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A Red Bull Instead of a Cigarette: Should the FDA Regulate Energy Drinks?

Joseph G. Hoflander

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A RED BULL INSTEAD OF A CIGARETTE: SHOULD THE FDA REGULATE ENERGY DRINKS?

I. INTRODUCTION

Law is merely the expression of the will of the strongest for the time being, and therefore laws have no fixity, but shift from generation to generation.

—Henry Brooks Adams¹

When a new American generation is born, innovation ensues; but, as progress advances, obstacles arise.² How the public handles these setbacks differentiates the United States from other nations.³ Morals, values, and beliefs transform with each new generation, and the American legal system adapts.⁴

To illustrate this principle, compare the sentiment Americans expressed toward tobacco usage during the World War I and World War II eras to the modern sentiment.⁵ Plainly stated, tobacco is no longer fashionable or sexy.⁶ Scientific evidence relating to the adverse health effects of tobacco usage and expensive anti-tobacco advertising campaigns largely account for the decline in tobacco use.⁷ Also, with the recent enactment of the Family Smoking Prevention and Tobacco

¹ THE NEW LAWYER'S WIT AND WISDOM: QUOTATIONS ON THE LEGAL PROFESSION, IN BRIEF 256 (Bruce Nash & Allan Zullo eds., 2001).

² See generally ERIC H. GREENBERG & KARL WEBER, GENERATION WE: HOW MILLENNIAL YOUTH ARE TAKING OVER AMERICA AND CHANGING OUR WORLD FOREVER 12-14 (2008) (discussing how the Millennial (We) Generation—individuals born between 1978 and 2000—is emerging as a powerful political and social force).

³ *Id.* at 12. According to Greenberg, “[g]reat leaders play an important role in shaping history. But an even greater role is played by the generations of ordinary people from whom the great leaders arise. Without those millions of people, sharing a common vision and ready to shape the future together, even great leaders can accomplish little.” *Id.*

⁴ *Id.* at 9. Regarding the greatness of American culture, Greenberg writes, “I have faith that with open, informed debate, Americans can use the system we inherited from the Founders to make the wisest long-term choices and get our country back on the track toward peace, prosperity, and freedom.” *Id.*

⁵ See MICHAEL RABINOFF, ENDING THE TOBACCO HOLOCAUST: HOW BIG TOBACCO AFFECTS OUR HEALTH, POCKETBOOK, AND POLITICAL FREEDOM—AND WHAT WE CAN DO ABOUT IT 74 (Barbara McNichol ed., 2006) (“Partly as a result of cigarette rationing in World War I and World War II, 47 percent of adult Americans were smokers by 1950.”).

⁶ See *id.* at 97 (providing the text of a statement by former U.S. Secretary of Department of Health and Human Services Donna E. Shalala regarding the trendiness of cigarettes).

⁷ See *infra* Part II.C (discussing the Family Smoking Prevention and Tobacco Control Act).

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Control Act ("FSPTCA"), tobacco use may diminish further.⁸ Consequently, the question arises, what new alluring product is seizing tobacco's position? The answer is energy drinks.⁹

Consumers throughout the world purchase millions of energy drinks daily, and indisputably, United States citizens lead in consumption of those beverages.¹⁰ This result is advantageous for domestic beverage manufacturers, but what about those who consume the beverages? Results of scientific studies vary, but recent research evidences that energy drinks can cause adverse health effects and even death to the unknowing consumer.¹¹ Some argue regulation of this industry is excessive, while others contend that regulation is necessary to limit caffeine content and inform the public of consumption risks.¹² Regardless, findings prompted several foreign nations to regulate energy drinks and influenced legislators in the United States to introduce bills with the intention of protecting the public health.¹³

Currently, the U.S. Food and Drug Administration ("FDA") holds little authority to regulate energy drinks because the Federal Food, Drug, and Cosmetic Act ("FDCA") categorizes the beverages as dietary supplements.¹⁴ For instance, if the FDA attempts to compel energy drink manufacturers to limit caffeine content or display new warning statements on the packaging, the manufacturers could challenge the

⁸ See *infra* Part II.C (discussing the Family Smoking Prevention and Tobacco Control Act and its anticipated effect on the tobacco industry).

⁹ This Note evaluates the similarities between the pharmacological and therapeutic effects of tobacco usage and energy drink consumption. These two consumer products compare readily because both create adverse health effects and attract young consumers. Tobacco manufacturers historically marketed their products to younger demographics by presenting the product as trendy or chic, and energy drink manufacturers are utilizing a similar marketing strategy. For many years, the populace remained unaware of the negative health consequences caused by tobacco, and currently, many are unaware of the effects of energy drink consumption. These similarities provide helpful insight as to the necessity for the increased regulation of energy drinks.

¹⁰ See *infra* notes 48–49 and accompanying text (specifying global and domestic sales figures of the rapidly expanding energy drink industry).

¹¹ See *infra* Part III.B (analyzing the efficacy of energy drink ingredients and evaluating the results of clashing scientific studies).

¹² See *infra* Part III.B (discussing the competing viewpoints as to whether regulation is prudent).

¹³ See *infra* notes 102–12 and accompanying text (describing the efforts of several United States legislators to regulate energy drinks as well as the successful and unsuccessful attempts by multiple foreign nations to regulate heavily caffeinated beverages).

¹⁴ See *infra* notes 54–61 and accompanying text (explaining why a manufacturer's marketing claims determine whether a product, such as an energy drink, is classified as a dietary supplement).

directive and would likely succeed.¹⁵ Without a congressional amendment to the FDCA, the FDA's regulatory authority regarding energy drinks may remain minimal.¹⁶

First, this Note provides a history of the FDA and a discussion of its congressional mandate to protect the public health and safety.¹⁷ In addition, Part II discusses the rapidly expanding energy drink industry and presents a foundation for dietary supplement regulation modeled after provisions of the FSPTCA.¹⁸ Part III analyzes the regulation of energy drinks, including pharmacological elements, economic theory, FDA jurisdiction concerns, and discord relating to the FDA's potential lack of resources.¹⁹ Part IV proposes amendments to the FDCA that will enable the FDA to regulate energy drinks.²⁰ More specifically, the first proposed amendment provides a statutory definition of an energy drink, and the second proposed amendment clearly grants the FDA the requisite power to regulate the manufacturing, marketing, and distribution of energy drinks.²¹

II. BACKGROUND

Heavily caffeinated energy drinks have addictive qualities similar to the nicotine found in cigarettes.²² This reality is creating speculation as to whether Big Energy Beverage is the new Big Tobacco and should thus be regulated similarly.²³ Part II discusses the FDA's mandate to regulate the manufacturing, marketing, and labeling of certain consumer products as well as a scientific and economic assessment of the rapidly expanding energy drink market.²⁴ Through enabling statutes, such as the FDCA, Congress afforded the FDA increased authority to protect the

¹⁵ See *infra* notes 70–72 and accompanying text (discussing circumstances where the FDA exceeded its statutory grant of authority).

¹⁶ See *infra* Part IV (proposing amendments to the FDCA that enable the FDA to regulate the manufacturing, marketing, and distribution of energy drinks).

¹⁷ See *infra* Part II (discussing the statutory creation of the FDA and its growing authority).

¹⁸ See *infra* Part II.B–C (discussing the global energy drink market and the FSPTCA).

¹⁹ See *infra* Part III (providing a comprehensive analysis of several elements that will influence the FDA's ability to regulate energy drinks).

²⁰ See *infra* Part IV (proposing statutory amendments to the FDCA).

²¹ See *infra* Part IV (proposing statutory amendments to the FDCA).

²² See *infra* Part III.B (detailing the addictive characteristics of caffeine).

²³ See *infra* Part II.C (providing an overview of tobacco regulation and its potential applicability to the energy drink industry).

²⁴ See *infra* Part II (discussing the FDA's mandate to regulate consumer products, such as tobacco and dietary supplements).

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public's health and safety by preventing adulterated, misbranded, or untested consumer products from reaching the interstate market.²⁵

More specifically, Part II.A discusses the essential legislation and judicial decisions that are the pillars of the FDA's mandate.²⁶ Next, Part II.B offers an economic overview of the energy drink market and an explanation of why the FDA lacks the requisite power to oversee the energy drink industry.²⁷ Part II.C outlines the foundation for a regulatory scheme applicable to energy drinks based on the framework of the FSPTCA with an overview of the new law's social and economic impact in the United States.²⁸ Part II.D examines the regulation of energy drinks in foreign countries and energy drink regulatory bills proposed by legislators in the United States.²⁹ Finally, this Part examines numerous and lengthy acts and amendments through which Congress progressively broadened the FDA's authority to regulate in order to keep Americans safe from dangerous products.³⁰

A. *The FDA's Authority to Regulate Food Products*

In 1906, Congress passed the Pure Food and Drugs Act ("Pure Food Act"), which was the first major piece of legislation making it unlawful for a person to adulterate or misbrand any drug or food.³¹ Section 4 of

²⁵ See Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007); Dietary Supplement Health and Education Act, Pub. L. No. 103-417, 108 Stat. 4325 (1994); Drug Amendments of 1962, Pub. L. No. 87-781, § 101, 76 Stat. 780 (1962) (codified as amended at 21 U.S.C. § 351 (2006)); Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 321 (2006)); Pure Food and Drugs Act, Pub. L. No. 62-301, 37 Stat. 416 (1912) (amending the 1906 Act); Pure Food and Drugs Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed by 21 U.S.C. § 329(a)); see also *United States v. Sullivan*, 332 U.S. 689, 696-97 (1948) (discussing the FDA's authority to prohibit misbranded articles to be transported in interstate commerce); *United States v. Dotterweich*, 320 U.S. 277, 278, 285 (1943) (holding that a president of a corporation may be found guilty for violating the FDCA, independent of the corporation's guilt).

²⁶ See *infra* Part II.A (discussing the creation of the FDA through enabling legislation and its purpose presented through legislative history).

²⁷ See *infra* Part II.B (providing an industry analysis and description of the FDA's power to regulate dietary supplements and health products).

²⁸ See *infra* Part II.C (discussing the scope of the Family Smoking Prevention and Tobacco Control Act and examining the financial and social effects of the Act regarding private industries and the American populace).

²⁹ See *infra* Part II.D (providing a description of the regulation of energy drinks in foreign countries and the movement in America by legislators and academics to regulate the energy drink industry).

³⁰ See *infra* Part II.A (discussing the creation of the FDA and expansion of regulatory authority enabled by multiple statutes passed by Congress).

³¹ See Pure Food and Drugs Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed by 21 U.S.C. § 329(a)) (ensuring that products are labeled correctly and paving the way for the

the Pure Food Act authorized the Bureau of Chemistry to perform examinations of the allegedly substandard food or drug article.³² If the food or drug article was deemed misbranded or adulterated, the Bureau would first inform the responsible party. After the party had an opportunity to be heard and if a violation still existed, the Bureau would notify the proper United States District Attorney of the violation.³³ The Pure Food Act provided for removal of the misbranded or adulterated article but failed to include a provision regulating false claims of effectiveness.³⁴ Although the Pure Food Act was amended in 1912 to remedy this particular omission of misbranding regulation, a new act was passed two decades later, fashioning a new agency armed with a congressional mandate to regulate.³⁵

Congress officially created the FDA in 1938 by passing the FDCA.³⁶ The chief purpose of the FDCA is to forbid “the movement in interstate

formation of the FDA). Congress enacted the Pure Food Act in 1906 “in response to criticism by the Progressive movement of widespread food and drug impurities [to] establish[] liability for the manufacture of adulterated or misbranded drugs.” Steven R. Salbu, *Regulation of Drug Treatments for HIV and AIDS: A Contractarian Model of Access*, 11 YALE J. ON REG. 401, 406 (1994) (footnotes omitted) (detailing the history of the FDA approval process).

³² Pure Food and Drugs Act § 4. See Salbu, *supra* note 31, at 407 (discussing the creation of the Pure Food and Drugs Act).

³³ Pure Food and Drugs Act § 4. See Salbu, *supra* note 31, at 406–07 (providing a brief background regarding the Pure Food Act and discussing the primary purpose of why Congress passed the Pure Food Act). The Pure Food Act held manufacturers responsible for the safety (or lack thereof) of their products and it loosely required them to monitor their products for errors in “strength, quality, and purity,” and to accurately label the products. *Id.* at 407.

³⁴ See generally Deborah F. Buckman, Annotation, *Remedies Available for Violations of Federal Food, Drug, and Cosmetic Act (FDCA)*, 25 A.L.R. FED. 2D 431 (2008) (providing a general overview of the Federal Food, Drug, and Cosmetic Act). In 1911, in *United States v. Johnson*, 221 U.S. 488, 498 (1911), the Supreme Court held that although the Pure Food Act prohibited mislabeling of drug ingredients, it did not forbid other kinds of fraudulent claims made on product labels. “Moreover, the 1906 Act failed to enumerate standards or specific methods of pre-market testing that would prevent adulteration, or to provide any mechanism for centralized regulatory approval of new drugs.” Salbu, *supra* note 31, at 407 (discussing the primary purposes of why Congress passed the Pure Food Act).

³⁵ Sherley Amendment of 1912, Pub. L. No. 62-352, 37 Stat. 416, 416 (1912). The Pure Food Act of 1912 amended Section 8 of the Pure Food Act of 1906 by adding a third paragraph, which states: “[i]f its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent.” *Id.* Congress passed the Pure Food Act of 1912 following *United States v. Johnson*, where the Supreme Court held that the statute does not cover misleading statements on labels. *Johnson*, 221 U.S. at 498–99.

³⁶ Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 321 (2006)). The FDCA required that drug manufacturers provide proof that their products were safe before they could be marketed

commerce of adulterated and misbranded food, drugs, devices, and cosmetics.”³⁷ Prior to 1938, the federal government did not require manufacturers to perform pre-market reviews of their products before selling them to the public.³⁸ In 1962, however, Congress amended the FDCA following a thalidomide drug tragedy that generated thousands of birth defects.³⁹ These amendments require the FDA to ensure that manufacturers of drugs demonstrate that their products are effective and safe through “substantial evidence.”⁴⁰ In addition, the amendments require the manufacturer to properly label their products and prohibit the manufacturer from misleading consumers through false statements contrary to test results.⁴¹

In the 1970s, the failure of medical devices and thousands of tort claims prompted Congress to pass the Medical Device Amendments of 1976 (“MDA”), which imposed heightened government oversight.⁴² The

to the public. See *Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach*, 495 F.3d 695, 705–06 (D.C. Cir. 2007) (discussing the conception of the FDA). In his Yale law journal article, Steven Salbu describes drug tragedies and congressional reaction to those tragedies. Salbu, *supra* note 31, at 407. For instance,

[i]n 1937, the shortcomings of the 1906 Act were demonstrated by the tragedy brought on by the use of Elixir Sulfanilamide, marketed by the drug manufacturer Massengill. While the “elixir” was merely a liquid version of a drug already available in pill form, the solvent used in the solution had not been tested for safety. Its toxicity resulted in 107 deaths. Under the 1906 Act, Massengill was fined \$26,100 for product mislabeling.

Id. Most importantly, the FDCA required prospective manufacturers to file applications for the sale of new drugs with the Secretary of Agriculture, “describing drug components and composition, methods of production control, and proposed labeling language.” *Id.* at 408.

³⁷ Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 321 (2006)); see also *supra* note 36 (providing a background of the FDCA).

³⁸ See Buckman, *supra* note 34 (providing a historical analysis of the FDCA).

³⁹ Drug Amendments of 1962, Pub. L. No. 87-781, § 101, 76 Stat. 780, 780–96 (1962) (codified as amended at 21 U.S.C. § 351 (2006)). Similar to how the Elixir Sulfanilamide disaster inspired the 1938 Act, the Kefauver-Harris Amendments (“1962 Amendments”) resulted from a thalidomide tragedy. Salbu, *supra* note 31, at 408. German pharmaceutical manufacturer, Grünenthal, marketed Thalidomide as a sedative for pregnant women. *Id.* at 408, n.41. Consumption of the drug caused birth defects in thousands of infants. *Id.* “The 1962 Amendments required more rigorous pre-approval drug testing than was required under the 1938 Act, instituting a series of clinical testing ‘phases’ that comprise the norm under current law.” *Id.* at 408.

⁴⁰ Drug Amendments of 1962 § 101.

⁴¹ *Id.*

⁴² Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976); Riegel v. Medtronic, Inc., 552 U.S. 312, 315–16 (2008) (describing reasons for enactment of the MDA). Congress enacted the MDA “[t]o amend the Federal Food, Drug, and Cosmetic Act to provide for the safety and effectiveness of medical devices intended for human use, and for other purposes.” Medical Device Amendments of 1976, 90 Stat. at 539. “A series of high-

FDA's regulatory strength continued to grow subsequent to the enactment of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), enforced by the Center for Food Safety and Applied Nutrition ("CFSAN").⁴³ Once more, Congress amended the FDCA by passing the Food and Drug Administration Amendments of 2007, and in doing so, permitted the FDA the authority to require manufacturers of previously approved products to adhere to modern FDCA regulation.⁴⁴

profile medical device failures that caused extensive injuries and loss of life propelled adoption of the MDA." *Riegel*, 552 U.S. at 336 (Ginsburg, J., dissenting). The most conspicuous failure was the Dalkon Shield intrauterine device used by approximately 2.2 million women in the United States between 1970 and 1974. *Id.*; *In re N. Dist. of Cal., Dalkon Shield IUD Prods. Liab. Litig.*, 693 F.2d 847, 848 (9th Cir. 1982). The Dalkon Shield was aggressively promoted as a safe and effective form of birth control and was linked to sixteen deaths and twenty-five miscarriages by mid-1975. H.R. REP. NO. 94-853, at 8 (1976). By early 1976, "more than 500 lawsuits seeking compensatory and punitive damages totaling more than \$400 million" were filed. *Riegel*, 552 U.S. at 336. In *Riegel*, Justice Ginsburg stated, "[g]iven the publicity attending the Dalkon Shield litigation and Congress' awareness of the suits at the time the MDA was under consideration, I find informative the absence of any sign of a legislative design to preempt state common-law tort actions." *Id.* at 336-37.

⁴³ Dietary Supplement Health and Education Act, Pub. L. No. 103-417, 108 Stat. 4325 (1994); see *infra* note 57 (providing the statutory requirements for a product to be classified as a dietary supplement). The DSHEA was designed to afford the FDA procedural provisions applicable only to dietary supplements. Peter Barton Hutt, *FDA Statutory Authority to Regulate the Safety of Dietary Supplements*, 31 AM. J.L. & MED. 155, 156 (2005) [hereinafter Hutt, *FDA Statutory Authority to Regulate the Safety of Dietary Supplements*]. The procedural provisions include the following:

[f]irst, DSHEA specifically places the burden of proof in a civil enforcement action relating to the safety of a dietary supplement on [the] FDA. . . . Second, the court must decide the issue of adulteration of a dietary supplement on a de novo basis. . . . Third, [the] FDA must provide a person an opportunity to present both oral and written views at least ten days before the agency refers a matter to the Department of Justice for civil court enforcement.

