

## DIET STARTS MONDAY: AN ANALYSIS OF CURRENT U.S. DIETARY SUPPLEMENT REGULATIONS THROUGH AN INTERNATIONAL COMPARISON

### I. INTRODUCTION

It only takes a few moments walking through a grocery store, browsing through a magazine, or even just flipping through the channels to understand the massive role that dietary supplements play in American culture. In 2008, American consumers spent roughly \$25 billion on dietary supplements,<sup>1</sup> making up a sizeable portion of the massive \$228.3 billion global nutrition industry.<sup>2</sup> Dietary supplement use has soared in popularity to an estimated 150 million Americans<sup>3</sup>—approximately half of the U.S. population.<sup>4</sup> In line with their popularity in the United States, dietary supplements are highly popular abroad as well. Up to seventy percent of all Canadians take some form of supplement<sup>5</sup> and European consumers are responsible for roughly seventeen percent of the entire global dietary

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1. Carlotta Mast, *Supplement Industry Adds \$61 Billion to U.S. Economy*, NUTRITION Bus. J., May 28, 2009, <http://blog.nutritionbusinessjournal.com/nbj/2009/05/28/supplement-industry-adds-61-billion-to-us-economy/>. See also Patrick Rea, *2009 Supplement Industry – What Can We Expect?*, NUTRITION BUS. J., Nov. 11, 2008, <http://blog.nutritionbusinessjournal.com/nbj/2008/11/11/2009-supplement-industry-what-can-we-expect/> (noting that in 2008, in spite of the economic downturn, total sales figures would likely be higher than 2007 due to sales-growth in multivitamins and a renewal of consumer interest in herbs and vitamin D).

2. NUTRITION BUS. J., GLOBAL SUPPLEMENT & NUTRITION INDUSTRY REPORT 2007 (2007), [http://nutritionbusinessjournal.com/nutrition-industry/market-research/global\\_supplement\\_nutrition\\_industry\\_report\\_2007/index.html](http://nutritionbusinessjournal.com/nutrition-industry/market-research/global_supplement_nutrition_industry_report_2007/index.html) (demonstrating the global nutrition industry includes dietary supplements, but also includes other products like natural and organic foods).

3. Press Release, Council for Responsible Nutrition, Issues Surrounding Healthcare Key Priority for Supplement Users (Jan. 15, 2009), available at [http://www.crnusa.org/prpdfs/CRNPR09\\_ConsumerHC011509.pdf](http://www.crnusa.org/prpdfs/CRNPR09_ConsumerHC011509.pdf).

4. See Press Release, U.S. Census Bureau, Census Bureau Projects U.S. Population of 305.5 Million on New Year's Day (Dec. 29, 2008), available at [http://www.census.gov/Press\\_Releases/www/releases/archives/population/013127.html](http://www.census.gov/Press_Releases/www/releases/archives/population/013127.html).

5. CANADIAN HEALTH FOOD ASS'N, Western Canadians Big Users of Natural Health Products in a \$2.5 Billion Dollar Industry (Apr. 7, 2007) (on file with author) (statement of Canadian Health Food Association president Valerie Bell) ("Canada's natural health products sector has become a significant contributor to the Canadian economy.").

supplement market.<sup>6</sup> Due to the popularity of dietary supplements and the increasing size of the global industry, the importance of product safety has grown into a main concern for governmental regulatory bodies.<sup>7</sup>

Depending on the country, dietary supplements may have different definitions and different levels of regulation, if any. In the United States, dietary supplements are classified by the Dietary Supplement Health and Education Act of 1994 (DSHEA).<sup>8</sup> Under DSHEA, a dietary supplement can generally be described as a product taken orally that contains a "dietary ingredient" intended to *supplement* the diet. These dietary ingredients may include vitamins, minerals, herbs, and amino acids, among others.<sup>9</sup>

Dietary supplement regulations in the United States are distinct from both food and pharmaceutical regulations. Regulated primarily under DSHEA, the dietary supplement industry receives specific guidance for manufacturing and labeling of dietary supplements<sup>10</sup> Importantly, in a stark departure from the regulation of pharmaceuticals, dietary supplement manufacturers do not have to prove the safety of their products before they enter the market; rather the burden of proof is on the U. S. Food and Drug Administration (FDA).<sup>11</sup> Unfortunately, there is a subsequent history of unsafe dietary supplement products that have made their way into the market and have caused harm and even death to consumers.<sup>12</sup> Public

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6. See Peter Zambetti, Global Market Growth for Dietary Supplements (Apr. 17, 2008) (noting that Western and Eastern Europe's global market shares for dietary supplements are 14.4% and 2.7%, respectively), <http://www.naturalproductsinsider.com/articles/2008/04/global-market-growth-for-dietary-supplements.aspx>.

7. For example, depending on the country and regulatory framework, dietary supplements may either be regulated with specific guidance (United States) or they may be regulated under general food or drug regulations (Australia). See *infra* part III.

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

9. See 21 U.S.C. § 321(ff) (2006).

10. *Id.* §§ 342(g), 343(s).

11. *Id.* § 342(f).

12. See e.g., U.S. FOOD & DRUG ADMIN., INFORMATION PAPER ON L-TRYPTOPHAN AND 5-HYDROXY-L-TRYPTOPHAN (2001) [hereinafter FDA INFORMATION PAPER] (noting that in 1989 an epidemic outbreak of eosinophilia-myalgia syndrome (EMS), which resulted in thirty-seven known deaths, occurred in the U.S. due to the use of dietary supplements containing L-tryptophan), available at <http://www.cfsan.fda.gov/~dms/ds-tryp1.html>. See also Editorial, *The Ephedra Ban Is Not Enough*, N.Y. TIMES, Jan. 5, 2004, at A16 (discussing the dangers of ephedra-containing weight loss products, "Ephedra has generated far more reports of adverse effects than any other supplement and has been linked to cases of heart attack, stroke and sudden death").

outcry cast a shadow over the industry as a seeming lack of regulation was blamed for such adverse events.<sup>13</sup>

U.S. lawmakers responded in the last few years to complaints concerning the need for more stringent dietary supplement rules with the adoption of two important regulatory changes. In 2006, the Dietary Supplement and Non-prescription Drug Consumer Protection Act (DSNCPA) was passed, *requiring* dietary supplement manufacturers to report to the FDA any serious adverse events potentially associated with their products.<sup>14</sup> The DSNCPA became effective on December 22, 2007.<sup>15</sup> Also, in June 2007, Congress adopted the FDA's proposal for Current Good Manufacturing Practices for dietary supplements (CGMPs).<sup>16</sup> The CGMPs create the minimum current good manufacturing practices for dietary supplement manufacturing, packaging, labeling, or holding of dietary supplements, in an effort to increase product quality<sup>17</sup> and to help create a level playing field for supplement manufacturers.<sup>18</sup>

With the passage of DSHEA, the DSNCPA, and the CGMPs, it may appear that the government is strengthening its grip on the dietary supplement industry. But in reality, the FDA's power over dietary supplement manufacturers remains relatively weak. The passage of DSHEA did not create a framework to restrict dietary supplements; it arguably created the opposite. By placing the burden of proof on the government, DSHEA explicitly guarantees that dietary supplement manufacturers do not have to prove their products' safety before marketing and sale of the products to consumers. Even with the passage and implementation of the DSNCPA and the CGMPs, dietary supplement regulation in the United States is widely open to criticism that the regulations do not ensure safety.<sup>19</sup>

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13. See e.g., David Lazarus, *Supplement Makers Need Stricter FDA Oversight*, L.A. TIMES, Sept. 3, 2008, at C1 (arguing that dietary supplements should undergo pre-market testing in order to protect consumers).

14. Dietary Supplement and Non-prescription Drug Consumer Protection Act, Pub. L. No. 109-462, 120 Stat. 3469, 3469 (2006) (codified at 21 U.S.C. § 379aa-1(b) (2006)).

15. *Id.* § 379aa-1(i).

16. Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 72 Fed. Reg. 34942, 34942 (June 25, 2007) (to be codified at 21 C.F.R. pt. 111).

17. *Id.*

18. Todd Zwillich, *FDA OKs Dietary Supplement Regulations*, WEBMD HEALTH NEWS, June 22, 2007 (quoting Steve Mister, President and CEO of industry lobbying group, The Council for Responsible Nutrition, "I'm sure we won't agree with everything in the rule, but we are pleased that the new GMPs are here as it's a step forward for our industry."), [www.webmd.com/news/20070622/fda-oks-dietary-supplement-regulations](http://www.webmd.com/news/20070622/fda-oks-dietary-supplement-regulations).

19. See e.g., Katherine Wong, *New Mandatory Reporting Requirements for Dietary Supplements and Nonprescription Drugs Solve Very Little*, 35 J.L. MED. & ETHICS 336, 336

Further, when compared to dietary supplement regulations in jurisdictions that are also heavily influenced by dietary supplements—like the European Union, Japan, Canada, and Australia—current regulations in the United States are much less restrictive. However, as this note argues, “less restrictive” does not necessarily mean that the regulations in the U.S. are inferior when compared to those abroad. With the exponential growth in this newly regulated industry, it appears that most countries have yet to figure out how to adequately regulate dietary supplements. Therefore, a critique of the recent dietary supplement regulations in the United States and a comparison to dietary supplement regulations abroad is necessary to provide guidance on how dietary supplement regulation in the United States should develop, and also to provide caution for potential problems.

