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Dietary Supplementary Regulation: A Comparative Study

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DIETARY SUPPLEMENT REGULATION: A COMPARATIVE STUDY

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INTRODUCTION

On February 3, 2010, Senator John McCain (R., Ariz.) announced his support of the Dietary Supplement Safety Act of 2010.[1] This Act would require that drug manufacturers disclose all of the ingredients in their dietary supplements and give the Food and Drug Administration (FDA) power to regulate dietary supplements' safety.[2] His support for the bill was influenced by a United States Governmental Accountability Office (GAO) report concluding that the "FDA should take further action to improve oversight and consumer understanding."[3]

This was not the first time that Senator McCain had been publicly involved with dietary supplement regulation. In 2003, Senator McCain was a leading force in the increased regulation and ban of ephedra.[4] However, although publicly encouraging dietary supplement regulation on multiple occasions, on March 5, 2010, he withdrew his support for the bill.[5] Senator Orrin Hatch from Utah, the state with the largest production of dietary supplements, personally thanked Senator McCain for withdrawing his support as he believed the bill would have "devastating effects on in supplement industry as a whole."[6]

About half of adults in the United States report regularly using dietary supplements,[7] and the dietary supplement industry and market is growing every year. In 1994, there were only 4000 dietary supplement products available to consumers.[8] Fast forward to 2008 and there were an estimated 75,000 dietary supplement products available in the market.[9] The industry has more than

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1. John McCain, Ariz. Senator, United States Senate, Introduction of the Dietary Supplement Safety Act of 2010 (Feb. 3, 2010), *available at* http://mccain.senate.gov/public/index.cfm?FuseAction=PressOffice.Speeches&ContentRecord_id=952dda07-b71c-4034-4f34-c38974978f7d [hereinafter McCain Speech].

2. Dietary Supplement Safety Act of 2010, S. 3002, 111th Cong. (2010).

3. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-250, DIETARY SUPPLEMENTS: FDA SHOULD TAKE FURTHER ACTION TO IMPROVE OVERSIGHT AND CONSUMER UNDERSTANDING (2009). [hereinafter GAO Report]; McCain Speech, *supra* note 1.

4. Reilley Michelle Dunne, Note, *How Much Regulation Can We Swallow? The Ban on Ephedra and How it May Affect Your Access to Dietary Supplements*, 31 J. LEGIS. 351, 360 (2005).

5. Dan Schiff, *McCain Withdraws Support for Dietary Supplement Safety Act*, OVER THE COUNTER TODAY (March 5, 2010), http://www.overthecountertoday.com/2010/03/mccain-withdraws-support-for-dietary-supplement-safety-act.html.

6. *Id.*

7. Dietary Supplement Health and Education Act of 1994, Pub L. No. 103-417, 108 Stat. 4325, §2(9)(1994) [hereinafter DSHEA]; *see also* Michael A. McCann, *Dietary Supplement Labeling: Cognitive Biases, Market Manipulation & Consumer Choice*, 31 AM. J.L. & MED. 215, 219 (2005).

8. GAO Report, *supra* note 3, at 1.

9. *Id.*

quintupled its annual sales since 1994.[10] In 1994, the industry's annual sales were $4 billion.[11] In 2007, sales were approximately $23.7 billion.[12]

There are a variety of reasons for the dramatic increase in the dietary supplements industry. One reason is that people in the United States are becoming more health conscious and believe that dietary supplements will improve their health and well-being.[13] People also use dietary supplements as a preventative measure for numerous ailments.[14] Physicians recommend dietary supplements to their patients as well.[15] Lastly, consumers are looking for natural remedies in lieu of seeking costly medical care.[16]

While all of those reasons partly contribute to the increase in dietary supplement usage, the main cause for the dramatic increase in the size of the dietary supplements industry is the passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA).[17] The DSHEA effectively prohibits the FDA from regulating dietary supplements for safety and efficacy before they enter the market.[18] Manufacturers of dietary supplements have taken advantage of the lack of regulation by the government and have introduced more than 71,000 dietary supplements to the market in fourteen years.[19]

The DSHEA was passed because dietary supplements were presumed safe and effective,[20] and with the exception of a few supplements that have received broad media coverage for their safety concerns—namely L-tryptophan[21] and ephedra[22]—dietary supplements are relatively safe.[23] However, their effectiveness is often

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10. *See* McCann, *supra* note 7, at 218; *see also* GAO Report, *supra* note 3, at 1.

11. McCann, *supra* note 7, at 218.

12. GAO Report, *supra* note 3, at 1.

13. *Dietary Supplement Facts and Figures*, CONSUMER HEALTHCARE PRODUCTS ASSOCIATION, http://www.chpa-info.org/pressroom/DS_FactsFigures.aspx (last visited August 29, 2010); Robert K. Blendonet al., *Americans' Views on the Use and Regulation of Dietary Supplements*, 161 ARCH INTERN MED. 805, 805 (2001).

14. Cathy Wong, *What's in a Bottle? Introduction to Dietary Supplements*, ABOUT.COM (Feb. 3, 2004), http://altmedicine.about.com/cs/govtregulation/a/Intro_Supps.htm.

15. *Id.*

16. DSHEA, *supra* note 7, at §2(10); Edgar R. Cataxinos, Comment, *Regulation of Herbal Medications in the United States: Germany Provides a Model for Reform*, 1995 UTAH L. REV. 561, 561 (1995).

17. *See generally* DSHEA, *supra* note 7.

18. GAO Report, *supra* note 3, at 2.

19. *Id.* at 1.

20. DSHEA, *supra* note 7, at §2(14).

21. Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,696 (proposed June 18, 1993) (to be codified at 21 C.F.R. Ch. I).

22. Jeff O'Connell, *Dshea Works: the FDA's Ephedra Ban Proves the Agency Already has the Power to Regulate Dietary Supplements*, MUSCLE & FITNESS, May 2004, at 1, *available at* http://findarticles.com/p/articles/mi_m0801/is_5_65/ai_n6005946/.

