

“Supplementing” the DSHEA: Congress Must Invest the FDA with Greater Regulatory Authority over Nutraceutical Manufacturers by Amending the Dietary Supplement Health and Education Act

ABSTRACT

This paper addresses the various deficiencies of the Dietary Supplement Health and Education Act, or "DSHEA." In it, I argue that the DSHEA (a federal statute passed by Congress in 1994, superseding the Food Drug and Cosmetics Act as the applicable law governing the sale of nutraceutical products) gives impermissible latitude to manufacturers of dietary supplements by allowing them to sell products without establishing whether they are safe or effective. The DSHEA also allows manufacturers to employ unsubstantiated and misleading labeling claims in marketing their products.

I assert that the DSHEA promotes deceptive labeling practices. I also suggest that the current regulatory regime is ineffective in assessing health risks posed by dietary supplements to the general public. I propose a way to amend the statute, by implementing a testing regime to better ensure both the safety and efficacy of supplements (comparable to, but distinguishable from and not nearly as stringent as the testing regime governing the distribution of pharmaceutical drugs). Furthermore, the paper advocates alleviating the burden the DSHEA imposes on the FDA in banning potentially dangerous supplements, by requiring courts to defer to FDA findings that a supplement is harmful (under the DSHEA, the FDA bears the burden of proof in showing that a supplement poses an "unreasonable or significant risk of harm" before removing it from the market; moreover, courts must apply de novo review to questions of law and fact in determining whether the FDA is justified in

prohibiting the sale of a supplement). Additionally, I articulate a litigation strategy (based on California statutory law) that might incentivize enactment of an amendment by Congress.

Alternative medicine implicates many controversial issues. The public's obsession with dietary supplements, despite the inadequacy of evidence demonstrating their benefits, is rather disturbing. I feel the government's lack of regulation over this industry should be addressed (especially in light of the deaths linked to the herbal supplement ephedra).

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I. INTRODUCTION

In May 2007, CNN reported on a dermatologist who takes 20 dietary supplements every morning and another 20 supplements in the afternoon, all in an attempt to ward off illness and death.¹ That same report declared that “virtually no evidence exists that supplements can improve your health.” Indeed, it cited studies evidencing the absence of any correlation between health benefits and dietary supplement intake. Nevertheless, the federal government estimates that Americans “spend at least 5.8 billion dollars a year” on dietary supplements.²

In addition to advertisements, manufacturers rely on labeling to market their supplements.³ Unfortunately, the regulations governing labeling requirements within the nutraceutical industry are quite permissive.⁴ Vitamins and other supplements often carry

1. Caleb Hellerman, *No Scientific Evidence Dietary Supplements Slow Aging*, CNN, May 9, 2007, <http://www.cnn.com/2007/HEALTH/04/09/chasing.supplements/index.html>.

2. *Id.*

3. See Peter A. Vignuolo, *The Herbal Street Drug Crisis: An Examination of the Dietary Supplement Health and Education Act of 1994*, 21 SETON HALL LEGIS. J. 200, 202-205 (1997) (discussing the importance manufacturers placed on labeling in marketing the weight-loss supplement ephedra).

4. Peter J. Cohen, *Science, Politics, and the Regulation of Dietary Supplements: It's Time to Repeal DSHEA*, 31 AM. J.L. & MED. 175, 186-187 (2005).

labels that claim ambiguous health benefits, but fail to demonstrate any measurable degree of efficacy.⁵ Though deceptive, this practice remains legal.

One problem is that the Food and Drug Administration does not require dietary supplements to undergo tests, unlike drugs.⁶ A drug is any compound devised to treat or cure an illness.⁷ Drugs are subject to vigorous pre-market testing, involving lengthy double-blind studies, to determine both their safety and therapeutic potential.⁸ The FDA will release a drug only after determining that its likelihood of success in treating a disease outweighs any cognizable side-effects.⁹ By contrast, dietary supplements constitute “food” and fall outside this regulatory apparatus.¹⁰

In 1994, Congress enacted a new law superceding the Food, Drug, and Cosmetics Act (FDCA) as the applicable statute governing the sale of dietary supplements: the Dietary Supplements Health and Education Act, or “DSHEA.”¹¹ The DSHEA is based on two policy considerations: 1) dietary supplements are presumptively “safe,” and 2) access to dietary supplements trumps concerns over safety.¹² Accordingly, it places the burden of proof on the

5. *Id.*

6. 21 U.S.C. § 321(c) (1994).

7. 21 U.S.C § 321(g)(1)(b) (1994) (defining drugs as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease”).

8. FDA Consumer Magazine, *Inside Clinical Trials: Testing Medical Products in People*, <http://www.fda.gov/fdac/special/testtubetopatient/trials.html> (last visited November 30, 2008).

9. *Id.*

10. Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 679-681 (1997).

11. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994) (codified as amended in various sections of 21.U.S.C. §301 et seq.). The “DSHEA” became law on Oct. 25, 1994.

12. See Ali Sachani, *Warning: Overconsumption of this Product may be Harmful to Your Health! Applying the Proposed Canadian Natural Health Product Regulatory Framework to Clarify the Level of Substantiation*

FDA to show that a “dietary supplement presents a significant or unreasonable risk of illness or injury” before prohibiting its sale.¹³ However, studies suggest that many dietary supplements serve no beneficial value. Certain supplements contain ingredients that can actually harm or aggravate health.¹⁴ Consequently, the DSHEA’s prioritization of access over safety and its failure in stipulating guidelines for determining efficacy are misguided.

The purpose of this paper is twofold: 1) to propose an amendment to the DSHEA that would require nutraceutical manufacturers to undertake controlled studies establishing both the safety and efficacy of their products, and 2) articulate a litigation strategy that might incentivize enactment of such legislation by Congress. In order to maintain accessibility, the amendment could allow manufacturers to sell their products while conducting these studies. If results suggest that a dietary supplement is unsafe (as opposed to “unreasonably” or “significantly” unsafe), the FDA should reserve discretion to remove it from the market. Alternately, if studies indicate that a supplement’s efficacy is questionable, the FDA should require the manufacturer to remove the claim or provide documentation of the study’s results within the product’s packaging.

The first part of this paper will discuss the DSHEA’s legislative history and inadequacies. The second part will assess the type of unsubstantiated claims manufacturers can lawfully make. The third part will describe and delineate the aforementioned legislative amendment to the DSHEA: that amendment will place the burden on manufacturers to prove

Required for Dietary Supplements, 9 SW. J.L. & TRADE AM. 391, 394 (2003) (suggesting that the current regime “appears to value big business over consumer health by presuming that dietary supplements and their claims of nutritional support are safe”).

13. 21 U.S.C § 342(f)(1) (2005).

14. Roseanne B. Termini, *Pharmanex, Inc. v. Shalala: A Wake up Call for Congress and a Not So Bitter Pill for the FDA*, 26 OHIO N.U.L. REV. 268, 280 (identifying numerous adverse side-effects, including dizziness, nausea, heart palpitation, and death, linked to dietary supplements) (2000).

that a dietary supplement is safe and effective. The fourth part will propose a litigation strategy (based on California statutory claims) that might compel Congress to redress the DSHEA's deficiencies and exact the nutraceutical industry's compliance with any new regulatory scheme. The fifth part will anticipate legal challenges manufacturers might mount against the new amendment, and recommend ways the FDA can clarify its standards for authenticating health claims so that courts are inclined to rule in its favor.

II. THE LEGISLATIVE HISTORY OF THE DSHEA AND ITS SHORTCOMINGS

A. *The state of regulations governing dietary supplements prior to enactment of the DSHEA*

The FDA's ability to regulate dietary supplements has traditionally been limited.¹⁵ The agency's concern with dietary supplements dates back to 1938, with the passage of the Federal Food, Drug, and Cosmetic Act (or FDCA).¹⁶ The FDCA formally brought dietary supplements within the regulatory purview of the government. The FDA established "detailed labeling requirements" for foods marketed for "special dietary uses."¹⁷ However, beyond investigating individual complaints, the FDA's supervision over nutraceutical manufacturing practices was minimal. In 1962, the FDA imposed new regulations restricting the sale of high-level dosage vitamins, but withdrew them in response to consumer protests.¹⁸

15. Laura A.W. Katcheressian, *Regulation of Dietary Supplements: Five Years of DHSEA*, 54 FOOD & DRUG L.J. 623, 624 (1999) (describing the FDA's changing "level and focus" of concern with dietary supplements since the FDCA's passage in 1938).

16. Federal Food Drug and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. § 301 et seq.).

17. Katcheressian, *supra* note 15 at 624-625.

18. *Id.* at 625.

