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Dietary Supplements: A Historical Examination of its Reg

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Abstract

The subject of this paper is the regulation of dietary supplements, with the passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA) marked as a turning point. The paper examines the history of regulation prior to DSHEA, and then it proceeds to examine DSHEA itself as legislation. The problems with DSHEA and its enforcement by the Food and Drug Administration (FDA) are then discussed, and I use ephedra as a specific example in illustrating those problems. To complete the examination of the entire regulatory scheme behind dietary supplements, I then address the concurrent regulatory responsibilities that the Federal Trade Commission (FTC) has with the FDA in regulating supplements. As a counterpoint to government regulation, I also examine some areas of products liability law that will be relevant in dietary

supplement litigation as an illustration of private regulation via litigation. I conclude the paper by discussing some proposals that can be implemented to improve the dietary supplement regulatory scheme.

I. Introduction

The presence of dietary supplements in the American mainstream culture and economic markets has boomed in the last several years. According to a recent issue of U.S. News and World Report, approximately 123.5 million Americans have used dietary supplements to treat a variety of health conditions.¹ In 1999, United States consumers spent approximately \$31 billion for dietary supplements and certain food products that claim to have additional health benefits beyond basic nutrition.² When one enters a supermarket or a drugstore, it is a common sight to see a growing number of dietary supplements that promise to do things such as combat stress, reduce cholesterol levels, eliminate cellulite, improve mental alertness, and sharpen memory. Manufacturers of these supplements often intentionally select brand names or use words on their labels and in promotional materials to imply the improbable or impossible: “fat burner” or “detoxifies.” For example, consumers can buy “natural Viagra,” the “#1 rated herbal” for impotence.³ Manufacturers of these supplement products have jumped on the opportunity to take liberties with regard to health claims on labels. They can state the manner in which the product is intended to “affect the structure or function of the body”⁴ but cannot claim its use for a specific disease. We often see examples where the manufacturer can just claim that their product promotes “wellness” as opposed to “sickness,” or that their product “promotes regularity” as opposed to “treating constipation,” and under existing laws, these

¹Amanda Spake, Natural Hazards, U.S. News And World Report, Feb. 12, 2001

²United States General Accounting Office, Report to Congressional Committees, Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and “Functional Foods”, GAO/RCED-00-156 (July 2000)

³Paul D. Rheingold, Association of Trial Lawyers of America Winter Convention Reference Materials -- Hot Topics: Bitter Pill: Indications / Complications in Drug Litigation, Ephedra and Other Dangerous Herbals -- and Its Cousin PPA (Winter 2001)

⁴21 U.S.C. §321 (g)(1)(C) (1994 & Supp. III 1997)

claims would be allowable.

This paper will primarily focus on examining the evolution of the regulatory scheme that governs the dietary supplement industry today. In Section II, I summarize how dietary supplements were regulated prior to 1994. In Section III, I discuss the changes that occurred in 1994 as a result of the passage of the Dietary Supplement Health and Education Act (DSHEA). In Section IV, I address the problems that are associated with DSHEA and its enforcement by the Food and Drug Administration. In Section V, I examine a specific example of a dietary supplement ingredient, ephedra, to show how manufacturers have abused the loopholes in DSHEA and the regulatory scheme. In Section VI, I flesh out the remainder of the examination of the regulatory scheme by discussing FTC regulation of dietary supplements and its problems. I also discuss the areas of law that may be involved in dietary supplement litigation, as they are a form of private regulation of the industry, as opposed to governmental regulation. In Section VII, I conclude by addressing some possible changes that can improve the current regulatory scheme.

II. Background of the Dietary Supplement Health and Education Act (DSHEA)

Much of this explosive dietary supplement phenomenon can be traced to 1994, when Congress enacted the DSHEA in an effort to protect consumers' right to purchase dietary supplements. DSHEA is arguably one of the most important examples of a deregulation of a federal health and safety program.

Before examining DSHEA, it is important to discuss the regulatory procedures and institutions that preceded it. Prior to DSHEA, the Food and Drug Administration (FDA) regulated dietary

supplements as “food, drugs, or both.”⁵ The FDA typically used its authority over drugs and food additives, as stated in the FDCA provisions, to regulate these dietary supplements. A dietary supplement manufacturer seeking to sell its product as a drug was required to obtain pre-market approval from the FDA showing that the proposed product was safe, and also effective if the manufacturer wanted to make a drug claim.⁶ Drugs may only enter the product market if they survive the FDA’s “new drug approval” (NDA) review process.⁷ This rigorous pre-market approval process often involves a significant duration of time in order to ensure that the claims are supported by “adequate and well-controlled investigations.”⁸ There are generally two types of the above-mentioned drug claims. The first type relates to therapeutic claims to treat or prevent disease. The second type, which is more relevant to this paper, includes claims that purport to “affect the structure or function of the body.”⁹ This second type of claim was originally included in legislation because Congress had been convinced by the proposition that the claims language needed to be expanded in order to facilitate the regulation of various products that do not necessarily treat disease, as traditionally understood. The FDA’s power to regulate dietary supplements as drugs was upheld in a landmark case in 1948, Kordel v. United States.¹⁰ In that case, the Supreme Court broadly defined the term labeling to include statements made within leaflets and pamphlets mailed separately by the dietary supplement manufacturer to the retailer. Thus, the Court concluded that the FDA could invoke its authority over drugs against dietary supplements such as herbal remedies when the information pamphlets accompanying the product suggest a use of disease prevention or treatment or a use that affects

⁵FDA Advance Notice of Proposed Rulemaking, Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, at 33692 (1993)

⁶21 U.S.C. §355 (d) (1994)

⁷21 U.S.C. §321 (p)(1) (1994)

⁸21 U.S.C. §355 (d) (1994)

⁹See supra note 4

¹⁰335 U.S. 345 (1948)

body structure or function. The ultimate effect of the FDA's use of its authority over drugs was to prevent the marketing of these products until the pre-market approval for both safety and effectiveness was obtained.

Also, the FDA often used its authority to regulate food additives as an easier means of declaring a dietary supplement ingredient unsafe or inadequately tested. If the FDA declared that the dietary supplement was not safe according to the food additive provisions of the Federal Food, Drug, and Cosmetic Act (FDCA)¹¹, then the manufacturer would have the burden of proving that the supplement in question was exempt from such requirements.

The more typical scenario of regulation involved dietary supplements that were sold as foods, not drugs. As noted, the process for approving drug claims is a rigorous one. Foods, however, when they claim to affect the body's structure or function, are not considered drugs; food products can make "structure-function" claims without FDA approval.¹² The statute indicates that foods inherently have these effects on body structure and function. On the other hand, according to the courts, supplements were only able to fit into the food classification if their claims related to food uses, such as aroma, nutrition, or taste.¹³ So, claims about these food uses, including nutritional effects would be acceptable, and we often saw these kinds of claims with supplements such as vitamin pills. But, other claims about the effects of the supplements, including reducing cholesterol, increasing memory, and other claims we often see currently, were still considered drug claims, and thus subject to more stringent review by the FDA. Manufacturers typically did not want to run the risk of having their products classified as drugs on the basis of a structure-function claim, so the practical effect was

¹¹Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. §§ 301 et. Seq. (1994))

¹²21 U.S.C. §321 (g)(1) (1994)

¹³Nutrilab, Inc. v. Schweiker, 713 F.2d 335, 338 (7th Cir. 1983)

one that limited the claims made on their dietary supplement products. For instance, manufacturers of St. John's Wort could not refer to its alleged mood-brightening qualities despite its history of antidepressant efficacy.