Part II of this article provides a historical background of dietary supplements’ turbulent past and their seemingly ever-increasing popularity. Next, as dietary supplement regulations around the world continue to change, Part III provides an overview of current dietary supplement regulations in the United States, European Union, Japan, Canada, and Australia, and addresses criticisms of DSHEA, the DSNDCPA, and the CGMPs. Finally, Part IV analyzes the differences between the varying regulatory frameworks abroad with the dietary supplement regulations currently in place in the United States. Based upon an international comparison of dietary supplement regulations, this note concludes that the United States is not alone in its struggle to properly address the regulatory needs of the expanding dietary supplement industry, and therefore, DSHEA, the DSNDCPA, and the CGMPs may be the targets of excessive criticism.

## II. HISTORY OF DIETARY SUPPLEMENTS

Although the term “dietary supplement” may be relatively new, the beneficial properties of certain vitamins and herbs have been appreciated for centuries. Treatments using ancient Chinese herbs date back 2,500 years to when healers employed herbal remedies to treat various afflictions.<sup>20</sup> Such remedies are still used today around the world in what is now known as “traditional Chinese herbal medicine.”<sup>21</sup> Likewise, Native Americans have used herbs such as echinacea for more than 400 years to

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(2007) (arguing that the DSNDCPA addresses some problems with DSHEA, but “it seems unlikely that it will substantially increase manufacturer or supplier accountability”).

20. See College of Traditional Chinese Medicine, University of Technology Sydney, History of Chinese Herbal Medicine, (noting that Chinese herbal medicine grew out of beliefs that herbs could protect individuals from evil forces), <http://www.science.uts.edu.au/centres/tcm/herbal.html> (last visited Nov. 22, 2009).

21. *See id.*

treat wounds and injuries.<sup>22</sup> In 2006 alone, American consumers spent an estimated \$129 million on echinacea.<sup>23</sup>

The understanding of vitamin properties was not developed until more recently, and scurvy played an important role. Caused by a deficiency in vitamin C consumption, scurvy can manifest itself through skin bumps, leg hemorrhages, and swollen gums.<sup>24</sup> "If we exclude straightforward famine, scurvy is probably the nutritional deficiency disease that has caused most suffering in recorded history."<sup>25</sup> In 1747, a British naval physician conducted an experiment where he provided lemons and limes to sailors who suffered from scurvy and quickly concluded that there were properties in the fruits that helped the sailors battle scurvy's serious effects.<sup>26</sup> Consequently, British sailors carried limes onboard as part of their diets and earned the nickname "limeys."<sup>27</sup> Although the sailors did not know it at the time, the vitamin C that treated and protected them from scurvy would someday become one of the most popular dietary supplements in the world. Over time, the effects of vitamins, herbs, and amino acids continued to draw attention from scientists and ultimately progressed into the synthesis of thousands of specific dietary supplements that are available to consumers around the world.

Today, dietary supplements maintain a high level of popularity because most consumers believe they are safe, effective, and good for health.<sup>28</sup> However, the dietary supplement industry is no stranger to controversy. In 1989, a dietary supplement containing the amino acid L-tryptophan was responsible for an outbreak of eosinophilia-myalgia syndrome (EMS) in the United States.<sup>29</sup> EMS is a "painful blood disorder [that] can cause high fever, rash, weakness and shortness of breath, among other symptoms."<sup>30</sup> The manufacturer of the dietary supplement, Showa Denko Inc., a Japanese company, cut corners in their purification procedures and experimented with

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22. University of Maryland Medical Center, Medical Reference, Echinacea, ("Throughout history people have used echinacea to treat scarlet fever, syphilis, malaria, blood poisoning, and diphtheria.") <http://www.umm.edu/altmed/articles/echinacea-000239.htm> (last visited Nov. 20, 2009).

23. Elizabeth Weise, *Lance: Echinacea Does Fight Colds*, USA TODAY.COM, June 25, 2007, [http://www.usatoday.com/news/health/2007-06-25-echinacea-colds\\_N.htm](http://www.usatoday.com/news/health/2007-06-25-echinacea-colds_N.htm).

24. Roger K. French, *Scurvy*, in THE CAMBRIDGE WORLD HISTORY OF HUMAN DISEASE 1000, 1001 (Kenneth F. Kiple et al. eds., 1993).

25. KENNETH J. CARPENTER, THE HISTORY OF SCURVY & VITAMIN C vii (1988).

26. S.O. Waife, *Lind, Lemons, and Limeys*, 1 J. CLINICAL NUTRITION 471, 472 (1953).

27. *Id.* at 472-73.

28. MERCK RESEARCH LABORATORIES, THE MERCK MANUAL OF DIAGNOSIS AND THERAPY 2724 (Mark H. Beers et al. eds., 18th ed., 2006) [hereinafter MERCK MANUAL].

29. FDA INFORMATION PAPER, *supra* note 12.

30. *Illness Is Tied to Way Diet Additive Was Made*, N.Y. TIMES, Aug. 9, 1990, at D24.

bacteria to accelerate and increase the efficiency of production of their dietary supplement product that was used as a sleep aid.<sup>31</sup> As a result, there were more than 1,500 reported cases of EMS associated with L-tryptophan—of which there are at least thirty-seven known deaths.<sup>32</sup> Further, the actual number of people affected is estimated to be much higher.<sup>33</sup> The FDA consequently took action to limit the availability of dietary supplements that contain L-tryptophan through advising consumers about the substance's potential effects.<sup>34</sup>

Similar to L-tryptophan, the dietary supplement ephedra has a deadly past. Ephedra was marketed as a weight loss and bodybuilding supplement in the late 1990s and early 21<sup>st</sup> century.<sup>35</sup> The supplement is an "amphetamine-like herb"<sup>36</sup> that has been linked to seizure, heart attack, stroke, and death.<sup>37</sup> By the end of 2001, ephedra was banned by the National Football League, National Collegiate Athletic Association, and the International Olympic Committee.<sup>38</sup> Finally, at the beginning of 2004, ephedra became the first FDA-banned dietary supplement.<sup>39</sup> Unfortunately, the ban was too late for many as it is believed that dietary supplements containing ephedra contributed to 155 deaths.<sup>40</sup> The FDA ban stated that products containing ephedra "present an unreasonable risk of illness or injury," and therefore are unsafe for consumers' use.<sup>41</sup>

The failure to resolve the ephedra issues until several years after the beginning of linked deaths is believed to be one of the biggest problems to face the dietary supplement industry in the first decade since the enactment

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31. National Eosinophilia-Myalgia Syndrome Network, Eosinophilia-Myalgia Syndrome, <http://www.nemsn.org> (last visited Nov. 21, 2009).

32. FDA INFORMATION PAPER, *supra* note 12.

33. *Id.* ("Some individuals suffering from L-tryptophan-related EMS have recovered, while other individuals' illnesses have persisted or worsened over time.").

34. *See id.*

35. *See Nationwide Ban on Ephedra Goes into Effect: Judge Rejects Manufacturers' Request to Halt Action*, Apr. 13, 2004 [hereinafter Ephedra Ban], <http://www.msnbc.msn.com/id/4721505/>.

36. *Id.*

37. JENNA HOLLENSTEIN, UNDERSTANDING DIETARY SUPPLEMENTS 53 (2007).

38. Ephedra Ban, *supra* note 35.

39. *Id.*

40. *Id.*

41. News Release, U.S. Dep't of Health & Human Services, FDA Announces Plans to Prohibit Sales of Dietary Supplements Containing Ephedra: Consumers Advised to Stop Using Ephedra Products Immediately (Dec. 30, 2003) (quoting FDA Commissioner Mark B. McClellan, "Consumers should stop buying and using ephedra products right away, and FDA will make sure consumers are protected by removing these products from the market as soon as the rule becomes effective."), available at <http://www.hhs.gov/news/press/2003pres/20031230.html>.

of DSHEA.<sup>42</sup> Annette Dickinson, the President of the Council for Responsible Nutrition, testified in front of the Subcommittee on Human Rights and Wellness that the delay in assessing the issues with ephedra was so monumental that it undermined consumer confidence in the entire dietary supplement industry.<sup>43</sup>

However, for each L-tryptophan or ephedra controversy, there are thousands of dietary supplements that have not been linked to deaths or serious adverse events. Millions of people safely take dietary supplements every day.<sup>44</sup> But just because a dietary supplement is not dangerous does not mean that the dietary supplement has any actual value to maintaining health. Some of the most popular vitamins and minerals used today have recently had their efficacy called into question.