In the 1970s, the FDA attempted to regulate dietary supplements again, focusing on the potential toxicity of overuse, but federal courts struck down these attempts.¹⁹

In the late 1980s and early 1990s, an increased incidence of side-effects associated with dietary supplements triggered greater FDA scrutiny. In 1989, the consumption of dietary supplements containing the amino acid L-tryptophan caused an outbreak of at least 1500 cases of eosinophilia myalgia syndrome, resulting in thirty-eight deaths. From 1993 to 1997, fifteen deaths and 400 “adverse reactions” were attributed to the supplement ephedra.²⁰ The FDA considered implementing a new regime that would allow it to uniformly evaluate the safety profile of dietary supplements. An FDA taskforce recommended that the agency reclassify dietary supplements as drugs rather than food to achieve such a regime.²¹

Congress and the dietary supplement industry caught wind of the FDA’s efforts. Led by Senator Orrin Hatch, Democratic and Republican legislators opposed any regulatory measures that might collapse the distinction between dietary supplements and drugs.²² In 1992, the dietary supplement industry spearheaded a grassroots lobbying campaign, advocating the adoption of new legislation that would expressly limit the FDA’s ability to require pre-market testing for dietary supplements.²³ In 1992, Congress passed the Dietary Supplement Act, which forced the FDA to “promulgate rules...reiterating that the FDA

19. *Id.*

20. *Id.*

21. *Id.* at 625-626

22. *See* Cohen, *supra* note 4 at 219 (identifying Senator Hatch as one of the DSHEA’s main sponsors DSHEA). *See also* 139 Cong. Rec. S4577 (daily ed. Apr. 7, 1993) (statement by Senator Hatch articulating his reasons for supporting the amendment).

23. Lauren J. Sloane, *Herbal Garden of Good and Evil: The Ongoing Struggle of Dietary Supplement Regulation*, 51 ADMIN. L. REV. 323, 325 (1999) (characterizing the DSHEA as the product of “overwhelming public pressure”).

would treat dietary supplements as conventional food.”²⁴ Two years later, Congress enacted the Dietary Supplement Health and Education Act (DSHEA), preempting the new rules promulgated by the FDA under the earlier 1992 Act and codifying Congress’ “desire for reduced regulation of dietary supplements.”²⁵ The DSHEA proved extremely accommodating to manufacturers, as dietary supplements would now be subject to less regulation than food additives (which require premarket clearance), drugs, and even “conventional foods.”²⁶

B. A glamorized perception of dietary supplements among consumers gave rise to the DSHEA

President Bill Clinton signed the DSHEA into law on October 25, 1994. Congress set forth fifteen separate findings justifying the DSHEA’s enactment, among them “overwhelming public pressure” favoring deregulation. Congress felt that the FDA’s regulation of the nutraceutical industry was “too stringent” and “unnecessarily limited consumer access to dietary supplements” (ironic, considering that the FDA never issued rules subjecting nutraceutical practices to heightened regulatory scrutiny; the FDA had merely contemplated, for a brief period, applying a more rigorous standard of review).²⁷ The rationale for deregulation is persuasive. Dietary supplements attract consumers for a myriad of reasons: some gravitate to supplements that promise weight loss without requiring exercise,

24. Jennifer J. Spokes, *Confusion in Dietary Supplement Regulation: The Sports Products Irony*, 77 B.U. L. REV. 181, 190 (1997).

25. *Id.*

26. *Id.* at 191. The regulations concerning dietary supplements are comparable to those governing the sale of food. See 21 U.S.C. § 342 (f)(1) (2005). See also Robert G. Pinco 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*, 54 FOOD & DRUG, L.J. 567, 567-568 (1999) (clarifying the distinction between food additives and dietary supplements).

27. Federal Food Drug and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. § 301 et seq.).

while others take supplements hoping they might induce the same effects as prescription medication, obviating expensive visits to the doctor.²⁸ This near-universal perception of dietary supplements, as possessing significant therapeutic properties without any of the risks commonly associated with drugs, catalyzed support for the DSHEA.²⁹

Like the Dietary Supplement Act, the DSHEA classifies dietary supplements as food.³⁰ The distinction between food and drugs is critical. Unlike laws regulating drugs, the DSHEA places the burden on the FDA to prove that a dietary supplement is unsafe before removing it from the market.³¹ While pharmaceuticals must undergo years of clinical testing before the FDA will approve them for use, as “food” dietary supplements are not subject to pre-market tests.³² Most dietary supplements become available to consumers without FDA review or approval, and only in limited instances do new dietary ingredients (ingredients found only in products sold after 1994) receive pre-market evaluation to determine safety.³³

28. See Michael A. McCann, *Dietary Supplement Labeling: Cognitive Biases, Market Manipulation, & Consumer Choice*, 31 AM. J.L. & MED. 215, 219 (2005) (describing the positive ways in which consumers view dietary supplements).

29. William J. Skinner, *Allowable Advertisements for Dietary Supplements*, 5 J. Pharmacy & L. 309, 309-310 (1996) (suspecting that the DSHEA was “solely responsible for the purchase of many telephone answering machines by Congressional committee staff offices and Members of Congress”).

30. 21 U.S.C. § 321(g)(1) (2007).

31. Federal Food Drug and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. § 301 et seq.).

32. 21 U.S.C § 355(a)(1) (2008) (stating that “no person shall introduce or deliver for introduction into interstate commerce any new drug, unless n approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug”; the DSHEA contains no comparable provision).

33. McCann, *supra* note 28 at 220. See also 21 U.S.C § 350(b) (Supp.1998), and *Pearson v. Shalala*, 164 F.3d 650, 652 (D.C. Cir. 1999) (holding that “the actual sale of dietary supplements is only regulated when the supplement contains a new dietary ingredient or poses a safety risk”). 21 U.S.C. § 350(c) defines a new dietary ingredient as one “that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994.” Under §350(b), while the manufacturer is not obligated to conduct tests, it must present data to the FDA 75 days prior to releasing the product indicating that ingredient is reasonably “expected to be safe.” An exception applies to unaltered ingredients not marketed as dietary supplements, but present within the food supply as an article of food prior to October 15, 1994.

Moreover, under section three of the DSHEA, the FDA can only prevent the release of a dietary supplement if it poses a “significant or unreasonable risk of harm.” The statute’s language proscribes courts from deferring to the FDA’s classification of a dietary supplement as hazardous: the standard for assessing the validity of an FDA finding is *de novo* review.³⁴ The DSHEA limits the FDA’s ability to withhold a dietary supplement from the general public, even when the product’s safety profile is questionable. It encourages the agency to wait until reports of adverse effects surface before launching a substantive inquiry or issuing a recall order.

Tommy Thompson, the former Secretary of Health and Human Services, said the following about the DSHEA: “I really think Congress should take a look at the food supplement law again. It doesn’t make any sense to me.”³⁵ As Michael A. McCann in the *American Journal of Law and Medicine* notes, a “health law that make no sense to the Secretary of Health and Human Services should certainly draw the attention of academics and policy-makers alike.”³⁶

C. Another critical distinction that the DSHEA virtually ignores: efficacy versus safety

Like food, dietary supplements need not be efficacious in order to be sold to consumers.³⁷ However, the food/drug distinction is fallacious as far as dietary supplements are concerned: people do not take dietary supplements because they are hungry or for their

34. 21 U.S.C. § 342(f)(1) (2005).

35. McCann, *supra* note 28 at 215.

36. *Id.*

37. *Id.* at 220-221.

taste. They take them because of perceived therapeutic properties.³⁸ Yet a dietary supplement can serve no beneficial purpose and continue to be sold in stores, as long as it does not pose an unreasonable risk of harm and is properly branded (i.e., the label correctly lists the product's ingredients).

D. The risk of harm posed by dietary supplements can be substantial

As the FDA's website points out, it remains the dietary supplement manufacturer's responsibility to ensure that "its product is safe before it is marketed."³⁹ This statement represents the DSHEA's ultimate objective: to invest the dietary supplement industry with autonomy in regulating its own products.⁴⁰ As a result, there is "no general requirement for manufacturers of dietary supplements to submit evidence of product safety" to the FDA.⁴¹ As for efficacy, the FDA will only evaluate the beneficial effects of a dietary supplement in order to determine the veracity of certain labeling claims.⁴² However, even its role in this regard is limited.

This discussion of the DSHEA should not be framed within a theoretical vacuum: dietary supplements can cause genuine harm. Many people turn to dietary supplements in

38. *Id.* at 222 (suggesting that "dietary supplements are often marketed as medicinal products rather than as food products").

39. U.S. Food and Drug Administration (FDA), *Dietary Supplements: Overview*, <http://www.cfsan.fda.gov/~dms/supplmnt.html> (last visited November 20, 2008).

40. McCann, *supra* note 28 at 244.

41. *Id.*

42. Dietary Supplements Health and Education Act, Pub. L. No. 103-417, 108 Stat 4325 (1994) (codified as amended 21 U.S.C. § 342 et seq.). Part III of this paper will discuss the types of labeling claims the FDA regulates and prohibits.

43. McCann, *supra* note 28 at 224 (stating that "consumers who select dietary supplements because they regard conventional treatments as expensive are almost twice as likely to report poorer health status, and four times more likely to be uninsured").

44. *Id.*

lieu of traditional medicine because they are poor, lack health insurance, and cannot afford expensive prescription medication.⁴³ Some individuals believe that by taking dietary supplements, they are engaging in preventive healthcare; they also feel that dietary supplements can substitute for regular doctor's visits.⁴⁴ While the side-effects posed by drugs are not always evident even after approval, those associated with dietary supplements are significantly less clear.