23. McCann, *supra* note 7, at 215-16.

questioned,[24] and consumers are not educated enough about dietary supplements.[25]

What half of consumers fail to realize is that dietary supplements in the United States are not regulated by the government.[26] When consumers were asked about government involvement in supplement regulation, 81% believed that the FDA should regulate and test for the safety of dietary supplements before they enter the market.[27] Although it seems like a good idea for the FDA to regulate dietary supplements, there are many obstacles within the United States. Some scholars have suggested that the United States should have a regulation system similar to that of the European Union (EU) or China,[28] and some have gone so far as to suggest Germany's regulation system for a model, which treats dietary supplements like drugs.[29]

This Note will give economic, industry, and policy rationales for why the United States will not change its current deregulated system in regard to dietary supplements. Part I will discuss why dietary supplement regulation is important for preventative and public health reasons. Part II will give a historical background as to how dietary supplements in the United States have been regulated in the past and how the DSHEA came into existence. Part III will analyze how the EU regulates dietary supplements and will contrast the EU's method of regulation to the United States' method of regulation. Part IV will discuss China's recent move to regulate traditional Chinese medicine (TCM) in order to promote their uses internationally. Finally, Part V will give economic, industry, and policy reasons why the United States will not and cannot adopt a more strict regulation system like that of the EU or China.

I. WHY DIETARY SUPPLEMENTS SHOULD BE REGULATED

As stated earlier, Americans are horribly misinformed as to the benefits and regulation of dietary supplements.[30] Many Americans view dietary supplements as safe and believe that they will receive more benefits from the supplements if they take them in megadoses.[31] Contrary to popular belief, megadoses of dietary supplements

24. *See id.* at 256.
25. GAO Report, *supra* note 3, at 30.
26. *Id.* at 32.
27. Blendon, *supra* note 13, at 809.
28. *See generally* Iona N. Kaiser, Comment, *Dietary Supplements: Can the Law Control the Hype?*, 37 HOUS. L. REV. 1249 (2000).
29. *See* Cataxinos, *supra* note 16, at 579.
30. GAO Report, *supra* note 3, at 32.
31. Mark A. Kassel, *From a History of Near Misses: The Future of Dietary Supplement Regulation*, 49 FOOD & DRUG L.J. 237, 237 (1994).

do more harm than good. Research indicates a "correlation between megadoses of dietary supplements and toxic reactions, illness, and death."[32] "Americans are more likely to die from vitamin toxicity than from vitamin deficiency."[33] Americans use the availability of and easy access to dietary supplements as an indication of their safety, which is just not the case. This is evidenced by the two most popular examples of dietary supplements harming the public: L-Tryptophan and ephedra.

A. The L-Tryptophan Example

Amino acids are considered the building blocks of nature. Some, the nonessential amino acids, are produced naturally within the human body and others, the essential amino acids, cannot be produced in the body so we have to ingest them through foods or dietary supplements.[34] L-tryptophan is an essential amino acid found in many foods—poultry, red meat, seafood, vegetables, and legumes.[35] The L-tryptophan dietary supplement claimed to combat insomnia and premenstrual syndrome and suppress a person's appetite.[36]

In 1989, before the enactment of the DSHEA, a contaminated batch of L-tryptophan hit the market. This contaminated batch caused an outbreak of eosinophilia-myalgia syndrome (EMS), a rare blood disorder.[37] The first adverse report was made on November 7, 1989.[38] The FDA was able to track reports and swiftly warned the public to discontinue use of L-tryptophan products by November 11th.[39] On November 17th, the FDA ordered a recall of L-tryptophan supplements of one hundred milligrams or more.[40] On November 21st, the FDA stopped importation of L-tryptophan.[41] Even with its swift action, "[o]ver 1500 people were adversely affected by the tainted L-tryptophan, with a reported 38 individuals dead and others paralyzed for life."[42]

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32. *Id.* at 238.
33. *Id.*
34. *The Chemistry of Amino Acids*, THE BIOLOGY PROJECT, http://www.biology.arizona.edu/biochemistry/problem_sets/aa/aa.html (last visited Aug. 29, 2010).
35. *Foods Highest in Tryptophan*, SELF NUTRITION DATA, http://www.nutritiondata.com/foods-000079000000000000000.html (last visited Aug. 29, 2010).
36. Kassel, *supra* note 31, at 241.
37. *Id.* at 241-42.
38. Carter Anne McGowan, Note, *Learning the Hard Way: L-Tryptophan, the FDA, and the Regulation of Amino Acids*, 3 CORNELL J.L. & PUB. POL'Y 383, 399 (1994).
39. *Id.*
40. *Id.*
41. *Id.*
42. Kassel, *supra* note 31, at 242.

Since this incident happened before the enactment of the DSHEA, the FDA was able to quickly investigate the adverse reactions and take immediate action to protect the public. Even then, there were still catastrophic results for the people who were diagnosed with EMS. After the DSHEA, the FDA would not be able to make such swift determinations or recall unsafe products, which is evidenced by the ephedra incidents.

B. The Ephedra Example

Ephedrine, the active ingredient in the dietary supplement ephedra, is known to boost metabolism, burn calories, act as adrenaline, excite the nervous system, open blood vessels, and stimulate the heart.[43] Many athletes took ephedra to "minimize fatigue, control weight, and enhance athletic performance."[44] Steve Bechler, a pitcher for the Baltimore Orioles, died from heatstroke and ephedra complications.[45] Korey Stringer, an offensive lineman for the Minnesota Vikings, died from heatstroke and ephedra complications as well, along with Rashidi Wheeler of Northwestern University and Devaughn Darling of Florida State University.[46]

The FDA recognized the potential dangers of ephedra and ephedrine-containing products as early as 1994 when it issued a "Medical Bulletin" to discourage consumers from taking products with ephedrine as an ingredient.[47] However, the FDA was restricted from taking more active actions because of the enactment of the DSHEA, which prohibited the FDA's control over dietary supplements. It took nearly 150 deaths, 16,000 adverse event reports, and 9 years before the FDA and the Department of Health and Human Services banned ephedrine products in 2003.[48]

C. How Regulations Would Have Made a Difference

All of the deaths and adverse reactions to dietary supplements were completely preventable. If the FDA had the power to regulate dietary supplements before they went into the market and into people's homes as they do with drugs, then many people may still be alive today.[49] And these aren't the only dietary supplements with potentially harmful effects. Vitamin A, vitamin B, vitamin D,

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43. Dunne, *supra* note 4, at 358.
44. *Id.* at 351.
45. *Id.*
46. *Id.*
47. *Id.* at 359.
48. *Id.* at 352, 360.
49. Kassel, *supra* note 31, at 247-48.

vitamin E, E-ferol, and L-carnitine are just some examples of dietary supplements that can cause serious injuries when taken in megadoses.[50] When there are so many potential side effects from dietary supplements, how can the FDA not be involved in their regulation? The next section outlines the history of dietary supplement regulation in the United States, ending with complete deregulation after the DSHEA was passed.