Initial tests and studies of vitamins suggested that they may help prevent cancer, stroke, and heart disease.<sup>45</sup> In 2008, after the investment of hundreds of millions of dollars in clinical trials to further understand the capabilities of popular vitamins and minerals, two large trials failed to prove that vitamin C and vitamin E reduce the risk of certain cancers.<sup>46</sup> However, the results of the clinical trials do not mean that vitamin C and vitamin E are worthless. Vitamins may serve other important functions, as "[s]cientists remain convinced that vitamins are essential to health."<sup>47</sup> Further, the bad publicity surrounding the recent results of the clinical trials on vitamins may not be as significant for consumers as people may think. Many American consumers believe that dietary supplements can lead to better health,<sup>48</sup> including data that suggests that fifty-seven percent of regular dietary supplement users in 1999 believed dietary supplement claims in advertisements generally were true.<sup>49</sup> At the same time, only fifty-three percent of respondents to a different 1999 survey were aware that dietary supplements were not heavily regulated by the government.<sup>50</sup>

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42. *10 Years After the Implementation of DSHEA: The Status of Dietary Supplements in the United States: Hearings Before the Subcomm. on Hum. Rights and Wellness*, 108th Cong. 8-9 (2004) [hereinafter *Subcomm. on Human Rights*] (testimony of Annette Dickinson, President of the Council for Responsible Nutrition).

43. *Id.*

44. See Council for Responsible Nutrition, *supra* note 3.

45. See Karen Kaplan, *Vitamins Aren't a Cure-All*, L.A. TIMES, Dec. 21, 2008, at A1.

46. See *id.* "This month, two long-term trials with more than 50,000 participants offered fresh evidence that vitamin C, vitamin E and selenium supplements don't reduce the risk of prostate, colorectal, lung, bladder or pancreatic cancer." *Id.*

47. *Id.*

48. Robert J. Blendon et al., *Americans' Views on the Use and Regulation of Dietary Supplements*, 161 ARCHIVES INTERNAL MED. 805, 806-07 (2001).

49. *Id.* at 808.

50. *Id.*

Consumers may also be unaware that certain popular dietary supplements may be dangerous when combined with prescription drugs or over-the-counter medications. "Vitamins A, B6, B12, C, E and K; niacin; folic acid; calcium; magnesium; iron; and zinc can be hazardous when combined with various prescription drugs and over-the-counter remedies. Yet patients often fail to mention using such supplements to physicians."<sup>51</sup> Even more worrisome, almost seventy percent of older adults who regularly take a prescription medication also take an over-the-counter medication, dietary supplement, or both.<sup>52</sup> But data suggests that it may be difficult to discourage consumers from taking their favorite supplements. Studies show that seventy-one percent of regular users of dietary supplements claimed that they would continue to take their most-used supplement even if a government agency told them the supplement was ineffective.<sup>53</sup>

### III. DIETARY SUPPLEMENT REGULATIONS IN THE UNITED STATES AND ABROAD

#### A. *Regulations in the United States*

##### 1. Dietary Supplement Health and Education Act

Before DSHEA, the Food Drug & Cosmetic Act (FDCA) regulated dietary supplements as either foods or drugs because there still was no category for dietary supplements.<sup>54</sup> The FDCA created food standards and mandated pre-market approval for all new drugs, but lumped vitamins, minerals, and herbs together as foods.<sup>55</sup> Consequently, such substances received little regulation.<sup>56</sup> Food and drug regulations developed over time, but it took until the 1990s for Congress to address the expanding market for dietary supplements by creating regulations specific to the dietary supplement industry.

By the early 1990s, Congress focused its attention on legislation to address the questionable health claims made on nutritional product labels.<sup>57</sup> Two bills were considered: "One proposal would have strengthened the FDA's enforcement powers and increased penalties for violating the [FDCA].

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51. Jane E. Brody, *Potential for Harm in Dietary Supplements*, N.Y. TIMES, Apr. 8, 2008, at F7.

52. Roni Caryn Rabin, *Seniors Mixing Prescription and O.T.C. Drugs*, N.Y. TIMES, Jan. 8, 2009, <http://www.nytimes.com/2009/01/09/health/08seniors.html>.

53. Blendon, *supra* note 48, at 807.

54. See Peter Barton Hutt, *FDA Statutory Authority to Regulate the Safety of Dietary Supplements*, 31 AM. J.L. & MED. 155, 155 (2005).

55. *Id.* at 156.

56. *Id.*

57. See Peter J. Cohen, *Science, Politics, and the Regulation of Dietary Supplements: It's Time to Repeal DSHEA*, 31 AM. J.L. & MED. 175, 179 (2005).

The other would have imposed tight controls on the marketing of nutritional supplements by forbidding manufacturers to advertise therapeutic claims that, by law, could not be placed on the supplement's label.<sup>58</sup> In response to potential regulations that would regulate vitamins and other supplements, the health-food industry mounted a massive lobbying campaign.<sup>59</sup> "A coalition composed of health food stores, supplement users, the supplement industry, lobbyists, and sympathetic members of Congress created a new class of products and simultaneously declared that this new class would not be subject to the mission of the FDA."<sup>60</sup> Senator Orrin Hatch (R-UT) spearheaded the campaign and the Dietary Supplement Health and Education Act (DSHEA) of 1994 was signed into law by President Bill Clinton.<sup>61</sup> "As a result, the necessary controls that the FDA was legally able to exert over prescription products were completely invalidated for dietary supplements . . ."<sup>62</sup>

DSHEA provides dietary supplements with their own specific regulatory framework, but the level of regulation DSHEA created over the dietary supplement industry is weak.<sup>63</sup> Viewed optimistically, "[DSHEA] was passed in 1994 for two primary reasons: to ensure that consumers would continue to have access to a wide variety of safe dietary supplements and to provide consumers with more information about the dietary supplements they purchase."<sup>64</sup> However, such a statement is far too simplistic for the reach, or lack thereof, of the Act.

Specifically, DSHEA classifies a dietary supplement as a product other than tobacco that is intended to supplement the diet; contains one or more dietary ingredients (including vitamins, minerals, herbs or other botanicals, amino acids, and other substances, concentrates, metabolites, constituents, extracts, or combinations of these ingredients); is intended for ingestion in powder, softgel, gelcap, capsule, tablet, or liquid form; is not represented for use as a conventional food or as the sole item of a meal or diet; and is

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58. *Id.*

59. *Id.*

60. W. Steven Pray, *Consult Your Pharmacist: The FDA, Vitamins, and the Dietary Supplement Industry*, U.S. PHARMACIST, Oct. 2008, at 15.

61. *Id.*

62. *Id.*

63. See Michael H. Cohen, *U.S. Dietary Supplement Regulation: Belief Systems and Legal Rules*, 11 HASTINGS WOMEN'S L.J. 3, 4 (2000) ("DSHEA reaffirms that dietary supplements are 'foods' and not 'drugs,' thus exempting dietary supplements from the requirement of new drug approval under the Federal Food, Drug & Cosmetic Act (FDCA). A 'drug' includes, among other things, 'articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.'").

64. *Subcomm. on Human Rights, supra* note 42, at 2.

labeled as a dietary supplement.<sup>65</sup> These products can be purchased in a wide variety of stores throughout the country. "Dietary supplements are the most commonly used of all complementary and alternative therapies, primarily because they are widely available and can be bought without consulting a professional health practitioner."<sup>66</sup>

Although the definition of a dietary supplement is liberal, there is an important distinction between traditional dietary supplements and new dietary supplements. Dietary ingredients on the market prior to October 15, 1994 were "grandfathered" into the regulations, allowing for their default marketing and sale.<sup>67</sup> Therefore, dietary supplement manufacturers are allowed to continue to develop and market these "traditional" dietary supplements as they had before the passage of DSHEA. New dietary ingredients, those not marketed in the United States before October 15, 1994,<sup>68</sup> face some specific hurdles. New dietary ingredients may be allowed to be a part of a dietary supplement only if they

have been present in the food supply as an article used for food in a form in which the food has not been chemically altered[or] [t]here is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended . . . will reasonably be expected to be safe . . .<sup>69</sup>

In order to bring new dietary ingredients to market, companies are required to notify the FDA about any new ingredient that the companies plan to market at least seventy-five days before actual marketing.<sup>70</sup> Such notifications must provide a basis for the FDA to determine whether or not the new dietary ingredient is reasonably expected to be safe.<sup>71</sup>

Another important regulatory element developed by DSHEA concerns the restrictions upon the types of claims dietary supplements can make. "Claims that can be used on food and dietary supplement labels fall into three categories: health claims, nutrient content claims, and structure/function claims."<sup>72</sup> Manufacturers and the FDA are responsible for ensuring the legitimacy of the claims made on dietary supplement labels,

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65. 21 U.S.C. §§ 321(ff)(1)-(2) (2006); *id.* § 350(c)(1)(B)(ii).

66. MERCK MANUAL, *supra* note 28, at 2724.

67. 21 U.S.C. § 350b(c).

68. *Id.*

69. *Id.* § 350b(a)(1)-(2).

70. *Id.* § 350b(a)(2).

