

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

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## INTRODUCTION

In May 2007, CNN reported on a dermatologist who takes twenty dietary supplements every morning and another twenty supplements in the afternoon, all in an attempt to ward off illness and death.<sup>1</sup> That same report declared that “virtually no evidence exists that supplements can improve your health.”<sup>2</sup> Indeed, it cited studies evidencing the absence of any correlation between health benefits and dietary supplement intake.<sup>3</sup> Nevertheless, the federal government estimates that Americans “spend at least \$5.8 billion a year” on dietary supplements.<sup>4</sup>

While the Food and Drug Administration (FDA) regulates—and has always regulated—both dietary supplements and drugs, the two products are distinguishable.<sup>5</sup> A drug is any compound devised to treat or cure an illness.<sup>6</sup>

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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. *Id.*

4. *Id.*

5. 21 U.S.C. § 321(c) (1994).

Drugs are subject to vigorous premarket testing, involving lengthy double-blind studies, to determine both their safety and their therapeutic potential.<sup>7</sup> The FDA will release a drug only after determining that its likelihood of success in treating a disease outweighs any cognizable side effects.<sup>8</sup> By contrast, dietary supplements are categorized as “food” and require no premarket testing of safety or efficacy.<sup>9</sup>

In order to market their supplements, manufacturers rely on both advertising and labeling.<sup>10</sup> Unfortunately, the regulations governing labeling requirements within the supplement industry are quite permissive.<sup>11</sup> “Nutraceutical” products—functional foods taken to enhance health, like vitamins or herbal and botanical products intended for ingestion<sup>12</sup>—often carry labels that claim ambiguous benefits, but fail to demonstrate any measurable degree of efficacy.<sup>13</sup> Though deceptive, this practice remains legal under the current regulatory regime.

In 1994, Congress enacted a new law superseding the Food, Drug, and Cosmetics Act (FDCA) as the applicable statute governing the sale of dietary supplements: the Dietary Supplement Health and Education Act (DSHEA).<sup>14</sup> The findings incorporated in the statute suggest that the DSHEA was based on two policy considerations: (1) dietary supplements are presumptively “safe,” and (2) access to dietary supplements trumps concerns over safety.<sup>15</sup>

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6. 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”).

7. *Inside Clinical Trials: Testing Medical Products in People*, FDA CONSUMER MAG. (SPECIAL REPORT), Jan. 2006, available at <http://permanent.access.gpo.gov/lps1609/www.fda.gov/fdac/special/testtubetopatent/trials.html> (last visited Apr. 25, 2010).

8. *Id.*

9. Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 679–81 (1997).

10. 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, 202–05 (1997) (discussing the importance manufacturers placed on labeling in marketing the weight loss supplement ephedra).

11. Peter J. Cohen, *Science, Politics, and the Regulation of Dietary Supplements: It's Time to Repeal DSHEA*, 31 AM. J.L. & MED. 175, 186–87 (2005).

12. Kristen N. Nichols, *Nutraceuticals: In the Realm of Consumer Protection, Is the United States' Regulation Too Much or Not Enough*, 9 MICH. ST. U.J. MED. & L. 369, 369–70 (2005); see also 21 U.S.C. § 321(a) (1994).

13. Nichols, *supra* note 12, at 369–70.

14. Dietary Supplement Health and Education Act of 1994 (DSHEA), Pub. L. No. 103-417, 108 Stat. 4325 (1994) (codified as amended in scattered sections of 21 U.S.C.). The DSHEA became law on October 25, 1994.

15. See *id.* (stating multiple justifications for enactment of the DSHEA, including that “the nutritional supplement industry is an integral part of the economy of the United States,” that the industry “consistently projects a positive trade balance,” that “dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare,” and that consumers “should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements”); see also Ali Sachani, *Warning: Over-Consumption of This Product May Be Harmful to Your Health! Applying the Proposed Canadian Natural Health Product Regulatory Framework to Clarify the*

Accordingly, the DSHEA places the burden of proof on the FDA to show that a “dietary supplement . . . presents a significant or unreasonable risk of illness or injury,” and the FDA must make this showing before it can prohibit the sale of a supplement.<sup>16</sup> However, studies suggest that some dietary supplements serve no beneficial value.<sup>17</sup> Indeed, certain supplements contain ingredients that can actually worsen health.<sup>18</sup> Consequently, the DSHEA’s prioritization of access over safety and its failure to set guidelines for determining efficacy are misguided.

This Comment’s policy preferences are unequivocal: the need for a legislative framework that strengthens consumer protection constitutes a greater governmental interest than promoting access to goods.<sup>19</sup> Therefore, the purpose of this Comment 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) to 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.

First, to better ensure the safety of dietary supplements on the market, the amendment should replace the “significant or unreasonable risk of harm” provision of the DSHEA with a more specific, three-part standard for determining when a supplement warrants removal on safety grounds. Specifically, the amendment could advise removal where the supplement poses a risk of: (1) causing an allergic reaction; (2) compromising a patient’s immune system; or (3) adversely affecting the functionality of a patient’s organ systems. If the FDA feels that the risk of harm is negligible, it should compel the manufacturer to list any side effects linked to the supplement on the label of the product. Second, if studies indicate that a supplement’s efficacy is questionable, the amendment should vest the FDA with the authority to require the manufacturer to remove the claim or provide documentation of the study’s results within the product’s packaging.

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*Level of Substantiation 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”).

16. 21 U.S.C § 342(f)(1) (2006).

17. See Lauren J. Sloane, *Herbal Garden of Good and Evil: The Ongoing Struggle of Dietary Supplement Regulation*, 51 ADMIN. L. REV. 323, 332 (1999) (discussing the rise of products introduced to the market that have been proven neither safe nor effective).

18. 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. 269, 280 (2000) (identifying numerous adverse side effects, including dizziness, nausea, heart palpitation, and death, linked to dietary supplements).

19. See Jennifer Sardina, *Misconceptions and Misleading Information Prevail—Less Regulation Does Not Mean Less Danger to Consumers: Dangerous Herbal Weight Loss Products*, 14 J.L. & HEALTH, 107, 131–32 (suggesting that enactment of consumer-oriented legislation would increase the credibility and prosperity of the dietary supplement industry, because more consumers will gain confidence in the system).

Part I of this Comment discusses the DSHEA's legislative history and inadequacies. Part II assesses the type of unsubstantiated claims manufacturers can lawfully make. Part III delineates the aforementioned legislative amendment to the DSHEA, which would place the burden on manufacturers to prove that a dietary supplement is safe and effective. Part IV proposes a litigation strategy based on two California statutory claims (the Unfair Competition Law and the Consumer Legal Remedies Act) that might compel Congress to redress the DSHEA's deficiencies and exact the nutraceutical industry's compliance with any new regulatory scheme. Part V anticipates legal challenges manufacturers might mount against the new amendment and recommends ways in which the FDA can clarify its standards for authenticating health claims so that courts are inclined to rule in its favor.

## I

### THE LEGISLATIVE HISTORY OF THE DSHEA AND ITS SHORTCOMINGS

#### *A. Regulation of Dietary Supplements Was More Stringent Prior to Enactment of the DSHEA*

The FDA's ability to regulate dietary supplements has traditionally been limited.<sup>20</sup> The agency's concern with dietary supplements dates back to 1938, with the passage of the FDCA.<sup>21</sup> 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."<sup>22</sup> However, beyond investigating individual complaints, the FDA's supervision over nutraceutical manufacturing practices was minimal.<sup>23</sup> In 1962, the FDA imposed new regulations restricting the sale of high-level dosage vitamins, but withdrew them in response to consumer protests.<sup>24</sup> 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.<sup>25</sup>

In the late 1980s and early 1990s, an increased incidence of side effects associated with dietary supplements triggered greater FDA scrutiny. In 1989,

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20. Laura A.W. Khatcheressian, *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).

21. Federal Food Drug and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended in scattered sections of 21 U.S.C.).

22. Khatcheressian, *supra* note 20, at 624.

23. *Id.* (describing the obstacles the FDA faced in regulating dietary supplements).

24. *Id.* at 625.

25. *See, e.g.*, *United States v. Two Plastic Drums*, 984 F.2d 814 (7th Cir. 1993) (holding that because "encapsulated black currant oil," the single active ingredient of a dietary supplement, is not a "food additive," the FDA cannot require the manufacturer to prove that the substance is safe); *see also* *United States v. Twenty-Nine Cartons of an Article of Food*, 987 F.2d 33 (1st Cir. 1993) (holding, like the Seventh Circuit, that black currant oil is properly classified as "food" and therefore subject to minimal regulation).

the consumption of dietary supplements containing the amino acid L-tryptophan caused an outbreak of at least 1,500 cases of eosinophilia-myalgia syndrome, resulting in thirty-eight deaths.<sup>26</sup> From 1993 to 1997, fifteen deaths and four hundred “adverse reactions” were attributed to the supplement ephedra.<sup>27</sup> In response to the earlier outbreak of eosinophilia-myalgia, the FDA considered implementing a new regime that would allow it to evaluate uniformly the safety profile of dietary supplements.<sup>28</sup> In May 1991, an FDA taskforce recommended that the agency reclassify dietary supplements as drugs rather than as food in order to achieve such a regime.<sup>29</sup>

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.<sup>30</sup> 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 premarket testing for dietary supplements.<sup>31</sup> In 1992, Congress passed the Dietary Supplement Act, which forced the FDA to “promulgate rules . . . reiterating that the FDA would treat dietary supplements as conventional food.”<sup>32</sup> Two years later, Congress enacted the DSHEA, preempting the new rules promulgated by the FDA under the earlier 1992 Act and codifying Congress’s “desire for reduced regulation of dietary supplements.”<sup>33</sup> The DSHEA proved extremely accommodating to manufacturers; dietary supplements are now subject to less regulation than food additives (which require premarket clearance), drugs, and even “conventional foods.”<sup>34</sup>

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26. Regulation of Dietary Supplements, 58 Fed. Reg. 33,690-01 (June 18, 1993) (to be codified at 21 C.F.R. ch. I); see also Carter Anne McGowan, *Learning the Hard Way: L-Tryptophan, the FDA, and the Regulation of Amino Acids*, 3 CORNELL J.L. & PUB. POL’Y 383, 399-400 (1994) (defining eosinophilia-myalgia as a systemic illness characterized by fever, muscle aches, cough, shortness of breath, skin swelling, and skin rash).

27. Khatcheressian, *supra* note 20, at 624-25.

28. *Id.*

29. *Id.* at 625-26.

30. See Cohen, *supra* note 11, at 219 (identifying Senator Hatch as one of the DSHEA’s main sponsors); see also 139 CONG. REC. S4577 (daily ed. Apr. 7, 1993) (statement of Sen. Hatch) (articulating reasons for supporting the amendment).

31. Sloane, *supra* note 17, at 325 (characterizing the DSHEA as the product of “overwhelming public pressure”).

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

33. *Id.*

34. *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 & 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, 567-68 (1999) (clarifying the distinction between food additives and dietary supplements).

*B. Public Pressure Favoring Deregulation Spurred Enactment of the DSHEA*

President Bill Clinton signed the DSHEA into law on October 25, 1994.<sup>35</sup> In it, Congress set forth fifteen separate findings justifying the DSHEA's enactment, among them "overwhelming public pressure" favoring deregulation.<sup>36</sup> Congress felt that the FDA's regulation of the nutraceutical industry was "too stringent" and that it "unnecessarily limited consumer access to dietary supplements."<sup>37</sup> This is 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. Public pressure favoring deregulation is strong. Dietary supplements attract consumers for myriad reasons: some gravitate to supplements that promise weight loss without requiring exercise, while others take supplements hoping they might induce the same effects as prescription medication, obviating expensive visits to the doctor.<sup>38</sup> This near-universal perception of dietary supplements (that they possess significant therapeutic properties without any of the risks commonly associated with drugs) catalyzed support for the DSHEA.<sup>39</sup>

*C. The DSHEA Classifies Dietary Supplements as Food, Thereby Curtailing FDA Oversight*

Like the Dietary Supplement Act, the DSHEA classifies dietary supplements as food.<sup>40</sup> The distinction between food and drugs is critical. Unlike the laws on drugs, the DSHEA places the burden on the FDA to prove that a dietary supplement is unsafe before removing it from the market.<sup>41</sup> While pharmaceuticals must undergo years of clinical testing before the FDA will approve them for use, as a "food," dietary supplements are not subject to premarket tests.<sup>42</sup> Most dietary supplements become available to consumers without FDA review or approval, and only in limited instances do new dietary

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35. Khatchereessian, *supra* note 20, at 624.