II. BACKGROUND ON THE REGULATION OF DIETARY SUPPLEMENTS IN THE UNITED STATES

A. Early Regulation of Dietary Supplements

Until the mid-nineteenth and early twentieth centuries, dietary supplements were basically unregulated. Things changed in 1850 when the Massachusetts Sanitary Commission published a report that connected contaminated food and drug products to increasing mortality rates.[51] States began enacting laws that allowed them to regulate food and drugs, but that proved harder for the federal government.[52] At this point, the Supreme Court was narrowly interpreting the Commerce Clause.[53] The narrow reading allowed the government only to regulate food and drugs that literally crossed state borders, and at this time, most food and drugs only moved intrastate, leaving the government without recourse.[54]

However, in 1906, the government finally took action and enacted the Pure Food and Drug Act of 1906 (1906 Act), the first act to regulate food and drugs within the United States.[55] This legislation prevented adulterated food and drugs from being transported in interstate commerce.[56] The 1906 Act also allowed the FDA enforcement mechanisms to seize food and drugs that were adulterated and to go after the manufacturers.[57] Similar to current law, the government had to prove that an ingredient was unsafe *after* it entered the market before anything could be done to protect public health.[58]

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50. *Id.* at 245-49.
51. McCann, *supra* note 7, at 232.
52. *Id.*
53. *Id.*
54. *Id.*
55. *Id.* at 232-33; Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768, (1906) [hereinafter 1906 Act]; McCann, *supra* note 7, at 232-33.
56. 1906 Act, *supra* note 55, at § 2. . *See also* 21 U.S.C. § 342 (2006).
57. Peter B. Hutt & Peter B. Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food,* 39 FOOD DRUG COSM. L. J. 2, 8-9 (1984).
58. 1906 Act, *supra* note 55, at § 2.

Another shortfall of the 1906 Act was that it still allowed manufacturers to have misleading labels as to the safety of their products.[59] Congress tried to curtail this practice when it enacted the Shirley Amendment in 1912, which allowed the government to prosecute manufacturers when their product labels were "false and fraudulent."[60] The heavy burden was on the government to prove not only that the label was not true, but also that the manufacturer was aware of it being false.[61]

Although state governments were enacting more strict regulations for dietary supplements using their state police power, it was not until 1938 when the federal government took more action in regulating dietary supplements after seventy-three people died from the dietary supplement Elixir Sulfanilamide, which had not been tested before entering the market.[62]

B. More Regulation

After the Elixir Sulfanilamide incident, Congress replaced the 1906 Act with the Food, Drug, and Cosmetic Act of 1938 (FDCA).[63] The FDCA gave the FDA more discretion for regulating dietary supplements.[64] Although the FDCA had given the FDA more authority to regulate dietary supplements, it did not require premarket approval, which allowed dietary supplements to enter the market without safeguards.[65] However, it did allow the FDA to police the labeling of dietary supplements, which was lacking from previous regulation.[66]

Although the FDA had no power to regulate the safety or efficacy of dietary supplements, during this time, they were becoming safer because of other reasons.[67] Due to private tort liability and the desire to avoid bad publicity, manufacturers began testing the safety of their products before putting them on the market.[68] However, without minimum safety standards from the government or FDA, manufacturers could still put unsafe products on the market if they chose to do so.

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59. McCann, *supra* note 7, at 233; *see also* United States v. Johnson, 221 U.S. 488, 497-98 (1911).
60. Shirley Amendment, Pub. L. No. 62-301, 37 Stat. 416 (1912).
61. *Id.*
62. McCann, *supra* note 7, at 234.
63. *Id.*
64. Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (1938).
65. McCann, *supra* note 7, at 234.
66. *Id.*
67. *Id.* at 234-35.
68. *Id.* at 235.

The FDA took advantage of its policing powers when it came to dietary supplements' labels. In the Supreme Court case *Kordel v. United States*, the Court held that mailed pamphlets and advertisements constituted labeling according to the FDCA, which is a liberal and broad interpretation of the Act.[69] Just when the FDA was making progress on one front, Congress passed the Food Additives Amendment to the FDCA, which shifted the burden to the FDA to prove that dietary supplements were not safe.[70] However, the Food Additives Amendment did provide the FDA with more oversight by mandating that food additives needed premarket approval.[71] Dietary ingredients were included under the definition of food additive, so dietary supplements were affected by this legislation.[72]

The FDA gained momentum in the 1960s, bringing hundreds of misleading label claims in court and rallying to establish premarket approval of drug efficacy claims and potency limits with the Kefauver-Harris Amendment.[73] However, the industry and consumers started to actively speak out against more stringent dietary supplement regulations.[74] The industry obviously did not want to abide by a governmental agency if it did not need to, and consumers were worried about their favorite products being pulled off the market.[75] Because of lobbying efforts, Congress passed the Proxmire Amendments, which "eliminated maximum limits on the potency of supplements and on combinations of vitamins and minerals and prohibited the classification of any supplement as a drug based on presumptively excessive potency."[76] With the limited regulatory authority the FDA now had over the dietary supplement industry, the industry exploded and produced more supplements than ever.

C. Nutrition Labeling and Education Act of 1990

With consumers popping dietary supplements like they were candy and being misinformed about the supplements, Congress passed the Nutrition Labeling and Education Act of 1990

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69. Kordel v. U.S., 335 U.S. 345, 348-49 (1948).

70. Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (1958).

71. Lars Noah & Richard A. Merrill, *Starting from Scratch?: Reinventing the Food Additive Approval Process*, 78 B.U. L. REV. 329, 331-32 (1998).

