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Dietary Supplements and Structure-Function Claims: The Dysfunctional Structure of Current Regulation

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DIETARY SUPPLEMENTS AND STRUCTURE-FUNCTION CLAIMS: THE DYSFUNCTIONAL STRUCTURE OF CURRENT REGULATION

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I. INTRODUCTION

Twenty percent of Americans report using one of the more than thirty thousand dietary supplement products generated by an estimated one thousand manufacturers, contributing to an industry exceeding twenty billion dollars globally.[1] Fueled by increasing public interest in individual health, dietary supplement manufacturers in the United States (U.S.) continue to exploit the weaknesses in the way the Food and Drug Administration (FDA) regulates these products. Dietary supplement manufacturers perpetuate the perceived safety of supplements through the advertisement of structure-function claims, which many consumers mistakenly assume to be the same as FDA-regulated health claims.[2]

Structure-function claims are a subset of health claims, and while the FDA has yet to provide a precise definition, these claims may be identified as any assertion that states, suggests, or implies the role of a food category, a food, or one of its constituents in the growth, de-

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1. Lars Noah & Barbara A. Noah, *A Drug By Any Other Name..?: Paradoxes in Dietary Supplement Risk Regulation*, 17 STAN. L. & POL'Y REV. 165, 165 (2006); *see also* Katherine Wong, *New Mandatory Reporting Requirements for Dietary Supplements and Nonprescription Drugs Solve Very Little*, 35 J.L. MED. & ETHICS 336, 336 (2007).

2. *See* discussion *infra* Part III.A.3-III.A.4.

velopment, or normal physiological function of the body.[3] Stated differently, a structure-function claim asserts that a specific food or ingredient aids in the normal functioning of the body. Conversely, a disease or risk reduction claim states, suggests, or implies that the consumption of a specific food or ingredient significantly reduces the development of a human disease.[4] For example, the claim "a diet high in calcium may reduce the risk of osteoporosis" is a risk reduction claim, while the claim "a diet high in calcium aids in the growth and maintenance of bones" is a structure-function claim.[5]

The average consumer's inability to distinguish between disease and structure-function claims combined with a lack of premarket approval for dietary supplements has allowed dangerous products into the market leading to preventable deaths.[6] Unlike prescription medications, dietary supplements are not subjected to premarket scientific analysis or clinical trials before the FDA approves a product for consumer use.[7] Instead, the FDA restricts or prohibits the sale of a certain supplement only after the agency receives well-documented reports of health risks associated with the product.[8]

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3. *See* 21 U.S.C § 343(r)(6) (2000) (explaining, "a statement for a dietary supplement may be made if...[it] describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans"); *see also* 21 C.F.R. § 101.93(f) (2000) (restating the types of structure-function claims allowable under §343(r)(6)). For a detailed source of information explaining the lack of a precise definition for structure-function claims, *see* CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, U.S. FOOD AND DRUG ADMIN. (FDA), STRUCTURE/FUNCTION CLAIMS: SMALL ENTITY COMPLIANCE GUIDE, (Jan. 2002), *available at* www.fda.gov/ohrms/dockets/98fr/98n-0044.gd10001.pdf.

4. *See* 21 C.F.R. § 101.93 (g)(1) (2000) (defining disease as, "damage to an organ, part, structure, or system of the body such that it does not function properly"); *see also* 21 C.F.R. §§ 101.93(g)(2)(i)-101.93(g)(2)(x) (2000) (listing ten criteria for determining whether a statement is a disease claim). For an explanation of these ten criterion, *see* CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, *supra* note 3, at 4-11; *see generally* Nicole Coutrelis, *The Legal Status and Regulatory Context of "Health Foods" in the European Union*, 58 FOOD & DRUG L.J. 35, 48 (2003).

5. Martijn B. Katan & Nicole M. de Roos, *Toward Evidence-Based Health Claims for Foods*, 299 SCI. MAG., 206, 207 (2003), *available at* http://www.sciencemag.org/cgi/reprint/299/5604/206.pdf.

6. *See* discussion *infra* Part III.

7. Peter Cohen, *Science, Politics, and the Regulation of Dietary Supplements: It's Time to Repeal DSHEA*, 31 AM. J.L & MED. 175, 182 (2005).

8. *See generally* Dietary Supplement Health and Education Act of 1994 (DSHEA), Pub. L. No. 103-417, 108 Stat. 4325, [hereinafter DSHEA] (codified as various amended sections of 21 U.S.C. §§ 301-399 (1994)). To date, ephedra is the only supplement to have been banned by the FDA when the ingredient was declared adulterated under the provisions of the DSHEA. *See also* Consumer Reports, *Dangerous Supplements: Still at Large*, (May 2004) *available at* http://

By contrast, manufacturers in the European Union (EU) are excluded from including health claims on their product labels.[9] However, policymakers in the EU are making progress as the scheduled effective date for the EU Health Claims Directive approaches.[10] Due to go into force January 1, 2010, the Health Claims Directive requires the support of Member States to administer and enforce food law regulations adopted by the European Parliament.[11] Similar to the FDA, the European Food Safety Authority (EFSA) seeks to ensure the safety of the food supply.[12] Any general similarities end there. Unlike the FDA, the EFSA is an independent agency providing scientific advice and gathering data related to the potential risks a dietary supplement may pose to humans *before* the product is available for purchase.[13]

In 1994, the FDA began drawing attention to the risks associated with the consumption of ephedra in a series of consumer reports and medical bulletins.[14] Ten years and at least 155 ephedra-related deaths later, the FDA finally banned the sale of dietary supplements containing the ephedrine alkaloid on April 12, 2004.[15] The

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www.consumerreports.org/cro/food/diet-nutrition/dangerous-supplements/dangerous-supplements-504/overview/index.htm (quoting Bruce Silverglade, legal director for the Center for Science in the Public Interest (CSPI), "[T]he standards for demonstrating a supplement is hazardous are so high that it can take the FDA years to build a case"); *see also* Reilley Michelle Dunne, *How Much Regulation Can We Swallow? The Ban on Ephedra and How it May Affect Your Access to Dietary Supplements*, 31 J. LEGIS. 351, 374 (2005); *see also* Henry Miller & David Longtin, *Death by Dietary Supplement: How to Regulate a Booming Industry*, 102 POLICY REVIEW 15, 16 (2000).

