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## Overview of Federal Regulation of Dietary Supplements: Past, Present, and Future Trends

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# Overview of Federal Regulation of Dietary Supplements: Past, Present, and Future Trends

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## **Introduction**

The federal regulation of dietary supplements has traditionally been one of the most contro

The tension between those who favor greater regulation and those who oppose it stems from a concern about consumer safety poised against a concern about consumer choice. The FDA and other public health organizations have expressed and continue to express safety concerns about the increased availability of dietary supplements and the decreased ability of the government to regulate them after the enactment of the DSHEA. Other groups, especially Congress and the dietary supplement industry, regard the DSHEA as a long overdue bastion of consumer choice and health freedom. This controversy has made the federal regulation of dietary supplements a hot topic for academics and practitioners. The purpose of this paper is not to endorse a particular view on the proper course for regulation. Rather, this paper is designed to inform the reader of the various points of view at play in the regulatory arena and how those viewpoints translate into policy.

Because this topic is so controversial, the information available to the researcher is vast. This paper seeks to provide the researcher with a general overview of the past, present, and future of the federal regulation of dietary supplements. Part I of the paper briefly describes the regulation of dietary supplements between the enactment of the Food, Drug, and Cosmetic Act in 1938 and the enactment of the DSHEA in 1994. During the early stages of regulation,

the FDA was focused on classifying dietary supplements in order to gain the maximum amount of authority to regulate them. Predictably, Congress and the courts responded to further define the proper contours of federal regulation of dietary supplements.

Part II of this paper explores the legislative history of the enactment of the DSHEA. Specifically, it details the relevant congressional hearings, reports and amendments to the bill that would eventually become the DSHEA. Part III of this paper explores each of the major provisions of the DSHEA.

The next sections of the paper focus on the post-DSHEA dietary supplement regulatory developments. Part IV addresses the regulation of dietary supplement health and structure/function claims. Part V examines the aftermath of the DSHEA's broadening of the definition of "dietary supplement." Part VI of the paper details the safety and burden of proof issues established by the DSHEA, and Part VII describes the specific regulatory developments of the DSHEA's labeling and third party literature provisions. As Parts IV-VII will demonstrate, the post-DSHEA regulatory arena has been marked by attempts on the part of the FDA to tighten its regulatory hold. Much like pre-1994 dietary supplement regulation, the courts have recently stepped in to quash the efforts of the FDA. Currently, the FDA is developing new regulations to conform to the mandates issued by the federal courts.

Part VIII of the paper looks to the future of the federal regulation of dietary supplements by examining recent bills proposed in Congress. Without a doubt, if the future of the federal regulation of dietary supplements mirrors its past, it,

too, will be marked by power struggles and controversy. Congress, the courts, the FDA, industry and consumers will all have different opinions as to the best course for dietary supplement regulation. This tension will only grow with the ever-increasing availability of vitamins, minerals, and herbal dietary supplements.

## Part I – Pre-1994 Federal Regulation of Dietary Supplements

The proper method of regulation of dietary supplements posed a unique and difficult challenge for the Food and Drug Administration (FDA) from the very beginning. The early period of regulation was marked by a set of attempts by the FDA to classify the dietary supplements in order to gain regulatory authority over them. FDA's first attempts were to classify dietary supplements as drugs, followed by a later attempt to classify them as food additives. With each classification effort, the FDA was trying to gain some pre-market regulatory power over dietary supplements in order to protect consumers from the increasing amount of dietary supplements on the markets, especially those making dubious health claims. With each attempt to regulate, the FDA was met by resistance from both Congress and the dietary supplement industry. This section addresses the early phase of the regulation of dietary supplements and explores the Nutrition Labeling Education Act of 1990, the Dietary Supplement Act of 1992, and other relevant legislative enactments, as well as the FDA's earliest regulatory stance toward dietary supplements.

### A. Early Regulation of Dietary Supplements as Drugs

Until the Federal Food, Drug, and Cosmetic Act (FDCA) was passed in 1938, dietary supplements were not an issue for federal regulation.<sup>1</sup> With the

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<sup>1</sup>The Pure Food and Drug Act of 1906 did not address the regulation of dietary supplements at all. See Pub. L. No. 59-384, 34 Stat. 768 (1906), 21 U.S.C. §§ 1-15 (1934) (repealed by 21 U.S.C. § 329(a) (1938)).

passage of the FDCA,<sup>2</sup> however, the FDA was alerted to the existence of foods “for special dietary use” as well as the “vitamin, mineral, and other dietary properties” of those foods.<sup>3</sup> The FDA then began its long struggle to classify dietary supplements as either a food or a drug under the Act. The strategy employed by the FDA shortly after the passage of the FDCA was to place dietary supplements within the “drug” provisions of the FDCA because of the health claims made on the labels and in literature. The strategy quickly became a subject for scrutiny and Supreme Court review.<sup>4</sup>

The Supreme Court construed the precise meaning of the term “label” for regulatory purposes in a set of cases in 1948. In Kordel v. United States, the Court held that the term “labeling” is not restricted to “labels that are on or in the article or package that is transported.”<sup>5</sup> Such things as accompanying booklets or literature could also be considered labeling as long as the labeling and the accompanying booklets or literature were “parts of an integrated distribution program.”<sup>6</sup> In United States v. Urbuteit, the Supreme Court further explained that the formal label and supplementary materials do not have to be attached or mailed simultaneously if the two transactions are integrated.<sup>7</sup> Kordel and Urbuteit opened the door for the FDA to challenge dietary supplements based on their labeling and supplementary labeling claims. However, this authority was tempered in United States v... “Sterling Vinegar and Honey...” in which

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<sup>2</sup>Pub. L. No. 75-717, 52 Stat. 1040 (1938), as amended 21 U.S.C. §§ 301 et seq.

<sup>3</sup>21 U.S.C. 343(j).

<sup>4</sup>Bass, I. Scott and Anthony L. Young. Dietary Supplement Health and Education Act: A Legislative History and Analysis. The Food and Drug Law Institute, 1996, p. 9.

<sup>5</sup>335 U.S. 345, 349 (1948).

<sup>6</sup>Id. at 350.

<sup>7</sup>335 U.S. 355, 353 (1948).



the Second Circuit held that “labeling does not include every writing which bears some relation to the product.”<sup>8</sup>For the next three decades after Kordel and Urbuteit, the proper use of supplementary materials as labeling under the FDCA became one of many highly controversial issues between the FDA and the dietary supplement industry.

In addition to regulating dietary supplements based on labeling, the FDA also initiated an attack on the substantive potency of dietary supplements following the enactment of the FDCA. After at least a decade of debate about the scope of the regulation of vitamins, the FDA issued final regulations in 1973 stating that vitamins and minerals with greater than 150% of the Recommended Daily Allowance potency must be classified as “drugs.”<sup>9</sup> Congress responded to the FDA’s increased regulatory power in 1976 with the enactment of The Proxmire Act, named for its sponsor Senator William Proxmire, which amended the FDCA.<sup>10</sup> The Proxmire Act (1) took away FDA’s authority to set maximum limits on the potency of any vitamin or mineral, (2) revoked FDA’s authority to regulate vitamin and mineral potency for purposes of classifying the vitamin or mineral as a drug, (3) expanded the terms under which the vitamins and minerals could be marketed, and (4) permitted certain special dietary needs claims that would not be considered drug claims.<sup>11</sup> Essentially, after the enactment of the Proxmire Act, the FDA could no longer declare high doses of dietary

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<sup>8</sup>338 F.2d 157, 158-159 (2d Cir. 1964).

<sup>9</sup>38 Fed. Reg. 20,730, 20,732 (Aug. 2, 1973). Exceptions to this final regulation were Vitamin A (classified as a drug in doses exceeding 200% of the RDA) and Vitamin D (classified as a drug in doses exceeding 100% of the RDA).

<sup>10</sup>Pub. L. No. 94-278, 90 Stat. 401 (1976), 21 U.S.C. § 350.

<sup>11</sup>21 U.S.C. §§ 350(a)(1-2); Bass at 12-13.

supplements to be drugs in order to regulate them.<sup>12</sup>

## B. Early Regulation of Dietary Supplements as Food Additives

From then on, the FDA took the position that a dietary supplement ingredient could be characterized as a “food additive” because it was added to a capsule or tablet to create the dietary supplement. Therefore, the additive could be subject to the pre-market approval process (assuming it is not generally recognized as safe or subject to a food additive regulation) and subsequently be deemed adulterated as or as containing “unsafe food additives” under the FDCA.<sup>13</sup> The manufacturers asserted that dietary supplement ingredients were generally recognized as safe. They also believed that the FDA’s interpretation of the FDCA placed the burden of proving the safety of the dietary supplements (“foods”) on them instead of on the FDA.<sup>14</sup>

In 1993, the First and Seventh Circuits responded and struck down the FDA’s interpretation as to **single**-ingredient dietary supplements<sup>15</sup> but not multiple ingredient dietary supplements.<sup>16</sup> In United States v. Two Plastic Drums . . . Black Currant Oil,<sup>17</sup>

the most often cited of the two cases, the Seventh Circuit Court of Appeals

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<sup>12</sup>Consequently, “if such products did not bear unauthorized ‘drug claims,’ then a new drug or drug misbranding theory also could not be applied.” Bass at 13.

<sup>13</sup>21 U.S.C. § 348.

<sup>14</sup>Bass at 14.

<sup>15</sup>See United States v. 29 Cartons of . . . An Article of Food, Etc., 987 F.2d 33 (1<sup>st</sup> Cir. 1993); United States v. Two Plastic Drums . . . Black Currant Oil, 984 F.2d 814 (7<sup>th</sup> Cir. 1993).

<sup>16</sup>See United States v. 42/194 kg. Drums of Pure Vegetable Oil, 961 F.2d 808 (9<sup>th</sup> Cir.), cert. denied, 506 U.S. 940 (1992) (supplement containing both Evening Primrose Oil and Vitamin E held to be an unapproved food additive).

<sup>17</sup>Black Currant Oil, 984 F.2d 814 (7<sup>th</sup> Cir. 1993).

struck down an FDA seizure and condemnation of black current oil. The FDA, relying on its food additive stance for dietary supplements, claimed that the glycerin and gelatin capsules were food and thus the oil in the capsules was an unsafe food additive. The Court, however, rejected the FDA’s argument, holding that black currant oil is a dietary supplement itself, not a component of dietary supplement and, thus, is a food and not a food additive.<sup>18</sup> The Court reasoned that a substance that is simply a component of food does not satisfy the food additive standard. Instead, a substance must have the effect of altering a food’s characteristics to be considered a food additive.<sup>19</sup> Clearly upset with the FDA’s interpretation, the Court stated that “the FDA’s food additive definition is so broad, however, that it would... classify every component of food—even single active ingredients—as food additives. Thus, it would seem, even the addition of water to food would make the food a food additive. The only justification for this Alice-in-Wonderland approach is to allow the FDA to make an end-run around the statutory scheme and shift to the processors the burden of proving the safety of a substance in all circumstances. To be sure, the paramount objective of the Act is to protect the public health.”<sup>20</sup> Consequently, this decision and other decisions echoing its sentiment significantly decreased the FDA’s ability to regulate dietary supplements as food additives.

### **C. Early Regulation of Dietary Supplement Health Claims**

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<sup>18</sup>Id. at 817.