Id. See *About the Center for Food Safety and Applied Nutrition*, FDA, <http://www.fda.gov/AboutFDA/CentersOffices/CFSAN/default.htm> (last visited Sept. 12, 2010) (providing general information about the CFSAN); *CFSAN – What We Do*, FDA, <http://www.fda.gov/AboutFDA/CentersOffices/CFSAN/WhatWeDo/default.htm> (last visited Sept. 12, 2010) (detailing the CFSAN's statutory obligations); FOOD & DRUG ADMINISTRATION, DETAIL OF FULL-TIME EQUIVALENT (FTE) EMPLOYMENT PROGRAM LEVEL, available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM153892.pdf> (last visited Oct. 6, 2010) (providing a detailed report of FDA employment figures); FOOD & DRUG ADMINISTRATION, FY 2010 ALL PURPOSE TABLE—BUDGET AUTHORITY, available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM153876.pdf> (last visited Oct. 6, 2010) (providing an itemized FDA budget allocation for 2010).

⁴⁴ See Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007) (codified as amended at 21 U.S.C. § 301 (2006)). Congress amended the FDCA "to revise and extend the user-fee programs for prescription drugs and for medical devices, to enhance the postmarket authorities of the Food and Drug Administration with

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As a result of these acts and amendments, the FDA has the cumbersome task of ensuring that food, drug, and cosmetic products are of high integrity so that consumers can trust the products are safe without question.⁴⁵

B. *The Rapidly Expanding Energy Drink Industry & the FDA's Lack of Regulatory Authority*

Energy drinks commonly include additives, such as caffeine, guarana, taurine, ginseng, ginkgo, and glucuronolactone that are intended to improve cognitive abilities, mental focus, and muscle endurance.⁴⁶ The market for energy drinks in the United States began in

respect to the safety of drugs." *Id.* Congress amended the FDCA consequent to "[a] report from the Institute of Medicine suggest[ing] the FDA has not effectively monitored the safety of pharmaceuticals subsequent to initial approval for use and recommend[ing] changes to the process by which the FDA monitors postmarketing-adverse-event-surveillance." Leslie Kushner, Note, *Incentivizing Postmarketing Pharmaceutical Product Safety Testing with Extension of Exclusivity Periods*, 19 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 519, 520 (2009). See generally INST. OF MED., THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC (Alina Baciu, Kathleen Stratton & Sheila P. Burke eds., 2007).

⁴⁵ See *supra* note 36 (explaining the history of the FDCA); see also Peter Barton Hutt, *Recent Developments: The State of Science at the Food and Drug Administration*, 60 ADMIN. L. REV. 431, 434-36 (2008) [hereinafter Hutt, *The State of Science*] (providing a history of the FDA and the products it regulates); FDA, FISCAL YEAR 2010 CONGRESSIONAL JUSTIFICATION, EXECUTIVE SUMMARY: INTRODUCTION AND MISSION, available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM153491.pdf> (last visited Sept. 12, 2010) ("FDA affects the lives of every American every day. Each year, consumers spend nearly \$1.5 trillion on FDA-regulated products. This represents twenty percent of all consumer expenditures.").

⁴⁶ See generally Michele Simon & James Mosher, *Alcohol, Energy Drinks, and Youth: A Dangerous Mix*, MARIN INST., 2007, available at <http://www.marininstitute.org/alcopops/resources/EnergyDrinkReport.pdf> (last visited Sept. 12, 2010) [hereinafter Simon & Mosher] (discussing the purpose of an energy drink). Energy drink companies, such as the industry-leading Red Bull, attribute their product's stimulant effect to the interaction of such ingredients. *Id.* at 9. On its website, Red Bull describes its product as a "functional beverage with a unique combination of ingredients . . . specially developed for times of increased mental and physical exertion." *Red Bull Energy Drink*, RED BULL USA, http://www.redbullusa.com/cs/Satellite/en_US/Red-Bull-Home/Products/011242746208542 (last visited Sept. 25, 2010). Additionally, Red Bull states that its formula "increases performance[,] increases concentration and reaction speed[,] improves vigilance[,] improves the emotional status[,] and] stimulates metabolism." *Id.* "The term *energy drink* refers to a beverage that contains caffeine in combination with other ingredients such as taurine, guarana, and B vitamins, and that claims to provide its consumers with extra energy. This term was created by [beverage] companies . . . and is not recognized by the [FDA] or the [USDA]." Karrie Heneman & Sheri Zidenberg-Cherr, *Nutrition and Health Info Sheet: Energy Drinks*, ANR COMM'N. SERVS., PUBL'N 8265 (2007), available at <http://ucanr.org/freepubs/docs/8265.pdf> (last visited Sept. 12, 2010). Energy drink

1997 with the introduction of the Austrian-produced Red Bull.⁴⁷ From 2002 to 2007, the energy drink market grew by an estimated 440% and

companies commonly make the following effective functional claims regarding the ingredients of their products:

[C]arnitine: improves endurance, increases fat metabolism; protects against cardiovascular disease[;]

[G]lucuronolactone: promotes excretion of toxins and protects against cancer[;]

[G]uarana: increases energy, enhances physical performance and promotes weight loss[;]

[I]nositol: decreases triglyceride and cholesterol levels, lowering risk of cardiovascular disease[;]

[P]anax [G]inseng: speeds illness recovery; improves mental, physical and sexual performance; controls blood glucose and lowers blood pressure[;]

[S]uper [C]itramax: suppresses appetite, resulting in weight loss[;]

[T]aurine: lowers risk of diabetes, epilepsy, and high blood pressure[; and]

[Y]ohimbine HCl: improves sexual performance and promotes weight loss.

Id. at 2. (footnotes omitted) (formatting omitted). Because energy drinks are quite new in America, there is limited scientific evidence regarding the interaction of ingredients; however, evidence of efficacy of individual ingredients are as follows:

[C]arnitine: [t]here is no clinical evidence that carnitine use is effective for increased endurance or weight loss, but it may protect against heart disease.

[G]lucuronolactone: [s]cientific evidence does not exist to support claims regarding the efficacy of glucuronolactone.

[G]uarana: [a] major component of guarana is caffeine. Caffeine consumption has been associated with increased energy, enhancement of physical performance, and suppressed appetite.

[I]nositol: [s]cientific evidence does not exist to support claims regarding the efficacy of inositol.

[P]anax [G]inseng: [s]cientific evidence does not exist to support claims regarding the efficacy of panax ginseng.

[S]uper [C]itramax: [t]here is scientific evidence that use of this supplement decreases food consumption.

[T]aurine: [c]linical evidence is insufficient to show that taurine is effective in treating diabetes or epilepsy, but it may lower blood pressure.

[Y]ohimbine HCl: [a]lthough yohimbine HCl may increase blood flow to sexual organs, there is no evidence that it increases sexual arousal. It may be effective at treating erectile dysfunction. Currently no evidence exists to support the claim that use of this supplement leads to weight loss.

Id. (footnotes omitted) (formatting omitted). See *Caffeine Myths and Facts*, WEBMD, <http://www.webmd.com/balance/caffeine-myths-and-facts?page=3> (last visited Sept. 12, 2010) (describing positive and negative effects of energy drink consumption).

⁴⁷ Simon & Mosher, *supra* note 46, at 3. Energy drink sales have exploded since the introduction of Red Bull in 1997. *Id.* The Center for Science in the Public Interest compiled

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included more than 500 energy drink companies worldwide.⁴⁸ As a result of this extremely rapid expansion, annual energy drink sales in the United States alone totaled a lofty \$6.6 billion.⁴⁹ Additionally, analysts predict U.S. energy drink sales to top \$9 billion by 2011.⁵⁰ This accomplishment is likely the result of non-paternalistic regulation, aggressive advertising, and the promotion of energy drinks as performance enhancers to a target market of young adults.⁵¹ In order to

caffeine content (mg) of food and drug products on its website, and caffeine content of top-selling energy drinks are as follows:

Spike Shooter 8.4 oz., 300; Cocaine 8.4 oz., 288; Monster Energy 16 oz., 160; Full Throttle 16 oz., 144; Rip It, all varieties 8 oz., 100; Enviga 12 oz., 100; Tab Energy 10.5 oz., 95; SoBe No Fear 8 oz., 83; Red Bull 8.3 oz., 80; Red Bull Sugarfree 8.3 oz., 80; Rockstar Energy Drink 8 oz., 80; SoBe Adrenaline Rush 8.3 oz., 79; Amp 8.4 oz., 74; Glaceau Vitamin Water Energy Citrus 20 oz., 50; SoBe Essential Energy, Berry or Orange 8 oz., 48.

Caffeine Content of Food & Drugs, CTR. FOR SCI. IN THE PUB. INTEREST, Sept. 2007, available at <http://www.cspinet.org/new/cafchart.htm> (last visited Sept. 12, 2010) (formatting omitted).

⁴⁸ JORGE S. OLSON & CARLOS LOPEZ, *BUILD YOUR BEVERAGE EMPIRE* 27 (Gloria L. Olson ed., 2009).

⁴⁹ *Id.*; see Kevin Mayhood, *Jolted by Studies, Researchers Want Caffeine Labels on Energy Drinks*, COLUMBUS DISPATCH, Sept. 24, 2008, http://www.dispatch.com/live/content/local_news/stories/2008/09/24/drink_label.ART_ART_09-24-08_A1_UHBDNBA.html (reporting why researchers want energy drink regulation); Simon & Mosher, *supra* note 46, at 3 (providing a synopsis of the energy drink market share); Elizabeth Weise, *Petition Calls for FDA to Regulate Energy Drinks: Critics Want Caffeine Levels Listed, Limited*, USA TODAY, Oct. 22, 2008, at 6D (describing energy drink sales figures). Since 2006, BevNet has published an annual comprehensive compilation of energy drink brands and market analysis of the previous year. *BEVNET Energy Drink Buyer's Guide 2007*, BEVERAGE SPECTRUM, available at http://www.bevnet.com/news/2007/04-10-2007-energy_drink_guide_free.asp. The market share of the top five energy drinks in 2007 are as follows: Red Bull, 42.6%; Monster, 14.4%; Rockstar, 11.4%; Full Throttle, 6.9%; Sobe No Fear, 5.4%. *Id.* The market share of the top five energy drinks in 2008 are as follows: Red Bull, 35.2%; Monster, 27.3%; Rockstar, 11.1%; Full Throttle, 6.6%; Amp, 5.1%. *2008 Energy Drink Guide*, BEVERAGE SPECTRUM, available at <http://www.bevnet.com/news/2008/4-14-2008-EDG.asp>. The market share of the top five energy drinks (currently in 2009) are as follows: Red Bull, 40.1%; Monster, 16.2%; Rockstar, 11.0%; Amp, 4.0%; Monster Java, 2.6%. *2009 Energy Drink Guide*, BEVERAGE SPECTRUM, available at <http://www.bevnet.com/news/2009/4-13-2009-free-energy-drink-guide>. The 2009 analysis separates market share percentage by each individual variety and flavor of energy drink, not just the brand name as the 2006 and 2007 analyses provide.

⁵⁰ OLSON & LOPEZ, *supra* note 48, at 27.

⁵¹ See Weise, *supra* note 49, at 6D ("The drinks are advertised as able to increase endurance, reaction time and concentration, with names such as Full Throttle, Amp Energy and No Fear."). *But cf.* TEVFIK F. NAS, *COST-BENEFIT ANALYSIS: THEORY AND APPLICATION* 1-2 (Diane S. Foster ed., 1996) (discussing cost-benefit analyses consumers perform every day); *THE POLITICS OF REGULATION: INSTITUTIONS AND REGULATORY REFORMS FOR THE AGE OF GOVERNANCE* 36 (Jacint Jordana & David Levi-Faur eds., 2004) (inferring that consumers are competent in their assessment of a product and whether to purchase it); STEVEN D.

reach this target audience, energy drink companies commonly market their products at the grassroots level to form one-on-one relationships with the consumer.⁵² Energy drink companies market and sell these drinks as dietary supplements, not as soft drinks such as Coca-Cola or Pepsi.⁵³

SODERLIND, CONSUMER ECONOMICS: A PRACTICAL OVERVIEW 245 (2001) (providing an economic and marketing perspective to government regulation); Gerald Dworkin, *Paternalism*, in THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY (Edward N. Zalta ed., 2006), available at <http://plato.stanford.edu/entries/paternalism/> (last visited Sept. 12, 2010) (defining paternalistic regulation); Edward L. Glaeser, *Homo Economicus, Homo Myopicus, and the Law and Economics of Consumer Choice: Paternalism and Psychology*, 73 U. CHI. L. REV. 133, 133 (2006) (providing an overview of regulation theory); Christine Jolls & Cass R. Sunstein, *Debiasing Through Law*, 35 J. LEGAL STUD. 199, 200-01 (2006) (discussing the varying degrees of paternalistic regulation); Michael A. McCann, *Economic Efficiency and Consumer Choice Theory in Nutritional Labeling*, 2004 WIS. L. REV. 1161, 1175-78 (2004) (explaining the consumer choice theory in terms of food purchases); Mario J. Rizzo & Douglas Glen Whitman, *Little Brother is Watching You: New Paternalism on the Slippery Slopes*, 51 ARIZ. L. REV. 685, 689-91 (2009) (presenting policy arguments regarding why consumers are affected by government regulation); *Theory of Consumer Choice*, BASIC ECONOMICS, <http://www.basiceconomics.info/theory-of-consumer-choice.php> (last visited Sept. 12, 2010) (explaining that consumers combine budget constraints and preferences when choosing certain products).

⁵² See Simon & Mosher, *supra* note 46, at 4 (describing energy drink advertising and marketing strategies); Weise, *supra* note 49 (providing examples of advertising claims). These relationships are “gained through events, extreme sports sponsorships, [and] Internet interactions For example, the Monster brand’s ‘ambassadors’ give away free samples at sporting events, concerts, and other teen venues. Red Bull owns teams such as the New York Red Bulls soccer team and plans to start its own NASCAR team.” Simon & Mosher, *supra* note 46, at 4. Other energy drink manufacturers, such as Full Throttle, Amp Energy, and Cocaine target their products to young males and “promote the psychoactive, performance-enhancing, and stimulant effects of energy drinks and appear to glorify drug use.” Chad J. Reissig et al., *Caffeinated Energy Drinks – A Growing Problem*, DRUG ALCOHOL DEPENDENCE (2008), available at <http://www.hopkinsmedicine.org/bin/w/y/Griffiths.pdf>. Even more extreme is the energy drink “Blow,” which is “packaged in glass vials and shipped with a mirror and plastic credit cards in an apparent attempt to model cocaine use.” *Id.* “Recently, the FDA claimed jurisdiction over both ‘Cocaine’ and ‘Blow,’ informing the companies that their products were marketed as an alternative to an illicit street drug, not a dietary supplement, and subject to regulation as a drug.” *Id.* (citations omitted).

⁵³ Kelly Brewington, *High-Energy Drink Jitters: Hopkins Researchers Report on Possible Caffeine Risks*, BALT. SUN, Sept. 24, 2008, at 1A. According to Senior Staff Attorney Ilene Heller, “[i]f a caffeinated energy drink is marketed as [conventional] food, it would come under food additive regulations and thus have to adhere to FDA’s caffeine limit in soda.” *Study Urges FDA to Step Up Oversight of Caffeine in Supplements*, 14 FDA WEEK 39, 39 (Sept. 26, 2008) (providing proponents’ argument for FDA energy drink regulation). The FDA has set a caffeine content limit on soft drinks at sixty-eight milligrams for twelve fluid ounces. See Michele Morgan Bolton, *Some Schools Put the Lid on High-Caffeine Beverages: Say Energy Drinks Pose Health Risk Packed With Caffeine*, BOS. GLOBE, July 25, 2009, at 1 (providing data regarding caffeine content of soft drinks and energy drinks).

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Current governing statutes afford the FDA little authority to regulate energy drinks because the FDCA treats energy drinks as dietary supplements.⁵⁴ The FDA classifies food products as either dietary supplements or conventional foods based on the manufacturer's representations and marketing claims.⁵⁵ Strangely, however, food products are classified not by their ingredients, composition, safety, or nutritional value, but rather by the producer's marketing claims.⁵⁶ The Dietary Supplement Health and Education Act thus effectively constrains the FDA's power to regulate by creating a subcategory of food—dietary supplements.⁵⁷ If a manufacturer markets its product as a dietary supplement, the DSHEA requires that the product's label conspicuously state that it is a dietary supplement and not a conventional food.⁵⁸ However, an effect of this congressionally created subcategory is that a food product can concurrently be classified as both

⁵⁴ See Michael McCarthy, *Energy Drink Abuse Worries Health Pros: Big Quantities Might Result in Problems*, USA TODAY, July 2, 2009, at 6C (discussing the FDA's lack of power to regulate dietary supplements like energy drinks). FDA spokeswoman Susan Cruzan stated, "[w]e have no guidance or regulations that govern the formulation of energy drinks Under current law, the manufacturer is responsible for ensuring that its products are safe and such products do not require FDA premarket review or approval." *Id.*

⁵⁵ See 21 U.S.C. § 321(ff) (2006) (providing the statutory definition of a dietary supplement); Hutt, *FDA Statutory Authority to Regulate the Safety of Dietary Supplements*, *supra* note 43, at 166 (stating procedural provisions of the DSHEA).

⁵⁶ See Hutt, *FDA Statutory Authority to Regulate the Safety of Dietary Supplements*, *supra* note 43, at 166 (discussing why a food product may be considered a dietary supplement); Suzan Onel, *Dietary Supplements: A Definition That is Black, White, and Gray*, 31 AM. J.L. & MED. 341, 348 (2005) (claiming that the DSHEA is a lenient and ambiguous statute).

⁵⁷ See Barbara A. Noah, *Foreword: Dietary Supplement Regulation in Flux*, 31 AM. J.L. & MED. 147, 148 (2005) (explaining Congress's intention in drafting the DSHEA). 21 U.S.C. § 201(ff)(1) of the FDCA, as augmented by DSHEA, defines a "dietary supplement" as a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

- (A) a vitamin;
- (B) a mineral;
- (C) an herb or other botanical;
- (D) an amino acid;
- (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
- (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).

21 U.S.C. § 201(ff)(1) (2006). See Hutt, *FDA Statutory Authority to Regulate the Safety of Dietary Supplements*, *supra* note 43, at 159 (discussing the statutory overlap regarding the definition of dietary supplements and conventional foods).

⁵⁸ See Hutt, *FDA Statutory Authority to Regulate the Safety of Dietary Supplements*, *supra* note 43, at 166 (discussing labeling requirements for dietary supplements and conventional foods).

a conventional food and as a dietary supplement.⁵⁹ Likewise, two products containing the exact same vitamins and minerals can be classified as either a dietary supplement or conventional food product depending on marketing claims.⁶⁰ Simply changing the label can remove a product from one category and place it in the other.⁶¹ Although it may appear that the FDA's regulatory authority of dietary supplements is lacking, the FDA nonetheless mandates producers of dietary supplements to abide by the labeling guidelines promulgated by 21 C.F.R. § 101.36.⁶²

The DSHEA permits dietary supplement manufacturers to market their products without receiving any pre-market authorization from the FDA.⁶³ Thus, as long as a manufacturer marketed its "new dietary ingredient" ("NDI") before October 15, 1994, it could sell its dietary supplement without FDA approval.⁶⁴ The DSHEA assumes that individual components of a whole food product cannot cause harm, even when ingested in large quantities.⁶⁵ Ultimately, however, the manufacturer's "product definition, product safety, nutritional support claims, and labeling" determine the extent of the FDA's regulatory power.⁶⁶ Although the FDA's authority to regulate dietary supplements and conventional foods is relatively weak, the FDA possesses considerably broader authority to control the tobacco industry.⁶⁷

⁵⁹ *Id.* at 159.