9. Katan & de Roos, *supra* note 5, at 206 (explaining the traditional European view that foods are either harmful or harmless, therefore, claims that dietary supplements can treat or prevent disease are forbidden).

10. Regulation 1924/2006, 2006 O.J. (L 404) 9 (EC) [hereinafter Health Claims Directive].

11. Steve Keane, *Can a Consumer's Right to Know Survive the WTO?: The Case of Food Labeling*, 16 TRANSNAT'L & CONTEMP. PROBS. 291, 294 (2006).

12. Emilie H. Leibovitch, *Food Safety Regulation in the European Union: Toward Unavoidable Centralization of Regulatory Powers*, 43 TEX. INT'L L.J. 429, 434 (2008).

13. *Id.*

14. *See* U.S. Food and Drug Administration (FDA), *Adverse Events with Ephedra and Other Botanical Dietary Supplements*, FDA Medical Bulletin (Sept. 1994), *available at* http://www.fda.gov/Food/DietarySupplements/ Alerts/ucm111208.htm (noting the FDA received an increasing number of reports of adverse reactions associated with the use of products containing ephedra); *See also* Noah, *supra* note 1, at 182.

15. 21 C.F.R. § 119.1 (2004) (stating, "dietary supplements containing ephedrine alkaloids are adulterated under section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act); *see also* Carol Rados, *Ephedra Ban: No Shortage of Reasons*, FDA CONSUMER MAGAZINE (March/April 2004) *available at* http://permanent.access.gpo.gov/Lps1609/www.fda.gov/fdac/features/2004/203_ephedra.htm

causes for the delays were threefold: 1) the FDA's inability to link undesirable effects with specific supplements; 2) the lack of premarket approval for dietary supplements; and 3) the consumer perception that all dietary supplements safely increase desirable aspects of proper bodily function.

Part II describes the regulatory and market conditions preceding the Dietary Supplement Health and Education Act of 1994 (DSHEA) in the U.S. and the European Food Supplement Directive of 2002 in the EU. Part III discusses the current risks that remain despite attempts at regulation, as well as the potential for future harm to consumers due to insufficient governmental involvement and regulation within the dietary supplement industry. Part IV then compares the various regulatory schemes implemented and proposed in both markets designed to police the sale of dietary supplements. Finally, Part V suggests that both premarket approval and prohibition of structure-function claims are necessary to ensure the public's safety. This Article provides a comparative analysis whereby the strengths and weaknesses of both the U.S. and EU regulatory schemes may be examined in order to improve the effectiveness of regulation.

II. HISTORICAL BACKGROUND

Prior to the Dietary Supplement Health and Education Act of 1994 (DSHEA), the FDA regulated dietary supplements as food additives under the Food, Drug and Cosmetics Act and required premarket approval before products entered the marketplace.[16] Then, in 1989, the FDA linked over 1,500 cases of permanent disability and at least thirty-eight deaths to L-Tryptophan[17] supplements.[18]

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1 (reflecting final rule to ban dietary supplements containing ephedra effective April 12, 2004); *see also* Mark Moran, *Did Delay of Ephedra Ban Cause Unnecessary Deaths?*, 39 PSYCHIATRIC NEWS 3, 24 (2004) *available at* http://pn.psychiatryonline.org/cgi/content/full/39/3/24.

16. Food, Drug and Cosmetics Act, 21 U.S.C. § 321(s) (1992).

17. L-Tryptophan is an essential amino acid, which can be used to treat insomnia and anxiety when taken as a supplement. *See generally* Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration (FDA), *Economic Characterization of the Dietary Supplement Industry Final Report*, at Table 4-3 (March 1999) *available at* http://www.rti.org/pubs/econ_char.pdf.

18. Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration (FDA), *Information Paper on L-tryptophan and 5-hydroxy-L-tryptophan* (Feb. 2001) *available at* http://www.cfsan.fda.gov/~dms/ds-tryp1.html; *see also*, Jennifer Akre Hill, Comment, *Creating Balance: Problems Within DSHEA and Suggestions for Reform*, 2 J. FOOD L. & POL'Y 361, 370 (2006).

Fearing the dietary supplement industry was in danger, manufacturers responded with a massive lobbying campaign designed to fight greater FDA regulation.[19] Part of this campaign included a series of television advertisements depicting actor "Mel Gibson handcuffed by FDA agents for possessing vitamins".[20] Backed by Senator Orin Hatch of Utah, the home base of many supplement manufacturers, the DSHEA was passed over the objections of the FDA.[21] The DSHEA established dietary supplements as a new class of food product not subject to the regulations applied to food additives or drugs.[22] In essence, the DSHEA took away the authority of the FDA to regulate dietary substances before they entered the marketplace, and replaced it with a system in which the FDA is limited to retroactively removing products after the harm has already occurred. The result: Congress substantially reduced governmental oversight of dietary supplements when it decided consumers are capable of making informed decisions regarding the supplements they may choose to take.[23] Then, Congress passed the Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2007 (DSNDCPA of 2007) in an effort to address the shortcomings of the DSHEA.[24] The DSNDCPA of 2007 attempts to limit the shortcomings of the DSHEA by requiring manufacturers to report instances of undesirable effects associated with the use of dietary supplements.[25]

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19. Henry Miller & David Longtin, *Death by Dietary Supplement: How to Regulate a Booming Industry*, 102 POLICY REVIEW 15, 16 (2000).