<sup>19</sup>Id.

<sup>20</sup>Id. at 819.

The need for some further type of regulation of dietary supplements was obviated in 1989 when there was an outbreak of at least 1500 cases of eosinophilia myalgia syndrome caused by the use of substances containing L-tryptophan, an amino acid.<sup>21</sup> L-tryptophan purported to improve one's health. Its use, however, resulted in thirty-eight deaths.<sup>22</sup> The FDA's increased attempts to regulate dietary supplements as either drugs or food additives were sparked in part by this outbreak and also by a general concern about unsubstantiated health claims. The FDA began to consider the availability of some health claims for foods, but it pointed out that health claims for dietary supplements were unlikely to be approved.<sup>23</sup> Particularly, the FDA believed there was no scientific basis for health claims for dietary supplements.

To stem the rise of unsubstantiated health claims, Congress enacted the Nutrition Labeling and Education Act of 1990 (NLEA).<sup>24</sup> Basically, the NLEA allowed the FDA to screen health claims for scientific soundness.<sup>25</sup> The NLEA authorized the use of health claims that characterized the "relationship of any nutrient... to a disease or health-related condition" on food labels, but the claim had to be deemed reliable.<sup>26</sup> To determine what claims are reliable, Congress directed the FDA to promulgate regulations for both conventional foods and dietary supplements. For conventional food products, Congress directed the FDA

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<sup>21</sup>Khatcheressian, Laura A.W. "Regulation of Dietary Supplements: Five Years of DSHEA." 54 Food and Drug Law Journal 623, 625 (1999).

<sup>22</sup>Id. at 625.

<sup>23</sup>See 52 Fed. Reg. 28,843 (Aug. 4, 1987); 55 Fed. Reg. 5176 (Feb. 13, 1990).

<sup>24</sup>Pub. L. No. 101-535, 104 Stat. 2353 (1990), 21 U.S.C. §§ 301 note, 321, 337, 343, 343 notes, 343-1, 343-1 note, 345, 371.

<sup>25</sup>Vladeck, David C. "Devaluing Truth: Unverified Health Claims in the Aftermath of Pearson v. Shalala." 54 Food and Drug L.J. 535 (1999).

<sup>26</sup>21 U.S.C. § 343(r)(1)(B).

to use a standard of “significant scientific agreement” based on the totality of available scientific evidence among qualified experts to evaluate such claims.<sup>27</sup> Congress delegated the task of establishing dietary supplement standards to the FDA.<sup>28</sup> It is evident from the statements of the House Floor Managers of both parties of Congress that Congress intended that the standards of reliability for dietary supplement labelings be at least as strong as the standards for food labeling under the NLEA.<sup>29</sup>

Therefore, pursuant to the NLEA, the FDA was allowed to consider different approval procedures and scientific evaluation standards for dietary supplement health claims and conventional food health claims.<sup>30</sup> FDA was given authority to bring enforcement actions when supplements were marketed with claims that were not approved by the FDA.<sup>31</sup> The NLEA further instructed the FDA to evaluate the following potential health claims for dietary supplements and other conventional foods:

- calcium and osteoporosis;

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<sup>27</sup>21 U.S.C. § 343(r)(3)(B)(i).

<sup>28</sup>Id. § 343(r)(5)(D).

<sup>29</sup>Cong. Rec. H12953 (Oct. 26, 1990) (dietary supplements “covered by this provision should be subject to at least as strong a standard as is applicable to other foods”).

<sup>30</sup>Id. § 343(r)(5)(D).

<sup>31</sup>21 U.S.C. § 343(r)(1)(B).

dietary fiber and cancer;

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lipids and cardiovascular disease;

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lipids and cancer;

- 

sodium and hypertension;

- 

dietary fiber and cardiovascular disease;

- 

folic acid and neural tube defects;

- 

antioxidant vitamins and cancer;

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zinc and immune function in the elderly; and

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omega-3 fatty acids and heart disease.<sup>32</sup>

In late 1991, the FDA proposed implementing regulations that opted to use the “significant scientific agreement” standard for dietary supplements, as well as for foods.<sup>33</sup> In the absence of “significant scientific agreement,” the claim is to be considered “unreliable.” Using this standard, FDA rejected nearly all of the above health claims for dietary supplements.<sup>34</sup>

Predictably, the FDA faced much resistance from industry because of its reluctance to approve health claims on dietary supplements. By the early 1990s, the dietary supplement industry in the United States had grown to a several billion-dollar business.<sup>35</sup> The industry was angry not only about the FDA’s food additive enforcement theory and its decision not approve most health claims, but also about the FDA’s stance regarding “structure/function” claims.<sup>36</sup> Specifically, the FDCA defined a drug as “articles (*other than food*) intended to affect the structure or any function of man or other animals.”<sup>37</sup>The dietary supplement industry interpreted this provision, specifically the “other than food” statement, to provide a basis for structure/function claims for foods. The FDA, however, maintained the position that “food” did not include dietary supplements other

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<sup>32</sup>21 U.S.C. § 343 note 7.

<sup>33</sup>S.Rep.No. 103-410, 103d Cong., 2d Sess., October 8, 1994 at 15.

<sup>34</sup>Id. The health claim that calcium may prevent osteoporosis was proposed for a limited population of white and Asian women. 58 Fed. Reg. 2665 (Jan. 6, 1993). A folic acid/neutral tube defect health claim for pregnant women or women of child bearing years was added later. 59 Fed. Reg. 433 (Jan. 4, 1994).

<sup>35</sup>Bass at 15.

<sup>36</sup>Id.

<sup>37</sup>21 U.S.C. 321(g) (1)(C) (emphasis added).

than vitamins and minerals with recognized nutritional value.<sup>38</sup> Therefore, under the FDA's view, any structure/function claim made by a dietary supplement (other than a vitamin or mineral with recognized nutritional value) was an unapproved drug claim. The FDA's position, despite industry protest, was ratified in the courts.<sup>39</sup> The battle between the industry and FDA set the stage for the enactment of the Health Freedom Act of 1992 and the Dietary Supplement Act of 1992.

#### **D. Congressional Reaction**

The Health Freedom Act of 1992<sup>40</sup> attempted to change the landscape of the regulation of dietary supplements in the following ways: (1) it broadened the definition of "dietary supplement to include herbs and other nutritional substances, (2) it recognized that prior efforts to regulate dietary supplements as either a food or drug were inappropriate, (3) it precluded dietary supplements from being regulated as drugs upon a proper showing, and (4) it exempted dietary supplement health claims from pre-market approval. A large public relations and lobbying battle ensued in Congress, and ultimately, it became clear to the bill's sponsor, Senator Orrin Hatch, that the likelihood of passage was low.<sup>41</sup>

Therefore, Senator Hatch proposed two measures to address the NLEA's dietary supplement provisions and the FDA's stance regarding the regulation of

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<sup>38</sup>Bass at 15.

<sup>39</sup>See, e.g., *Nutrilab v. Schweiker*, 713 F.2d 335 (7<sup>th</sup> Cir. 1983).

<sup>40</sup>S. 2385. 102d Cong., 2d Sess. (1992).

<sup>41</sup>Bass at 20.



dietary supplements.<sup>42</sup> First, Senator Hatch proposed a one-year moratorium on implementing the dietary supplement provisions of the NLEA, noting that:

We [the Congress] did not intend for the FDA to treat dietary supplements like drugs, which is the way they are treating them, or intend to treat them. Instead... the FDA decided to put herbs in the same regulatory category as tetracycline, and vitamin A in the same category as insulin. People are outraged about this, and I am too.<sup>43</sup>

The amendment passed the Senate but did not proceed any further. However, the second measure to change the regulatory scheme was already being proposed. The Dietary Supplement Act (DSA) was added to the Prescription Drug User Fee Act of 1992<sup>44</sup> and provided a one-year moratorium on dietary supplement health claims, nutrient content claims, and labeling. The FDA was required to issue proposed rules for the claims involved in the moratorium by June 15, 1993. The FDA was instructed to issue its final rules by December 31, 1993.<sup>45</sup>

Additionally, the DSA required that three reports be issued. The first report involved the Health and Human Services Department detailing the enforcement policies and practices of the FDA to determine whether there was discrimination against dietary supplements. The report was issued in May of 1993 and concluded that no discrimination had occurred.<sup>46</sup> A second similar report by the Comptroller General issued no conclusion.<sup>47</sup>

The third report was a comparison of dietary supplement regulation and mar-

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<sup>42</sup>Id. at 20-21.

<sup>43</sup>Cong. Rec. S13,974-75 (Sept. 18, 1992).

<sup>44</sup>Pub. L. No. 102-571; 106 Stat. 4491 (1992).

<sup>45</sup>Bass at 21.

<sup>46</sup>Id.

<sup>47</sup>Id.

keting in the United States and foreign countries. The report was issued by the Office of Technology Assessment and was mainly a historical study. Thus, it did not directly address the controversies within the regulation of dietary supplements.<sup>48</sup>

The DSA, however, set the stage for an expanded debate on the federal regulation of dietary supplements. This debate, marked by power struggles and tension between the Congress, industry and the FDA, would eventually lead to the enactment of the Dietary Supplement Health and Education Act during the next legislative session.

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<sup>48</sup>Id.

## Part II – The Legislative History of the Dietary Supplement Health and Education Act

The legislative history for the Dietary Supplement Health and Education Act is a very interesting and thorough look at the competing views and compromises that carved out the final bill. The battle between the FDA, regulated industry and Congress carried over from the pre-1992 regulatory context to the debate about the passage of the bill that would eventually become the DSHEA.

The documents in the unofficial legislative history consist of numerous floor excerpts, four principal hearings, and one extremely thorough Senate Report. The bill that was eventually passed was introduced in the Senate, and a companion bill was introduced in the House. This section will explore the purpose of the bills introduced in the House and Senate and will compare and contrast the two bills. Additionally, it will examine the hearings that accompanied the bills and the suggestions to amend them. Finally, this section will examine the Senate Report accompanying the passage of the Senate bill, focusing in on the examples of the health advantages of dietary supplement use put forth by Congress to spark the passage of the bill.

### **A. Purpose of the Bills**

Less than one year after the Dietary Supplement Act, Senator Orrin Hatch introduced S. 784<sup>49</sup> on April 7, 1983. H.R. 1709,<sup>50</sup> the companion bill to S. 784,

<sup>49</sup>S. 784, 103d Cong., 1<sup>st</sup> Sess. § 3 (1993).

<sup>50</sup>H.R. 1709, 103d Cong., 1<sup>st</sup> Sess. § 2 (1993).

was introduced in the House on the same day by Congressman Bill Richardson of New Mexico. The purpose of both bills was to balance the need for the quality and safety of dietary supplements against the consumer's desire to have access to health information about dietary supplements.