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² 21 C.F.R. § 101.36 (2006); Hutt, *FDA Statutory Authority to Regulate the Safety of Dietary Supplements*, *supra* note 43, at 166. "A product that is explicitly labeled as a dietary supplement must bear the 'Supplement Facts' box on the label, in accordance with FDA regulations promulgated under the authority of DSHEA." *Id.* at 166. However, "[a] food that is not explicitly labeled as a dietary supplement on the principal display panel of the label must instead bear the 'Nutrition Facts' box in accordance with regulations promulgated by FDA under the authority of the Nutrition Labeling and Education Act of 1990." *Id.* (footnotes omitted).

⁶³ See Noah, *supra* note 57, at 149 (defining "dietary supplement" as stated in the DSHEA).

⁶⁴ *Id.* However, if the manufacturer marketed the NDI after October 15, 1994, the company must file a notification with the FDA at least seventy-five days prior to market introduction, which provides the basis for the manufacturer's conclusion that the supplement is reasonably safe and must demonstrate only that there is a history of use or other evidence of safety. *Id.* (internal quotation marks omitted). See 21 U.S.C. § 350b(a)(2) (2006) (providing safety guidelines for dietary supplements).

⁶⁵ Peter J. Cohen, *Science, Politics, and the Regulation of Dietary Supplements: It's Time to Repeal DSHEA*, 31 AM. J.L. & MED. 175, 176 (2005).

⁶⁶ Jennifer Kay Braman, Note, *Food for Sport or Faustian Bargain: Regulating Performance Enhancing Dietary Supplements*, 47 CLEV. ST. L. REV. 417, 431 (1999).

⁶⁷ See *infra* Part II.C (discussing the Family Smoking Prevention and Tobacco Control Act of 2009); see also *Chevron, U.S.A., Inc. v. Nat'l Res. Def. Council, Inc.*, 467 U.S. 837

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C. *The Family Smoking Prevention and Tobacco Control Act of 2009*

Amidst the fervor of President Obama's election, Congress passed a law granting the FDA extensive authority to regulate a sector not far removed from the energy drink business—the tobacco industry.⁶⁸ On June 22, 2009, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act (“FSPTCA”), which now grants the FDA the broad power to regulate the manufacturing, marketing, and distribution of tobacco products.⁶⁹

Some academics contend that in the last forty years, the FDA was creative in interpreting its own statutory authority.⁷⁰ In the early 1970s, top FDA officials offered the opinion that the FDCA represents a “broad ‘constitution’ authorizing the FDA to protect the public health by any

(1984) (providing a two-part test to determine whether an agency properly interpreted its enabling statute); Nathan Alexander Sales & Jonathan H. Adler, *The Rest is Silence: Chevron Deference, Agency Jurisdiction, and Statutory Silences*, 2009 U. ILL. L. REV. 1497, 1513–15 (2009) (providing case law that challenged the FDA's scope of authority under the FDCA); Craig A. Conway, *FDA Gains Regulatory Authority over Tobacco*, HEALTH LAW PERSPECTIVES, July 2009, available at [http://www.law.uh.edu/healthlaw/perspectives/2009/\(CC\)%20Tobacco.pdf](http://www.law.uh.edu/healthlaw/perspectives/2009/(CC)%20Tobacco.pdf) (discussing the FSPTCA and the FDA's expanded authority to regulate tobacco).

⁶⁸ See *infra* note 74 and accompanying text (providing the purpose of the Family Smoking Prevention and Tobacco Control Act).

⁶⁹ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified as amended at 15 U.S.C. § 1333 (2006 & Supp. 2009)). Congress passed the FSPTCA “[t]o protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products.” *Id.*; see also *Hunter v. Philip Morris USA*, 582 F.3d 1039, 1046–48 (9th Cir. 2009) (discussing whether state law claims are preempted by congressional policy).

⁷⁰ See Lars Noah & Barbara A. Noah, *Nicotine Withdrawal: Assessing the FDA's Effort to Regulate Tobacco Products*, 48 ALA. L. REV. 1, 7 (1996) (alleging that the FDA may be interpreting its statutory authority to regulate tobacco too broadly); see also, e.g., *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126 (2000) (deciding whether Congress intended for the FDA to regulate tobacco under the FDCA); 62 *Cases of Jam v. United States*, 340 U.S. 593, 600 (1951) (“In our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop.”); *Se. Minerals, Inc. v. Harris*, 622 F.2d 758, 767 (5th Cir. 1980) (criticizing the FDA's “bureaucratic hubris that confuses abuse of power with reason”); *United States v. Parkinson*, 240 F.2d 918, 921 (9th Cir. 1956) (“The record of the past few decades is replete with examples of the tendency of executive agencies to expand their field of operations. A passion and a zeal to crusade affects their operations.”); H. Thomas Austern, *Philosophy of Regulation: A Reply to Mr. Hutt*, 28 FOOD DRUG COSM. L.J. 189, 191 (1973) (criticizing the suggestion that “a well-motivated administrative agency can legally do what it alone deems desirable unless Congress has in advance specifically prohibited it”); James D. Poliquin, Comment, *The Incremental Development of an Extra-Statutory System of Regulation: A Critique of Food and Drug Administration Regulation of Added Poisonous and Deleterious Substances*, 33 ME. L. REV. 103, 103 (1981) (“[T]he agency has chosen to take advantage of the statute's ambiguity to enhance its regulatory powers, often assigning strained interpretations of the statute to advance the agency's perceived goals.”).

necessary and proper means, rather than a limited and precise delegation of Congress' legislative power."⁷¹ In many cases, courts give deference to the FDA's statutory authority and do not challenge its interpretation of regulations; however, the same cannot be said for tobacco regulation.⁷²

Preceding ratification of the FSPTCA, the majority of legislative proposals to control the tobacco industry were in the form of tax increases, advertising bans, or warning labels.⁷³ The FSPTCA heightened the FDA's ability to regulate the tobacco industry in that it could now control the manufacturing, marketing, and distribution of tobacco products.⁷⁴ On March 3, 2009, Representative Henry Waxman of

⁷¹ Noah & Noah, *supra* note 70, at 7–8; see Peter Barton Hutt, *Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act*, 28 FOOD DRUG COSM. L.J. 177, 178 (1973) [hereinafter Hutt, *Philosophy of Regulation*] (Hutt writes, "the Act must be regarded as a constitution. . . . The mission of the [FDA] is to implement [its fundamental] objectives through the most effective and efficient controls that can be devised"). See also *United States v. Dotterweich*, 320 U.S. 277, 280 (1943) (suggesting that the FDCA is "a working instrument of government and not merely as a collection of English words").

⁷² See generally Hutt, *Philosophy of Regulation*, *supra* note 71, at 178–79. See, e.g., *Miss. Power & Light Co. v. Miss. ex rel. Moore*, 487 U.S. 354, 386 (1988) (Brennan, J., dissenting) ("Our agency deference cases have always been limited to statutes the agency was 'entrusted to administer.'") (quoting *Chevron*, 467 U.S. at 844).

⁷³ See Shaukat Karjeker, *Federal Preemption of Cigarette Products Liability Claims Creates a Need for Congressional Action*, 6 REV. LITIG. 339, 364 (1987); Scott Richardson, *Attorney General's Warning: Legislation May Now Be Hazardous to Tobacco Companies' Health*, 28 AKRON L. REV. 291, 312–21 (1995) (providing a general background regarding tobacco legislation and descriptions of multiple tobacco-related state and federal cases); see also Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, 96 Stat. 324 (1982) (taxing specific products such as tobacco and alcohol, also known as a sin tax). In 1984, Congress decided to add content to the "is dangerous" assertion by mandating the use of four warnings of specific health effects. Karjeker, *supra*, at 345. Congress required manufacturers to print one of the following four warnings on their cigarette packages:

SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer,
Heart Disease, Emphysema, and May Complicate Pregnancy[.]

SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly
Reduces Serious Risks to Your Health[.]

SURGEON GENERAL'S WARNING: Smoking By Pregnant Women
May Result in Fetal Injury, Premature Birth, And Low Birth Weight[;
or]

SURGEON GENERAL'S WARNING: Cigarette Smoke Contains
Carbon Monoxide.

Comprehensive Smoking Education Act of 1984, Pub. L. No. 98-474, 98 Stat. 2200 (1984) (internal quotation marks omitted) (codified as amended at 15 U.S.C. § 1331 (2006)).

⁷⁴ U.S. FOOD & DRUG ADMIN., REGULATING TOBACCO—AN FDA PERSPECTIVE, <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm171683.htm> (last visited Oct. 3, 2010). The Family Smoking Prevention and Tobacco Control Act empowers the FDA with the broad authority to:

Requir[e] companies who manufacture or import tobacco products to
provide FDA with a listing of the amounts of all ingredients in the

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California first introduced the bill in the House of Representatives as H.R. 1256.⁷⁵ In his opening remarks of a floor debate, Representative Waxman asserted that in the past tobacco companies misled the American public, and if the bill passed, it would be a “great victory for all Americans, especially our children.”⁷⁶ A number of Representative Waxman’s colleagues expressed concern that the FDA would be overburdened and the FSPTCA underfunded if the Act passed.⁷⁷ The

tobacco products they produce[;] . . . [r]equire companies to provide information about the amount of nicotine in their products to FDA and the public[;] . . . [w]hen appropriate for protecting public health, to adopt standards for nicotine yields and for the reduction or elimination of other harmful substances that may be present in tobacco products[;] [r]equir[e] that FDA must review an application and determine the product meets certain standards before tobacco products can be marketed and promoted as being “light,” “mild” or “low”[;] Premarket review by FDA is also required for tobacco products that were not commercially marketed as of February 15, 2007, or were modified after that date[;] [r]equir[e] the warnings on tobacco products to cover 50 percent of the front and back panels of the package and that text be large and legible[;] . . . issue regulations regarding the advertising of, and access to, tobacco products[; and] [e]stablish[] a Tobacco Products Scientific Advisory Committee to provide advice, information, and recommendations to FDA, such as on safety, dependence, or other health issues related to tobacco products.

Id. The law also “contains provisions designed to limit young people’s access to tobacco products, as well as restrictions on marketing to curb the appeal of these products to minors.” Family Smoking Prevention and Tobacco Control Act, 74 Fed. Reg. 31, 458 (July 1, 2009); see also *Effective Dates of New FDA Tobacco Law Provisions*, CAMPAIGN FOR TOBACCO-FREE KIDS, http://www.tobaccofreekids.org/reports/fda/fda_effective_dates.pdf (last visited Oct. 3, 2010) (providing a timeline for implementation of the FSPTCA).

⁷⁵ 155 CONG. REC. H2923 (daily ed. March 3, 2009) (statement of Rep. Waxman). This bill was passed in the House of Representatives on April 2, 2009, by recorded vote. 155 CONG. REC. H4414 (daily ed. April 2, 2009) The totals were 298 ayes, 112 noes, and 21 not voting. *Id.* The bill passed in the Senate on June 11, 2009, by roll call vote. 155 CONG. REC. S6501 (daily ed. June 11, 2009). The totals were 79 yeas, 17 nays, and 3 not voting. *Id.*

⁷⁶ 155 CONG. REC. H4318-39 (daily ed. Apr. 1, 2009) (statement of Rep. Waxman). Rep. Waxman further stated, “[i]n 1996, the Food and Drug Administration tried to regulate tobacco products, but the Supreme Court told them that they needed Congress to give them specific legal authority. Now, 13 years later, here we are finally giving FDA that authority to regulate the leading preventable cause of death in America.” *Id.*

⁷⁷ *Id.* Representative Waxman addressed this concern by stating the following:
[t]he tobacco program will be fully funded through a new user fee paid for by the industry. That money will go exclusively to the new tobacco center and will be enough for FDA to handle this task well. Furthermore, by doing so, we will ensure that the new tobacco program will have no impact on other missions at the Food And Drug Administration.

Id.; see also Halimah Abdullah, *Senators Who Opposed Tobacco Bill Received Top Dollar from Industry*, MCCLATCHY NEWSPAPERS, June 11, 2009, <http://www.mcclatchydc.com/257/story/69925.html> (providing statements from various Senators who believe the FDA lacks

Congressional Budget Office (“CBO”), however, estimates that the FSPTCA will reduce the budget deficit by \$200 million over the 2010 to 2014 period and by \$800 million over the 2010 to 2019 period.⁷⁸ Moreover, the FSPTCA assesses fees on companies that manufacture or import tobacco products and utilizes the money in a discretionary fund to regulate the tobacco products.⁷⁹ The CBO estimates that the amount of tax revenues and settlement funds collected by state and local governments may decline due to reduced consumption of tobacco products.⁸⁰

the resources needed to direct and enforce the FSPTCA). *But see* 155 CONG. REC. H4341 (Apr. 1, 2009) (describing that the FDA does not have the resources necessary to more comprehensively regulate the tobacco industry).

⁷⁸ CONGRESSIONAL BUDGET OFFICE, COST ESTIMATE, H.R. 1256: FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT (Mar. 16, 2009), *available at* <http://www.govtrack.us/data/us/111/bills.cbo/h1256.pdf>; *see also* FDA, FISCAL YEAR 2010 CONGRESSIONAL JUSTIFICATION, EXECUTIVE SUMMARY: INTRODUCTION AND MISSION, *available at* <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM153491.pdf> (providing an overview of the proposed 2010 FDA budget).

⁷⁹ FDA, FISCAL YEAR 2010 CONGRESSIONAL JUSTIFICATION, EXECUTIVE SUMMARY: INTRODUCTION AND MISSION, *supra* note 78. The legislation would authorize the quarterly assessment of fees on manufacturers and importers of such products. It would authorize the appropriation of assessments equal to \$85 million in 2009, \$235 million in 2010, \$450 million in 2011, \$477 million in 2012, \$505 million in 2013, \$534 million in 2014, \$566 million in 2015, \$599 million in 2016, \$635 million in 2017, \$672 million in 2018, and \$712 million in 2019 and each subsequent year. *Id.* In addition, the Congressional Budget Office estimates that implementing the program to assess fees to cover new FDA costs associated with regulating tobacco would reduce net discretionary outlays by \$149 million over the 2010–2014 period and by \$70 million over the 2010–2019 period because the spending of fees would lag behind their collection. *Id.* Further, the CBO articulated that

H.R. 1256 would impose a number of private-sector mandates, as defined in UMRA, on companies that manufacture or import tobacco products. CBO estimates that the total direct cost of these mandates would exceed the threshold established by UMRA (\$139 million in 2009, adjusted annually for inflation) in each year, beginning with 2010. The bill would assess a fee on manufacturers and importers of tobacco products to cover the cost to FDA of regulating those products. The aggregate payments would sum to \$235 million in 2010, and rise to more than \$500 million a year by 2013.

Id.; *see* 155 CONG. REC. H4339 (daily ed. Apr. 1, 2009) (explaining that the FSPTCA will be fully funded through a new user fee paid for by the tobacco industry); U.S. FOOD & DRUG ADMIN., TOBACCO PRODUCT FEES, <http://www.fda.gov/ForIndustry/UserFees/TobaccoProductFees/default.htm> (last visited Oct. 3, 2010) (stating that the user fee program will generate \$4.5 billion from 2009–2018); U.S. FOOD & DRUG ADMIN., USER FEES, <http://www.fda.gov/ForIndustry/UserFees/default.htm> (last visited Oct. 3, 2010) (discussing the user fee program and funding for years 2009–2018).

⁸⁰ CONGRESSIONAL BUDGET OFFICE, COST ESTIMATE, H.R. 1256: FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT (Mar. 16, 2009), *available at* <http://www.govtrack.us/data/us/111/bills.cbo/h1256.pdf>. The CBO stated that

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Congress's rationale behind the enactment of the FSPTCA was that advertising, marketing, and the promotion of tobacco products attracts young people to use tobacco products, and these efforts have resulted in increased use.⁸¹ Congress expressed concern that promotional marketing and advertising methods expose minors to tobacco products.⁸²

[i]n 2008, state and local governments collected about \$19 billion in revenues from excise and general sales taxes levied on tobacco products. CBO estimates that this bill would lower consumption of those products and that excise taxes collected by state and local governments would fall by about \$20 million in 2010, with that reduction growing to over \$330 million in 2014. Similarly, the CBO estimates that state and local governments would see a decline in sales-tax revenues of about \$170 million over the 2010-2014 period.

Id.

⁸¹ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776, 1777 (2009) (codified as amended at 15 U.S.C. § 1333 (2006 & Supp. 2009)). This Act states:

Tobacco use is the foremost preventable cause of premature death in America. It causes over 400,000 deaths in the United States each year, and approximately 8,600,000 Americans have chronic illnesses related to smoking.

Reducing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco-induced disease.

Id. (original numbering omitted). "In 2005, the cigarette manufacturers spent more than \$13,000,000,000 to attract new users, retain current users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use." *Id.* § 1333, 123 Stat. at 1778, ¶16. Numerous reports conclude that tobacco use is harmful for an individual's health largely due to the chemicals included in cigarettes, cigars, and smokeless tobacco. See ANTHONY L. KOMAROFF, HARVARD MEDICAL SCHOOL FAMILY HEALTH GUIDE 58 (1999) (providing an overview of the deleterious effects of tobacco use). According to Komaroff, "[t]obacco smoke contains more than 4,000 chemicals, many of which are known to be carcinogens (cancer-causing agents). . . . Nicotine is an addictive chemical that, when absorbed through the lungs, affects the cardiovascular and nervous systems." *Id.* More specifically, "[s]moking has been established as a factor in the development of coronary artery disease; lung cancer; bronchitis; emphysema; cancer of the larynx; lip, and oral cavity; cancer of the bladder and stomach; duodenal ulcer; and allergies." GORDON EDLIN & ERIC GOLANTY, HEALTH & WELLNESS 396 (10th ed. 2010).

⁸² Family Smoking Prevention and Tobacco Control Act § 1333. Congress also found that

[c]hildren are exposed to substantial and unavoidable tobacco advertising that leads to favorable beliefs about tobacco use, plays a role in leading young people to overestimate the prevalence of tobacco use, and increases the number of young people who begin to use tobacco.

....

Children are more influenced by tobacco marketing than adults: more than 80 percent of youth smoke three heavily marketed brands, while only 54 percent of adults, 26 and older, smoke these same brands.

“Through advertisements during and sponsorship of sporting events, tobacco has become strongly associated with sports and has become portrayed as an integral part of sports and the healthy lifestyle associated with rigorous sporting activity.”⁸³ The FSPTCA regulations will further the government’s substantial interest in preventing life-threatening health consequences to the populace and advance the goal of reducing tobacco usage by the youth of America.⁸⁴ As a result of ratification of the FSPTCA, the United States may possibly become a model nation piloting the pathway to a healthier public that is less dependent on tobacco.⁸⁵ Congress can further this aim of developing a healthier public by uniting with other foreign nations in their endeavor to regulate heavily caffeinated beverages, such as energy drinks.⁸⁶

D. The Thirst for Regulation in America and the Nourishment of Regulation Abroad

As the market for energy drinks in the United States increases, so does the push for FDA regulation.⁸⁷ Compared to its regulation

Tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market.

Id. § 1333, 123 Stat. at 1778, ¶¶20, 23, 24 (original numbering omitted).

⁸³ *Id.*; see also *supra* note 52 (discussing the energy drink target market and advertising efforts by energy drink manufacturers).

