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**SAFE UNTIL PROVEN UNSAFE: SOLVING THE GROWING
DEBATE AROUND DIETARY SUPPLEMENT REGULATION**

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I. INTRODUCTION

American consumers spent \$13 billion on dietary supplements in 2013.¹ The multi-billion dollar supplement industry continues to grow while consumers remain clueless to the regulatory process in place, or lack thereof.² Society often idolizes weight loss, but not through the traditional approach of diet and exercise.³ Instead, Americans spend \$40 billion on weight-loss programs and products annually,⁴ as supplement manufacturers capitalize on the market's lack of regulation. An increased prevalence of diet-related illnesses, such as diabetes, heart disease, and cancer, warrants increased regulation of the dietary supplement industry to ensure safety and effectiveness of products available to consumers.⁵

The United States Food and Drug Administration ("FDA") is tasked with regulating dietary supplements and ingredients.⁶ Enacted by Congress in 1994 to amend the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Dietary Supplement Health and Education Act ("DSHEA") established standards for regulating dietary supplements.⁷ Although this legislation reflects progress towards protecting consumers, twenty years have transpired and revealed the need for more stringent regulations.⁸

The average consumer may be unaware, but dietary supplements are not regulated in the same way as conventional food or drugs.⁹ In fact, the regulations covering dietary supplements are somewhat lax.¹⁰ For

¹ Jason Millman, *Americans Are Ignoring the Science and Spending Billions on Dietary Supplements*, WASH. POST (Feb. 4, 2015), <http://www.washingtonpost.com/blogs/wonkblog/wp/2015/02/04/americans-are-ignoring-the-science-and-spending-billions-on-dietary-supplements/>.

² *See id.*

³ See Rebecca Reisner, *The Diet Industry: A Big Fat Lie*, Bloomberg Business, http://www.businessweek.com/debateroom/archives/2008/03/the_diet_industry_a_big_fat_lie.html (last visited May 25, 2015).

⁴ *Id.*

⁵ *Dietary Supplements*, FDA.GOV, <http://www.fda.gov/Food/DietarySupplement/s/> (last visited May 21, 2015).

⁶ *See* 21 C.F.R. § 111 (2014).

⁷ *See* 21 U.S.C. § 301 et seq. (1994); Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended in scattered sections of 21 U.S.C.) (2006).

⁸ *See* Todd Harrison, *Regulatory Review: 20 Years Since DSHEA*, NUTRACEUTICALS WORLD (Sept. 1, 2014), http://www.nutraceuticalsworld.com/issues/2014-09/view_columns/regulatory-review-20-years-since-dshea/.

⁹ *Dietary Supplements*, *supra* note 5.

¹⁰ *See About FDA Approval*, FDA.GOV, <http://www.fda.gov/NewsEvents/ProductsApprovals/ucm106288.htm> (last updated Feb. 26, 2009).

example, although food additives and drugs must receive approval from the FDA prior to entering the market, no prior approval for dietary supplements is necessary.¹¹ The controversial issue regarding dietary supplement regulation is that, while drugs must be proven safe before entering the market, supplements are *presumed* safe until proven unsafe.¹²

The dietary supplement industry has recently received a lot of criticism in regards to the lack of regulations.¹³ Consumers continue to purchase supplements under the assumption that they are safe and effective; however, it is not until after a consumer has reported harm that the FDA gets involved.¹⁴ Dietary supplements are assumed to be safe, thus an unsafe product is sold to the public at large until someone has an adverse reaction.¹⁵ Due to the lack of consumer reporting, the true extent of harm caused by dietary supplements is not realistically known.¹⁶ If a consumer reports an adverse reaction, the FDA may recall the supplement.¹⁷ In more extreme situations, a harmed person may sue a manufacturer for personal injuries or false and misleading advertising. The FDA engages in a *reactionary* role by monitoring the reports of doctors or ill members of the public.¹⁸

This comment will examine dietary supplement regulation from the perspective of the substantial benefits that increased regulation of supplements could provide consumers. Part II will discuss the evolution of the FDA's role in regulating this industry and the changes warranted, including the history of and current requirements for dietary supplement regulation. Part II will also illuminate the role politics has played in the last twenty years of stagnant regulation. Finally, Part III will analyze the lack of regulations regarding the safety and effectiveness of dietary supplements, illustrating the need for reform, proposed methods for

¹¹ *Id.*; *FDA Regulation of Drugs Versus Dietary Supplements*, AM. CANCER SOC'Y, <http://www.cancer.org/treatment/treatmentsandsideeffects/complementaryandalternativemedicine/dietarysupplements/dietary-supplements-fda-regulations> (last updated Mar. 31, 2015).

¹² AM. CANCER SOC'Y, *supra* note 11.

¹³ *See* Millman, *supra* note 1.

¹⁴ AM. CANCER SOC'Y, *supra* note 11.

¹⁵ Pieter A. Cohen, *Assessing Supplemental Safety—The FDA's Controversial Proposal*, 366 NEW ENG. J. MED. 389, 389 (2012), available at <http://www.nejm.org/doi/full/10.1056/NEJMp1113325>.

¹⁶ *See* AM. CANCER SOC'Y, *supra* note 11.

¹⁷ *Dietary Supplements - Adverse Event Reporting*, FDA.GOV, <http://www.fda.gov/Food/DietarySupplements/ReportAdverseEvent/default.htm> (last updated Jan. 1, 2014).

¹⁸ *See How Consumers Can Report an Adverse Event or Serious Problem to the FDA*, FDA.GOV, <http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053074.htm> (last updated Feb. 11, 2014).

reform, and a critique of opponents' arguments to increased regulation.

II. BACKGROUND

A. The History of Dietary Supplement Regulation

1. *The Dietary Supplement Health and Education Act of 1994*

Congress enacted The Dietary Supplement Health and Education Act of 1994 ("DSHEA")¹⁹ in response to growing debate surrounding consumer access to current and accurate information regarding supplements.²⁰ Senator Orrin Hatch, the chief sponsor, originally introduced this bill to Congress.²¹ Ironically, Senator Hatch represents Utah, a state responsible for manufacturing 25% of the supplements produced in the United States.²² After Congress enacted this legislation, the dietary supplement industry has become Utah's largest industry, its worth increasing from \$92 million in 1992 to over \$7 billion in 2012.²³

DSHEA defined supplements as a special category of food.²⁴ The implication of this scheme is that dietary supplements are not regulated as conventional food or drugs.²⁵ While DSHEA implemented regulations for any "new ingredient," supplements sold prior to October 1994 were exempted from the legislation, and thus grandfathered into the new system.²⁶ A dietary ingredient may be one or a combination of more than one of the following: vitamin, mineral, herb or other botanical, amino acid, dietary substance to increase total dietary intake, a concentrate, metabolite, constituent, or extract.²⁷

All drugs, even those that do not require a prescription, must be proven safe and effective prior to being sold to consumers on the

¹⁹ Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended in scattered sections of 21 U.S.C.) (2006).