71. *Id.*

72. U.S. Food & Drug Admin., Claims That Can Be Made for Conventional Foods and Dietary Supplements (2003), [http://www.fda.gov/Food/LabelingNutrition/Label\\_Claims/ucm111447.htm](http://www.fda.gov/Food/LabelingNutrition/Label_Claims/ucm111447.htm) [hereinafter Supplement Claims].

while the Federal Trade Commission is responsible for the regulation of product advertising.<sup>73</sup>

Health claims are considered claims that describe the relationship between the product and a reduction in the risk of a disease or health-related condition.<sup>74</sup> As opposed to claims that the dietary supplement may help *prevent a condition*, a dietary supplement "may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases."<sup>75</sup> An example of a permissible health claim for a dietary supplement could be: "Diets high in calcium may reduce the risk of osteoporosis."<sup>76</sup>

Nutrient content claims are different. "Nutrient content claims describe the level of a nutrient or dietary substance in the product, using terms such as *free*, *high*, and *low*, or they compare the level of a nutrient in a food to that of another food, using terms such as *more*, *reduced*, and *lite*."<sup>77</sup> Nutrient content claims typically only apply to dietary substances with recognized daily values recommendations.<sup>78</sup> An example of a nutrient content claim could be: "Twice the omega-3 fatty acids per capsule (80 mg) as in 100 mg of menhaden oil (40 mg)."<sup>79</sup>

Dietary supplement manufacturers may also describe the supplement's effects on "structure or function" of the body or the "well-being" achieved through consumption of the supplement.<sup>80</sup> Structure/function is understood "to refer to food label statements that describe the role of a nutrient or other dietary supplement ingredient in maintaining normal structure or function in humans (e.g. calcium builds strong bones) or to promote general well-being."<sup>81</sup> As opposed to actual health claims, structure/function claims may not state or otherwise imply any relationship between the product and a disease or health condition.<sup>82</sup> However, a structure/function claim may relate to a disease or health condition if the claim expresses how widespread the disease is in the United States.<sup>83</sup>

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73. *Id.*

74. *Id.* (noting that the FDA regulates health claims through the 1990 Nutrition Labeling and Education Act (NLEA), the 1997 Food and Drug Administration Modernization Act (FDAMA), and the 2003 FDA *Consumer Health Information for Better Nutrition Initiative*).

75. 21 U.S.C. § 343(r)(6)(C).

76. Supplement Claims, *supra* note 72.

77. *Id.*

78. *Id.*

79. *Id.*

80. 21 U.S.C. § 343(r)(6)(A) (2006).

81. James E. Hoadley & J. Craig Rowlands, *FDA Perspectives on Food Label Claims in the USA*, in *NUTRACEUTICAL AND FUNCTIONAL FOOD REGULATIONS IN THE UNITED STATES AND AROUND THE WORLD* 115, 128 (Debasis Bagchi ed., 2008).

82. *Id.* at 128-29.

83. *Id.* at 129.

Regardless of the category the claim falls into, it is necessary for the manufacturer to have "substantiation that such statement is truthful and not misleading . . ."<sup>84</sup> Also, the product label must include: "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>85</sup>

Finally, as previously noted the most controversial declaration DSHEA makes concerns the burden of proof for product safety. Under DSHEA, dietary supplement manufacturers do not have to prove to the FDA that their product is either safe or effective before marketing or sale of that product.<sup>86</sup> The burden of proof in showing the safety of a dietary supplement was removed from the responsibilities of the manufacturer and shifted to the FDA.<sup>87</sup>

In the last few years, dietary supplement regulation has consequently expanded to include new regulations that focus upon adverse event reports and good manufacturing practices.

## 2. The Dietary Supplement and Non-prescription Drug Consumer Protection Act

In order to monitor health problems associated with the use of pharmaceuticals and therapeutic biological products, the FDA relies on the compilation of adverse event reports.<sup>88</sup> Adverse event reports are most well known for their application to pharmaceuticals. "The Adverse Event Reporting System (AERS) is a computerized information database designed to support the FDA's post-marketing safety surveillance program for all approved drug and therapeutic biologic products."<sup>89</sup>

When DSHEA was first passed, DSHEA notably did not contain a mandatory reporting requirement for adverse events related to dietary supplements. However, apparently due to public outrage over the slow development of information and reaction related to the ephedra deaths, Senator Orrin Hatch (R-UT), along with Senators John Cornyn (R-TX), Richard Durbin (D-IL), Michael Enzi (R-WY), Thomas Harkin (D-IA), and Edward Kennedy (D-MA) introduced the Dietary Supplement and

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84. 21 U.S.C. § 343(r)(6)(B) (2006).

85. *Id.* § 343(r)(6)(C).

86. *Id.* § 342(f).

87. *Id.*

88. FDA.gov, Adverse Event Reporting System (AERS), <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm> (last visited Nov. 21, 2009).

89. *Id.*

Nonprescription Drug Consumer Protection Act (DSNDCPA).<sup>90</sup> The DSNDCPA was signed into law by President Bush on December 22, 2006 and came into effect on December 22, 2007.<sup>91</sup>

The DSNDCPA attempts to improve consumer protection by requiring manufacturers to report adverse events.<sup>92</sup>

The manufacturer, packer, or distributor of a dietary supplement whose name . . . appears on the label of a dietary supplement marketed in the United States . . . [is required to] submit to the Secretary any report received of a serious adverse event associated with such dietary supplement when used in the United States, accompanied by a copy of the label on or within the retail packaging of such dietary supplement.<sup>93</sup>

The act classifies a “serious adverse event” as an “adverse event that results in death; a life-threatening experience; inpatient hospitalization; a persistent or significant disability or incapacity; or a congenital anomaly or birth defect; or requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described [above].”<sup>94</sup> The FDA evaluates the adverse event reports and determines whether or not regulatory action is necessary.<sup>95</sup>

In September 2008, the FDA lowered its cumulative 2008 estimate for the total number of expected adverse event reports potentially related to dietary supplements from 960 to 856.<sup>96</sup> For the first quarter of 2008, the FDA received a total of 214 mandatory reports of serious adverse events related to dietary supplements.<sup>97</sup> However, it is estimated that the *actual* number of *all* adverse events relating to dietary supplements may be more than 50,000 per year.<sup>98</sup>

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90. GovTrack.us, S. 3546: Dietary Supplement and Nonprescription Drug Consumer Protection Act, <http://www.govtrack.us/congress/bill.xpd?bill=s109-3546> (last visited Nov. 21, 2009).

91. 21 U.S.C. § 379aa-1(i).

92. *Id.* § 379aa-1(b)(1).

93. *Id.* § 379aa-1(b)(1).

94. *Id.* § 379aa-1(a)(2).

95. See FDA.gov, *supra* note 88 (stating in reference to the AERS system for drugs, “Based on an evaluation of the potential safety concern, FDA may take regulatory action(s) to improve product safety and protect the public health, such as updating a product’s labeling information, restricting the use of the drug, communicating new safety information to the public, or, in rare cases, removing a product from the market”).

96. Notice: Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act, 73 Fed. Reg. 53253 (Sept. 15, 2008).

97. *Id.*

98. *Id.* at 53254.

Importantly, an adverse event does not necessarily signify the existence of a causal relationship.<sup>99</sup> Some adverse events may be reported by people who already were ill and had been using either over-the-counter or prescription drugs at the time of the adverse event.<sup>100</sup> Regardless, the FDA is required by law to investigate serious adverse events and subsequently determine whether or not the dietary supplement is the cause of the adverse event.<sup>101</sup>

### 3. Dietary Supplement Good Manufacturing Practices Final Rule

Another important rule recently developed for the dietary supplement industry concerns the creation and implementation of standards for the manufacturing of dietary supplements. The pharmaceutical industry has required drug manufacturers to follow current good manufacturing practices (CGMPs) since they were adopted in 1963.<sup>102</sup> In 2007, the FDA finalized CGMPs for the dietary supplement industry.<sup>103</sup> As Janice Oliver, Deputy Director of the Center for Food Safety and Applied Nutrition explains,

[t]he dietary supplement market has changed significantly since the passage of DSHEA. The industry itself has grown exponentially and so has the number of Americans buying these products. Access to dietary supplements has also changed. Today a wide range of dietary supplements can be purchased in supermarkets or through the Internet. The dynamic nature of this industry underscores the importance of and the necessity for Good Manufacturing Practice requirements for dietary supplements.<sup>104</sup>

Given authority under DSHEA, the FDA published its proposed rule on CGMPs in 2003<sup>105</sup> and the Final Rule was adopted June 25, 2007.<sup>106</sup> The Final Rule creates the minimum CGMPs for dietary supplement

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99. Natural Products Association, *FDA Reports Lower Supplement AERs than Expected* (Sept. 24, 2008), <http://www.npicenter.com/anm/templates/newsATemp.aspx?articleid=22220&zoneid=2>.

100. *Id.*

101. *Id.*

102. Current Good Manufacturing Practice in Manufacture, Processing, Packing, or Holding, 28 Fed. Reg. 6385, 6385 (June 20, 1963).

103. Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 21 C.F.R. § 111 (2007).

104. Janice Oliver, Deputy Director, Center for Food Safety and Applied Nutrition, Overview of the Implementation of the Current Good Manufacturing Practices for Dietary Supplements Guidance for Industry, FDA Satellite Broadcast (Oct. 24, 2007), <http://www.fda.gov/Food/DietarySupplements/GuidanceComplianceRegulatoryInformation/RegulationsLaws/ucm173996.htm>.

105. Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements, 68 Fed. Reg. 12158, 12158 (proposed Mar. 13, 2003) (codified at 21 C.F.R. pt. 111).