36. Sloane, *supra* note 17, at 332.

37. Federal Food Drug and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended in scattered sections of 21 U.S.C.).

38. See Michael A. McCann, *Dietary Supplement Labeling: Cognitive Biases, Market Manipulation, & Consumer Choice*, 31 AM. J.L. & MED. 215, 219 (2005) (describing consumers' positive views of dietary supplements).

39. See William J. Skinner, *Allowable Advertisements for Dietary Supplements*, 5 J. PHARM. & L. 309, 309-10 (1996) (speculating that the DSHEA was "solely responsible for the purchase of many telephone answering machines by Congressional committee staff offices and Members of Congress").

40. 21 U.S.C. § 321(g)(1) (2006).

41. Federal Food Drug and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended in scattered sections of 21 U.S.C.).

42. 21 U.S.C. § 355(a)(1) (2006) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an 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.

ingredients—such as those found in products sold after 1994—receive premarket evaluation to determine safety.<sup>43</sup>

Moreover, under Section 342 of the DSHEA, the FDA can only prevent the release of a dietary supplement if it poses a “significant or unreasonable risk of harm.”<sup>44</sup> 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.<sup>45</sup> 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.<sup>46</sup> It encourages the agency to wait until reports of adverse effects surface before launching a substantive inquiry or issuing a recall order.<sup>47</sup>

Because dietary supplements are classified as food, supplement manufacturers do not need to establish that their products are efficacious before marketing them to consumers.<sup>48</sup> However, unlike food, people do not take dietary supplements because they are hungry or for the supplement’s taste; they take them because of their perceived therapeutic properties.<sup>49</sup> 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 the label correctly lists the product’s ingredients.

#### *D. The Risk of Harm Posed by Dietary Supplements Can Be Substantial*

The DSHEA requires the FDA to adopt a “sit and wait” approach to the regulation of potentially harmful nutraceuticals.<sup>50</sup> Even if it wishes to remove a supplement from the market, it must first compile evidence indicating that the

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43. McCann, *supra* note 38, at 220; *see also* 21 U.S.C. § 350(b) (1994 & Supp. III 1998); *Pearson v. Shalala*, 164 F.3d 650, 652 (D.C. Cir. 1999) (holding that “[t]he actual sale of dietary supplements is regulated only when the supplement contains a ‘new dietary ingredient,’ 21 U.S.C.A. § 350b (Supp. 1998), or poses a safety risk, *id.* § 342(f)”). 21 U.S.C. § 350b(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) of that statute, while the manufacturer is not obligated to conduct tests, it must present data to the FDA seventy-five 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.

44. 21 U.S.C. § 342(f)(1) (2000 & Supp. V 2005).

45. *Id.*

46. *See* Sean Harmon, *Melatonin Mania: Can the FDA Regulate Hormonal Dietary Supplements to Protect Consumer Interests in Light of the Dietary Supplement Health and Education Act of 1994?*, 22 U. DAYTON L. REV. 77, 91 (1996) (stating that one purpose of the DSHEA is to “stop certain FDA actions which directly prevented the free market sale of dietary supplements”).

47. *Id.* at 91 (stating that the DSHEA limits the FDA’s ability to act proactively).

48. McCann, *supra* note 38, at 220–21.

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

50. Termini, *supra* note 18, at 278.

supplement presents a “significant or unreasonable risk of harm.”<sup>51</sup> 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).<sup>52</sup>

As the FDA’s website points out, it remains the dietary supplement manufacturer’s responsibility to ensure that its products “are safe before they are marketed.”<sup>53</sup> This statement represents the DSHEA’s ultimate objective: to invest the dietary supplement industry with the autonomy to regulate its own products.<sup>54</sup> As a result, there is “no general requirement for manufacturers of dietary supplements to submit evidence of product safety” to the FDA.<sup>55</sup> 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.<sup>56</sup> However, even its role in this regard is limited.<sup>57</sup>

The large number of consumers purchasing dietary supplements—thereby putting themselves at potential risk—underscores the need for a stronger regulatory system.<sup>58</sup> According to the DSHEA’s findings, 50 percent of Americans consume dietary supplements regularly.<sup>59</sup> Many people turn to dietary supplements in lieu of traditional medicine because they are poor, lack health insurance, and cannot afford expensive prescription medication.<sup>60</sup> The DSHEA recognizes this trend: Section 2 of the statute states that “studies

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51. 21 U.S.C. § 342(f)(1)(A) (2000).

52. Dietary Supplement Health and Education Act, Pub. L. No. 103-417, 108 Stat. 4325 (1994) (codified as amended at scattered sections of 21 U.S.C.).

53. FDA, Dietary Supplements: Overview, <http://www.fda.gov/Food/DietarySupplements/ConsumerInformation/ucm110417.htm#what> (last visited Apr. 25, 2010).

54. McCann, *supra* note 38, at 244.

55. *Id.*

56. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994) (codified as amended at scattered sections of 21 U.S.C.). Part III of this paper will discuss the types of labeling claims the FDA regulates and prohibits.

57. On June 22, 2007, the FDA announced a final rule—effective as of August 24, 2007—requiring dietary supplement manufacturers to ensure that dietary supplements are produced in a quality manner, do not contain contaminants or impurities, and are accurately labeled. The regulations provide instructions to manufacturers on how to implement quality control measures and prevent contamination. *See* 21 C.F.R. § 111.3 (2008); *see also* Press Release, Food & Drug Admin., FDA Issues Dietary Supplements Final Rule (June 22, 2007), *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108938.htm>. Neither the rule nor the announcement requires manufacturers to conduct controlled, double-blind studies involving patients to determine safety and efficacy—the testing protocol that this Comment advocates.

58. *See* McCann, *supra* note 38, at 218–20 (stating that the billion-dollar supplement industry evidences Americans’ concern with maintaining and improving their overall health).

59. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325, 4326 (1994).

60. *See* McCann, *supra* note 38, at 224 (“Consumers who select supplements because they regard conventional treatments as expensive are almost twice as likely to earn incomes below the poverty line, significantly more likely to report poorer health status, and four times more likely to be uninsured.”); Ha T. Tu & J. Lee Hargraves, CTR. FOR STUDYING HEALTH SYS. CHANGE, DATA BULLETIN NO. 28: HIGH COST OF MEDICAL CARE PROMPTS CONSUMERS TO SEEK ALTERNATIVES (2004), *available at* <http://www.hschange.com/CONTENT/722/>.

indicate that consumers are placing increased reliance on the use of nontraditional health care providers to avoid the excessive costs of traditional medical services and to obtain more holistic consideration of their needs."<sup>61</sup> 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.<sup>62</sup> Nevertheless, while the side effects posed by drugs are not always evident even after approval, those associated with dietary supplements are significantly less clear.<sup>63</sup>

The risks and side effects of supplements burden some groups more heavily than others. For example, out-of-work seniors are more likely than other groups to purchase dietary supplements, because these individuals often face cost limitations when considering treatment options and are generally more susceptible to illness.<sup>64</sup> For instance, many seniors purchase antioxidants because they believe, based on word-of-mouth and improper labeling, that these substances help prevent cancer.<sup>65</sup> However, current studies have identified at least two antioxidants, vitamin E and beta carotene, that can actually *increase* the risk of lung cancer in some individuals.<sup>66</sup> 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.

Adolescents constitute another susceptible group of consumers, given their propensity for making uninformed purchasing decisions.<sup>67</sup> Many teenagers take the supplement "creatine monohydrate" because of its supposed beneficial effects on athleticism and endurance.<sup>68</sup> However, scientists have not made any clinical determination regarding the safety or efficacy of creatine monohydrate.<sup>69</sup> In fact, studies have shown that creatine monohydrate can produce various side effects, including cramps, gastrointestinal complications, and even kidney dysfunction.<sup>70</sup> Sometimes, supplements marketed as boosting athleticism may even become a gateway to anabolic steroid use.<sup>71</sup>

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61. 21 U.S.C. § 321.

62. McCann, *supra* note 38, at 224.

63. Sloane, *supra* note 17, at 332–33 (1999) (arguing that "millions of Americans are potentially more susceptible to unknown hazards by their consumption of products that are regulated far less stringently than prescription medicines").

64. McCann, *supra* note 38, at 224.

65. *Id.*

66. *Id.* But see Bruce N. Ames, *The Causes and Prevention of Cancer: The Role of Environment*, CA51 ALI-ABA 49 (1995) (suggesting that some antioxidants, like vitamin C and E, can reduce environmental damage to cells that can trigger the onset of cancer).

67. *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").

68. *Id.* at 226.

69. *Id.*

70. *Id.*

71. *Id.*; see also Khatcheressian, *supra* note 20, at 629 (describing the initial classification

Recent examples of side effects associated with dietary supplements also evidence the need for more strenuous oversight. Between October 2007 and February 2009, the FDA received over seven hundred reports of adverse events related to dietary supplement consumption.<sup>72</sup> A large number of these reports involved consumers experiencing rashes, itchy skin, trouble breathing, and other symptoms attributable to allergic reactions and anaphylactic shock.<sup>73</sup> Eight percent of the reports indicated that consumers had experienced various heart problems, including irregular heartbeats, heart attacks, and chest pains.<sup>74</sup> Some of the dietary supplements identified in the reports that may have been linked to these symptoms included One A Day multivitamins, Men's Health formula, Prenatal, Cholesterol Plus, and All Day Energy.<sup>75</sup>

Other supplements that the FDA has recently identified as adulterated or misbranded are Viga, protein supplements containing instant whey protein concentrate, and Liquid Acidophilus.<sup>76</sup> In April 2003, the FDA determined through its own laboratory tests that the supplement Viga for Women, promoted for "increasing desire, confidence and sexual performance," contained the undeclared prescription drug ingredient Sildenafil, commonly known as Viagra.<sup>77</sup> The side effects of Viagra include heart problems, blurred vision, and urinary tract infections.<sup>78</sup> After the FDA notified the manufacturer, Best Life International, Inc., of the results of its tests, Best Life announced that it would recall its product.<sup>79</sup> In 2009, the FDA determined that protein supplements containing instant whey protein concentrate, a substance advertised as protecting muscle tissue from breakdown due to strenuous physical activity, had the potential to be contaminated by Salmonella.<sup>80</sup> In 2008, a manufacturer recalled its supplement, Liquid Acidophilus, after learning that the label incorrectly listed that the product contained no wheat or gluten.<sup>81</sup>

The discontinuation of the popular weight loss supplement Hydroxycut likewise demonstrates the potential dangers of admitting supplements into the

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and marketing of "androstenedione," an anabolic steroid, as a dietary supplement, and noting that Mark McGwire was one famous user of this product).

72. Ashish R. Talati, *Dietary Supplement Adverse Event Reports: Review and Analysis*, 64 FOOD & DRUG L.J. 503, 506 (2009).

73. *Id.*

74. *Id.*

75. *Id.* at 510.

76. FDA, Recall Notice, Event ID 26400 (June 2, 2003); FDA, Recall Notice, Event ID 44925 (July 2, 2008); FDA, Recall Notice, Event ID 52648 (July 27, 2009).