Still, even before the passage of the DSHEA in 1994, the courts and Congress reacted to what was perceived to be FDA over-regulation of these products, and this legislative and judicial action has had the effect of limiting FDA's authority to regulate supplements as drugs based merely on consumer use without additional evidence to show the manufacturer's intent to market their product as a drug.¹⁴

For example, during the 1960's, the FDA took a more aggressive position in regulating vitamin and mineral supplements.¹⁵ It was concerned by the elevated use of higher dosages of vitamins and minerals, and it used its drug authority as the primary regulatory tool. This increased regulation escalated, and in 1973, the FDA drafted regulations that prohibited irrational combinations of vitamins and minerals when sold as foods, and set the maximum and minimum potency levels for nutrients.¹⁶ If a nutrient's potency level exceeded the maximum threshold set by the FDA, then the agency would regulate that product as an unapproved drug.

These new regulations were challenged in federal court in National Nutritional Foods Ass'n v. FDA.¹⁷ The court held that the FDA was allowed to establish limits for vitamin and mineral doses in order to protect consumers from being confused about the therapeutic effects.¹⁸ More importantly, however, the court ruled that the mere fact that a nutrient is sold in high doses will not automatically subject it to regulation as an unapproved drug, as the FDA had originally intended.¹⁹

¹⁴Margaret Gilhooley, Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice, 49 Fla. L. Rev. 663, 671 (1997)

¹⁵See id. at 673

¹⁶Definitions and Standards of Identity for Food and Special Dietary Uses, 38 Fed. Reg. 20730, 20738 (1973)

¹⁷504 F.2d 761, 789-92 (2d Cir. 1974)

¹⁸See id.

¹⁹See id. at 789

The court's holding weakened the FDA's drug authority as a regulatory tool against dietary supplements because the FDA would now have to satisfy an escalated burden of proof in order to establish that the manufacturer intended consumers to use its product as a drug therapy. This momentum against regulation led to subsequent lobbying efforts that resulted in the passage of the Proxmire Amendment.²⁰ The Amendment codified the holding in National Nutritional Foods Ass'n that prohibited the FDA from using drug authority against a vitamin or mineral product merely because the level of potency exceeds the FDA recommended level. The Amendment also nullified the FDA's authority to subject vitamins and minerals to regulation for the sole reason of irrational combinations or high dosage.

Another example of the weakening of FDA authority occurred in Fmali Herb, Inc. v. Heckler.²¹ At stake was the FDA argument that the grandfather exemption²² for commonly used food additives in existence prior to 1958 exempted only those additives that were present in the country before 1958; the FDA sought to exclude various traditional herbs and substances that were used in Chinese and other cultures using this exemption. However, the FDA suffered a defeat when the Fmali Herb court ruled against it and allowed herbal ingredients used widely outside of the country to fall within the grandfather exemption.²³ The FDA food additive authority against herbal supplements was weakened by this decision.

Now with the FDA's drug and food additive authority weakened, the FDA assumed a more reactive role in regulation, often acting in response to safety problems or explicit drug claims, as opposed to enforcing a standard requiring manufacturers to prove their products' lack of harm.²⁴ Its regulatory stance against dietary supplements had to be relaxed. The Proxmire Amendment

²⁰21 U.S.C. §350 (1994)

²¹715 F.2d 1385 (9th Cir. 1983)

²²21 U.S.C. §321(s) (1994)

²³See supra note 21, at 1389-90

²⁴United States General Accounting Office, Report to Senator Kennedy, at 4 (B252966, July 2, 1993)

and the court decisions discouraged the agency from engaging in routine and close regulation of the dietary supplement product market. During this era of scaled-back enforcement and regulation, the FDA's reactive role, as under their food authority, consisted of enforcing the pre-market approval requirements on manufactures when a specific safety issue arose regarding a food additive. Under its drug authority, the FDA pursued enforcement when the labeling of the product had unauthorized drug claims. Under this scaled-back regulation, it was much easier for supplement manufacturers to bring their products into the consumer market, and this was evidenced by the surge in the number of supplements on the market in the early 1990's. Naturally, the increased availability of these products gave consumers the new opportunity to abuse or misuse them, in the sense that the uses were neither approved by the FDA nor indicated on the product labeling. A turning point in this period of reduced FDA regulation occurred in 1993 when thirty-eight deaths and fifteen hundred adverse effects were attributed to L-tryptophan, an amino acid that approximately thirty million Americans used as an antidepressant or as an aid to body-building.²⁵ The FDA employed a Task Force to weigh different options in connection with issues raised by not only L-tryptophan, but also all dietary supplements.²⁶ The Task Force recommended in its report that L-tryptophan and other amino acids be regulated as drugs because their "primary intended use... is for therapeutic rather than nutritional purposes," and because they were marketed heavily.²⁷ In addition, the FDA was concerned that many supplements that were on the market had "no known history of food use and, even without drug claims are used for medical purposes."²⁸ Further, the Task Force explored "Issues of Concern" about herbal supplements and pointed out that the FDA's immediate goal was "to ensure their safety and to remove hazardous

²⁵See supra note 5, at 33,695-66, and 33,698-99

²⁶Id. at 33,694-99

²⁷Id. at 33,697

²⁸Id.

products from the market...in accordance with the priorities established in FDA's health fraud program.''²⁹ Despite these strong statements, the Task Force still appeared to only have desired to target specific enforcement at very serious product frauds and safety risk, as it '‘attempted to balance the agency's statutory mandate to protect the public health with some accommodation of the desire of a substantial segment of the public to obtain dietary supplements, including ones with possibly little or no documented nutritive value.’’³⁰

However, for many, this event signaled an FDA return to the stronger regulatory era that preceded the Proxmire Amendment, when it tried to classify high-dosage vitamins as drugs based upon widespread consumer use. In response to the Task Force's finding, the dietary supplement industry moved to appeal to the public. The industry characterized the FDA's new approach as having extensive reach and threatening to take many products, including basic vitamins and minerals, away from the consumer market. This marked the beginning of momentum for the passage of DSHEA. Another impetus toward the movement for DSHEA was the FDA's interpretation of the Nutrition Labeling and Education Act of 1990 (NLEA).³¹ The NLEA allowed conventional foods to assert certain health claims that met an evidentiary standard of '‘significant scientific agreement,’’ and were approved by the FDA.³² The NLEA appeared to give the opportunity for health claims to describe a relationship between dietary supplements and disease, and it gave the FDA decision whether or not to employ a lower standard for scientific proof for approval of these health claims on dietary supplements.³³ The FDA decided to hold herbal supplement manufacturers to

²⁹Id. at 33,698

³⁰Id. at 33,691

³¹Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified as amended at 21 U.S.C. §§301, 321, 337, 343, 345, 371 (1994))

³²21 U.S.C. §343(r) (1994)

³³Nutrition Labeling and Education Act of 1990, §3 (b)(1)(A)(x)

the higher standard of ‘‘significant scientific agreement,’’ and declined to approve health claims for dietary supplements such as linking dietary fiber and cancer, antioxidant vitamins and cancer, and omega-3 fatty acids and heart disease.

By 1993, dietary supplement manufacturers and consumers realized that the era of reduced enforcement of FDA regulations against dietary supplements during the 1970’s and 1980’s might be coming to an end. The FDA appeared more than willing to use its authority against suspect supplements, but consumer demand for these supplements was still increasing. In response, interest groups, the dietary supplement industry, and supplement consumers banded together. There was a national ‘‘blackout day’’ in which retailers of these dietary supplements covered all the dietary supplements, which might be taken away by the FDA under its new expansive regulatory goals, with black fabric. This arguably marked the symbolic beginning of a public grassroots consumer letter writing campaign, largely organized by the supplement industry, for legislation that eventually became the Dietary Supplement Health and Education Act.