20. *Id.*

21. *Id.*; *See generally* Loren Israelsen & Thomas Aarts, *DSHEA Ten Years Later: Now What?*, NUTRITION BUS. J., June 2004, *available at* http://www.supplementquality.com/editorials/DSHEA_anniversary.html (explaining the DSHEA was a "political Hail Mary" and that "last-minute deal making resulted in the addition of the structure-function claim disclaimer").

22. See S. Rep. No. 103-410, at 2 (1994) (explaining the purpose of DSHEA is "to clarify that dietary supplements are not drugs or food additives, that dietary supplements should not be regulated as drugs, and that burden of proof is on the Food and Drug Administration (FDA) to prove that a product is unsafe before it can be removed from the marketplace"); *see also* Miller & Longtin, *supra* note 19, at 16.

23. Wong, *supra* note 1, at 336-37.

24. Dietary Supplement and Nonprescription Drug Consumer Protection Act, Pub. L. No. 109-462 (2007) (codified as amended section of 21 U.S.C. § 371 (2007)) [hereinafter DSNDCPA of 2007]. Although the Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2007 is commonly referred to as DSNDCPA, this Article uses DSNDCPA of 2007 to help distinguish it from the DSHEA.

25. *See infra* Part IV.

By contrast, the traditional EU approach strictly limits the availability and advertising of dietary supplements. Passed in 2002, the EU Food Supplement Directive, Directive 2002/46/EC (Food Supplement Directive), proclaims the need to protect consumers from unsafe products that mislead, and to prevent presenting food as medicine.[26] However, during this same period, many European governments began promoting the use of certain dietary supplements.[27] For instance, it is illegal for manufacturers to state that a supplement high in folic acid reduces the risk of birth defects,[28] yet many European governments advocate that would-be mothers take these supplements.[29]

In response to the multiplicity of rules and policies among the EU Member States and the prohibition of certain claims supported by significant scientific authority,[30] the European Food Safety Authority (EFSA) pushed Regulation 1924/2006 (Health Claims Directive) through the European Council (EC) in December 2006.[31] The Health Claims Directive seeks to create a framework for standardizing and eventually permitting health and structure-function claims on food labels.[32] The EFSA's charge is to implement nutrient profiles and criteria by January 1, 2010 in order to govern proposed claims.[33]

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26. Council Directive 2002/46, 2002 O.J. (L 183) 51 (EC) [hereinafter Food Supplement Directive].

27. *See e.g.*, Richard A. Hubner, et al., *Should Folic Acid Fortification be Mandatory? No*, 334 BRITISH MED. J. 1253 (2007), *available at* http://www.bmj.com/cgi/reprint/334/7606/1253 (explaining "the UK's Food Standards Agency recently proposed mandatory folic acid fortification of some foods"); *see also* Bruce Jancin, *Added Folic Acid Lowers Congenital Heart Defects Risk: Preconceptual Supplementation Backed*, 43 OB.GYN. NEWS 24 (2008) (noting the recent media campaign by the Dutch government to encourage women take folic acid before conception).

28. See Council Directive 2000/13, art. 2, §1b, 2000 O.J. (L 109) 29 (EC) (Stating labeling must not attribute to any food ..the property of preventing, treating or curing a human disease, or refer to such properties").

29. Katan, & de Roos, *supra* note 5, at 206.

30. For instance, it is well recognized that folic acid supplements prevent birth defects for mothers who do not receive enough of the vitamin through their regular diet. *See* Centers for Disease Control and Prevention, Dept. of Health and Human Services, *Facts about Folic Acid*, http://www.cdc.gov/ncbddd/folicacid/basics.htm (last visited Oct. 31, 2009).

31. Commission Regulation 1924/2006, 2006 O.J. (L 404) 9 (EC) [hereinafter Health Claims Directive].

32. Christian Falk, *United States: The New EU Health Claims Regulation: Tightened Rules for Advertising and Labeling of Foodstuffs*, Faegre & Benson LLP (Sep. 8, 2008), http://www.mondaq.com/article.asp?articleid=65996 (last visited Oct. 31, 2009).

33. Jon Felce, *European Union Food Labeling and Packaging: The Need to Strike a Balance*, 63 FOOD & DRUG L.J. 113, 115 (2008).

III. THE DANGER OF CONSUMERS' INACCURATE PERCEPTION OF DIETARY SUPPLEMENT LABELING AND HEALTH CLAIMS

Nevertheless, new requirements and regulations covering ingredients with the potential for use in dietary supplements might not be enough to protect consumers from their inaccurate beliefs regarding structure-function claims and government involvement in the dietary supplement industry. Research shows that many consumers misunderstand the role of government in regulating supplements, do not understand the required disclaimers on labels that contain structure-function claims, do not discuss supplement use with their medical providers, and often concurrently take supplements and prescription medications without realizing the very real possibility of dangerous interactions.[34]

A. Consumer Misperception

Dietary supplements, like drugs, have risks and side effects, but are generally self-prescribed.[35] This is especially worrisome considering the amount of inaccurate information about the safe use and potential risks of supplements. Adverse reactions to supplement use resulted in 26,000 calls to U.S. poison control centers in 2007, with at least one death attributable to supplement exposure.[36]

1. Megadosing

One common misperception is that because dietary supplements are sold over the counter (OTC), some with no direction on the label, they are safe to take even in high doses.[37] This is commonly known as megadosing,[38] and many people continue to take large doses of various supplements such as vitamin C.[39] Although

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34. *See infra* Part III.A.1-III.B

35. American Cancer Society, *Dietary Supplements: How to Know What is Safe*, http://www.cancer.org/docroot/ETO/content/ETO_5_3x_How_to_Know_What_Is_Safe_Choosing_and_Using_Dietary_Supplements.asp (last visited Oct. 31, 2009).