Manufacturers frequently target retired or out-of-work seniors, as these individuals often face cost limitations when considering treatment options and are generally more susceptible to illness.⁴⁵ For instance, many seniors purchase anti-oxidants because they believe, based on word-of-mouth and improper labeling, that these substances help prevent cancer.⁴⁶ However, current studies have identified at least two anti-oxidants, Vitamin-E and Beta Carotene, which actually *increase* the risk of lung cancer.⁴⁷ Sadly, elderly consumers might compromise their ability to afford proper medical treatment by spending money on products that predispose them to the very conditions that necessitate treatment.

Similarly, manufacturers often target adolescents, given their propensity for making uninformed purchasing decisions.⁴⁸ Many teenagers take the supplement "creatin monohydrate" because of its supposed beneficial effects on athleticism and endurance.⁴⁹ Yet, scientists have not made any clinical determination regarding the safety or efficacy of creatin

45. *Id.*

46. *Id.*

47. *Id.*

48. *Id.* at 225 (stating that adolescents have "a greater tendency than adults to take dangerous risks, weigh short-term consequences more heavily than long-term consequences, and act impulsively").

49. *Id.* at 226.

monohydrate.⁵⁰ In fact, studies have shown that creatin monohydrate can produce various side-effects, including cramps, gastrointestinal complications, and even kidney dysfunction.⁵¹ Sometimes, supplements marketed as boosting athleticism may even become a gateway to anabolic steroid use.⁵²

The DSHEA has forced the FDA to adopt a “sit and wait” approach to the regulation of potentially harmful nutritional supplements. Even if it wishes to remove a supplement from the market, it must first compile evidence indicating that the supplement presents a “significant or unreasonable risk of harm.” It bears the burden of proof at trial, and courts are statutorily proscribed from deferring to its findings (or so a literal interpretation of the statute suggests).⁵³ Unless Congress changes the law, the autonomy manufacturers enjoy might precipitate an outbreak of severe and lethal side-effects, comparable to those caused by ephedra in the early 1990s (when legislation had not yet expressly limited the FDA’s regulatory authority).⁵⁴

III. LABELING CLAIMS UNDER THE DSHEA

A. The two types of labeling claims that manufacturers can make: health and structure/function claims

50. *Id.*

51. *Id.*

52. *Id.* See also Katcheressian, *supra* note 15 at 629 (describing the initial classification and marketing of “androstenedione,” an anabolic steroid, as a dietary supplement. Mark McGuire was one famous user of this product).

53. Dietary Supplements Health and Education Act, Pub. L. No. 103-417, 108 Stat 4325 (1994) (codified as amended 21 U.S.C. § 342 et seq.).

54. Cohen, *supra* note 4 at 181 (arguing that the FDA’s regulation of dietary supplements prior to the DSHEA was based on “the belief that only strong government action could protect individuals from harm that they had no way of combating on their own,” rather than the importance of access to dietary supplements).

The DSHEA allows the FDA to evaluate statements made by manufacturers on the label. However, the FDA does not typically evaluate statements made in advertisements or literature that does not physically accompany the supplements.⁵⁵ That role has been delegated to the FTC, and deserves separate attention in another paper.⁵⁶

The only affirmative labeling requirement that applies to all manufacturers concerns the labeling of ingredients. As a general rule, dietary supplements must bear labels accurately indicating their ingredients: the manufacturer must properly identify the name of the ingredient and its quantity. The label only needs to identify ingredients present “in significant quantities.”⁵⁷ Additionally, products that contain herbal or botanical ingredients “must state from which part of the plant” the ingredients are derived.⁵⁸ The label must also identify the product as a dietary supplement.⁵⁹

Efficacy only becomes an issue when a manufacturer claims its dietary supplement does something. The manufacturer cannot state that a supplement can be used to “cure or

55. See John E. Villafranco and Andrew B. Lustigman, *Regulation of Dietary Supplement Advertising: Current Claims of Interest to the Federal Trade Commission, Food and Drug Administration and National Advertising Division*, 62 FOOD & DRUG L.J. 709, 709-710 (2007) (stating that “under a liason agreement, the Federal Trade Commission (FTC) acts as the primary regulator of dietary supplement advertising and the Food and Drug Administration (FDA) possesses primary enforcement responsibility for dietary supplement claims made in ‘labeling’”). See also *supra* note 41 (distinguishing labels from advertisements when the latter is “physically separate from the dietary supplements”)

56. 15 U.S.C. § 52(a)(1) (vesting the FTC with authority to prohibit false advertisement that “is likely to induce, directly or indirectly, the purchase in or having an effect upon commerce, of food, drugs, devices, services, services, or cosmetics). The FDA can and does aid the FTC in its investigation of nutraceutical advertising, supplying it with the scientific information it needs.

57. 21 U.S.C. § 343(b)(F)(i) (1994) (stating that “a dietary ingredient shall not be required to be listed if it is not present in a significant amount). § 343(b) does not define “significant amount.”

58. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, <http://www.cfsan.fda.gov/~dms/dietsupp.html> (last visited November 20, 2008).

59. 21 U.S.C. § 321(ff)(2)(C) (1994).

60. 21 U.S.C. § 343(r)(6) (1994).

treat” a disease: this prohibition constitutes the DSHEA’s strictest requirement.⁶⁰ However, the DSHEA allows manufacturers to make two types of claims 1) health claims (e.g., “the consumption of Omega-3 has been linked to a reduced risk of cancer”),⁶¹ and 2) structure/function claims (e.g., “the consumption of Omega-3 has been linked to improved cardiovascular function”).⁶²

The distinction between a “health claim” and a statement indicating that a supplement can be used to treat or cure a disease (a “disease claim”) is vague. Notwithstanding the DSHEA’s prohibition against disease claims, courts have limited the FDA’s ability to restrict health claims (claims describing the relationship between consumption of a nutrient and incidence of a particular disease), even when third-party studies regarding efficacy are inconclusive. Structure/function claims, moreover, are subject to an even lesser standard of substantiation.

i. Health claims under the DSHEA

While the DSHEA prohibits manufacturers from stating that a dietary supplement can be used to treat a disease, the label can describe the relationship between a supplement and disease prevention. This description constitutes a health claim (like, “the use of beta-carotene helps decrease the risk of cancer”).⁶³ While the manufacturer is not required to conduct

61. See 21 U.S.C. § 343(r)(6) (1994). See also Trisha L. Beckstead, *Caveat Emptor, Buyer Beware: Deregulation of Dietary Supplements upon Enactment of the Dietary Supplement Health and Education Act of 1994*, 11 SAN JOAQUIN AGRIC. L. REV. 107, 113-115 (2001) (defining a “health claim” as one that associates a supplement with disease prevention).

62. 21 U.S.C. § 343 (r)(6)(A) (1994) (defining a permissible structure/function claim as one that “describes the role of a nutrient or a dietary supplement intended to affect the structure or function in humans”).

63. 21 C.F.R. § 101.14 (1998) (describing a health claim as “a claim that characterizes the relationship of any nutrient in the food to a disease or health-related condition”).

64. *Id.*

studies verifying its statements, the FDA must review and authorize any health claim made on the label.⁶⁴

The FDA requires “significant scientific agreement” that a health claim is accurate.⁶⁵ This standard does not derive from the DSHEA, but was established by the FDA pursuant to the Administrative Procedure Act (which invests federal agencies with rulemaking authority to execute laws passed by Congress).⁶⁶ The FDA has asserted that its evaluation of health claims is based on objective factors, most importantly scientific consensus as evidenced by institutional (governmental and nongovernmental) studies.⁶⁷

The FDA can exercise one of two options in dealing with an improper health claim: 1) it can reclassify the statement as a disease claim, and remove the product from the market, or 2) determine that the statement remains a health claim, but is based on inadequate findings and therefore unsubstantiated.⁶⁸ In either instance, it can require the manufacturer to re-label its product.⁶⁹ The manufacturer’s duty under the final rule is to notify the FDA of its claim

65. *Id.*

66. 21 C.F.R. § 101.70 (2005) (investing the FDA with discretionary authority to approve or reject health claims); 5 U.S.C. § 553 (investing executive agencies with broad rulemaking authority). *See also generally* James Robert Dean, Jr., *FDA at War: Securing the Food that Secured Victory*, 53 Food & Drug L.J. 453, 509-511 (1998) (discussing the interaction between the FDCA and the APA within the realm of administrative law).

67. 21 C.F.R. § 101.14(c) (stating that the FDA will authorize a health claim “when it determines, based on the totality of publicly available scientific evidence,” including “evidence from well-designed studies conducted in a manner which is consistent with generally recognized procedures and principles,” that “there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence”).

68. *Id.*

69. 21 C.F.R. § 101.14(e)

within 30 days of marketing the dietary supplement, and submit all necessary documentation in support of the claim.⁷⁰

Manufacturers can circumvent FDA scrutiny by making “qualified” health claims. In *Pierson v. Shalala*, the D.C. Circuit held that a prohibition on a “potentially misleading” health claim is an unconstitutional infringement on commercial speech, where inclusion of a disclaimer could cure the misleading nature of that claim.⁷¹ For example, if a health claim regarding antioxidants is accompanied by a disclaimer stating, “Studies regarding the effects of antioxidants in reducing cancer are inconclusive,” the claim is no longer misleading and the agency must approve its use.⁷²

ii. *Structure/function claims*

Structure/function claims are statements that describe the beneficial effects a nutrient has on a physiological function or system (e.g., cardiovascular function or the immune system).⁷³ For instance, the statement “studies indicate that Omega-3 acids can promote ocular health” constitutes a structure/function claim. It does not name a disease or purport to treat a condition, but expressly suggests that the product can enhance a physiological function.⁷⁴ While the manufacturer is required to keep in its possession third-

70. 21 U.S.C. § 343(r)(6)(B).