72. Stephen H. McNamara, *Dietary Supplements of Botanicals and Other Substances: A New Era of Regulation*, 50 FOOD & DRUG L. J. 341, 343 (1995).

73. McCann, *supra* note 7, at 236.

74. *Id.* at 237.

75. *Id.*

76. *Id.* at 238 (internal citations omitted).

(NLEA).[77] The NLEA added two new labeling sections to the FDCA.[78] The first sets forth general nutritional and labeling standards, and the second prohibits manufacturers from giving false promises of disease prevention on dietary supplement labels.[79]

The newly appointed FDA Commissioner, David Kessler, took his newfound authority over dietary supplements and ran with it. Without clear guidelines as to how to enforce the NLEA,[80] Kessler proposed drastic changes.[81] Kessler wanted to ban many dietary ingredients as unapproved food additives, severely affecting the dietary supplement industry.[82] The FDA realized how drastic its proposed changes were and prefaced them with this statement: "The Agency recognizes that proposing the same standard for conventional food and dietary supplements is contrary to the view expressed by some members of Congress."[83]

As one can imagine, Congress did not appreciate being undercut by the FDA and passed the Dietary Supplement Act of 1992, which delayed enacting the FDA's changes and gave Congress time to develop more industry-friendly legislation,[84] the Dietary Supplement Health and Education Act of 1994 (DSHEA).

D. The Dietary Supplement Health and Education Act of 1994

In 1994, Congress passed the very industry-friendly DSHEA legislation. The "DSHEA sought to 'supersede the [existing] ad hoc patchwork regulatory policy on dietary supplement' with one that removed 'unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers.' "[85] One of the main reasons for imposing such industry-friendly legislation was that Congress worked off of the premise that "dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare."[86]

The DSHEA expanded the definition of "dietary supplement" to be:

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77. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990) [hereinafter NLEA].

78. *Id.* at § 3.

79. *Id.*

80. McCann, *supra* note 7, at 240.

81. *Id.*

82. *Id.*

83. *Id.* at 241 (citing Monica Miller, *The History of Dietary Supplement Regulation*, FOUNDATION FOR THE ADVANCEMENT OF INNOVATIVE MEDICINE, *available at* http://www.faim.org/supplements.htm).

84. Dietary Supplement Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491 (1992).

85. McCann, *supra* note 7, at 243.

86. DSHEA, *supra* note 7, at § 2(14).

> a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
>
> (A) a vitamin;
> (B) a mineral;
> (C) an herb or other botanical;
> (D) an amino acid;
> (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
> (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).[87]

The DSHEA now assures that dietary supplements are treated separately from food additives. The main effect of the DSHEA is that it removed any premarket testing for safety or efficacy of dietary supplements.[88] This put Kessler's plans for more FDA regulations regarding dietary supplements to an instant halt.[89] The DSHEA only allows the FDA to take action against individual supplements after it is on the market and there is a public health concern—basically, after the damage is done.[90] The DSHEA imposes the burden of proof on the FDA to show the public health concern of the product.[91]

The FDA's limited ability to regulate the safety of dietary supplements before they enter the market has given manufacturers an incentive to make false claims regarding the nutritional efficacy of their products.[92] Manufacturers engage in this "puffery" because they want their products to sell better, and more importantly, because they know the FDA has a huge burden to bear to show a "significant or unreasonable risk" if it wants to remove the product from the market.[93]

The burden of proof for the FDA is high. When the DSHEA was first passed, manufacturers of dietary supplements were not required to report adverse effects of their products to the FDA.[94] This made the FDA's burden almost impossible to meet because it had no access to information it needed to show "a significant or unrea-

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87. 21 U.S.C. § 321(ff)(1) (2006).
88. McCann, *supra* note 7, at 244.
89. *See* Kaiser, *supra* note 28, at 1262.
90. Fiona LeCong, Comment, *Food Supplements Directive: An Attempt to Restore the Public Confidence in Food Law*, 29 LOY. L.A. INT'L & COMP. L. REV. 105, 116 (2007).
91. DSHEA, *supra* note 7, at § 4.
92. Kaiser, *supra* note 28, at 1262.
93. *Id.* at 1262-63.
94. McCann, *supra* note 7, at 251.

sonable risk."[95] However, since December 22, 2007, manufacturers are now required to report serious adverse events to the FDA.[96] Even with this change in legislation, the FDA still has obstacles to meeting its burden: "FDA has limited information on the number and location of dietary supplement firms, the identity and ingredients of products currently available in the marketplace, and mild and moderate adverse events reported to industry."[97]

Therefore, the FDA's burden is still hard to meet and without "mandatory recall authority,"[98] the hoops the FDA has to jump through make it extremely difficult to remove unsafe products from the market. For example, the removal of ephedra came about ten years after the FDA issued its initial advisory against it.[99] Although the 2007 legislation is a step in the right direction, the FDA's hands are still tied in a lot of respects.

The DSHEA does provide some safeguards to protect consumers, such as labeling of "statements of nutritional support."[100] Under the DSHEA, labels "may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases," and it also mandates that a warning stating that the FDA has not approved the use of the dietary supplement must be on the label.[101] While this does prevent some "puffery" on the part of manufacturers, they are still able to make statements such as "improves memory and concentration," "nutritionally supports healthy liver function," "helps promote general well-being during the cold and flu season," and "gives adults a competitive edge."[102]

The DSHEA also called for the opening of the Office of Dietary Supplements (ODS) as part of the National Institute of Health (NIH). The responsibilities of the ODS, as outlined by DSHEA, are:

- To explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care.
- To promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions.
- To conduct and coordinate scientific research within NIH relating to dietary supplements.

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95. Kaiser, *supra* note 28, at 1262.
96. GAO Report, *supra* note 3, at 11.
97. *Id.* at 17.
98. *Id.*
99. *Id.* at 2.
100. Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 685 (1997).
101. Kaiser, *supra* note 28, at 1273-74.
102. Gilhooley, *supra* note 100, at 685.