III. The Dietary Supplement Health and Education Act of 1994 (DSHEA)

Because the popular support for DSHEA was so overwhelming, it became law on October 25, 1994, and it took effect in 1996. For millions of consumers of dietary supplements, they viewed this passage of law as an enormous victory under the threat of unreasonable regulatory guidelines advocated by the FDA. Meanwhile, the passage of DSHEA was viewed as a failure and defeat from the FDA’s perspective, and it has been described as Commissioner Kessler’s ‘‘greatest failure’’

as the head of the FDA.³⁴

The text of the statute directly addresses the concern of FDA over-regulation by asserting that “the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers” and that “dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare.”³⁵ The statute further asserts that “improving the health status of United States citizens ranks at the top of the national priorities of the Federal Government” and that “the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies.”³⁶ Before proceeding further, I will summarize the three major changes that have occurred since the passage of DSHEA.

The first major change under DSHEA involves the redefinition of dietary supplements. Dietary supplements are now vaguely redefined as a new category distinct from food and drugs: a product (other than tobacco) intended to supplement the diet that bears or contains one of more of the following ingredients: (A) a vitamin; (B) a mineral; (C) a herb or other botanical; (D) an amino acid; (E) a dietary substances 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).³⁷ Any product that fits within this broad definition is eligible for sale in stores, and its manufacturer is now legally able to make health-like claims as long as it has some scientific evidence for them. This expansive definition of dietary supplement has led to an explosion in the amount of dietary supplements

³⁴Marion Burros, “F.D.A. Commissioner Is Resigning After 6 Stormy Years in Office,” New York Times, Nov. 26, 1996, at A1

³⁵Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994), §2

³⁶Id.

³⁷21 U.S.C. §321

we now see in retailers after the passage of DSHEA.

Going past the definitional revision, the second major change made by the DSHEA is in connection with labeling. Now, provided the requirements outlined by the statute is satisfied, it is allowable for dietary supplements to make statements about the role of a ‘‘dietary ingredient’’ in affecting ‘‘the structure or function of the body’’ without have the statement being considered a drug claim by the FDA.³⁸ In order to satisfy the statutes’ requirements, such a claim must be accompanied by an information disclosure that ‘‘statement has not been evaluated by [the FDA]’’ and the product ‘‘is not intended to diagnose, treat, cure, or prevent disease.’’³⁹ Also, the dietary supplement manufacturer has to substantiate that their claim is ‘‘truthful and not misleading.’’⁴⁰ The biggest difference between these claims made by dietary supplements and traditional drug claims is that there is no requirement for prior FDA approval of the statement.⁴¹ Section six of the DSHEA outlines the statements of nutritional support that are allowed in dietary supplement labeling. These include a statement that: 1) claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, 2) describes the role of a nutrient of dietary ingredient intended to affect the structure or function in humans, 3) characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, and 4) describes general well-being from consumption of a nutrient or dietary ingredient.⁴² This is a very significant provision in the statute because as noted above, previous to the DSHEA, the courts held that the definition of ‘‘food’’ only included the standard foods ingested primarily for the purposes

³⁸21 U.S.C. §343(r)(6)(A) (1994)

³⁹21 U.S.C. §343(r)(6)(C) (1994)

⁴⁰21 U.S.C. §343(r)(6)(B) (1994)

⁴¹Id.

⁴²DSHEA, *supra* note 35, §6

of ‘‘taste, aroma, or nutritive value.’’⁴³

The statute further suggests that these claims can be made for nutrients and also for ‘‘dietary ingredients.’’⁴⁴ So, it appears that claims for dietary supplements would be allowable even if the claim were not connected to nutrition directly. For example, we have seen such claims to include claims about the role of a nutrient or dietary ingredient regarding the structure or formation of the human body, and declarations of general well bring from the consumption of a nutrient or other dietary ingredient. This differs from the past where a test that was used for food supplement claims had been a determination of nutritional value. So, the major effect of the DSHEA provision regarding claims is to permit herbs, botanical and other products to be sold as dietary supplements and to make claims about their effects and benefits despite the understanding that they are not foods in the traditional nutritional sense and despite the fact that these products often have been used as medicines in other foreign countries. The third major change brought by DSHEA was the shifting of the burden of proving product safety from the manufacturer to the FDA. Currently, a dietary supplement will be considered ‘‘safe’’ if the new ingredient does not present a significant or unreasonable risk of illness or injury under conditions of use recommended in the product labeling.⁴⁵ Should the FDA attempt to remove a dietary supplement from the product market, it must demonstrate that the supplement would be harmful if consumed as recommended.

However, the FDA is not without any regulatory teeth. If the FDA concludes that a product poses an ‘‘imminent hazard to public safety,’’ the agency may immediately remove that product from the market, but it must initiate a proceeding afterwards to evaluate that decision.⁴⁶

⁴³See supra note 13.

⁴⁴21 U.S.C. §343(r)(6)(A) (1994)

⁴⁵21 U.S.C. §342(4) (1994)

⁴⁶21 U.S.C. §342 (f)(1)(C) (1994)

Furthermore, the FDA is able to take action if a dietary supplement ‘‘is or contains a dietary ingredient that renders it adulterated... under the conditions of use recommended or suggested in the labeling of such dietary supplement.’’⁴⁷ For example, the FDA, after receiving reports of serious injuries and deaths, concluded that Nature’s Nutrition Formula One, a dietary supplement supposedly produced from ma huang and kola nut, posed a significant risk of illness or injury.⁴⁸ Thereafter, the FDA issued a warning letter to the product manufacturer advising that its product was adulterated and unsafe, and the owner later pleaded guilty and served some jail time.⁴⁹ Nonetheless, most of the time, this burden shifting to the FDA to prove product safety has made it much more challenging for the agency to remove a dietary supplement from the consumer market than it has in the past. The shift in the burden of proof to the FDA forces the agency to make very hard resource allocation decisions. In the area of dietary supplement regulation, this has unfortunately translated into supplement manufacturers being more easily able to market its products liberally without any imminent threat of close regulatory monitoring.

IV. New Problems Related to DSHEA and its Enforcement by the FDA

As has been suggested, DSHEA has elements of vagueness in its language. In the definition of ‘‘dietary supplement,’’ the meaning of ‘‘dietary’’ is not stated, nor is the catch-all provision in subsection (E) of 21 U.S.C. §321(ff)(1). But perhaps the largest and most important difficulty

⁴⁷21 U.S.C. §342 (f)(1)(D) (1994)

⁴⁸Vani Singhal, FDA’s Regulation of Dietary Supplements Fueled by Industry Growth, 1 Pharmaceutical & Med. Devices L. Bull. 5 (2001)

⁴⁹Id.

with the new statute lies in the question of how to distinguish disease/drug claims from the permissible claims that relate to structure and function. This is a very significant difficulty because since the passage of DSHEA, many manufacturers are deciding to forgo efforts to gain FDA approval for health claims and instead are marketing their products as dietary products on the basis of structure-function claims, which as noted can be made without prior FDA approval. The FDA itself has recognized the troubling nature of this part of DSHEA, and it has stated that diseases, ‘‘by definition, adversely affect some structure and function of the body.’’⁵⁰ It is true that distinguishing between structure-function claims and disease claims is not as significant for drug regulation since both kinds of claims require pre-market approval from the FDA. However, since DSHEA permits structure-function claims for dietary supplements, the issue of how to draw the line between these two kinds of claims has become even more important. The FDA has attempted to identify some elements to help clarify the line between disease claims and structure-function claims in its rulemaking.⁵¹ I will try to briefly highlight below some of the more important elements that the FDA has recognized under its rules.

While the supplement manufacturing industry has tried to maintain that a claim is only a disease claim if it makes an express reference to a disease, the FDA has not adopted that position, and it has continued to disallow implied disease claims for dietary supplements. Instead, the FDA has taken the position that while disease claims refer to specific diseases, statements that ‘‘refer broadly to body systems or functions without sufficient reference to specific abnormalities or symptoms to be understood as references to particular diseases’’ are permissible structure-function claims.⁵² Hence, general statements regarding body systems, such as ‘‘promotes

⁵⁰Proposed Rule, Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 82 Fed. Reg. 23624 (1998) (proposed April 29, 1998)

⁵¹FDA Final Rule, Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure and Function of the Body, 65 Fed. Reg. 999 (2000)

⁵²See supra note 48, at 23,626

relaxation’’ or ‘‘increases mental awareness,’’ are allowable.