106. 21 C.F.R. § 111 (2007).

manufacturing, packaging, labeling, or holding.<sup>107</sup> Prior to the implementation of the recent Final Rule, dietary supplements were subject to the same manufacturing practice requirements as conventional foods.<sup>108</sup>

The CGMPs provide requirements for the quality production of dietary supplements and ensures that the products are labeled properly and do not contain contaminants or impurities.<sup>109</sup> The goal is to provide consumer confidence that the dietary supplements on the market have been manufactured to ensure their identity, purity, strength, and composition.<sup>110</sup> The FDA Commissioner Andrew Von Eschenbach remarked that “[t]his rule helps to ensure the quality of dietary supplements so that consumers can be confident that the products they purchase contain what is on the label.”<sup>111</sup> If there is evidence of contaminants or the dietary supplements do not contain the dietary ingredients that they claim, then the FDA considers those supplements to be adulterated or misbranded and subject to regulatory action.<sup>112</sup> However, it is important to note that the CGMPs do not require any proof of *efficacy*.

The FDA estimates that there are 1,460 manufacturers, packers, and holders of dietary supplements.<sup>113</sup> Depending on the size of the business, there is a specific date when the CGMPs take effect.<sup>114</sup> For businesses with 500 employees or more, the effective compliance date was June 25, 2008.<sup>115</sup> For businesses with 20–499 employees, the effective compliance date was June 25, 2009; and for businesses with fewer than twenty employees, the effective compliance date is June 25, 2010.<sup>116</sup>

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107. 21 C.F.R. § 111 (2007); Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 72 Fed. Reg. 34752 (June 25, 2007).

108. *Subcomm. on Human Rights, supra* note 42, at 5.

109. See 21 C.F.R. § 111 (2007); Press Release, FDA, FDA Issues Dietary Supplements Final Rule (June 22, 2007), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108938.htm>.

110. Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 72 Fed. Reg. at 34761.

111. Julia Sommerfeld, *Dietary Supplements Face Stricter Regulations: For First Time, Companies Must Test Products for Contamination, FDA Says*, MSNBC.COM, June 22, 2007, <http://www.msnbc.msn.com/id/19370824/>.

112. Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 72 Fed. Reg. at 34762-64; Press Release, *supra* note 109.

113. Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 72 Fed. Reg. 34752, 34920 (June 25, 2007).

114. *Id.* at 34752.

115. *Id.*

116. *Id.*

### B. Regulations in other Countries

Dietary supplements are not only popular in the U.S., but around the world consumers, manufacturers, and regulatory bodies have started to see the effects of an emerging and continually expanding market for dietary supplements.<sup>117</sup> As one industry manager wrote in 2008, “[g]lobal demand for dietary and nutritional supplements continues to escalate—steadily in mature major markets and exponentially in smaller emerging markets.”<sup>118</sup> With demand for dietary supplements increasing, regulatory bodies have tried to keep pace in covering these products. Some countries regulate dietary supplements with specific laws and regulations, while others regulate dietary supplements by categorizing them as either foods or drugs. In order to analyze different regulatory approaches to dietary supplements, this section looks at dietary supplement regulations in large, developed dietary supplement markets outside of the U.S., with specific focus on regulations in the European Union, Japan, Canada, and Australia.

#### 1. Dietary Supplement Regulation in the European Union

In 2007, Japan, the United States, and the EU represented roughly eighty-six percent of the global dietary supplement market.<sup>119</sup> Dietary supplement regulation in the EU is grounded in Directive 2002/46/EC (the Food Supplements Directive), adopted June 10, 2002.<sup>120</sup> The Food Supplements Directive was created as a comprehensive regulatory framework to resolve previous issues concerning the multiple regulatory bodies of the different member countries of the EU.<sup>121</sup> Different national rules for dietary supplements “may impede their free movement, create unequal conditions of competition, and thus have a direct impact on the functioning of the internal market.”<sup>122</sup> Therefore, regulation across the European Union is necessary.<sup>123</sup>

The Food Supplements Directive specifies which food supplements may be sold in the European Union, using two different annexes—also known as the “positive list.”<sup>124</sup> Since August 1, 2005, manufacturers, distributors, and

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117. See Charles Thurston, *Dietary Supplements: The Latest Trends & Issues*, NUTRACEUTICALS WORLD, Apr. 2008, at 54.

118. Zambetti, *supra* note 6.

119. Thurston, *supra* note 117, at 54.

120. Council Directive 2002/46, On the Approximation of the Laws of the Member States Relating to Food Supplements, 2002 O.J. (L 183) 51, 51 (EC).

121. *Id.*

122. *Id.*

123. *Id.*

124. *Id.* at 51, 52.

‘[F]ood supplements’ means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a

retailers of food supplements in Europe are prohibited from selling food supplements not listed on the positive list.<sup>125</sup> As written, the positive list includes only thirteen vitamins in thirty-two possible forms, and fifteen minerals in eighty possible forms.<sup>126</sup> If an EU member state wants to allow use of vitamins and minerals not included on the positive list, the state may do so until December 31, 2009 provided: 1) the substance was already in a supplement marketed in the state at the time of the adoption of the directive, and 2) the European Food Safety Authority has not given an unfavorable opinion of that substance based upon a dossier supporting the use of that substance.<sup>127</sup>

For nutritional supplements on the market, the Food Supplements Directive contains requirements for the labeling of food supplements. Labels of food supplements must contain: the term "food supplement", the names of the categories of substances that characterize the product, the recommended daily portion of that supplement, a warning to not exceed the recommended daily portion, a statement that the supplement is not a substitute for a varied diet, and a warning that the product should be stored out of the reach of young children.<sup>128</sup> Likewise, there are prohibited statements. The food supplement label must not contain any statement that the product is capable of preventing, treating, or curing a human disease, or any statement or implication that a balanced diet cannot provide adequate amounts of the nutrients.<sup>129</sup>

The Food Supplements Directive was met with massive opposition in Europe over the loss of consumer choice for certain products. "The plans caused controversy from the start, prompting a petition of more than a million signatures, a letter of protest to Tony Blair from more than 300 doctors and scientists, and motions opposing the law in both Houses of

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nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.

*Id.* at art. 2. Annex I provides the vitamins and minerals that are allowed, and Annex II provides the forms of those vitamins and minerals that may be used for the manufacture of food supplements. *Id.* at art. 4.

125. See Council Directive 2002/46, art. 15, 2002 O.J. (L 183) 51, 55 (EC).

126. *Id.* at 55, 56.

127. *Id.* at art. 4 (noting that the deadline for submitting a dossier for consideration was July 12, 2005); Christine Eberhardie, *Nutritional Supplements and the EU: Is Anyone Happy?*, 66 PROC. NUTRITION SOC'Y 508, 509 (2007) (noting that the application requirement had already resulted in applications for 421 substances).

128. See Council Directive 2002/46, art. 6, 2002 O.J. (L 183) 51, 55 (EC).

129. *Id.* at art. 6, 7.

Parliament.<sup>130</sup> In July, 2005, the European Court of Justice upheld the application of the Food Supplements Directive, effectively striking down an appeal from the health food industry challenging its legality.<sup>131</sup> In the comparatively large supplement market of the UK, the Directive will ban roughly 300 forms of vitamins and minerals unless they are included on the positive list.<sup>132</sup> Consumers consequently lost access to vitamins and minerals previously sold in the EU for many years.<sup>133</sup>

## 2. Dietary Supplement Regulation in Japan

Japan is another very important member of the dietary supplement industry. As noted above, in 2007, Japan, the United States, and the EU represented roughly eighty-six percent of the global dietary supplement market.<sup>134</sup> Dietary supplement regulation in Japan exists under a complex system of regulations that have developed and changed over time, but there still are no specific regulations or even a specific term for dietary supplements.<sup>135</sup> Due to the complexity of the regulations that cover dietary supplements, it "may often make it difficult to comprehend the Japanese regulatory system of [health foods] for the food industry in foreign countries."<sup>136</sup>

In Japan, foods and drugs are regulated by the Japanese Ministry of Health, Labor and Welfare (MHLW).<sup>137</sup> Since Japan does not specifically address dietary supplements in a statutory framework, dietary supplements instead fall under a network of food and drug regulations that have developed and changed multiple times within the last few years.<sup>138</sup> In 1991, 'health foods' (which are roughly analogous to dietary supplements in the

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130. Sam Lister, *Health Groups Lose Appeal on EU Food Supplement Ban*, TIMES (London), July 13, 2005, at 14.

131. *Id.*

132. *Id.*

133. *Id.* (noting that the 'positive list' includes and allows the sale of vitamin C, calcium, and iron, but other "popular substances, such as selenium yeast, tin, manganese and vitamin K2, have been omitted and are subject to 505 separate appeals").

134. Thurston, *supra* note 117, at 54; see Hirobumi Ohama et al., *Health Foods and Foods with Health Claims in Japan*, in NUTRACEUTICAL AND FUNCTIONAL FOOD REGULATIONS IN THE UNITED STATES AND AROUND THE WORLD 249, 275 (Debasis Bagchi ed., 2008) (noting that Japan's market for dietary supplements is "almost equivalent to the EU market" while accounting for \$12.1 billion in 2006).

135. See Ohama et al., *supra* note 134, at 252.

136. *Id.*

137. See Paul Yamaguchi, Japan's Nutraceuticals Today – A Big Disappointment in Food-Drug Reclassification: Expectations Are Not Always Realized (Apr. 16, 2007), <http://www.npicenter.com/anm/templates/newsATemp.aspx?articleid=18281&zoneid=45>.