71. See *Pierson v. Shalala*, 164 F.3d 650, 657-659 (D.C. Cir. 1999) (holding that a restriction on potentially misleading health claims that are curable through disclaimers violates the First Amendment). Part IV of this paper will discuss the role of the First Amendment within the context of health and structure/function claims.

72. *Id.*

73. 21 U.S.C. § 343(r)(6)(A) (1994).

74. Apart from its general or purported meaning, a patient with glaucoma or macular degeneration might infer from the label that the product can slow or reverse the progression of her disease, and even restore lost vision.

75. 21 U.S.C. § 343 (r)(6)(B). The DSHEA requires that a manufacturer “ha[ve] substantiation” regarding the truthfulness of a claim; it does not require the manufacturer to submit evidence of substantiation to the FDA.

party studies substantiating any structure/function claims, it is not required to submit documents before marketing products with these claims.⁷⁵ Moreover, the FDA does not usually evaluate scientific studies regarding the veracity of a structure/function claim.⁷⁶ Unsubstantiated structure/function claims are permissible as long as they are accompanied by the following 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.”⁷⁷ The manufacturer’s only duty is to notify the FDA “no later than 30 days after marketing the dietary supplement that such a statement is being made.”⁷⁸

B. Glaring deficiencies in the DSHEA’s labeling provisions

The most significant problem concerning labeling claims is that the DSHEA does not require proper testing on the part of manufacturers, nor does it articulate preclearance criteria for structure/function claims. As some customers have relatively subdued expectations regarding dietary supplements (largely because they have no way of gauging whether a supplement measures up to claims made on the label or in advertising), they are not likely to lodge complaints with the FDA over a product’s inefficacy.⁷⁹ Thus, manufacturers can continue selling supplements carrying labels that advertise a variety of beneficial effects on the human body, in the absence of any clinical determination authenticating those claims.

76. See generally Stephen H. McNamara, *So You Want to Market a Food and to Make a Health Claim—How Far Can You Go? What Rules of Law Will Govern the Claims You Want to Make*, 53 FOOD & DRUG L.J. 421, 431 (1998) (suggesting that there is little to no preclearance scrutiny that the FDA applies to structure/function claims).

77. 21 U.S.C. § 343(r)(6)(c).

78. *Id.*

79. McCann, *supra* note 28 at 221.

80. Cohen, *supra* note 4 at 186.

Furthermore, as one writer puts it, the “role of spin cannot be ignored.”⁸⁰ While prohibited from claiming that a supplement can be used to treat arthritis, a manufacturer can claim that its product “improves joint health and flexibility.” Consumers are likely to construe that structure/function claim as evidence that the supplement can mitigate arthritis.⁸¹

The standards governing the regulation of health claims since the passage of the DSHEA are also lax. Prior to the DSHEA, a dietary supplement making a health claim of any kind was reclassified as a drug, and the manufacturing entity was subject to criminal prosecution for making any unauthorized claims.⁸² Now, since *Pierson*, manufacturers can claim that their products help in preventing specific diseases, even if studies are inconclusive, as long as a disclaimer is displayed on the label. The problem with disclaimers is that consumers often neglect to pay attention to them. Also, advertisements (which are not subject to FDA regulation) typically communicate information to consumers that dissuade them from acknowledging the disclaimers: they feel that they know enough without having to read the label to make an educated purchasing decision.

IV. CONGRESS MUST AMEND THE DSHEA AND IMPOSE A HIGHER STANDRD OF ACCOUNTABILITY ON MANUFACTURERS

Congress must amend the DSHEA to better ensure the safety of dietary supplements and require manufacturers to authenticate labeling claims through clinical testing. One of the difficulties in proposing a meaningful amendment is that it must accommodate the interests

81. *But See* Robert Pinco and Paul D. Rubin, *Ambiguities of the Dietary Supplement and Health Education Act of 1994*, 51 FOOD & DRUG L.J. 383, 390 (suggesting that the FDA might prohibit a statement of this kind as an impermissible disease claim).

82. *See* Termini, *supra* note 14 at 276 (stating that prior to Congress’ adoption of the DSHEA, the “FDA used its power of seizure, prosecution or the threat of treating health claims of dietary supplements under the tough ‘new drug’ approval standards to control the dietary supplement industry”).

of three separate groups: the government, manufacturers, and consumers.⁸³ The government's interest is in protecting public health: the FDA's objective is that dietary supplements are safe and that all claims made on the label are truthful.⁸⁴ The manufacturer's interest is in maximizing profits and minimizing the risk of litigation. The consumer's interest is in maintaining affordable access to alternative medicines that improve health.⁸⁵ Drafting legislation that can reconcile these divergent interests will prove challenging, but Congress must hold manufacturers to a higher standard of accountability than that imposed under the DSHEA.

A. Congress should amend section 342 of the DSHEA so that the FDA only has to show a "risk of harm," rather than a "significant or unreasonable" risk before removing a dietary supplement from the market

Section 342 of the DSHEA authorizes removal of a supplement from the market only if it presents a "significant or unreasonable risk of harm."⁸⁶ The government bears the burden of proof: the FDA must show by a preponderance of the evidence that a dietary supplement poses a significant or unreasonable risk of harm to consumers.⁸⁷ The question becomes: what constitutes an "unreasonable" risk of harm? When assessing reasonableness in other contexts (e.g., negligence), courts will perform a risk-benefit analysis, balancing the benefits accruing from a particular activity against the harm. Is that the sort of analysis courts must undertake in determining whether the FDA is justified in banning a dietary supplement? In

83. Iona N. Kaiser, *Dietary Supplements: Can the Law Control the Hype*, 37 HOUS. L. REV. 1249, 1271 (2000).

84. *Id.*

85. *Id.* at 1272.

86. 21 U.S.C §342 (f)(1) (1994).

short, yes: according to the FDA, the term “unreasonable risk” entails a “balancing test in which the benefits of the product or activity are weighed against its dangers.”⁸⁸

By contrast, the term “significant” entails “an evaluation of risk alone.”⁸⁹ The risk can be significant but reasonable if the benefits “were great enough to outweigh the risks.”⁹⁰ The language of Section 342 is disjunctive: even if a supplement poses a reasonable risk of harm, the FDA retains discretion to prohibit its sale if the risk is “significant.”

However, a more appropriate standard would allow for removal of a dietary supplement where it poses any risk of harm. The terms “significant” and “unreasonable” are subject to permissive interpretation. The statute suggests that certain risks of harm may be reasonable or insignificant. Consequently, a manufacturer can argue that even though its product poses a risk, the risk is not substantial or significant in comparison to the benefits, and that removal is therefore unjustified. Obviously, the manufacturer’s first defense would be that its product does not pose any risks. Yet the phrase “significant or unreasonable” empowers the manufacturer to resist removal efforts by the FDA, even when it acknowledges that its nutraceutical is harmful.⁹¹

87. 21 U.S.C. §342 (f)(1)(D) (1994).

88. 69 Fed. Reg. 6788-01, 6822-23 (Feb. 11, 2004) (to be codified at 21 C.F.R. pt. 119), page 6823. *See also* Hi-Tech Pharmaceuticals Inc. v. Crawford, 505 F. Supp. 1341, 1353 (N.D. Ga., 2007) (holding that the proper standard of analysis under section 342 constitutes the “risk-benefit” balancing test).

89. 69 Fed. Reg. 6788-01, 6822-23 (Feb. 11, 2004) (to be codified at 21 C.F.R. pt. 119), page 6823.

90. *Id.*

91. *See* Jennifer Akre Hill, *Creating Balance: Problems within DSHEA and Suggestions for Reform*, 2 J. FOOD L. & POL’Y 361, 391 (2006) (suggesting that section 342 divests the FDA of its powers of enforcement).

92. 505 F. Supp. 2d at 1347.

Hi-Tech Pharmaceuticals, Inc. v. California exemplifies the inclination of manufacturers to make this argument. In *Hi-Tech*, a manufacturer challenged the FDA’s prohibition of any supplement containing the ingredient ephedrine alkaloids (or EDS).⁹² The FDA pointed to multiple studies demonstrating that EDS raises blood pressure and increases heart rate, compounding the risk of stroke, heart attack, and death. However, Hi-Tech argued that the FDA had “minimized and disregarded” the benefits associated with EDS, including “weight loss,” and that it had therefore acted in an “irrational” and “arbitrary” manner.⁹³

The district court ruled in the FDA’s favor, holding that the agency had undertaken a proper risk-benefit analysis and identified only a “short-term weight loss” associated with use of ephedrine, which by itself was “insufficient to positively affect cardiovascular risk factors associated with being overweight or obese.”⁹⁴ The court granted summary judgment for the FDA partly because there was no genuine issue of material fact that ephedrine posed a *fatal* risk of harm. However, the FDA’s obligation to undertake a risk-benefit analysis before prohibiting the sale of a dangerous substance like ephedrine suggests that a less severe risk may not justify a ban on a dietary supplement.