In Senator Hatch's Statement on Introduction of S. 784, he stated:

This legislation empowers consumers to make choices about their personal preventative health care regiments based on accurate health benefits related to particular dietary supplements. These claims will be based on either an FDA-approved claim or on a claim that accurately reflects the current state of scientific evidence concerning a dietary supplement's health benefits. The FDA will continue to have the responsibility and power to ban a supplement found to present a substantial risk to consumers. This legislation provides consumers with needed information about dietary supplements and provides the FDA and the dietary supplement industry with clear direction for a *much needed overhaul of the current regulatory approach*. This legislation provides for more and accurate information on labels than is currently found on dietary supplement labeling and contains additional consumer safety provisions.<sup>51</sup>

It is clear from the opening remarks of Senator Hatch that the bill that would eventually become the Dietary Supplement Health and Education Act (DSHEA) was designed from its inception to change the face of federal regulation of dietary supplements. The Statement of Rep. Richardson on Introduction of H.R. 1709 echoes Senator Hatch's sentiment:

Dietary supplements still lack an appropriate regulatory framework that will allow appropriate health claims. We need a standard that will allow truthful nonmisleading health claims for dietary supplements based upon a reasonable level of scientific evidence. My legislation will accomplish this objective by allowing health claims to be made for dietary supplements if: First, the FDA has approved a claim for the same nutrient contained in a food. For example, if the FDA approves claims for beta-carotene in cruciferous vegetables like broccoli, a beta carotene supplement may make the same claim; or second, accurate statements that consider the totality of scientific evidence concerning a nutrient/disease relationship. Manufacturers are required to provide information in advance to the FDA about any claims made about the product. Supplements

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<sup>51</sup>Cong. Rec., S4577 (April 7, 1993). (emphasis added).

will also be permitted to describe truthful physiological benefits that are not health claims, as in the statement: “Calcium builds strong bones.”

This legislation seeks to both protect consumers’ rights to obtain dietary supplements and herbs; and assures them that they will be safe, of high quality, and that the information about them will be truthful and not misleading. Americans want greater freedom, participation, and expanded options for themselves in health care, not less.<sup>52</sup>

#### B. Comparison and Contrast of the Proposed House Version and Proposed Senate Version of the Bills

While the House and Senate versions of the bills were similar in their purposes, the two bills were different in some respects as well. The definitions of dietary supplement in both versions were essentially the same. Each broadened the “special dietary use” definition by expanding the scope from vitamins and minerals to include herbs, amino acids, and others.<sup>53</sup> H.R. 1709 also broadened the admissible form of dietary supplements, permitting them to take essentially any form, while the Senate version restricted the dietary supplement forms to the traditional dietary supplement forms. Additionally, each version also excluded dietary ingredients and/or ingredients to be used in dietary supplements from the statutory definition of “food additive.”

A somewhat important difference between the House and Senate versions concerned the existence of the broad exclusion of dietary supplements from the drug category. The Senate version contained this exclusion, which expanded the Health Freedom Act’s prohibition on potency as a basis for categorizing a vitamin or mineral as a drug for regulatory purposes.<sup>54</sup> § 3(b) of S. 784 stated explicitly that the term “drug” did not include a dietary supplement or dietary supplement ingredient. H.R. 1709 did not contain a parallel exclusion.

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<sup>52</sup>Cong. Rec., E920 (April 7, 1993).

<sup>53</sup>Bass at 24.

<sup>54</sup>Id.

Each bill attempted to respond to public criticism about safety issues. The elimination of FDA authority to regulate based on the food additive theory in combination with proposed restrictions on regulations derived from the Health Freedom Act left the FDA virtually powerless to regulate the safety of dietary supplements. In response to these concerns, the bills provided the FDA with explicit rulemaking authority in the case of a “substantial or unreasonable risk of illness or injury” posed by a dietary supplement or dietary supplement ingredient.<sup>55</sup> Additionally, each bill proposed that a manufacturer or supplier of a dietary supplement be required to substantiate safety through (1) evidence of a history of safe use and the absence of information that brings safety into question, (2) by scientific studies conducted with generally recognized scientific procedures or principles, or (3) by any other appropriate means.<sup>56</sup>

The final safety issues addressed in both versions of the bill were manufacturing-induced safety or contamination issues.<sup>57</sup> H.R. 1709 required raw material manufacturers to notify the FDA if they made significant changes in their manufacturing process that had been shown to present adverse safety consequences.<sup>58</sup> S. 784 had a milder requirement – it called for a report on the subject from the “Director of the Office of Dietary Supplements.”<sup>59</sup>

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<sup>55</sup>S. 784, supra note 49, § 4; H.R. 1709, supra note 50, § 3(a).

<sup>56</sup>Any dietary supplement that had an established RDA or an estimated safe dietary intake level was excluded. S. 784, supra note 49, § 4; H.R. 1709, supra note 50, § 3.

<sup>57</sup>This safety issue was brought to the attention of Congress in part because of the L-tryptophan outbreak in 1989. See “Regulation of Dietary Supplements,” Hearing Before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, ( July 29, 1993), p. 65. (statements of Rep. Bill Richardson and David A Kessler, FDA Commissioner, expressing concern about the proposed legislation with respect to safety issues).

<sup>58</sup>H.R. 1709, supra note 50, § 3(a).

<sup>59</sup>S. 784, supra note 49, § 5.

There were no substantive differences between the bills with respect to the issues of permissible and non-permissible health claims. H.R. 1709 and S. 784 both removed the “significant scientific agreement” standard used previously by the FDA to approve health claims and replaced it with a more lenient standard. Under each version, the FDA was authorized to approve dietary supplement health claims if (1) the FDA previously authorized the claim for a conventional food containing the particular dietary supplement ingredient or (2) the health claim “accurately represent[ed] the current state of scientific evidence.”<sup>60</sup> The second prong of the proposed standard was designed to allow the FDA to approve health claims when they were based on something less than scientific consensus. Additionally, it would have permitted precatory language in health claims, e.g., “studies may indicate a relationship between the consumption of this nutrient and the prevention of chronic heart disease.”<sup>61</sup> This portion of the proposed bills represented a clear break from past FDA procedures and manifested Congress’s intent to more freely provide consumers with dietary supplement health-related information.

Additionally, the bills contained an exemption for “truthful and non-misleading” information about the about how the supplement affects the “physiological processes of the body” or how it prevents or repairs damage caused by diet or other environmental factors.<sup>62</sup> These claims would therefore not be subject to the

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<sup>60</sup>S. 784, *supra* note 49, § 7; H.R. 1709, *supra* note 50, § 4.

<sup>61</sup>Bass at 25.

<sup>62</sup>S. 784, *supra* note 49, § 7; H.R. 1709, *supra* note 50, § 4.

NLEA health claims approval process.

The bills also contained the following provisions:

(1)

In response to the dietary supplement industry's belief that FDA's warning letters were being overutilized as a way to obtain compliance, both bills deemed warning letters to be a final adjudication for purposes of attaining judicial review.<sup>63</sup>

(2)

Both bills contained a provision that protected all forms of dietary supplements from any FDA compositional or potency limits.

(3)

Each bill contained new misbranding and labeling standards. These standards were designed primarily to ensure label uniformity and potency.

(4)

Both bills created an Office of Dietary Supplements within the National Institutes of Health to provide guidance on dietary supplement use based on its own research and analysis. This new office would not be a part of the FDA.

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<sup>63</sup>The FDA took the position that an issuance of a warning letter was not a final agency action and therefore not reviewable in federal court.



C.

The Hearings in Congress

To understand the hearings process, it is necessary to discuss briefly the activities going on in the FDA at the time. Within the FDA, Commissioner Kessler appointed a Task Force on Dietary Supplements to issue a report that addressed the many inquiries the FDA received from the public regarding the regulation of dietary supplements.<sup>64</sup> The report was issued in June of 1993. Much of the report was used as background information for an advance notice of proposed rulemaking on dietary supplements that the FDA was about to issue.<sup>65</sup> The advance notice of proposed rulemaking angered many people in Congress and certainly the dietary supplement industry because it took the position that dietary supplements should be regulated as drugs. This occurred immediately before the hearings process began in Congress.

There were several committee hearings in Congress, all of which brought out various interests and points of view. The following is a list of relevant hearings that occurred in various subcommittees in Congress.

(1) “Food and Drug Administration’s Regulation of Dietary Supplements,” Hearing Before the Subcommittee on Human Resources and Intergovernmental Relations, Committee on Governmental Relations, House of Representatives, July 20, 1993.

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<sup>64</sup>Bass at 26.

<sup>65</sup>58 Fed. Reg. 33,690, 33,691 (June 18, 1993).

This early hearing is focused primarily on the dietary supplement issues under the NLEA. Specifically, this hearing contains testimony from food science and nutrition professors endorsing FDA's health supplement labeling requirements to protect consumers.

(2) "Regulation of Dietary Supplements," Hearing Before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, House of Representatives, July 29, 1993.

This was one of the major hearings on the issue presided over by Congressman Waxman. Congressman Waxman pointed out the fact that the FDA was in a very difficult situation because it was receiving a good deal of mixed signals from Congress and the public. He noted that the goal of the legislative process should be to "guarantee the availability of safe dietary supplements as long as they make no unproven claims."<sup>66</sup>

David Kessler (FDA Commissioner) and Samuel Broder (Director, National Cancer Institute) (as well as others) testified and expressed concern about the proposed legislation and the possibility of future unsubstantiated health claims. Specifically, Commissioner Kessler noted the hundreds of dietary supplements that claim to cure or treat various serious illnesses such as cancer. Moreover, he noted safety concerns about the dietary supplements, since many adverse reactions could go unrecognized and unreported. Finally, he argued that the

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<sup>66</sup>"Regulation of Dietary Supplements," Hearing Before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, House of Representatives, July 29, 1993, p. 1.

Senate bill would have the practical affect of putting the burden of proof for safety on the FDA, rather than on industry. Additionally, various representatives from differing groups also testified to the need for decreased regulation of dietary supplements.

(3) “Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 1994. Dietary Supplements,” Hearing Before the Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies Appropriations, Committee on Appropriations, House of Representatives, October 18, 1993.

This hearing examined the FDA’s interpretation of the NLEA and the bills (S. 784 and H.R. 1709) to restrict the FDA’s power to regulate dietary supplements. Sen. Hatch and others testified to the need to restrict FDA regulation in this area. Victims of complications regarding the use of dietary supplements and representatives from various interest groups testified to the contrary need for the increased FDA regulation of dietary supplements. Dr. David Kessler testified as to the necessity for regulation and related complications regarding regulation.

(4) “Legislative Issues Relating to the Regulation of Dietary Supplements,” Hearing Before the Committee on Labor and Human Resources, U.S. Senate, October 21, 1993.

Dr. David Kessler testified to issues relating to unsubstantiated health

claims and the safety of various dietary supplements. He tried to diffuse rumors that the FDA was planning to remove dietary supplements from the shelves, stating that the FDA had no problem with industry selling dietary supplements that were indeed safe.<sup>67</sup> The FDA, therefore, focused more on the health claims of dietary supplements than on the safety of their ingredients in this particular hearing.<sup>68</sup>

Senator Hatch, however, stated that he recognized that the Senate bill may not adequately address safety concerns, and acknowledged that the language of the bill may need to be more clearly written to prevent false and misleading health claims.<sup>69</sup> Senator Hatch also criticized the FDA Report, noting that he believed the much of the information in the report was inaccurate or out of date.

Timothy Dyk, an attorney with Jones, Day, Reavis, and Pogue, testified at this hearing that the proposed regulation of dietary supplements by the FDA could have First Amendment consequences. Various doctors testified that they had seen very little in the way of serious side effects from the use of dietary supplements.

Additionally, representatives from the Nutritional Health Alliance and the Center for Preventative Medicine testified generally to their concerns about the FDA regulation of dietary supplements.