²⁰ *See id.*

²¹ Michael A. Maynard, *Are We Safe From Congress? Senator Orrin Hatch and the Politics of Vitamins*, POLITICUSUSA.COM (Nov. 10, 2013, 9:08 PM), <http://www.politicususa.com/2013/11/10/safe-congress-senator-orrin-hatch-politics-vitamins.html>.

²² *Id.*; Stephen Daniells, *Dietary Supplements Become Utah's #1 Industry, Topping \$7.2 Billion*, NUTRAINGREDIENTS-USA.COM (May 23, 2012, 5:18 PM), <http://www.nutraingredients-usa.com/Markets/Dietary-supplements-become-Utah-s-1-industry-topping-7.2-billion>.

²³ Daniells, *supra* note 22.

²⁴ AM. CANCER SOC'Y, *supra* note 11.

²⁵ *Id.*

²⁶ *Id.*

²⁷ *What is a Dietary Supplement?*, FDA.GOV, <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm195635.htm> (last updated Apr. 29, 2015).

market.²⁸ Therefore, unlike supplements, they are considered unsafe until proven safe.²⁹ The FDA drug approval process requires a drug to undergo a series of clinical trials, which must exhibit “substantial evidence” that the drug is safe and effective for its intended use.³⁰ Furthermore, a drug must be manufactured under carefully monitored conditions and the package must include: conditions the drug is proven to treat, known side effects, contraindications, and unsafe interactions with other drugs.³¹

On the other hand, prior to marketing a dietary supplement, DSHEA requires *manufacturers* to ensure its products are safe, any claims made about the products are not false or misleading, and the products comply with the FDCA.³² The FDA imposes a few other regulations not pertaining to this comment, such as manufacturers registering with the FDA pursuant to the Bioterrorism Act³³ before it produces or sells products.³⁴ DSHEA prohibits supplements from containing anything that may have “a significant or unreasonable risk of illness or injury” when used as the label advises.³⁵ A supplement manufacturer is required to provide the FDA with “reasonable evidence” that a *new*—any old ingredients are still exempt and grandfathered in—ingredient is safe before it is marketed to the public.³⁶ However, companies in the dietary supplement industry are only held to a “current good manufacturing practices” standard.³⁷ Manufacturers do not have to test new ingredients or conduct clinical trials, which could reveal potential risks to the consumer.³⁸ Instead, manufacturers and distributors are responsible for evaluating the safety and labeling of *their own* products to ensure compliance with DSHEA and FDA.³⁹

The FDA does require manufacturers to register their facilities with

²⁸ AM. CANCER SOC’Y, *supra* note 11.

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² *Questions and Answers on Dietary Supplements*, FDA.GOV, http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/default.htm#FDA_role (last updated Apr. 28, 2015).

³³ Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-88, 116 Stat. 594 (2002).

³⁴ *Questions and Answers on Dietary Supplements*, *supra* note 32.

³⁵ AM. CANCER SOC’Y, *supra* note 11.

³⁶ *Id.*

³⁷ See 21 C.F.R. § 111.1 (2014); see also *Dietary Supplements*, FDA.GOV, *supra* note 5; *Current Good Manufacturing Practices (CGMPs)*, FDA.GOV, <http://www.fda.gov/food/guidanceregulation/cgmp/default.htm> (last updated Sept. 25, 2014).

³⁸ *Dietary Supplements*, *supra* note 5.

³⁹ *Id.*

the FDA, but no prior approval of any supplement is required before producing or marketing the supplement.⁴⁰ Most consumers self-prescribe supplements.⁴¹ As a result, adverse effects or reactions are underreported.⁴² While manufacturers are required to report adverse effects to the FDA, doctors and patients are not.⁴³ This reflects a bias and can consequently delay a recall of a harmful supplement, or worse, contribute to an adverse effect going unreported.⁴⁴ However, the FDA only requires supplement manufacturers to report “serious” adverse event reports such as death, a life-threatening experience, a birth defect, or inpatient hospitalization.⁴⁵ Unbeknownst to many supplement consumers, the FDA does not require a manufacturer to report “mild adverse effects,” such as headaches, which are not “serious.”⁴⁶

A common legal issue facing supplement manufacturers is false or misleading labeling and advertising.⁴⁷ The Federal Trade Commission (“FTC”) has jurisdiction over advertising claims for supplements.⁴⁸ However, if the FDA discovers a supplement claim that it believes violates the FDCA, it sends a letter to the manufacturer or marketer which points out potential violations and requests claims to be withdrawn.⁴⁹ The FDA allows three categories of claims to be used on dietary supplement labels: health claims, nutrient content claims, and structure/function claims.⁵⁰ These claims are not pre-approved by the FDA, but a manufacturer must submit “substantiation that the claim is

⁴⁰ *Id.*

⁴¹ *Dietary Supplements: What is Safe?*, AM. CANCER SOC’Y, <http://www.cancer.org/acs/groups/cid/documents/webcontent/002385-pdf.pdf> (last updated Mar. 31, 2015).

⁴² AM. CANCER SOC’Y, *supra* note 11.

⁴³ *Id.*

⁴⁴ *Id.*; Josh Long, *Dietary Supplement Adverse Event Reports Increase*, NATURALPRODUCTSINSIDER.COM (Apr. 2, 2014), <http://www.naturalproductsinsider.com/news/2014/04/dietary-supplement-adverse-event-reports-increase.aspx> (citing a study from the Health and Human Services Office of Inspector General which found that 20% of a sample of dietary supplements did not contain phone numbers or complete addresses, decreasing the likelihood a consumer could reach a company in regards to an emergency).

⁴⁵ *See* Dietary Supplement and Nonprescription Drug Consumer Protection Act, Pub. L. No. 109-462, 120 Stat. 3470 (2006); Long, *supra* note 44.

⁴⁶ Long, *supra* note 44.

⁴⁷ Joel Rothman, *Features—Researching Laws and Information on Nutritional and Dietary Supplements on the Web*, LLRX.COM (June 10, 2006), <http://www.llrx.com/features/nutrisup.htm>.

⁴⁸ *See* 21 U.S.C. § 301 (2006).