36. *Id.*

37. *Id.*

38. For an overview of megadosing, sometimes referred to as "megavitamin therapy", *see generally* BC Cancer Agency, *Vitamin Therapy, Megadose/ Orthomolecular Therapy*, http://www.bccancer.bc.ca/PPI/Unconventional Therapies/Vitamin TherapyMegadoseOrthomolecularTherapy.htm (last visited Oct. 31, 2009).

39. Douglas RM, et al., *Vitamin C for Preventing and Treating the Common Cold*, 2007 COCHRANE DATABASE OF SYSTEMATIC REVIEWS 3, *available at*

there has never been any scientific evidence to show large doses of vitamin C can prevent or cure the common cold, many people still believe this is true.[40] In fact, megadosing certain vitamins and minerals has actually been shown to cause dangerous side effects.[41] Too much vitamin C can interfere with the body's ability to absorb copper, a metal essential to the body's proper functioning.[42] Too much phosphorous can inhibit the absorption of calcium, a mineral vital to the maintenance of healthy bones, while high doses of vitamins A, D, and K are not easily digested by the body and can quickly reach toxic levels.[43]

2. All Natural

Another common mistaken belief is that supplements marketed as "all natural" are safe to take in any amount.[44] This is simply not true. Just because something is natural does not mean that it is good for you. Different parts of plants contain many different chemicals, which can have very different effects on humans.[45] The popular supplement ginkgo biloba, named after the tree from which it is derived, is usually consumed as an extract prepared from the dried leaves.[46] However, people do not generally consume the tree's fruit, and research links ingestion of the seed to fatal human poisoning.[47] Additionally, ginkgo biloba extract (GBE) is a highly concentrated substance that appears to be more effective in treating health ailments.[48] While not considered all natural because of the alteration from its natural state, GBE is generally preferred over ingesting

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http://medschool.umaryland.edu/integrative/cochrane-reviews/cochrane-rev-commoncold.asp.

40. American Cancer Society, *supra* note 35.

41. *See* Miranda Hitti, *FDA Flags Megadose of Selenium Supplement*, WEBMD HEALTH NEWS (Apr. 9, 2008), http://www.webmd.com/news/20080409/fda-flags-supplement-selenium-mega-dose (last visited Nov. 3, 2009) (noting selenium may boost the immune system, but too much can lead to hair loss, muscle cramps, fatigue, and skin blisters).

42. American Cancer Society, *supra* note 35.

43. *Id.*

44. Cohen, *supra* note 7, at 196 (indicating it is not uncommon for dietary supplements claiming to be "all natural" contaminated with synthetic materials).

45. American Cancer Society, *supra* note 35.

46. University of Maryland Medical Center, *Complementary Medicine: Echinacea*, http://www.umm.edu/altmed/ articles/ginkgo-biloba-000247.htm (last visited Nov. 3, 2009) [hereinafter G*inkgo biloba*].

47. *Id.*

48. *Id.*

the leaves themselves. Therefore, all natural supplements are often not as effective or helpful because they have not been refined to remove dangerous chemicals or parts of a plant that do not contribute to the desired effects.[49]

There can also be allergic reactions to substances that are all natural. Some consumers take bee pollen to prevent hay fever, increase energy, and to aid in memory.[50] The problem is some people have serious allergies to various pollens without knowing it.[51] Documented reports have linked fatal reactions to the consumption of bee pollen.[52] With no scientific evidence supporting the idea that bee pollen has benefits, combined with the risk of death, it is hard to understand why some consumers buy the product.[53]

People also tend to think that supplements such as echinacea[54] and ginkgo biloba,[55] ingested for their medicinal effects for thousands of years, must be safe due to their continued use and popularity.[56] The truth is that while occasional use of these substances may provide relief for certain conditions, it has not been until recently that the medical profession has looked at the long-term effects of daily use in higher doses.[57] Without additional research, the side effects of long-term supplement use remain uncertain.

3. Governmental Regulation

One of the most disturbing instances of consumer misperception is the belief the FDA approves dietary supplements. In a recent survey, ten percent of respondents indicated they believed dietary supplements required FDA approval, while forty-two percent were

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49. American Cancer Society, *supra* note 35.

50. *See* William Jarvis, *Bee Pollen*, NATIONAL COUNCIL AGAINST HEALTH FRAUD 1996, http://www.ncahf.org/ articles/a-b/beepollen.html (last visited Nov. 3, 2009).

51. *See id.*

52. *Id.*

53. *Id.*

54. Echinacea supplements are commonly ingested for their ability to promote a healthy immune system, relieve pain, reduce inflammation, as well as its effects as an antioxidant. *See* Ginkgo biloba, *supra* note 46.

55. *See id.* Ginkgo biloba is primarily used to increase blood flow to the brain, with evidence suggesting it improves memory and learning among Alzheimer's patients. *See* University of Maryland Medical Center, *supra* note 46.

56. American Cancer Society, *supra* note 35.

57. *Id.*

unsure whether a product required approval or not.[58] However, as recently as 2001 another study found thirty-five percent of respondents believed the FDA approved dietary supplements.[59] Although the data from the more recent survey may seem to indicate confusion among consumers regarding governmental regulation is decreasing, it is worth noting that studies on the issue are scarce and differing methodologies between experiments might explain the disparity between these two results. Indeed, it is troubling any consumers believe dietary supplements are FDA-approved.

The 2001 study also found that an individual's education had a direct impact on his or her belief that the government approved supplements.[60] Individuals whose highest level of education was high school were over two-times more likely to be mistaken when compared with those possessing a college education.[61] This misunderstanding may provide a false sense of security regarding the safety of dietary supplements. When people assume a product is safe it only increases the likelihood injury will occur.

