999).

⁵⁴ Lawrence J. Dyckman, and Keith W. Oleson, Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and Functional Foods, United States General Accounting Office, at 9 (July 2000).

⁵⁵ Lawrence J. Dyckman, and Keith W. Oleson, Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and Functional Foods, United States General Accounting Office, at 9 (July 2000).

⁵⁶ Lawrence J. Dyckman, and Keith W. Oleson, Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and Functional Foods, United States General Accounting Office, at 9 (July 2000).

⁵⁷ Lawrence J. Dyckman, and Keith W. Oleson, Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and Functional Foods, United States General Accounting Office, at 9 (July 2000).

safety, during the 75 day pre-market notification.⁵⁸ Also, the burden is on the FDA to prove in court that inadequate evidence was provided and that the product would be harmful, in order to get the product removed from the market.⁵⁹ Finally, the DSHEA provision that allows dietary supplements to exist in conventional food form makes absolutely no sense. It entirely confuses the distinction between food and supplements. Various granola bars and teas that contain herbs, could be dietary supplements incorrectly marketed as food products and vice versa. This blurring of the distinction between dietary supplements and food products not only confuses the distributors of food, it is certainly going to confuse and misinform consumers.

C. Summary

By increasing the number of substances considered to be dietary supplements and by decreasing the FDA's regulatory ability, the DSHEA has caused the dramatic increase of the distribution of dietary supplements.⁶⁰ Placing the burden of proof on the FDA in regulating dietary supplements cripples the agency's ability to regulate these products and thereby protect the public from unsafe dietary supplements.⁶¹ The FDA is forced to target specific products after they are in the market rather than move against a class of products before they can reach consumers and cause harm.⁶² Since dietary supplements do not require pre-market approval, some of them could pose a risk to consumer's health, and many more do absolutely nothing positive for a person's health. In passing this legislation Congress rejected the FDA's attempts to

⁵⁸ Lawrence J. Dyckman, and Keith W. Oleson, Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and Functional Foods, United States General Accounting Office, at 13 (July 2000).

⁵⁹ Laura A. W. Khatcheressian, Regulation of Dietary Supplements: Five Years of DSHEA, 54 Food & Drug L.J. 623, 628 (1999).

⁶⁰ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 662 (Winter 2004).

⁶¹ Peter Vignuolo, The Herbal Street Drug Crisis: An Examination of the Dietary Supplement Health and Education Act of 1994, 21 Seton Hall Legis. J. 200, 227 (1997).

⁶² Peter Vignuolo, The Herbal Street Drug Crisis: An Examination of the Dietary Supplement Health and Education Act of 1994, 21 Seton Hall Legis. J. 200, 227 (1997).

limit the access of dietary supplements through a variety of regulatory devices.⁶³ DSHEA resulted in the promotion and expansion of the dietary supplement industry and an increase in risk to the health and well-being of consumers.

III. Social Costs vs. Benefits of DSHEA

A. Triumph of Politics Over Science?

Many companies are using this broad definition of dietary supplements in order to promote their products. Companies have aggressively explored ambiguities in the meanings of this new definition and taken advantage of the more lenient dietary supplement rules pertaining to formulation and claims.⁶⁴ These companies position their products so as to avoid FDA regulations related to drugs and sell their products as foods while suggesting a kind of drug benefit.⁶⁵ For example, ephedra is a plant species which has long been used for medicinal purposes.⁶⁶ Ephedra contains naturally occurring chemical stimulants that cause numerous physiological responses in the body such as increased blood pressure and heart rate.⁶⁷ Many people take ephedra in order to increase energy or lose weight. Synthetic versions of ephedra are regulated by the FDA as a drug, while the botanical versions tend to be regulated as dietary supplements.⁶⁸ This creates regulatory law where combination of botanical ephedra and caffeine has the same biological effects on the body as the synthetic version, yet the dietary supplement

⁶³ Scott Bass and Emily Marden, The New Dietary Ingredient Safety Provision of DSHEA: A Return to Congressional Intent, 31 Am. J.L. & Med. 285 (2005).

⁶⁴ Suzan Onel, Dietary Supplements: A Definition That is Black, White, and Gray, 31 Am. J. L. & Med. 341, 348 (2005).

⁶⁵ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 662-3 (Winter 2004).

⁶⁶ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 662-3 (Winter 2004).

⁶⁷ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 662-3 (Winter 2004).

⁶⁸ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 662-3 (Winter 2004).

version is legal and the synthetic version is not legal.⁶⁹ Companies can side step the more stringent drug regulations and market the botanical version. Critics argue that products like ephedra, which cause physiological changes in the body, should be regulated by the FDA more aggressively, even if it is a botanical version.