The two most important hearings were the House hearing before the Sub-

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<sup>67</sup>“Legislative Issues Relating to the Regulation of Dietary Supplements,” Hearing Before the Committee on Labor and Human Resources, U.S. Senate, October 21, 1993, p. 19.

<sup>68</sup>Bass at 28.

<sup>69</sup>“Legislative Issues Relating to the Regulation of Dietary Supplements,” Hearing Before the Committee on Labor and Human Resources, U.S. Senate, October 21, 1993, p. 9.

committee on Health and the Environment and the Senate hearing before the Committee on Labor and Human Resources. The tension between the FDA, Congress, and regulated industry was apparent in the hearings and grew to its highest point immediately after the hearings. In response, the industry organized a “National Blackout Day” where retailers draped targeted dietary supplements in black to show consumers what could be taken off the shelf.<sup>70</sup> Partly in response to the growing tension, Congressman Waxman proposed a compromise amendment to establish a cooling-off period.<sup>71</sup> The “Dietary Supplement Access and Claims Moratorium Act of 1993” was designed to ensure access to dietary supplements and provided a moratorium on dietary supplement claims through June 1994. The access portion of the bill provided that foods and dietary supplements were adulterated if they contained a dietary ingredient or were a dietary supplement that could be injurious to health. This bill, however, did not make it to a floor vote and was not considered in the 1994 term of Congress. It did, however, influence the debate in the next term of Congress.<sup>72</sup>

#### **D. The Next Term of Congress and the Senate Amendment**

At the beginning of the next term of Congress, Senator Hatch introduced an amended version of S. 784 in order to forge a compromise between the Senate and the House. The new version contained the following changes:

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<sup>70</sup>Bass at 28.

<sup>71</sup>H.R. 3650, 103d Cong., 1<sup>st</sup> Sess. § 2 (1993).

<sup>72</sup>Bass at 29.

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FDA was given greater safety authority for emergency situations. The Secretary was given authority to act against dietary supplements that posed a substantial and imminent public health threat.<sup>73</sup>

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While still not considered a “drug,” the definition of dietary supplement was tightened.<sup>74</sup>

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The amendment makes clear the fact that health claims for dietary supplements will be subject to pre-market approval under the NLEA. Thus, the portion of the previous version that allowed an unrestricted right to make a health claim was deleted.<sup>75</sup>

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The amendment allowed dietary supplement manufacturers to make structure/function claims or statements of nutritional support.<sup>76</sup>

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<sup>73</sup>Cong.Rec. S11,705, 11,709 (Aug. 13, 1994).

<sup>74</sup>Id.

<sup>75</sup>Id. at S11,710.

<sup>76</sup>Id. at S11,709.

The amendment allowed for truthful and non-misleading third-party literature to be distributed to consumers as part of the marketing of dietary supplements, provided the information is balanced, does not promote any specific brand, and is kept physically separate from the products.<sup>77</sup>

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The amendment included a general good manufacturing process requirement for manufacturers of dietary supplements.<sup>78</sup>

## **E. Passage of the Final Bill**

This bill passed the Senate unanimously on August 13, 1994. When the bill got to the House, Senator Waxman offered an amendment that made further changes to Senator Hatch's version. The further amended S. 784 passed the House by unanimous voice vote on October 6, 1994.<sup>79</sup>

The bill was named the "Dietary Supplement Health and Education Act" and was signed into law on October 25, 1994. At the signing, President Clinton noted:

After several years of intense efforts, manufacturers, experts in nutrition, and legislators, acting in a conscientious alliance with consumers at the grassroots level, have moved successfully to bring common sense to the treatment of dietary supplements under regulation and law. More often than not, the government has been their ally. And the private market has responded to this development with

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<sup>77</sup>Id.

<sup>78</sup>Id. at S11,710.

<sup>79</sup>Bass at 30. The final version of the bill will be discussed in length in Part III of this paper.

the manufacture of an increasing variety of safe supplements. But in recent years, the regulatory scheme designed to promote the interests of consumers and a healthful supply of good food has been used instead to complicate choices consumers have made to advance their nutritional and dietary goals. With perhaps the best intentions, agencies of government charged with protecting the food supply and the rights of consumers have paradoxically limited the information to make healthful choices in an area that means a great deal to over 100 million people.... Simply stated, the legislation amends the [FDCA] to establish new standards for the regulation of dietary supplements including vitamins, minerals, and herbal remedies.<sup>80</sup>

**President Clinton's Signing Statement makes clear that the intent of the DSHEA was to change the existing regulatory stance toward dietary supplements in a fairly dramatic way. It directly criticizes the FDA's current policy on dietary supplements. After its passage, nearly every provision of the DSHEA would prove to be controversial. Within the next few years, many would argue that the FDA was correct in wanting to keep a tight reign on the unfettered proliferation of dietary supplements and health claims.**

## **F. The Senate Report**

The Senate Report issued to accompany S. 784 contains a wealth of information about the background, purpose and specific provisions of the DSHEA. Specifically, the Senate Report addresses the potential benefits of vitamins and minerals, herbs, amino acids, and other dietary supplements. In order to understand how the DSHEA was designed to benefit consumers, it is also necessary to briefly explore the purported benefits of these various dietary supplements.

Noting that a vast majority of people do not get the full Recommended Daily Allowance of 10 key vitamins and minerals, the Senate Report<sup>81</sup> stated that

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<sup>80</sup>President's Signing Statement, October 25, 1994.

<sup>81</sup>S.Rep.No. 103-410, 103d Congress, 2d Sess, October 8, 1994.



dietary supplements are necessary to ensure Americans meet their basic nutritional requirements. In particular, the poor and elderly are especially likely to have poor vitamin intake. Vitamins and minerals are also necessary to protect fetal health and to decrease the risk of birth defects. In particular, the Report notes the example of folic acid (a B vitamin) to prevent neural tube defects such as spina bifida and anencephaly. Additionally, the Report notes that current research shows that a number of vitamins and minerals can help protect against a lot of chronic, deadly diseases, such as heart disease, cancer, and osteoporosis.<sup>82</sup>

The Report focuses on the impact that over-regulation may have on the prevention of life-threatening diseases. In particular, if an individual consumes 10 times the RDA of vitamin E, there is a known potential to reduce the risk of heart disease. The FDA had recently proposed to limit the amounts of vitamins that could be sold to the RDA or a small multiple of the RDA. The Report states that “if such a limit had been in place, people would not have access to vitamin E in the amounts of 100 IU and more, and we would never have learned about the potential effect of vitamin E in reducing heart disease risk.”<sup>83</sup>The Report goes on to list numerous other instances in which high doses of vitamins provide a significant health advantage to consumers.

The Report also identifies herbs as an important method to enhance diets with substances found in plants and vegetables. The Report takes pains

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<sup>82</sup>S.Rep.No. 103-410 at 5.

<sup>83</sup>Id. at 6.

to distinguish herbs from conventional drugs: “Unlike many drugs, the role of herbal dietary supplements is to enhance the diet by adding safe and natural plants and their constituents to support and protect bodily functions and processes. Containing combinations of numerous naturally occurring plant chemicals, herbs generally act in a wider, more general, less specific way than most single-ingredient pharmaceutical drugs. Their actions are more ‘gentle’ than conventional medicines and work usually in more long-term situations.”<sup>84</sup> The Report cites various studies, including studies pointing to the effect of garlic on cholesterol, ginkgo on peripheral circulation, ginseng on endurance and stamina, and ginger on nausea and stomach distress. Finally, the Report notes that other modern, industrialized nations such as Canada, England, France, and Germany have regulatory systems that acknowledge the potential benefits of herbs.

The Report states that amino acids may also be useful in improving health in America. Like the herbal and vitamin examples, the Report cites many studies showing a correlation between amino acid intake and increased health. For example, the Report cites research that reveals that L-Arginine (an amino acid) increased the body’s immune response of white blood cells by over 350 percent. Additionally, other amino acids have been shown to reduce ailments ranging from depression to narcolepsy.

The Senate Report also details the history of the FDA’s regulatory efforts, noting the FDA’s “heavy-handed enforcement agenda against dietary supplements for over 30 years.”<sup>85</sup> The Report discusses briefly the FDA’s attempts to reg-

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<sup>84</sup>Id. at 7. Quoting Weiss, R.F. 1988 “Herbal Medicine.” Beaconsfield Publishers, England.

<sup>85</sup>Id at 10.

ulate dietary supplements as drugs and food additives and notes that both of these avenues have been unsuccessful. Additionally, the Report notes the many times courts have struck down FDA policies, discussing specifically the Black Current Oil case.<sup>86</sup> The Report noted that the court decisions show that “the FDA has been distorting the law in its actions to try to prevent the marketing of safe dietary supplement substances.”<sup>87</sup>

The remainder of the Senate Report discusses the views of the Committee of Labor and Human Relations on the specific provisions of the DSHEA. When necessary and to avoid duplication, the Committee’s views will be incorporated into Part III of this paper.

#### G. The “Official” Legislative History

While the Senate Report and the hearings appear to be useful tools, it is interesting to note that they are excluded from the “official” legislative history accompanying the DSHEA. The official one-page “Statement of Agreement” notes that “no other reports or statements [should] be considered as legislative history for the bill.”<sup>88</sup> Thus, the formal legislative history gives virtually no insight into Congress’ intentions regarding the enactment of the DSHEA. As this part of the paper has tried to demonstrate, however, the *unofficial* legislative history contains a good deal of information about what Congress intended the DSHEA to accomplish.

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<sup>86</sup>See *supra* note 15.

<sup>87</sup>S.Rep.No. 103-410 at 10.

<sup>88</sup>1994 U.S.C.C.A.N. § 3523.

Part III – The Specific Provisions of the Dietary Supplement Health and Education Act

The DSHEA significantly altered the way in which the FDA regulated dietary supplements. First, the DSHEA prohibited the FDA from regulating dietary supplements as “food additives”<sup>89</sup> or generally as drugs. Therefore, the FDA could no longer require pre-market clearance under the rubric of food additives or drugs from dietary supplement manufacturers. The DSHEA created a new category of “dietary supplements” to be regulated in an attempt to clear up earlier confusion about the regulation of dietary supplements as foods or drugs. Finally, the DSHEA liberalized the laws governing dietary supplement labeling and created special offices outside of the FDA designed to research and develop dietary supplement health issues and policy.

A. The Definition of “Dietary Supplement”

The DSHEA as enacted defines “dietary supplement” as “a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A)

a vitamin;

(B)

a mineral;

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<sup>89</sup>Note that only products composed of multiple ingredients were regulated as food additives before the DSHEA. See supra notes 15 and 16.

(C)

an herb or other botanical;

(D)

an amino acid;

(E)

a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(F)

a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).<sup>90</sup>

Section (F) “was intended to capture the widest range of dietary ingredients and the materials that make up those ingredients.”<sup>91</sup> Therefore, the new definition of dietary supplements was designed to be broad.

The DSHEA also removed dietary supplements and dietary supplement ingredients from the definition of food additive.<sup>92</sup> This clause was passed in Congress without argument,<sup>93</sup> given that the FDA had largely been prevented from regulating dietary supplements as food additives before this provision was passed.

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<sup>90</sup>21 U.S.C. § 321(ff)(1)(A-F).

<sup>91</sup>Bass at 35.

<sup>92</sup>21 U.S.C. § 321(s).

<sup>93</sup>Bass at 33.