B. Congress should shift the evidentiary burden onto manufactures and require Courts to defer to the FDA’s findings

Congress must also shift the burden onto manufactures to refute findings that a dietary supplement is hazardous. Currently, Section 342 of the DSHEA states that the government shall bear the burden of proof “on each element to show that a dietary supplement is adulterated” (i.e., presents a significant or unreasonable risk of harm).

93. *Id.* at 1356.

94. *Id.* at 1356-1357.

Moreover, it requires courts to apply de novo review in determining whether a dietary supplement is unsafe.⁹⁵

This standard impairs the FDA's ability to protect the public from potentially dangerous dietary supplements, and constitutes a departure from the general approach courts take in according deference to administrative agencies.⁹⁶ It may transform trial proceedings regarding the safety of a product into a "battle of the experts," giving rise to pharmacological or medical issues that judges are ill-suited to decide.⁹⁷ Since the FDA must show by a preponderance of the evidence that its own studies prevail over those submitted by the manufacturer, in particularly close cases, where evidence regarding the safety of a product is inconclusive, manufacturers may overcome an FDA ban.

Fortunately, appellate courts have been reticent in strictly interpreting this statutory language. For example, in *NVE, Inc. v. Department of Health and Human Services*, the Third Circuit declined to apply de novo review and deferred to the FDA's finding that any supplement containing EDS posed an unreasonable risk of harm.⁹⁸ The Court declared that under the Administrative Procedures Act, where a private party challenges the findings of an administrative agency, the ordinary standard of review is abuse of discretion.⁹⁹ The Court also held that the provision in section 324 requiring de novo adjudication is limited to

95. *Id.*

96. *See Chevron U.S.A. v. Natural Resources Defense Council, Inc.* 467 U.S. 837, 86 (1984) (holding that absent congressional intent, an administrative agency's interpretation of statute is entitled to judicial deference).

97. *See generally* *Nutraceutical Corp v. Von Eschenbach* 459 F.3d 1033, 1043 (2006) (holding that the "review of scientific literature is properly in the province of the FDA) (10th Cir. 2006); *Weinberger v. Bentex Pharms, Inc.*, 412 U.S. 645, 653-654 (stating that the FDA is "peculiarly suited" to assess conflicting scientific reports, a task "not well left to a court without chemical or medical background," as it "necessarily implicates complex chemical and pharmacological considerations").

98. *NVE, INC. v. Department of Health and Human Services*, 463 F.3d 182, 196-197 (3rd Cir. 2006).

99. *Id.* at 191.

“enforcement actions” brought by the FDA (where the FDA seeks injunctive relief or criminal penalties against a manufacturer).¹⁰⁰

Similarly, in *Nutraceutical Corp. v. Von Eschenbach*, the Tenth Circuit overruled the District Court and deferred to the FDA’s construction of the phrase “significant or unreasonable risk of harm.”¹⁰¹ Like the Third Circuit, the Court upheld the FDA’s ban on all supplements containing ephedrine and explained that the judiciary may set aside agency action only if the action is arbitrary, capricious, or an abuse of discretion.¹⁰² However, it simultaneously acknowledged that courts must apply the de novo standard in enforcement actions brought against private manufacturers.¹⁰³

The distinction between “APA actions” and “enforcement actions” indicates that when the FDA seeks an injunction prohibiting a company from selling its product, courts will apply de novo review.¹⁰⁴ Quite possibly, the Tenth Circuit’s expansive reading of section 324 stems from the number of deaths caused by ephedrine. Other courts may not espouse that reading, especially when considering actions against less harmful supplements. The lower court in *Nutraceutical* interpreted section 342 literally: it held that the FDA had not met its burden in demonstrating that ephedrine at a dosage of 10 milligrams or less poses a significant or unreasonable risk of harm.¹⁰⁵ Similarly, the district court in *NVE, Inc.* asserted that Congress “intended all issues, *both factual and legal* [emphasis added], to decide any

100. *Id.* at 194-195.

101. 453 F.3d at 1043.

102. *Id.* at 1037-1038.

103. *Id.* at 1037.

104. *Id.*

105. *Nutraceutical Corp. v. Crawford*, 364 F.Supp.2d 1310, 1320-21 (D.Utah 2005).

issue under this paragraph [21 U.S.C. §342(f)(1)] on a de novo basis.”¹⁰⁶ Therefore, giving the “FDA deference on its legal determinations would be inconsistent with Congress’ intentions.” Consequently, it held that the FDA’s “scientific evaluations are entitled to deference.”¹⁰⁷

While *Nutraceutical* deserves credit for recognizing the FDA’s authority to prohibit ephedrine, a congressional mandate reinforcing that authority will generate stronger protections for consumers. Section 342 clearly states that “the Court shall decide any issue under this paragraph on a de novo basis.”¹⁰⁸ Section (1)(A) of that “paragraph” includes the “significant or unreasonable risk” element that the FDA bears the burden of meeting. The Third and Tenth Circuit declined to read the de novo provision literally, but other circuits and lower courts (like the district courts in *Nutraceutical* and *NVE*) may do so. To avoid a potential split, Congress should change the standard of review to abuse of discretion and prescribe agency deference.

C. The DSHEA should require manufacturers to conduct tests to determine the long-term safety and efficacy of their products:

In order to ensure (as adequately as possible) safety and efficacy, Congress must implement testing guidelines. Under the current “reactive” regulatory scheme, the government might not remove a dietary supplement unless a significant number of consumers become sick.¹⁰⁹ Take ephedrine: as the Tenth Circuit put it, the FDA “never

106. *NVE Inc. v. Department of Health and Human Services*, No. 04-cv-999 (JAP) , slip op. at 6 (D.N.J. Aug. 4, 2004).

107. *Id.* at 4.

108. 21 U.S.C. § 342(f)(1) (2005).

required manufactures to provide data on the benefits or safety of ephedrine use.” The FDA allowed ephedrine to “enter the market without findings of safety or efficacy.”¹¹⁰ Only after its adverse effects became public knowledge did the agency pull it from the market.

Mandatory testing will enable the FDA to discern threats to public health and act before harm ensues. Moreover, it will enhance the likelihood that claims made on the label are truthful.

i. The European Union requires testing for vitamins

The European Union, in response to several episodes of food contamination in the late 1990s, enacted measures to protect consumers from potentially hazardous dietary supplements.¹¹¹ In 2002, the European Parliament and Council adopted the “Food Supplements Directive,” or FSD.¹¹² The FSD established a “positive list” of 112 substances that EU regulatory agencies had deemed fit for consumption (like Vitamin C and Iron) based on existing data. A manufacturer that wishes to sell a product not included on that list must apply for approval and submit “good quality data” demonstrating that its product is safe.¹¹³ The application process can take two or three years, and upon receiving approval the manufacturer must make its data publicly available.¹¹⁴ EU legislation overrides domestic legislation, so all member states must enforce the FSD.¹¹⁵

109. See generally Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 702 (describing the DSHEA’s enforcement approach as “similar to that used at the beginning of the century”).

110. *Nutraceutical Corp.*, 459 F.3d at 1039.

111. Fiona LeCong, *Food Supplements Directive; An Attempt to Restore the Public Confidence in Food Law*, 29 LOY. LA. INT’L & COMP. L. REV. 105, 106 (2007).

112. *Id.*

113. *Id.* at 109.

114. *Id.*

115. *Id.* at 108.

The FSD has sustained several challenges by manufacturers in European courts, particularly in Britain, and has forced domestic governments to remove hundreds of dietary supplements from the market.¹¹⁶ Yet it stands as good law.¹¹⁷ It does not require showings of efficacy, but it goes far beyond the DSHEA in imposing on manufacturers an affirmative duty to ascertain that their products are safe. The FSD inverts the DSHEA's most basic assumption that a dietary supplement is safe until proven otherwise, and provides a constructive example of government oversight that does not compromise access to goods.

ii. Manufacturers should be allowed to sell their products while conducting tests and submitting data to the FDA

The FDA needs broad discretion to develop whatever standard of efficacy and safety it believes manufacturers should meet, comparable to the discretion it wields over drugs. The regulations governing pharmaceuticals require years of FDA-approved testing, divided into phases, before a drug can be sold on the market. For instance, Phase I studies usually involve a small number of healthy participants (20 to 80), and are limited to determining appropriate dosing, documenting how a drug is metabolized, and identifying short-term side-effects.¹¹⁸ Phase II trials not only include a greater number of participants, anywhere from 100 to 300, but also include participants suffering from a disease the drug is intended to treat. Phase II

116. *Id.* at 111.

117. *Id.*

118. U.S. Food and Drug Administration (FDA), *Inside Clinical Trials: Testing Medical Products in People*, <http://www.fda.gov/fdac/special/testtubetopatient/trials.html> (last visited November 30, 2008).