Critics argue that DSHEA represents the triumph of politics over science, while supporters argue DSHEA is very prudent legislation that promotes consumer choice and freedom. Critics argue that this Act was passed only after years of public pressure from interest groups, and with only limited hearings and debate.⁷⁰ Supporters argue that the process was careful and deliberative and was a response to consumer demand for more information about and access to a broad range of dietary supplements.⁷¹

The evolution of dietary supplement regulation, as discussed in Part I of the paper, demonstrates this constant pressure from the industry to push back against FDA regulations. It was a constant struggle for the FDA to regulate dietary supplements and they were consistently restrained due to the political pressure placed on Congress. Finally, in the 1990's, interest groups were finally able to push back successfully and really deliver a blow to FDA's ability to regulate dietary supplements, with the passage of DSHEA. It is important to keep this political history in mind, when considering the explosion of dietary supplements since the enactment of DSHEA. With the passage of DSHEA, companies are now able to define their products in such a way so as to avoid FDA regulations, to avoid the pre-market review, and get their new products to consumers more quickly and effectively, and with greater prevalence. This political context

⁶⁹ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 662-3 (Winter 2004).

⁷⁰ Roseann B. Termini, Pharmanex, Inc. v. Shalala: A Wake Up Call For Congress and a Not So Bitter Pill for the FDA, 26 Ohio N. U. L. Rev. 269, 269-70 (2000).

⁷¹ Scott Bass and Emily Marden. The New Dietary Ingredient Safety Provision of DSHEA: A Return to Congressional Intent, 31 Am. J.L. & Med. 285 (2005).

helps us understand not only why DSHEA was passed, but also how companies manipulate the new regulatory structure that DSHEA created. The social costs of DSHEA, and the explosion of the dietary supplement industry has negative social consequences that only a legislative reform of DSHEA can correct.

B. Benefits of DSHEA

Supporters of DSHEA make certain libertarian style arguments when advocating for the DSHEA and deregulation of the dietary supplement industry. First, they argue that dietary supplements can serve as an inexpensive means to promote public health.⁷² Basically this means that dietary supplements are cheaper for consumers to purchase than pharmaceuticals. Second, consumers should be empowered to make choices in preventative health care.⁷³ Individual freedom is valued in this society, and when it comes to a person's own health, that person should be allowed to seek cures for their ailments that are not always strictly authorized by the government. Third, dietary supplements tend to be relatively harmless, and less impacting than drugs, therefore they are less dangerous to the public. Some supporters of DSHEA even claim that dietary supplements are safer than FDA-approved drugs and that the FDA unfairly portrays dietary supplements as a threat to the public.⁷⁴ Fourth, there is an attitude of "buyer beware," in that the government can try and educate consumers, but essentially it is up to the consumer to decide how he/she will spend his money. Basically, supporters of DSHEA argue that dietary supplements provide an important health benefit for consumers and it is important for

⁷² Neal D. Fortin, Food & Drug Regulation: Law, Science, Policy, and Practice, X-6 (2005) (electronic casebook, on file with the author and the Institute for Food Laws and Regulations, Michigan State University).

⁷³ Neal D. Fortin, Food & Drug Regulation: Law, Science, Policy, and Practice, X-6 (2005) (electronic casebook, on file with the author and the Institute for Food Laws and Regulations, Michigan State University).

⁷⁴ Joshua H. Beisler, Dietary Supplements and their Discontents: FDA Regulation and the Dietary Supplement Health and Education Act of 1994, 31 Rutgers L.J. 511 (Winter, 2000).

government to essentially get out of the way, so that consumers can take advantage of the life saving and life enhancing benefits that dietary supplements provide.

Basically, supporters tend to denigrate the FDA as the enemy and praise the passage of the DSHEA as the will of the people. Some supporters argue that the FDA cannot be trusted with greater regulatory oversight power over dietary supplements.⁷⁵ They argue that the FDA's active role in portraying dietary supplements as a threat to the public health demonstrates the FDA's biased perspective and their inability to be an honest broker. This adversarial and almost paranoid fear of the FDA makes it difficult for supporters to desire any kind of compromise.

C. Costs of DSHEA

A response to the claims by the supporters of DSHEA is necessary in order to justify the reform of DSHEA. Since DSHEA promotes or at least allows for a greater number and variety of dietary supplements to be distributed in the market, it is important to demonstrate that dietary supplements do in fact cause harm to the public. Proving these arguments is beyond the scope of this paper. This section of the paper will simply introduce some of the criticisms of dietary supplements under the current regulatory regime.

There are numerous social costs related to the existing dietary supplement regulatory regime. First of all, some dietary supplements have been proven to be unhealthy. For example, ephedra, a dietary supplement designed to assist with weight loss, was found to cause nausea, vomiting, anxiety, autonomic hyperactivity, and heart palpitations.⁷⁶ Second, many dietary supplements are fraudulent. Many people are wasting their money on products that do not improve their health or mental condition. Billions of dollars are poured into an industry that has

⁷⁵ Joshua H. Beisler, Dietary Supplements and their Discontents: FDA Regulation and the Dietary Supplement Health and Education Act of 1994, 31 Rutgers L.J. 511, 513 (Winter, 2000).