Similarly, the FDA construes references to abnormal conditions, or to the typical signs or symptoms of a specific disease, as implicit disease claims. Claims relating to general maintenance of bodily functions are permitted, and the FDA rationalizes that some of these general signs and symptoms ‘‘may be associated with a number of disease, but are not, by themselves, sufficient to characterize specific diseases.’’⁵³ Again, the problem here is that the test for differentiating the types of claims is very slight. I do not think there is enough of a difference between, for example, a presently impermissible claim of ‘‘lowers cholesterol’’ and a permissible claim of ‘‘maintains cholesterol levels’’, to justify the existence of significantly lower thresholds of regulation for the more general claims.

Because many claims that are permissible under the DSHEA are so difficult to distinguish from drug claims, they raise the same concerns that new drug claims pose for the consumer and the government despite the disclaimer that instructs the consumer not to depend on the product as an FDA-approved drug. In this difficulty, we see the clash between the consumer’s and the government’s interests in ensuring safe, effective health products and DSHEA’s promotion of the consumer’s other interest in having access to dietary supplements and the information necessary to exercise that freedom to make personal health choices.

This clash between interests lends itself to aspects of how DSHEA fails as a regulatory instrument. For example, for the average consumer who wishes to use dietary supplements to treat or improve negative health conditions, DSHEA fails in the sense that the average consumer is compelled to take a risk when making his decision as to which dietary supplement to use. The labeling on these products often contains claims suggesting the product’s therapeutic *potential*. However,

⁵³Id.

paradoxically, the legally required disclaimer that accompanies the product, stating that the FDA has not specifically endorsed such claims, tells the average consumer to be aware and skeptical of these claims relating to the product's potential effects. This sending of mixed messages only promotes confusion and ambiguity, elements that we should strive to avoid in connection with consumer health and safety.

Moreover, under the current state of DSHEA and FDA regulation of such products, the average consumer has a very difficult time in making an accurate judgment of the product's efficacy or even safety; products could potentially produce unintentional results and even cause unwanted side effects for the unknowing consumer. It is not difficult to see how the new regulatory scheme under DSHEA can raise important safety and efficacy issues for the average consumer who wishes to use dietary supplements as alternative methods of treatment for certain health conditions.

While it is certainly arguable that the FDA's rules are a reasonable effort by the agency to comply with DSHEA's broadening deregulation, there are undoubtedly difficulties in the applications of the rules, as mentioned above. Even for an expert in the field, it would be difficult to differentiate some of the claims as permissible or impermissible under the FDA's rules. Again, one of the most important concerns here relates to the average consumer, who could be misled by questionable claims on dietary supplements. We cannot blame the FDA for DSHEA's vagueness, but the line that the FDA has tried to draw is also vague and potentially problematic.

The method of how manufacturers label their supplement products with "non-disease" claims has been described as "an art form of doublespeak," with medical uses being implied, but still almost obvious as in the example of claims to "promote prostate health."⁵⁴ The FDA

⁵⁴Editorial, Alternative Medicine -- The Risk of Untested and Unregulated Remedies, 339 New Eng. J. Med. 839, 841 (1998)

seeks to draw the line between disease prevention and maintenance, but it is a line that can too often be circumvented. Consumers can potentially misinterpret dietary supplement claims related to maintenance as meaning that the product is necessary for maintenance, thereby steering these consumers away from other, perhaps safer and proven methods of maintaining that particular body function. This element of potential deception on the part of manufacturers is enough to warrant reconsideration of the current test for claims. Furthermore, the federal courts have not been receptive to increased efforts by the FDA to inspect and pursue questionable claims. For example, in Pearson v. Shalala, the D.C. Circuit held that the FDA may not prohibit the marketing of dietary supplements with health claims when there is evidence to support those claims.⁵⁵ The permissibility of these claims stands even if the evidence is not conclusive.⁵⁶ In light of class discussions in Professor Peter Hutt's Food and Drug Law course, we must recognize that the FDA is not an all-powerful super-agency, but an agency that is still constrained by budget and other resource allocation factors. With the shifting of the burden of proof to the agency to prove a specific dietary supplement's harmfulness, it is much more expensive in terms of resource constraints for the FDA to pursue every product.⁵⁷ It is inevitable that although DSHEA in its language still indicates the commitment of the government to the safety and well being of the dietary supplement consumer, the regulating agency in this case is simply not able to thoroughly enforce the stated goals of DSHEA.

While DSHEA permits supplements to make claims without prior approval by the FDA, the claims are still required to have substantiation, by law. The difficulty of enforcement also arises here in that the FDA lacks the express authority to obtain the records and studies of food and supplement manufacturers. Lacking this authority, it is significantly more difficult for

⁵⁵Pearson v. Shalala, 164 F. 3d 650 (D.C. Cir. 1999), reh'g en banc denied, 172 F.3d 72 (D.C. Cir. 1999)

⁵⁶Id.

⁵⁷See generally 1 James T. O'Reilly, Food and Drug Administration §10.15 (2d ed. 1995).

the FDA to regularly inspect the studies the supplement manufacturers have supposedly undertaken in order to substantiate their claims on their supplement products.

All of the above problems with regard to DSHEA and its enforcement points to the necessity of scrutinizing whether DSHEA is an adequate method of protecting consumers from unsafe products. With the explosion of dietary supplements on the market, it is not unreasonable to assume that many consumers experiment with these products because they regard them as safe. Consumers may falsely believe that these supplements are just as safe as traditional foods because they are “‘dietary supplements,’” a potentially vague and not fully defined term for the typical consumer. The exemption of dietary supplements from FDA pre-market approval under the DSHEA for safety amplifies this concern.

One of the main problems with dietary supplements is simply that we, including the scientific community and the consumers, do not know enough about them due to lack of experience or study. According to the FDA, the safety and benefits of “‘many’” supplements on the market has not yet been proven by adequate testing.⁵⁸

Because of the incomplete information we have regarding many dietary supplements, this points to one of DSHEA’s most important weaknesses: the lack of a requirement for dietary supplement manufacturers to affirmatively substantiate the safety of their products. DSHEA does have a requirement for safety substantiation, but the statute limits this requirement to new ingredients that are sold after 1994.⁵⁹ Furthermore, “‘new’” ingredients are not to include any dietary ingredient marketed prior to the passage of DSHEA, even if the ingredient was for a different use.⁶⁰

It almost seems obvious that all supplements should have to substantiate their safety at the

⁵⁸Final Claims Rule, 65 Fed. Reg. 999, 1003 (2000)

⁵⁹21 U.S.C. §350(b) (1994)

⁶⁰Id.

very minimum, but that does not even appear to be the case under DSHEA. A requirement for universal safety substantiation would appear to be very helpful for the protection of consumers. Manufacturers would be required to undertake scientific studies and tests on their products, and this would contribute to better assessing the risks associated with the product use and establishing safe amounts of the product to be consumed.

As some have argued, since the passage of DSHEA, ‘‘chaos’’ has taken over the dietary supplement market.⁶¹ This ‘‘chaos’’ is not even necessarily limited to some unpredictability related to the products in themselves. From my own experience having been raised in a very traditional Chinese family, I am familiar with the use of certain herbal substances and other products for medicinal purposes. I may not completely understand the technical science behind the substances and their therapeutic effects, but I am a supporter and proponent of their efficacy, as I have seen the results and cannot contest them on a scientific basis. From my experience and from my understanding of my culture’s experience with these alternative medicines, the traditional use of these products is safe and certainly effective, and it is logical to conclude that the traditional use and preparation of these substances was the natural result of process of trial and error over the long history of their use, and this has narrowed the use of these substances to only the safe and more effective prescriptions/versions.