Generally under the DSHEA, dietary supplements are not considered “drugs.” However, dietary ingredients first marketed as new drugs are not included in the definition of dietary supplements unless the FDA has issued a regulation to the contrary.<sup>94</sup> Ingredients that became new drugs but were first marketed as foods could continue to be sold as dietary supplements unless the FDA issued a regulation to the contrary.<sup>95</sup> While dietary supplements are not to be construed as drugs generally, the FDA was given the power to declare a product to be a drug if inappropriate claims are made for it.<sup>96</sup> The DSHEA states that “except for purposes of section 201(g), a dietary supplement shall be deemed to be a food within the meaning of the Act.”<sup>97</sup> Section 201(g) contains the definition of a drug and includes “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.”<sup>98</sup> It also includes articles, other than food, intended to affect the structure or function of the body.<sup>99</sup>

#### B. Provisions for New Dietary Ingredients on the Market

Under the DSHEA, a dietary supplement which contains a new dietary ingredient will be considered adulterated unless one of the following requirements are met:

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<sup>94</sup>21 U.S.C. § 321(ff)(3)(B).

<sup>95</sup>21 U.S.C. § 321(ff)(3)(A).

<sup>96</sup>21 U.S.C. § 321(g).

<sup>97</sup>21 U.S.C. § 321(ff)

<sup>98</sup>21 U.S.C. § 321(g)(1)(B).

<sup>99</sup>21 U.S.C. § 321(g)(1)(C). This provision will be discussed in detail in Part IV of this paper.

(1)

the dietary supplement contains only dietary ingredients, which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered.

(2)

there is a history of use or other evidence of safety establishing that the dietary ingredient when used correctly and according to the label will reasonably be expected to be safe, and the manufacturer provides the FDA with studies or articles showing the dietary ingredient will reasonably be expected to be safe.<sup>100</sup>

Once a manufacturer has the above information, it must be provided to the FDA no more than 75 days prior to introduction. The FDA after 90 days is instructed to put the non-confidential information on public display.<sup>101</sup> As an alternative to the notification requirement, manufacturers can petition the FDA setting forth the circumstances under which the new dietary ingredient will be expected to be safe. The FDA then must evaluate the petition within 6 months.<sup>102</sup>

Dietary ingredients on the market before October 15, 1994 are not covered by the new dietary ingredient requirements. They are instead “grandfathered.”<sup>103</sup>If the manufacturer fails to provide the FDA with the information necessary to

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<sup>100</sup>21 U.S.C. § 350b(a).

<sup>101</sup>Id.

<sup>102</sup>21 U.S.C. § 350b(b).

<sup>103</sup>Bass at 40.

show a reasonable expectation of safety for the new dietary ingredient, the dietary supplement will be deemed adulterated. Adulteration in the context of a new dietary ingredient means that “there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.”<sup>104</sup> The FDA bears the burden of proof on this issue. Therefore, the dietary ingredient will be considered adulterated only if the FDA proves the following:<sup>105</sup>

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it is “new”;

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there is “inadequate information”;

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to provide “reasonable assurance”;

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that “such ingredient does not present a significant or unreasonable risk of illness or injury.”

### C. The Safety of Dietary Supplements under the DSHEA

<sup>104</sup>21 U.S.C. § 342(f)(1)(B).

<sup>105</sup>Bass at 41-42,



Since the DSHEA removed dietary supplements from the definition of food additives, the DSHEA strengthened the existing food adulteration provisions. Basically under the new DSHEA provisions, a dietary supplement will be deemed to be an adulterated food if it “presents a significant or unreasonable risk of illness or injury under (1) conditions of use recommended or suggested in labeling or (2) if not conditions of use are suggested or recommended in the labeling, under ordinary conditions of use.”<sup>106</sup> Under this provision, if a consumer uses a dietary supplement in extreme doses or under extraordinary conditions, the use will not be covered under the adulteration provision.<sup>107</sup>

Additionally, a dietary supplement will be deemed adulterated if it contains an ingredient that the Secretary finds poses “an imminent hazard to public health or safety.”<sup>108</sup> Finally, the new adulteration provisions for dietary supplements encompass the “may be injurious” or “ordinarily injurious” standards set forth in an earlier food adulteration provision<sup>109</sup> “under the conditions of use recommended or suggested in the labeling of such dietary supplement.”<sup>110</sup> The government bears the burden of proof on each element of adulteration.<sup>111</sup>

Finally, the DSHEA encompasses a good manufacturing practices provision.<sup>112</sup> This provision is designed to ensure the proper treatment of dietary supplements while they are being prepared, packed or held. The FDA has subsequently issued an advance notice of proposed rulemaking to implement the DSHEA good

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<sup>106</sup>21 U.S.C. § 342(f)(1)(A).

<sup>107</sup>Bass at 46.

<sup>108</sup>21 U.S.C. § 342(f)(1)(C).

<sup>109</sup>21 U.S.C. § 342(a)(1).

<sup>110</sup>21 U.S.C. § 321(f)(1)(D).

<sup>111</sup>21 U.S.C. § 342(f)(1).

<sup>112</sup>21 U.S.C. § 342(g)(1).

manufacturing practices.<sup>113</sup>

#### D. Health Claims and Structure/Function Claims under the DSHEA

There are roughly three kinds of claims that a dietary supplement manufacturer can make: drug claims, health claims, and structure/function claims. This provision addresses all three types of claims and was the provision that was most lobbied and most feverishly debated. It remains one of the most controversial provisions today.<sup>114</sup>

While *classic drug claims* are not allowed on the labeling, the new provisions provide a safe harbor for structure/function claims that comply with substantiation, labeling, and notification procedures:

For purposes of paragraph (r)(1)(B), a statement for a dietary supplement may be made if—

(A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient *intended to affect the structure or function in humans*, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient,

(B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and

(C) the statement contains, prominently displayed and in boldface type, the following: This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”

*A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.* If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made.<sup>115</sup>

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<sup>113</sup>See 62 Fed. Reg. 5700 (February 6, 1997).

<sup>114</sup>Id. at 55.

<sup>115</sup>21 U.S.C. § 343(r)(6) (emphasis added).

Therefore, under the DSHEA, a manufacturer can make “structure/function” claims as long as he complies with the substantiation, labeling and notification procedures of this section. This provision is best understood, however, in light of the previous rules allowing manufacturers to make certain kinds of structure/function claims for “foods”. The FDCA drug definition permitted foods to be labeled with claims that involved the nutrient’s affect on the structure/function of the body.<sup>116</sup> Traditional nutritional function claims such as “calcium builds strong bones” were permitted before the DSHEA. Under the DSHEA, however, dietary supplements are not deemed to be “food” for purposes of the food exemption in the drug definition.<sup>117</sup> Section 403(r)(6) of the DSHEA thus affirms that structure/function claims are acceptable for dietary supplements, as long certain conditions are met.

Under the NLEA amendment to the FDCA, “health claims” relating a nutrient to a disease or health condition were allowed if they were authorized by FDA regulation.<sup>118</sup> The DSHEA creates an exemption to the NLEA provision by allowing certain statements of nutritional support that meet the relevant criteria (substantiation, labeling, and notification) to be made without a health

<sup>116</sup>This section defines drugs as “articles (other than food) intended to affect the structure or any function of the body of man or other animals.” 21 U.S.C. § 321(g)(1)(C). The dietary supplement industry interpreted this section to mean that structure/function claims could be made for foods. Bass at 15. The FDA maintained, however, that “food” did not include dietary supplements other than those vitamins and minerals with recognized nutritional value. Thus, a structure/function claim for any herb, amino acid, etc., was deemed an unapproved drug claim by the FDA. See, e.g., 58 Fed. Reg. at 33,697-99.

<sup>117</sup>21 U.S.C. § 321 (ff).

<sup>118</sup>21 U.S.C. § 343(r)(1)(B).

claim regulation promulgated by the FDA.<sup>119</sup> The exact meaning of this section of the DSHEA and the interpretation of the labeling and notification procedures for structure/function claims have been frequently debated among practitioners and academics.<sup>120</sup> However, it is pretty clear that under the DSHEA that:

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dietary supplements cannot claim to diagnose, treat, or cure a disease;

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claims describing “general well-being from consumption of a nutrient or dietary ingredient” are allowed if the manufacturer follows the substantiation, notification, and labeling procedures of the DSHEA; and,

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supplements claiming an impact on the structure or function of the body are allowed if the manufacturer follows the substantiation, notification, and labeling procedures of the DSHEA.<sup>121</sup>

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<sup>119</sup>Bass at 56.

<sup>120</sup>Bass and Young state that traditional dietary ingredient structure/function claims can still be made by manufacturers of dietary supplements without meeting the DSHEA requirements. However, where the claim is not a classic nutritional function claim, the DSHEA requirements of notification and labeling apply. *Id.* at 56. See also McNamara, Stephen H. “Structure/Function Claims in Dietary Supplement Labeling: Not All of These Claims Need to Be Submitted to FDA and Accompanied in Labeling by the DSHEA Disclaimer.” 54 *Food and Drug L.J.* 35, 36 (1999) (arguing that the “effect of the opening phrase of section 403(r)(6) is to provide that, in the case of a dietary supplement, a statement that is a health claim may be made in labeling without the usual requirements for health claims, if instead the statement complies with provisions of the section, including use of the disclaimer and notification to FDA. Under the plain language of sections 403(r)(1)(B) and 403(r)(6), however, there is no need for a structure/function claim to comply with section 403(r)(6) requirements unless the claim [is a health claim].”

<sup>121</sup>21 U.S.C. § 343(r)(6).

### E. The DSHEA’s Dietary Supplement Labeling Requirements

Under the labeling guidelines set forth in the NLEA, a dietary supplement must be labeled in an appropriate manner and meet the following criteria:<sup>122</sup>

(i) nutrition information shall first list those dietary ingredients that are present in the product in a significant amount and for which a recommendation for daily consumption has been established by the Secretary, except that a dietary ingredient shall not be required to be listed if it is not present in a significant amount, and shall list any other dietary ingredient present and identified as having no such recommendation;

(ii) the listing of dietary ingredients shall include the quantity of each such ingredient (or of a proprietary blend of such ingredients) per serving;

(iii) the listing of dietary ingredients may include the source of a dietary ingredient; and

(iv) the nutrition information shall immediately precede the ingredient information required under subclause (i), except that no ingredient identified pursuant to subclause (i) shall be required to be identified a second time.

Congress instructed the FDA to issue regulations that are “appropriate to the product,” but left open the specific format of the nutrition information panel.<sup>123</sup>

Under the DSHEA, the labeling of a supplement must state that it is a “dietary supplement.”<sup>124</sup> Dietary supplements now must also list the name of each dietary ingredient and the quantity of each dietary ingredient.<sup>125</sup> If the ingredient is an herb or botanical product, the label must list the part of the plant from which it was derived.<sup>126</sup>

### F. The DSHEA’s Exception to the Definition of “Labeling” – Third Party Literature

This section of the DSHEA changes the state of the law established by the Ko-

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<sup>122</sup>21 U.S.C. 343(q)(5)(F).

<sup>123</sup>Id.

<sup>124</sup>21 U.S.C. 343(s)(2)(B)

<sup>125</sup>21 U.S.C. 343(s)(2)(A)(ii)(I).