119. *Id.*

trials test for efficacy.¹¹⁹ Phase III trials involve an even larger number of participants (anywhere from 1,000 to 3,000), and yield a more nuanced assessment of the product's benefits and side-effects. If Phase III tests indicate that a product is effective, and the risks of side-effects are acceptable, the FDA will approve it for use. However, the FDA will occasionally mandate phase IV trials. Phase IV trials are conducted after a drug is approved and placed on the market, with the purpose of ascertaining the drug's long-term effects.¹²⁰

If the FDA possesses substantial data concerning the safety and efficacy of a dietary supplement, it should not require the manufacturer to conduct tests. For instance, since data regarding the safety and structure/function benefits of Vitamin C is fairly established, additional testing is not necessary.¹²¹ On the other hand, if the FDA has reason to suspect that the interaction of Vitamin C with other substances contained in a supplement poses a risk, it should require tests. If it lacks substantial data regarding the veracity of structure/function claims made on the label, it should also require tests.

In general, *pre-market* tests (tests a manufacturer must conduct before its product can be approved for sale) should not become the norm. The DSHEA's distinction between dietary supplements and drugs is not based on some notion unique to members of Congress; it is indicative of society's positive attitude toward dietary supplements. Many people who take supplements daily, who may not be confident of their effects but buy them anyway, would not wish compromise access to these products by subjecting them to lengthy tests. They see dietary supplements as something different than drugs. Dietary supplements are viewed as "natural," and lacking the synthetic properties that make pharmaceutical products

120. *Id*

121. *But See* McCann, *supra* note 28 at 265 (stating that while past studies have demonstrated that Vitamin C at a reasonable dosage is safe, recent studies "suggest that certain levels of Vitamin C consumption might even prove harmful").

risky.¹²² Thus, extending the FDA's drug testing scheme to dietary supplements would elicit little support. The reality is that many dietary supplements are safe, and as a practical matter do not require the rigorous testing imposed on drugs.

Instead, the FDA should use phase IV trials as an appropriate testing model for dietary supplements. Phase IV trials test pharmaceutical products that have already been approved for use; their purpose is to assess the long-term efficacy and side-effects of a drug. The FDA can narrow the scope of these trials by requiring testing of supplements that prior studies have not proven safe or effective, according to whatever scientific consensus the FDA deems appropriate. Since manufacturers can continue selling dietary supplements while conducting tests, they retain a source of revenue to subsidize their research.

The FDA should determine the duration of tests and degree of efficacy that a nutraceutical must demonstrate.¹²³ Double-blind studies are one way of evidencing efficacy; manufacturers might have to show some statistical disparity in health improvements between subjects taking the test supplement and those taking a placebo.¹²⁴ The FDA should formulate its efficacy determinations based on the type of health or structure/function claims each manufacturer makes. The FDA should encourage manufacturers of the same supplement to conduct joint studies and share in the cost of testing. If tests indicate that a dietary supplement does not comport with the manufacturer's health or structure/function claims, the FDA should force the manufacturer to issue a recall and re-label its product accordingly. Conversely, the FDA might require the manufacturer to provide a copy of the study's results

122. *Id.* at 226 (describing the tendency of consumers to equate the word "natural" with "harmless").

123. Kaiser, *supra* note 82 at 1274 (advocating a new regulatory model whereby the FDA must approve all nutraceutical labeling statements).

124. *See generally* Kathleen M. Boozang, *The Therapeutic Placebo: The Case for Patient Deception*, 54 FLA. L. REV. 687, 690-691 (2002) (describing the therapeutic potential of placebos in great detail, and suggesting that many of the beneficial effects associated with alternative medicine are based on the "placebo response").

within the package of the dietary supplement (comparable to the documentation accompanying the purchase of prescription medication), so that the consumer can make an educated decision if she contemplates buying that supplement again.

A testing regime of this kind will not lack problems. It could increase the cost of supplements, and determining whether a dietary supplement lives up to a very general structure/function claim, like “improves heart health,” will prove difficult. Congress could direct the FDA to impose more lenient testing standards than those applied to drugs in assessing efficacy. By contrast, the standards for determining safety should not be lenient; the FDA should reserve broad discretion to remove harmful products from the market. Any new regulatory scheme must be flexible and responsive to the needs of consumers and manufacturers. But Congress, in seeking to appease the nutraceutical industry, should not sacrifice testing as a basic requirement. It may increase costs, but ensuring that a hazardous dietary supplement does not evade FDA scrutiny and replicate the ephedrine disaster is a far greater priority than augmenting profit margins.

V. THE LITIGATION STRATEGY THAT MIGHT ACHIEVE THIS AMENDMENT

Litigation can be an effective way to encourage Congress in changing the DSHEA. Manufacturers will recognize that by taking measures to produce safe and effective dietary supplements, they can avoid paying costly judgments and the negative publicity that might result from a trial proceeding. The media attention that trials often generate can galvanize support among constituents for greater legislative protections. Litigation will also furnish a record of the type of side-effects associated with nutraceutical use, and the prevalence of fraud within the industry. This section will focus on California statutory claims, as California

has traditionally been among the friendliest forums for consumers (though the passage of Proposition 64 in 2004 has undermined that conception).¹²⁵ However, the strategy employed under California law can be used to bring claims against manufacturers in other states.

A. California's Unfair Competition Law can furnish one type of claim

California's Unfair Competition Law, or UCL (Bus. & Prof. Code §§17200), covers "a wide range of conduct,"¹²⁶ but has proven effective in vesting consumers with a private cause of action against manufacturers of FDA-regulated products.¹²⁷ The UCL proscribes any unlawful, unfair, or fraudulent business practice. Conduct can be "unfair" even if it does not violate another law. Section 17200 permits courts "to enjoin ongoing wrongful business conduct in whatever context such activity might occur."¹²⁸ The UCL is "equitable in nature," and precludes the recovery of compensatory or punitive damages.¹²⁹ However, restitution is recoverable: a court can compel a manufacturer to disgorge profits obtained through unfair business practices.¹³⁰

The UCL's scope is quite broad: a business practice needs to meet only one of the three statutory criteria (i.e., unlawful, unfair, or fraudulent) to constitute unfair

125. See Eugene S. Suh, *Stealing from the Poor to Give to the Rich? California Competition Law Requires Further Reform to Properly Restore Business Stability*, 35 SW. U.L. REV. 229, 239 (2006) (characterizing California's Unfair Competition Law prior to the enactment of Proposition 64 as the "most liberal approach to unfair competition law when compared to states with similar provisions"). Proposition 64 imposed new standing requirements on private plaintiffs bringing lawsuits against companies under the UCL. The following section will discuss these requirements.

126. Cal.Bus. & Prof.Code § 17200 (West 2008).

127. See generally *Cel-Tech Communications, Inc. v. Los Angeles Cellular*, 20 Cal.4th 163, 191-195 (Cal. 1999).

128. Cal.Bus. & Prof.Code § 17200 (West 2008).

129. *Id.*

130. *Corbett v. Superior Court*, 101 Cal.App.4th 649, 654-656 (Cal. Ct. App. 2002).

131. Cal.Bus. & Prof.Code § 17200 (West 2008).

competition.¹³¹ However, the phrasing of the statute suggests that a business practice can be lawful, but unfair or fraudulent and therefore actionable. In *Cel-Tech Communications v. Los Angeles Cellular Telephone Company*, the Supreme Court of California held that as long as the legislature has not expressly characterized a particular activity as lawful, it is actionable under the second or third elements of the UCL even if no other law prohibits the activity.¹³² Consequently, while a manufacturer's claims might comport with the DSHEA, the UCL still enables consumers to challenge deceptive labeling practices.

i. Manufacturers can be liable for fraud under the UCL

The UCL's fraud predicate differs from common-law fraud. It does not require intent to induce reliance or scienter, or actual reliance; the standard is whether a business practice is likely to deceive the public.¹³³ Courts have characterized the UCL as a "strict-liability" law. A party can establish fraud even if no one was deceived.¹³⁴

For example, *Pastoria v. Nationwide Ins.* held that an insurer's practice of not disclosing imminent policy changes was fraudulent under the UCL, because the changes were "material" and only disclosed after consumers purchased their policies.¹³⁵ Similarly, in *People v. McKale* the Court declared that the owner of a mobile home park acted fraudulently by requiring tenants to sign a contract containing rules and regulations that he was prohibited from enforcing.¹³⁶ For instance, one contractual provision allowing the owner

132. *Id.*

133. *Community Assisting Recovery, Inc. v. Aegis Security*, 92 Cal.App.4th 886, 191 (Cal. Ct. App. 2001).

134. *Id.*

135. *Pastoria v. Nationwide*, 112 Cal.App.4th 1490, 1498-99 (Cal. Ct. App. 2003).

136. *People v. McKale*, 25 Cal.3d 626, 632-633 (Cal. 1979).

137. *Id.* at 637.

to close the park's recreation hall at any time violated an ordinance stipulating that the recreation hall was not subject to closure by park management during reasonable hours.¹³⁷ Since tenants were unlikely to know of the existence of this law, the owner's attempt to impose an unenforceable agreement on them was deceptive and fraudulent.¹³⁸

One can argue that unsubstantiated structure/function health claims are also likely to deceive the public. It matters little whether the manufacturer has slapped a disclaimer on the label; the FDA's reluctance to evaluate the veracity of a statement does not negate its deceptive nature. Like the tenants in *McKale*, who lacked legal acumen, consumers will not infer that a structure/function claim is meaningless simply because the FDA has abstained from verifying that claim. They are more likely to assume that a claim is true, because the government has not taken action to prohibit use of the supplement.