To make an analogy, a modern dietary supplement’s lifetime on the product market for a substantial amount of time is partially reflective of its safety and effectiveness for similar reasons why certain Chinese herbal prescriptions have lasted so long in their use and availability. However, DSHEA alters this in the sense that it encourages a market where dietary supplement manufacturers experiment with the products they market. If we examine just the herbal supplement

⁶¹Jane E. Brody, ‘‘Americans Gamble on Herbs as Medicine: With Few Regulations, No Guarantee of Quality,’’ N.Y. Times, Feb. 9, 1999, at D1.

market, we see that manufacturers sometimes make their own herbal combinations to make new products that haven't survived the test of time that the more traditional herbal products have.⁶² Manufacturers also promote traditional products for new, less proven purposes.⁶³ The products may also differ from the traditional ones in the form they take when marketed, whether it be as a pill, capsule, powder, tea, etc. And perhaps most egregiously, manufacturers can also sell their products in a diluted or less effective form because it leads to cost cutting for their production processes.⁶⁴

V. Ephedra -- An Example of a Dietary Supplement Exploiting the Problems Associated with DSHEA and its Enforcement by the FDA.

I will use ephedra as the example for this paper's examination of how a dietary supplement manufacturer can potentially abuse the provisions of DSHEA and its enforcement at the consumer's expense. Ephedra, also known as ma huang in Chinese, is an herb that has been used in the Chinese herb for centuries. Chemically, it is referred to as ephedrine or as an ephedrine alkaloid, and its composition is close to the over-the-counter drug pseudoephedrine, commonly found in cold medicines. Under traditional use in Chinese culture, ephedra is used as a decongestant for symptoms resulting from colds, allergies, hay fever, and asthma. As evidence of agreement in this use of product in this respect, the FDA has even approved ephedrine for use in cold medicine as well.⁶⁵

However, because of the holes that DSHEA leaves for manufacturers, which were discussed previously, we

⁶²Varro E. Tyler, "Get the Best Herbal Medicine: Golden Rules to Guide You Safely Through the Herb Aisles," *Prevention's Guide: Healing Herbs*, March 2, 1999, at 18

⁶³See *infra* note 52 and Jim O'Brien, *Herbal Cures for Common Ailments*, at 96, (1998)

⁶⁴Jane E. Brody, "'Natural, Drug-Free' Herb May Have Risks of Its Own," *N.Y. Times*, Feb. 9, 1999, at D6

⁶⁵Paul D. Rheingold, "Herbal Supplements May Be Dangerous: Supplements May Look Like Magic Bullets for Health Problems, But Users May Be Playing Russian Roulette," *Trial*, Nov. 1999, at 42, 45

have seen dietary supplements containing ephedra or ephedrine marketed in this country with vague claims such as being an energy or metabolic enhancer or even a fat burner. This is the major hole that is the result from DSHEA's language allowing dietary supplement manufacturers to imply both non-traditional and traditional therapeutic uses by using structure-function claims without having to obtain pre-market approval from the FDA. This is very troubling considering most American consumers are not knowledgeable of the traditional uses and effects of the product and could be persuaded by such vague and even deceptive advertising.

This is even more troubling when one considers some recent studies and commentaries on the abuse of ephedra. The New England Journal of Medicine undertook a study on the health risks of ephedra, and the authors of the article concluded that thirty-one percent of the one hundred forty adverse reports sent to the FDA involving ephedra were definitely or probably related to its use.⁶⁶ The more serious potential side effects of its use were described to either affect the cardiovascular or central nervous system. Products containing ephedra can speed up the heart rate and increase blood pressure, which could potentially lead to stroke, seizures, hypertension, and cardiac arrhythmias. The article continues by describing the likely reasons for the side effects, including constriction of the arteries and shortening of the cardiac refractory period brought on by the use of ephedra and other related alkaloids. However, under the provisions of DSHEA, ephedra supplements are not required to contain directions for use and contraindications on their labels, or any other additional warnings about the product's potential side effects. Thus far, the FDA has reported approximately forty deaths and hundreds of serious injuries, primarily involving cardiovascular problems, in connection with the use of ephedra.⁶⁷

In addition to the inherent risks of ephedra, other studies have cautioned that it is often difficult for the consumer to know exactly how much active ephedrine is contained in the products that they purchase or

⁶⁶Haller & Benowitz, 'Adverse Cardiovascular and Central Nervous System Events Associated with the Dietary Supplements Containing Ephedra Alkaloids,' New England Journal of Medicine, Dec. 2000.

⁶⁷FDA Statement on Street Drugs Containing Botanical Ephedrine, HHS News, Apr.10, 1996

which of the many different alkaloids are being added. It is not uncommon to find drastically different amounts of the substance than from what is indicated on the product label, and it is even possible to find instances where the amount of ephedra differed by 2.4 times the labeled amount.⁶⁸ Under DSHEA, the manufacturers do not have to guarantee that the ephedra product contains the actual levels stated on the labels, or that the ephedra was extracted from the part of the plant that traditionally is considered necessary for effective use.⁶⁹ For ephedra and other herbal products, DSHEA requires manufacturers to name each ingredient, its quantity, and the part of the plant where it was extracted. The problem here is that DSHEA only requires the disclosure of the daily percentage value of the ingredients for which that daily percentage value has been established, however, that value has not been established for ephedra and many other substances that are sold in dietary supplements.

As mentioned previously, the FDA faces practical resource and time constraints in its efforts, and the DSHEA has dramatically affected the agency's approach to regulation of these dietary supplements. In our example using ephedra, from one perspective, it is very disturbing that it took the FDA four years, and more than one hundred reports of life-threatening symptoms and thirty-eight deaths, to take action against the product. As this example will illustrate below, DSHEA has forced the FDA into a much more passive regulatory role, employing methods that promote consumer knowledge and awareness of safety and efficacy issues, as opposed to an aggressive regulatory role where the agency could make a unilateral decision to just remove the product from the market and subject it to further and more thorough testing.

Under the current safety provisions of the DSHEA, the difficulty and resource pressures of monitoring dietary supplements is further evidenced by the FDA's ongoing efforts to control the level of ephedrine in supplement products. The FDA's proposed rule in regulating ephedrine identified eight hundred adverse

⁶⁸ 'Herbal Remedies: The Market is a Bit Too Free', *Business Week* 75 (Sept. 4, 2000)

⁶⁹ Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, §7, 108 Stat. 4325, 4329-31 (1994)

events associated with supplements containing the substance.⁷⁰ The proposal sought to limit the individual ephedrine dosage levels, the duration of use to not in excess of seven days, and it also called for a warning stating that exceeding the limits of ephedrine “may cause heart attack, stroke, seizure, or death.”⁷¹ Under the proposal, the FDA would have allowed claims relating to short-term effects such as increased alertness or energy levels.⁷² However, the proposal disallowed any claims relating to long-term effects such as weight loss.⁷³ Still, this effort by the FDA is not yet conclusive as the FDA later partially withdrew its proposal to limit ephedrine use, in light of a GAO recommendation that the FDA obtain stronger evidence for its proposal.⁷⁴

In light of the inconclusive result of the FDA attempt at regulating ephedrine, I am concerned with the weight loss claims on such supplement products. If such claims are permissible, at the minimum, the FDA has to ensure that the labeling is entirely clear about the intended use of the product and the potential consequences of its misuse. The regulators have to recognize the possibility that without very clear warnings on the labels, there will be some consumers who choose to exceed the label’s limits. Moreover, in connection with the safety of the product, one inevitably has to consider the substantiation of the claim being made. If the effectiveness of the weight loss claim cannot be substantiated, that is another reason to disallow such claims. The substantiation of the claim should be viewed in conjunction with the safety of the product to make a proper assessment whether to allow the claim or not.