<sup>126</sup>21 U.S.C. 343(s)(2)(C).

rdel and Urbuteit cases addressing the definition of “accompanying labeling.”<sup>127</sup>

The DSHEA states that:

A publication, including an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publication, which is reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of a dietary supplement to consumers when it—

- (1) is not false or misleading;
- (2) does not promote a particular manufacturer or brand of a dietary supplement;
- (3) is displayed or presented, or is displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement;
- (4) if displayed in an establishment, is physically separate from the dietary supplements; and
- (5) does not have appended to it any information by sticker or any other method.

(b) Application

Subsection (a) of this section shall not apply to or restrict a retailer or wholesaler of dietary supplements in any way whatsoever in the sale of books or other publications as a part of the business of such retailer or wholesaler.

(c) Burden of proof

In any proceeding brought under subsection (a) of this section, the burden of proof shall be on the United States to establish that an article or other such matter is false or misleading.<sup>128</sup>

This section allows manufacturers and distributors to send sales publications to retailers as long as they meet the criteria set out in the section.<sup>129</sup> This section was put into the statute in response to a public outcry against existing FDA policies deemed to be “censorship.”<sup>130</sup> The DSHEA puts no restrictions on who may author a publication, as long as it meets the five criteria in the statute (i.e., is not false or misleading, does not promote a particular brand, is balanced, is physically separate, and is not stickered with information.)<sup>131</sup>

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<sup>127</sup>See supra notes 5 and 7.

<sup>128</sup>21 U.S.C. § 343-2.

<sup>129</sup>Bass at 51.

<sup>130</sup>Id.

<sup>131</sup>Id.

### G. The DSHEA’s Establishment of the Office of Dietary Supplements

The DSHEA establishes both a Commission on Dietary Supplement Labels and an Office of Dietary Supplements within the National Institutes of Health. Specifically, the Commission on Dietary Supplement Labels—a seven-member Commission appointed by the President—was established to conduct a study on the regulation of dietary supplement label claims.<sup>132</sup> The Commission is given the power to hold hearings, take testimony, receive evidence, and obtain necessary information directly from any federal agency or department to evaluate how to provide truthful and non-misleading information about dietary supplements to consumers.<sup>133</sup> The members of the Commission should have “expertise and experience in dietary supplements and in the manufacture, regulation, distribution and use of such supplements.”<sup>134</sup> The DSHEA further requires that three or more members of the Commission be “qualified by scientific training and experience to evaluate the benefits to health of the use of dietary supplements” and at least one of the three to have “experience in pharmacognosy, medical botany, traditional herbal medicine, or other related sciences.”<sup>135</sup> The Senate Report goes on to state that the Commission should look into the issue of whether the FDA is the most appropriate governmental body to make final decisions regarding health claims.<sup>136</sup>

Additionally, the Commission was charged with making recommendations about

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<sup>132</sup>21 U.S.C. § 343 note, § 12(b).

<sup>133</sup>21 U.S.C. § 343 note, § 12(d).

<sup>134</sup>21 U.S.C. § 343 note, § 12(b).

<sup>135</sup>21 U.S.C. § 343 note, § 12(b)(2).

<sup>136</sup>S. Rep. No. 410, 103d Cong., 2d Sess. 30 (1994).

the “use of literature in connection with the sale of dietary supplements.”<sup>137</sup> The members of the Commission were appointed in late 1995 and were given the task of submitting a final report on the study by October 1996. The DSHEA also requires the establishment of an Office of Dietary Supplements.<sup>138</sup> The purpose of the office is to “explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care” and to “promote scientific study of the benefits of dietary supplements.”<sup>139</sup> The Senate Report accompanying the statute states that the major function of the office would be to provide advocacy and scientific information regarding the benefits of dietary supplements.<sup>140</sup> Thus, this office was not intended to have regulatory authority over dietary supplements.<sup>141</sup>

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<sup>137</sup>21 U.S.C. § 343 note, § 12(c).

<sup>138</sup>42 U.S.C. § 287c-11(b).

<sup>139</sup>42 U.S.C. § 287c-11(b).

<sup>140</sup>S.Rep.No. 103-410.

<sup>141</sup>Id.



## Part IV – Post-DSHEA Regulation of Dietary Supplement Structure/Function and Health Claims

As previously discussed, the DSHEA permits dietary supplement manufacturers to make so-called structure/function claims under certain conditions without pre-clearance. Moreover, since dietary supplements are regulated as foods under the DSHEA, the use of pre-approved health claims on labeling became an issue for dietary supplement manufacturers and the FDA. These issues have generated the most interest and controversy in the legislative, judicial, and regulatory arena and are at the heart of the statute’s intent—to increase consumer access to quality information about dietary supplements. This section explores the controversy and current state of law with respect to structure/function and health claims.

### A. Health Claims

Congress passed the NLEA to prohibit unfounded and/or inaccurate health claims that have the potential to defraud consumers while at the same time to permit health claims based on scientifically valid information.<sup>142</sup> The NLEA authorizes the dissemination of health claims where the FDA has found that such claims are reliable. To determine reliability, Congress required the FDA to promulgate rules. For foods, Congress required the FDA to use a “significant scientific agreement standard.”<sup>143</sup> Because the DSHEA requires the FDA to regulate dietary supplements as foods, the health claim procedure then also applied to dietary supplements.

<sup>142</sup>Vladeck, David C. “Devaluing the Truth: Unverified Health Claims in the Aftermath of *Pearson v. Shalala*.” 54 Food and Drug L.J. 535 (1999).

<sup>143</sup>21 U.S.C. § 343(r)(3)(B).

The FDA defines a health claim as “any claim... that expressly or by implication... characterizes the relationship of any substance to a disease or health-related condition.”<sup>144</sup> Congress gave the FDA the task to determine the standard for dietary supplements, and the FDA decided that the procedures used for health claims in food should also apply to health claims for dietary supplements.<sup>145</sup> Thus, the FDA permits a health claim for dietary supplements only where “significant scientific agreement” supports the claim. The FDA must pre-authorize the health claim. As of 1999, the FDA had approved only a handful of health claims for use by dietary supplements.<sup>146</sup>

The Food and Drug Administration Modernization Act of 1997 (FDAMA) changed the landscape of regulation of health claims somewhat. The FDAMA added a new procedure for using health claims in labeling.<sup>147</sup> Specifically, the FDAMA allows for a health claim based on “an authoritative statement of a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition...”<sup>148</sup> In order to use the health claims on the label, the manufacturer must submit to the FDA, at least 120 days before the introduction of the supplement into interstate commerce: (1) a notice of the claim; (2) a copy of the authoritative

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<sup>144</sup>21 C.F.R. § 101.14(a).

<sup>145</sup>21 C.F.R. §§ 101.14, 101.70.

<sup>146</sup>Examples of approved health claims are (1) claims that described the relationship between calcium and osteoporosis and (2) claims that described the relationship between folic intake and neural tube defects.

<sup>147</sup>Pinco, Robert C. and Todd H. Halpern, “Guidelines for the Promotion of Dietary Supplements: Examining Government Regulation Five Years After Enactment of the Dietary Supplement Health and Education Act of 1994.” 54 Food and Drug L.J. 567, 573. (1999).

<sup>148</sup>21 U.S.C. § 343(r)(3)(C)(i). This portion of the Act did not apply to health claims based on authoritative statements for dietary supplements. See 64 Fed. Reg. 3250, 3251 (January 21, 1999). The FDA, however, has proposed to interpret the regulations the same way for conventional foods and dietary supplements. See 64 Fed. Reg. at 3251-3252.

statement relied on; and (3) a balanced representation of the scientific literature relating to the health claim.<sup>149</sup> The claim must be an accurate depiction of the authoritative statement and may not be misbranded.<sup>150</sup>

The FDA, however, significantly cut back on the strength of the FDAMA in its subsequent regulations by limiting the definition of “authoritative statement” and narrowly interpreting “significant scientific agreement.”<sup>151</sup> In an interim final rule issued in response to various health claims presented to the FDA, the FDA denied all petitions on various grounds.<sup>152</sup> The FDA determined that some of the statements were invalid because they were not conclusive enough and further studies were required. Other studies were held invalid because they did not *confirm* that the health claim was scientifically valid or well-established. Other authoritative statements were rejected because they were based on scientific review by only one segment of the scientific body, rather than the entire scientific body, or did not reflect consensus of the entire scientific body.<sup>153</sup> Even more were denied because the evidence implied the studies were only preliminary rather than conclusive.<sup>154</sup> Predictably, the narrow view taken by the FDA with respect to health claims angered many, including Rep Dan Burton, who argued the regulations were tantamount to censorship.<sup>155</sup>

Apparently, the courts are starting to agree with Rep. Burton’s view on the FDA’s regulatory policy. In Nutritional Health Alliance v. Shalala, the Sec-

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<sup>149</sup>21 U.S.C. § 343(r)(3)(C)(ii).

<sup>150</sup>21 U.S.C. § 343(r)(3)(C)(iii-iv).

<sup>151</sup>Pinco at 573.

<sup>152</sup>63 Fed. Reg. 34,084-34,112 (June 22, 1998).

<sup>153</sup>Id. at 34,093.

<sup>154</sup>Id.

<sup>155</sup>Letter from Rep. Dan Burton (R-IN) to Michael Friedman, Lead Deputy Commissioner, Food and Drug Administration (August 13, 1998).

ond Circuit held that the NLEA’s requirement for prior approval of all health claims—a requirement that could produce a prior restraint of 540 days—was constitutionally acceptable.<sup>156</sup> However, the leading court decision in the area of health claims is Pearson v. Shalala, issued one year after Nutritional Health Alliance.<sup>157</sup> On January 15, 1999, the Pearson Court held that the FDA’s policy regarding evaluation of health claims was unconstitutional. The plaintiffs in the case were dietary supplement marketers who wanted the FDA to authorize four health claims in order to boost the “allure” of their dietary supplement labels. The health claims were as follows:

(1) “

Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer.”

(2) “

Consumption of fiber may reduce the risk of colorectal cancer.”

(3) “

Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease.”

(4) “

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<sup>156</sup>144 F.3d 200 (2<sup>nd</sup> Cir. 1998).

<sup>157</sup>164 F.3d 650 (D.C. Cir. 1999).

.8 mg. of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form.”<sup>158</sup>

The FDA denied all four health claims because, in their view, all four claims failed to demonstrate “significant scientific agreement.”<sup>159</sup> The D.C. Circuit found that the FDA’s policy was an unconstitutional restriction on free speech. Specifically, the Court found that the FDA was required to consider whether inclusion of some appropriate disclaimers with the health claim would negate the potentially misleading nature of the health claims.<sup>160</sup> Additionally, the Court found that the “significant scientific agreement” standard was too vague and ordered the FDA to define the phrase and consider the adequacy of the claims in the context of the proposed disclaimers.<sup>161</sup> The D.C. Circuit also held that the Administrative Procedure Act requires the FDA to explain why it rejected the four health claims. To do so, the Court reasoned, the FDA must give some definitional content to “significant scientific agreement.”<sup>162</sup>

The aftermath of Pearson is not yet entirely determined. The FDA has issued a notice requesting scientific information related to the four health claims in the case.<sup>163</sup> The FDA will use the data to evaluate the Pearson health claims pursuant to the directives of the D.C. Circuit. Even more recently, the FDA has issued an announcement of a public meeting to solicit comments regarding the

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<sup>158</sup>Id. at 652.