⁴⁹ *Id.*

⁵⁰ *Label Claims for Conventional and Dietary Supplements*, FDA.GOV, <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm111447.htm> (last updated Nov. 26, 2014).

truthful” within thirty days after it has begun marketing the product.⁵¹ A consumer may overlook that a label that uses one of these claims must provide a “disclaimer” that the FDA has not evaluated the claim.⁵² The FDA has determined almost 300 fraudulent products that contain hidden or deceptively labeled ingredients.⁵³ Thus, as long as there is *some* “substantiation” for truth and a “disclaimer” regarding the claim, a manufacturing company is free to market unapproved, and potentially untrue, health-related claims to consumers.

Notably, the FDA does not review or approve a serving size or limit on the amount of a particular nutrient in a dietary supplement.⁵⁴ The FDA continues to warn consumers of the danger that some dietary supplement products contain prescription ingredients at a much higher level than those in an approved drug.⁵⁵ Furthermore, aside from the rules regarding “new dietary ingredients,” there is no requirement placed on manufacturers to disclose to consumers any known information pertaining to purported safety or benefits of their products.⁵⁶ Manufacturing companies are responsible for verifying the “Supplement Facts” on a product’s label, thus consumers are at the mercy of this profit-seeking industry to disclose honest and accurate information.⁵⁷

According to the Council for Responsible Nutrition (“CRN”), 83% of adults express confidence in the “safety, quality, and effectiveness of dietary supplements.”⁵⁸ The CRN, a trade association representing over 150 dietary supplement manufacturers and suppliers, claims consumer confidence stems from consumers recognizing that a majority of these companies are responsible and prioritize product quality.⁵⁹ However, if this confidence was a true assessment of the supplement industry, there

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Beware of Fraudulent Dietary Supplements*, FDA.GOV, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm246744.htm> (last updated Jan. 28, 2015) (noting fraudulent products usually promote weight loss, sexual enhancement, and bodybuilding).

⁵⁴ *Questions and Answers on Dietary Supplements*, *supra* note 32.

⁵⁵ *Beware of Fraudulent Dietary Supplements*, *supra* note 53 (noting numerous harmful reports connected with use of these products, including but not limited to, stroke, liver injury, kidney failure, heart palpitations, and death).

⁵⁶ *See id.*

⁵⁷ *Id.*

⁵⁸ *New Survey Reveals High Percentage of U.S. Population Take Dietary Supplements—and with High Confidence*, COUNCIL FOR RESPONSIBLE NUTRITION (Oct. 30, 2014), <http://www.crnusa.org/prpdfs/CRNPR14-CRNCCSurvey103014.pdf>.

⁵⁹ *Id.*

would not be a hot political debate regarding issue.⁶⁰ If DSHEA sufficiently regulated the dietary supplement industry, harm to consumers would be prevented, instead of addressed after-the-fact.⁶¹ A preventative regulatory scheme would, in turn, reduce millions of dollars that companies pay to settle claims involving the adverse effects of their products.⁶²

2. *The Politics of Dietary Supplement Regulation*

The dietary supplement industry extensively advertises to consumers the alleged benefits of its products.⁶³ Ultimately, it is a profit-seeking business, not a health-promoting business.⁶⁴ The chief sponsor of DSHEA, Senator Hatch, is a politician from Utah, a state which leads the country in the sales of supplements.⁶⁵ One in four dollars in the supplement market passes through Utah.⁶⁶

The lack of regulatory authority in the industry, for example, no prior approval required by the FDA, attracts businesses to the market.⁶⁷ Even pharmaceutical companies, which are usually subject to very rigorous regulations for producing drugs, have entered the market.⁶⁸ Giant pharmaceutical companies essentially own the dietary supplement industry.⁶⁹ For example, Pfizer owns Centrum, Bayer owns One A Day, and Proctor & Gamble owns New Chapter.⁷⁰ The multi-billion dollar industry has invested exorbitant amounts of money on lobbyists to campaign against any increased regulatory control by the FDA.⁷¹ Although Congress has reexamined and considered bills to

⁶⁰ See Timothy Egan, *The Politics of Fraudulent Dietary Supplements*, N.Y. TIMES, (Feb. 6, 2015), http://www.nytimes.com/2015/02/06/opinion/the-politics-of-fraudulent-dietary-supplements.html?_r=2.

⁶¹ Megan Dagerman, *Incentivizing Safety in the Dietary Supplement Industry*, 31 REV. LITIG. 173, 206 (2012).

⁶² See Cassandra Burke Robertson, *Separating Snake Oil from Therapeutic Supplements: The Nexus Between Litigation and Regulation in the Dietary Supplement Industry*, 35 U. TOL. L. REV. 317, 327 (2003).

⁶³ *Dietary Supplements: An Advertising Guide for Industry*, FED. TRADE COMM'N, <http://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry> (last visited May 25, 2015).

⁶⁴ See Lynn Stuart Parramore, *Time to Tame the Dietary Supplement Industry*, ALJAZEERA AMERICA (Nov. 12, 2013, 6:00 AM), <http://america.aljazeera.com/opinions/2013/11/vitamins-herbal-dietarysupplementsregulatefda.html>.

⁶⁵ See Maynard, *supra* note 21.

⁶⁶ Egan, *supra* note 60.

⁶⁷ Parramore, *supra* note 64.

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ See Alessa Thomas, *Making Sense of Supplements: Suggestions for Improving*

address the regulatory debate, the manufacturing industry lobbyists are too powerful to allow legislative change.⁷² As the industry continues to exponentially grow, any increased regulation has been stalled since 1994.

III. ANALYSIS

A. Adverse Health Effects of Dietary Supplement Use

Two words—“all natural”—can be used as a marketing tool to attract consumers to products. The FDA defines “natural ingredients” as those that are derived from “natural sources,” whereas other ingredients are not found in nature and must be synthetically produced.⁷³ Consumers automatically think that a natural ingredient must be better and safer than one that is not. However, this assumption is naïve—many toxic substances occur in the world naturally and many plants are made up of various chemicals.⁷⁴ For example, botanical supplements derived from plants can contain harmful chemicals, yet be marketed as “all natural.”⁷⁵ Moreover, often labels highlight a product’s positive aspect, such as “healthy” or “high in antioxidants,” which fails to encourage a consumer to seek any more information.⁷⁶ Consumer exposure to supplements accounted for over 35,000 calls to US poison control centers in 2011.⁷⁷ The number of adverse events reported to the FDA has continued to climb each year: 1,009 in 2010; 2,047 in 2011; and 2,844 in 2012.⁷⁸

Dietary supplements can produce similar adverse health effects as drugs, illustrating the need for increased regulation more similar to the drug industry.⁷⁹ The range of adverse effects of supplements, including the potential unknown effects, warrant increased regulation. In

the Regulation of Dietary Supplements in the United States, 2010 MICH. ST. L. REV. 203, 212 (2010).