4. Labeling Confusion and Ineffectiveness

The DSHEA requires all products with structure-function claims contain the disclaimer, "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."[62] In 2005, researchers conducted the first published experiments to determine how consumers interpret the different labels found on food and supplement products.[63] The analysis hypothesizes that once a consumer has developed a belief, new information is interpreted in a manner that will confirm the preexisting belief.[64] For example, a purchaser may hold the belief government watches out for consumers, and would

58. Bimal H. Ashar, et al., *Patient's Understanding of the Regulation of Dietary Supplements*, 33 JOURNAL OF COMMUNITY HEALTH 22, 25 (2008) *available at* http://www.medscape.com/viewarticle/570150_4.

59. *Id.* at 27.

60. *Id.* at 25.

61. *Id.* at 26.

62. 21 C.F.R. § 101.93(c) (2000).

63. Karen France & Paula Bone, *Policy Makers' Paradigms and Evidence from Consumer Interpretations of Dietary Supplement Labels*, 39 J. OF CONSUMER AFF. 27, 34 (2005).

64. *Id.* The hypothesis relies on confirmatory bias theory, which predicts new information is interpreted in a way to avoid information and explanations contradictory to prior beliefs.

not allow dangerous products to enter the marketplace.[65] This trust in government may lead the purchaser to discount any disclaimer found on a product's label.[66]

Another instance was recorded when a particular supplement, such as the popular cold remedy Airborne,[67] received publicity over its ability to prevent a particular disease.[68] Under these circumstances, consumers were more likely to believe in the product's ability to prevent or treat a disease regardless of the DSHEA disclaimer.[69] This indicates that where publicity and the FDA disclaimer come into contradiction people give more credibility to positive press over a government warning. Also interesting is the fact that people who place higher importance on disease prevention and healthy living attributed more significance to structure-function and disease claims.[70] Additionally, the studies found heavy supplement users are more likely to believe the FDA evaluates dietary supplements despite the fact they are the ones most exposed to the DSHEA disclaimer.[71] The evidence collected during the study led researchers to conclude consumers made no distinction between non-regulated structure-function claims and FDA-approved disease claims.[72] This leads to the conclusion Congress was incorrect in finding consumers were capable of making informed decisions regarding the dietary supplements they choose to take. The data suggests people do not pay attention to the FDA disclaimer, and therefore need protection from themselves and their mistaken beliefs.

B. Failure to Disclose Supplement Use to Physicians

The fact consumers are uncertain as to the meaning of heath and structure-function claims, as well as the misunderstanding and

65. *Id.* at 35.
66. *Id.* at 36.
67. *Infra* note 69.
68. France & Bone, *supra* note 63, at 36.
69. *Id.* As an example, the initial buzz surrounding Airborne, a supplement which touted its ability to prevent and cure the common cold, caused consumers to purchase the product en masse. Although the product bore the required FDA disclaimer, the public perception was that the product was effective until significant scientific research concluded Airborne's ability to prevent or cure the common cold was unsubstantiated. Eventually, a class action lawsuit was initiated by those who were misled. *See* Airborne Settlement, *Settlement Information and Claim Filing Website*, http://www.airbornehealthsettlement.com (last visited Feb. 18, 2010).
70. France & Bone, *supra* note 63, at 34.
71. *Id.* at 47.
72. *Id.* at 46.

ineffectiveness of disclaimers is exacerbated by the fact that people who use supplements generally do not share this information with their health care providers.[73] Surveys indicate that as many as forty-nine percent of Americans aged fifty-seven through eighty-five years of age reported taking a dietary supplement in the preceding twelve months.[74] While most reported using a multivitamin, these seemingly safe substances are not without their risks. Of the four percent who believed they suffered an adverse reaction due to supplement usage, over thirteen percent attributed it to multivitamins or multiminerals.[75] Moreover, studies indicate those who use prescription drugs were more likely to be taking dietary supplements concurrently.[76]

Evidence suggests consumers of dietary supplements are less likely to reveal supplement usage when compared to prescription or OTC medication.[77] This is problematic because generally there are no tests conducted on dietary supplements to determine potential adverse interactions with prescription medication that can cause dangerous reactions or death.[78] Many medical professionals are also unaware of the potential risks involved from mixing dietary supplements and prescription drugs.[79] This creates a dangerous situation where the true effects of supplements go unreported.

A recent study revealed fifty-two percent of people in the U.S. between the ages of fifty-seven and eighty-five concurrently took prescription medications and dietary supplements.[80] The article notes the lack of current information regarding the simultaneous use of drugs and supplements is sparse, which may contribute to the adverse reactions.[81] The study concludes by finding four percent of the individuals who participated in the survey were at risk of having a major adverse interaction.[82]

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73. J.L. Greger, *Dietary Supplement Use: Consumer Characteristics and Interests*, 131 J. OF NUTRITION 1339S, 1342S (2001).

74. Babgaleh Timbo et al., *Dietary Supplements in a National Survey: Prevalence of Use and Reports of Adverse Events*, 106 J. AM. DIETETIC ASS'N 12, 1966 (2006).

75. *Id.* at 1966.

76. *Id.* at 1972.

77. *Id.*

78. Cohen, *supra* note 7, at 195-96.

79. Noah, *supra* note 1, at 193.

80. Timbo, *supra* note 74, at 1972.

81. *Id.*

82. *Id.* at 1966.

The fact many doctors do not ask their patients whether they are currently taking a dietary supplement exacerbates the problem.[83] One reason many doctors do not ask patients about supplement use is that they do not believe in the effectiveness of alternative medicines.[84] Another reason commonly cited by physicians is that they do not know enough about dietary supplements to give an informed opinion to a patient who does inform them of supplement usage.[85] However, as the instances of adverse supplement-drug interactions continue to increase, more sources are becoming available for doctors to consult before a recommendation is given to the patient.[86]

When patients do not inform their doctor of their supplement usage, the doctor is not receiving the information he or she needs to make an accurate diagnosis. Supplement use has even been shown to increase the symptoms and severity of diseases when combined with prescription drugs.[87] Thus, failure to report supplement use and adverse events has led to inaccurate figures that under-represent the harm done by dietary supplements.[88] Moreover, this lack of reporting perpetuates a cycle that denies medical professionals and nutritionists the information necessary to understand potential harmful drug-supplement interactions.