<sup>159</sup>Id. at 653.

<sup>160</sup>Id. at 658.

<sup>161</sup>Id. at 661.

<sup>162</sup>Id. at 660.

<sup>163</sup>64 Fed. Reg. 48,841 (Sept. 8, 1999).

implementation of the Pearson decision.<sup>164</sup> Specifically, the meeting will discuss whether claims about an effect on an existing disease may be made as health claims, or whether they should be regulated as drug claims. The meeting will also address the disclaimer issue raised in Pearson, namely whether a disclaimer placed on the label qualifying the health claim would render the statement non-misleading.

While the proponents of Pearson think they have won a battle for more consumer choice, others argue that the Pearson decision will actually harm consumers. For example, manufacturers may now try to forgo the new drug approval process and market what seemingly are new drugs as dietary supplements.<sup>165</sup> This is because after Pearson, it is possible that dietary supplements may make the same claims as drugs but do not have to go through the new drug approval process.<sup>166</sup> It would thus be irrational for a manufacturer to go through the new drug approval process when it could put its product on the market as a supplement and make disease prevention claims.<sup>167</sup>

#### B. Structure/Function Claims

As previously noted, the DSHEA explicitly authorizes dietary supplement labeling to contain statements of nutritional support or structure/function statements as long as the following criteria are met:

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<sup>164</sup>65 Fed. Reg. 14219 (March 16, 2000).

<sup>165</sup>Vladeck at 552.

<sup>166</sup>Id.

<sup>167</sup>Id. at 552-553.

(1)

the manufacturer of the dietary supplement has substantiation at the time the claim is made that the statement is truthful and non-misleading to the consumer<sup>168</sup>

(2)

the labeling contains the mandatory disclaimer “this statement has not been evaluated by the food and drug administration. This product is not intended to diagnose, treat, cure, or prevent any disease” prominently displayed in bold-faced type<sup>169</sup>

(3)

the manufacturer of dietary supplement must notify the FDA of the structure/function claim within 30 days after the marketing of the dietary supplement.<sup>170</sup>

If the FDA after receiving notice disapproves of a claim, it will issue a courtesy letter, but the letter has no legally binding effect.<sup>171</sup> The letter merely puts the manufacturer on notice that the claim may lead to future regulatory action.

Under the terms of the DSHEA, a structure/function claim cannot claim to di-

<sup>168</sup>21 U.S.C. § 343(r)(6)(B).

<sup>169</sup>21 U.S.C. § 343(r)(6)(C).

<sup>170</sup>21 U.S.C. § 343(r)(6).

<sup>171</sup>Pinco at 576.

agnose, treat, cure or prevent a disease.<sup>172</sup> On April 29, 1998, the FDA issued a proposed rule attempting to define the parameters of a structure/function claim.<sup>173</sup> Therefore, the definition of “disease” became very important in distinguishing disease claims that are not allowed for dietary supplements from structure/function claims that are allowed. The rule proposed to broaden the definition of “disease” to include:

any deviation from, impairment of, or interpretation of the normal structure or function of any part, organ or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms. For purposes of this definition, “signs or symptoms” include laboratory or clinical measurements that are characteristic of a disease, such as elevated cholesterol fraction, uric acid, blood sugar and glycosylated hemoglobin, and characteristic signs of disease, such as elevated blood pressure or intraocular pressure.<sup>174</sup>

The comments to the FDA’s definition of disease and related regulatory stances were based primarily in a notion that Congress did not intend the FDA to use such a broad definition of disease.<sup>175</sup> Specifically, FDA opponents argued that Congress must have been aware of the prior definition of disease when it enacted the DSHEA and therefore intended the FDA to use the older, narrower definition. Additionally, they argued that FDA’s definition was so broad that it would sweep in many minor abnormalities that would not ordinarily be considered a disease.<sup>176</sup> If the FDA can stretch the definition of disease broadly enough, the broad definition will effectively eliminate the structure/function

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<sup>172</sup>21 U.S.C. § 343(r)(6).

<sup>173</sup>63 Fed. Reg. 23624.

<sup>174</sup>64 Fed. Reg. 36,824, 36825. (definition contained in FDA’s response to comments generated by April 29, 1998 proposed rulemaking).

<sup>175</sup>Id. at 36,825.

<sup>176</sup>Id.



claims that Congress intended to be allowable under the DSHEA.

In addition to broadening the definition of disease, the regulations also stated that natural states such as aging, menopause, pregnancy, and the menstrual cycle were not themselves diseases, but “could be associated with abnormal conditions that were diseases.”<sup>177</sup> Therefore, the FDA proposed to treat statements that a dietary supplement has an effect on a condition associated with a natural state as a disease claim if the condition presented symptoms of an abnormality.<sup>178</sup> The FDA presented the following as examples of abnormal conditions: hot flashes, decreased sexual function associated with aging, and premenstrual syndrome. Many comments on this issue suggested that some of the examples were so common that they could not be considered an abnormality nor a disease.<sup>179</sup>

Moreover, the FDA proposed to treat express *and implied* disease claims as disease claims requiring prior approval by the FDA. FDA’s reason for treating implied disease claims like express claims was that it did not want a savvy manufacturer to craft an implied disease claims in a manner that will be understood by consumers as an express disease claim. It gave the following example:

- Express claim – “for the treatment of lung cancer”

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<sup>177</sup>Id.

<sup>178</sup>Id.

<sup>179</sup>Id.

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Implied claim – “shrinks tumors of the lung”<sup>180</sup>

Opponents to the FDA stance on implied disease claims argued that Congress intended to permit implied disease claims in the DSHEA and the FDA stance was therefore contrary to congressional intent.<sup>181</sup>

The massive public outcry caused the FDA to reevaluate its position with respect to the regulation of structure/function claims, and led eventually to a final rule issued in January of 2000.<sup>182</sup> The final regulations soften the FDA’s stance somewhat toward the regulation of dietary supplement structure/function claims. The final regulations made the following changes:<sup>183</sup>

(1)

proposed broader definition of “disease” was deleted;

(2)

FDA will use the preexisting definition of “disease or health-related condition” found in 21 C.F.R. § 101.14(a)(5). This is the definition put forth as part of the implementation of the NLEA.

(3)

express disease claims such as “prevents osteoporosis” are precluded are not

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<sup>180</sup>Id. at 36,826.

<sup>181</sup>Id. at 36,825-36,826.

<sup>182</sup>65 Fed. Reg. 1000 (January 6, 2000).

<sup>183</sup>Id. at 1000.

considered to be permissible structure/function claims;

(4)

implied disease claims such as “prevents bone fragility in post-menopausal women” are not considered to be permissible structure/function claims;

(5)

clarifies that disease claims (express and implied) can be made through the name of a product, a statement about the formulation of a product, or through the use of pictures or symbols;

(6)

clarifies that health maintenance claims and non-disease claims are permissible claims under this rule;

(7)

certain conditions that are associated with natural states or processes that do not cause significant or permanent harm will NOT be treated as diseases – ex. hot flashes, common symptoms associated with the menstrual cycle, mild memory loss and hair loss associated with aging, and noncystic acne; and,

(8)

uncommon or serious conditions associated with natural states or processes

WILL be treated as diseases – ex. toxemia of pregnancy, senile dementia, severe depression associated with the menstrual cycle, and cystic acne.

The FDA has softened its position in terms of the definition of disease by reverting to the prior, narrower definition of disease. Also, the FDA has decided to include statements made about common conditions associated with life's natural processes as long as the condition is not significant. Consequently, the FDA did compromise its earlier position somewhat in response to the public outcry. There have been no significant developments since the final regulation was put into place. However, the FDA has announced a meeting to discuss safety issues associated with dietary supplement use during pregnancy.<sup>184</sup> This meeting was announced in response to health professionals and other individuals concerned about safety after the enactment of the January final rules. At any rate, while these new regulations are only a few months old, they seem to indicate that the FDA will be more willing to allow manufacturers to make certain structure/function claims without pre-approval.

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<sup>184</sup>65 Fed. Reg. 9230 (February 24, 2000).

Part V – Post-DSHEA Changes in the Definition of “Dietary Supplements”

As previously discussed, the definition of “dietary supplements” established by the DSHEA is very broad. It includes vitamins, minerals, herbs, amino acids, and others. It also includes articles approved as a new drug, as long as the article was previously marketed as a dietary supplement or food.<sup>185</sup>

Under the DSHEA, an article is *not* a dietary supplement if it is an article that is approved as a new drug, a certified antibiotic, or a licensed biologic, assuming they were not previously marketed as a food or dietary supplement.<sup>186</sup>

Additionally, articles authorized for investigation as a new drug, antibiotic or biological for which substantial investigations have been instituted and made public are also not included in the definition of “dietary supplement,” assuming they weren’t previously marketed as a food or a dietary supplement.<sup>187</sup>

The exact meaning of the exclusionary and inclusionary definitional provisions were tested in Pharmanex v. Shalala.<sup>188</sup> Pharmanex marketed Cholestin as a dietary supplement. Cholestin was composed solely of milled red yeast rice. Cholestin was intended for use in helping to maintain a health cholesterol level. The red yeast rice in Cholestin was a natural source of mevinolin, which is chemically indistinguishable from lovastatin. Lovastatin is the active ingredient in the prescription drug Mevacor, approved as a new drug in 1987. Therefore, a natural ingredient found in Cholestin was also an active ingredient in a prescription drug.

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<sup>185</sup>21 U.S.C. § 321(ff)(3)(A).

<sup>186</sup>21 U.S.C. § 321(ff)(3)(B)(i).

<sup>187</sup>Id.

<sup>188</sup>35 F.Supp.2d 1341 (D.Utah 1999)

The FDA advised Pharmanex that it considered Cholestin to be a drug that required pre-approval by the FDA for marketing. FDA subsequently barred Pharmanex from importing red yeast rice, and Pharmanex in turn brought an action for preliminary injunction and declaratory judgment against the FDA. The District Court in Utah examined whether Cholestin was subject to the clause in the DSHEA, which excludes “an article that is approved as a new drug” from the definition of “dietary supplement.”<sup>189</sup> FDA maintained the position that lovastatin itself was an “article” approved as a new drug. The District Court, however, determined that “article” refers to the finished drug product, not a component of the product.<sup>190</sup>

This decision could significantly limit FDA’s ability to regulate dietary supplements and has been met with some controversy. One argument is that the “decision essentially eviscerates the exclusionary component of the dietary supplement definition, which was enacted to protect pioneer pharmaceuticals approved via the NDA process from direct competition from the same active ingredient by makers of dietary supplements. Under the District Court’s interpretation, any slight variant... would circumvent the exclusion.”<sup>191</sup> Moreover, this decision could encourage “unscrupulous dietary supplement manufacturers” to “find either variants or ‘phyto’ alternatives to major pharmaceutical products.”<sup>192</sup> Along the same lines, others have noted that the “decision encourages manufacturers of dietary supplements to find and market ‘natural’ substances,

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<sup>189</sup>21 U.S.C. § 321(ff)(3)(B).

<sup>190</sup>35 F.Supp.2d at 1348.

<sup>191</sup>Pinco at 571.