138. See *id.* (noting that food and drug reclassifications have been conducted "almost once a year, but over the last 3 years the agency still hasn't completed one").

U.S.) were integrated into the "Foods for Specified Health Uses" (FOSHU) system.<sup>139</sup> "The Japanese government developed FOSHU to identify conventional foods that positively contribute to physiological systems in the human body from other foods by allowing these foods to have health claims and an approved logo printed on their package."<sup>140</sup> Substances that are considered dietary supplements in the U.S. would fall under either the drug regulations or the non-drug food regulations, depending on many different factors.<sup>141</sup> "Many ingredients in the U.S. are still tightly guarded under Japan's Pharmaceutical Affair Law. They can't be formulated into foods or supplements."<sup>142</sup>

Japanese food and drug regulations are strict and have prohibited open trade of dietary supplements between Japan and the U.S., resulting in requests to deregulate the 'health food' system and re-classify ingredients.<sup>143</sup> 'Reclassification' can be understood as the process where the MHLW takes a product out from under drug regulations, and moves it under non-drug regulations.<sup>144</sup> Once the MHLW allows an ingredient to move to a non-drug status, the ingredient may be used as a supplement.<sup>145</sup> Since 2001, the MHLW has reclassified a list of ingredients every few years.<sup>146</sup> In 2007, MHLW released its fourth food-drug reclassification, which included fifty-five ingredients.<sup>147</sup> Also of significant importance and seen as a sign of progress, in 2007 the MHLW for the first time announced that it intends to allow a public hearing concerning the products to be placed on the next reclassification list.<sup>148</sup>

However, the nutritional industry in Japan still "needs a boost every few years in order to grow."<sup>149</sup> The downturn in the Japanese economy hit the

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139. Paul Yamaguchi, Japan's Nutraceuticals Today – FOSHU Ready to Change – Again (June 26, 2004), <http://www.npicenter.com/anm/templates/newsATemp.aspx?articleid=10457&zoneid=45>.

140. *Id.*

141. See Ohama et al., *supra* note 134, at 253, 257-58.

142. See Yamaguchi, *supra* note 137.

143. See Ohama et al., *supra* note 134, at 252 (noting that prior to 2001, "only the form of conventional foods was permitted while other forms such as tablets or capsules were not allowed").

144. See Yamaguchi, *supra* note 137.

145. *Id.* (noting that in 2002, the supplement "CoQ 10 moved to non-drug status and the market grew from almost zero to \$100 million in two short years").

146. *See id.*

147. *See id.* Categories include botanical, animal, and chemical ingredients. Out of the 55 ingredients reclassified, 33 were botanicals and only one was a chemical (L-citruline). *Id.*

148. *See id.*

149. Paul Yamaguchi, Japan's Nutraceuticals Today – Japan's Economic Recovery Leaves Nutrition Industry Behind (Oct. 9, 2007), <http://www.npicenter.com/anm/templates/newsATemp.aspx?articleid=19613&zoneid=45>.

nutritional industry hard in 2006, and the nutrition market contracted for the first time in its history.<sup>150</sup> But the economy is not the only factor to blame. "The Japanese nutrition industry, especially the nutritional supplement category, is still fragile and unsettled because of the lack of nutritional supplement laws. Until the laws that recognize supplements are written, the Japanese nutritional supplement market will remain unsettled."<sup>151</sup>

### 3. Dietary Supplement Regulation in Canada

In Canada, dietary supplements are known as natural health products (NHP), defined under the *Natural Health Product Regulations*. Like Americans, Canadians have become heavy users of dietary supplements, as studies have shown that seventy percent of Canadians consume one or more natural health products.<sup>152</sup> In 2006, it was estimated that the Canadian health products industry was worth \$2.5 billion.<sup>153</sup>

The Natural Health Products Directorate (NHPD), under the Health Products and Food Branch of Health Canada, acts as the regulatory authority for natural health products in Canada.<sup>154</sup> Like the American system, dietary supplement products do not fit within the regulatory framework for pharmaceuticals, nor do they fit within the regulatory framework for foods.<sup>155</sup> But in stark contrast to the American regulatory framework, the NHP Regulations require that NHPs obtain a product license through pre-market approval by the Minister of Health.<sup>156</sup> The NHP Regulations place requirements upon manufacturers, distributors, importers, packagers, and labelers.<sup>157</sup> As the *Regulatory Impact Analysis Statement* reports, "[t]hese Regulations are intended to provide Canadians with ready access to natural health products that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity."<sup>158</sup>

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150. *Id.* (reporting that the Japanese nutrition market has averaged twelve percent annual growth over the last twenty years, but in 2006 the fell two percent).

151. *Id.*

152. CANADIAN HEALTH FOOD ASSOCIATION, *supra* note 5.

153. *Id.*

154. *Regulatory Impact Analysis Statement of the Natural Health Products Regulations*, 137 C. GAZ. PART II, NO. 13 at 1571 (June 18, 2003) [hereinafter *Regulatory Impact Analysis Statement*] (the Regulatory Impact Analysis Statement is not part of the Natural Health Products Regulations).

155. *Id.* at 1592-93 (noting that "[i]t was decided the most effective regulatory mechanism was to create a new set of Regulations specific to NHPs . . .").

156. Natural Health Products Regulations SOR/2003-196, s. 4(1) (Can). An application for a product license requires specific information such as the recommended purpose of the NHP and supporting safety and efficacy data. *Id.* at s. 5.

157. *Id.* at s. 2(1).

158. *Regulatory Impact Analysis Statement*, *supra* note 154, at 1571.

The NHP Regulations provide a regulatory structure for an estimated 40,000 supplement products and traditional and alternative medicines.<sup>159</sup> NHPs include homeopathic and traditional medicines,<sup>160</sup> as well as plants, fungi, vitamins, amino acids, essential fatty acids, minerals, and probiotics.<sup>161</sup> NHPs must be safe enough to be considered for over-the-counter use and must not require a prescription to be sold.<sup>162</sup> Products that do require prescriptions are regulated under the Food and Drug Regulations.<sup>163</sup> Once pre-market approval is given, NHPs can make "a full range of health claims, including structure-function, risk-reduction, and therapeutic or treatment claims."<sup>164</sup>

To be considered an NHP, the product must have both a function component and a substance component.<sup>165</sup> The function component covers substances which are

manufactured, sold or represented for use in: the diagnosis, treatment, mitigation or prevention of a disease, disorder, or abnormal physical state or its symptoms in humans[;] restoring or correcting organic functions in humans; or modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.<sup>166</sup>

The substance component is the medicinal ingredient of the product (which includes, among others, vitamins, minerals, and amino acids).<sup>167</sup> NHP Regulations are mainly comprised of regulations pertaining to "definitions, product licensing, adverse reaction reporting, site licensing, good manufacturing practices, clinical trials involving human subjects, and labelling [sic] [and] packaging."<sup>168</sup>

Like American dietary supplement regulations, Canadians have adopted good manufacturing practices for NHPs.<sup>169</sup> Canada also utilizes mandatory

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159. Stephanie Martyres et al., *Emerging Policies and Practices Under the Canadian Natural Health Product Regulations*, in *NUTRACEUTICAL AND FUNCTIONAL FOOD REGULATIONS IN THE UNITED STATES AND AROUND THE WORLD* 159, 160 (Debasis Bagchi ed., 2008).

160. *Regulatory Impact Analysis Statement*, *supra* note 154, at 1574.

161. Natural Health Products Regulations SOR/2003-196, Schedule 1 (Can).

162. See *id.* at s. 2(2); see also *Regulatory Impact Analysis Statement of the Natural Health Products Regulations*, *supra* note 154, at 1572.

163. Natural Health Products Regulations SOR/2003-196, s. 2(2) (Can).

164. See *Regulatory Impact Analysis Statement*, *supra* note 154, at 1574.

165. *Id.* at 1573.

166. *Id.*

167. *Id.* at 1574-76.

168. *Id.* at 1578.

169. HEALTH CAN., NATURAL HEALTH PRODUCTS DIRECTORATE, GOOD MANUFACTURING PRACTICES GUIDANCE DOCUMENT i (2006), available at [http://hc-sc.gc.ca/dhp-mps/alt\\_formats/hpfb-dgpsa/pdf/prodnatur/gmp-bpf-eng.pdf](http://hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/gmp-bpf-eng.pdf).

adverse event reporting systems.<sup>170</sup> The licensee or product license holder of a natural health product in Canada is required to report to Health Canada any adverse reactions that are associated with the use of its licensed natural health product.<sup>171</sup> The licensee is required to develop and maintain procedures to properly collect information about adverse event reports, prepare and submit to Health Canada adverse reaction reports, and respond fully and promptly to Health Canada for additional safety information.<sup>172</sup>

Critics of the NHP Regulations claim that the pre-market approval system is difficult on smaller companies due to the cost of compliance for product licensing.<sup>173</sup> Critics also find that the costs of complying with the mandatory GMPs weaken incentives to create new products.<sup>174</sup> Finally, industry members have been highly frustrated with the delay between applying for product approval and actual approval or denial.<sup>175</sup> Accordingly, “[t]he current regulatory environment has left everyone frustrated at the promise of the new regulations not being met.”<sup>176</sup>

#### 4. Dietary Supplement Regulation in Australia

Australia does not contribute to a large portion of the global dietary supplement industry in terms of consumer sales, but it still provides an interesting regulatory framework for dietary supplements. Australia and New Zealand share one framework for the regulation of foods, the Australia New Zealand Food Standards Code, but they do not agree on the regulation of dietary supplements or medicines.<sup>177</sup> In Australia, the line is drawn between whether the ingested product is a food or a medicine—there is no classification for dietary supplements—while in New Zealand, dietary

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170. HEALTH CAN., CANADA VIGILANCE PROGRAM, GUIDANCE DOCUMENT FOR INDUSTRY – REPORTING ADVERSE REACTIONS TO MARKETED HEALTH PRODUCTS 1 (2009), available at [http://www.hc-sc.gc.ca/dhp-mps/alt\\_formats/hpfb-dgpsa/pdf/medeff/2009\\_guidance-directrice\\_reporting-notification-eng.pdf](http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/medeff/2009_guidance-directrice_reporting-notification-eng.pdf) (An adverse reaction is “a noxious and unintended response to a natural health product that occurs at any dose used or tested for the diagnosis, treatment or prevention of a disease or for modifying an organic function”). *Id.* at 2.