C. Industry Practice

The risk of concurrent use of dietary supplements and prescription drugs continues to increase as supplements enter into new areas of the food supply. As early as 1998, major corporations began attempting to enter the supplement market in an effort to avoid the

83. Stacey Butterfield, *If Physicians Don't Ask, Patients Won't Tell About CAM*, ACP OBSERVER (Nov./Dec. 2007) *available at* http://www.acpinternist.org/archives/2007/11/ask.htm.

84. *Id.*

85. *Id.*

86. *Id.*

87. For example, certain dietary supplements are known to increase the risk of internal bleeding when taken with prescription blood thinners. *See* Nutrition Counseling Services, *Dietary Supplements*, http://nutritionsowa.com/dietarysupplements.aspx (last visited Feb. 18, 2010).

88. Keane, *supra* note 11, at 295.

greater FDA regulation associated with functional foods.[89] Functional foods are products fortified with minerals, vitamins, or dietary supplements and require that any ingredient provide taste, aroma, nutritional value, or have a technological effect on the food such as preservation, color, etc.[90]

Campbell Soup Company marketed its popular V8 Juice with the structure-function claim that the antioxidants contained in the product help slow normal aging.[91] Not only would this statement fail to qualify as an FDA-approved health claim concerning the consumption of fruits and vegetables due to its high levels of sodium, the label is especially misleading because diets high in sodium have been linked to high blood pressure, which is associated with aging.[92]

Campbell Soup is not alone. Another company marketed a line of soup known as "Kitchen Prescription," which includes chicken and noodle with Echinacea and split pea with St. John's Wort.[93] Yet another example is a caffeinated gum branded "Stay Alert,"[94] which is being marketed as a dietary supplement. Caffeine is only approved for food use in non-alcoholic carbonated beverages, but because dietary supplements are not regulated as foods, manufacturers seem to have found a loophole with this product containing the name of a conventional food (gum) and sold alongside other chewing gums.[95]

By labeling a product as a supplement, the manufacturer is able to avoid Generally Recognized As Safe requirements that these substances are not dangerous when used as food ingredients.[96] Moreover, the addition of dietary supplements into food categories people generally believe to be safe could increase the perception that the supplements themselves are safe. Furthermore, as consumers find dietary supplements introduced into new and different markets, the risk for adverse events and drug interactions may increase as more people encounter these products.

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89. Center for Science in the Public Interest, *United States - A Good System Gone Bad: Marketplace Implications and Consumer Impact*, http://www.cspinet.org/reports/functional_foods/usa_market.html (last visited Feb. 11, 2010).

90. *Id.*

91. *Id.*

92. *Id.*

93. *Id.*

94. *See* Stay Alert Gum, http://www.stayalertgum.com (last visited March 9, 2009).

95. Center for Science in the Public Interest, *supra* note 89.

96. *Id.*

IV. CURRENT REGULATORY SCHEMES IN THE U.S. AND EU

The FDA's delay in banning ephedra caused a few states within the U.S. to pass their own laws banning the sale of the supplement.[97] In the years following the FDA's own ban of ephedra, it became clear the current voluntary reporting system for companies with information regarding undesirable effects of supplement use was unworkable.[98] Congress responded with the Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2007 (DSNDCPA of 2007).[99] The DSNDCPA of 2007 requires the mandatory filing of Adverse Event Reports (AER) by manufacturers within fifteen days of receiving such information from consumers.[100] In order to facilitate reporting, manufacturers are required to include contact information on the labels of the supplements they produce.[101] Six months after the implementation of mandatory AER reporting, the FDA announced over six hundred adverse events with at least five deaths attributable to the ingestion of dietary supplements.[102]

A. Weaknesses of Current U.S. Regulation

Most experts contend that even the new mandatory reporting guidelines promulgated by the DSNDCPA of 2007 do not produce figures that accurately represent the true number of adverse events

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97. *See* 720 ILL. COMP. STAT. ANN. 602/1 (Supp. 1 2009); *See, e.g.*, Jim Ritter, *Ephedra Sales Banned in Illinois: Linked to Strokes, Herbal Stimulant is Sold in Other States*, CHICAGO SUN-TIMES, (May 26, 2003) *available at* http://www.encyclopedia.com/doc/1P2-1485246.html (explaining Illinois became the first state to ban ephedra); *see also* N.Y. GENERAL BUSINESS LAW § 391-0 (Supp. 1 2009); *see, e.g.*, Chuck Bell, *Consumers Union Applauds New York State Law Banning Ephedra*, CONSUMER UNION, Aug. 25, 2003, *available at* http://www.consumersunion.org/pub/core_product_safety/000285.html (applauding New York as the second state to ban the sale of ephedra); *see also* CAL. HEALTH AND SAFETY CODE § 110423.100 (2004); *see e.g.* Jennifer Morey, *Statewide Ephedra Ban Now in Effect*, THE TIMES-STANDARD, Jan. 4, 2004 (explaining the California law which took effect two months before the FDA ban became effective).

98. Hill, *supra* note 18, at 380 (indicating the Inspector General for the Department of Health and Human Services believed the voluntary system revealed less than one percent all negative reactions to dietary supplement use).

99. DSMDCPA of 2007, *supra* note 24.

100. 21 U.S.C. § 379aa-1(c)(1) (2006).

101. 21 C.F.R. § 101.93(a) (2000).