⁸⁴ Family Smoking Prevention and Tobacco Control Act, § 1333, 123 Stat. at 1779; see Barak Y. Orbach, *The New Regulatory Era – An Introduction*, 51 ARIZ. L. REV. 559, 561–65 (2009) (discussing regulatory trends); Justice Sonia Sotomayor & Nicole A. Gordon, *Returning Majesty to the Law and Politics: A Modern Approach*, 30 SUFFOLK U. L. REV. 35, 40 (1996) (noting that many believe that reliance on regulatory measures may decrease personal responsibility and accountability); see also Credit Card Accountability Responsibility and Disclosure Act of 2009 (“the Credit CARD Act”), Pub. L. No. 111-24, 123 Stat. 1734 (2009) (illustrating that personal responsibility is essential to the success of regulation); Lilly Ledbetter Fair Pay Act, Pub. L. 111-2, 123 Stat. 5 (2009) (expanding the scope of protection against discrimination for employees); *Ledbetter v. Goodyear Tire & Rubber Co.*, 550 U.S. 618 (2007) (prompting the Lilly Ledbetter Fair Pay Act); Remarks by President Barack Obama at Signing of the Credit Card Accountability, Responsibility and Disclosure Act (May 22, 2009) (underscoring the tension between responsibility and regulation).

⁸⁵ See *supra* note 81 (providing the goals of tobacco regulation through the FSPTCA).

⁸⁶ See *infra* Part II.D (explaining how many foreign nations regulate heavily caffeinated beverages).

⁸⁷ See generally Reissig, *supra* note 52, at 2 (discussing beverage regulatory aspects). In 2008, neuroscientist Roland Griffiths from Johns Hopkins School of Medicine in Baltimore wrote to the FDA urging the agency to require manufacturers to list caffeine content of energy drinks on the can, to set a threshold on the amount of stimulant in the drinks, and to require conspicuous warning labels. Weise, *supra* note 49, at 6D. One hundred scientists and physicians joined Griffiths in writing letters to the FDA requesting heightened regulation of energy drinks because the drinks’ high caffeine content puts young drinkers at risk for caffeine intoxication and alcohol-related injuries. *Id.* Griffiths also claimed that

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regarding over-the-counter (“OTC”) caffeine-containing stimulants, the FDA is lenient in regulating the caffeine content of energy drinks and permits manufacturers to market and sell their products devoid of warning labels that would recommend proper consumption and display the amount of caffeine contents.⁸⁸ According to the FDA, an OTC product identified as a “stimulant” or “alertness aid” must display specific warnings on the packaging.⁸⁹ Moreover,

[i]t is a striking inconsistency that, in the U.S. an OTC stimulant medication containing 100 mg of caffeine per tablet (e.g. NoDoz) must include . . . warnings, whereas a 500 mg energy drink can be marketed with no such warnings and no information on caffeine dose amount in the product.⁹⁰

because federal law does not require energy drink companies to disclose the amount of caffeine in their drinks, it “is like having a glass of alcohol to drink . . . and you don’t know whether you’re drinking straight vodka or beer.” Mayhood, *supra* note 49.

⁸⁸ Reissig, *supra* note 52, at 2. The energy drink market is not slowing down, and energy drink manufacturers are trying to “one-up” each other; thus, “energy shots” have entered the picture. See William Neuman, “Energy Shots” Stimulate Power Drink Sales, N.Y. TIMES, July 11, 2009, <http://www.nytimes.com/2009/07/11/business/11energy.html>. Neuman explains the following:

The two-ounce drinks, which give people a concentrated dose of caffeine, B vitamins and amino acids, were all but unheard-of four years ago. Today they are the hottest drink category in the country, with sales expected to almost double this year from last, to about \$700 million. . . . The market is dominated by a tiny company in suburban Detroit called Living Essentials, which began test sales in late 2004 of a product called 5-Hour Energy, packaged in small plastic bottles.

Id.

⁸⁹ 21 C.F.R. § 340.50 (2009). The statute identifies one of the labeling requirements as follows:

The labeling of the product contains the following warnings under the heading “Warnings”:

(1) “The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.”

(2) “For occasional use only. Not intended for use as a substitute for sleep. If fatigue or drowsiness persists or continues to recur, consult a” (select one of the following: “physician” or “doctor”).

(3) “Do not give to children under 12 years of age.”

Id. § 340.50(c).

⁹⁰ See Reissig, *supra* note 52, at 3 (describing the regulatory guidelines OTC caffeine stimulants must follow).

Although there is dispute regarding whether energy drink and caffeine consumption is beneficial, there is nonetheless a consensus among researchers that caffeine consumption can result in adverse health consequences, especially at high doses.⁹¹ For example, such adverse effects of over-consumption may include nervousness, irritability, sleeplessness, increased urination, abnormal heart rhythms (arrhythmia), decreased bone density, and upset stomach.⁹² Another harmful consequence of over-consumption is caffeine intoxication—a

⁹¹ Simon & Mosher, *supra* note 46. One modern study concluded that [c]affeine does not improve maximal oxygen capacity directly, but could permit the athlete to train at a greater power output and/or to train longer. It has also been shown to increase speed and/or power output in simulated race conditions. These effects have been found in activities that last as little as 60 seconds or as long as 2 hours.

GRAHAM, T.E., *Caffeine and Exercise: Metabolism, Endurance and Performance*, Abstract, 31 SPORTS MED. 785–807 (2001), available at <http://www.ncbi.nlm.nih.gov/pubmed/11583104>. “The limited information available suggests that caffeine non-users and users respond similarly and that withdrawal from caffeine may not be important.” *Id.* See Jerome H. Jaffe, *Psychoactive Substance Use Disorders*, in COMPREHENSIVE TEXTBOOK OF PSYCHIATRY 642, 683 (1989) (illustrating that energy drinks are one of the most widely used psychoactive drugs in the world); see also Wallace B. Pickworth, *Caffeine Dependence*, LANCET, Apr. 29, 1995, at 1066 (stating that caffeine is “a psychoactive drug used by 80% of the population of the USA”), cited in Gwendolyn Prothro, *The Caffeine Conundrum: Caffeine Regulation in the United States*, 27 CUMB. L. REV. 65, 66 (1996–1997) (describing the scientific composition of caffeine).

⁹² Heneman & Zidenberg-Cherr, *supra* note 46; see Drug Products for Over-the-Counter Human Use, 53 Fed. Reg. 6100, 6103 (Feb. 29, 1988) (codified at 21 C.F.R. pt. 340); ANN MARIE SCHULTZ, ET AL., CITIZEN PETITION FOR NEW LABELING REQUIREMENTS FOR CAFFEINE IN FOOD, Jan. 15, 2006, available at <http://www.fda.gov/OHRMS/DOCKETS/dockets/06p0039/06p-0039-cp00001-01-vol1.pdf> (providing a description of the adverse effects of caffeine consumption); Prema B. Rapuri et al., *Caffeine Intake Increases the Rate of Bone Loss in Elderly Women and Interacts with Vitamin D Receptor Genotypes*, 74 AM. J. CLINICAL NUTRITION 694, 699 (2001) (follow <http://www.ajcn.org/cgi/content/full/74/5/694> hyperlink; then follow “Full Text (PDF)” hyperlink) (finding a correlation between bone loss in post-menopausal women and caffeine consumption); News Release, Duke University Medical Center, *Caffeine’s Effects are Long-Lasting and Compound Stress*, <http://www.dukemednews.org/news/article.php?id=5687> (full article appears in the July/August, 2002 issue of *Psychosomatic Medicine*) (providing the findings of a study comparing caffeine consumption with stress levels); Denise Grady, *Pregnancy Problems Tied to Caffeine*, N.Y. TIMES, Jan. 21, 2008, <http://www.nytimes.com/2008/01/21/health/21caffeine.html> (finding that the risk of miscarriage significantly increases with caffeine consumption); James Lane et al., *Cutting Caffeine May Help Control Diabetes*, DUKE MEDICINE NEWS & COMMUNICATIONS, Jan. 28, 2008, http://www.dukehealth.org/Health_Library/News/10226 (last visited Sept. 14, 2010) (finding that excessive caffeine consumption undermines efforts to control type 2 diabetes); Alex M. McDonald, *Energy Drinks and Exercise*, POWERBAR, http://www.powerbar.com/articles/109/Energy_Drinks_and_Exercise.aspx (last visited Oct. 3, 2010); *Watch Your Caffeine Intake if You Are Prone to Kidney Stones*, MED. NEWS TODAY (Sept. 5, 2004), available at <http://www.medicalnewstoday.com/articles/12937.php> (summarizing a study regarding caffeine’s effects on the development of kidney stones).

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syndrome recognized by the Diagnostic and Statistical Manual of Mental Disorders and the World Health Organization's International Classification of Diseases.⁹³ Due in large part to the soaring popularity of energy drinks and a steadily increasing amount of consumption by young people, more serious cases of caffeine intoxication are being reported in poison centers.⁹⁴ The media has reported multiple cases of

⁹³ AMERICAN PSYCHIATRIC ASSOCIATION, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 212 (Am. Psychiatric Ass'n 1994); WORLD HEALTH ORGANIZATION, THE ICD-10 CLASSIFICATION OF BEHAVIOURAL AND MENTAL DISORDERS: DIAGNOSTIC CRITERIA FOR RESEARCH, 5-6, available at http://www.who.int/substance_abuse/terminology/ICD10ResearchDiagnosis.pdf (last visited Oct. 3, 2010); Reissig, *supra* note 52, at 4.

⁹⁴ Heneman & Zidenberg-Cherr, *supra* note 46. "A recently-released report from University of Massachusetts Medical School noted 4600 caffeine-related calls to the American Association of Poison Control Centers in 2005, the most recent data available. More than half involved people under 19, and 2345 required treatment in a health care facility." "Caffeine Intoxication" Cases on Rise, CBS NEWS (July 17, 2008), http://www.cbsnews.com/stories/2008/07/17/earlyshow/health/main4267600.shtml?source=RSSattr=Health_4267600. Caffeine abuse is occurring more frequently in the United States and one study states:

Forty-one cases of caffeine abuse from caffeine-enhanced beverages were reported to a U.S. poison control center from 2002 to 2004. Another U.S. poison control center reported nine cases of adverse reactions to the energy drink Redline from January 2004 to March 2006. Eight of the nine patients were male, the youngest being 13 years of age.

Reissig, *supra* note 52, at 5 (citation omitted). Research scientist Kathleen E. Miller of the University of Buffalo Research Institute on Addictions examined the relationships between energy drink consumption and risk-taking in college students and found a positive correlation between consumption and substance abuse and unsafe sexual activity. See Kathleen E. Weaver, *Energy Drinks Linked to Risk-Taking Behaviors Among College Students*, UNIV. OF BUFF. RES. INST. ON ADDICTIONS (July 24, 2008), <http://www.ria.buffalo.edu/news/2008-07-24.html>. Recently, 795 Western New York college students participated in the study, which concluded:

Frequent energy drink consumers (six or more days a month), according to Miller's findings, were approximately three times as likely as less frequent energy drink consumers or non-consumers to have smoked cigarettes, abused prescription drugs and been in a serious physical fight in the year prior to the survey. They reported drinking alcohol, having alcohol-related problems and using marijuana about twice as often as non-consumers. They were also more likely to engage in other forms of risk-taking, including unsafe sex, not using a seatbelt, participating in an extreme sport and doing something dangerous on a dare. The associations with smoking, drinking, alcohol problems and illicit prescription use were found for white but not black students.

Id.; see Heather Warlick, *Energy Drink Use May Cause Addiction, Risky Behavior Email*, OKLAHOMAN (Okla. City, Okla.), Nov. 4, 2008, at 2E (providing statistics regarding the behavior of students following drinking alcohol with energy drinks); *Public Health; Study Shows Energy Drink "Cocktails" Lead to Increased Injury Risk*, MED. LETTER ON THE CDC &

caffeine toxicity resulting from consumption of energy drinks affecting a wide range of consumers from middle school-aged children to professional athletes.⁹⁵ One serious case occurred in Australia where a twenty-eight-year-old motocross athlete's heart stopped in a competition because he had consumed eight cans of Red Bull over five hours.⁹⁶ As evidenced by such tragic anecdotes, different individuals respond differently to caffeine—non-habitual users may experience dramatic boosts in athletic and cognitive performance because they are not tolerant to caffeine's stimulant effect.⁹⁷

FDA VIA NEWSRX.COM & NEWSRX.NET, Nov. 25, 2007, at 74 (providing the results of a Wake Forest University School of Medicine study regarding alcohol and energy drinks).

⁹⁵ Heneman & Zidenberg-Cherr, *supra* note 46. For instance, the King Philip Regional School District in Massachusetts decided to rewrite the middle school student handbook to discourage the consumption of energy drinks after a student got sick on a school ski trip. Michele Morgan Bolton, *Some Schools Put the Lid on High-Caffeine Beverages; Say Energy Drinks Pose Health Risk Packed With Caffeine*, BOST. GLOBE, July 25, 2009, at 1. Parents and school officials from Dudley-Charlton School Committee became concerned when some middle school students were "bouncing off the walls as the first bell of the day rang, with racing pulses and pounding hearts, and then suffering a sluggish crash an hour or two later." *Id.* One death apparently linked to the consumption of Red Bull made the headlines in 2000 when Irish athlete, Ross Cooney, eighteen, died of sudden adult death syndrome hours after drinking four cans of the drink and playing in a basketball match. Following the incident, France prohibited the energy drink, but it removed the ban only days later. However, in countries such as Norway, Uruguay, and Denmark, it remains banned. See *French Ban on Red Bull (Drink) Upheld by European Court*, MEDICAL NEWS TODAY, Feb. 8, 2004, <http://www.medicalnewstoday.com/articles/5753.php>. But see NANCY CLARK, NANCY CLARK'S SPORTS NUTRITION GUIDEBOOK 178-79 (Heather Healy ed., Human Kinetics 4th ed. 2008) (1990) (stating that energy drink consumption can enhance athletic performance); BENNETT ALAN WEINBERG & BONNIE K. BEALER, THE CAFFEINE ADVANTAGE: HOW TO SHARPEN YOUR MIND, IMPROVE YOUR PHYSICAL PERFORMANCE, AND ACHIEVE YOUR GOALS—THE HEALTHY WAY 14 (2002) (describing the benefits of caffeine).

⁹⁶ Daniel Dasey, *Man's Heart Stops After Red Bull Overdose*, SYDNEY MORNING HERALD, Aug. 19, 2007, <http://www.smh.com.au/articles/2007/08/18/1186857834956.html>. Dr. Malcolm Barlow, a cardiologist who treated Mr. Penbross at Newcastle's John Hunter Hospital, said it appeared that excessive consumption of energy drinks had precipitated the heart attack. *Id.* He further stated that Mr. Penbross had no other risk factors apart from smoking and Mr. Penbross had previously told Dr. Barlow that he experienced chest pain at times when his intake of the drinks was high. *Id.*

⁹⁷ *Id.* According to Nancy Clark:

A study comparing regular caffeine users to nonusers reports that the nonusers lasted eight and a half minutes longer when biking very hard to exhaustion, as compared with when they had no preexercise caffeine. The regular caffeine users exercised for only four minutes longer when they had the caffeine fix.

CLARK, *supra* note 95, at 179. Because there is such a variance of efficacy with a drug like caffeine, dosage is determined by these factors: "[y]our individual sensitivity to caffeine (determined by genetics, personality type, state of health, and other factors); [t]he rate at which you metabolize caffeine; and [t]he benefit you are trying to receive from caffeine."

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Regarding neurological effects, some studies show that the benefits of caffeine ingestion depend on an intricate alteration of neurotransmitters and an increased production of dopamine and serotonin.⁹⁸ As a result, caffeine can control neurotransmitters in a manner that can improve temperament, reduce pain, suppress appetite, and even protect brain cells from disease.⁹⁹ Remarkably, a few experts describe caffeine as the pop-icon drug of the twenty-first century—one that offers the widest range of benefits among all drugs in the pharmacopoeia.¹⁰⁰ Regardless, the benefits of caffeine are complex and variable, and according to those experts, “[w]hen using caffeine, the guiding motto must be ‘[k]now thyself.’”¹⁰¹ These circumstances prompted legislators in the United States and abroad to introduce legislation that imposes stringent labeling requirements on energy drinks and their packaging.¹⁰²

For European Union (“EU”) member states, it is an arduous task to maintain stringent regulations on energy drinks due to conflicts with EU

WEINBERG & BEALER, *supra* note 95, at 14. *See id.* (providing an overview of caffeine’s benefits).

⁹⁸ *See id.* at 11–12.

⁹⁹ *Id.* Other benefits of caffeine consumption include the following:

As a stimulant, it perks us up in the morning and generally restore[s] mental alertness or wakefulness during [states of] fatigue or drowsiness. It may improve semantic memory, logical reasoning, recall and recognition memory, at least transiently. As an analgesic adjuvant in aspirin and aspirin/acetaminophen combinations, it helps to reduce pain. And as an ingredient in menstrual drug products, it is effective in combating the fatigue and water weight gain associated with menstrual and pre-menstrual periods.

Prothro, *supra* note 91, at 68–69 (alterations in original) (footnotes omitted) (internal quotation marks omitted).

¹⁰⁰ WEINBERG & BEALER, *supra* note 95, at 1.

¹⁰¹ *Id.* The Yerkes-Dodson curve of caffeine activity illustrates the “highs” and “lows” caffeine users experience. *Id.* at 14. Psychologists theorize “that there is an optimum level of arousal for efficient performance. Other scientists explain the up then down dynamics by theorizing that higher doses of caffeine have additional effects on the body that suppress performance.” *Id.* (footnote omitted) (internal quotation marks omitted). Weinberg and Bealer iterate that “as you increase your dose, the positive effects of caffeine increase until you reach a certain level, at which time these effects begin to reverse themselves.” *Id.*

¹⁰² *See generally* Reissig, *supra* note 52 (implying that Congress should enact legislation to protect Americans from the harmful effects of caffeine); Thaddeus Mason Pope, *Balancing Public Health Against Individual Liberty: The Ethics of Smoking Regulations*, 61 U. PITT. L. REV. 419, 433–34 (2000) (discussing the appropriateness for the government to intervene and regulate under certain circumstances).

trade agreements.¹⁰³ The EU does require, however, that beverages in excess of 150 mg/L of caffeine contain a warning label next to the title of the product stating “[h]igh caffeine content” and the quantity of caffeine.¹⁰⁴ France, Sweden, and Denmark originally restricted the sale of Red Bull, but following a slightly pro-energy drink decision by the European Court of Justice, they removed the ban.¹⁰⁵ Non-member States, such as Norway, Iceland, and Turkey, however, may enact strict legislation to regulate energy drinks because, as non-member States, EU trade agreements do not bind them.¹⁰⁶

¹⁰³ EUROPEAN CENTRE FOR MONITORING ALCOHOL MARKETING, THE RAISE OF ALCOHOLIC ENERGY DRINKS IN EUROPE 3 (2008), available at http://www.alcoholreclame.nl/content/bestanden/the_raise_of_alcoholic_energy_drinks_in_europe8.pdf.

¹⁰⁴ EUROPA, COMMISSION DIRECTIVE 2002/67/EC OF JULY 18, 2002 ON THE LABELLING OF FOODSTUFFS CONTAINING QUININE, AND OF FOODSTUFFS CONTAINING CAFFEINE, http://europa.eu/legislation_summaries/consumers/product_labelling_and_packaging/121140_en.htm (follow “2002/67/EC” hyperlink).