Additionally, like the failure to disclose material policy changes in *Pastoria*, a manufacturer's failure to specify on a nutraceutical label that studies pertaining to a structure/function claim are inconclusive amounts to deception. For instance, in 2003 Nature's Youth, LLC, a manufacturer of anti-aging supplements, made all sorts of unsubstantiated structure/function claims on the labels of its nutraceutical, like "improves physical performance," and "speeds recovery from training and increases immune function."¹³⁹ Though reliance is not a requirement under the UCL, these statements could induce reliance. The FDA took no formal action against Nature, but after warning the company that its labeling practices were improper Nature voluntarily destroyed 5700 boxes

138. *Id.*

139. FDA, *Dietary Supplement Enforcement Report*, http://www.fda.gov/oc/whitepapers/chbn_summary.html (last visited Nov. 30, 2008).

of its misbranded product.¹⁴⁰ Unless manufacturers substantiate these types of claims by presenting adequate evidence of efficacy (to the extent the labeling advertises a particular health benefit), they could be liable for deception under the UCL, even before the FDA intervenes.

ii. *Labeling practices within the nutraceutical industry are “unfair” under the UCL*

The UCL’s “unfair” prong has been subject to intense debate, and appellate opinions have articulated various tests for distinguishing an unfair business practice from one that is fraudulent or unlawful.¹⁴¹ One test defines an unfair practice as conduct that is “immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers.”¹⁴² Alternately, *State Farm Fire & Casualty Co.* declared that courts “must weigh the utility of the defendant’s conduct against the gravity of the harm to the alleged victim.”¹⁴³ Another case, *Bardin v. Daimlerchrysler Corp.*, held that a UCL claim alleging unfairness within the consumer context must be “tethered” to violations of “specific constitutional, statutory, or regulatory provisions.”¹⁴⁴

Courts have characterized conspiratorial acts that deny consumers a meaningful choice as “unfair.” In *Smith v. State Farm Mutual Automobile Company et. al.*, plaintiffs filed suit against several insurance companies for requiring multi-vehicle owners to purchase

140. *Id.*

141. See Eugene S. Suh, *supra* note 129. See also *Cel-Tech*, 20 Cal.4th at 183-184 (illustrating inconsistent case law regarding the types of business practices that qualify as “unfair”).

142. See *People v. Casa Blanca Convalescent Homes, Inc.*, 159 Cal. App.3d 509, 530 (Cal. Ct. App. 1984).

143. See *Smith v. State Farm Mutual Automobile Ins. Co.* 93 Cal.App.4th 700, 718-719 (Cal. Ct. App. 2001).

144. See *Bardin v. Daimlerchrysler Corp.*, 136 Cal.App.4th 1255, 1261 (Cal. Ct. App. 2006).

a single policy covering all of their vehicles.¹⁴⁵ The Court of Appeal declared that the practice was unfair, because the gravity of harm (consumers were forced to purchase insurance for vehicles they do not drive) outweighed the utility of the conduct (consolidating all policies and maximizing the insurer's revenue).¹⁴⁶ Similarly, *State Farm Fire & Casualty Co. v. Superior Court* held that “systemically breaching a form contract affecting many consumers” would give rise to a claim of unfairness.¹⁴⁷

Under any of these standards, the sale of dietary supplements that manufacturers have neither proven safe nor effective amounts to unfair activity. A dietary supplement that poses a significant or unreasonable risk of harm can be tethered to a violation of section 342 of the DSHEA. For example, in May 2002 Best Life International issued a voluntary recall of one of its dietary supplements, Viga, after “it was found to contain sildenafil, the active ingredient in Pfizer’s Viagra.”¹⁴⁸ Sildenafil can cause “life-threatening lowering of blood pressure when taken with nitrates.”¹⁴⁹ Insofar as *Bardin* requires a regulatory or statutory violation for UCL claims alleging unfairness, the sale of Viga constitutes a violation of the DSHEA and satisfies that requirement (it also furnishes a UCL claim under the unlawful prong).

Alternatively, under the *State Farm* balancing test, the gravity of harm posed by selling a dietary supplement like Sinfadil greatly outweighs the benefits that accrue from use of that product. Furthermore, the sale of a dietary supplement that induces no beneficial

145. 93 Cal.App.4th at 718-720.

146. *Id.*

147. *State Farm Fire & Casualty Co. v. Superior Court*, 45 Cal.App.4th 1093, 1104 (Cal. Ct. App. 1996).

148. FDA, *Dietary Supplement Enforcement Report*, http://www.fda.gov/oc/whitepapers/chbn_summary.html (last visited Nov. 30, 2008).

149. *Id.*

effects is analogous to the systematic breach of a form agreement “affecting many consumers,” one example of an unfair business practice offered by *State Farm*. A dietary supplement that promises enhanced athletic performance can generate a breach of warranty claim if expert testimony shows that there is no causal relationship between that supplement and superior athleticism (a structure/function claim can be construed as an express warranty). The breach affects “many consumers,” thus meeting *State Farm’s* definition of an unfair business practice.

iii. The “injury in fact” requirement imposed by Proposition 64 will not impair UCL claims against manufacturers

The preceding discussion offers merely a general treatment of what plaintiffs have to assert in a UCL claim against nutraceutical manufactures. The passage of Proposition 64 in November 2004 has complicated UCL litigation. Prior to Proposition 64, plaintiffs alleging a violation of the UCL did not have to allege damage in their complaints. However, as modified by Proposition 64 plaintiffs under the UCL (section 17204) must show both injury-in-fact and the loss of property or money. Courts have also imposed a causation requirement: the unfair competition “must have caused the plaintiff to lose money or property.”¹⁵⁰

The phrase “injury-in-fact *and* the loss of property or money” is seemingly redundant. It suggests that monetary or proprietary damage is insufficient and that plaintiffs must show physical injury in order to file a UCL claim. However, courts have accepted monetary damage as meeting the “injury-in-fact” standing requirement. Examples of appropriate injuries include incidental damages suffered by the plaintiff in curing the defendant’s

150. *Hall v. Time, Inc.* 158 Cal. App.4th 847, 851-852 (Cal. Ct. App. 2008); *Laster v. T-Mobile USA, Inc.* 407 F. Supp.2d 1181, 1194 (S.D.Cal. 2005).

unlawful acts,¹⁵¹ or the loss of financial resources.¹⁵² Also, attorneys general, city attorneys, and district attorneys are not subject to section 17204's standing limitations: they do not need to show injury-in-fact or the loss of property to assert a UCL claim on behalf of the public.¹⁵³

Where evidence shows that a dietary supplement poses a risk of harm (e.g., lowers blood pressure, induces gastrointestinal complications, etc.), an injury-in-fact is probably demonstrable, especially if a plaintiff can show some physical injury resulting from consumption of that dietary supplement. However, the customer's monetary expenditure remains an adequate injury. Causation can be readily established: but for the structure/function claim made on the label, the plaintiff would not have bought the dietary supplement. Conversely, the attorney general can bring a UCL claim against a manufacturer without having to prove injury-in-fact; the attorney-general's only burden is to prove that the label was likely to deceive the public.

As a final note on California's Unfair Competition Law, because monetary damages are unavailable under section 17200, the optimal way to bring UCL claims against manufacturers is through class-action litigation. A class-action would allow for disgorgement of a significant portion of the manufacturer's profits as restitution.¹⁵⁴ Finding consumers who have purchased dietary supplements based on unsubstantiated claims should not prove difficult.

151. *Monarch Plumbing Co. v. Ranger Ins. Co.*, No. Civ. S-06-1357, 2006 U.S. Dist. LEXIS 68850 at 20 (E.D. Cal. Sept. 25, 2006).

152. *Southern California Housing Rights Center v. Los Feliz Towers Homeowners Assn. Bd.*, 426 F.Supp.2d 1061, 1069 (C.D. Cal. 2005).

153. Cal. Bus. & Prof. Code § 17204 (West 2008).

154. *Kraus v. Trinity Management Services, Inc.* 23 Cal.4th 116, 127 (Cal. 2000) (holding that disgorgement as a restitutionary remedy in class action suits is available under section 17200).

B. The California Legal Remedies Act: A way to bolster UCL claims

The California Legal Remedies Act, or “CLRA” (Cal. Civ. Code §1750) amplifies the legal arsenal of consumers. While the two are closely related, the CLRA lacks the UCL’s broad prohibition against deceptive activities: instead, section 1770 lists 23 “unlawful” business practices that trigger liability under the CLRA. Examples of prohibited acts applicable to FDA-regulated products include: passing off goods or services as those of another; misrepresenting the source, sponsorship, approval, or certification of goods or services; and misrepresenting that goods or services are of a particular standard, quality, or grade.¹⁵⁵ A practice that violates the CLRA can also give rise to a claim under the “unlawful” prong of the UCL.¹⁵⁶ The standing requirement is met if the unlawful business practices damages the consumer.¹⁵⁷ Section 1782, subdivision (b) contains a safe-harbor provision: the plaintiff must notify the defendant of the unlawful practice, and the defendant has 30 days after receipt of such notice to cure the plaintiff’s injury.¹⁵⁸ However, this safe-harbor does not apply where the plaintiff seeks injunctive relief. Under the CLRA, the plaintiff is entitled to compensatory and punitive damages or injunctive relief.¹⁵⁹

A nutraceutical manufacturer that makes unsubstantiated health claims has “misrepresented the...certification” of goods under section 1770. By placing the label “improves heart health” on a bottle of Omega-3 pills, the manufacturer has made a “certification” within the meaning of the statute: that Omega-3 promotes cardiovascular

155. Cal. Civ. Code §1770(a)(1)-(23).

156. Trenton H. Norris, *Consumer Litigation & FDA-Regulated Products: The Unique State of California*, 61 FOOD & DRUG L.J. 547, 558 (2006).