- To collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources.
- To serve as the principal advisor to the Secretary and to the Assistant Secretary for Health and provide advice to the Director of NIH, the Director of the Centers for Disease Control and Prevention, and the Commissioner of the Food and Drug Administration on issues relating to dietary supplements.[103]

However, very little of the research done by the ODS is known by the public. All of the information is publicly available on the ODS Web site; however, consumers, because of the assumption that dietary supplements are safe, do not take advantage of this system. Even if the scientific research reveals problems with dietary supplements, the FDA does not have power to do anything about it.

The DSHEA gives dietary supplement manufacturers a lot of freedom to create and market dietary supplements without necessarily testing for safety or efficacy beforehand. The FDA has some regulatory authority to control labels and to pull products off the market, but according to the Government Accountability Office (GAO), the FDA needs to do more.[104]

III. THE EUROPEAN UNION

A. The EU's Regulation System

Before 2002, there was no Europe-wide dietary supplement legislation.[105] Dietary supplements were regulated by the individual member states of the European Union, and some chose a system very similar to the system of regulation in the United States.[106] There were no clear guidelines as to whether dietary supplements were to be considered foods or medicines, so they could have been regulated as either.[107]

After the occurrence of a few instances that weakened the public's confidence in food safety, the European Union began to harmonize its food safety regulations "in order to offer consumers a wide range of safe and high quality products coming from all

103. ABOUT THE OFFICE OF DIETARY SUPPLEMENTS, http://ods.od.nih.gov/About/about_ods.aspx (last visited Aug. 29, 2010).

104. *See generally* GAO Report, *supra* note 3.

105. LeCong, *supra* note 90, at 106-07.

106. *Id.*

107. *Id.* at 106-07.

Member States."[108] In 2002, the European Parliament and Council adopted the Directive 2002/46/EC, the Food Supplements Directive.[109] According to the Directive, "food supplements" are defined as

> foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a 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.[110]

The Food Supplements Directive provides a list of vitamins and minerals that are safe to use in food supplements,[111] and if a vitamin or mineral is not on the list, then it must receive premarket approval before it can be offered for sale on the market.[112] There are 112 vitamins and minerals on the "positive list" of approved supplements.[113] If a supplement is not included in the list, the manufacturer must seek approval.[114] It is estimated that it could take two to three years before there is enough data to put a supplement on the positive list.[115] This research can cost the manufacturer $119,000 to $372,000.[116]

The Food Supplements Directive was quite controversial when it was first introduced, both with dietary supplement manufacturers and consumers.[117] The Health Food Manufacturers Association (HFMA), a United Kingdom-based group, claimed that the Food Supplements Directive would cripple the "supplements industry by banning hundreds of nutrients and thousands of supplements if it could not be invalidated or amended."[118] Manufacturers are partic-

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108. *Id.* at 107.

109. Council Directive 2002/46 art. 2, 2002 O.J. (L 183) 51, 52 (EC) [hereinafter Food Supplements Directive].

110. *Id.* at art. 4.

111. Nicole Coutrelis, *The Legal Status and Regulatory Context of "Health Foods" in the European Union*, 58 FOOD & DRUG L.J. 35, 39 (2003).

112. LeCong, *supra* note 90, at 108-09.

113. *Id.* at 108.

114. *Id.* at 108-09.

115. *Id.* at 109.

116. *Id.*

117. *See* Greg Lindquist, Comment, *Diet Starts Monday: An Analysis of Current U.S. Dietary Supplement Regulations Through an International Comparison*, 3 ST. LOUIS U. J. HEALTH L. & POL'Y 123, 139-40 (2009).

118. Shane Starling, *Industry Ponders Court's Latest Directive Action*, FUNCTIONAL FOODS & NUTRACEUTICALS, Sept. 2005, at 6.

ularly concerned about the ambiguity that remains after the Directive was passed.[119] The science and regulatory director at Solgar, UK has stated:

> We have accepted that it is a complete wait-and-see situation. Of course we keep up our lobbying efforts but a lot of it is out of our hands now, especially in regard to the Food Supplements Directive (FSD). That's why we have not panicked with this thing because you just can't tell how it is going to pan out. A lot of it comes down to interpretation.[120]

Manufacturers believe that the uncertainty surrounding the Directive is hurting product development so that European manufacturers cannot compete with U.S. manufacturers, where the DSHEA has a "develop first, ask questions later" approach.[121]

However, Markos Kyprianou, EU commissioner for health and consumer protection, has expressed that the Directive will not negatively affect liberal markets such as the U.K., Netherlands, and Sweden, but will have positive effects on less liberal markets like Spain, France, and Italy.[122] Despite these reassurances, members of Consumers for Heath Choice (CHC) are fighting for their country's own policies regarding dosing levels of supplements, afraid the Directive will limit their choices.[123] It is estimated that up to "three hundred nutrients and nutrient sources" could be taken off the shelves in the U.K. alone.[124]

When brought to the European Court of Justice (ECJ), the ECJ upheld the Food Supplements Directive with advice to improve the process of getting ingredients on the positive list.[125] As of 2007, the $6 billion market for supplements in the EU has not felt drastic effects from the Directive.[126]

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119. *Regulatory Uncertainty Reigns in European Supplement Markets: Food Supplements Directive Overview*, NUTRITION BUS. J., May/June 2007, at 16 [hereinafter Regulatory Uncertainty Article].

120. *Id.*

121. *Id.*

122. Simon Robinson, *Court Approves EU Vitamin Bill*, EUROPEAN CHEMICAL NEWS, July 18, 2005, at 8.

123. Regulatory Uncertainty Articles, *supra* note 119, at 16.

124. LeCong, *supra* note 90, at 105.

125. Starling, *supra* note 118, at 6.

126. Regulatory Uncertainty Articles, *supra* note 119, at 16.

B. Similarities and Differences Between the EU and U.S. Systems

1. Similarities

The DSHEA and the Food Supplements Directive are both concerned with consumer safety and choice, but go about protecting them in different ways. In the United States, the DSHEA was passed on the premise that dietary supplements are relatively safe.[127] There are certain supplements whose safety and efficacy are not questioned, so only completely new dietary supplements need to be questioned. The EU takes a different approach by listing the particular ingredients that are allowed to be used and the dosage in which the ingredients can be used.[128] Although the underlying policy between the two systems is the same, the United States and EU regulate dietary supplements differently.[129]

2. Differences

The obvious and main difference between the regulation system in the United States and the system in the EU is whether premarket approval is required before a dietary supplement enters the market.[130] The United States has a "develop first, ask questions later" approach,[131] while the EU only allows supplements into the market after they have been proven safe.[132] After a vitamin or nutrient is proven safe and effective, it is put on the "positive list" (Annexes I and II to the Directive), and manufacturers are free to use them for their dietary supplements.[133] If a vitamin or nutrient is not on the positive list, then the manufacturer needs to seek approval by showing that it is safe and effective before it can be used in the supplement.[134] The testing necessary to show that a vitamin or nutrient is safe and effective can take up to three years,[135] delaying the opportunity for the supplement to enter the market and delaying profits by the manufacturer.