¹⁰⁵ *Id.* The European Court of Justice’s job is to ensure that EU legislation is interpreted and applied consistently in all EU countries so that the law is equal for everyone. EUROPA, EUROPEAN UNION INSTITUTIONS AND OTHER BODIES, THE COURT OF JUSTICE, http://europa.eu/institutions/inst/justice/index_en.htm (last visited Sept. 14, 2010). It ensures, for example, that individual national courts do not contradict each other on the same issue. *Id.* In *Commission of the European Communities v. French Republic*, 3.4.2004 OFFICIAL JOURNAL OF THE EUROPEAN UNION, 85/02 (Feb. 5, 2004), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2004:085:0002:0003:EN:PDF>, the Court of Justice held that the French Republic failed to fulfill its obligations under the European Commission Treaty

by hindering the marketing in France of certain foodstuffs, such as food supplements and dietary products containing the substances L-tartrate and L-carnitine, and confectionery and drinks to which certain nutrients have been added, without establishing that the marketing of such foodstuffs entails a real risk for public health.

Id. Prior to France’s efforts to ban Red Bull, Italy attempted unsuccessfully to ban the marketing of energy drinks in excess of a certain limit. See *Commission of the European Communities v. Italian Republic*, 2.8.2003 OFFICIAL JOURNAL OF THE EUROPEAN UNION, 184/12 (June 19, 2003), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2003:184:0012:0013:EN:PDF>.

¹⁰⁶ EUROPEAN CENTRE FOR MONITORING ALCOHOL MARKETING, *supra* note 103, at 3. According to the USDA Foreign Agricultural Service:

[a] regulation released [by Turkey] in April 2005 modified the energy drinks regulation and limited the caffeine levels to 320 mg per liter and required health warnings on the label. On October 2006, another directive numbered 2006/47 lowered the caffeine level to 150 mg per liter, and required the labels to indicate a “Nutrition Facts” chart. Also with this regulation, it is now required to indicate on the labels of energy drinks, “Should not be consumed by mixing with alcohol. This is not a sports drink. Not more than 500 ml should be consumed per day. It is not recommended for children under 18, elderly, diabetics, pregnant or breastfeeding women, or people sensitive to caffeine.”

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Currently, scientific researchers, psychiatrists, and law professors alike are expressing growing concern about the adverse effects of excessive caffeine consumption.¹⁰⁷ Moreover, legislators are joining the bandwagon to “force drink-makers to come clean on caffeine,” especially those who produce and distribute alcoholic energy drinks.¹⁰⁸ In

USDA FOREIGN AGRICULTURAL SERVICES, GAIN REPORT, TURKEY: FOOD AND AGRICULTURAL IMPORT REGULATIONS AND STANDARDS—NARRATIVE (2009). According to the Official Gazette, on July 4, 2006, the Republic of Turkey decided to limit caffeine amounts in energy drinks to 150 mg/L. *Id.* at 6. Individual energy-blend ingredients were limited as well. *Id.* at 6–7. For instance, inositol cannot exceed 100 mg/L, glucuronolactone 20 mg/L, and taurine 800 mg/L. *Id.*

Australia, Thailand, Uruguay, and Canada have also banned or imposed regulations on the caffeine content and labeling of energy drinks.

See generally Weaver, *supra* note 94 (discussing energy drink regulation in foreign countries); Reissig, *supra* note 52, at 2 (discussing labeling related to energy drinks). Australia requires high-caffeinated beverages to display on the label advisory statements that the food contains caffeine and the food is not recommended for children, pregnant or lactating women, and individuals sensitive to caffeine. FOOD STANDARDS AUSTRALIA NEW ZEALAND, STANDARD 2.6.4, FORMULATED CAFFEINATED BEVERAGES, available at <http://www.foodstandards.gov.au/thecode/foodstandardscode/standard264formulate4270.cfm> (follow “PDF” hyperlink) (last visited Oct. 4, 2010). In addition, the label on an energy drink must include an advisory statement such as, “[c]onsume no more than [amount of one-day quantity (as cans, bottles or mL)] per day.” *Id.* (alterations in original). In Thailand in 2002, the Thai Food and Drug Administration (“Thai FDA”) ruled that

advertisements for energy drinks be subject to certain restrictions on the grounds that they were “misleading.” Officials said the advertisements appeared to be encouraging children to consume too many energy drinks, with potential ill-health effects. After consulting with industry, the [Thai] FDA decided to mandate a health warning on all energy drink advertisements. The depiction of sports stars and labourers in advertisements for energy drinks was also prohibited, but the threat to ban the use of celebrities in advertisements was not implemented.

Corinna Hawkes, WORLD HEALTH ORGANIZATION, MARKETING FOOD TO CHILDREN: THE GLOBAL REGULATORY ENVIRONMENT 32 (2004), available at <http://whqlibdoc.who.int/publications/2004/9241591579.pdf> (footnotes omitted). See generally Weaver, *supra* note 94 (discussing regulations of energy drinks in various countries). In 2004, Canada decided to permit sales of energy drinks but “now requires warning labels cautioning against use by children or pregnant women, use in large quantities, or use with alcohol.” *Id.*

¹⁰⁷ See Reissig, *supra* note 52 (providing a background of the ill effects of energy drink consumption); SCHULTZ, *supra* note 92 (discussing physiological effects and illnesses that may arise from excessive caffeine ingestion). The Food and Drug Law Class of Michigan State University College of Law, directed by Adjunct Professor Neal Fortin, submitted a Citizen Petition to the FDA “to request the Commissioner of Food and Drugs to issue a regulation that would efficaciously inform the general public about the quantitative caffeine content of the foods they consume.” *Id.* at 1.

¹⁰⁸ Sen. Michael Switalski, Editorial, *Force Drink-Makers to Come Clean on Caffeine*, DETROIT NEWS, Apr. 10, 2009. The caffeine regulation disagreement can actually be a catalyst for progress. See, e.g., LLOYD ALBERT JOHNSON, A TOOLBOX FOR HUMANITY: MORE THAN 9000 YEARS OF THOUGHT 117 (2003) (providing thoughts and quotes about “Progress”). In a

February 2009, Michigan Senator Michael Switalski introduced Michigan Senate Bill 230 that would require energy drink manufacturers to print the product's caffeine content on the label.¹⁰⁹ One month prior to the

warning letter to Phusion Projects Inc. ("Phusion"), the FDA informed the company that the combination of ingredients (namely alcohol and caffeine), as it is used in its extremely popular alcoholic energy drink, "Four Loko," render the beverage adulterated, as defined in section 402(a)(2)(c) of the FDCA. WARNING LETTER: PHUSION PROJECTS INC., INSPECTIONS, COMPLIANCE, ENFORCEMENT, AND CRIMINAL INVESTIGATIONS, U.S. FOOD AND DRUG ADMINISTRATION (Nov. 17, 2010), available at <http://www.fda.gov/iceci/enforcementactions/warningletters/ucm234023.htm>. Four Loko, sold in an enormous 23-ounce can, containing twelve percent alcohol and an energy blend, is widely consumed by college-aged individuals callous to the beverage's adverse effects. Abby Goodnough, *F.D.A. Expected to Take a Stand on Alcoholic Energy Drinks*, N.Y. TIMES (Nov. 15, 2010), <http://www.nytimes.com/2010/11/16/us/16drinks.html?pagewanted=1&r=1>. In the warning letter, Joann M. Givens, Acting Director of the Chicago FDA Office of Compliance Center for Food Safety and Applied Nutrition, stated that

[t]here is no food additive regulation authorizing the use of caffeine as a direct addition to alcoholic beverages, and we are not aware of any information to establish that caffeine added directly to alcoholic beverages is the subject of a prior sanction. Likewise, we are not aware of any basis to conclude that caffeine is GRAS ["Generally Recognized As Safe"] under these conditions of use.

WARNING LETTER: PHUSION PROJECTS INC., *supra*. Givens further informed Phusion that it "should take prompt action to correct [the] violation and prevent its recurrence" and "[f]ailure to do so may result in enforcement action [such as seizure of the product and injunctions and prosecutions] without further notice." *Id.* Phusion was allowed fifteen days to respond to the warning to state the specific steps it had taken to correct the violation and to assure that similar violations would not occur. *Id.* Phusion immediately released a public statement that it would remove the caffeine, guarana, and taurine from Four Loko and iterated that the company "works with its distributors to share information about the appropriate way to stock and market its products [and provides] point of sale information that reinforces the importance of asking for ID when selling any alcoholic beverage." *News Release: Phusion Projects to Remove Caffeine, Guarana and Taurine from Products*, PHUSION PROJECTS (Nov. 16, 2010), http://www.phusionprojects.com/media_reformulation.html. Notably, the FDA also issued warning letters to Charge Beverages Corp. (maker of "Core"), New Century Brewing Co. (maker of "Moonshot"), and United Brands Company, Inc. (maker of "Joose" and "Max"). Molly Peterson, *Caffeinated Alcoholic Drinks Are Unsafe*, BLOOMBERG (Nov. 17, 2010), <http://www.bloomberg.com/news/2010-11-17/caffeinated-alcohol-drinks-called-unsafe-in-warning-by-u-s-regulators.html>; *FDA Warns Makers of Alcoholic Energy Drinks*, FOX NEWS (Nov. 17, 2010), <http://www.foxnews.com/health/2010/11/17/fda-warns-makers-alcoholic-energy-drinks/>.

¹⁰⁹ S. 230, 95th Leg., Reg. Sess. (Mich. 2009). In an editorial, Senator Switalski asserted, "I am a Democrat, but I got the two doctors in the Senate, both Republicans, to co-sponsor my caffeine bill. You have a right to know the ingredients in your drink and your kid's. It should be on the label." Switalski, *supra* note 108. Cf. Christine A. Klein, *The Environmental Deficit: Applying Lessons From the Economic Recession*, 51 ARIZ. L. REV. 651, 674 (2009) ("There is a growing acceptance of the value of federal regulation, at least to prevent egregious practices harmful to important national interests."); David Leonhardt, *A Free-Market-Loving, Big-Spending, Fiscally Conservative Wealth Redistributionist*, N.Y. TIMES, Aug. 24, 2008, at 30 (providing a snapshot of America's future economic policies); President's

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introduction of Switalski's bill, Maine Representative Peggy Pendleton initiated her bill in the Maine House of Representatives that would prohibit the sale of energy drinks to minors.¹¹⁰ Danny Ford, a Representative from Kentucky, also introduced a bill that would make it illegal for stores to sell energy drinks to minors.¹¹¹ With the healthcare debate at the forefront of American political thought, President Barack Obama declared that taxation of sugar-sweetened beverages, such as energy drinks, should be explored by Congress in order to reduce consumption and protect the public health.¹¹² Before Congress reaches the decision to regulate, perhaps it could engage in the following inquiry: first, assess the positive and negative health effects; second, if a health risk is present, determine the extent of regulation necessary; and third, ascertain whether adequate resources are available to enforce the regulation.¹¹³

Remarks in New York City Regarding Financial Regulations, PUB. PAPERS (Sept. 14, 2009) (implying that Congress should enact common sense regulation to protect Americans).

¹¹⁰ H.P. 12, 124th Leg., Reg. Sess. (Me. 2009). Representative Pendleton's bill was referred to the Committee on Health and Human Services, but the Senate voted to kill the bill pursuant to the Committee's recommendation. Kevin Miller, *Bill Curtailing Sale of Energy Drinks Spiked*, BANGOR DAILY NEWS, Feb. 5, 2009, available at <http://www.bangordailynews.com/detail/98909.html>.

¹¹¹ H.B. 374, 2008 Reg. Sess. (Ky. 2008). Representative Ford's bill defined energy drink as "a carbonated beverage that exceeds a caffeine content of seventy-one (71) milligrams per twelve (12) ounce serving and contains taurine and glucuronolactone." *Id.* The bill died at the end of the 2008 Regular Session because it did not make it out of the Health & Welfare Committee. Kentucky Legislature, H.B. 374, <http://www.lrc.ky.gov/RECORD/08RS/HB374.htm>. (last visited Mar. 14, 2010).

¹¹² See generally Elizabeth Lopatto, *Soft-Drink Tax Could Pare Waistlines, Cover Health-Care Costs*, BLOOMBERG, Sept. 16, 2009, <http://www.bloomberg.com/apps/news?pid=21070001&sid=aHd62qwNQ6t6g> (describing obesity statistics in the United States and President Obama's solution to the problem). Public health and economic researchers posit that "[a] penny-per-ounce tax on soda and other sugary drinks would raise about \$150 billion over a decade while slimming Americans' waistlines." *Id.* "The tax would apply to soft drinks, energy drinks, sports beverages and many juices and iced teas, but not sugar-free diet drinks." *Soft Drink Tax Debate Rages On*, CONVENIENCE STORE NEWS (Sept. 18, 2009), http://www.csnews.com/csn/cat_management/pack_bev/article_display.jsp?vnu_content_id=1004014003. Moreover,

[a] group of doctors, scientists and policy makers, though, have argued the tax could be a weapon to reduce obesity, similar to the way cigarette taxes have helped curb smoking. . . . They estimate a cent tax per ounce on sugary beverages would raise \$14.9 billion in its first year, to be spent on health care initiatives, while also lower consumption of soda and lead to weight loss and reduced health risk for some Americans.

Id.

¹¹³ See Michael H. Cohen, *U.S. Dietary Supplement Regulation: Belief Systems and Legal Rules*, 11 HASTINGS WOMEN'S L.J. 3, 8 (2000) (explaining the tensions between increased and

III. ANALYSIS

From its creation in 1938 to its present-day status as a multifaceted agency, the FDA continues to follow a straightforward but difficult congressional mandate—to protect the American public from adulterated and misbranded food, drugs, devices, and cosmetics.¹¹⁴ Through the enactment of a bill that alters the language regarding the manufacturing, marketing, and distribution of dietary supplements, Congress could remedy the FDA's lack of authority to regulate heavily caffeinated energy beverages.¹¹⁵ Part III.A explores economic, political, and philosophical elements that ultimately influence Congress's decision of whether to increase FDA regulatory power.¹¹⁶ Part III.B evaluates the merits of caffeine regulation, focusing on the similarity between the health consequences of tobacco use and caffeine consumption.¹¹⁷ Part III.C explains whether the FDA, through its Congressional mandate and support of amended acts, possesses the jurisdiction to regulate energy drinks more effectively.¹¹⁸ Also, Part III.C compares this jurisdictional question to the public policy concerns raised by those in opposition to the newly enacted FSPTCA.¹¹⁹ Part III.D analyzes whether the FDA has the monetary and human capital required to keep pace with such a booming and rapidly expanding energy drink industry.¹²⁰

A. *An Economic and Philosophic Assessment of Regulation Applied to Energy Drinks*

The dispute regarding whether Congress should afford the FDA broader authority to regulate consumer products like heavily caffeinated beverages contains both political and philosophical elements.¹²¹ Passage

decreased governmental interference); Simon & Mosher, *supra* note 46, at 13 (proposing a proactive course of action to increase regulation of energy drinks).

¹¹⁴ See *supra* note 25 (listing the multiple acts and amendments essential to the FDA's creation and expansion).

¹¹⁵ See *infra* Part IV (proposing a model regulation that affords the FDA with the power to regulate the manufacturing, marketing, and labeling of energy drinks).

¹¹⁶ See *infra* Part III.A (evaluating various clashing arguments regarding increased FDA regulatory authority).

¹¹⁷ See *infra* Part III.B (providing a comparison of the pharmacological and therapeutic effects of tobacco and energy drinks).

¹¹⁸ See *infra* Part III.C (discussing whether the FDA has the power to regulate energy drinks currently classified as dietary supplements).

¹¹⁹ See *infra* Part III.C (providing arguments in opposition to the FSPTCA that involve policy concerns).

¹²⁰ See *infra* Part III.D (discussing the plausibility concerning the notion that expanded FDA regulation is infeasible due to a scarcity of resources).

¹²¹ See Cohen, *supra* note 113, at 8 (discussing the contradictory political and philosophical ideologies in light of the DSHEA). Cohen generalizes that FDA regulation

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of such legislation may hinge upon either the occurrence of a distinct political event or a philosophical shift of public opinion.¹²² Moreover, the regulation debate concerns the regulatory proposal, policy, values, and belief system of American society.¹²³ Conceptually, the progression of regulation is illustrated sequentially in that, “[o]ne’s core belief system generates . . . [o]perative values, which generate . . . policy choices, which generate . . . the regulatory proposal and arguments for such a proposal.”¹²⁴ This analytical framework, however, is unlikely to succeed seamlessly from the bottom level to the peak because of the reality that society has differing beliefs, morals, and values.¹²⁵

It is imperative to note that these differences in opinion give rise to three fundamental disagreements regarding increased FDA regulatory power: whether the consumer is competent; whether paternalistic regulation is obligatory; and whether such regulation leads to the notorious slippery slope.¹²⁶ The competent consumer approach is illustrated by both economic and common sense methodologies that suggest consumers continually and perhaps unknowingly engage in cost-benefit analyses.¹²⁷ From a macroeconomic outlook, the cost-benefit methodology assumes that “all potential gains and losses from a

presents a tension between paternalism and autonomy, but “[p]aternalism involves interference with autonomous choices.” *Id.*

¹²² *Id.*

¹²³ *Id.* at 12. In his article, Michael H. Cohen provides a framework to analyze potential dietary supplement regulations in a format analogous to Maslow’s Hierarchy of Needs—each level generates the succeeding one. *Id.*

¹²⁴ *Id.* The bottom level, “Belief System,” “addresses what we ultimately believe about such large topics as truth, human existence, the nature and purpose of the body. Do we ultimately believe that science has all the answers?” *Id.* at 13. The next level, “Values,” “asks who or what the rules and policies are attempting to protect. Is it the individual, the wealth of an industry or the power of a government institution? What is foremost: consumer autonomy, medical authority, or regulatory control? What are the ultimate values guiding any balancing of these interests?” *Id.* The following level, “Policy,” “asks what overall stance should legislation or regulation adopt What attitude should govern rule-making? How should lawmakers, FDA officials, and others regard these products . . . in health care? Should the posture be favorable or unfavorable?” *Id.* The top level, “Regulatory Proposal,” “asks what legal rule is the most appropriate. . . . Or should some intermediate category be created in which access is more carefully controlled by federal officials?” *Id.* at 12.

¹²⁵ *Cf.* Cohen, *supra* note 113, at 21 (“By creatively examining our core beliefs and the values that underlie regulatory positions, the debate may be clarified, the doors of perception may be opened, and, ideally, the laws that govern self-care may more faithfully track the core of human aspirations toward health.”).

¹²⁶ *See infra* notes 127–33 (discussing the competent consumer argument); *infra* notes 138–44 (discussing whether the FDA should act preemptively with regulation); *infra* notes 145–52 (providing the slippery slope argument regarding regulation of caffeine).