171. *Id.* at 4, 7.

172. *See id.* at 7-9.

173. *See* Bill Reynolds, *Canada Prepares for New Supplement Regs*, NATURALPRODUCTSINSIDER.COM (July 29, 2002), <http://www.naturalproductsinsider.com/articles/2002/07/canada-prepares-for-new-supplement-reg.aspx>.

174. *Id.*

175. Len Monheit, *Canada: The Status of Natural Health Product Regulations*, NUTRACEUTICALS WORLD, July–Aug. 2006, at 42, 44.

176. *Id.*

177. Jane L. Allen et al., *Functional Foods: Australia/New Zealand*, in REGULATION OF FUNCTIONAL FOODS AND NUTRACEUTICALS: A GLOBAL PERSPECTIVE 321, 321 (Clare M. Hasler ed., 2005).

supplements comprise their own specified category apart from food and medicine.<sup>178</sup>

Without a specific category for dietary supplements, Australia employs a blanket approach to regulation. Products such as vitamins, minerals, and nutritional supplements are regulated as complementary medicines under the Therapeutic Goods Act of 1989.<sup>179</sup> Under the Act, dietary supplements are regulated equally with other 'complementary' medicines,<sup>180</sup> allowing for a "substantially uniform national system of controls over therapeutic goods . . .".<sup>181</sup> The popularity of complementary medicines in Australia is signified by the fact that more than half of all Australians have used complementary medicines at least once, contributing to the estimated \$2 billion per year Australian complementary medicine market.<sup>182</sup>

For all medicines, Australia separates them among different risk levels.<sup>183</sup> "Most complementary medicines, including most vitamin and mineral supplements are considered to be low risk medicines, as they may only contain substances that have been approved by the TGA [Therapeutic Goods Administration] as being of low risk."<sup>184</sup> Through placement in this low-risk category, these products must be tested for both quality and safety, but are not required to be tested for effectiveness.<sup>185</sup> Further, Australia requires that these complementary medicine products must conform to industry GMPs and that adverse event reports be submitted to the TGA.<sup>186</sup>

However, even with the seemingly strict regulatory control, critics point out that by not requiring manufacturers to prove efficacy of low-risk

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178. *Id.*

179. Australian Government Department of Health and Ageing, Therapeutic Goods Administration, The Regulation of Complementary Medicines in Australia – An Overview (2006), <http://www.tga.gov.au/cm/cmreg-aust.htm>.

180. *Id.* Other products that fall under the Australian 'Complementary Medicines' category include: herbal medicines, homeopathic medicines, aromatherapy products, and traditional medicines (which include ayurvedic medicines, traditional Chinese medicines, and other traditional medicines).

181. *Id.*

182. *The World Today: Complementary Medicine Industry Rejects Calls for Better Regulation* (transcript of ABC radio broadcast June 10, 2008), <http://www.abc.net.au/worldtoday/content/2008/s2270226.htm>.

183. Australian Government Department of Health and Ageing, Therapeutic Goods Administration, Codex Fact Sheet: Proposed Codex Guidelines Will Not Impact on the Way Vitamin and Mineral Supplements Are Regulated in Australia (2005), [http://www.tga.gov.au/cm/fs\\_codex.htm](http://www.tga.gov.au/cm/fs_codex.htm) ("Australia has a risk-based system where the level of evaluation and regulatory control of a medicine is based on the relative risk of the product and the seriousness of the condition for which it is intended to be used."). *Id.*

184. *Id.*

185. *Id.*

186. Australian Government Department of Health and Ageing, *supra* note 179.

complementary medicines, consumers do not receive adequate information about the products and are therefore not protected through current law.<sup>187</sup> In response, Dr. Wendy Morrow, the Executive Director of the Complimentary Healthcare Council disagrees that Australian consumers need more product information. Dr. Morrow states that the Australian complementary medicine regulations provide one of the "most scientifically rigorous regulatory frameworks for complimentary medicines internationally."<sup>188</sup> Dr. Morrow notes that two reviews of the complementary medicine framework have supported the risk-based regulatory system and proposed only minor modifications.<sup>189</sup>

### C. Back to the United States: Criticism of DSHEA, DSNDCPA, and CGMPs

With a general understanding of U.S. dietary supplement regulations and other regulatory structures used around the world, there exists proper context to look at criticisms of the regulations in the U.S. Like most controversial topics, criticisms concerning how the US handles dietary supplement regulations vary across a wide range of perspectives. DSHEA itself has been targeted with the most disapproval as it is the backbone of dietary supplement regulation and it has been effective for much longer than more recent legislation.

#### 1. Criticism of DSHEA

Critics of DSHEA have many different concerns, but only the most controversial will be discussed here. First and most obvious, critics do not agree that the burden of proof for safety of dietary supplements should be the responsibility of the FDA. "A major weakness in DSHEA is that it does not impose on all dietary supplements the burden and obligation to affirmatively substantiate their safety."<sup>190</sup> The FDA is a factor only after a product has already been on the market and it may only remove a dietary supplement from the market if it proves that the dietary supplement is adulterated.<sup>191</sup> Therefore, the authority of the FDA largely appears to be reactionary as opposed to preventative, and consequently consumer safety is put at issue. As L-tryptophan and ephedra have shown, a delay in assessing the dangers of a product can result in serious harm or even death.<sup>192</sup> "DSHEA yielded significant latitude to dietary supplement

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187. See *The World Today*, *supra* note 182.

188. *Id.*

189. *Id.*

190. Margaret Gilhooley, *Deregulation and the Administrative Role: Looking at Dietary Supplements*, 62 MONT. L. REV. 85, 119 (2001).

191. 21 U.S.C. § 342(f)(1)(D).

192. See FDA INFORMATION PAPER, *supra* note 12. See also Editorial, *supra* note 12.

companies in manufacturing and promoting their products, arguably at the expense of consumer safety.”<sup>193</sup>

As noted, the only substantiation claims that DSHEA requires are for dietary ingredients considered “new” after 1994.<sup>194</sup> However, critics claim that “new” is classified in DSHEA in a narrow fashion that does not require substantiation for dietary supplements that were used before 1994 for a different purpose.<sup>195</sup> They note that even though the dietary supplement may have been used prior to 1994, and therefore is “grandfathered” into protection, new uses of the supplement do not require safety substantiation.<sup>196</sup> Consequently, new uses of the dietary supplement have no actual proof of consumer safety. Therefore, some propose that if all dietary supplement manufacturers are required to substantiate the safety of their products, then the manufacturers would therefore use the necessary means to assure safety of the products and consumer safety would theoretically increase.<sup>197</sup>

The criticisms of DSHEA hold the most weight when looking solely at DSHEA itself. However, Congress attempted to appease critics with the passage of the DSNDCPA and the CGMPs.

## 2. Criticism of the DSNDCPA

While the DSNDCPA is an attempt to improve consumer safety by requiring dietary supplement manufacturers to report any serious adverse events to the FDA, it is likely too early to see realistic effects of the legislation because it only came into effect in December, 2007. Critics, however, have found multiple areas of contention where the law *may* fail. Critics argue that regardless of whether the reporting of adverse events is mandatory or not, the reporting inherently detects only a small proportion of the events that are actually due to the dietary supplement.<sup>198</sup> This is because it requires the consumer or a medical professional to actually create the link between the event and the dietary supplement.<sup>199</sup> This criticism may very well be accurate, but it is an inherent problem when dealing with adverse events. An adverse event report intrinsically requires someone to make the determination that there is a link, or a possible link, between a substance or action and an outcome. Therefore, some adverse events will surely never

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193. Michael A. McCann, *Dietary Supplement Labeling: Cognitive Biases, Market Manipulation & Consumer Choice*, 31 AM. J.L. & MED. 215, 243 (2005).

194. 21 U.S.C. § 350b(c) (2006).

195. Gilhooley, *supra* note 190, at 119.

196. *Id.*

197. *Id.*

198. See Wong, *supra* note 19, at 337.

199. *Id.*

be discovered. The same issue necessarily exists for adverse event reporting in the pharmaceutical industry, or for that matter, any industry that follows adverse events.