102. ORTHOMOLECULAR MEDICINE NEWS SERVICE, *FDA Claims "Food Supplement" Deaths; Hides Details from Public*, Oct. 9, 2008, *available at* http://www.orthomolecular.org/resources/omns/v04n13.shtml.

linked to the consumption of dietary supplements.[103] This is due, in part, to the FDA's history of minimal monitoring of dietary supplements post-DSHEA.[104] As of 2004, the FDA's supplement division consisted of sixty staff members working under a $10 million dollar budget in an attempt to regulate an industry with revenues exceeding $19 billion dollars annually.[105] In comparison, the FDA employs forty-eight times as many people and spends forty-three times the amount of money to regulate the drug industry, which sees revenues only twelve times greater than the dietary supplement industry.[106]

Prior to the passage of the DSNDCPA of 2007, all FDA data on adverse events was solely the product of voluntary reporting submitted by the manufacturers of the supplements themselves.[107] Two scholars analogize this to the IRS relying on taxpayers to provide information on their own underreporting of income.[108] In fact, recent court documents show makers of the best-selling brand of ephedra supplement Metabolife[109] received more than 13,000 customer complaints regarding the product with none of these reports ever disclosed to the FDA.[110] With such a lengthy history of underreported adverse events, it will take time for mandatory reporting to create a difference in the regulation of supplements.[111]

What is surprising is that the FDA has refused to disclose the information it receives regarding adverse events to the public or the

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103. Wong, *supra* note 1, at 337.

104. *See generally id.*; *see also* Barbara A. Noah, *A Review of the New York State Task Force on Life & the Law's Report Dietary Supplements: Balancing Consumer Choice & Safety*, 33 J.L. MED. & ETHICS 860, 862 (2005) (indicating that before mandatory reporting the FDA received reports of less than one percent of all adverse events associated with dietary supplements).

105. Consumer Rep., *Dangerous Supplements: Still at Large*, (May 2004) *available at* http://www.consumerreports.org/cro/food/diet-nutrition/dangerous-supplements/dangerous-supplements-504/overview/index.htm.

106. *Id.* (quoting William Hubbard, FDA associate commissioner for policy and planning as saying, "The law has never been fully funded...[t]here's never been the resources to do all the things the law would command us to do").

107. Hill, *supra* note 18, at 380.

108. Miller & Longtin, *supra* note 19, at 17.

109. ISI Brands, Metabolife, http://www.metabolife.com/ (last visited Nov. 23, 2009).

110. Associated Press, *Criminal Investigation Sought for Diet Supplement Seller*, U.S.A. TODAY Aug. 15, 2002, *available at* http://www.usatoday.com/news/health/2002-08-15-ephedra_x.htm (indicating supplement manufacturer denied FDA requests for access to reports of adverse reactions over a period of several years until the Justice Department became involve in a criminal investigation).

111. Wong, *supra* note 1, at 337.

medical profession.[112] Now that the FDA is actively soliciting reports of adverse events, one would assume this information would be available to consumers so they may educate themselves and make informed decisions, consistent with the spirit of the DSHEA.[113] However, this is not the case, and the FDA has refused to release the details of which specific supplements are causing problems.[114] Without full accountability for AERs, it seems the DSNDCPA of 2007 will change little in the way the FDA regulates dietary supplements. After all, even if the system works as intended, it will only serve to notify the FDA when a particular product causes harm to consumers rather than giving the FDA the ability to prevent these substances from entering the market and injuring consumers in the first place.

B. The EU Approach

It is possible to view the EU approach of using a "positive list" as existing on the opposite end of the spectrum when it comes to regulation of dietary supplements. Between 1980 and 2000, Germany tested more than 300 herbal remedies, finding approximately two-thirds to be safe and at least minimally effective.[115] However, even those substances approved for consumer use are regulated in the same way as prescription drugs.[116] Consumer desire for greater access to alternative medicines and herbal remedies, as well as pressure from European supplement manufacturers, led to the creation of the EFSA and the passage of the Health Claims Directive set to take effect in 2009.[117] The Health Claims Directive focuses on the ingredients used in manufacturing vitamins and minerals, maximum

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112. ORTHOMOLECULAR MEDICINE NEWS SERVICE, *supra* note 102.

113. *Id.* While the FDA does release information identifying specific products the agency has determined present a health risk, it does not release the details of the Adverse Event Reports themselves. This appears to be in conflict with the Freedom of Information Act (5 U.S.C. § 552 (2000)), but that issue is beyond the scope of this Article.

114. ORTHOMOLECULAR MEDICINE NEWS SERVICE, *supra* note 102.

115. Miller & Longtin, *supra* note 19, at 16. Similar tests have been conducted in various countries across the EU including Ireland, *see* M.M. O'Brien, et al., *The North/South Ireland Food Consumption Survey*, 4 PUBLIC HEALTH NUTRITION 5b, 1069 (2001), and the United Kingdom, *see* Angela E. Johnson, et al., *Dietary Supplement Use Later in Life*, 102 BRITISH FOOD JOURNAL 40 (2000).