⁷² See *id.*

⁷³ *Overview of Food Ingredients, Additives, & Colors*, FDA.GOV, <http://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm094211.htm#qanatural> (last updated Dec. 12, 2014).

⁷⁴ *Common Misconceptions About Dietary Supplements*, AM. CANCER SOC’Y, <http://www.cancer.org/treatment/treatmentsandsideeffects/complementaryandalternativemedicine/dietarysupplements/dietary-supplements-misconceptions> (last updated Mar. 31, 2015).

⁷⁵ *Id.*

⁷⁶ *Id.*; see also Nicole E. Negowetti, *Defining Natural Foods: The Search for a Natural Law*, 26 REGENT U. L. REV. 329, 329 (2013-14).

⁷⁷ AM. CANCER SOC’Y, *supra* note 11.

⁷⁸ *Id.*; Long, *supra* note 44.

⁷⁹ See *Label Claims for Conventional and Dietary Supplements*, *supra* note 50.

Lineberger v. Max Muscle Mktg Inc.,⁸⁰ a dietary supplement manufacturer and distributor paid over \$4.2 million to settle a suit with a previously healthy twenty-nine year old man who developed acute liver and kidney failure after using its products.⁸¹ Metabolife and other defendants paid \$56 million to settle personal injury claims stemming from its ephedra-related products in which it faced over 300 personal injury claims in a consolidated proceeding.⁸² Metabolife's insurance company paid the entire global settlement and Metabolife subsequently went bankrupt.⁸³ The FDA specifically received over 900 reports of possible ephedra toxicity, some of those including severe adverse events such as stroke, heart attack, and sudden death.⁸⁴

Moreover, the FDA recalled Hydroxycut products in 2009 because of twenty-three reports of serious health problems, including one death and one liver transplant.⁸⁵ Hydroxycut advertised itself as "America's number one weight loss supplement;"⁸⁶ however, it was compelled to pay a \$23.5 million to settle a suit for deceptive practices.⁸⁷ This amount did not even include personal injury or wrongful death claims.⁸⁸

⁸⁰ See Debra S. Dunne, Laurie A. Henry, & Madeleine McDonough, \$4.2 Million Paid to Man Harmed by Supplements With Anabolic Steroids, LEXOLOGY (Feb. 7, 2014), <http://www.lexology.com/library/detail.aspx?g=f6e8f22e-f833-47e6-a1e6-968c95954df0>.

⁸¹ *Id.*

⁸² See *Brown Rudnick Reaches Settlement in Metabolife Suit*, BOSTON BUSINESS JOURNAL (Nov. 13, 2006, 2:52 PM), <http://www.bizjournals.com/boston/stories/2006/11/13/daily14.html>.

⁸³ *Id.*

⁸⁴ *Ephedra*, NAT'L CTR. FOR COMPLIMENTARY & INTEGRATIVE HEALTH, <https://nccih.nih.gov/health/ephedra> (last updated Jan. 25, 2015); see also Sara Atherton Mason, *Dietary Supplement Regulation: A Comparative Study*, 20 FLA. ST. J. TRANSNAT'L L. & POL'Y 103, 108 (2010-11) (highlighting that the FDA did not ban ephedrine products for nine years until 150 deaths occurred and it had received 16,000 adverse event reports).

⁸⁵ See *Warning on Hydroxycut Products*, FDA.GOV, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm152152.htm> (last updated Apr. 29, 2015); see also Aaron Kase, *Hydroxycut Weight Loss Drug Settles Suit for \$23.5 Million*, LAWYERS.COM (Nov. 27, 2012), <http://blogs.lawyers.com/2012/11/hydroxycut-settles-23-million/> (listing other symptoms such as: nausea, vomiting, light-colored stools, excessive fatigue, weakness, stomach or abdominal pain, itching, and loss of appetite).

⁸⁶ See, e.g., *Diet: Hydroxycut*, AS SEEN ON TV SUPERSTORE, <http://www.asseenontv-superstore.com/fitness/hydroxycut.html> (last visited May 25, 2015).

⁸⁷ Juan Carlos Rodriguez, *Hydroxycut Consumers Reach \$25M Deal in False Ad MDL*, LAW360.COM (Nov. 5, 2012, 1:57 PM), <http://www.law360.com/articles/391821/hydroxycut-consumers-reach-25m-deal-in-false-ad-mdl>.

⁸⁸ Kase, *supra* note 85.

Regeneca Worldwide voluntarily recalled its appetite control dietary supplement, RegeneSlim, after the FDA confirmed the presence of DMAA, a potentially dangerous stimulant that can narrow blood vessels and arteries.⁸⁹ The various problems associated with the use of DMAA include a rise in blood pressure, shortness of breath, arrhythmias, tightening in the chest, and heart attack.⁹⁰

Supplements may also contain fillers, contaminants, ingredients with unknown effects, or even prescription drugs and compounds not listed on the label.⁹¹ Herbs are “sometimes tainted with germs, pesticides, or toxic heavy metals.”⁹² Several botanical supplements—major ingredients containing basil, fennel, nutmeg, saffron, cinnamon, or calamus—have been shown to contain high levels of alkenyl benzenes, a compound that is known to cause malignant tumors in lab animals.⁹³ The lack of regulations contributes to the mystery of unknown drug interactions. For example, a consumer may use both a supplement and a prescription, which have not been tested concurrently, and an allergic reaction or adverse effect could result.⁹⁴

Moreover, in addition to the safety issue with dietary supplements, increased regulation is warranted to address manufacturers’ misleading claims. Most of the recalls and litigation surrounding the business involve misleading claims for effectiveness or failing to disclose all ingredients in the supplement.⁹⁵ For example, multiple producers of glucosamine-based supplements paid \$3.1 million last year to settle a proposed class action based on misleading consumers by proclaiming joint health benefits, despite scientific evidence to the contrary.⁹⁶

⁸⁹ *Regeneca Worldwide, A Division of Vivaceuticals, Inc Voluntarily Recalls RegeneSlim Appetite Control Capsules Due to the Presence of DMAA That May Pose Possible Health Risk*, FDA.GOV, <http://www.fda.gov/Safety/Recalls/ucm408674.htm> (last updated Sept. 5, 2014).

⁹⁰ *Id.*

⁹¹ AM. CANCER SOC’Y, *supra* note 11.

⁹² *Id.*

⁹³ Nathan Gray, *Botanical supplements may contain harmful compounds: Study*, NUTRAINGREDIENTS.COM, <http://www.nutraingredients.com/Research/Botanical-supplements-may-contain-harmful-compounds-Study> (last updated Dec. 14, 2014).

⁹⁴ William J. Cromie, *Dietary Supplements Can Cause Harmful Reactions With Prescription Medications*, HARV. UNIV. GAZETTE (Oct. 26, 2006), <http://news.harvard.edu/gazette/2006/10.26/11-herbs.html>.