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127. DSHEA, *supra* note 7, at § 2(14).

128. LeCong, *supra* note 90, at 108.

129. *See* Richard E. Nowak, Note, *DSHEA's Failure: Why a Proactive Approach to Dietary Supplement Regulation is Needed to Effectively Protect Consumers*, 2010 U. ILL. L. REV. 1045, 1074-76 (2010) (analyzing the differences between the DSHEA and the Food Supplements Directive).

130. *See generally* DSHEA, *supra* note 7; *see generally* Food Supplements Directive, *supra* note 109.

131. Regulatory Uncertainty Article, *supra* note 119, at 16.

132. Food Supplements Directive, *supra* note 109.

133. *Id.* at art. 4(1).

134. LeCong, *supra* note 90, at 108-09.

135. *Id.*

In the United States, the DSHEA effectively removed any authority the FDA had to prevent unsafe and ineffective supplements from entering the market.[136] After the DSHEA passed, "manufacturers introduced an overwhelming array of products of unproven safety and efficacy" into the U.S. market.[137] Any supplement that was available before October 15, 1994 was grandfathered into the system, meaning that they do not have to make any showing of their safety or efficacy.[138] New dietary supplements have to meet one of two requirements:

> (1) it contains only dietary ingredients that 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 (2) there is evidence that the dietary ingredient is reasonably expected to be safe under the conditions of use recommended or suggested in the product's labeling.[139]

Manufacturers depending on the second prong of the requirement only have to notify the FDA of the evidence they used for the basis of their decision seventy-five days before the supplement is to go on the market.[140]

A mechanism that the FDA does have for controlling the supplements on the market is with the Dietary Supplement and Nonprescription Drug Consumer Protection Act.[141] This act requires companies to report any serious adverse reactions of a supplement to the FDA.[142] However, moderate and mild adverse reactions are not required to be reported, which limits the FDA's ability to determine if a product is unsafe.[143] In addition, there is a severe lack of underreporting, which leaves the FDA with incomplete information to do its job.[144]

Another major difference between the two systems is how the burden of proof is allocated. Even when the FDA determines that a dietary supplement is unsafe or ineffective, the burden remains on the FDA to prove that it is unsafe or ineffective.[145] In the EU, the manufacturer has the burden of proving that a supplement is safe

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136. GAO Report, *supra* note 3, at 2.

137. W. Steven Pray, *Health Fraud and the Resurgence of Quackery in the United States: A Warning to the European Union*, 11 PHARMACEUTICALS POL'Y & L. 113, 122 (2009).

138. GAO Report, *supra* note 3, at 10.

139. *Id.*

140. *Id.*

141. Dietary Supplement and Nonprescription Drug Consumer Protection Act, Pub. L. No. 109-462, 120 Stat. 3469 (2006).

142. GAO Report, *supra* note 3, at 11.

143. *Id.*

144. *Id.* at 6.

145. DSHEA, *supra* note 7.

before it is put on the market.[146] This makes sense because the manufacturer is privy to the research and tests regarding its supplements. Because of lack of information regarding manufacturers and their ingredients, limited research, lack of mandatory recall authority, and underreporting of adverse effects, the FDA is at a huge disadvantage to meet the burden of proof to remove a supplement from the market.[147] The EU removes all of those problems by making approval mandatory before a dietary supplement is available to the market.

IV. CHINA

A. Regulation of Traditional Chinese Medicines in China

Since the passage of the 1982 Chinese Constitution, the People's Republic of China (China) has regulated traditional Chinese medicines (TCMs) and is taking every effort to create an international market for its product.[148] In the past, TCMs have not been regulated by China, mostly because of their status as a cultural institution.[149] Although TCMs have a history of long use by the Chinese, there is "little evidence of uniformity in the preparation, ingredients, and dosage of traditional Chinese medical treatments."[150] The State Food and Drug Administration (SFDA) of China has the responsibility

> [t]o take charge of formulating regulations of Traditional Chinese Medicines (TCMs) and ethno-medicines, and supervise their implementation, draw up quality standards of TCMs and ethno-medicines, formulating Good Agricultural Practices for Chinese crude drugs and Processing Standards for prepared slices of Chinese crude drugs and supervising their implementation, and carry out protection system for certain TCMs.[151]

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146. *See* LeCong, *supra* note 90, at 108-09 (noting that manufacturers attempting to get substances added to the "positives list" face costly tests and a lengthy application process).

147. GAO Report, *supra* note 3, at 6-7; Nowak, *supra* note 129, at 1068.

148. Teresa Schroeder, Comment, *Chinese Regulation of Traditional Chinese Medicine in the Modern World: Can the Chinese Effectively Profit from One of Their Most Valuable Cultural Resources?*, 11 PAC. RIM. L. & POL'Y J. 687, 688 (2002).

149. *Id.* at 689.

150. *Id.*

151. *About SFDA:* Main Responsibilities, STATE FOOD AND DRUG ADMINISTRATION, P.R. CHINA, http://eng.sfda.gov.cn/eng (last visited Aug. 29, 2010).