77. FDA, Recall Notice, Event ID 26400; *see also* Stephen T. Kaminski, *Must Employers Pay for Viagra? An Americans with Disabilities Act Analysis Post-Bragdon and Sutton*, 4 DEPAUL J. HEALTH CARE L. 73, 76 (2000) (describing the initial development of Viagra for the treatment of angina, and the discovery of its incidental effects on erectile dysfunction).

78. Kaminski, *supra* note 77, at 77.

79. FDA, Recall Notice, Event ID 26400.

80. FDA, Recall Notice, Event ID 52547 (July 20, 2009); FDA, Recall Notice, Event ID 52648 (July 27, 2009); FDA, Recall Notice, Event ID 52731 (Aug. 6, 2009).

81. FDA, Recall Notice, Event ID 49120 (Aug. 1, 2008).

stream of commerce without first testing them for safety.<sup>82</sup> On May 1, 2009, the FDA issued a formal warning concerning the use of Hydroxycut products, manufactured by Iovate Health Sciences, after compiling several adverse event reports.<sup>83</sup> The FDA learned that consumption of Hydroxycut allegedly poses a severe risk of liver injury and also contributed to the death of one person.<sup>84</sup> It received twenty-three reports of serious liver injuries linked to Hydroxycut products.<sup>85</sup> Soon thereafter, Iovate voluntarily pulled Hydroxycut off the market.<sup>86</sup>

The Hydroxycut recall signifies an important lesson. Under the current framework, manufacturers essentially regulate themselves, and the majority of supplements, including vitamins, minerals, botanicals, and amino acids, are not tested for safety.<sup>87</sup> The FDA is likely to step in and request a recall only upon learning of a labeling omission from a manufacturer or receiving reports of side effects. Unless Congress changes the law and institutes a testing regime, the autonomy manufacturers enjoy might precipitate an outbreak of severe side effects, comparable to those caused by ephedra in the early 1990s—a period in which, unlike today, legislation had not expressly limited the FDA’s ability to regulate dietary supplements.<sup>88</sup>

## II

### LABELING CLAIMS UNDER THE DSHEA

#### *A. Manufacturers Can Make Two Types of Labeling Claims: Health and Structure/Function Claims*

The DSHEA allows the FDA to evaluate statements made by manufacturers on the label.<sup>89</sup> However, the FDA does not typically evaluate statements made in advertisements or literature that do not physically accompany the supplements.<sup>90</sup> That role has been delegated to the

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82. Sandra Young, *Stop Using Hydroxycut Products, FDA Says*, CNN, May 1, 2009, <http://www.cnn.com/2009/HEALTH/05/01/hydroxycut.fda.recall/index.html>.

83. Talati, *supra* note 72, at 512.

84. *Id.*

85. *Id.*

86. Press Release, Food & Drug Admin., Iovate Health Sciences U.S.A., Inc. Voluntarily Recalls Hydroxycut-Branded Products (May 1, 2009), <http://www.fda.gov/Safety/Recalls/ucm145164.htm>.

87. Judd Cooper Legum, *The Dangers of DSHEA: A Case for Expanded FDA Authority Over Dietary Supplements*, 6 MICH. ST. J. MED. & L. 103, 105 (2002).

88. Cohen, *supra* note 11, 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).

89. John E. Villafranco & 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, 714 (2007).

90. *See id.* at 709–10 (stating that “under a liaison agreement, the Federal Trade Commission (FTC) acts as the primary regulator of dietary supplement advertising and the Food

Federal Trade Commission (FTC) and deserves separate attention in another paper.<sup>91</sup>

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.<sup>92</sup> The label only needs to identify ingredients present in significant quantities.<sup>93</sup> Additionally, products that contain herbal or botanical ingredients have to state the part of the plant from which the ingredient is derived.<sup>94</sup> The label must also identify the product as a dietary supplement.<sup>95</sup>

Many dietary supplements carry labels stating that the product promotes health in some way. However, manufacturers are restricted in the types of labeling claims they can make. The manufacturer cannot make a “disease claim”: it cannot state that a supplement can be used to “cure or treat” a disease.<sup>96</sup> This prohibition constitutes the DSHEA’s strictest requirement.<sup>97</sup> However, the DSHEA allows manufacturers to make two other types of claims: (1) health claims, which describe the relationship between consumption of a particular supplement and the incidence of disease (e.g., “the consumption of Omega-3 has been linked to a reduced risk of cancer”),<sup>98</sup> and (2) structure/function claims, which describe the effect of a supplement on a particular physiological or anatomical function (e.g., “the consumption of Omega-3 has been linked to improved cardiovascular function”).<sup>99</sup> Notwithstanding the DSHEA’s prohibition against disease claims, courts have

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and Drug Administration (FDA) possesses primary enforcement responsibility for dietary supplement claims made in “labeling”); *see also* 21 U.S.C. 343-2 (2006) (distinguishing labels from advertisements when the latter is “physically separate from the dietary supplements”).

91. 15 U.S.C. § 52(a)(1) (2006) (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, or cosmetics”). The FDA can and does aid the FTC in its investigation of nutraceutical advertising, supplying it with the scientific information it needs. *See* Douglas W. Hyman, *The Regulation of Health Claims in Food Advertising: Have the FTC and the FDA Finally Reached a Common Ground?*, 51 *FOOD & DRUG L.J.* 191, 192 (1996).

92. 21 U.S.C. § 343(b), (f) & (i) (1994).

93. *Id.* (“A dietary ingredient shall not be required to be listed if it is not present in a significant amount.” Section 343(b) does not define “significant amount.”).

94. Food Labeling Regulation, Amendments; Food Regulation Uniform Compliance Date; and New Dietary Ingredient Premarket Notification; Final Rules, 62 *Fed. Reg.* 49,826 (Sept. 23, 1997) (to be codified at 21 C.F.R. pt.101).

95. 21 U.S.C. § 321(ff)(2)(C) (1994).

96. Margaret Gilhooley, *supra* note 9, 687.

97. 21 U.S.C. § 343(r)(6) (1994).

98. *See id.*; *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, 113–15 (2001) (defining a “health claim” as one that associates a supplement with disease prevention).

99. 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 ingredient intended to affect the structure or function in humans”).

limited the FDA's ability to restrict health claims, even when third-party studies regarding efficacy are inconclusive.<sup>100</sup> Structure/function claims, moreover, are subject to an even lesser standard of substantiation.<sup>101</sup> The following subsections clarify the distinction between health claims and structure/function claims and discuss the extent to which the FDA can regulate such claims.

### 1. 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.<sup>102</sup> This description constitutes a health claim (e.g., "the use of beta-carotene helps decrease the risk of cancer").<sup>103</sup> While the manufacturer is not required to conduct studies verifying its statements, the FDA must review and authorize any health claim made on the label.<sup>104</sup>

The FDA requires "significant scientific agreement" that a health claim is accurate.<sup>105</sup> This standard does not derive from the DSHEA, but instead was established by the FDA pursuant to the Administrative Procedure Act (APA), which invests federal agencies with rulemaking authority to execute laws passed by Congress.<sup>106</sup> 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.<sup>107</sup>

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) it can determine that the statement is in fact a health claim, but is based on inadequate findings and therefore

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100. See Cohen, *supra* note 11, at 187 ("[W]hen supplement manufacturers do imply efficacy in treating disease, the government's ability to enforce DSHEA's minimal standards is subject to significant limitations.").

101. Margaret Gilhooley, *supra* note 9, at 685 (describing the increased number of structure/function claims being made for dietary supplements since passage of the DSHEA).

102. 21 C.F.R. § 101.14(a)(1) (1998) (describing a health claim as "a claim that characterizes the relationship of any substance to a disease or health-related condition").

103. *Id.*

104. 21 C.F.R. § 101.14(d).

105. *Id.*

106. 21 C.F.R. § 101.70 (2005) (investing the FDA with discretionary authority to approve or reject health claims); 5 U.S.C. § 553 (2006) (investing executive agencies with broad rulemaking authority). See generally James Robert Dean, Jr., *FDA at War: Securing the Food that Secured Victory*, 53 FOOD & DRUG L.J. 453, 509–11 (1998) (discussing the FDA's reliance on the APA in issuing rules).

107. 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 scientific 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").

unsubstantiated.<sup>108</sup> In either instance, it can require the manufacturer to re-label its product.<sup>109</sup> The manufacturer must notify the FDA of its claim within thirty days of marketing the dietary supplement and submit all necessary documentation in support of the claim.<sup>110</sup>

Manufacturers can circumvent FDA scrutiny by making “qualified” health claims.<sup>111</sup> In *Pierson v. Shalala*, the D.C. Circuit Court of Appeals held that a prohibition on a “potentially misleading” health claim is an unconstitutional infringement on commercial speech where inclusion of a disclaimer can cure the misleading nature of that claim.<sup>112</sup> For example, if a health claim regarding antioxidants is accompanied by a disclaimer stating that “[s]tudies regarding the effects of antioxidants in reducing cancer are inconclusive,” the claim is no longer misleading and the agency must approve its use.<sup>113</sup>

## 2. 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).<sup>114</sup> For instance, the statement that a particular supplement can “improve joint and cartilage function”<sup>115</sup> 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.<sup>116</sup> While the manufacturer is required to keep in its possession third-party studies substantiating any structure/function claims, it is not required to submit documents before marketing products with these claims.<sup>117</sup>

Moreover, the FDA does not usually evaluate scientific studies regarding the veracity of a structure/function claim.<sup>118</sup> Unsubstantiated structure/function

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108. See Cohen, *supra* note 11, at 187 (stating that dietary supplements containing health claims that are not preapproved are “deemed misbranded and unapproved new drugs within the meaning of U.S.C. § 321(g)(1)(B) and may be seized or enjoined from being sold” under 21 U.S.C. §§ 333, 334); see also 21 C.F.R. § 101.14(c) (suggesting that the basis for substantiation is the “significant scientific agreement” standard).

109. 21 C.F.R. § 101.14(e).

110. 21 U.S.C. § 343(r)(6)(B).

111. See *Pearson v. Shalala*, 164 F.3d 650, 657 (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 Comment will discuss the role of the First Amendment within the context of health and structure/function claims.

112. *Id.*

113. *Id.*

114. 21 U.S.C. § 343(r)(6)(A) (1994).

115. Sachani, *supra* note 15, at 400.

116. 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, perhaps even restore lost vision.

117. 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.

118. See Stephen H. McNamara, *So You Want to Market a Food and to Make a Health*

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."<sup>119</sup> The manufacturer's only duty is to notify the FDA "no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made."<sup>120</sup>

*B. There Are Glaring Deficiencies in the DSHEA's Labeling Provisions*

The most significant problem concerning labeling claims is that the DSHEA neither requires proper testing on the part of manufacturers, nor articulates preclearance criteria for structure/function claims. Because some consumers assume that the government screened dietary supplements before being placed on store shelves, they are not likely to lodge complaints with the FDA over a product's inefficacy.<sup>121</sup> 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. Furthermore, as one writer puts it, the "role of 'spin' cannot be ignored."<sup>122</sup> 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 actually can mitigate arthritis.<sup>123</sup>

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.<sup>124</sup> But since *Pearson*, manufacturers can claim that their products help prevent specific diseases—even if studies are inconclusive—as long as they

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*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).

119. 21 U.S.C. § 343(r)(6)(c).

120. *Id.*

121. See MARK A. KASSEL, FROM A HISTORY OF NEAR MISSES: THE FUTURE OF DIETARY SUPPLEMENT REGULATION, 49 FOOD & DRUG L.J. 237, 238 (1994) (arguing that "Americans have come to rely so heavily on government regulation of commerce that it is often assumed that dietary supplement claims by manufacturers and advertisers would not reach consumers if they were not true"); see also Sardina, *supra* note 19, at 121 (stating that some consumers took the dietary supplement L-tryptophan because they believed that the FDA had monitored this product).