⁹⁵ *See* AM. CANCER SOC’Y, *supra* note 11; *Recalls of Food and Dietary Supplements*, FDA.GOV, <http://www.fda.gov/food/recallsoutbreaksemergencies/recalls/default.htm> (last visited May 25, 2015).

⁹⁶ Caroline Simson, *Supplement Makers Pay \$3M to End Joint Health False Ad Suit*, LAW360.COM (Sept. 17, 2014, 5:02 PM), <http://www.law360.com/articles/577795/supplement-makers-pay-3m-to-end-joint-health-false-ad-suit>.

Airborne Health, Inc. agreed to pay up to \$30 million to consumers who bought its product marketed as a cold prevention and treatment remedy, which the FTC later found to be unsubstantiated.⁹⁷

Recently, the New York State Attorney General's Office demanded four major retailers, Wal-Mart, Target, GNC, and Walgreens, to remove potentially dangerous herbal supplements from their shelves.⁹⁸ After tests revealed four out of five of the products did not contain any of the herbs listed on their labels, the authorities accused these retailers for selling fraudulent and potentially dangerous supplements.⁹⁹ As a result of this media attention, GNC is now defending a class action in Florida to enjoin selling four of its products: GNC Plus Gingko Biloba, GNC Herbal Plus St. John's Wort, GNC Herbal Plus Ginseng, and GNC Herbal Plus Echinacea.¹⁰⁰ The suit alleges deceptive labeling and violations of consumer protection laws.¹⁰¹ The economic growth of the industry due to the ability to escape regulations is too large for miniscule settlements to deter the industry from changing its own practices.

B. Proposed Changes to Current Dietary Supplement Industry Regulations

1. Incentivizing Manufacturing Companies

The dietary supplement industry's lack of regulation provides manufacturing companies with significant economic incentives to pursue this market. As previously discussed, these multi-billion dollar industries are able to pay lobbyists whatever is necessary to halt giving the FDA any further regulatory authority.¹⁰² Any successful regulatory reform also needs to provide these companies attractive economic

⁹⁷ *Makers of Airborne Settle FTC Charges of Deceptive Advertising; Agreement Brings Total Settlement Funds to \$30 Million*, FEDERAL TRADE COMM'N (Aug. 14, 2008), <https://www.ftc.gov/news-events/press-releases/2008/08/makers-airborne-settle-ftc-charges-deceptive-advertising>.

⁹⁸ Michelle Esteban, *Findings: Sand, Houseplants Found in Herbal Supplements*, KOMONEWS.COM (Feb. 3, 2015, 9:54 PM), <http://www.komonews.com/news/local/SAND-RADISH-POWDER-AND-HOUSEPLANTS-ALLEGEDLY-FOUND-IN-HERB-SUPPLEMENTS-290725721.html> (noting that sand and other fillers have been found in supplements sold by reputable companies, thus further raising suspicion).

⁹⁹ *Id.*

¹⁰⁰ Noreen Marcus, *A Public Danger? Lawsuit Claims GNC Herbal Supplements Are Not Herbal*, DAILY BUSINESS REVIEW (Feb. 11, 2015), <http://www.dailybusinessreview.com/id=1202717638114/A-Public-Danger-Lawsuit-Claims-GNC-Herbal-Supplements-Are-Not-Herbal?slreturn=20150206115557>.

¹⁰¹ *Id.*

¹⁰² See discussion *supra* Part II.A.ii.

incentives.

It is undisputed that the supplement industry has positively contributed to the economy;¹⁰³ however, this industry has profited to the detriment of consumers' lack of education.¹⁰⁴ Currently, many physicians disfavor the use of dietary supplements and therefore caution consumers to seek medical advice from a physician.¹⁰⁵ Requiring testing, scientific evidence, and overall prior-approval of supplements could effectively generate more support from the medical community at large, thus economically benefiting the industry. If manufacturers make a strong commitment to consumer safety, physicians would be more confident in administering these supplements, thus facilitating the industry to expand.

For example, to address doctors' and health care practitioners' concerns with the adverse effects of supplements, the Children's Hospital of Philadelphia was the first hospital to implement guidelines for the use of dietary supplements.¹⁰⁶ To quell doctors' skepticism towards administering supplements, manufacturers must provide a third-party written agreement that the supplement was produced under the FDA's required "good manufacturing practices," as well as a "certificate of analysis" assuring the ingredients listed on the label are actually what is in the product.¹⁰⁷ In its good faith effort to help parents decide whether to give their children supplements, the hospital has not received a positive response from manufacturers.¹⁰⁸ Roughly 90% of these companies failed to respond, and, moreover, other companies have refused to furnish documentation to authenticate their products.¹⁰⁹ Additionally, some companies lied about compliance with the FDA, even though they were found in violation of good manufacturing practices.¹¹⁰ Some companies even admitted that they were not in

¹⁰³ *What is the current economic contribution of the dietary supplement industry to the U.S. Economy?*, NATURAL PRODUCTS FOUNDATION, https://www.npainfo.org/App_Themes/NPA/docs/policy/Econ%20One%20sheet%2003-11%20final.pdf (last visited May 25, 2015).

¹⁰⁴ Michael Richman, *Over the counter steroid supplements: Are they safe?*, EXAMINER.COM (Aug. 4, 2010, 3:27 PM), <http://www.examiner.com/article/over-the-counter-steroid-supplements-are-they-safe>.

¹⁰⁵ See e.g., *id.*; Cromie, *supra* note 94.

¹⁰⁶ Greg Webb, *Children's Hospital of Phil. Concerned About Dietary Supplement Use*, THE LEGAL EXAMINER (Jan. 2, 2014, 7:45 AM), <http://charlottesville.legalexaminer.com/uncategorized/childrens-hospital-of-phil-concerned-about-dietary-supplement-use/>.

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

compliance.¹¹¹ The new plan now requires parents to sign a waiver confirming they understand the supplement may be dangerous for a child.¹¹²

Until Congress increases the FDA's regulatory authority, other medical facilities should follow the Childhood Hospital of Philadelphia's route and pressure manufacturers to be accountable for their products. Manufacturing companies are obviously incentivized by money, and declining sales from stricter guidelines in the medical community could trigger a positive response. If manufacturers commit to consumer safety, physicians may be more apt to administer and recommend the use of supplements, increasing potential sales for the industry.¹¹³

Moreover, until legislation increases the FDA's authority to regulate supplements, Congress could temporarily provide tax incentives for manufacturing companies that do seek prior approval from the FDA.¹¹⁴ With the increased budget allotted in 2015,¹¹⁵ available funds could be used by the FDA to review and approve dietary supplements. Furthermore, tax credits could be provided to manufacturing companies for consistent practices in accordance with FDA regulations, such as a credit awarded for five years without any recalls or a significant number of adverse reports.