Critics also argue that some manufacturers may choose to risk investigation by the FDA rather than to turn over injurious adverse event reports because of worries about the effects the reports may have on business.<sup>200</sup> However, the criticism that manufacturers will hide injurious information in order to protect profits is a criticism that can be made regardless of the law or particular level of regulation. If a manufacturer is likely to hide injurious information under the rules established by the DSNDCPA, then there is no evidence whatsoever that those same manufacturers would not attempt to hide the injurious information if there were a different law in place.

Finally, critics of the DSNDCPA argue that even if the FDA receives more adverse event reports, there are still both procedural and economic burdens that face the FDA. Procedurally, the FDA still bears the burden of proof in order to show that a dietary supplement or nonprescription drug should be taken off of the market, and the DSNDCPA does not lighten the FDA's burden.<sup>201</sup> Economically, the DSNDCPA does nothing to heighten the priority of dietary supplement or nonprescription drug regulation by the FDA because doing so would mean more competition for the already strained resources of the FDA.<sup>202</sup> Such criticisms seem valid at this point in time because the burden of proof that DSHEA created. Until the FDA is allowed to shift the burden of proof for product safety back to the manufacturer, the FDA will have to continue to accurately budget expenditures.

### 3. Criticism of the CGMPs

Critics previously argued that DSHEA does not provide quality standards for strength and purity and there are no manufacturing standards mandated by the law.<sup>203</sup> However, the CGMPs were created to specifically address this issue.<sup>204</sup> The CGMPs provide specific guidelines for the manufacturing of dietary supplements.<sup>205</sup>

Critics argue that the CGMPs do little for product safety. Sidney Wolf, health director for FDA watchdog group Public Citizen remarked, "[e]ven with these new manufacturing practices, there will be no assurance that

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200. *See id.*

201. *Id.* at 337-38.

202. *Id.* at 338.

203. *See* RICHARD R. ABOOD, PHARMACY PRACTICE AND THE LAW 48 (2005).

204. Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 72 Fed. Reg. 34751, 34752 (June 25, 2007).

205. 21 C.F.R. pt. 111.

dietary supplements work or are safe.<sup>206</sup> Similar to criticisms regarding the already-strained resources necessary to investigate adverse event reports, critics argue that there is a comparable strain on FDA resources for the enforcement of the CGMPs.<sup>207</sup> If there are not enough resources to implement the law, then it is unlikely that consumers will receive the benefit of the law's full potential.<sup>208</sup> However, in the same manner, the argument that resources are too strained for the implementation of the CGMPs is arguably going to be applicable no matter what the law is because the FDA still must prioritize the use of resources.

#### IV. HOW A GLOBAL COMPARISON CAN HELP GUIDE THE UNITED STATES

This note has demonstrated the level of controversy involved in dietary supplement regulation in the U.S., and how U.S. laws and regulations compare to those of other dietary supplement markets around the world. Surprisingly, the largest dietary supplement markets in the world have drastically different regulatory approaches to dietary supplement products. On one end of the spectrum, the U.S. supports the largest dietary supplement market in the world by providing the FDA with a relatively weak grasp on regulation. However, the DSNDCA and the CGMPs move regulation in the direction of a more restricted industry. At the same time, Japan, Australia, Canada, and the EU are spread out along the continuum, but mostly remain at the opposite end of the spectrum where dietary supplements are much more strictly controlled. Importantly, the strict regulatory control in Japan is moving away from the far end of the spectrum by allowing more products into the marketplace. By no means are the regulations in the U.S. and Japan close to meeting in the middle, but they appear to be slowly heading in from the extremes.

The EU made waves with the Food Supplements Directive by only allowing the sale of products on the positive list. Consumers and industry members fought the Food Supplements Directive every step of the way. It is safe to assume that if the same 'positive list' for dietary supplements in the EU were to be implemented in the U.S., the regulations would be met with equal, if not much more severe opposition. For example, the health industry already used its clout to help promote DSHEA from the beginning.<sup>209</sup> Surely a stronger and more politicized health food industry today would not cave easily into massively-restrictive regulations like the ones in the EU. However,

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206. Zwillich, *supra* note 18.

207. See Rick Liva, *New FDA cGMPs for Supplements: Smoke or Substance?*, 6 INTEGRATIVE MED. 28, 28 (2007).

208. See *id.*

209. See Pray, *supra* note 60, at 15.

as the EU updates substances for approval on the positive list, it also moves toward the middle of the regulatory spectrum.

As regulations around the world change, it is important to remember that the regulation of dietary supplements is very new, and therefore may require multiple adjustments over time. As one author commenting on a proposed Canadian natural health product bill said, “[the bill] is just the next step in this ongoing regulatory development process.”<sup>210</sup> In this aspect, dietary supplement regulations around the world are developing a theme: regulation of dietary supplements is a process. The U.S. adopted the DSNCPA and the CGMPs in the last few years;<sup>211</sup> Japan’s MHLW has changed and updated regulations multiple times since 2001;<sup>212</sup> Canada continues to address new possible regulations as the market changes;<sup>213</sup> and the EU passed the Food Supplements Directive in 2002 and is working towards accepting more supplements onto its positive list.<sup>214</sup> Australia, apparently content to regulate dietary supplements under the blanket framework for complementary medicines, is currently not considering amendments to its regulations.<sup>215</sup>

Even if Congress gave the FDA the authority to control dietary supplements as strictly as other parts of the world, the FDA would not have enough funding to undertake the responsibility. In 2007, a subcommittee looking at the state of the FDA published a report called “FDA Science and Mission at Risk.”<sup>216</sup> The subcommittee found that the FDA is massively underfunded and understaffed for the responsibilities that it has governing foods, drugs, medical devices, cosmetics, and dietary supplements.<sup>217</sup> William Hubbard, a former FDA associate commissioner commented,

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210. Barry Green, *Natural Health Product (NHP) Regulation in Canada*, OTTAWASKEPTICS.ORG (May 6, 2008), <http://www.ottawaskeptics.org/topics/alternative-medicine/48-alt-med/123-natural-health-product-nhp-regulation-in-canada>.

211. For a discussion of the DSNCPA and CGMPs, see *supra* notes 88-116 and accompanying text.

212. See Yamaguchi, *supra* note 137.

213. See Green, *supra* note 210.

214. See Eberhardie, *supra* note 127, at 509.

215. For a discussion of dietary supplement regulations in Australia, see *supra* notes 177-89.

216. See Julie Schmit, *Report: FDA So Underfunded, Consumers Are Put at Risk*, USA TODAY, Dec. 3, 2007, at 6B, available at [http://www.usatoday.com/news/washington/2007-12-02-fda\\_N.htm](http://www.usatoday.com/news/washington/2007-12-02-fda_N.htm) (noting that the subcommittee members were: Allen Roses of Duke University, an expert in neurology; Gail Cassell, a vice president of Eli Lilly; and Barbara McNeil, a public health policy expert at Harvard Medical School); see also FDA SUBCOMM. ON SCI. AND TECH., FDA SCIENCE AND MISSION AT RISK (2007).

217. See FDA SUBCOMM. ON SCI. AND TECH., *supra* note 216, at 6.

"[t]hese people were horrified by what they found," and they determined that the FDA "cannot even do its job now."<sup>218</sup>

Support and criticism of DSHEA, the DSNDCPA, and the CGMPs show that the debate over the "correct" way to regulate dietary supplements in the U.S. will likely never cease, as money and lobbying have proved to be highly influential in the rulemaking process.<sup>219</sup> Even though skeptics of the DSNDCPA and the CGMPs in the U.S. have criticized the rules by pointing out doomsday scenarios, the truth is that the actual effects on consumer choice and consumer safety have not yet been realized. No other free-market economy with a well-developed dietary supplement industry has yet found a regulatory framework that is either foolproof or free from controversy. When one adds to the argument that dietary supplement regulation has only existed in the U.S. since 1994 and that the dietary supplement market continues to expand each year, it becomes evident that the proper direction for dietary supplement regulation must be heavily calculated.

Finally, it does not appear that any of the regulatory frameworks in the world's largest dietary supplement markets can be classified as model systems. Each regulatory framework is both complex and unique to the market and culture that it serves, and each has its own advantages, disadvantages, criticisms, and praises.

Commenting on the EU Food Supplements Directive, one author writes, "[i]t can be seen that the whole area of regulation for food supplements and traditional herbal remedies is complex and necessary but controversial."<sup>220</sup> Controversy surely is one of the few things that all dietary supplement regulations have in common. And if the past is any indication, controversy surrounding the regulation of dietary supplements is here to stay, regardless of where supplements are sold.

GREG LINDQUIST\*

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218. Schmit, *supra* note 216.

219. See Pray, *supra* note 60, at 15.

220. Eberhardie, *supra* note 127, at 510.

\* JD/MHA Candidate, with Certificate in Health Law, Saint Louis University School of Law, 2010; BA, Molecular, Cellular, and Developmental Biology, University of Colorado at Boulder, 2006. The author would like to thank Professors Jesse Goldner and Yvette Liebesman for their guidance in writing this Comment, as well as the Staff and Executive Board of the *Saint Louis University Journal of Health Law & Policy* for their patience and effort. The author would also like to thank S. Andrew, Cynthia, and Geoffrey Lindquist for their endless support, and Elizabeth Gluck for her valuable advice, scholarship, and encouragement.

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