157. *Kagan v. Gibraltar Sav. & Loan Assn.*, 35 Cal.3d 582, 593 (Cal. 1984).

158. *Id.* at 590.

159. *Lazar v. Hertz Corp.*, 143 Cal. App. 3d 128, 142 (Cal. Ct. App. 1983).

functionality. Unverifiable labeling claims go beyond “puffery” (which courts have held is not actionable under either the CLRA or common-law fraud),¹⁶⁰ as a consumer might reasonably assume that the claim has been tested and is legitimate. While there is no affirmative duty on the manufacturer’s part to submit evidence of efficacy to the FDA, if the manufacturer is unable to present data verifying its claims, the plaintiff can make a compelling argument for misrepresentation at the summary judgment phase or trial.¹⁶¹

VI. DEFENSES MANUFACTURERS MIGHT ASSERT AGAINST ANY LEGAL CLAIMS

A. Manufacturers’ First Defense: The DSHEA preempts state law claims

The DSHEA lacks an express preemption provision. However, manufacturers may raise implied preemption as a defense, arguing that the regulation of dietary supplements falls within the federal government’s exclusive power and that state claims against manufacturers undermine federal regulatory policy.¹⁶² Manufacturers could allege that private litigation threatens the FDA’s ability to achieve uniformity in its regulation of food and drugs. Also, private litigation threatens the FDA’s primacy, because attorneys can challenge and courts can enjoin a manufacturing practice even when it does not violate an FDA rule, thereby usurping the agency’s role in making efficacy and safety determinations regarding dietary

160. Chamberlan v. Ford Motor Co. 369 F.Supp.2d 1138, 1144 (N.D. Cal. 2005); *see also Consumer Advocates et al., v. Echostar Satellite Corp.*, 113 Cal.App.4th 1351, 1361 (holding that statements akin to “mere puffing” do not give rise to liability).

161. *See Consumer Advocates et al.*, 113 Cal.App.4th at 1360 (holding that the standard for determining whether a statement by a company is deceptive, for all statutory causes of action, is whether the effect it would have on a reasonable consumer)

162. For a helpful discussion on preemption, *see In re Farm Raised Salmon Cases*, 42 Cal.4th 1077, 1089-1098 (Cal. 2008) (suggesting in dictum that a plaintiff would be barred by the doctrine of preemption from invoking a violation of the FDCA in order to bring a UCL claim against a food manufacturer).

supplements. This argument suggests that the FDA is in a better position, given its scientific expertise and experience, to authenticate labeling claims rather than courts.¹⁶³

At least one decision invalidates that argument: *Consumer Justice Center v. Olympian Labs, Inc.* held that the DSHEA does not preempt the UCL. That case concerned deceptive health claims regarding a dietary supplement. The California Court of Appeal maintained that Congress' decision not to allow private causes of action under the DSHEA has left "a considerable amount of room left for the states to occupy."¹⁶⁴ The defendant argued that the trial court's order of injunctive relief impaired the FDA's ability to impose uniform labeling requirements on manufacturers. The Court disagreed, stating that injunctive relief did not prevent manufacturers from complying with the FDA's separate labeling requirements.¹⁶⁵ The FDA's requirement of a labeling disclaimer was distinguishable from the issue of deceptive claims. Moreover, because Congress has included express preemption provisions in prior amendments to the FDCA (like the Medical Devices Act), its decision not to include express preemption in the DSHEA suggests that preemption runs contrary to congressional intent.

Under *Consumer Justice*, manufacturers resisting state claims in California on preemption grounds stand little chance of prevailing on that issue. Some commentators still argue that state action hinders access to dietary supplements, thereby conflicting with congressional objectives (e.g., promoting availability of dietary supplements).¹⁶⁶ Thus, a

163. See Norris, *supra* note 155 at 550 (arguing that a court's calculation of the risks posed by a particular drug or food article may conflict with the FDA's calculation of that risk).

164. *Consumer Justice Center v. Olympian Labs, Inc.*, 99 Cal. App.4th 1056, 1063 (Cal. Ct. App. 2002).

165. *Id.* at 1064.

166. Stephanie Kauflin, *Dietary Supplements: Is Availability Worth the Risks? Proposed Alternatives to the Present DSHEA Scheme*, 33 SETON HALL L. REV. 411, 432 (2003) (suggesting that because Congress' purpose

defense based on preemption seems credible from a policy perspective. However, unless *Consumer Justice* is overturned, preemption insofar as the DSHEA is concerned is not a legal bar against claims brought under California law.

B. Manufacturers' Second Defense: Restrictions on qualified health claims and structure/function claims violate the First Amendment, as these claims constitute a form of protected commercial speech

The seminal case on commercial speech, *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York*, held as a general matter that commercial speech receives some protection under the First Amendment, but less protection than non-commercial speech.¹⁶⁷ It advanced a four-part test for determining when restrictions on commercial speech violate the First Amendment: 1) the speech does not concern unlawful activity and is not misleading, 2) the asserted government interest is substantial, 3) the regulation directly advances the government interest, and 4) the restriction is not more extensive than is necessary to serve that interest.¹⁶⁸

In *Pierson v. Shalala*, the D.C. Circuit held that the standard for determining the constitutionality of FDA restrictions on health claims is whether the claim is “inherently misleading,” as opposed to “potentially misleading.”¹⁶⁹ In that case, the FDA declared that

in passing the DSHEA was to make dietary supplements more accessible to consumers, any state law undermining that purpose triggers the possibility of preemption).

167. *Central Hudson Gas & Elec. Corp v. Public Serv. Comm'n*, 447 U.S. 557, 563-64 (1980).

168. *Id.* at 566.

169. *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999).

the health claim, “consumption of fiber may reduce the risk of colorectal cancer,” was based on inconclusive evidence. The FDA argued that any health claims not supported by significant scientific agreement were “inherently misleading” and subject to restriction.¹⁷⁰

However, the Court stressed that “significant scientific agreement” was too amorphous a criterion for assessing whether a claim was inherently misleading.¹⁷¹ It stated that where evidence regarding a health claim is inconclusive, the claim is only “potentially misleading.” The effect of that distinction is that a potentially misleading claim cannot be suppressed if its misleading nature can be cured by inclusion of a disclaimer. The disclaimer need not be extensive: “The FDA does not approve this claim” is sufficient.¹⁷²

While *Shalala* does not undermine Congress’ authority to compel testing, it affects the FDA’s ability to impose labeling requirements on manufacturers. For instance, any amendment to the DSHEA authorizing the FDA to remove products that advertise unverified structure/function improvements may violate the First Amendment, because all structure/function claims are typically accompanied by the sort of disclaimer the D.C. Circuit has deemed acceptable (e.g., “this claim has not been evaluated by the FDA”). Though *Shalala* did not address restrictions on structure/function claims, health claims are subject to narrower scrutiny by the FDA than structure/function claims. If a restriction on qualified health claims is unconstitutional, a restriction on structure/function claims accompanied by disclaimers probably violates the First Amendment as well.

170. *Id.*

171. *Id.* at 660-661.

172. *Id.* at 654.

One way the FDA can comply with *Shalala* is by changing its criteria for evaluating the validity of health claims. The D.C. Circuit agreed with the plaintiff-manufacturer that the FDA is “obliged, at some point, to articulate a standard a good deal more concrete than the undefined ‘significant scientific agreement.’”¹⁷³ In creating that more definite standard, the FDA might require a statistical disparity between the weight of evidence supporting a claim and the weight of evidence against it. *Shalala* suggests that where the preponderance of evidence weighs against the veracity of a claim, a restriction on that claim will comport with the First Amendment.¹⁷⁴ If the FDA clarifies its standards for assessing health claims, courts will more readily defer to its findings. Manufacturers will also have clearer expectations of the efficacy showings they must make in order to substantiate their claims.

VII. CONCLUSION

The DSHEA necessitates revision. It has weakened the FDA’s regulatory authority over the dietary supplement industry, to the detriment of consumers. Congress’ decision to sacrifice safety for greater access has increased the risk of harm posed by nutraceutical products. Moreover, because manufacturers are not required to conduct tests, consumers are spending millions of dollars on products that are quite possibly ineffective. While devising new legislation to redress these problems may encounter significant resistance from manufacturers (and even some consumers), the need for greater oversight trumps the threat of resistance. The amendment this paper proposes may limit the number of dietary supplements

173. *Id.*

174. *Id.* at 659.

available on the market, but it will ensure that consumers are less likely to experience adverse side-effects and more likely to experience beneficial results.