2. *Improving the Current Regulatory Scheme*

To adequately address the current problems with the regulatory framework of dietary supplements, a *preventative* approach to regulation, as opposed to *reactionary*, is necessary.¹¹⁶ DSHEA

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *See id.*

¹¹⁴ *See About FDA: Promoting Safe and Effective Drugs for 100 Years*, FDA.GOV, www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/PromotingSafeandEffectiveDrugsfor100Years/ (last updated June 18, 2009); Ron Wilson, *Financial Assistance and Incentives for Research and Development of New Drug/Biological Products*, FDA.GOV, <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm127616.pdf> (last visited May 25, 2015); *FDA Should Take Further Actions to Improve Oversight and Consumer Understanding*, GOVERNMENT ACCOUNTABILITY OFFICE (Jan. 2009), <http://www.gao.gov/new.items/d09250.pdf>.

¹¹⁵ *Justification of Estimates of Appropriations Committees*, DEP'T OF HEALTH AND HUMAN SERVS. at 3, <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM432322.pdf> (last visited May 25, 2015).

¹¹⁶ *See* Mason, *supra* note 84, at 126 ("81% of adults believe that dietary supplements should only be sold after they pass FDA safety standards.").

effectively removed the FDA's authority for preventing unsafe or ineffective supplements available to consumers on the market.¹¹⁷ Currently, consumers are unaware if a manufacturing company made an unsupported or incorrect conclusion as to a product's safety until the product is widely sold to consumers.¹¹⁸ Consumers' lack of education regarding the safety, efficacy, and labeling of dietary supplements exposes them to potential health risks.¹¹⁹

Rather than Congress choosing between drugs or food in terms of categorizing the regulation, it should instead create a separate and distinct category for supplements. Although nicotine is a type of stimulant drug, given the differences between tobacco and over-the-counter or prescription drugs, Congress chose to regulate tobacco as its own separate category.¹²⁰ For example, in 2009 Congress passed the Family Smoking Prevention and Tobacco Control Act, granting the FDA authority to regulate the manufacturing, distributing, and marketing of tobacco products.¹²¹ Prior to the law's enactment, the FDA only regulated the tobacco industry to the extent a company made explicit health claims.¹²² The new law thus eliminated the ability of tobacco industries to introduce products without oversight from the FDA.¹²³ Similarly, dietary supplements are different from both drugs and food, and warrant a separate method of regulation.¹²⁴ A preventative, independent regulatory framework would cater to the specific risks and issues presented by dietary supplements.

A preventative framework would require prior approval of dietary supplements before manufacturers make their products available to consumers. Prior approval would improve quality control beyond just

¹¹⁷ See *id.*; GOVERNMENT ACCOUNTABILITY OFFICE, *supra* note 114.

¹¹⁸ GOVERNMENT ACCOUNTABILITY OFFICE, *supra* note 114.

¹¹⁹ *Id.*

¹²⁰ See *Federal Regulation of Tobacco*, PUBLIC HEALTH LAW CENTER, <http://publichealthlawcenter.org/topics/tobacco-control/federal-regulation-tobacco> (last visited May 25, 2015).

¹²¹ *Center for Tobacco Products Overview*, FDA.GOV, <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/AbouttheCenterforTobaccoProducts/ucm383225.htm> (last updated Feb. 14, 2014).

¹²² PUBLIC HEALTH LAW CENTER, *supra* note 120.

¹²³ *Overview of the Family Smoking Prevention and Tobacco Control Act: Consumer Fact Sheet*, FDA.GOV, <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm246129.htm> (last updated Mar. 6, 2015).

¹²⁴ *About FDA: What is the difference between a dietary supplement and a conventional food?*, FDA.GOV, <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194357.htm> (last updated Jan. 26, 2015).

“current good manufacturing practices.”¹²⁵ The primary goal of shifting regulation from reactionary to preventative is to increase safety and effectiveness of dietary supplements to the consuming public. Supplements are different from drugs in that they are not intended to treat, diagnose, prevent, or cure diseases; so a regulatory scheme in between that of drugs and the current supplement industry is appropriate.¹²⁶

The FDA should conduct testing for the composition and potency of supplements before these products are available to the public. Supplements can be as powerful as pharmaceutical drugs, so the potential for harmful effects increases.¹²⁷ Product purity refers to “lack of contamination or adulteration,” while product potency refers to whether “the product contains the stated amount of active ingredient.”¹²⁸ Unfortunately, manufacturing companies are in charge of ensuring both purity and potency.¹²⁹ As a consequence, adverse effects resulting from either purity or potency may occur before the FDA could require a manufacturer to stop production.¹³⁰ A preventative approach would address adverse effects before they occur and hold manufacturing companies accountable for what they produce.

In creating a distinct regulatory category for dietary supplements, the FDA also needs to define “natural product.” The FDA admits that it has not developed a definition for the term, but provides on its website, “it is difficult to define a food product that is ‘natural’ because the food has probably been processed and is no longer the product of the earth.”¹³¹ In 1993, the FDA claimed it would consider defining

¹²⁵ See 21 C.F.R. § 111 (2014).

¹²⁶ See *Dietary Supplements: What You Need to Know*, FDA.GOV (May 2006) <http://www.fda.gov/downloads/Food/DietarySupplements/UCM240978.pdf> (noting the potential strong biological effects supplements can have on the human body).

¹²⁷ Kris Gunnars, *4 Natural Supplements That Are as Powerful as Drugs*, AUTHORITY NUTRITION (Feb. 28, 2015, 2:30 PM), <http://www.care2.com/greenliving/4-natural-supplements-that-are-as-powerful-as-drugs.html> (listing four supplements that are as effective as drugs: berberine, curcumin, red yeast rice, and garlic).

¹²⁸ *Supplement Savvy, Part 2: Product Potency*, CANCER NUTRITION CENTERS FOR AMERICA, <http://admin.cnceahealth.com/explore/learn/nutrition-supplements/supplement-savvy-part-2-product-potency#.VVpzA-vXc0s> (last visited May 15, 2015).

¹²⁹ *Supplement Savvy, Part 4: Quality and Purity*, CANCER NUTRITION CENTERS FOR AMERICA, <http://admin.cnceahealth.com/explore/learn/nutrition-supplements/supplement-savvy-part-4-quality-and-purity#.VVqMtuvXc0s> (last visited May 15, 2015).

¹³⁰ AM. CANCER SOC’Y, *supra* note 11.