Disclosing proper use and potential harms on the labeling on these dietary supplement products is especially important when they pose potential health risks. The FDA sought for such information in their proposed rule for ephedrine by having the label indicate the risks of heart attack, stroke, seizure or death, but perhaps they could take the even further step of requiring a very clear and conspicuous disclosure of the warning as

⁷⁰Proposed Ephedrine Rule, 62 Fed. Reg. 30,677, 30,678 (1997)

⁷¹Id.

⁷²Id. at 30,718

⁷³Id. at 30,697

⁷⁴Dietary Supplements Containing Ephedrine Alkaloids; Withdrawal in Part, 65 Fed. Reg. 17,474 (2000)

with cigarettes. Considering the very real risks associated with overuse of the product and considering the potential for overuse if weight loss claims are allowed, this seems to be a prudent preventive measure.

Perhaps it would be wise to raise the standards of labeling for dietary supplements even higher. The labeling may need to provide information to consumers regarding the increased risk factors.⁷⁵ It does not seem an unreasonable goal to try to make the information on product labeling regarding the product's risks even more tangible for the users. Sometimes, scientific and medical warnings by themselves are dismissed by the average consumer as irrelevant information that does not really apply to him or her.

One suggestion to make label warnings more tangible is to actually provide concrete examples of what can happen if the product is misused. Another possibility is to regulate dietary supplements in a manner more resembling how drugs are regulated. This would include the options of limiting the distribution and availability of certain potentially dangerous dietary supplements or also having a requirement for a prescription in order to obtain the supplements. The opportunity to consult a physician before using some of the more potent dietary supplements would certainly mitigate safety issues associated with the products' overuse. These suggestions are still merely suggestions because it is not clear whether or not the FDA, under current law, has legitimate authority to pursue such measures.

Ephedra use is increasing in the United States, just as the use of all dietary supplements is. Currently, ephedra can be found in hundreds of products, and it is not limited to just products sold in tablet or capsule form. The average consumer is able to find ephedra in teas, sport and other health bars, and even in beverages. In light of ephedra's and other dietary supplements' widespread status in the market, we should be very concerned that DSHEA has made it difficult for the consumer, who wants to use these products for a traditional purpose, to accurately judge whether it is safe and to find the right product, in terms of correct dosage amount and source of substance extraction. Dietary supplements like ephedra, whose claimed effects

⁷⁵See note 66 at 30,692

parallel the effects of traditional regulated drugs, pose a unique public health threat due to their lowered levels of regulation resulting from their designation as dietary supplements and not as drugs.⁷⁶ Many dietary supplements, especially herbal products, are often automatically perceived by consumers to be safe because something about a natural product implies safety, which is obviously not always true.

Even in its victory with the passage of the DSHEA in 1994 and with its newly found ease in selling dietary supplements, the giant supplement manufacturer industry is still not content, and it has pressed forward for even more autonomy from government supervision and regulation on its products. For instance, the manufacturers have approached Congress to lobby for the passage of the “National Food Uniformity Act of 2000,” which would significantly limit the right of states to regulate the use of ephedra and other dietary supplements. The passage of such legislation would directly affect certain proposed laws in some states that seek to add health warnings to dietary supplement products that contain ephedra.

VI. FTC Regulation and Other Potential Litigation Against Dietary Supplement Manufacturers

The FDA regulation of dietary supplements is just one important perspective to view these products from. There are other standpoints from which dietary supplement regulation and litigation should be viewed from in order to paint a more complete picture. Thus far, much of the discussion has focused on the problems of DSHEA and the regulatory scheme of dietary supplements from the FDA’s perspective. However, these problems have translated into other substantial problems for the multitudes of users of these products, resulting in various litigation against the supplement manufacturers, which is a form of private, as opposed to

⁷⁶Sean Harmon, Comment, ‘Melatonin Mania: Can the FDA Regulate Hormonal Dietary Supplements to Protect Consumer Interests in Light of the Dietary Supplement Health and Education Act of 1994?’, 22 U. Dayton L. Rev. 77, 91-94 (1996)

governmental, regulation of the industry. The usual areas of law that courts refer to in dietary supplement litigation are federal trade laws and also products liability law. The following provides a brief overview of government regulation from the Federal Trade Commission's (FTC) perspective, because of its involvement in the enforcement of federal trade laws, and of other litigation and legal actions that have arisen in connection with federal trade and products liability law in the dietary supplement industry.

In connection with federal trade law, the Federal Trade Commission and the FDA divide the responsibilities of regulating dietary supplements. The FTC claims responsibility over advertising, which includes television commercials and infomercials, health catalogs, and broadcast and print advertisements.⁷⁷ As indicated earlier, the FDA takes the responsibility for overseeing the product's labeling, packaging materials, information pamphlets, and other promotional materials that may be distributed at retailers.⁷⁸

The FTC presence in the regulatory landscape was highlighted when on October 5, 2000, Weider Nutrition International agreed to a \$400,000 settlement with the FTC concerning charges that the company had made unsubstantiated efficacy and safety claims for its PhenCal products. The company placed advertisements in major newspapers such as the New York Times and Washington Post claiming that their products were "Proven Safe Without a Prescription," "Proven Effective as Prescription Treatments," and "Proven to Decrease Food Cravings."⁷⁹ The ads further declared that the products "cause significant weight loss," are as "effective as Phen-Fen," "significantly reduce food cravings and eating binges" and "prevent the regaining of lost weight."⁸⁰

The FTC's industry advertising guide provides a general overview of the various factors that manufacturers and advertisers need to be aware of with regard to federal trade law. According to the FTC guide, the

⁷⁷Federal Trade Commission, "Dietary Supplements: An Advertising Guide for Industry," <http://www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm>

⁷⁸Id.

⁷⁹Vani Singhal, FDA's Regulation of Dietary Supplements Fueled by Industry Growth, 1 *Pharmaceutical & Med. Devices L. Bull.* 5 (2001)

⁸⁰Id.

truth-in-advertising law can be broken down into two commonsense propositions: 1) advertising must be truthful and not be misleading to the consumers, and 2) before disseminating an ad, advertisers must have adequate substantiation for all objective product claims.⁸¹ These principles are articulated in the FTC's Deception Policy Statement⁸² and Advertisement Substantiation Policy Statement.⁸³ Moreover, the FTC has the authority to challenge unfair trade practices. Unfair trade practices are defined as actions that cause or would be likely to cause substantial injury to consumers, which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or competition.⁸⁴

The majority of litigation and investigations involving advertising are brought under the FTC's deception authority.⁸⁵ An ad will be deemed deceptive if it is violation of the basic two propositions of the truth-in-advertising law. The FTC will hold an advertiser equally liable for claims that are expressly deceptive as well as claims that are impliedly deceptive.⁸⁶ As a result, the FTC will examine an advertisement as a whole, including text, illustrations, and the product name, and determine if it is deceptive. Relevant information regarding safety and health risks are required to be disclosed to the consumer.

The FTC substantiation standard is a flexible one that depends on many factors, including type of claim, cost or feasibility of substantiation, the potential harms of a false claim, and also what level of substantiation experts in the field have determined to be reasonable.⁸⁷ The manufacturers must have a reasonable basis for substantiation, and claims regarding the efficacy and safety of dietary supplements are held to a substantiation standard of "competent and reliable scientific evidence."⁸⁸

The major problem occurs if we examine the last several decades, where the FTC has moved away from industry-wide regulation to an individual case-by-case enforcement. Their enforcement standards have usu-

⁸¹See supra note 77

⁸²Federal Trade Commission, "Deception Policy Statement," <http://www.ftc.gov/bcp/policystmt/ad-decept.htm>

⁸³Federal Trade Commission, "Advertisement Substantiation Policy Statement," <http://www.ftc.gov/bcp/guides/ad3subst.htm>

⁸⁴See supra note 77 at footnote 5

⁸⁵Id.

⁸⁶See supra note 77

⁸⁷Id.