122. Cohen, *supra* note 11, at 186.

123. But see Robert Pinco & Paul D. Rubin, *Ambiguities of the Dietary Supplement and Health Education Act of 1994*, 51 FOOD & DRUG L.J. 383, 390 (1996) (suggesting that the FDA might prohibit a statement of this kind as an impermissible disease claim).

124. See Termini, *supra* note 18, at 276 (stating that prior to Congress's 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").

display a disclaimer on the product label.<sup>125</sup> The problem with disclaimers is that consumers often neglect to pay attention to them.<sup>126</sup> Moreover, while manufacturers may evade FDA scrutiny of claims made on the product's label, FTC standards require manufacturers to substantiate all performance, efficacy, and safety claims used in advertising before releasing those claims to the public.<sup>127</sup> As a result, consumers "may internalize disparate messages for the same product," thereby potentially causing confusion.<sup>128</sup>

### III

#### AMENDING THE DSHEA TO IMPOSE A HIGHER STANDARD OF ACCOUNTABILITY ON MANUFACTURERS

Congress must amend the DSHEA to better ensure the safety of dietary supplements and to 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 of three separate groups: the government, manufacturers, and consumers.<sup>129</sup> The government's interest is in protecting public health; in particular, the FDA's objective is to ensure that dietary supplements are safe and that all claims made on a label are truthful.<sup>130</sup> The manufacturer's interest is in maximizing profits and minimizing the risk of litigation.<sup>131</sup> The consumer's interest is in maintaining affordable access to alternative medicines that improve health.<sup>132</sup> Since the DSHEA currently under-protects consumer interests, Congress should hold manufacturers to a higher standard of accountability than that which is currently imposed under the DSHEA.

#### *A. Congress Should Amend the DSHEA so That the FDA Only Has to Show a "Risk of Harm" 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 illness or injury."<sup>133</sup> The government bears the burden of proof: the FDA must show by a

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125. *Pearson v. Shalala*, 164 F.3d 650, 659–60 (D.C. Cir. 1999).

126. See Barbara A. Noah, *A Review of the New York State Task Force on Life & the Law's Report: Dietary Supplements: Balancing Consumer Choice & Safety*, 33 J.L. MED. & ETHICS 860, 862 (2005) (suggesting that consumers "may fail to appreciate the distinction between a true therapeutic claim and a structure or function claim," and may "misinterpret or ignore the disclaimer").

127. See McCann, *supra* note 38, at 232; see also 15 U.S.C. § 52 (2006) (prohibiting the dissemination of false advertisements).

128. McCann, *supra* note 38, at 250.

129. Iona N. Kaiser, *Dietary Supplements: Can the Law Control the Hype*, 37 Hous. L. Rev. 1249, 1271 (2000).

130. *Id.*

131. *Id.* at 1271–72.

132. *Id.* at 1272.

133. 21 U.S.C. § 342(f)(1) (1994).

preponderance of the evidence that a dietary supplement poses a significant or unreasonable risk of harm to consumers.<sup>134</sup> The question becomes: what constitutes an “unreasonable” risk of harm? When assessing reasonableness in other contexts (e.g., negligence), courts perform a risk-benefit analysis, balancing the benefits accruing from a particular activity against the harm.<sup>135</sup> Is that the sort of analysis courts must undertake in determining whether the FDA is justified in banning a dietary supplement? In short, the answer is 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.”<sup>136</sup>

By contrast, the term “significant risk” entails “an evaluation of risk alone.”<sup>137</sup> The risk can be significant but remain reasonable if the benefits “were great enough to outweigh the risks.”<sup>138</sup> The language of Section 342 is therefore disjunctive; even if a supplement provides enough benefits to make the risk-reward tradeoff a “reasonable” one, the FDA retains discretion to prohibit its sale if the risk it poses is nevertheless “significant.”

However, Congress should direct the FDA to implement more specific guidelines for removing dietary supplements from the market. The guidelines could recommend removal where the FDA determines that a dietary supplement poses a risk of (1) triggering symptoms characteristic of an allergic reaction (skin rash, congestion, coughing, fever, etc.), (2) compromising a person’s immune system, or (3) compromising the functionality of a person’s organ systems. Where the FDA feels that the risk is insignificant, or that the benefits of the product genuinely outweigh the risks, it should still require manufacturers to identify these risks both on the label of the dietary supplement and in documentation contained within the supplement’s packaging.

This more specific, three-part standard for determining when a supplement warrants removal is preferable because the terms “significant” and “unreasonable” are subject to permissive interpretation. The statute suggests that certain risks of harm may be reasonable or insignificant.<sup>139</sup> 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

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134. 21 U.S.C. § 342(f)(1)(D) (1994).

135. See 69 Fed. Reg. 6788, 6822–23 (Feb. 11, 2004) (to be codified at 21 C.F.R. pt. 119). The determination that something poses an unreasonable risk involves a balancing test that is “well-established in tort law,” in which “the benefits of the product or activity are weighed against its dangers.” *Id.* at 6823.

136. *Id.* at 6823; see also *Hi-Tech Pharms., Inc. v. Crawford*, 505 F. Supp. 2d 1341, 1353 (N.D. Ga. 2007) (holding that the proper standard of analysis under Section 342 constitutes the “risk-benefit” balancing test).

137. 69 Fed. Reg. at 6823.

138. *Id.*

139. See 69 Fed. Reg. at 6788, 6823 (stating that even a significant risk could be “reasonable if the benefits were great enough to outweigh the risks”).

unreasonable” empowers the manufacturer to resist removal efforts by the FDA, even when the manufacturer acknowledges that its nutraceutical is potentially harmful.<sup>140</sup>

One district court decision, which the Tenth Circuit has overturned, illustrates the difficulty the FDA faces in banning unsafe supplements. In *Nutraceutical Corp. v. Crawford (Nutraceutical I)*, a nutraceutical manufacturer challenged the FDA’s ban against all dietary supplements containing ephedrine alkaloids (EDS).<sup>141</sup> The FDA concluded, after reviewing over 133,000 pages of scientific data and peer-reviewed literature, that EDS poses an unreasonable risk of heart attack, stroke, and death under the conditions of use recommended in labeling (the recommended dosage was ten milligrams per day).<sup>142</sup> Applying a risk-benefit balancing test, the FDA found that the alleged benefits of EDS—weight loss and enhanced athletic performance—did not outweigh its risks.<sup>143</sup> Therefore, the FDA declared that all products containing EDS are adulterated under the DSHEA.<sup>144</sup>

Citing the DSHEA, the court asserted that the burden is on the government to prove by a preponderance of the evidence that a dietary supplement poses a significant or unreasonable risk of harm.<sup>145</sup> The court then held that the FDA had failed to meet its burden, for a number of reasons.<sup>146</sup> First, the FDA’s contention that ephedrine alkaloids produce negative physiological effects was based upon “chronic” or long-term intake of EDS, which was not the condition of use suggested on the labeling of the manufacturer’s product.<sup>147</sup> Second, the FDA’s study did not examine oral ingestion of ephedrine alkaloids—rather, the study relied upon data regarding the effects of intravenous injections of epinephrine, a substance similar to EDS.<sup>148</sup> Moreover, at trial the FDA’s expert witness testified that because he could not determine a safe dosage of EDS, no safe level of intake existed.<sup>149</sup> However, the court held that this inference failed to establish whether the

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140. 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).

141. *Nutraceutical Corp. v. Crawford (Nutraceutical I)*, 364 F. Supp. 2d 1310, 1313 (D. Utah 2005).

142. *Id.*; see also Cohen, *supra* note 11, at 190 (stating that the FDA had been investigating the effects of supplements containing ephedrine alkaloids for nearly seven years, and that the FDA’s ban against ephedra marked the first time U.S. officials had blocked the sale of an over-the-counter nutritional supplement on the grounds that it posed a significant and unreasonable risk of harm).

143. *Nutraceutical I*, 364 F. Supp. 2d at 1311–14.

144. *Id.* at 1314.

145. *Id.* at 1319.

146. *Id.* at 1319–21.

147. *Id.* at 1320.

148. *Id.*

149. *Id.*

intake of low-dose EDS poses a significant or unreasonable risk of harm.<sup>150</sup> The court stressed that “the statement that a safe level cannot be determined is simply not sufficient to meet the government’s burden.”<sup>151</sup> To suggest otherwise “would be to place the burden on the manufacturers of EDS to show that their recommended dosages are safe.”<sup>152</sup> Such a result “would be directly contrary to the statutory language . . . and to the intent of Congress in regulating dietary supplements as food.”<sup>153</sup> Accordingly, the court held that the FDA’s prohibition against EDS did not comply with the requirements under the DSHEA, and granted summary judgment for the manufacturer.<sup>154</sup>

Fortunately, the Tenth Circuit reversed the lower court’s decision in the FDA’s favor.<sup>155</sup> First, the court acknowledged the FDA’s “extensive research” into the matter and found its methodology proper.<sup>156</sup> Second, the court found that the comparisons between ephedrine alkaloids and epinephrine, a “pharmacologically related” drug, were an appropriate way to analyze the effects of EDS.<sup>157</sup> Third, because “the majority of data in the administrative record suggested that EDS poses an unreasonable threat to the public’s health” at any dosage level, the FDA had met its burden under the DSHEA.<sup>158</sup>

The point of this discussion is not to insist that district courts in other circuits will side with manufacturers when confronted with a factual dispute over the safety of a nutraceutical product. Rather, the discussion suggests that the DSHEA empowers manufacturers to resist removal efforts even in cases where substantial evidence exists that a dietary supplement may cause death.<sup>159</sup> Given the district court’s holding in *Nutraceutical I*, it remains conceivable that: (1) lower courts outside the Tenth Circuit may not defer to the FDA’s findings,<sup>160</sup> and (2) the FDA may fail in proving that a supplement poses a significant risk of harm, where studies on a particular supplement are lacking and the side effects reported do not rise to the level of a stroke or heart attack.<sup>161</sup> Instead of having to wait on studies in determining the safety of a

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150. *Id.* at 1320–21.

151. *Id.* at 1321.

152. *Id.*

153. *Id.*

154. *Id.*

155. *Nutraceutical Corp. v. Von Eschenbach (Nutraceutical II)*, 459 F.3d 1033, 1044 (10th Cir. 2006).

156. *Id.* at 1041–43.

157. *Id.* at 1042–43.

158. *Id.* at 1043–44.

159. *See id.* at 1042–44 (suggesting that ephedrine alkaloids at any dosage are unsafe and pose a risk of death).

160. *See* Jennifer Akre Hill, *Creating Balance: Problems Within DSHEA and Suggestions for Reform*, 2 J. FOOD L. & POL’Y 361, 384 (2006) (stating that under the DSHEA’s balancing test, the agency risks losing the benefit of deference in court).

161. The risks associated with ephedrine alkaloids include heart attack, stroke, seizures, and death. *Nutraceutical II*, 459 F.3d at 1043.

dietary supplement, the FDA should be able to take swift action upon receiving reports of adverse events.

*B. Congress Should Shift the Evidentiary Burden onto Manufacturers and Require Courts to Defer to the FDA's Findings*

To better protect consumer interests in affordable and safe alternative medicine, Congress must shift the burden of refuting negative findings on the safety of supplements onto the manufacturers of those supplements. 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).<sup>162</sup> It also requires courts to apply de novo review in determining whether a dietary supplement is unsafe.<sup>163</sup>

This de novo 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.<sup>164</sup> 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.<sup>165</sup> The FDA must show by a preponderance of the evidence that its own studies prevail over those submitted by the manufacturer.<sup>166</sup> As a result, in particularly close cases where evidence regarding the safety of a product is inconclusive, manufacturers may be able to overcome an FDA ban. Where a factual dispute exists, the better policy is to err on the side of consumer protection than to allow manufacturers to continue selling products that have not conclusively been proven safe. The DSHEA should be amended to reflect this policy by expressly requiring deference in all types of actions involving dietary supplements.