¹³¹ *What is the Meaning of “Natural” on the Label of Food?*, FDA.GOV <http://www.fda.gov/aboutfda/transparency/basics/ucm214868.htm> (last updated Apr. 29, 2015).

“natural;” however, over twenty years later, the term remains legally undefined.¹³² Consumers equate “natural” with healthy—86% of consumers think “natural” means processed foods which do not contain any artificial ingredients—however, the current standard only prohibits artificial colorings and additives.¹³³ Many consumers would be surprised to learn that high-fructose corn syrup, partially hydrogenated oils, and genetically modified organisms can still be used in “natural” foods.¹³⁴

As well as not necessarily healthy, “natural” does not always mean safe.¹³⁵ A supplement’s chemical makeup, how it works in the body, how it is prepared, and the dose used all contribute to a product’s safety.¹³⁶ For example, combining herbal supplements with prescription and nonprescription medications can cause adverse effects such as headaches, nausea, heart palpitations, and gastrointestinal problems, to name a few.¹³⁷ Instead of leaving it to the courts to define “natural,” the FDA should provide a legal definition to be used in dietary supplement regulation. Manufacturing companies could avoid potential litigation, all the while remaining accountable to consumers. Moreover, the FDA would have a clear method of enforcing a preventative regulatory framework by testing and assuring “natural” claims are actually safe and effective.

If a preventative regulatory framework is implemented, it is important to give the FDA the authority to issue civil monetary penalties. The FDA should be able to issue these penalties for non-compliance with prior approval before entering the market. Penalties could also be triggered upon a serious adverse event report. Furthermore, penalties could increase for manufacturers that are repeat violators of the FDA.

In creating a preventative regulatory framework, the European

¹³² See Lorraine Heller, ‘Natural’ Will Remain Undefined, Says FDA, FOODNAVIGATOR-USA.COM (Jan. 4, 2008), <http://www.foodnavigator-usa.com/Suppliers2/Natural-will-remain-undefined-says-FDA>.

¹³³ *Citizen Petition*, CONSUMERS UNION: NONPROFIT PUBLISHER OF CONSUMER REPORTS (June 26, 2014), http://www.greenerchoices.org/pdf/CR_FDAPetitionBanNaturalLabel.pdf.

¹³⁴ *Id.*

¹³⁵ See *Dietary Supplements: What You Need to Know*, OFFICE OF DIETARY SUPPLEMENTS, NIH, http://ods.od.nih.gov/HealthInformation/DS_WhatYouNeedToKnow.aspx (last updated June 17, 2011).

¹³⁶ *Id.*

¹³⁷ Yvette C. Terrie, *Herbal Supplements May Not Be as Safe as They Sound*, U.S. NEWS & WORLD REPORT (June 22, 2013, 9:00 AM), <http://health.usnews.com/health-news/health-wellness/articles/2013/06/22/herbal-supplements-may-not-be-as-safe-as-they-sound>.

Union (“EU”) regulation system provides an example for guidance.¹³⁸ The EU only allows dietary supplements to enter the market if they have first been proven safe.¹³⁹ The burden of proof rests on manufacturers to prove their products are safe.¹⁴⁰ In contrast, in the United States, the burden of proof remains on the FDA to prove a particular product is unsafe or ineffective.¹⁴¹ This mechanism in the United States is inefficient because the manufacturer possesses the relevant testing and research on its own products. As previously discussed, the FDA lacks resources, thus the burden of proving that a supplement is safe and effective should be placed on the multi-billion dollar industry before it markets the product.¹⁴² Furthermore, placing this burden on manufacturing companies would facilitate competition within the industry.¹⁴³ A company can surpass others in the industry by producing substantiated safe and effective products.¹⁴⁴

Consumers perceive supplements more similar to drugs than food, so they in turn assume that supplements are regulated and thus, safe.¹⁴⁵ Supplements become available to consumers, including those that will not be beneficial or could potentially harm the consumer. However, consumers’ misconceptions regarding dietary supplements illustrates the need for prior approval.¹⁴⁶ Consumers will be able to make more informed decisions regarding which supplements are safe, beneficial, and effective.¹⁴⁷ Although consumer choice is important, consumer confusion stemming from lack of regulation necessitates increased education. If consumers were more educated regarding the dietary supplement industry, it is likely they would put more pressure on the industry and legislature to increase regulation.¹⁴⁸ Currently, the lack of informed consumers contributes to a cycle of the supplement industry profiting without oversight of what it is providing to the public. Accurate information should be provided to consumers in a wider array of materials, such as health-related magazines.¹⁴⁹ The FDA should publicly stress to consumers that it does not have the regulatory

¹³⁸ See Mason, *supra* note 84, at 115.

¹³⁹ *Id.* at 116.

¹⁴⁰ *Id.* at 119–20.

¹⁴¹ *Id.* at 119.

¹⁴² *Id.* at 120.

¹⁴³ See *id.* at 122.

¹⁴⁴ See Ross Beard, *Why Customer Satisfaction is Important*, CLIENT HEARTBEAT (Jan. 20, 2014), <http://blog.clientheartbeat.com/why-customer-satisfaction-is-important/>.

¹⁴⁵ Dagerman, *supra* note 61, at 176, 199.

¹⁴⁶ *Id.* at 176.

¹⁴⁷ *Id.* at 199.

¹⁴⁸ *Id.* at 198.

¹⁴⁹ *Id.* at 199.

authority for prior approval. Increased awareness from the FDA may incentivize consumers to first research a supplement and its potential adverse effects and reactions with prescription medications prior to use. Until a campaign is initiated to properly inform consumers, they will continue to carry their assumptions and be at the mercy of the industry.

C. A Response to the Critics of Increased Dietary Supplement Regulation

1. The FDA Lacks the Resources to Enforce Increased Regulation

A common criticism of increased regulation of the dietary supplement market is the lack of necessary funds to implement a new regulatory scheme.¹⁵⁰ Similar to other governmental agencies, the FDA has limited resources for dietary supplement oversight.¹⁵¹ However, an insufficient budget affects every area of the government,¹⁵² and there are feasible methods to address this issue.

The Department of Health and Human Services, within which the FDA operates, has proposed a 9% increase in the FDA's budget for the fiscal year of 2016.¹⁵³ Reorganization of the available budget would provide the FDA with more resources for regulatory oversight over the dietary supplement industry. However, without a comprehensive change from Congress regarding the FDA's regulatory authority, a reallocation of budget funds will only have a limited effect on the resources available to the FDA. Another route to address the FDA's lack of resources is to afford incentives for states that increase their regulatory authority to assist the FDA. For example, states that provide employees and testing facilities to aid the FDA in regulatory oversight could be rewarded with tax subsidies.