⁸⁸Id.

ally been more lenient and flexible than their FDA counterparts.⁸⁹ Their enforcement policy statement indicates at one point that “there may be certain limited instances in which carefully qualified health claims may be permitted under section 5 [of the FTC Act] although not yet authorized by the FDA.”⁹⁰

Thus, the dietary supplement industry has generally favored the FTC enforcement policies over those of the FDA’s. In 1954, the FTC and FDA originally agreed to divide their responsibilities between food advertising and product labeling, respectively.⁹¹ It is interesting to note that although at the time of that agreement it may have been sensible for the FDA to rely on the FTC to regulate food advertising, it certainly no longer seems as appropriate to rely on the FTC, an agency with considerably less scientific training and background, when we observe the current trend of food advertisements that are replete with claims involving more complex scientific and health issues. The FTC, in its Enforcement Policy Statement on Food Advertising, states that it would defer to the FDA’s scientific expertise.⁹²

However, it is not clear that the FTC takes the necessary enforcement actions against violating claims in advertisements, even though the FDA has not approved those claims for labeling.⁹³ There are several noteworthy examples here. First, several years ago, Welch’s Foods, Inc. advertised that “[g]rowing evidence suggests that diets rich in antioxidants may reduce the risk of some cancers. . .” and then pointed out that “. . . Welch’s purple grape juice has more than three times the naturally-occurring antioxidants of other popular juices.”⁹⁴ Even though the FDA had rejected the health claim that antioxidants may reduce the risk of some cancers due to lack of significant scientific agreement, the FTC still did not engage in any action against those claims in the advertisements. Another example occurred with Heinz and its ketchup products. Heinz had advertisements that made that claim that lycopene, a substance in its product, “may help reduce

⁸⁹Federal Trade Commission “‘Enforcement Policy Statement on Food Advertising,’” <http://www.ftc.gov/opa/predawn/F95/adlabelhar>

⁹⁰Id.

⁹¹Working Agreement Between FTC and FDA, 3 Trade Reg. Rep. (CCH) ¶ 9,851 (1971)

⁹²See supra note 89

⁹³Ilene Ringel Heller, “‘Functional Foods: Regulatory and Marketing Developments,’” 56Food & Drug L.J. 197 (2001)

⁹⁴Id. at 216.

the risk of prostate and cervical cancer.”⁹⁵ Such a claim would clearly be illegal on the product labeling, however, Heinz was able to make such a health claim on the advertisements. The FTC informed Heinz that it may have violated some substantiation standards, and Heinz stopped that particular ad campaign. The FTC, however, has not followed through with Heinz’s similar claims in its promotional materials to the media.⁹⁶ So, the key point here is that while the FTC is supposed to defer to the FDA in the arena of scientific and medical issues, it does not always do so. It is also interesting to point out that these omissions in complete regulation shows that the FTC faces the same enforcement problems as the FDA in terms of lack of resources and prioritizing other regulatory duties.

Moving on from federal trade law as a potential basis for claims against dietary supplement manufacturers, the other significant area of law to examine in connection with these claims is products liability law. Litigation involving dietary supplements is still an area that is developing; therefore it would be helpful to examine examples involving pharmaceutical products, including prescription and over-the-counter drugs, to gauge what potential claims may be brought against dietary supplement manufacturers.

Generally speaking, a plaintiff may bring various claims against a commercial seller or distributor of a pharmaceutical product. Perhaps the most often seen claims against pharmaceutical companies are characterized by defects that are related to insufficient product warnings or instructions, otherwise known as the company’s duty to warn.⁹⁷ In traditional products liability law involving pharmaceutical prescription drug, the learned intermediary rule is recognized to stand for the proposition that “a drug manufacturer fulfills its legal obligation to warn by providing adequate warnings to the health-care provider”.⁹⁸ The Restatement, Third, rationalizes this rule by stating, “only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of

⁹⁵Id.

⁹⁶Id.

⁹⁷Restatement of the Law, Third, Torts: Products Liability §6, comment d. (1998)

⁹⁸Id. at comment e

prescription based-therapy.”⁹⁹

Regardless, it appears that dietary supplement manufacturers would not have this same defense at their disposal, or at least have a much more difficult time asserting it, for several telling reasons. First, dietary supplements differ from traditional prescription drugs in the sense that the consumer is usually able to obtain the product without a doctor’s prescription. In this way, dietary supplements are more akin to over-the-counter drugs. There have been cases where nutritionists recommended certain products for their clients, thus playing an analogous role to doctors making prescriptions for their patients.¹⁰⁰ In these cases, it is certainly feasible to imagine a scenario where the nutritionist or trainer would be held liable like doctors, and hence shielding the manufacturer from liability.

Again, however, there is another reason why it is harder to for supplement manufacturers to assert this defense; it is not clear that the relationship between a nutritionist or trainer and the client creates the same kind of inviolable relationship that exists between the physician and patient. Then, even if there is an actual physician involved, it is not clear that the supplement manufacturer would be able to reliably depend on the defense as DSHEA has made it difficult occasionally for even physicians to obtain full information regarding certain products.

Still, supplement manufacturers would be prudent to not depend on the learned intermediary rule as a safety net because most of the time, there really is no physician involved in the use of dietary supplements. So, the manufacturers still need to be most wary of providing sufficient warnings directly to the consumers, much like with over-the-counter drug products. The warnings should be directed to any information or risks the consumer needs to be aware of regarding any substances in the product that may have potential adverse health effects. While it is true that the manufacturers will have to be in compliance with FDA regulations regarding labeling, compliance does not equate to being fully shielded from potential consumer claims against

⁹⁹Id. at comment b

¹⁰⁰See *supra* note 65, at 46

the product. The gap between products liability common law's duty to warn and the standards set by federal regulation suggests that there is potential for manufacturer liability even if there is regulatory compliance. The other platform within products liability law where dietary supplement manufacturers can be exposed to potential claims is the doctrine of defects. Again, it would be helpful for supplement manufacturers to look at the law regarding prescription drugs. According to the Restatement, Third, a drug may be considered defective if it contains a manufacturing defect, or is not reasonably safe due to defective design, or it is not reasonably safe due to inadequate instructions or warnings.¹⁰¹

Pharmaceutical manufacturers may be exposed to strict liability for harms suffered by plaintiffs that result from a manufacturing defect.¹⁰² The Restatement defines the condition when a drug contains a manufacturing defect as when "the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product."¹⁰³ If strict liability is found to apply, then a manufacturer will be liable even if the plaintiff is unable to prove that the manufacturer should have discovered the defect or even was aware of it.¹⁰⁴ Strict liability is a very powerful doctrine, and dietary supplement manufacturers definitely are cautious of it. As consumers, we would like to think that the threat of being exposed to strict liability would pressure manufacturers to have higher standards of research and production. Also, similar to the issue of duty of care, compliance with FDA dietary supplement regulations does not necessarily shield the manufacturer from a manufacturing defect claim.

VII. Possible Changes to Improve the Current Regulatory Scheme

¹⁰¹Restatement of the Law, Third, Torts: Products Liability §6(b) (1998)

¹⁰²Id. at §2, comment n

¹⁰³Id. at §2(a)

¹⁰⁴Werner v. Upjohn Co., 628 F.2d 848 (4th Cir. 1980), cert. denied, 449 U.S. 1080 (1981) (stating that a plaintiff only has to show that the defendant placed the drug on the market)

After considering the above, there is clearly plenty of opportunity for costly, time-consuming litigation and government enforcement actions in the area of dietary supplements. In light of that, it would also be relevant to examine what potential changes can be made to the regulatory scheme to attempt to maximize consumer awareness and safety, minimize manufacturers' abuse of the regulations, and minimize litigation and government actions that are provoked by the occurrence of severe adverse health effects and hazards.