⁷⁶ Michael Sachs, Ephedra and the Failure of Dietary Supplement Regulation, 54 Cath. U. L. Rev. 661, 684 (Winter 2004).

many products that provide little or no measurable health benefit, and may in some cases actually cause harm.⁷⁷ Third, dietary supplements that make outlandish claims can provide false hope to people who suffer from a serious or even terminal illness. People with irreversible conditions may believe the false claims made by dietary supplements, and may expect to recover. When that recovery does not happen they can suffer depression.

Also, supporters of dietary supplements sometimes replace their real doctors and real medicine with alternative healers and dietary supplements. Too much reliance upon dietary supplements, to the exclusion of real medicine, could have a harmful impact on an individual's health. Finally, the prevalence of snake oil cures can fuel a culture of paranoia. Dietary supplements can help fuel a paranoia culture which rejects modern medicine and believes the FDA and the government is out to destroy them. When falsehoods generated by the dietary supplement industry are promulgated, they inspire certain groups of individuals who have adopted a paranoia myth explanation of the world that is divorced from reality. A life narrative that promotes magical alternative cures for physical illnesses and emotional conditions is very seductive to some people. Some of the more extreme propaganda of dietary supplements ends up encouraging people to turn away from rational thinking and to embrace superstition. Such magical thinking may appear harmless, but it sometimes may result in irrational anti-government ideas, a rejection of modern medicine, and an increase in paranoia.

D. Summary

The purpose of Part III of this paper was to summarize the rationale behind DSHEA and the role politics played, and also to outline some of the policy arguments for and against DSHEA. It is important that the costs of the existing dietary supplement regulatory regime outweigh the

⁷⁷ Lawrence J. Dyckman, and Keith W. Oleson, Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and Functional Foods, United States General Accounting Office, at 25 (July 2000).

benefits, in order to justify the changes that will be suggested in Part IV of the paper. When one considers the role politics played in interfering with the FDA's regulatory structure, and when the negative consequences of DSHEA are compared with the benefits, it becomes apparent that there is a need to reform the existing regulatory scheme.

IV. Reforming DSHEA

A. Overview

The ultimate goal for reforming DSHEA is to more effectively regulate dietary supplements and better protect consumers. This involves strengthening the authority of the FDA to adopt a more aggressive approach when regulating dietary supplements. This would include one or more of the following reforms. First, this would require clarifying and more narrowly defining dietary supplements, so that fewer products could claim to be dietary supplements. Second, prevent dietary supplements from using the structure/function claim to avoid meaningful regulations, and instead require them to use the health claim standards if they are making any claim that even remotely sounds like a health claim. If they wish to pretend they are drugs than they should be regulated as drugs. Third, prohibit dietary ingredients to be used in dietary supplements without being either approved food additives or “generally recognized as safe ingredients.” The most critical aspect of these reforms is to allow the FDA to conduct more pre-market approval of dietary supplements. The ultimate goal is that dietary supplements undergo the rigorous FDA review that is conducted for other products. Before dietary supplements are released, they should first have to undergo a rigorous, scientific review.

B. Change the Definition of “Dietary Supplement”

The purpose of this paper is not to draft a new statute but rather to suggest some changes to the regulatory regime of dietary supplements. However, one suggested reform is that the

statutory definition of dietary supplement as prescribed in DSHEA, should be changed. The ultimate goal in changing the definition of dietary supplement is to both narrow and clarify its meaning so that fewer products, and the correct products are labeled as dietary supplements. The way to do this is to delete language that is vague and retain or add language this is more concrete and limited. For example, deleting subsection (e) might be useful. It prescribes that a dietary supplement is "a dietary substance for use by man to supplement the diet by increasing the total dietary intake."⁷⁸ This statement is too vague, and it invites a great deal of products to be lumped in under the definition of dietary supplement. The current definition is too broad and vague to be very useful. When dietary supplements can take the form of such diverse items as granola bars, teas, pills, oils, nasal sprays, ointments, and powders, and when the claims can include everything from improving a skin condition to fighting depression, then clearly the definition is way too broad to be effective. The definition of dietary supplement should narrowly define the form and substance of the product and strictly limit the claims that can be made to market the product. When it enters the realm of health claims, then it should be regulated as a drug. When it takes the form of a granola bar or tea, then it should be regulated as a food, without the exemption from the food additive safety standards.