To further assist the FDA with its shortage of budget, the FDA could create a fund for research and development, clinical testing, and construction of new testing facilities. Instead of the FDA being the sole provider to this fund, state regulatory agencies, the Office of Dietary Supplements, and the Federal Trade Commission could pool resources together. Further economic incentives, such as rebates or tax benefits, would attract these entities to contribute. Not only does the pooling of

¹⁵⁰ *Id.* at 188; Negowetti *supra* note 76, at 331.

¹⁵¹ Dagerman, *supra* note 61, at 188.

¹⁵² See e.g., Otto Kreisher, *Carter, Dempsey Decry 'One-Year-at-a-Time' Budgeting*, SEAPOWERMAGAZINE.ORG (May 6, 2015), <http://www.seapowermagazine.org/stories/20150506-senapprops.html>.

¹⁵³ DEP'T OF HEALTH AND HUMAN SERVS., *supra* note 115.

resources increase the amount available to the FDA to use for regulating the supplement industry, but it also attracts the involvement of scientists.¹⁵⁴ To effectuate a more safe and effective industry, the FDA needs scientists to conduct studies and further research dietary supplements.¹⁵⁵ Research and development is expensive, but an increase in available funds could potentially attract scientists to the field.

As a result, an increase in available funds and need for the requisite expertise creates jobs. Contrary to criticism that increased regulation inevitably curtails employment, jobs available for scientists, technicians, or other employees in testing laboratories will actually increase.¹⁵⁶ It is true that increased regulations will cause a decrease of jobs in some areas; however, the data reflects that increased regulation more commonly affects the *distribution* of jobs, not the total number.¹⁵⁷

Critics of increased regulation of the dietary supplement industry argue that prices to consumers will inevitably rise.¹⁵⁸ However, supplement manufacturers can receive 50% profit margins, while most of the top ten manufacturing companies of drugs have profit margins at about 30%.¹⁵⁹ Overall profits may decrease for some manufacturing companies; however the proposed regulatory structure provides tax incentives and subsidies, mitigating the need to increase prices for consumers.¹⁶⁰ An excuse of decreased profits should not win the debate over consumer safety. It is not argued that dietary supplements should get the same regulatory treatment as drugs, thus the extra cost on the supplement industry for prior approval will not be as expensive as drugs.

As compared to drugs, dietary supplements are not permitted to claim cure or treatment of any disease. But, if manufacturing companies

¹⁵⁴ Dagerman, *supra* note 61, at 201.

¹⁵⁵ *Id.*

¹⁵⁶ Marian Wang, *Do Regulations Really Kill Jobs Overall? Not So Much*, PROPUBLICA.ORG (Sept. 21, 2011, 9:50 AM), <http://www.propublica.org/blog/item/whats-the-evidence-that-regulations-kill-jobs> (noting that the claim that increased regulation necessarily kill jobs is unfounded).

¹⁵⁷ *Id.*

¹⁵⁸ *Dietary Supplements: Safe, Beneficial, and Regulated*, COUNCIL FOR RESPONSIBLE NUTRITION, <http://www.crnusa.org/CRNRegQandA.html> (last visited May 25, 2015).

¹⁵⁹ See Devon Shire, *Muscle Pharm - 50% Revenue Growth and Expanding Profit Margins*, SEEKING ALPHA (Nov. 19, 2013, 9:47 AM), <http://seekingalpha.com/article/1848761-muscle-pharm-50-percent-revenue-growth-and-expanding-profit-margins>; *Pharmaceutical Industry*, WORLD HEALTH ORGANIZATION, <http://www.who.int/trade/glossary/story073/en/> (last visited May 25, 2015).

¹⁶⁰ See Shire, *supra* note 159.

are going to add prescription drugs to supplements without knowledge of the consumer, they should have to pay for the regulatory costs.¹⁶¹ For example, OxyElite Pro, a weight loss supplement, was found to contain the anti-depressant fluoxetine, a selective serotonin reuptake inhibitor (“SSRI”).¹⁶² SSRIs are prescribed to treat depression, bulimia, obsessive-compulsive disorder, panic disorder, and premenstrual dysphonic disorder.¹⁶³ Seven Slim, another weight loss supplement, was found to contain phenolphthalein, an active ingredient in laxatives until it was banned in the 1990’s because it was potentially carcinogenic.¹⁶⁴ These two examples illustrate why an increased cost argument fails. If dietary supplement manufacturers do not want to pay regulatory costs, they should not create products that mimic drugs.

In addition, some companies who have spiked supplements with prescription drugs have been found employing executives with criminal backgrounds or regulatory run-ins.¹⁶⁵ For example, some crimes have involved barbiturates, crack cocaine, ecstasy, and other narcotics, as well as arrests for selling or possessing steroids or human growth hormone.¹⁶⁶ Other records have included fraud, theft, assault, and money laundering.¹⁶⁷ These crimes exemplify the easy ability to enter the industry and the lax regulations that allow consumers to be taken advantage of. The multi-billion dollar industry should be subject to more oversight by the FDA to ensure that dietary supplements are safe and effective for consumers.

IV. CONCLUSION

Although legislation has been introduced to Congress since DSHEA in 1994,¹⁶⁸ any increased regulatory power of the FDA has been halted.

¹⁶¹ *Label Claims for Conventional Foods and Dietary Supplements*, FDA.GOV (Dec. 2013), <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm111447.htm>.

¹⁶² Brie Zeltner, *FDA Warns of Hidden Drugs in OxyElite, Seven Slim Weight Loss Supplements*, CLEVELAND.COM (Mar. 2, 2015, 12:24 PM), http://www.cleveland.com/healthfit/index.ssf/2015/03/fda_warns_of_hidden_drugs_in_o.html.

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ See Alison Young, *Makers of Tainted Supplements Have Criminal Pasts*, USA TODAY (Dec. 20, 2013, 9:57 AM), <http://www.usatoday.com/story/news/nation/2013/12/19/dietary-supplements-executives-criminal-records-spiked/4114451/>.

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

¹⁶⁸ See Shane Starling, *McCain ‘Revisiting’ Supplements Reform Bill*, NUTRAINGREDIENTS-USA (Mar. 8, 2010, 7:51 PM), <http://www.nutraingredients-usa.com/Regulation/McCain-revisiting-supplements-reform-Bill?nocount>.

The dietary supplement industry has exponentially grown in the past twenty years to the detriment of consumers. A happy medium between supplement manufacturers being able to market products without any oversight and allowing consumers choice in a free market is ideal. The supplement industry's pattern of marketing products which are sometimes dangerous, ineffective, or misleading entails a need for preventative regulation. Manufacturing companies which are profiting billions of dollars a year on this industry strongly oppose increased regulation. However, the industry has proven untrustworthy and consequently should be monitored more stringently.