In addition to the SFDA, China also has the State Administration of Traditional Chinese Medicine (SATMC) dedicated solely to regulating TCMs.[152]

National regulation of TCMs ramped up in 1992 with the passage of the Regulations of Protection of Traditional Chinese Medicines, which seeks "to raise the quality of all varieties of traditional Chinese medicines, promote the development of TCM medicines, and perhaps most importantly, protect the legal rights and interests of enterprises engaging in the production of TCM."[153] To receive a "Certificate of Variety of Traditional Chinese Medicine under Protection," the TCMs must have clinical and scientific research to support their efficacy and safety.[154] Under the new regulation system, TCMs "are held to the same standards as other Chinese drug manufacturers. Under these new laws, all manufacturers, producers, and wholesalers must be licensed by local and national agencies, all drug institutions are subject to investigation, and violation of the laws results in large fines and loss of license."[155]

TCMs are subjected to "rigorous pharmaceutical testing," similar to drugs.[156] TCMs are generally categorized as a Category I pharmaceutical, and they have special requirements to meet because they are TCMs. These requirements include providing information regarding "sourcing, cultivation, ecological environment, collection, handling, processing, and preparation . . . in the pretrial testing phase. Only after final completion, reporting, and examination may the medicines be approved for production."[157]

China is now taking an interest in how TCMs are developed because China wants a piece of the dietary supplement pie. Since the 1960s, TCMs, especially acupuncture and herbal remedies, have developed an international following.[158] The market for Chinese herbal medicines doubled in ten years, with Europe and the United States being the major importers.[159] China is responsible for 65% of raw exports to make TCMs in other countries, but it is only responsible for 2% of finished TCM products internationally.[160] For finished TCM products, international consumers turn to neighboring countries, such as Japan or Korea, most likely because

152. Schroeder, *supra* note 148, at 702.
153. *Id.* at 703.
154. *Id.* at 704.
155. *Id.* at 707.
156. *Id.*
157. *Id.* at 708 (internal citations omitted).
158. *Id.* at 691.
159. Jane Qiu, *China Plans to Modernize Traditional Medicine*, 446 NATURE 590, 590 (2007).
160. Schroeder, *supra* note 148, at 697.

of the lack of standardization and quality control in China.[161] China's new regulations hope to globalize TCMs by 2020.[162]

B. Comparison of China's and the U.S.'s Regulation Systems

Similar to the differences between the EU system of regulation and the U.S. system of regulation, China's regulations are much more strict than the regulations in the United States. "China's recently updated pharmaceutical laws, which include regulation of Chinese herbal medicines, are better equipped than U.S. domestic laws to ensure the quality of herbal remedies."[163] China now requires that TCMs go through a premarket approval process that the DSHEA eliminated from the U.S. regulation system. China enacted these regulations to be competitive in the international dietary supplement market by raising its standards for TCMs, which begs the question of why Americans are hesitant to purchase Chinese medicines, but hurry to the stores to buy American dietary supplements, which are not regulated.

V. WE CAN'T GO BACK NOW

After passing the DSHEA, Congress made the decision that supplements should be presumed safe, and FDA regulation should be kept at a minimum.[164] With this decision, Congress has sealed our fate. The explosion of the industry combined with consumer misconceptions make it extremely hard to transition back into a more heavily regulated regime.

A. Economic & Industry Arguments

The last thing the dietary supplement industry wants is to be regulated. Since the DSHEA passed, the industry has grown exponentially—going from 4000 supplements to 75,000 supplements available on the market.[165] The expenses on the industry to develop dietary supplements are quite low. Because ingredients on the market before October 15, 1994 are grandfathered into the DSHEA, manufacturers only need to seek FDA approval for new dietary ingredients.[166] The approval process for a new dietary in-

161. *Id.*
162. Qiu, *supra* note 159, at 590.
163. Schroeder, *supra* note 148, at 694.
164. DSHEA, *supra* note 7, at § 2(13-14).
165. GAO Report, *supra* note 3, at 1.
166. *Id.* at 1, 10.

gredient is not extensive. To receive approval the manufacturer must provide:

- [Their] name and complete address.
- The name of the new dietary ingredient. If the new dietary ingredient is an herb or other botanical, [they] must include the Latin binomial name (including the author).
- A description of the dietary supplement or dietary supplements that contain the new dietary ingredient, including the:
  - level of the new dietary ingredient in the product;
  - conditions of use of the product stated in the labeling or if no conditions of use are stated, the ordinary conditions of use; and
  - history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will be reasonably be [*sic*] expected to be safe.
    - Any reference to published materials must be accompanied by reprints or photostatic copies.
    - Any material in a foreign language must be accompanied by a translation.
- A signature by a person designated by [the proponent] who can be contacted if we have questions.[167]

The only outside research that the manufacturer has to conduct is the "history of use or other evidence of safety."[168] This is a small burden on manufacturers of dietary supplements compared to what drug manufacturers must prove to get FDA approval.

If dietary supplements were to be regulated similarly to drugs, manufacturing costs for dietary supplement developers would explode. It costs an average of $50 to $100 million per New Drug Application (NDA), and it is a long process to receive approval.[169] Between preclinical testing, three rounds of human clinical trials, and the FDA approval process, it can take six to nine years before a product can be sold to the public.[170] This application requires

167. New Dietary Ingredients in Dietary Supplements-Background for Industry, What Information Must the Notification Contain?, U.S. FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/Food/DietarySupplements/ucm109764.htm#whatinfo (last visited Aug. 29, 2010).

168. *Id.*

169. Cataxinos, *supra* note 16, at 574.

170. *Id.* at 573-74.

very extensive research and data to prove that a drug is safe and effective before it can be given to the public.[171] There can be 100,000 to 200,000 pages of raw data from research that the FDA has to review before it can grant approval.[172]

The opportunity costs of development would inhibit most manufacturers from investing in dietary supplements. Although it is unlikely that the FDA would have imposed such a severe application process for dietary supplements, the costs would have certainly increased, deterring manufacturers.

Dietary supplement manufacturers are predicting that the Food Supplements Directive will cripple the industry in the EU because of the costs and limitations associated with dietary ingredient approval.[173] With the capitalist, consumer-choice driven society in the United States, it is unlikely that we would ever try to regulate the dietary supplements industry like the EU or China does.