¹²⁷ *See* SODERLIND, *supra* note 51, at 245 (describing the purpose of paternalistic regulation).

proposal are identified, converted into monetary units, and compared on the basis of decision rules to determine if the proposal is desirable from society's standpoint."¹²⁸ However, on a microeconomic level and more relevant to energy drinks, the "consumer choice theory" demonstrates that individuals in a free-market setting choose products by weighing preference, price, and potential health consequences of the product.¹²⁹

Because consumers encounter trade-offs in their purchase decisions, they "must combine budget constraints (what they can afford), and preferences (what they would like to consume)."¹³⁰ The economic model of the consumer choice theory can also drive the supposition that consumers are competent in their assessment concerning whether a product with potential adverse effects requires regulation to protect the public interest.¹³¹ In abstract economic terms, a regulation is "a commodity made available in the political marketplace and supplied by politicians and bureaucrats by reference to the demand of those who will benefit from its promulgation."¹³² Accordingly, regulatory tension is present because individuals must face the consequences of their actions—they may enjoy all the benefits but will bear all the costs.¹³³

This regulatory conflict likely persists because of the notion that personal responsibility reduces the need for government regulation, and in turn, that regulation leads to dependency and irresponsibility.¹³⁴ An excellent expression regarding personal responsibility and regulation is simply "that bad things may happen to responsible individuals and that

¹²⁸ NAS, *supra* note 51, at 1-2.

¹²⁹ See McCann, *supra* note 51, at 1177 (explaining the consumer choice theory in terms of food purchases). McCann states: "In ranking, individuals determine the relative utility of one choice over another, balanced against abilities and budgetary constraints, which attach a relative cost to each prospective choice." *Id.*

¹³⁰ *Theory of Consumer Choice*, *supra* note 51.

¹³¹ See generally THE POLITICS OF REGULATION: INSTITUTIONS AND REGULATORY REFORMS FOR THE AGE OF GOVERNANCE, *supra* note 51, at 36 (providing a comparison of economic regulation and social regulation).

¹³² *Id.* On the other hand, this regulatory tradeoff may be:

principally between politicians and industries which would benefit from regulatory subsidies and barriers to entry. While different groups could furnish political support, the price necessary to secure the purchase, the transaction was most likely to be entered into by those groups which could coordinate their influence at lowest cost, thus tending to favour producers over, for example, consumers.

Id. (internal quotation marks omitted).

¹³³ SODERLIND, *supra* note 51, at 236. Soderlind writes, "[a]s economists see it, when consumers are independent of one another any policy that imposes a change in behavior constitutes an unwelcome encroachment on personal freedom." *Id.*

¹³⁴ Orbach, *supra* note 84, at 562; see, e.g., Sotomayor, *supra* note 84, at 40 ("Some would argue that reliance on regulations alone defuses the notion of personal responsibility and accountability.").

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regulations may support and enable, rather than replace, personal responsibility."¹³⁵ When sentiments in Washington tend to favor increased regulation, policies held by those in power may impede the ideology that responsible individuals can effectively control their fate and improve their own well-being.¹³⁶ Whether it actually materializes, President Obama and Congress seem to share a goal of reconciling the conflicting viewpoints concerning personal responsibility and regulation by offering a common sense approach to regulation.¹³⁷

¹³⁵ Orbach, *supra* note 84, at 562 (explaining the competent consumer theory in regard to government regulation). A current example of a regulation that implicates personal responsibility is the Credit Card Accountability Responsibility and Disclosure Act of 2009 ("the Credit CARD Act"). Pub. L. No. 111-24, 123 Stat. 1734 (2009). Upon signing the Credit CARD Act, President Obama emphasized that:

[Credit card] costs . . . often hit *responsible* credit card users. . . . With this bill, we're putting in place some common-sense reforms designed to protect consumers [W]e're not going to give people a free pass; we expect consumers to live within their means and pay what they owe. But we also expect financial institutions to act with the same sense of *responsibility* that the American people aspire to in their own lives.

Orbach, *supra* note 84, at 561-62 (alterations in original). President Obama's remarks underscore the tension between responsibility and regulation in that both the "common practices of credit card companies hit many responsible credit card holders and that the Credit CARD Act does not relieve consumers of their responsibility to pay debts to credit card companies in full." *Id.* at 562; see Remarks by President Barack Obama at Signing of the Credit Card Accountability, Responsibility and Disclosure Act, *supra* note 84; see also Lilly Ledbetter Fair Pay Act, Pub. L. 111-2, 123 Stat. 5 (2009) (expanding the scope of protection against discrimination for employees). The decision in *Ledbetter v. Goodyear Tire & Rubber Co.* (holding that employees are barred from filing pay discrimination claims based on employer's decisions made 180 days ago or more) prompted President Obama to sign into law the Lilly Ledbetter Fair Pay Act. "The Lilly Ledbetter Fair Pay Act overruled the Supreme Court decision, providing that the 180-day limitation starts with the last discriminatory act." Orbach, *supra* note 84, at 562, n.18.

¹³⁶ *Id.* at 565.

¹³⁷ See Klein, *supra* note 109, at 674 ("President Obama argued, 'Now, if we're honest with ourselves, . . . we have not always met [our] responsibilities—as a government or as a people. . . . Regulations were gutted for the sake of a quick profit at the expense of a healthy market.'"); Orbach, *supra* note 84, at 560 (noting that "[I]ike it or not, one of President Obama's campaign promises for change was 'common-sense regulation.'"). Barack Obama utilized this promise to distinguish himself from President Bush and his predecessors since President Reagan, who continuously deregulated markets. See *id.* ("The promise for a 'common-sense regulation,' of course, also struck a sharp contrast between President Obama and his opponent, Senator John McCain."). In a interview for *New York Times Magazine* concerning new regulation, Barack Obama stated:

Ronald Reagan . . . made people aware of the cost involved in government regulation. . . . Bill Clinton, to some extent, continued that pattern. . . . And George Bush took Ronald Reagan's insight and ran it over a cliff. . . .

[W]hat we need to bring about is the end of the era of unresponsive and inefficient government and short-term thinking in

In cases involving products that create the risk of addiction or negative health consequences, some contend that government policies designed to combat those problems face the risk of paternalism.¹³⁸ Many consumers opposed to paternalistic regulation invite danger and neglect warning labels, arguing that it is an essential right for Americans to be free to make their own mistakes.¹³⁹ It is important to note, however, that paternalistic governmental control is not a novel principle—it has existed for millennia.¹⁴⁰ At the heart of the regulatory debate is not necessarily the divisive distinction between “soft paternalism” and “hard paternalism,” but rather the risk of “slippage” from the former to the latter.¹⁴¹ Recently, a conceptual permutation of soft and hard

government, so the government is laying the groundwork, the framework, the foundation for the market to operate effectively and for every single individual to be able to be connected with that market and to succeed in that market.

Id. at 560, n.4 (alterations in original) (quoting Leonhardt, *supra* note 109, at 30 (interviewing Barack Obama during his Presidential campaign)); *see also* President’s Remarks in New York City Regarding Financial Regulations, PUB. PAPERS (Sept. 14, 2009) (providing the full text of President Obama’s speech concerning a major overhaul of regulations of the financial system). President Obama states:

I have always been a strong believer in the power of the free market. . . . I believe that the role of the government is not to disparage wealth, but to expand its reach; not to stifle markets, but to provide the ground rules and level playing field that helps to make those markets more vibrant—and that will allow us to better tap the creative and innovative potential of our people. . . .

So I promise you, I did not run for President to bail out banks or intervene in capital markets. But it is important to note that the very absence of *common-sense* regulations able to keep up with a fast-paced financial sector is what created the need for that extraordinary intervention—not just with our administration, but the previous administration. The lack of *sensible rules* of the road, so often opposed by those who claim to speak for the free market, ironically led to a rescue far more intrusive than anything any of us—Democratic or Republican, progressive or conservative—would have ever proposed or predicted.

President’s Remarks in New York City Regarding Financial Regulations, PUB. PAPERS (Sept. 14, 2009) (emphasis added).

¹³⁸ *See* SODERLIND, *supra* note 51, at 245 (discussing the negative aspects of paternalism).

¹³⁹ *Id.* According to Soderlind, “[m]ost of these cases involve consumers who persist in self-destructive behavior—smoking, drinking, sharing needles, and so on.” *Id.*

¹⁴⁰ Rizzo & Whitman, *supra* note 51, at 685. According to the Stanford Encyclopedia of Philosophy’s definition, “[p]aternalism is the interference of a state or an individual with another person, against their will, and defended or motivated by a claim that the person interfered with will be better off or protected from harm.” Dworkin, *supra* note 51; *see* Glaeser, *supra* note 51, at 133 (providing an overview of hard and soft paternalism).

¹⁴¹ *See* Orbach, *supra* note 84, at 569–70 (discussing “new paternalism” and objections to this ideology). Orbach articulates that, in contrast to his theory of new paternalism, “Rizzo and Whitman focus on the slippery-slope criticism against regulation and specifically the

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paternalism ideologies created what is now labeled the “new paternalism.”¹⁴² Advocates of new paternalism “distinguish their views from hard paternalism by emphasizing the moderate character of their proposals.”¹⁴³ In other words, the new paternalists proffer a theoretically ideal standard conceivably applicable to energy drink regulation—a significant improvement in individual health and welfare possibly attained through little governmental intrusion that does not substantially restrict liberty or autonomy.¹⁴⁴

argument that soft paternalism may lead to hard paternalism, or in their words: ‘moderation is not sustainable . . . slippage is most likely.’” *Id.* at 569 (quoting Rizzo & Whitman, *supra* note 51, at 688).

¹⁴² See Rizzo & Whitman, *supra* note 51, at 686 (“The new paternalism is supported by a growing body of research in behavioral economics showing that individuals are not fully ‘rational,’ as economists understand that term, but instead are subject to a variety of cognitive errors and biases.”). In contrast, “[w]hile Rizzo and Whitman raise serious valid concerns about potential sliding on slippery slopes, they do not examine actual changes in ideological hard paternalism with the rise of soft paternalism. Ideological hard paternalism has always been around and probably will never disappear.” Orbach, *supra* note 84, at 569 (emphasis omitted). Controversial examples of hard paternalism include:

bans on sodomy, restrictions on same-sex intimate relationships, bans on abortions, bans on same-sex marriage, prohibitions against teaching evolution in public schools, and criminalization of fornication. Some of these forms of hard paternalism were already abandoned because courts held them unconstitutional. Others are still in effect at least in some states. There is no conceptual link between soft paternalism that intends to improve individual decision-making and ideological hard paternalism. The governing political trend in the new regulatory era, however, seems to be hostile toward ideological hard paternalism. It is therefore unclear that the number of bans, mandatory requirements, and other forms of hard paternalism is likely to increase.

Id. at 569–71 (footnotes omitted) (citations omitted).

¹⁴³ Rizzo & Whitman, *supra* note 51, at 687. With regard to the conceptual permutation of soft and hard paternalism, “Christine Jolls and Cass Sunstein frequently refer to their proposals for debiasing behavior through law as a ‘middle ground’ between laissez-faire and more heavy-handed paternalism, one that is a ‘less intrusive, more direct, and more democratic response to the problem of bounded rationality.’” *Id.* (footnotes omitted) (quoting Jolls & Sunstein, *supra* note 51, at 200–01).

¹⁴⁴ See *id.* at 687 (explaining the chief purpose of the new paternalism ideology). Rizzo and Whitman challenge the new paternalism theory stating that

accepting new paternalist policies creates a risk of accepting, in the long run, greater restrictions on individual autonomy than have heretofore been acknowledged. Inasmuch as new paternalists claim to be interested in preserving autonomy, this surely must be taken into account as an unrecognized or unacknowledged cost to be balanced against any possible gains from their policies.

Id. at 688 (footnote omitted).

A major setback for those in favor of more extensive caffeine regulation is the notorious slippery slope argument.¹⁴⁵ “The term ‘slippery’ slopes is shorthand for two related phenomena: slippery slope arguments and slippery slope events.”¹⁴⁶ Generally, there are at least two sets of actors involved: the policymakers who created the legislation and the citizens the legislation affects.¹⁴⁷ Citizens opposed to potentially rigid energy drink regulation pose a basic but formidable slippery slope argument—if the government wishes to control the manufacturing, marketing, and labeling of energy drinks, why not be consistent and require the same of coffee, tea, chocolate, or other caffeinated products?¹⁴⁸

¹⁴⁵ See *id.* at 689–90 (providing an overview of a slippery-slope argument). Rizzo & Whitman note that “[a] slippery-slope argument (SSA) is an argument about how the acceptance of one argument (regarding a decision, act, or policy) may lead to the acceptance of other arguments (regarding other decisions, acts, or policies).” *Id.* In addition, “[a] slippery-slope event (SSE) refers to the actual manifestation of the events (decisions, acts, or policies) described in the SSA.” *Id.* at 690 (internal quotation marks omitted).

¹⁴⁶ *Id.* at 689 (emphasis omitted). Rizzo & Whitman point out that a slippery-slope argument “describes a process or mechanism by which accepting the initial argument and making the initial decision raise[s] the likelihood of accepting the later argument and making the later decision.” *Id.* at 690 (alteration in original) (internal quotation marks omitted).

¹⁴⁷ *Id.* An example of a slippery-slope situation is as follows: “the government imposes a policy that protects people from the consequences of their mistakes (e.g., national health insurance that covers the consequences of poor health choices), it may encourage moral hazard and thus result in more mistakes (more bad health choices).” *Id.* The traditional but highly controversial slippery-slope dilemma involves tobacco regulation. See Pope, *supra* note 102, at 423 (discussing how tobacco regulations may infringe upon individual autonomy). Regarding justification for government intrusion, Pope articulates that some commentators believe

[t]he focus on the economic costs of personal behavior like smoking . . . seems to suggest that if it were possible to limit the costs to the smoker . . . there would be little justification for tolerating government intrusion. According to the principle of the least restrictive alternative, they are absolutely correct. If the harm that smokers cause can be eliminated, prevented, or ameliorated in a feasible way that does *not* interfere with smokers’ liberty, then *ceteris paribus* that alternative ought to be preferred. Recouping the economic costs of smoking may increase the cost of cigarettes, but it interferes with liberty less than the direct prohibition of smoking. . . . On the contrary, the costs imposed by smokers cannot justify laws restricting smoking. . . . It would violate the least restrictive alternative principle to interfere with smokers’ liberty so as to *prevent* the costs (if any) of smoking when it is feasible, and in fact easier, to simply *recover* those costs.

Id. at 443–44 (footnotes omitted) (internal quotation marks omitted).

¹⁴⁸ See Brewington, *supra* note 53 (explaining opposing views regarding energy drink regulation). Craig Stevens, speaking on behalf of the American Beverage Association in

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Those who favor energy drink regulation commonly counter the slippery slope argument with the claim that a blanket regulation of caffeine would be politically impractical and nearly impossible to enforce.¹⁴⁹ In addition, proponents of energy drink regulation could assert that energy drinks, especially when paired with alcohol, are extremely dangerous; thus, they are distinguishable from other regulated beverages such as soft drinks.¹⁵⁰ Although the slippery slope concept is not novel or complex, it is likely the most compelling public policy argument against increased regulation of energy drinks.¹⁵¹ Energy drinks encompass many highs and lows, but because of the negative

regard to Chad Reissig and Roland Griffiths' energy drink review, states that "[i]t's unfortunate that the authors of this article would attempt to lump all energy drinks together in a rhetorical attack when the facts of their review clearly distinguish the mainstream responsible players from novelty companies seeking attention and increased sales based solely on sensationalistic names and extreme caffeine content." *Id.* (internal quotation marks omitted). Stevens also noted that

the "mainstream" energy drinks that his organization represents have about half the caffeine content found in an average serving of coffee. A 12-ounce cup of coffee contains about 200 milligrams of caffeine. An 8.3-ounce can of Red Bull has 80 milligrams. "So those suggesting that energy drinks should require warning labels should be aware of the slippery slope this would create. . . . To be consistent, products at coffeehouses also would require such unnecessary labeling."

Id. (internal quotation marks omitted). Conversely, Thaddeus Mason Pope claims that "[r]egulating public health risks with the goal of preventing harm to others has proven to be the most politically compelling rationale for government intervention." Pope, *supra* note 102, at 433-34. Pope counters the individual autonomy argument stating that

[t]oday, the argument that "[i]t's my body and I have the right to do as I please with it" is usually defeated not by denying the existence or validity of this right, but rather by illustrating that seemingly personal behavior does in fact violate the harm principle and is therefore subject to societal control.

Id. at 437 (footnote omitted).

¹⁴⁹ See, e.g., *id.* at 433-34 ("Regulating public health risks with the goal of preventing harm to others has proven to be the most politically compelling rationale for government intervention."). Pope articulates that the "ethical foundation" for regulation can be found in the writings of John Stuart Mill:

Mill maintained that "the only purpose for which power can be rightfully exercised over any member of a civilized community against his will, is to prevent harm to others." That, he argued, is the extent of the power we ceded when we entered into the social contract forming the basis of human society.

Id. at 434 (footnote omitted).

¹⁵⁰ See, e.g., Simon & Mosher, *supra* note 46, at 2 (discussing the need for energy drink regulation, especially those that include alcohol).

¹⁵¹ See Brewington, *supra* note 53 and accompanying text (providing the slippery-slope argument put forward by those opposed to greater energy drink regulation).

health effects, energy drinks, like tobacco, may be on the path to increased FDA regulation.¹⁵²

B. A Caffeine Conundrum – The Link to Tobacco and the Need for Regulation

In order to determine the necessity of energy drink regulation, one should take a step back and examine the drink's most potent ingredient, caffeine, one of the most widely used psychoactive drugs in the United States and the world.¹⁵³ Similar to the nicotine found in tobacco, the physiological effects of caffeine vary from person to person; however, once in the bloodstream, caffeine stimulates the heart and central nervous system within thirty minutes to an hour.¹⁵⁴ To that end, periodic as well as habitual consumers of caffeine typically ingest the drug to improve alertness, concentration, energy, focus, and even feelings of sociability.¹⁵⁵ Interestingly, the most noticeable physiological

¹⁵² See *infra* Part III.B (comparing the negative health consequences of tobacco use to adverse therapeutic effects of energy drink consumption).

¹⁵³ Jaffe, *supra* note 91, at 683; see also Pickworth, *supra* note 91, at 1066 (stating that caffeine is "a psychoactive drug used by 80% of the population of the USA") cited in Prothro, *supra* note 91, at 66. Regarding the safety of caffeine ingestion, Gwendolyn Prothro states that caffeine consumed in reasonable amounts "is a remedy as a stimulant and a diuretic. But in large doses, it is a poison, an addictive substance injurious to human health. Moderation, therefore, should be the goal of consumers and the goal communicated by the Food and Drug Administration (FDA)." Prothro, *supra* note 91, at 66. Caffeine is an alkaloid, or nitrogen-containing substance, with the chemical formula $C_8H_{10}N_4O_2$. *Id.* It belongs to the family of chemicals known as methylxanthines, which also includes the closely related chemicals theophylline and theobromine. *Id.* According to Prothro, caffeine in its purest form is

a white powder or a mass of glistening, white needles. It occurs naturally in Cocoa, the *Coffea arabica* plant, the kola nut, and the leaves of *Thea sinensis*. It can be created synthetically and by extraction from cocoa, coffee bean or tea leaf waste. It is present in a wide variety of prepared food and drugs: coffees, teas, soft drinks, chocolates, and various pain relievers; thus it is ingested daily by people across the world.

Id. at 66–67 (footnotes omitted) (internal quotation marks omitted).

¹⁵⁴ See Prothro, *supra* note 91, at 67 (explaining the definite effects of caffeine consumption on the heart, intestines, muscles, and central nervous system).

¹⁵⁵ *Caffeine Myths and Facts*, *supra* note 46. In addition, users of caffeine claim:
As a stimulant, it perks us up in the morning and generally restore[s] mental alertness or wakefulness during [states of] fatigue or drowsiness. It may improve semantic memory, logical reasoning, recall and recognition memory, at least transiently. As an analgesic adjuvant in aspirin and aspirin/acetaminophen combinations, it helps to reduce pain. And as an ingredient in menstrual drug products, it is effective in combating the fatigue and water weight gain associated with menstrual and pre-menstrual periods.