<sup>192</sup>Id.

which are the active ingredients in prescription drugs, without going through the [new drug approval] process otherwise required.”<sup>193</sup> Additionally, prescription drug manufacturers may be discouraged from going through clinical trials and medical studies for fear that a dietary supplement manufacturer could market the same product at a lower cost and with less regulation.<sup>194</sup>

As the Pharmanex decision winds through the appeals process, many argue that the decision could be problematic from a consumer safety standpoint. Lovastatin, the substance at issue in the Pharmanex case, can cause liver dysfunction and should not be used on women who are likely to conceive.<sup>195</sup> Additionally, it is recommended that physicians monitor patients taking lovastatin for possible drug interactions. Since many consumers taking the herbal medicine will not inform their physicians and will assume it is safe, this could be a problem from a consumer safety standpoint.<sup>196</sup>

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<sup>193</sup>Khatcheressian at 634.

<sup>194</sup>Id.

<sup>195</sup>Id. at 635.

<sup>196</sup>Id.

## Part VI – Safety and Burden of Proof Issues after the DSHEA

Since the DSHEA declares that dietary supplements are not to be regulated generally as food additives or drugs, manufacturers are not required to go through a pre-market approval process. Consequently, the DSHEA effectively shifts the burden of proof on safety from the dietary supplement manufacturer to the FDA. Therefore, if the FDA has a safety concern about a dietary supplement, it must affirmatively prove that the product will be harmful before it can remove the product from shelves.<sup>197</sup>

Specifically, the dietary supplement adulteration portion of the Act states that “in any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated. The court shall decide any issues under this paragraph on a de novo basis.”<sup>198</sup> One commentator has interpreted this provision to mean the FDA should issue guidelines instead of the traditional regulations in the context of dietary supplement adulteration:

Because of certain unique provisions of the DSHEA—provisions that were specifically considered during the enactment of DSHEA and that do not appear in other sections of the FDCA—any regulations that FDA issues to interpret or enforce the adulteration provisions of sections 402(a)(1) and (f)(1) of the FDCA with respect to dietary supplements cannot have the force and effect of law or be eligible for direct enforcement in court, and would have no more status than FDA’s nonbinding guidelines. Accordingly, it appears that *instead of issuing regulations, FDA should issue guidelines with respect to any agency-desired criteria for dietary supplements* under sections 402(a)(1) and (f)(1) of the FDCA.<sup>199</sup>

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<sup>197</sup>Khatchereessian at 628.

<sup>198</sup>21 U.S.C. § 342(f)(1).

<sup>199</sup>McNamara, Stephen H., A. Wes Singer, and Evan P. Phelps. “DSHEA Provisions Confine FDA’s Authority to Issue Regulations that Concern Allegedly Adulterated Dietary Supple-



Even if the adulteration provision does not constrain FDA's power to issue regulations in the way specified above, it is clear that at the very least that the DSHEA makes it more difficult for the FDA to find that a dietary supplement is adulterated. Since there is no longer any pre-market approval mechanism for dietary supplements under the DSHEA, the FDA will be fighting an up-hill battle in its attempts to keep unsafe dietary supplements off the market.

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ments." 54 Food and Drug L.J. 595, 597. (1999). (emphasis added).

## Part VII – Post-DSHEA Labeling Requirements/Third Party Literature Requirements

### A. The Dietary Supplement Label

The DSHEA mandates that dietary supplements bear nutrition labeling “in a manner which is appropriate” for the product.<sup>200</sup> Congress left it up to the FDA to determine what this would be. The FDA published proposed regulations regarding the labeling of dietary supplements on December 28, 1995<sup>201</sup> and issued final regulations on September 23, 1997.<sup>202</sup> Effective March 23, 1997, the final rules require dietary supplements to be labeled as such and to carry a “Supplement Facts” panel on the label (similar to the Nutrition Facts panel for foods). Specifically, the Supplements Facts panel will show:

- the manufacturer’s suggested serving size;
- information on nutrients present in significant level, including the percent Daily Value of the those nutrients; and,
- all other dietary ingredients present in the product.<sup>203</sup>

Additionally, the final rule requires that products that contain botanical

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<sup>200</sup>21 U.S.C. § 343(q)(5)(F).

<sup>201</sup>60 Fed. Reg. 67,197

<sup>202</sup>62 Fed. Reg. 49,883.

<sup>203</sup>Id.

ingredients be labeled with the common or usual name along with the part of the plant (such as root, stem, or leaf) used to make the products.<sup>204</sup> Finally, when the terms “high potency” and “antioxidant” are used on the label, the FDA has provided additional, specific guidance to manufacturers as to when these terms are acceptable for use on the dietary supplement label<sup>205</sup>

#### B. The Third Party Literature Exception

The “Third Party Literature” exception in the DSHEA allows third parties (presumably persons or entities other than the manufacturers or distributors of dietary supplements) to distribute certain publications to consumers in connection with the sale of particular dietary supplements.<sup>206</sup> In order to qualify for the exemption, however, the literature must not be false or misleading, must not promote a particular manufacturer or brand of dietary supplement, must present a balanced view of the available scientific information on the supplement, must be physically separate from the dietary supplement, and must not be stickered with information.<sup>207</sup>

There are many available contestable issues within the statute, but the FDA has been relatively cautious in contesting independent status of particular publishers so far.<sup>208</sup> A manufacturer appears to be free to commission a third party to publish information about a dietary supplement, as long as the manufacturer

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<sup>204</sup>Id.

<sup>205</sup>Id.

<sup>206</sup>21 U.S.C. § 343-2.

<sup>207</sup>Id.

<sup>208</sup>Raubicheck, Charles J. “DSHEA’s Third-Party Literature Exemption: Mail Order Sales, Direct Marketing, and Internet Use.” 54 Food and Drug L.J. 587, 589. (1999).

does not exercise any control over the content.<sup>209</sup> Recently, the FDA issued a warning letter to a manufacturer who issued cookbooks as third-party literature because the cookbooks were authored by the company's managerial employees who also had responsibility for marketing and labeling the company's dietary supplement.<sup>210</sup> It would appear that "permissible channels of dissemination include mail order, direct marketing, and Internet sales and promotion, in addition to sales and promotion in the traditional retail store context."<sup>211</sup>

As Internet use grows in popularity in the U.S., Internet sales and marketing in connection with the third-party literature exception will become very important. The FDA has determined in many instances that dietary supplement claims on the Internet are labeling.<sup>212</sup> Therefore, in order to fit within the third-party literature exception, Internet claims should be used on a website where dietary supplements are actually being sold to comply with the "in connection with the sale" requirement in the DSHEA.<sup>213</sup> Likewise, the requirement of "physical separation" could be met through hyperlinks. The hyperlinks should take the user first to generic pages that describe the *type* of supplements involved and then take the user to the third party literature page. This could prevent the information from being construed as endorsing a particular brand.<sup>214</sup> The Internet sale of dietary supplements is a relatively new issue, but

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<sup>209</sup>Id.

<sup>210</sup>Letter from Joseph R. Baca, Director of the Dallas District Office, Food and Drug Administration, to The Stevita Company (April 9, 1999).

<sup>211</sup>Raubicheck at 593.

<sup>212</sup>Id. at 592.

<sup>213</sup>Id.

<sup>214</sup>Id.

the FDA will no doubt have to address this issue further in the near future.

## Part VIII – Current Bills in Congress – The Future of DSHEA Regulation?

While the FDA was developing its regulatory stance on dietary supplements in response to the DSHEA, FDAMA, and related acts, Congress was also carving out new policy. During the 106<sup>th</sup> Congress, several pertinent bills were proposed to change the regulatory status of dietary supplements even more.

Rep. Ron Paul introduced the Consumer Health Free Speech Act<sup>215</sup> in the House in March of 1999. As introduced, the purpose of the bill is to change the food adulteration standards for dietary supplements. H.R. 1077 deems a dietary supplement adulterated if it (2) presents a significant AND unreasonable risk of illness or injury under ordinary or label-suggested use or (2) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that the ingredient does not present a significant AND unreasonable risk of illness. The current food adulteration provision uses a significant or unreasonable standard.<sup>216</sup> The bill was referred to the House Committee on Commerce. There has been no further action on the bill since the committee referral.

Sen. Michael D. Crapo proposed a bill entitled Dietary Supplement Fairness in Labeling and Advertising Act<sup>217</sup> in October of 1999. The bill was designed to nullify the proposed regulations issued by the FDA on structure/function claims in April of 1998.<sup>218</sup> Additionally, the bill substantially relaxed advertising requirements for dietary supplements to include the claims made on the labels of

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<sup>215</sup>H.R. 1077. 106<sup>th</sup> Cong., 1<sup>st</sup> Sess., (1999).

<sup>216</sup>See 21 U.S.C. § 342(f)(1)(A).

<sup>217</sup>S. 1749, 106<sup>th</sup> Cong., 1<sup>st</sup> Sess., (1999).

<sup>218</sup>63 Fed. Reg. 23624.

the supplements, so that Americans will gain more access to information about dietary supplements. The bill was sent to the Senate Health, Education, Labor, and Pensions committee on October 19, 1999. This was the last action on S. 1749.

Rep. Frank Pallone, Jr. proposed the Nutraceutical Research and Education Act<sup>219</sup> on October 1, 1999. The purpose of the Act was to establish and promote clinical research and development on the health benefits of dietary supplements. Additionally, the bill creates a new legal classification for dietary supplements and food with health benefits. The bill was referred to the House Committee on Commerce, Subcommittee on Health and the Environment and to the House Committee on the Judiciary.

Finally, Rep. Dan Burton, a big proponent of the health benefits of dietary supplements and consumer access to dietary supplements, proposed H.R. 3306<sup>220</sup> in November 1999 to provide that money spent on dietary supplements should be treated as medical expenses for purposes of the Internal Revenue Code. The Bill was referred to the House Committee on Ways and Means.

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<sup>219</sup>H.R. 3001, 106<sup>th</sup> Cong., 1<sup>st</sup> Sess. (1999).

<sup>220</sup>H.R. 3306, 106<sup>th</sup> Cong., 1<sup>st</sup> Sess. (1999).

## Conclusion

The regulation of dietary supplements has been a very contentious issue since its inception. Meanwhile, the number of dietary supplements on the market seems to be proliferating. A consumer is now able to find an assortment of dietary supplements for any one ailment, ranging from dietary supplements used to improve one's cholesterol to supplements used to improve one's mood. Advertising for dietary supplements has increased, and consumers now seem more willing to turn to dietary supplements, particularly some herbal supplements, before they obtain prescription medication for their specific problem. One could argue that this development is good. Consumers are now able to take control of their health care and make informed choices, given the information contained in dietary supplement labels after the enactment of the DSHEA. The DSHEA changed FDA's paternalistic attitude and forced the agency to realize the potential health benefits of dietary supplements.

The FDA, however, has long been concerned with the safety of these dietary supplements. Lately, there have been a number of high-profile incidents involving people being injured from using dietary supplements to supposedly improve their health. Thus, the conflict will continue as long as the FDA continues to maintain a consumer safety position and the industry and others maintain a consumer choice position.

The federal regulation of dietary supplements will remain an interesting and



dynamic issue that is marked by controversy. The future of dietary supplement regulation will be a continuation of the struggle to balance consumer protection against the necessity for consumer access to useful and non-misleading information about the role of dietary supplements in one's diet and health. With any luck, the ongoing battle on the part of the FDA, Congress, the courts, and industry to develop a regulatory scheme will result in a sensible and effective policy for the consumer.