116. Miller & Longtin, *supra* note 19, at 16.

117. Health Claims Directive, *supra* note 31; *See also* Leibovitch, *supra* note 12, at 435 (explaining that food scares during the 1990s and a lack of consistency in regulation between countries were also contributing factors to the creation of the EFSA).

allowable dosages, labeling, presentation, and advertising of food supplements.[118] In order to standardize manufacturing and marketing of supplements amongst Member States, the EFSA created a "positive list" to be used by the manufacturers of food supplements.[119] To date, the EFSA has approved 112 ingredients, adding them to the growing positive list.[120] As ingredients are added, the EFSA implicitly grants approval to manufacturers currently producing supplements containing substances on the positive list that continued production after the Health Claims Directive is allowed.[121]

However, those manufacturers who produce supplements that contain ingredients not included on the positive list may find it difficult to get those substances added. Studies estimate the required testing necessary to get an ingredient onto the positive list costs between $110,000 and $350,000 USD, and can take two to three years.[122] This presents a substantial obstacle to companies that currently make supplements with ingredients not on the positive list, and will probably be enough to force many to end production of certain supplements.[123] The Health Claims Directive also involves the creation of nutrient profiles with which supplements must comply in order to make certain claims.[124] This has the potential to price out small and medium sized businesses from making any claims at all, leaving the larger manufacturers with a considerable advantage when it comes to innovation and development of new claims.[125]

These negative aspects of the Health Claims Directive seem to outweigh any potential benefits. However, manufacturers and distributors should profit from a more secure legal environment created by close regulation of claims.[126] More importantly, consumers will benefit from the standardization of claims, labeling, ingredients, and manufacturing processes of supplements.[127] Additionally, a vast

118. Fiona LeCong, *Food Supplements Directive: An Attempt to Restore the Public Confidence in Food Law*, 29 LOY. L.A. INT'L & COMP. L. REV. 105, 108 (2007).
119. *Id.*
120. *Id.*
121. These "positive lists" are found in Annexes I and II of the Food Supplements Directive; *see also* LeCong, *supra* note 118, at 108.
122. Lecong, *supra* note 118, at 109.
123. *Id.*
124. Felce, *supra* note 33, at 115.
125. *Id.* at 116.
126. Leibovitch, *supra* note 12, at 436.
127. Keane, *supra* note 11, at 295.

majority of nutrient claims will likely be unaffected as they already meet the proposed requirements of the Health Claims Directive.[128]

V. THE NEED TO BAN STRUCTURE-FUNCTION CLAIMS AND REQUIRE PREMARKET APPROVAL FOR SUPPLEMENTS

Taken together, the facts overwhelmingly indicate the need to ban structure-function claims in the U.S. and prevent their future use in the EU relating to all food products and dietary supplements. The fact that the average consumer cannot distinguish a structure-function claim from a disease claim alone should be enough to warrant their prohibition. If a specific claim has scientific support, it should qualify as an approved health claim. It is simply too confusing to have a system with two different types of claims, both making very similar assertions, but where one is almost completely unregulated. Either a substance prevents, treats, or cures a disease, or it does not. If scientific evidence shows it does, manufacturers should be permitted to make that claim on a product's label. If there is not enough scientific evidence, manufacturers should not be allowed to make any type of health claim. The evidence and research clearly indicate disclaimers are not effective at conveying the intended message to the consumer.[129]

A. Recommendations for the U.S.

To effect change, President Obama will need to create proposals that specifically seek to reform the regulation of dietary supplements and overhaul the struggling FDA. Although Senators Hatch and Harkin continue to defend the DSHEA,[130] many members of Congress have been vocal in their criticisms of the statute.[131] There is a lot to be learned from the failures of the DSHEA including the pitfalls of vague definitions and a lack of effective regulatory authority.

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128. Felce, *supra* note 33, at 116.

129. *See supra* Part III.A.4.

130. *See* Loren Israelsen, *What Obama Means for Functional Foods and Supplements: Part I*, Nutraingredients-USA, (Jan. 20, 2009), http://www.nutraingredients-usa.com/On-your-radar/The-Obama-effect/What-Obama-means-for-functional-foods-and-supplements-Part-I. (last visited Feb. 19, 2009).

131. Henry Waxman (D-Calif.) has been an outspoken critic of dietary supplements. *See* Israelsen, *supra* note 130. Another DSHEA opponent is Senator Richard Durbin (D-Ill.), who happens to be one of the first key political figures to endorse Obama. *Id.*

Changes to the current structure of regulation should include a return to a system of premarket approval for all dietary supplements. The current regulatory scheme is obviously inefficient, with the FDA resorting to advisory opinions and warnings instead of preventing dangerous supplements from reaching the shelves.[132] Additionally, the costs would not be as prohibitive as industry lobbyists suggest. The FDA has already found many of the supplements currently sold safely promote good health and may help prevent disease.[133] A system of premarket approval would also shift the costs of supplement safety to the manufacturer.

Although the use of a positive list has its benefits, premarket approval will provide consumers with the protection they need. This is because there is little research on many of the ingredients found in dietary supplements. To add a specific ingredient to a positive list ignores the fact that some of these substances may cause dangerous interactions when mixed with other ingredients already on a positive list. Therefore, a system of premarket approval is best to avoid this potentially fatal possibility.

The most efficient way to achieve these changes in the U.S. is by repealing the DSHEA and replacing it with new legislation. Instead of trying to prove a specific supplement is unsafe, the FDA should have the authority to require proof products are safe before introduction to the public. This new legislation should provide an exact definition of what constitutes a dietary supplement in order to eliminate the uncertainty and the loopholes that currently exist.

B. Conclusion

These changes in the law will help to ensure that consumers of dietary supplements are well informed, not misled, and have access to products that are proven safe. This provides both legal security

132. The FDA has released reports of potential adverse effects associated with a dietary supplement as recently as January 27, 2009. *See* U.S. Food and Drug Administration (FDA), *FDA Warns Consumers Against Dietary Supplement Containing Undeclared Drug*, FDA NEWS (2009), *available at* http://www.fda.gov/bbs/topics/NEWS/2009/NEW01950.html (warning consumers about the risks of a dietary supplement containing Sibutramine, a controlled substance with risks of abuse and potentially dangerous health conditions).

133. *See* Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration (FDA), Health Claims that Meet Significant Scientific Agreement (SSA), http://www.cfsan.fda.gov/~dms/lab-ssa.html (last visited Feb. 18, 2009).

and certainty to companies who choose to manufacture these supplements. Proper regulation of the dietary supplement industry will allow numerous benefits to consumers while decreasing the instances of confusion and harm.