Prothro, *supra* note 91, at 68–69 (alterations in original) (footnotes omitted) (internal quotation marks omitted).

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effects of tobacco are strikingly similar to those of energy drinks.¹⁵⁶ These effects include “increased heart rate, increased release of adrenaline, and a direct stimulatory effect on the brain, which combine to produce the mild ‘rush’ cigarette smokers may experience when they light up.”¹⁵⁷ Some scientists and psychologists consider caffeine, like nicotine, to be a poison that causes addiction and negative health effects on the body.¹⁵⁸ Comparable to the adverse health consequences of tobacco use, studies conclude that chronic ingestion of caffeine can result in stress, hypertension, decreased bone density, kidney stones, diabetes, hypoglycemia, and obesity.¹⁵⁹ Equally detrimental, caffeine consumption may adversely affect pregnancy, and according to at least one study, may nearly double the risk for miscarriage.¹⁶⁰ The most

¹⁵⁶ See *supra* note 46 (detailing the pharmacological effects of energy drink consumption); *supra* note 81 (discussing the consequences of tobacco use).

¹⁵⁷ EDLIN & GOLANTY, *supra* note 81, at 394.

¹⁵⁸ See Prothro, *supra* note 91, at 72–73 (claiming that caffeine use is perhaps “[p]oison by [a]ddiction”). According to an FDA ruling, caffeine consumption can lead to addiction, or as the FDA defines it, a “habituation.” Drug Products for Over-the-Counter Human Use, 53 Fed. Reg. 6100, 6103 (Feb. 29, 1988) (codified at 21 C.F.R. pt. 340).

¹⁵⁹ SCHULTZ, *supra* note 92. A study by researchers at Duke University concluded that there is a direct correlation between caffeine consumption and increased levels of stress in the body. *Id.* at 5. More specifically, James D. Lane, Ph.D., an associate research professor at Duke and lead author of the study, stated that

[t]he effects of coffee drinking are long-lasting and exaggerate the stress response both in terms of the body’s physiological response in blood pressure elevations and stress hormone levels, but it also magnifies a person’s perception of stress People haven’t really accepted the fact that there could be a health downside to caffeine consumption, but our evidence—and that of other studies—shows that this downside exists and people should be aware of it in order to make the best possible health choices.

Id. (internal quotation marks omitted). With regard to bone density, research has shown there is an association between ingestion of caffeine and general skeletal weakness and osteoporosis. *Id.* at 6. In a study lead by Prema B. Rapuri, published in the American Journal of Clinical Nutrition, the researchers found that a higher rate of bone loss occurred at the spine in postmenopausal women (ages 65–77) with caffeine intake greater than three hundred milligrams per day. Rapuri, *supra* note 92, at 699. Another report published in the Journal of Urology concluded that caffeine consumption increases the levels of calcium, sodium, magnesium, and citrate—all of which increase the risk of developing kidney stones. See *Watch Your Caffeine Intake if You Are Prone to Kidney Stones*, *supra* note 92. Pertaining to diabetes, caffeine raises both the glucose and insulin levels of those affected by type two diabetes. See SCHULTZ, *supra* note 92, at 12 (explaining that continuous caffeine consumption can cause adult onset diabetes due to increased weight gain). In addition, a Duke University medical study deduced that caffeine consumption by people with established type two diabetes experienced a significant increase of glucose levels following ingestion of the caffeine. Lane, *supra* note 92.

¹⁶⁰ Grady, *supra* note 92. This study, published in The American Journal of Obstetrics and Gynecology, found “that pregnant women who consume 200 milligrams or more of caffeine a day—the amount in 10 ounces of coffee or 25 ounces of tea—may double their

common effect of habitual caffeine consumption, however, is physical and psychological dependence evidenced by a user's tolerance and withdrawal.¹⁶¹ For instance, studies in adult twins reveal that "caffeine toxicity and caffeine dependence are significantly and positively associated with various psychiatric disorders including major depression, generalized anxiety disorder, panic disorder, antisocial personality disorder, alcohol dependence, and cannabis and cocaine abuse/dependence."¹⁶² Collectively, these scientific results reinforce the pro-regulation arguments which provide that because energy drink consumption affirmatively causes many of the same negative physiological and pharmacological effects as nicotine, such beverages should be regulated in a fashion similar to the regulation of tobacco.¹⁶³

In contrast, those who reject the argument that drugs with similar physiological and pharmacological effects should be regulated similarly generally emphasize that although the results of caffeine ingestion are transitory, its stimulatory and diuretic properties can benefit your

risk of miscarriage. Pregnant women should try to give up caffeine for at least the first three or four months," according to the lead author of the study, Dr. De-Kun Li, a reproductive and perinatal epidemiologist at the Kaiser Permanente Division of Research in Oakland, California. *Id.*

¹⁶¹ Prothro, *supra* note 91, at 72-73 ("[C]affeine exhibits the features of a typical psychoactive substance of dependence.") (quoting Eric C. Strain et al., *Caffeine Dependence Syndrome: Evidence from Case Histories and Experimental Evaluations*, 272 J.A.M.A. 1043 (1994)). Dependence, the most common effect of continual ingestion of caffeine, manifests itself through at least three of these four symptoms: tolerance, withdrawal, persistent desire, or unsuccessful attempts to reduce consumption. *Id.* "The [Diagnostic and Statistical Manual of Mental Disorders] defines substance dependence using a generic set of cognitive, physiological, and behavioral symptoms, including the inability to quit, use despite harm, using more than intended, withdrawal, and tolerance." Reissig, *supra* note 52, at 5. Interestingly, the DSM-IV-TR does not categorize caffeine as a substance that can cause dependence; in fact, it "specifically excludes" it from its diagnostic schema. *Id.* The World Health Organization, on the other hand, considers caffeine as a substance that can cause dependence. *Id.* Most experts agree that withdrawal is the most common symptom related to caffeine reliance. See Prothro, *supra* note 91, at 73 (footnote omitted) ("Withdrawal . . . can occur after ceasing the consumption of as little as two cups of coffee a day (roughly 250 milligrams), within eighteen to twenty-four hours after the last caffeine intake."). According to a medical review led by Chad J. Reissig, "[i]n addition to headache, other caffeine withdrawal symptoms include tiredness/fatigue, sleepiness/drowsiness, dysphoric mood (e.g., miserable, decreased well-being/contentedness), difficulty concentrating/decreased cognitive performance, depression, irritability, nausea/vomiting, and muscle aches/stiffness." Reissig, *supra* note 52, at 5.

¹⁶² Reissig, *supra* note 52, at 6. Relating to the relationship of cigarettes and caffeine, Reissig writes that "human and animal studies show that caffeine increases the reinforcing effects of nicotine. Epidemiology studies show that cigarette smokers consume more caffeine than nonsmokers, an effect that may be partially due to increased caffeine metabolism among cigarette smokers." *Id.* (citations omitted).

¹⁶³ See *id.* (discussing the relationship of caffeine to dependence on tobacco).

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health.¹⁶⁴ Further, opponents to regulation argue that caffeine stimulates brain function and may even enhance athletic performance.¹⁶⁵ Critics of the purported caffeine and nicotine comparison might also argue that even if many of the physiological effects are the same, energy drinks should not be regulated like tobacco because, frankly, caffeine is far less lethal.¹⁶⁶ Further, those critics might assert that the majority of tobacco studies conclude that the “death rate from cancer, heart disease, and respiratory diseases [are] higher among cigarette smokers than among nonsmokers,” and the same cannot be said for consumers and non-consumers of energy drinks.¹⁶⁷

Both sides of the energy drink regulation debate form persuasive arguments and rely on credible scientific evidence, but the public health concern remains.¹⁶⁸ Although caffeine dependence does not present as grave a problem as alcohol and nicotine addiction and does not cause nearly as many deaths, caffeine dependence is not trivial—caffeine is one of the most widely used drugs in the United States, and it causes numerous harmful health consequences each year.¹⁶⁹ Scientific investigation establishes that alcohol, tobacco, and caffeine interconnect,

¹⁶⁴ See Prothro, *supra* note 91, at 68 (explaining why there is a caffeine conundrum).

¹⁶⁵ See CLARK, *supra* note 95, at 178–79 (explaining the effects of caffeine with regard to exercise). “The vast majority of the studies conclude that caffeine does indeed enhance performance (by about 11 percent) and makes the effort seem easier (by about 6 percent). Endurance athletes notice more benefits than those who do shorter bouts of exercise.” *Id.* (citation omitted).

¹⁶⁶ See *supra* note 46 (detailing the therapeutic effects of energy drink consumption); RABINOFF, *supra* note 5, at 11 (discussing the lethality of tobacco and its effect on Americans). Sadly, “[e]very single day, more than a thousand Americans—in excess of 8,000 a week or more than 35,000 a month—are killed by the effects of smoking. Its cost in dollars and human lives staggers the imagination.” *Id.* at 11.

¹⁶⁷ EDLIN & GOLANTY, *supra* note 81, at 396. Edlin and Golanty state that “smoking decreases a person’s life expectancy by an average of seven years. Smokers between the ages of 35 and 70 have death rates three times higher than those who have never smoked.” *Id.*

¹⁶⁸ See *infra* Part IV (proposing amendments to the FDCA with the aim of protecting the public health and safety from harmful effects of energy drinks).

¹⁶⁹ Prothro, *supra* note 91, at 73–74. Restating conclusions of multiple studies regarding the relationship of caffeine to dependence on other substances, Chad Reissig articulates the following:

[a] study examining the co-occurrence of substance use among drug abusers concluded that dependence on caffeine, nicotine and alcohol were governed by the same factors. . . . More specifically, with regard to cigarette smoking, human and animal studies show that caffeine increases the reinforcing effects of nicotine. Epidemiology studies show that cigarette smokers consume more caffeine than nonsmokers, an effect that may be partially due to increased caffeine metabolism among cigarette smokers.

Reissig, *supra* note 52, at 10 (citations omitted).

and this correlation fuels the dispute regarding more extensive regulation of caffeine.¹⁷⁰ But, before any form of increased regulation is promulgated, the FDA must first determine whether it possesses jurisdiction to direct a new legislative policy.¹⁷¹

C. *The FDA's Newly Acquired Jurisdiction of Tobacco—Is It Operative for Energy Drinks?*

Now that the FSPTCA has officially been enacted, the FDA possesses broad authority to regulate the manufacturing, marketing, and distribution of tobacco products.¹⁷² The DSHEA, in contrast, is an ambiguous and skeletal statute that may actually encourage manufacturers to characterize their product as a dietary supplement in order to circumvent regulatory red tape.¹⁷³ Because the DSHEA does not expressly provide the FDA with the power to regulate heavily caffeinated beverages, some suggest the FDA could interpret the scope of the statute more broadly as it did with tobacco in the past.¹⁷⁴ Such a course of action, however, could prove unsuccessful; perhaps the best solution for Congress is either to amend the FDCA or to pass a new statute expressly affording the FDA regulatory power over energy drinks similar to the power it now exercises over tobacco.¹⁷⁵

To ascertain whether the FDA has jurisdiction to regulate energy drinks in both pre- and post-market divisions, a comparison to the

¹⁷⁰ See generally Reissig, *supra* note 52, at 10 (describing the association between caffeine, alcohol, and tobacco usage). Some scientists and psychologists claim that caffeine acts as a gateway to other types of drug dependence and causes reckless behavior. *Id.* “In one study published by the American College of Health in March, [2008], students who drank at least six energy drinks per month were three times as likely to have smoked cigarettes, abused prescription drugs and been involved in fights.” Warlick, *supra* note 94, at 2E. Further, researchers from Wake Forest University School of Medicine found that [s]tudents who consumed alcohol mixed with energy drinks were twice as likely to be hurt or injured, twice as likely to require medical attention, and twice as likely to ride with an intoxicated driver, as were students who did not consume alcohol mixed with energy drinks. Students who drank alcohol mixed with energy drinks were more than twice as likely to take advantage of someone else sexually, and almost twice as likely to be taken advantage of sexually.

Public Health; Study Shows Energy Drink “Cocktails” Lead to Increased Injury Risk, supra note 94, at 74.

¹⁷¹ See *infra* Part III.C (applying principles of tobacco regulation to dietary supplements).

¹⁷² See *supra* note 69 (discussing the Family Smoking Prevention and Tobacco Control Act and the FDA’s authority promulgated by the statute).

¹⁷³ See Onel, *supra* note 56, at 341 (providing an overview of the DSHEA).

¹⁷⁴ *Cf. id.* at 348 (stating that companies exploit the legal ambiguities of the DSHEA to gain a stronghold in the market).

¹⁷⁵ See *infra* Part IV (proposing a modified version of the DSHEA that will provide the FDA with authority to regulate dietary supplements on a level similar to tobacco).

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FDA's attempt to regulate tobacco pre-FSPTCA is instructive.¹⁷⁶ For example, "[a]lmost invariably, when courts (and academics) grapple with whether an agency's views on the extent of its own powers should merit *Chevron* deference, they refer to such issues, without differentiation, as 'jurisdictional.'"¹⁷⁷ Essentially, there are three situations pertaining to an agency's jurisdictional interpretation: expansion or contraction of agency authority; fabrication or transformation of power; and alteration of regulatory scope.¹⁷⁸ A noteworthy case involving the FDA's scope of authority is *FDA v. Brown & Williamson Tobacco Corp.*, in which the Court held that Congress did not intend to allow the FDA to regulate tobacco under the FDCA.¹⁷⁹ Congress effectively superseded the *Brown & Williamson Tobacco Corp.* decision by passing the FSPTCA, which ultimately could open the door for the FDA to extend the FDCA's statutory scope and regulate other addictive products such as energy drinks.¹⁸⁰

D. *Is the FDA Re-emerging from the Depths of Congressional Neglect?*

Critics of more expansive FDA regulatory authority commonly claim that the FDA is overburdened, underfunded, and understaffed.¹⁸¹ This

¹⁷⁶ Cf. Sales & Adler, *supra* note 67, at 1513-15 (providing case law that challenged the FDA's scope of authority under the FDCA).

¹⁷⁷ *Id.* at 1502. Justice Stevens, writing for the majority in the landmark decision of *Chevron, U.S.A., Inc. v. NRDC, Inc.*, articulated the following:

When a court reviews an agency's construction of the statute which it administers, it is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.

467 U.S. 837, 842-43 (1984) (footnotes omitted).

¹⁷⁸ See Sales & Adler, *supra* note 67, at 1503-06 (providing a categorization of agency jurisdictional interpretation).

¹⁷⁹ 529 U.S. 120, 126 (2000). In her majority opinion, Justice O'Connor stated that "although agencies are generally entitled to deference in the interpretation of statutes that they administer, a reviewing 'court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.'" *Id.* at 125-26 (quoting *Chevron*, 467 U.S. at 842-43) (footnote omitted).

¹⁸⁰ Conway, *supra* note 67.

¹⁸¹ See Abdullah, *supra* note 77 (providing statements from various senators who believe the FDA lacks the resources to direct and enforce the FSPTCA).

repetitious criticism was evident during floor debates concerning the FSPTCA and the questioning that followed.¹⁸² Most notably, Senator Saxby Chambliss of Georgia made the following assertion:

I voted against the FDA tobacco bill because I'm opposed to the overregulation of an industry that's already highly regulated, from farmer to manufacturer The bill saddles the already overburdened FDA with even more oversight duties, and does nothing to reduce the rate of smoking among Americans—cigarettes already on the shelves will remain on the market.¹⁸³

¹⁸² *Id.* Abdullah writes that Minority Leader Mitch McConnell of Kentucky, Senator Richard Burr of North Carolina, Senator Saxby Chambliss of Georgia, and Senator Jim Bunning of Kentucky “[a]ll oppose giving additional tobacco regulatory powers to the FDA, an agency they argue doesn’t have adequate resources for the task.” *Id.* Senator McConnell argues that “[m]andating the FDA to regulate and approve the use of tobacco would be a distortion of the agency’s mission and a tremendous misuse of its overstretched priorities We should focus FDA resources on protecting the public health, not burdening it with an impossible assignment.” *Id.* In his opening remarks of the floor debate, Representative Henry Waxman articulated that

[s]ome have objected that this bill is too big a challenge for an already overburdened FDA. But it is clear to me that FDA’s recent struggles are primarily a result of years of chronic underfunding. . . . [W]hen we give the agency this new responsibility, we also must give it the resources necessary to do the job and to do it well.

155 CONG. REC. H4338–39 (Apr. 1, 2009) (statement of Rep. Waxman).

¹⁸³ Abdullah, *supra* note 77. Some speculate that the senators from Kentucky, North Carolina, and Georgia voted against the FSPTCA to protect the Big Tobacco companies located in their respective states. *See id.* (“[Those senators] say cigarette companies’ campaign contributions didn’t color their positions on the legislation.”). Concerning campaign contributions, it is interesting to note:

Over the course of his nearly quarter-century Senate career, Minority Leader Mitch McConnell, who hails from the tobacco-rich state of Kentucky, has received \$419,025 from the tobacco industry, more than any other member of Congress, according to the Center for Responsive Politics, a nonprofit, nonpartisan organization that analyzes the influence of money on politics and policy. North Carolina Republican Sen. Richard Burr, who led the opposition to the bill, is the second highest recipient and netted \$359,100 from tobacco-related political action committees and individual contributions. His state is the nation’s largest tobacco grower and is home to R.J. Reynolds, the nation’s second largest tobacco manufacturing company, which contributed \$196,850 to Burr’s campaigns. Georgia Sen. Saxby Chambliss, the ranking Republican on the Senate Agriculture Committee, is the third highest recipient with \$228,700. Kentucky Sen. Jim Bunning, who’s up for re-election next year and is considered the most vulnerable Senate Republican, ranks eighth with \$194,166.

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Conversely, a user fee funds the FSPTCA, which will generate \$4.5 billion over nine years by requiring tobacco companies to directly transfer a percentage of revenue to the FDA.¹⁸⁴ Because of this user fee, lack of funding is likely not a problem for the FDA to effectively regulate; therefore, the argument that the FDA is overburdened and understaffed may be more persuasive.¹⁸⁵

As evidence to support the notion that the FDA may be understaffed, it currently employs only 11,000 scientific, technical, and professional staff to carry out its mission of protecting the health and safety of more than 300 million Americans.¹⁸⁶ Over the years, Congress has simultaneously expanded the size and power of the FDA, while encumbering it with an increasingly broad and arduous task.¹⁸⁷ Peter

Id. (citing statistics from the Center for Responsive Politics).

¹⁸⁴ See 155 CONG. REC. H4339 (Apr. 1, 2009) (statement of Rep. Waxman) (“The tobacco program will be fully funded through a new user fee paid for by the industry.”). User fee taxes are also referred to as “sin taxes,” which are taxes of immediate-gratification goods. See Rizzo & Whitman, *supra* note 51, at 734 (providing examples of sin taxes). According to the FDA, “[t]he User Fee program allows FDA to fulfill its mission of protecting the public health and accelerating innovation in the industry. . . . The Division of User Fees is responsible for the overall management of the program . . . and [it] maintains an accounts receivable system used for user fee invoicing and collections.” FDA, USER FEES, *supra* note 79. More specifically, “[t]he Family Smoking Prevention and Tobacco Control Act User Fee program will generate over \$4.5 [billion] in user fees over nine years (2009–2018).” FDA, TOBACCO PRODUCT FEES, *supra* note 79.