C. Apply Health Claims Rather than Structure/Function Claims

The second major reform of DSHEA should involve prohibiting the dietary supplement industry from using structure/function claims in order to avoid pre-market reviews of products. Ultimately, the current problem with structure/function claims is the difficulty for the average consumer to be able to distinguish them from health claims. For example, a claim that says, "helps maintain healthy cholesterol levels," is considered a disease claim.⁷⁹ However, a claim

⁷⁸ Suzan Onel, Dietary Supplements: A Definition that is Black, White, and Gray, 31 Am. J. L. & Med. 341 (2005).

⁷⁹ Neal D. Fortin, Dietary Supplements, Power point presentation (Fall 2006).

that says, "helps maintain cholesterol levels that are already within the normal range," is considered a structure/function claim.⁸⁰ It is very difficult to tell the difference between these two claims. Therefore, the only solution is to eliminate or at least dramatically cut back on the ability for dietary supplements to be able to make structure/function claims. The way to provide clarity for consumers is to require that a dietary supplement actually prove a health benefit, or not make a claim in that area at all. If a dietary supplement makes a claim that even remotely sounds like a health claim, then it should be considered a health claim and therefore be required to go through the rigorous FDA review of the scientific evidence, before the product or ingredient can be used by the public. By dramatically narrowing the definition of dietary supplements, and by applying a health claim standard of review to any claim that sounds even remotely like a health claim, will prevent dietary supplements from being marketed as drug-like products.

D. Apply Food Additive Safety Standards to Dietary Supplements

The third reform of DSHEA should involve strengthening the safety standards. The FDA attempts to ensure that the ingredients making up a food product are safe for their intended use.⁸¹ When an ingredient is added to a food, the FDA requires that the ingredient either be determined to be "generally recognized as safe" (GRAS) by qualified experts or go through FDA's review and approval process for a food additive.⁸² The problem arises because FDA regulates the safety of dietary supplements under the provisions set out in DSHEA, which exempted new dietary ingredients in dietary supplements from the safety requirements that apply to food additives.

⁸⁰ Neal D. Fortin, Dietary Supplements, Power point presentation (Fall 2006).

⁸¹ Lawrence J. Dyckman, and Keith W. Oleson, Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and Functional Foods, United States General Accounting Office, at 8 (July 2000).

⁸² Lawrence J. Dyckman, and Keith W. Oleson, Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and Functional Foods, United States General Accounting Office, at 8 (July 2000).

The reform here is to apply the food additive safety standard to dietary supplements. This should be written into the DSHEA so that dietary supplement ingredients either pass the GRAS standard or go through the rigorous FDA review that is applied to food additives. No matter what form the dietary supplement takes, whether a pill or as a granola bar, it should undergo a similar FDA review as a food. If the dietary supplement is ingested like a food, and even takes the form of a food then of course it should be treated like a food and regulated in similar fashion as a food.

E. Summary

If the dietary supplement is regulated under the health claim standard or under the safety standards mentioned previously, then it will likely undergo a pre-market review. At the heart of reforming DSHEA is requiring a pre-market review of dietary supplements. Anything ingested by consumers should have to undergo a rigorous and scientific-based pre-market review. When products make claims that sound like they have the curative powers of drugs, then this should raise the regulatory standards even more and require that they be regulated as drugs. Should the product advertise itself as a food or take the form of a conventional food, such as a tea or a granola bar, then it should be regulated under the food additive safety standards. Since consumers often can't tell the difference between a dietary supplement and a drug, or a dietary supplement and a food, it is critical that the FDA be more pro-active in protecting consumers. As the dietary supplement industry gets more creative and more aggressive in marketing its products, it is important that the FDA be given the regulatory tools it needs to protect consumers.

Conclusion

Adopting these reforms will be a return toward regulating food and drug products more rationally and scientifically. The struggle between the FDA and the dietary supplement industry

has been going on for years. The FDA was active in the past, struggling to regulate dietary supplements and meeting resistance from the dietary supplement industry. In the 1990's, with the passage of DSHEA, the dietary supplement industry achieved a victory. Essentially, the DSHEA weakened the ability of the FDA to provide adequate pre-market oversight of dietary supplements. It did this by broadening the definition of dietary supplement, allowing dietary supplements to avoid health claim regulations, and safety regulations regarding food additives.

The reforms mentioned in this paper represent a response to the political triumph of DSHEA, and are designed to restore to the FDA the regulatory authority it needs to effectively regulate the dietary supplement industry. These reforms basically suggest regulating as a drug, dietary supplements that advertise themselves as a drug, and regulating as a food, dietary supplements that take the form and substance of foods. Essentially, the reforms suggest ending the special exemptions provided to dietary supplement by the DSHEA. These reforms should give FDA the regulatory authority it needs to conduct pre-market reviews of dietary supplements. The dietary supplement industry is growing more powerful everyday as companies are increasingly becoming more creative in their efforts to market and expand their products to more consumers. Now is the time for Congress to undue some of the damage it caused with the DSHEA by passing legislation that protects consumers.