Two district court decisions, *Nutraceutical I* and *NVE, Inc. v. Department of Health & Human Services (NVE I)*, evidence the need for an amendment because of their literal interpretation of Section 342. *Nutraceutical I* held that the FDA had not met its burden in demonstrating that ephedrine alkaloids at a dosage of ten milligrams or less poses a significant or unreasonable risk of harm.<sup>167</sup> *NVE I*, like *Nutraceutical I*, involved a manufacturer's challenge

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162. 21 U.S.C. § 342(f)(1)(D) (2006).

163. *Id.*

164. See *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 866 (1984) (holding that absent congressional intent, an administrative agency's interpretation of a statute is entitled to judicial deference).

165. See *Nutraceutical II*, 459 F.3d at 1043 (holding that the “review of scientific literature is properly in the province of the FDA”); *Weinberger v. Bentex Pharms, Inc.*, 412 U.S. 645, 653–54 (1973) (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”).

166. *Hi-Tech Pharms., Inc. v. Crawford*, 505 F. Supp. 2d 1341, 1354 (N.D. Ga. 2007).

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

against the FDA’s ban on ephedrine alkaloids.<sup>168</sup> The district court in *NVE I* similarly asserted that Congress “intended all issues, *both factual and legal*, to be determined de novo.”<sup>169</sup> Therefore, the court decided that giving the “FDA deference on its legal determinations would be inconsistent with Congress’ intentions.” Consequently, it held that neither the FDA’s scientific determinations nor its legal conclusions were entitled to deference.<sup>170</sup> After deciding on the issue of agency deference, the court declined to determine the propriety of the FDA ban—instead, at the request of the parties, it submitted that issue to the Third Circuit Court of Appeals.<sup>171</sup>

Fortunately, appellate courts have been reluctant to interpret strictly Section 342. On appeal, the Third Circuit in *NVE, Inc. v. Department of Health & Human Services (NVE II)* declined to apply de novo review and deferred to the FDA’s finding that any supplement containing EDS posed an unreasonable risk of harm.<sup>172</sup> In the court’s view, the provision in Section 342 requiring de novo review applies solely to “enforcement actions” brought by the FDA, in which the FDA seeks injunctive relief or criminal penalties against a manufacturer.<sup>173</sup> Accordingly, the court applied an abuse-of-discretion standard rather than de novo review, declaring that the APA mandates an abuse of discretion standard when a private party challenges an administrative agency’s findings.<sup>174</sup>

Similarly, in *Nutraceutical Corp. v. Von Eschenbach (Nutraceutical II)*, the Tenth Circuit deferred to the FDA’s finding of “significant or unreasonable risk of harm.”<sup>175</sup> 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 constitutes an abuse of discretion.<sup>176</sup> However, the Tenth Circuit simultaneously acknowledged that courts must apply the de novo standard in enforcement actions brought against private manufacturers.<sup>177</sup>

*Nutraceutical II* and *NVE II* distinguished “APA suits” (suits brought by private parties seeking judicial review of agency actions under the APA)<sup>178</sup>

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168. *NVE, Inc. v. Dep’t of Health & Human Servs. (NVE I)*, No. 04-cv-999 (JAP), 2004 WL 5561798, at \*2 (D.N.J. Aug. 4, 2004).

169. *Id.* at \*6 (emphasis added).

170. *Id.* at \*4.

171. *Id.* at \*6.

172. *NVE, Inc. v. Dep’t of Health & Human Servs. (NVE II)*, 436 F.3d 182, 196–97 (3d Cir. 2006).

173. *Id.* at 194–95.

174. *Id.* at 191.

175. *Nutraceutical II*, 459 F.3d at 1043.

176. *Id.* at 1037–38.

177. *Id.* at 1037.

178. The APA vests federal agencies with informal rulemaking authority to implement legislation. Administrative Procedure Act, Pub. L. No. 79-404, 60 Stat. 238 (1946) (codified as amended in scattered sections of 5 U.S.C. (2006); *see also* William F. Pedersen, Jr., *Formal Records and Informal Rulemaking*, 85 YALE L.J. 38 (1975) (providing a comprehensive overview

from “enforcement actions” (suits brought by federal agencies seeking injunctive relief against private parties).<sup>179</sup> Accordingly, where the FDA seeks an injunction prohibiting a company from selling a particular product, courts in the Third and Tenth Circuit will adhere to the letter of the DSHEA and apply de novo review.<sup>180</sup> The Third and Tenth Circuit’s narrow reading of Section 342 quite possibly stems from the number of deaths caused by ephedrine. Other courts may not espouse that reading, especially when considering actions against less harmful supplements.

While *Nutraceutical II* recognized the FDA’s authority to prohibit ephedrine, a congressional mandate will reinforce that authority and generate stronger protections for consumers. Section 342 clearly states that “the court shall decide any issue under this paragraph on a de novo basis.”<sup>181</sup> Subsection (1)(A) of that paragraph includes the “significant or unreasonable risk” element that the FDA bears the burden of meeting.<sup>182</sup> The Third and Tenth Circuit declined to read the de novo provision literally, instead opting to apply de novo review only to suits where the FDA seeks injunctive relief against dietary supplement manufacturers. The implications of this statutory construction remain unclear, but it would seem that the propriety of any agency rule pertaining to a dietary supplement should be decided under the APA rather than the DSHEA.<sup>183</sup> *NVE II* embraces such an approach.<sup>184</sup> In that case, because the DSHEA’s de novo provision asserts that “the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated,” the court suggested that Congress was likely referring to proceedings brought by the government as a plaintiff against a private manufacturer (e.g., enforcement actions).<sup>185</sup> Conversely, where a manufacturer challenges an agency rule or action, the United States, rather than the

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of the APA). Under 5 U.S.C. § 706, federal courts can review the propriety of agency rules or actions. Specifically, under 5 U.S.C. § 706(2)(A), private parties can challenge an agency rule or action for being “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”

179. The FDA can bring enforcement actions against manufacturers under 21 U.S.C. § 332 (2006).

180. *NVE, Inc. v. Dep’t of Health & Human Servs. (NVE II)*, 436 F.3d 182, 192 (3d Cir. 2006); *Nutraceutical II*, 459 F.3d at 1037–38.

181. 21 U.S.C. § 342(f)(1) (2000 & Supp. IV 2005).

182. 21 U.S.C. § 342 (f)(1)(A) (1994).

183. One district court decision supports this interpretation and its application to actions where the government files a complaint for forfeiture of dietary supplements. *Hi-Tech Pharms., Inc. v. Crawford*, 505 F. Supp. 2d 1341, 1345–46 (N.D. Ga. 2007). *Hi-Tech* held that where the FDA brings a forfeiture action and lacks the benefit of a regulation to support its contention that a dietary supplement at issue is adulterated, under the DSHEA’s “de novo” language, it bears the burden of proof at trial in proving adulteration. *Id.* at 1358. By contrast, where the agency has the support of a valid regulation declaring the supplement in question adulterated, then “the court must defer to the agency’s regulation and should not review anew the question of adulteration.” *Id.*

184. *NVE II*, 436 F.3d at 191–92.

185. *Id.*

manufacturer, is named as the defendant.<sup>186</sup> Because in that type of proceeding, the burden is on the manufacturer (rather than the United States) to prove each element of its claim, such actions should be decided under the APA.<sup>187</sup>

Ultimately, other circuits and lower courts, like the district courts in *Nutraceutical I* and *NVE I*, may choose not to read the DSHEA in this way, since the statute does not expressly preclude the application of the de novo provision to FDA rulemaking, nor does it state that the provision only applies to enforcement actions (or cases where the United States is the plaintiff).<sup>188</sup> To avoid a potential split and fix any confusion, 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*

To ensure safety and efficacy as fully as possible, 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.<sup>189</sup> For example, in the case of ephedrine, the Tenth Circuit explained that the FDA “never required manufacturers to provide data on the benefits or safety of ephedrine use,” thereby allowing ephedrine to “enter the market without findings of safety or efficacy.”<sup>190</sup> Only after its adverse effects became public knowledge did the agency pull it from the market.<sup>191</sup> 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.

*1. European Union Testing for Dietary Supplements*

The European Union (EU) has taken steps to avoid this risk. In response to several episodes of food contamination in the late 1990s, the EU enacted measures to protect consumers from potentially hazardous dietary supplements.<sup>192</sup> In 2002, the European Parliament and Council adopted the

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186. *Id.* at 192.

187. *Id.*

188. The Third Circuit inverted this interpretation by stating that Congress did not express “any intention that rulemaking was to be reviewed on a de novo basis,” as there is “no mention in DSHEA of ‘review’ of agency action.” *See id.* at 191.

189. *See Gilhooly, supra* note 9, at 702 (taking issue with the DSHEA’s passive approach to enforcement and regulation, comparing it to “that used at the beginning of the century”).

190. *Nutraceutical Corp. v. Von Eschenbach (Nutraceutical II)*, 459 F.3d 1033, 1039 (10th Cir. 2006).

191. By the time the FDA had actually instituted its prohibition against ephedrine alkaloids, the agency had received over 17,000 adverse event reports stemming from use of supplements containing ephedrine alkaloids. Dietary Supplement Containing Ephedrine Alkaloids, 68 Fed. Reg. 10417, 10418 (Mar. 5, 2003).

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

Food Supplements Directive (FSD).<sup>193</sup> The FSD established a “positive list” of 112 substances that EU regulatory agencies had deemed fit for consumption, such as 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 scientific data demonstrating that its product is safe.<sup>194</sup> The application process can take two or three years, and upon receiving approval, the manufacturer must make its data publicly available.<sup>195</sup> EU legislation overrides domestic legislation, so all member states must enforce the FSD.<sup>196</sup>

The FSD reflects the EU’s adherence to “the precautionary principle”: the pursuit of a risk-averse policy to product availability within free markets, based on the premise that such products should not be introduced until they are proven safe.<sup>197</sup> According to this principle, manufacturers bear a greater burden in demonstrating product safety, and product benefits receive diminished priority.<sup>198</sup> The precautionary principle stresses the importance of scientific testing and evaluation in determining whether a product poses an acceptable risk of harm and emphasizes the need to make this information available to consumers at the time of purchase.<sup>199</sup>

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.<sup>200</sup> Yet it stands as good law.<sup>201</sup> The FSD does not require showings of efficacy, but nonetheless it goes far beyond the DSHEA in imposing an affirmative duty on manufacturers 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.

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193. Council Directive 2002/46 on the Approximation of the Laws of the Member States Relating to Food Supplements, 2002 O.J. (L 183) 51 (EC) [hereinafter Food Supplements Directive].

194. LeCong, *supra* note 192, at 109; *see also* Food Supplements Directive, *supra* note 193.

195. LeCong, *supra* note 192, at 109; *see also* Food Supplements Directive, *supra* note 193 (providing that “generally acceptable scientific data” should govern the sale and labeling of dietary supplements, and that food supplements should be monitored to ensure safety).

196. LeCong, *supra* note 192, at 108.

197. McCann, *supra* note 38, at 254–55; *see also* George E.C. York, *Global Foods, Local Tastes & Biotechnology: The New Legal Architecture of International Agriculture Trade*, 7 COLUM. J. EUR. L. 423, 443–46 (2001) (explaining Europe’s adherence to the precautionary principle).

198. McCann, *supra* note 38, at 254–55.

199. *See* York, *supra* note 197, at 444–45.