¹⁸⁵ See FDA, FISCAL YEAR 2010 CONGRESSIONAL JUSTIFICATION, EXECUTIVE SUMMARY: INTRODUCTION AND MISSION, *supra* note 78, at 2 (providing an overview of the 2010 proposed budget for the FDA). The Commissioner of the FDA, Margaret A. Hamburg, summarizes the 2010 budget changes as follows:

The fiscal year (FY) 2010 President’s Budget request for FDA is \$3,178,369,000. This represents a total program level increase of \$510,554,000 above the amount enacted into law for FY 2009. The total program level request includes new budget authority, current law user fees, and new proposed user fees. The FY 2010 increase for user fees is \$215,359,000, including \$141,000,000 in proposed new user fees. The FY 2010 increase in budget authority is \$295,195,000, of which \$29,536,000 is for the cost of living pay increase.

Id.

¹⁸⁶ *Id.* The Executive Summary further states that the “FDA affects the lives of every American every day. Each year, consumers spend nearly \$1.5 trillion on FDA-regulated products. This represents twenty percent of all consumer expenditures.” *Id.*

¹⁸⁷ *Id.* Succinctly, the FDA responsible for protecting the public health by assuring the safety of America’s foods, the safety, efficacy, and security of human and veterinary drugs, biological products and medical devices, and the safety and security of cosmetics and products that emit radiation. FDA is also responsible for advancing the public health by helping to speed innovations that make medicines safer and more effective. FDA also provides the public with accurate, science-based information about medicines and foods to improve their health.

Barton Hutt, former FDA chief counsel, contends that this situation is a “paradigmatic example of the ‘hollow government’ syndrome—an agency with expanded responsibilities, stagnant resources, and the consequent inability to implement or enforce its statutory mandates.”¹⁸⁸ This syndrome drives the bureaucratic, anti-regulatory contention that the FDA is not capable of effectively regulating yet another large industry—the energy drink industry.¹⁸⁹

A branch of the FDA, the Center for Food Safety and Applied Nutrition (“CFSAN”) headquartered in College Park, Maryland, currently regulates energy drinks as dietary supplements.¹⁹⁰ In the past, Congress has expected the CFSAN to implement multiple complex statutes while receiving less funding each fiscal year and a reduced

Id. See generally Hutt, *The State of Science*, *supra* note 45, at 434–36 (providing a history of the FDA and the products it regulates).

¹⁸⁸ Hutt, *The State of Science*, *supra* note 45, at 432. Hutt further discusses the troubles the FDA is facing by stating the following:

In terms of both personnel and the money to support them, the agency is barely hanging on by its fingertips. The accumulating unfunded statutory responsibilities imposed on the FDA, the extraordinary advance of scientific discoveries, the complexity of the new products and claims submitted to the FDA for premarket review and approval, the emergence of challenging safety problems, and the globalization of the industries that the FDA regulates—coupled with chronic underfunding by Congress—have conspired to place demands upon the scientific base of the agency that far exceed its capacity to respond.

Id.

¹⁸⁹ Cf. 155 CONG. REC. H4341 (Apr. 1, 2009) (statement of Rep. Buyer) (claiming that the FDA does not have the resources necessary to more comprehensively regulate the tobacco industry). In a floor debate regarding the FSPTCA, Representative Steve Buyer of Indiana stated that

Congress has spent a great deal of time investigating the ways in which the FDA has been unable to fulfill its core mission. Burdening the FDA with additional responsibilities outside the agency’s expertise and core missions at this time will have dire consequences for the American people and the FDA’s ability to ensure the safety and efficacy of our Nation’s food, drugs and medical devices. . . . At a time when FDA is struggling to perform many of its core functions, diversion of its limited resources will negatively impact the safety of the American public.

Id.

¹⁹⁰ See Hutt, *The State of Science*, *supra* note 45, at 459–60 (discussing the disintegrating state of the CFSAN due to insufficient funding and personnel). On its website, the FDA emphasizes that “[t]he Center has over 800 employees, who range from secretaries and other support staff to highly specialized professionals—such as chemists, microbiologists, toxicologists, food technologists, pathologists, molecular biologists, pharmacologists, nutritionists, epidemiologists, mathematicians, sanitarians, physicians and veterinarians.” *About the Center for Food Safety and Applied Nutrition*, *supra* note 43. The CFSAN ensures that the “nation’s food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled.” *CFSAN – What We Do*, *supra* note 43.

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allotment of full-time equivalent employees.¹⁹¹ More recently however, in the fiscal years of 2008 and 2009, the CFSAN employed 753 and 854 workers, respectively.¹⁹² To help address this understaffing issue, Congress is planning to increase the employment allotment for the CFSAN to an estimated 947 skilled positions in the fiscal year 2010.¹⁹³ In the 2008 and 2009 CFSAN budget for salaries and expenses, Congress authorized \$576,659,000 and \$648,722,000, respectively.¹⁹⁴ For fiscal year 2010, the FDA requested \$782,915,000, which also tends to indicate that the CFSAN is gaining strength.¹⁹⁵ Consequently, it appears that the FDA, and more specifically, the CFSAN, is on the rebound pertaining to funding and employment figures.¹⁹⁶ Although critics of increased FDA regulatory power contend the FDA is already overburdened, underfunded, and understaffed, in actuality, the FDA seems to be reemerging from the depths of congressional neglect and setting sail on the proper course to protect and promote healthy lifestyles.¹⁹⁷

Although there is fervent disagreement regarding the therapeutic effects of caffeine, the necessity of regulation, and the amount of FDA resources, it is not necessarily a negative atmosphere.¹⁹⁸ Rather, as

¹⁹¹ See Hutt, *The State of Science*, *supra* note 45, at 459–61 (detailing concerns regarding the viability of the food safety program in the CFSAN). According to Hutt, “[i]n the fifteen years from 1992 to 2007, CFSAN suffered a reduction in force of 138 people, from 950 to 812, or fifteen percent of its staff.” *Id.* at 459. Although the CFSAN suffered enormous losses in funding and personnel, Congress

expected [the CFSAN] to implement such complex statutes as the Nutrition Labeling and Education Act of 1990, the Dietary Supplement Health and Education Act of 1994, the FDA Modernization Act of 1997, the Food Safety and Security Amendments of 2002, the Food Allergen Labeling and Consumer Protection Act of 2004, and the Sanitary Food Transportation Act of 2005, and most recently the Dietary Supplement Adverse Event Reporting Act of 2006 and the Food Safety Amendments of 2007—to name just the most important unfunded food statutes enacted during this period—while facing a loss of 138 people.

Id.

¹⁹² FOOD & DRUG ADMINISTRATION, DETAIL OF FULL-TIME EQUIVALENT (FTE) EMPLOYMENT PROGRAM LEVEL, *supra* note 43, at 265.

¹⁹³ *Id.*

¹⁹⁴ FOOD & DRUG ADMINISTRATION, FY 2010 ALL PURPOSE TABLE—BUDGET AUTHORITY, *supra* note 43.

¹⁹⁵ *Id.*

¹⁹⁶ See *supra* notes 194–95 and accompanying text (providing the fiscal budgets for 2008, 2009, and estimated budget for 2010).

¹⁹⁷ See *infra* Part IV (proposing a plan to increase FDA funding and personnel so the agency may more effectively regulate the energy drink industry).

¹⁹⁸ See *supra* Part III.A (providing a comparison of the various forms of regulation); *supra* Part III.B (comparing the therapeutic effects of caffeine to tobacco); *supra* Part III.D (analyzing the scarcity of resources argument regarding the FDA’s ability to regulate).

Mahatma Gandhi wisely articulated, “[h]onest disagreement is often a good sign of progress.”¹⁹⁹ Progress in energy drink regulation could come by means of a congressional act to amend the FDCA that increases funding and employee allotment for the CFSAN, as well as modifies the language of the FDCA to permit increased regulation of dietary supplements and an implementation of an energy drink user fee program to raise capital.²⁰⁰

IV. PROPOSED AMENDMENT TO THE FDCA

A practical and efficient solution to the energy drink regulation conundrum is for Congress to pass legislation amending the FDCA and expressly afford the FDA regulatory power over energy drinks similar to that which it now exercises over tobacco. If Congress amends the FDCA allowing the FDA to implement certain protective measures, the FDA will effectively avoid jurisdictional obstacles.²⁰¹ The FSPTCA resolved ambiguity regarding tobacco regulation, and an amendment of the FDCA can do the same.²⁰² The following subsections provide a proposed statutory definition, a FSPTCA provision applicable to energy drink regulation, suggested directives for implementation, and recommended warning label requirements for energy drinks.²⁰³

A. *Proposed Statutory Definition of an Energy Drink*

Congress should amend the FDCA (21 U.S.C. § 321) by inserting a provision following section 321(ff)(2) that explicitly defines an energy drink as “*a heavily-caffeinated liquid substance for use by man to supplement the diet.*”²⁰⁴ This provision will remove ambiguity as to whether an energy drink is classified as a conventional food product or a dietary supplement.²⁰⁵ Proposed subsection (ss), following section 321(rr), will

¹⁹⁹ JOHNSON, *supra* note 108, at 117.

²⁰⁰ See *infra* Part IV (proposing a modification of the FDCA that would afford the FDA the requisite authority and capital to regulate energy drinks).

²⁰¹ See *supra* Part III.C (explaining FDA jurisdictional issues).

²⁰² The following proposals are the author’s contributions. Specifically, proposed additions are italicized, and existing statutory language is left unchanged. The author’s commentary and suggestion for implementation follows each proposed FDCA amendment.

²⁰³ See *infra* Part IV (providing amendments to the FDCA and directives for FDA regulation of energy drinks).

²⁰⁴ See 21 U.S.C. § 321(ff) (2006) (defining dietary supplement).

²⁰⁵ See *supra* text accompanying notes 54–61 (explaining the statutory overlap regarding dietary supplement and conventional food products).

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define the phrase “heavily caffeinated liquid substance.”²⁰⁶ Proposed subsection (ss) provides the following:

(ss) *The term “heavily caffeinated liquid substance” means any fluid liquid beverage containing:*

(1) *a quantity of caffeine in excess of eighty (80) milligrams per eight (8) ounces; or*

(2) *one or more of the following ingredients constituting an “energy blend”:*

(A) *Carnitine;*

(B) *Glucuronolactone;*

(C) *Glucose;*

(D) *Guarana;*

(E) *Inositol;*

(F) *Maltodextrin;*

(G) *Panax Ginseng;*

(H) *Super Citramax (Hydroxy Citric Acid, Garcinia Cambogia Extract);*

(I) *Taurine; or,*

(J) *Yohimbine HCL.*

Eighty milligrams caffeine per eight ounces is generally the minimum threshold amount of caffeine that energy drink manufacturers include in their beverages.²⁰⁷ In addition, energy drinks contain “energy blends” commonly concocted of the above-listed ingredients.²⁰⁸ Thus, this proposed subsection categorizes a heavily caffeinated beverage as an energy drink according to its ingredients, rather than the manufacturer’s marketing claims.²⁰⁹

B. Application of FSPTCA Provisions to Energy Drink Regulation

Next, Congress should amend the FDCA and afford the FDA the authority to regulate heavily caffeinated beverages in a way similar to how it regulates tobacco. In the first line of the FSPTCA regarding the purpose of the statute, Congress unequivocally granted the FDA power to regulate the manufacturing, marketing, and distribution of tobacco

²⁰⁶ See *supra* note 46 (listing common energy drink ingredients and discussing the advertised and actual pharmacological effects of each ingredient).

²⁰⁷ See *supra* note 47 and accompanying text (discussing typical caffeine content of energy drinks).

²⁰⁸ See *supra* note 46 (listing common energy drink ingredients contained in “energy blends”).

²⁰⁹ See *supra* notes 54–61 (explaining why the DSHEA permits manufacturers to categorize its product as a dietary supplement solely based on marketing claims).

products—a power that can be operative in regulating energy drinks as well.²¹⁰ In section 342(f)(1) of the FDCA, Congress should include a new subsection (E), which grants the FDA the requisite authority to regulate energy drinks.²¹¹ The proposed amendment to section 342(f)(1) is as follows:

- (f) Dietary supplement or ingredient: safety.
 (1) If it is a dietary supplement or contains a dietary ingredient that—

.....

(E) presents a genuine risk of illness or injury proximately resulting from ingestion of a heavily caffeinated liquid substance (as defined by 21 U.S.C. § 321(ss)), the Secretary shall have discretion to regulate the manufacturing, marketing, and distribution in the least restrictive manner appropriate to protect the public health.

To begin, proposed subsection (E) provides that the FDA will retain the initial burden of proof. In order to regulate an energy drink, the FDA (or more specifically, the CFSAN) must prove by a preponderance of the evidence that one or more of the ingredients in the energy drink presents a “genuine risk of illness or injury.”²¹² This standard is not as onerous as the “significant or unreasonable risk of illness or injury” standard stated in subsection (A), but it still requires the FDA to show that one or more of the ingredients contained in a given energy drink should be regulated to protect the public health.²¹³ This requirement benefits manufacturers because the FDA cannot issue blanket regulations for the entire industry. Instead, the FDA must evaluate the ingredients of each individual product with regard to safety. More specifically, the CFSAN must show,

²¹⁰ See *supra* Part III.C (providing an analysis whether certain provisions of the FSPTCA are applicable to energy drink regulation). See *generally supra* Part II.C (discussing the Family Smoking Prevention and Tobacco Control Act of 2009). In addition to amending the FDCA, Congress should pass a directive, which implements an energy drink user-fee program to help fund the FDA’s regulatory efforts.

²¹¹ See 21 U.S.C. § 342(f)(1) (2006) (defining safety requirements for dietary supplements).

²¹² See *e.g.*, BLACK’S LAW DICTIONARY (8th ed. 2004). *Black’s Law Dictionary* defines “genuine” as “(Of a thing) authentic or real; having the quality of what a given thing purports to be or to have.” *Id.* Comparatively speaking, the “genuine risk” standard is less burdensome to prove than the “significant or unreasonable risk” standard stated in subsection (A) but is a greater standard to surpass than, for instance, a legitimate or justifiable risk.

²¹³ *Id.*

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through empirical evidence, that one or more of the ingredients included in the energy drink yields a genuine risk of illness or injury.²¹⁴

Next, the second clause of proposed subsection (E) grants the Secretary of the FDA authority to regulate the manufacturing, marketing, and distribution of energy drinks as he or she deems necessary. This authority is constrained, however, by the third clause that allows the Secretary to implement regulations as needed to protect the public health, but only in a minimally intrusive manner. The third clause will help prevent an FDA Secretary from exceeding his or her grant of authority, thus hopefully averting a potential *Chevron*-type conflict.²¹⁵

C. *Suggested Directives for Implementation and Enforcement*

Proposed subsection (E) provides the FDA with the power to regulate the manufacturing, marketing, and distribution of energy drinks; however, what does that entail?²¹⁶ Although listed first in the proposed statute, the Secretary may only use the authority to regulate manufacturing as a last resort where an impending, perilous risk to the public is present. If the situation requires, the Secretary may compel the manufacturer to remove the energy drink from the market and modify its ingredients. Once the manufacturer makes the required changes, it must file for re-approval.

When the CFSAN determines that a certain energy drink poses a genuine risk of illness or injury to the populace, the Secretary should initially focus his or her efforts on issues associated with energy drink marketing. For example, a straightforward and effective regulatory strategy would require conspicuous warning labels on the cans, packaging, and advertisements.²¹⁷ For years, the FDA required tobacco companies to print, in rotation, various Surgeon General Warnings to inform tobacco users of the risks involved with tobacco use.²¹⁸ The FDA should implement a similar requirement for energy drinks because it is simple to institute and does not increase manufacturing costs.

²¹⁴ *Id.*

²¹⁵ See generally *supra* note 177 (discussing the *Chevron* analysis courts apply when faced with a question whether a governmental agency exceeded its grant of authority).

²¹⁶ The subsequent implementation suggestions and guidelines are of the author's opinion.

²¹⁷ See *supra* note 74 and accompanying text. According to the FSPTCA, tobacco manufacturers will be required as of June 22, 2011, to print text and graphic warning labels covering fifty percent of the front and rear panels of the package. See *Effective Dates of New FDA Tobacco Law Provisions*, *supra* note 74 (discussing FSPTCA implementation guidelines).

²¹⁸ See *supra* note 73 (listing common Surgeon General's Warnings displayed on tobacco packaging).

D. Recommended Warning Label Requirements

Similar to tobacco labeling standards, the FDA should require energy drink manufacturers to display, in a contrasting color, various bold-font warnings determined by the FDA.²¹⁹ Further, the FDA should require manufacturers to display the warning above the brand label and rotate the warning statements on a quarterly basis. For instance, the warnings could state the caffeine content in milligrams and give a proportional comparison to a standard unit, such as a single cup of coffee (e.g., *"This beverage contains the equivalent amount of caffeine in 2.5 cups of coffee."*). In addition, cautionary statements should be displayed on a rotating basis stating the following:

"Do not consume this beverage if you are pregnant or nursing, or less than 13 years of age";
"This beverage may cause nervousness, irritability, sleeplessness, and occasional rapid heartbeat";
"Do not consume this beverage if you experience chest pains";
and
"This beverage may cause caffeine intoxication and lead to addiction."

Finally, proposed subsection (E), pursuant to CFSAN findings and the Secretary's judgment, permits the FDA to regulate the distribution of energy drinks. This power should not be employed for punitive measures but rather used for protective purposes. For instance, the FDA could restrict the sale and supply of energy drinks in public elementary and middle schools. Several schools nationwide already ban the sale and supply of energy drinks; thus, this restriction is merely an extension of locally enforced policy. In closing, the former propositions serve as a plan to achieve a theoretical objective. In order for this regulatory scheme to develop and flourish, Congress must amend the FDCA, thereby affording the FDA greater regulatory authority analogous to the recently enacted FSPTCA.

V. CONCLUSION

As time passes and new generations are born, government policy evolves. In the United States' representative democracy, sometimes elected officials speak for the majority of their constituents and sometimes for themselves. Further, the scope of government regulation

²¹⁹ See *supra* note 74 (discussing the broad authority Congress granted the FDA by passing the FSPTCA).

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is perpetually debated, and political majorities generally control the argument. However, one tenet that elected officials typically share is the dedication to protect the public's health and safety.

Legislators commonly rely on scientific evidence when determining whether to regulate a product. In the case of energy drinks, results of scientific studies conflict, but the safety concern remains. Congress retains the power to amend the FDCA and insert provisions that enable the FDA to regulate heavily caffeinated beverages. Regardless of the political party in power, Congress often responds too late after the harm occurs. Perhaps preemptive regulation is imprudent, but it is worth an attempt. Therefore, an amendment of the FDCA granting the FDA authority to regulate energy drinks would be a step in the right direction.

Joseph G. Hoflander*

* J.D. Candidate, Valparaiso University School of Law (2011); B.A., Political Science, Magna Cum Laude, Westminster College (2008). I would like to thank my parents, Harold and Kay Hoflander, for their love and encouragement and for teaching me that no matter what obstacle may arise, hard work, integrity, and faith will guide me toward excellence. Additionally, I must thank Red Bull and Monster for providing me with not only an intriguing issue to write about, but also the energy and mental stimulation needed to author this Note.