With regards to the FDA, it just does not have the money or resources to seriously regulate dietary supplements. The FDA's budget for fiscal year 2010 is $3.2 billion, the largest budget ever for the FDA.[174] For fiscal year 2011, the FDA was able to secure 30% more funding from the government,[175] putting its budget at $4 billion.[176] These budget increases are going to "set standards for safety, expand laboratory capacity, pilot track and trace technology, strengthen [the FDA's] import safety program, improve data collection and risk analysis and begin to establish an integrated national food safety system with strengthened inspection and response capacity."[177]

Although the FDA is receiving a larger budget every year, most of the money is going to strengthen and improve systems already in place. The FDA would require a huge boost in its budget to take on regulating dietary supplements. If the DSHEA had never passed, FDA regulation of dietary supplements would have been more realistic because there were only 4000 supplements on the

171. *Id.* at 573.

172. *Id.*

173. Starling, *supra* note 118, at 6.

174. *Summary of the FDA's FY 2010 Budget,* U.S. FOOD AND DRUG ADMINISTRATION http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/ucm153154.htm (last visited Aug. 29, 2010).

175. Tom Karst, *FDA Budget Would Boost Food Safety Funds 30%*, THE PACKER, Feb. 1, 2010 *available at* http://thepacker.com/FDA-budget-would-boost-food-safety-funds-30/Article.aspx?oid=981684&aid=117&fid=PACKER-HANDLING-AND-DISTRIBUTING.

176. Andrew Zajac, FDA Budget Draws Cries of 'Not Enough,' L.A. TIMES, Feb. 11, 2010, at A12, *available at* http://articles.latimes.com/2010/feb/11/nation/la-na-fda-budget11-2010feb11.

177. Karst, *supra* note 175.

market, not 75,000.[178] It is now too burdensome to require the FDA to approve supplements before they enter the market because of the sheer number of supplements, lack of funds to provide this type of regulation, and lack of personnel.

B. Policy Arguments

1. Why the EU and China decided to regulate dietary supplements

One of the EU's main concerns when passing the Food Supplements Directive was "to ensure a high level of protection for consumers and facilitate their choice, the products that will be put on to the market must be safe and bear adequate and appropriate labeling."[179] First and foremost, the EU wanted to ensure that its consumers would be protected from unsafe dietary supplements.[180] Secondly, by having only safe products with proper labeling on the market, the EU believed that consumers will be able to make more informed decisions regarding which supplements will be beneficial to them.[181] This approach prescreens the beneficial properties of the supplements before they are put onto the market, while the United States' approach makes everything available and allows consumers to make decisions regarding which supplements they want, regardless of whether the supplement will actually be beneficial to the consumer.

Another reason for this legislation in the EU was for harmonization purposes.[182] With an EU directive, all member states are required to uphold the minimum standards of this directive. Some states, like Germany, impose even stricter requirements,[183] so the Directive is a floor, not a ceiling, for regulations. Harmonization within the EU allows manufacturers to sell their supplements to many states without requiring different procedures than the Directive sets out. This streamlines the development, labeling, and marketing process for manufacturers and ensures safe products throughout the EU.

China had other motives. TCMs are already very popular in China. Most people in China do not have healthcare insurance and cannot afford to go to the hospital, so many turn to TCMs.[184] Chinese political leaders actually advocate for the use of TCMs by the

178. GAO Report, *supra* note 3, at 1.
179. Food Supplements Directive, *supra* note 109, at 5.
180. LeCong, *supra* note 90, at 108.
181. *Id.* at 109.
182. Cataxinos, *supra* note 16, at 588.
183. *Id.* at 585.
184. Qiu, *supra* note 159, at 590.

masses.[185] China wants to break into the international market for dietary supplements. Since the 1960s, the United States has been interested in TCMs, and insurance companies have even begun covering TCM treatments.[186] However, China has not been exporting its TCMs; it really only has been exporting the raw materials to have the TCMs produced elsewhere.[187] China is trying to gain recognition in the international community so that they can export their TCMs, which have been helping their people for ages.

2. Why the United States decided not to regulate dietary supplements

This idea of consumer choice is deeply rooted in our society; however, consumers remain largely *un*informed regarding dietary supplements *because* of the deregulation.[188] According to a 2002 Harris Poll, over half of adults who responded to the poll believe that dietary supplements are regulated by the government.[189] Consumers are more likely to associate dietary supplements with drugs rather than food, so they assume that supplements are regulated and do not inform themselves as to the safety and efficacy of the products they are using.[190] Therefore, although there is a strong public policy reason for keeping dietary supplements essentially unregulated (allowing informed consumer choices), consumer expectation is that they are regulated, so they do not inform themselves to make good choices.[191] "[C]onsumers may believe that if a product is natural, it must be safe; if a little is good, then more must be better; and if a product does not have a warning label, it must be safe."[192] In fact, based on multiple national surveys, 81% of adults believe that dietary supplements should only be sold after they pass FDA safety standards.[193]

Despite all of this, Congress maintains that consumer choice and free commercial speech outweigh the need for governmental regulation for dietary supplements. Luckily, there have been only a few incidents of unsafe dietary supplements, so Congress' premise that dietary supplements are usually safe has proven true thus far.

185. Schroeder, *supra* note 148, at 688.
186. *Id.* at 695.
187. *Id.* at 697.
188. McCann, *supra* note 7, at 247.
189. GAO Report, *supra* note 3, at 32.
190. McCann, *supra* note 7, at 247.
191. *Id.*
192. GAO Report, *supra* note 3, at 33.
193. Blendon, *supra* note 13, at 809.

CONCLUSION

The United States' current regulation system puts Americans' health at risk. Congress believes that dietary supplements are presumably safe, but the L-tryptophan, ephedra, and other incidents with dietary supplements prove that is not always the case. The EU and China recognize that for their dietary supplements to be recognized as safe and effective, premarket approval is needed. This ensures that consumers know dietary supplement ingredients, that dietary supplements do what they claim to do, and that the government has power to recall dangerous products from the market. The DSHEA effectively removed any power the FDA had over dietary supplement regulation, resulting in the FDA's hands being tied when it comes to dangerous products on the market, as evidenced by the ephedra case. Complications and adverse reactions to dietary supplements could be avoided if the FDA had premarket approval power. However, now that we have deregulated dietary supplements and the dietary supplement industry is so powerful, it is unlikely that, without a catastrophic incident, the regulation system in the United States will change.