200. LeCong, *supra* note 192, at 111.

201. *Id.*

## 2. Maintaining Product Availability During Testing

The FDA needs broad discretion to develop whatever standard of efficacy and safety it believes manufacturers should meet. The FDA’s discretion over supplements should more closely resemble its discretion over drugs, rather than food, since some supplements—like ephedra and hydroxycut—have rather dangerous side effects. The regulations governing pharmaceuticals require years of FDA-approved testing, divided into phases, before a drug can be sold on the market.<sup>202</sup> Phase I studies usually involve approximately twenty to eighty healthy participants and are limited to determining appropriate dosing, documenting how a drug is metabolized, and identifying short-term side effects.<sup>203</sup> Phase II trials not only include a greater number of participants, anywhere from one hundred to three hundred, but also include participants suffering from a disease the drug is intended to treat.<sup>204</sup> Phase II trials test for efficacy.<sup>205</sup> Phase III trials involve even more participants (anywhere from one thousand to three thousand), and yield a more nuanced assessment of the product’s benefits and side effects.<sup>206</sup> 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.<sup>207</sup> The FDA will occasionally mandate Phase IV trials as well. Nevertheless, 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.<sup>208</sup>

Ensuring the safety and efficacy of dietary supplements may not require such extensive testing. If the FDA possesses substantial data concerning the safety and efficacy of a dietary supplement, it should not require the manufacturer to conduct tests.<sup>209</sup> For instance, since data regarding the safety and structure/function benefits of vitamin C is fairly well established, additional testing is not necessary.<sup>210</sup> On the other hand, if the FDA has reason to suspect that the interaction of vitamin C with other substances contained in a

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202. See Bruce H. Schindler, *Where There’s Smoke There’s Fire: The Dangers of the Dietary Supplement Industry*, 42 N.Y.L. SCH. L. REV. 261, 265–67 (1998) (describing the drug approval process). See generally FDA, *Understanding Clinical Trials*, <http://clinicaltrials.gov/ct2/info/understand#Q01> (last visited Mar. 19, 2010) [hereinafter FDA, *Understanding Clinical Trials*].

203. FDA, *Understanding Clinical Trials*, *supra* note 202.

204. *Id.*

205. *Id.*

206. *Id.*

207. *Id.*

208. *Id.*

209. See Michael Sachs, *Ephedra and the Failure of Dietary Supplement Regulation*, 54 CATH. U. L. REV. 661, 696 (2005) (arguing that premarket approval for all dietary supplements would “effectively grind the dietary supplement industry to a halt because all dietary supplements would have to apply for premarket certification and an overwhelmed FDA would be unable to act quickly”).

210. *But see* McCann, *supra* note 38, at 265 (stating that while past studies have demonstrated that vitamin C is safe, recent studies suggest that certain levels of vitamin C consumption might prove harmful).

supplement poses a risk, it should require tests. If the FDA lacks substantial data regarding the veracity of structure/function claims made on the label, it should also require tests.

Notwithstanding this possibility, premarket tests should not become the norm. These are tests that a manufacturer must conduct before its product can be approved for sale. 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—an attitude that exacerbates the respective risks of these goods, because consumers might exercise less diligence in determining whether the supplements they consume are safe or effective.<sup>211</sup> Many people who take supplements daily, who may not be confident of their effects but who buy them regardless, would not wish to compromise their access to these products by subjecting them to lengthy tests.<sup>212</sup> They see dietary supplements as something different from drugs.<sup>213</sup> Dietary supplements are viewed as harmless and lacking in the synthetic properties that make pharmaceutical products risky.<sup>214</sup> Thus, extending the FDA's drug-testing scheme to dietary supplements might 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.<sup>215</sup>

Instead of imposing lengthy and expensive premarket tests on supplement manufacturers, 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. When applying these trials to the supplement market, the FDA can narrow their scope of these trials by requiring only testing of supplements that prior studies have not proven safe or effective, according to whatever scientific consensus the FDA deems appropriate. For instance, there is undeniable evidence proving not only vitamin C's safety, but also its health benefits.<sup>216</sup> Consequently, there would be no need to mandate tests for vitamin C or comparable products. Since manufacturers would be able to continue selling dietary supplements while conducting tests, they retain a source of revenue to subsidize their research.

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211. See McCann, *supra* note 38, at 221–22.

212. *Id.*

213. *Id.*

214. *Id.* at 226 (describing the tendency of consumers to equate the word “natural” with “harmless”).

215. Or at least Congress concluded so. See 21 U.S.C. § 321(d)(14) (2006) (stating that “dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare”). It may prove difficult to divest Congress of this view, so a testing regime that is just as strict as that employed for drugs probably will not secure wide support.

216. Morgan J. Wais, *Stomaching the Burden of Dietary Supplement Safety: The Need to Shift the Burden of Proof Under the Dietary Supplement Health and Education Act of 1994*, 28 SEATTLE U. L. REV. 849, 851 (2005).

In implementing this regulatory scheme, the FDA should determine the duration of tests and the degree of efficacy that a nutraceutical must demonstrate to remain on the market.<sup>217</sup> The FDA, rather than Congress, is in the best position to determine which dietary supplements should be subject to testing, given its scientific expertise and familiarity with nutraceutical products currently on the market. Additionally, the FDA has already developed reliable methods for testing these products. Double-blind studies, commonly used by the agency in testing drugs, are one way the FDA could test the efficacy of supplements. In such a study, the agency might require manufacturers to show some statistical disparity in health improvements between subjects taking the test supplement and those taking a placebo.<sup>218</sup>

In implementing this testing, the FDA should formulate its efficacy determinations based on the type of health or structure/function claims each manufacturer makes. It could encourage vendors of the same supplement to conduct joint studies and to 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. Alternatively, the FDA might require the manufacturer to provide a copy of the study’s results within the package of the dietary supplement so that the consumer could make an educated decision before buying that supplement again. This approach would be comparable to the documentation accompanying the purchase of prescription medication.<sup>219</sup>

A testing regime will not lack problems. Any regulatory system will very likely increase the cost of supplements for consumers. Additionally, both the FDA and manufacturers may face difficulties in determining whether a dietary supplement lives up to a very general structure/function claim, like “improves heart health.” To mitigate some of these problems, Congress could direct the FDA to impose more lenient testing standards than those applied to drugs in

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217. Kaiser, *supra* note 129, at 1274 (advocating a new regulatory model whereby the FDA must approve all nutraceutical labeling statements).

218. See generally Kathleen M. Boozang, *The Therapeutic Placebo: The Case for Patient Deception*, 54 FLA. L. REV. 687, 690–91 (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”).

219. See Glen Bradford & Charles C. Elben, *The Drug Package Insert and the PDR as Establishing the Standard of Care in Prescription Drug Liability Cases*, 57 J. Mo. B. 233, 234 (2001) (describing the role of the prescription drug “insert” contained within the product’s package, which is to outline the drug’s approved uses, its recommended dosing and duration of use, and its possible beneficial and harmful effects); see also *Prescription Drug Insert Information Made Clearer*, CNN, Jan. 20, 2006, <http://www.cnn.com/HEALTH/library/DI/00053.html> (describing the FDA’s efforts to make printed information included with prescription drugs easier for doctors and consumers to understand). The drug insert usually includes possible side effects of the drug and contraindications (conditions that preclude the patient from taking the drug, like an underlying heart problem).

assessing the efficacy of supplements. Nevertheless, 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 of marketing a dietary supplement. It may increase costs, but ensuring that a hazardous supplement does not evade FDA scrutiny and replicate the ephedrine disaster is a far greater priority than augmenting manufacturers' profit margins. Furthermore, testing may actually enhance profitability within the industry by increasing confidence in the reliability of products, which will give consumers a greater incentive to purchase legitimized dietary supplements.<sup>220</sup>

#### IV

#### CREATING AWARENESS OF THE NEED FOR REFORM THROUGH STRATEGIC LITIGATION

Pressure on Congress to amend the FDA could be achieved through legal activism. The term "social impact litigation" refers to the strategic use of class action lawsuits by private plaintiffs' attorneys to achieve social policy reform.<sup>221</sup> Because of the enormous damages at stake, class action lawsuits can be an effective way to secure change in industry practices.<sup>222</sup> For example, a 1998 class action litigation against the tobacco industry culminated in a massive settlement, largely beneficial to consumers, wherein tobacco companies agreed to restrictions on their advertising practices—restrictions that Congress had earlier failed to adopt.<sup>223</sup>

Class action lawsuits can also trigger government intervention. In *Ridgeway v. Flagstar Corp.*, African-American customers filed class action suits against the Denny's restaurant chain, alleging discrimination in how the company treated African-American and other minority customers.<sup>224</sup> Denny's parent company, Flagstar, eventually agreed to pay more than \$54 million in damages to an estimated 290,000 people and to provide sensitivity training to Denny's employees.<sup>225</sup> However, the Justice Department also stepped in and appointed a private civil rights lawyer to monitor compliance with the settlement agreement.<sup>226</sup> Subsequently, customers throughout the country

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220. McCann, *supra* note 38, at 217.

221. Deborah R. Hensler, *The New Social Policy Torts: Litigation as a Legislative Strategy Some Preliminary Thoughts on a New Research Project*, 51 DEPAUL L. REV. 493, 497–99 (2001) (discussing, more generally, the role of litigation in encouraging social reform, and more specifically, the positive impact of mass tort litigation on the practices of tobacco companies).

222. *Id.* at 494.

223. *Id.*

224. *Id.* at 506; *Ridgeway v. Flagstar Corp.*, Nos. C 93-20202 JW, C 93-20208 JW (N.D. Cal. 1994).

225. Hensler, *supra* note 221, at 506.

226. *Id.* at 507.

charged Denny's with continuing discriminatory practices, and the federal government began investigating incidents in which customers alleged that they had been harassed by the Denny's staff.<sup>227</sup> This type of government intervention, in response to concerns raised through private class action litigation, was quite significant.

Similar to the way the Justice Department intervened in *Ridgeway*, litigation can be an effective way to encourage Congress to change the DSHEA. The media attention that trials often generate can galvanize support among voters for greater legislative protections.<sup>228</sup> Litigation will also furnish a record of the type of side effects associated with nutraceutical use, and of the prevalence of fraud within the industry. Such a record would indicate to Congress that a sufficient number of consumers are being harmed by dietary supplement consumption, thereby evidencing the need for a change in the law. If state courts begin issuing judgments against manufacturers, Congress may recognize that the federal government is doing an inadequate job of protecting consumers from unsafe or ineffective products. This recognition constitutes a requisite step in revising the DSHEA.

Also, like the effects of class action litigation on the tobacco industry, litigation may bring about a change in the way dietary supplement manufacturers advertise and market their products. Manufacturers may be more willing to test their products, so as to protect themselves from product liability claims.<sup>229</sup> Manufacturers will recognize that by taking measures to produce safe and effective dietary supplements, they can avoid paying costly judgments and can shield themselves from the negative publicity that might result from a trial proceeding.<sup>230</sup>

This Section will focus on California statutory claims, as California has traditionally been among the friendliest forums for consumers; although, the passage of Proposition 64 in 2004 has undermined that notion, which the following Section will explain more fully.<sup>231</sup> The strategy employed under

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227. *Id.*

228. See Peter D. Jacobson & Shannon Brownlee, *The Mass Media's Influence on Health Law and Policy Symposium*, 5 HOUS. J. HEALTH L. & POL'Y 235, 240-41 (2005) (describing the ways in which criminal trials, like the O.J. Simpson trial, can "create a groundswell of interest" concerning particular issues, and how the media can also change public opinion on managed health care).

229. McCann, *supra* note 38, at 217.

230. *Id.*

231. 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 (UCL) 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 the provisions of the UCL and its standing requirements.

California law can be used to bring claims against manufacturers in other states.

The discussion's shift in focus to state law is necessary because neither the DSHEA nor the FDCA vest private parties with a cause of action.<sup>232</sup> Under both statutes, only the federal government can bring an action against a dietary supplement or drug manufacturer.<sup>233</sup> Consequently, there is no way to effectuate legislative change through federal litigation. The best strategy for class action plaintiffs' attorneys and state attorneys general is to bring claims under state consumer protection laws.