The obvious answer for an ideal situation, strictly in terms of consumer safety, is to start treating the category of dietary supplements the same way as drugs in the arena of government regulation. However, the passage of DSHEA prevents the FDA from approaching the issue in this way. In addition, even though there have been more serious consequences of DSHEA relating to safety and manufacturer abuse of the regulations, there is still another important consideration, and that is the purpose behind DSHEA in the first place. One of the major driving forces behind DSHEA was to increase consumer freedom and choice. Although DSHEA has not been the ideal vehicle for attaining these goals, these goals are still legitimate concerns that should be incorporated by our regulatory scheme. Regulating supplements in the same vein as drugs definitely sacrifices these later goals in favor of ultimate consumer safety.

Once again, in connection with these concerns, I would like to bring up my own Chinese heritage and positive experience with products that would be labeled under dietary supplements in the American market. Many of these products have very real health benefits that Western science seems to want to disbelieve or avoid further testing and research to confirm the effects. These herbs and other substances have been used in the Chinese culture safely for longer than probably any prescription medicine in the American market today. Not only are they safe when properly used and in accordance with tradition use guidelines, but also, in my mind, it is unquestionable that there are health benefits associated with their use. It is baffling when I read commentators who question the existence of *any* benefits with their use. It would be almost an injustice to deny consumers access to safe and effective dietary supplements such as the ones I have had experience with.

With the case for consumer freedom and choice stated, however, the safety and efficacy of dietary supplements are just as important, if not more so. Therefore, the possible solutions that follow are ones that represent a compromise between the conflicting interests of safety versus complete freedom and access to the products. The ideals of consumer freedom and the driving forces behind DSHEA are commendable. The deception that is often involved in the marketing and promotion of these supplements as a result of DSHEA's new provisions are not. So, the min-max statement from the beginning of this section of the paper should be amended to also seek to maximize consumer freedom choice, while maximizing consumer safety and minimizing manufacturer abuses and resulting litigation. Assuming that the option for regulating dietary supplements as traditional drugs is not available, we can examine some suggestions that might be more feasible and agreeable to all parties as the regulatory scheme stands today under DSHEA.

It would seem that there is much room for improvement in the aspect of dietary supplement labeling. The first possibility is to have FDA require the placement of warnings on the labels explicitly indicating that the FDA has not evaluated the safety and efficacy of that particular supplement. With the FDA having such high levels of credibility and faith with the general public, an FDA disclaimer on products would have the effect of making consumers consider their choice and use of products more carefully and ideally, also with more knowledgeably. This solution would also be a compromise in order to try to increase one of the DSHEA's goals of consumer freedom and access.¹⁰⁵ This is also consistent with the court's ruling in Pearson v. Shalala.¹⁰⁶ In that case, even though the court ruled against the FDA in the particular fact pattern, the language of the ruling still suggests that the FDA would not violate the commercial speech doctrine and would still be allowed to use these disclaimers on products in order to address "misleading" health claims.¹⁰⁷

I also believe a major benefit could be realized by requiring more substantive information on the labeling

¹⁰⁵See *supra* note 35, at §4

¹⁰⁶See *supra* note 55

¹⁰⁷*Id.* at 657.

in regards to a dietary supplement's possible adverse health effects if misused. Reading examples of actual effects that may occur to your body if misused certainly reinforces the effect of a warning on consumers, who arguably do not read labels and warnings closely enough. It is not even clear to me how effective the conspicuous and unambiguous warnings on cigarette packs, for example, are today on the cigarette consumer. Perhaps warnings need to be elevated to another level to catch the attention of people. A potential side effect of increased, heftier warnings is that manufacturers would then be given additional incentives to cooperate with the FDA in terms of providing the agency with scientific evidence that substantiates the product's safety and efficacy so their product can avoid the need to put such an alarming warning on the labeling. Moreover, as mentioned previously, the issue of discrepancies between actual ingredient content and the labeling on the dietary supplement product could be addressed if the FDA established standards such as Daily Recommended Allowance for the ingredients. Again, I realize that this suggestion involves a tremendous or maybe even an impossible amount of resources in order to test and research the involved ingredients. However, in theory, it is a legitimate method to achieve the goals of reducing consumer deception and increasing consumer safety and awareness.

Perhaps the most effective change would be to address the tremendous loophole of allowing supplement manufacturers to make structure-function claims. The difficulty in distinguishing the fine differences between some structure-function claims and claims that would require pre-market approval have been shown to be slight. The FDA could make it more difficult for manufacturers to take advantage of structure-function claims by requiring these claims to be based on "universally recognized factual statements concerning known and substantively significant relationships regarding the effect of a substance on the structure or functioning of the body."¹⁰⁸ For example, established, concrete claims such as "calcium is necessary for bone growth and development" or "Vitamin A is necessary for good vision" would be permissible.¹⁰⁹ However, unsub-

¹⁰⁸See note 93 at 219

¹⁰⁹Id.

stantiated, vague claims such as “antioxidants may play an important role in slowing changes that occur with normal aging” or that “lycopene may help ensure normal functioning of the prostate gland” need to be disallowed by the FDA until such claims can be substantiated.¹¹⁰

There are also other possibilities to improve the regulatory scheme aside from changing the practices regarding supplement labeling. The FDA can also enforce another effective rule in connection with new dietary supplements that are introduced to the market. The agency could enforce the requirement for manufacturers to produce documentation and other evidence that the substantiation requirement for safety has been fulfilled.¹¹¹ It is important to note that the FDA probably could not use this rulemaking power with respect to existing, old dietary supplements. The aim of providing increased access to information regarding the supplement products is clearly consistent with the min-max proposal from above and also with DSHEA’s stated goals.

The FDA, in connection with over-the-counter drugs, has already raised the following proposal, and it sounds like it is a promising step towards ensuring a higher level of safety and efficacy of the products on the market. In 2000, the FDA, in an effort to make the over-the-counter drug approval process more flexible, made the proposal to consider foreign marketing experience when they had to evaluate whether a product can be included in the over-the-counter monograph system.¹¹² According to one author, the monograph system is critical for OTC drugs because an “OTC drug product that does not meet monograph requirements is considered to be an unapproved new drug for which a new drug application (“NDA”) must be filed and approved” before entering the consumer market.¹¹³ As mentioned, the NDA is a very costly process for manufacturers, and the result for dietary supplement products, such as herbal remedies that are often sold

¹¹⁰Id.

¹¹¹Food Labeling: Nutrient Claims and Health Claims; Special Requirements, 61 Fed. Reg. 3884 (1996)

¹¹²Eligibility Criteria for Considering Additional Conditions in the Over-the-Counter Drug Monograph System: Request for Information and Comments, 61 Fed. Reg. 51,625 (1996)

¹¹³Robert G. Pinco, Implications of the FDA’s Proposal to Include Foreign Marketing Experience In the Over-the-Counter Drug Review Process, 53 Food & Drug L.J. 105 (1998)

as drugs in most other countries, frequently is that they become sold in the safe harbor category of dietary supplement in the United States.¹¹⁴ So, the logical step from these observations would be to also include dietary supplements in the OTC monograph system, in order to subject them to the same higher standards of efficacy and safety as the OTC drugs. This seems to be a very good compromise between one extreme of regulating dietary supplements in the same vein as traditional prescription drugs and the other extreme of minimal regulation, as under DSHEA.

VIII. Conclusion

The growth in the use of dietary supplements is unquestionable. There are also numerous dietary supplements on the market that have legitimate health benefits. Consumer access to these supplements is also a worthy goal, which spurred the passage of DSHEA. We have examined how the regulatory landscape behind dietary supplements has evolved. The problem with the current state of dietary supplements appears to lie squarely in the regulatory scheme that currently governs them. DSHEA has problems inherent in it, and there are also problems with the regulation of dietary supplements by the FDA and FTC. This paper has discussed some possible methods of improvement. Hopefully, these agencies can follow in that spirit and adjust to find new ways to preserve the ultimate goals of safety, knowledge, choice, and health.

¹¹⁴Id. at 115