*A. California's Unfair Competition Law Gives Consumers a Private Cause of Action Against Manufacturers*

California's Unfair Competition Law (UCL) covers a wide range of conduct<sup>234</sup> and has proven effective in vesting consumers with a private cause of action against manufacturers of FDA-regulated products.<sup>235</sup> The UCL proscribes any unlawful, unfair, or fraudulent business practice.<sup>236</sup> Conduct can be "unfair" even if it does not violate another law.<sup>237</sup> Section 17200 of the UCL permits courts to enjoin ongoing wrongful business conduct in whatever context such activity might occur. The UCL is equitable in nature and precludes the recovery of compensatory or punitive damages.<sup>238</sup> However, restitution is recoverable: a court can compel a manufacturer to disgorge profits obtained through unfair business practices.<sup>239</sup>

The UCL's scope is quite broad. Under the law, a business practice needs to meet only one of the three statutory criteria—unlawful, unfair, or fraudulent—to constitute unfair competition.<sup>240</sup> 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, Inc. v. Los Angeles Cellular Telephone Co.*, the California Supreme Court held that as long as the legislature has not expressly characterized a particular activity as lawful, it is

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232. See *Grove Fresh Distribs., Inc. v. Flavor Fresh Foods*, 720 F. Supp. 714, 715 (N.D. Ill. 1989) (stating that "courts have held that there is no private cause of action under the FDCA"); see also *NVE, Inc. v. Dep't of Health & Human Servs. (NVE II)*, 436 F.3d 182, 189 (3d Cir. 2006) (holding that the DSHEA "does not provide a private cause of action"); *Consumer Justice Ctr. v. Olympian Labs, Inc.*, 99 Cal. App. 4th 1056, 1063 (Ct. App. 2002) (holding that there is no private cause of action under the FDCA).

233. *Consumer Justice Ctr.*, 99 Cal. App. 4th at 1063 (holding that there is no private cause of action under the FDCA).

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

235. See generally *Cel-Tech Commc'ns, Inc. v. L.A. Cellular Tel. Co.*, 20 Cal. 4th 163, 191–95 (1999).

236. Cal. Bus. & Prof. Code § 17200.

237. *Cel-Tech Commc'ns*, 20 Cal. 4th at 191–95.

238. *Id.*

239. *Corbett v. Superior Court*, 101 Cal. App. 4th 649, 655 (Ct. App. 2002).

240. Cal. Bus. & Prof. Code § 17200.

actionable under the second or third elements of the UCL even if no other law prohibits the activity.<sup>241</sup> Consequently, even where a manufacturer's claims might comport with the DSHEA, given its lax labeling requirements, the UCL enables consumers to challenge otherwise deceptive labeling practices.

### *1. Manufacturer Liability for Fraud Under the UCL*

Deceptive labeling is particularly well suited to a UCL claim, because the UCL's fraud predicate differs from common-law fraud. The UCL does not require intent (scienter) to induce reliance, or actual reliance.<sup>242</sup> Instead, the standard is whether a business practice is likely to deceive the public.<sup>243</sup> Courts have characterized the UCL as a "strict-liability" law.<sup>244</sup> A party can establish fraud even if no one was deceived.<sup>245</sup>

One decision involving UCL claims brought against a dietary supplement manufacturer proves especially pertinent. In *Nagel v. Twin Laboratories, Inc.*, a manufacturer indicated on the label of its herbal supplement that the product was "standardized for 6% ephedrine."<sup>246</sup> However, evidence at trial suggested that the actual amount of ephedrine varied dramatically.<sup>247</sup> Accordingly, the California Court of Appeals held that a "reasonable consumer concerned about the amount of ephedrine in the product would likely be misled by Twin Labs' advertising."<sup>248</sup> Therefore, the plaintiff had established a probability of proving his claim under the UCL.<sup>249</sup> The manufacturer argued that its product complied with an FDA regulation requiring that the "nutrient content of a composite is at least equal to 80 percent of the value for that nutrient declared on the label."<sup>250</sup> However, the court held that the federal government's determination that a 20 percent inaccuracy on the label of a dietary supplement is acceptable "does not mean a reasonable consumer would not be misled by it, nor does it mean that under California law the advertising cannot be deemed false."<sup>251</sup> Thus, the

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241. *Cel-Tech Commc'ns*, 20 Cal. 4th at 191–95.

242. *See* *People v. Regan*, 95 Cal. App. 3d Supp. 1, 5–6 (Ct. App. 1979) (holding that where "qualifying words such as knowingly, intentionally, or fraudulently are omitted from provisions creating the offense it is held that guilty knowledge and intent are not elements of the offense"); *see also* Seong Hwan Kim, *California's Unfair Competition Act: Will It Give Rise to Another 'Wave' in Smoking and Health Litigation?*, 35 SANTA CLARA L. REV. 193, 212 n.97 (1994) (stating that "scienter is not a requisite element of an unfair competition claim").

243. *Cnty. Assisting Recovery, Inc. v. Aegis Sec.*, 92 Cal. App. 4th 886, 892 (Ct. App. 2001).

244. *See* Kim, *supra* note 242, at 193, n.97 (1994) (characterizing the UCL as a strict liability law).

245. *Id.*

246. *Nagel v. Twin Labs., Inc.*, 109 Cal. App. 4th 39, 43 (Dist. Ct. App. 2003).

247. *Id.* at 52.

248. *Id.*

249. *Id.*

250. *Id.* at 53; 21 C.F.R. § 101.9(g)(4) (2002).

251. *Nagel*, 109 Cal. App. 4th at 53.

court affirmed the trial court's denial of the manufacturer's motion to strike the plaintiff's claims.<sup>252</sup>

Even cases outside the nutraceutical context could serve as precedent for UCL actions brought against dietary supplement manufacturers. The court in *Pastoria v. Nationwide Insurance* held that an insurer's practice of not disclosing imminent policy changes was fraudulent under the UCL because the changes were "material" and were only disclosed after consumers purchased their policies.<sup>253</sup> 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 unenforceable rules and regulations.<sup>254</sup> For instance, one contractual provision allowing the owner 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.<sup>255</sup> Since tenants were unlikely to know of the existence of this law, the owner's attempt to impose the agreement on them was deceptive and fraudulent.<sup>256</sup> These cases demonstrate that where a commercial practice undermines the interests of consumers (e.g., tenants), courts will hold companies accountable by interpreting the UCL liberally.

One can argue that unsubstantiated structure/function health claims are also likely to deceive the public. It matters little whether the manufacturer has placed 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. This lack of government action is actually more likely to lead consumers to assume that a claim about the efficacy of a supplement is true. Also, in *Nagel*, the California Court of Appeals expressly stated that a product's label can comply with FDA regulations and still be misleading and therefore actionable under California law.<sup>257</sup> Consequently, even dietary supplements that comport with the DSHEA might still trigger claims under the UCL.

Additionally, like the failure to disclose material policy changes in *Pastoria*, a manufacturer's failure to specify that studies pertaining to a structure/function claim are inconclusive on a nutraceutical label 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

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252. *Id.* at 55.

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

254. *People v. McKale*, 25 Cal. 3d 626, 632–33 (1979).

255. *Id.* at 637.

256. *Id.*

257. *Nagel*, 109 Cal. App. 4th at 53.

“speeds recovery from training and increases immune function.”<sup>258</sup> Though reliance is not a requirement under the UCL, these statements could induce reliance. Nature voluntarily destroyed 5,700 boxes of its misbranded product after receiving a warning from the FDA that its labeling practices were improper.<sup>259</sup> 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.

## 2. “Unfair” Labeling Procedures Under the UCL

Additionally, labels may be considered unfair under the UCL. The UCL’s “unfair” prong has been the subject of some debate, and appellate opinions have articulated various tests for distinguishing an unfair business practice from one that is fraudulent or unlawful.<sup>260</sup> One test defines an unfair practice as conduct that is “immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers.”<sup>261</sup> Alternatively, *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.”<sup>262</sup> 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.”<sup>263</sup>

California courts have also grappled with the meaning of “unfair” in the UCL. One court has characterized business practices as “unfair” where the gravity of harm outweighs the utility of a particular practice. In *Smith v. State Farm Mutual Automobile Co.*, plaintiffs filed suit against several insurance companies for requiring multi-vehicle owners to purchase a single policy covering all of their vehicles.<sup>264</sup> The Court of Appeal declared that the practice was unfair, because the gravity of harm (forcing consumers to purchase insurance for vehicles they do not drive) outweighed the utility of the conduct (consolidating all policies and maximizing the insurer’s revenue).<sup>265</sup> Similarly, *State Farm Fire & Casualty Co. v. Superior Court* held that “systematically

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258. *The Status of Dietary Supplements in the U.S.: Hearing Before the Subcomm. on Human Rights and Wellness of the H. Comm. on Government Reform*, 108th Cong. (2004) (statement of Robert Bracket, Director, FDA, Ctr. for Food Safety and Nutrition), available at <http://www.fda.gov/NewsEvents/Testimony/ucml14758.htm> (last visited Mar. 19, 2010).

259. *Id.*

260. See Suh, *supra* note 231; see also *Cel-Tech Commc’ns, Inc. v. L.A. Cellular Tel. Co.*, 20 Cal. 4th 163, 183–84 (1999) (illustrating inconsistent case law regarding the types of business practices that qualify as “unfair”).

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

262. *Smith v. State Farm Mut. Auto. Ins. Co.*, 93 Cal. App. 4th 700, 719 (Ct. App. 2001).

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

264. *Smith v. State Farm Mut. Auto. Ins. Co.*, 93 Cal. App. 4th 700, 704–06 (Ct. App. 2001).

265. *Id.* at 718–22.

breaching a form contract affecting many consumers” would give rise to a claim of unfairness.<sup>266</sup>

Under any of these standards, the sale of dietary supplements that manufacturers have proven neither 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, Best Life International’s dietary supplement Viga contained the prescription drug Sildenafil, commonly known as Viagra.<sup>267</sup> The labeling of the product made no mention of this ingredient. The product was clearly misbranded under the DSHEA.<sup>268</sup> This mislabeling constitutes a violation of the unfair and unlawful prongs of the UCL. The *Bardin* court held that to show “unfairness” under the UCL, the plaintiff must be able to point to a violation of some other law.<sup>269</sup> The sale of Viga constitutes a violation of the DSHEA and satisfies that requirement. It also furnishes a UCL claim under the unlawful prong. These violations favor FDA prohibitions on the sale of Viga.

Likewise, an analysis under the *State Farm* balancing test supports the recall of Viga, since 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 elicits no beneficial effect is analogous to the systematic breach of a form agreement “affecting many consumers,” which is one example of an unfair business practice offered by *State Farm*.<sup>270</sup> 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. This is because 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.

### 3. Proposition 64’s “Injury in Fact” Requirement

The preceding discussion offers merely a general treatment of what plaintiffs have to assert in a UCL claim against nutraceutical manufacturers. California’s passage of Proposition 64 in November 2004 has made UCL litigation more difficult for plaintiffs.<sup>271</sup> Prior to Proposition 64, plaintiffs alleging a violation of the UCL did not have to allege damages in their

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

267. FDA, Recall Notice, Event ID 26400 (June 2, 2003).

268. *See* 21 U.S.C. § 343(s)(2)(A) (2006) (stating that the label of the supplement must properly list the ingredients of the supplement).

269. *Bardin v. Daimlerchrysler Corp.*, 136 Cal. App. 4th 1255, 1265 (Ct. App. 2006).

270. *Smith v. State Farm Mut. Auto. Ins. Co.*, 93 Cal. App. 4th 700, 719 (Ct. App. 2001).

271. *See* Suh, *supra* note 231, at 230 (stating that Proposition 64 imposed a more stringent standing requirement for private plaintiffs bringing suit under the UCL).

complaints.<sup>272</sup> 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.<sup>273</sup> Courts have also imposed a causation requirement: the unfair competition "must have caused the plaintiff to lose money or property."<sup>274</sup>

Including both "injury-in-fact" and "the loss of property or money" seems redundant. It suggests that monetary or proprietary damage is insufficient and that plaintiffs must show physical injury in order to bring 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 unlawful acts<sup>275</sup> or the loss of financial resources.<sup>276</sup> Moreover, 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.<sup>277</sup> Thus, these civil servants can be powerful advocates on behalf of the public in litigating against manufacturers selling unsafe or ineffective supplements.

The requirement of injury may be less problematic to supplement regulation. 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.<sup>278</sup> Causation can be established by showing that but for the structure/function claim made on the label, the plaintiff would not have bought the dietary supplement. Additionally, the office of the attorney general can bring a UCL claim against a manufacturer without having to prove injury-in-fact; its only burden is to prove that the label was likely to deceive the public.<sup>279</sup>

Even if an individual has a cognizable claim under the UCL, the optimal way to bring UCL claims against manufacturers is still through class action litigation because monetary damages are unavailable under Section 17200. A class action would allow for disgorgement of a significant portion of the

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272. *Id.* at 233.

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

274. *Hall v. Time, Inc.*, 158 Cal. App. 4th 847, 849 (Ct. App. 2008); *Laster v. T-Mobile USA, Inc.*, 407 F. Supp. 2d 1181, 1194 (S.D. Cal. 2005).

275. *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).

276. *S. Cal. Hous. Rights Ctr. v. Los Feliz Towers Homeowners Ass'n Bd.*, 426 F. Supp. 2d 1061, 1069 (C.D. Cal. 2005).

277. Cal. Bus. & Prof. Code § 17204.

278. *See S. Cal. Hous. Rights Ctr.*, 426 F. Supp. 2d at 1069 (stating that the loss of financial resources meets the injury requirement under the UCL).

279. *Id.*

manufacturer's profits as restitution and offer a greater monetary incentive for litigating these types of cases.<sup>280</sup>

*B. The California Legal Remedies Act: A Way to Bolster UCL Claims*

The California Legal Remedies Act (CLRA) amplifies the legal arsenal consumers have.<sup>281</sup> While the two are closely related, the CLRA lacks the UCL's broad prohibition against deceptive activities. Instead, Section 1770 of the CLRA lists twenty-four "unlawful" business practices that trigger liability under the CLRA.<sup>282</sup> 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.<sup>283</sup> A practice that violates the CLRA can also give rise to a claim under the "unlawful" prong of the UCL.<sup>284</sup> The standing requirement is met if the unlawful business practices damage the consumer.<sup>285</sup> However, Section 1782(b) contains a safe-harbor provision. The plaintiff must notify the defendant of the unlawful practice, and the defendant has thirty days after receipt of such notice to cure the plaintiff's injury.<sup>286</sup> Nevertheless, this safe-harbor provision does not apply where the plaintiff seeks injunctive relief.<sup>287</sup> Under the CLRA, the plaintiff is entitled to compensatory and punitive damages or injunctive relief.<sup>288</sup>

A nutraceutical manufacturer that makes unsubstantiated health claims has "misrepresented the . . . certification" of goods under Section 1770.<sup>289</sup> 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 functionality. Unverifiable labeling claims go beyond "mere puffing," which courts have held is not actionable under either the CLRA or the common-law doctrine of fraud.<sup>290</sup> 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

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280. Kraus v. Trinity Mgmt. Servs., Inc., 23 Cal. 4th 116, 127 (2000) (holding that disgorgement as a restitutionary remedy in class action suits is available under Section 17200).

281. Cal. Civ. Code § 1750 (West 2009).

282. Cal. Civ. Code § 1770.

283. Cal. Civ. Code § 1770(a)(1)–(23).

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

285. Kagan v. Gibraltar Sav. & Loan Ass'n, 35 Cal. 3d 582, 593 (1984).

286. *Id.* at 590.

287. *Id.*

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

289. Cal. Civ. Code § 1770(a)(2) (West 2009).

290. Chamberlan v. Ford Motor Co., 369 F. Supp. 2d 1138, 1144 (N.D. Cal. 2005); *see also* Consumer Advocates v. EchoStar Satellite Corp., 113 Cal. App. 4th 1351, 1361 (Ct. App. 2003) (holding that statements akin to "mere puffing" do not give rise to liability).

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.<sup>291</sup>

While this discussion is admittedly “California-centric,” it should be noted that consumers in other states have brought claims against dietary supplement manufacturers for fraud and deceptive practices. For instance, in *Delahunt v. Cytodyne Technologies*, a consumer of ephedrine alleged that a dietary supplement manufacturer had violated the Ohio Consumers Sales Practices Act by failing to warn the plaintiff and class members of the true dangers of ephedrine.<sup>292</sup> Ultimately, the plaintiff was successful in defeating the manufacturer’s motion to dismiss her class action claim under that statute.<sup>293</sup> Similarly, in *McClain v. Metabolife International, Inc.*, a district court in Alabama indicated that a manufacturer of dietary supplements and other goods is negligent as a matter of law under the Alabama Extended Manufacturer’s Liability Doctrine (AEMLD), when it sells a product that is “not reasonably safe when applied to its intended use in the usual and customary manner.”<sup>294</sup> In that case, while the court granted the defendant’s motion for summary judgment on the plaintiff’s AEMLD claim, it denied summary judgment on the plaintiff’s failure to warn claim.<sup>295</sup> These cases illustrate that California is not the only forum for consumers of dietary supplements seeking judicial redress.

### *C. Defenses Manufacturers Might Assert Against Any Legal Claims*

#### *1. Manufacturers’ First Defense: The DSHEA Preempts State Law Claims*

In order to defend themselves against claims, manufacturers might try to raise a preemption argument. 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.<sup>296</sup> 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

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291. See *Consumer Advocates*, 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 based on the effect it would have on a reasonable consumer).

292. *Delahunt v. Cytodyne Techs*, 241 F. Supp. 2d 827, 834–36 (S.D. Ohio 2003).

293. *Id.*

294. *McClain v. Metabolife Int’l, Inc.*, 193 F. Supp. 2d 1252, 1254–57 (N.D. Ala. 2002).

295. *Id.* at 1257.

296. For a helpful discussion on preemption, see *In re Farm Raised Salmon Cases*, 42 Cal. 4th 1077, 1089–98 (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).

when it does not violate an FDA rule, thereby usurping the agency's role in making efficacy and safety determinations regarding dietary supplements. This argument suggests that the FDA's scientific expertise and experiences put it in a better position to authenticate labeling claims than courts.<sup>297</sup>

At least one decision invalidates that argument. *Consumer Justice Center v. Olympian Labs, Inc.* held that the DSHEA does not preempt the UCL.<sup>298</sup> That case concerned deceptive health claims regarding a dietary supplement.<sup>299</sup> The California Court of Appeal maintained that Congress's decision not to allow private causes of action under the DSHEA has left "a considerable amount of room . . . for the states to occupy."<sup>300</sup> The defendant argued that the trial court's order of injunctive relief impaired the FDA's ability to impose uniform labeling requirements on manufacturers.<sup>301</sup> The court disagreed, stating that injunctive relief did not prevent manufacturers from complying with the FDA's separate labeling requirements.<sup>302</sup> According to the court, because the government's labeling requirements are likely consistent with any order imposed by a court concerning deceptive labeling, a court order would not preclude a manufacturer from adhering to the government's separate labeling requirements.<sup>303</sup> Moreover, because Congress has included express preemption provisions in prior amendments to the FDCA like the Medical Devices Act, the court felt that Congress's decision not to include express preemption in the DSHEA suggests that preemption runs contrary to congressional intent.<sup>304</sup>

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).<sup>305</sup> Thus, a 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.

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297. See Norris, *supra* note 284, 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).

298. *Consumer Justice Ctr. v. Olympian Labs, Inc.*, 99 Cal. App. 4th 1056, 1058–66 (Ct. App. 2002).

299. *Id.* at 1063.

300. *Id.* at 1063.

301. *Id.* at 1062.

302. *Id.* at 1064.

303. *Id.* at 1062 n.8.

304. *Id.* at 1059.

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

## 2. *Manufacturers’ Second Defense: The First Amendment*

Another defense manufacturers can assert is that FDA restrictions on labeling claims infringe upon protected commercial speech, thereby violating the First Amendment. The seminal case on commercial speech, *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, held as a general matter that commercial speech receives some protection under the First Amendment, but less protection than noncommercial speech.<sup>306</sup> 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.<sup>307</sup>

In *Pearson v. Shalala*, the D.C. Circuit clarified the requirements of this test. It 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.”<sup>308</sup> In that case, the FDA declared that a company making a health claim that “consumption of fiber may reduce the risk of colorectal cancer” based that claim on inconclusive evidence.<sup>309</sup> According to the FDA, health claims not backed by significant scientific agreement were “inherently misleading” and subject to restriction.<sup>310</sup> However, the court stressed that “significant scientific agreement” was too amorphous a criterion for assessing whether a claim was inherently misleading.<sup>311</sup> It stated that where evidence regarding a health claim is inconclusive, the claim is only “potentially misleading.”<sup>312</sup> By contrast, the court seemed to suggest that a claim is inherently misleading only when the weight of evidence contradicts it.<sup>313</sup> The distinction between a “potentially misleading” health claim and a claim that is “inherently misleading” is important. The court suggested that the FDA cannot suppress a potentially misleading claim if the inclusion of a disclaimer would cure the misleading nature of that claim; instead, the FDA must allow the manufacturer an opportunity to remedy the defect by placing a disclaimer on the label before entirely banning the claim.<sup>314</sup> The disclaimer need not be extensive: “The FDA does not approve this claim” is a sufficient disclaimer.<sup>315</sup>

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306. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n*, 447 U.S. 557, 563–64 (1980).

307. *Id.* at 566.

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

309. *Id.* at 658.

310. *Id.*

311. *Id.* at 660–61.

312. *Id.* at 655.

313. *Id.* at 659–60.

314. *Id.*

315. *Id.* at 654.

While *Shalala* does not undermine Congress's 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 technically all unverified structure/function claims rest on inconclusive evidence and are therefore only "potentially misleading." Given the court's distinction between potentially misleading and inherently misleading claims, does *Shalala* mean that a manufacturer can always make an unverified structure/function claim on the label, so long as it places a disclaimer underneath that claim?

The court was not entirely clear on this point; in fact, it did not address the permissibility of restrictions on structure/function claims. Instead, it addressed the constitutionality of restrictions on health claims. However, the court did state that where the weight of evidence undermines the veracity of a claim, the FDA could deem the claim incurable "and ban it outright."<sup>316</sup> The term "weight of evidence" suggests that the absence of evidence in support of a claim would not mean that a claim of efficacy is inherently misleading. The FDA must still present affirmative evidence that the claim is inaccurate and that evidence must outweigh evidence in support of the claim.<sup>317</sup> Otherwise, a total ban on the claim will not be justified. This standard probably applies to structure/function claims in the same way it does to health claims. As for the outcome in *Shalala*, the D.C. Circuit invalidated the FDA's blanket prohibition against the manufacturer's health claims that consumption of its products limited the incidence of coronary heart disease, colorectal cancer, and neural tube defects. It instructed the district court to remand to the FDA for reconsideration of the manufacturer's health claims.<sup>318</sup>

One way the FDA can comply with *Shalala* is by changing its criteria for evaluating the validity of health claims. The D.C. Circuit seemed to suggest this when it 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.'"<sup>319</sup> 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 weight of evidence weighs against the veracity of a claim, a restriction on that claim will comport with the First Amendment.<sup>320</sup> 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.

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316. *Id.* at 659.

317. *Id.* at 659–60.

318. *Id.*

319. *Id.*

320. *Id.* at 659.

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## CONCLUSION

Due to the above reasons, Congress must revise the DSHEA. It has weakened the FDA’s regulatory authority over the dietary supplement industry to the detriment of consumers. Congress’s 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.<sup>321</sup> While devising new legislation to redress these problems may encounter significant resistance from manufacturers and some consumers, the need for greater oversight trumps the threat of resistance. The amendment this Comment proposes may limit the number of dietary supplements 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.

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321. See McCann, *supra* note 38, at 218 (stating that in 2003, the dietary supplement industry recorded \$20.1 billion dollars in sales).

