# COMMENT

## RETURN TO REGULATION: FDA, ENERGY DRINKS, AND OUR YOUTH*

TABLE OF CONTENTS



* J.D. Candidate, University of Houston Law Center, 2016. Special thanks to the many editors of the *Houston Law Review* for their dedication and commitment in preparing this Comment for publication, and my wife, Leah.

## I. INTRODUCTION

Throughout the history of human consumption, caffeine has been a unique substance.[1] No other addictive psychoactive substance has withstood restriction and regulation, is freely available almost everywhere, sold without license, offered over the counter, and even added to beverages intended for children.[2]

This Comment examines a relatively new group of caffeinated beverages: energy drinks and energy shots (referred to collectively as "energy drinks").[3] Over the past decade, the energy drink industry experienced staggering growth, becoming a multi-billion dollar industry.[4] Over this same period of time, energy drinks became extremely popular with children and adolescents.[5] Many believe the popularity of energy drinks among the country's youth directly results from targeted advertising efforts by energy drink companies.[6]

The Food and Drug Administration (FDA) is the principle agency in charge of regulating the safety of these products.[7] However, because of lenient FDA requirements for caffeinated

---

1. BENNETT ALAN WEINBERG & BONNIE K. BEALER, THE WORLD OF CAFFEINE: THE SCIENCE AND CULTURE OF THE WORLD'S MOST POPULAR DRUG, at xi (2001); *see also* GOODMAN & GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 622 (Laurence L. Brunton et al. eds., 11th ed. 2006) (describing caffeine as the "most widely used psychoactive *drug* in the world" (emphasis added)).

2. WEINBERG & BEALER, *supra* note 1, at xi.

3. Carey Polis, *Energy Drinks Survey Finds Confusing Marketing, Unclear Caffeine Content*, HUFFINGTON POST (Apr. 11, 2013, 1:55 PM), http://www.huffingtonpost.com/2013/04/11/energy-drinks-survey_n_3061047.html.

4. *See infra* notes 51–55 and accompanying text (describing the substantial growth of the energy drink industry since 2008, with experts predicting that the energy drink industry will be a $21.5 billion industry by 2017); *see also Top Selling Energy Drink Brands*, CAFFEINE INFORMER, http://www.caffeineinformer.com/the-15-top-energy-drink-brands (last visited Apr. 22, 2016) (reporting that the two leading energy drink products, Red Bull and Monster, brought in $4.5 and $3.6 billion in 2015 respectively).

5. *See infra* notes 56–59 and accompanying text (noting that approximately half of the energy drink market consists of consumers under the age of twenty-five and that the energy drink market is the fastest growing segment of the overall beverage market).

6. *See* EMERGENCY DEPARTMENT VISITS INVOLVING ENERGY DRINKS, DRUG ABUSE WARNING NETWORK 2 (2011), http://archive.samhsa.gov/data/2k11/WEB_DAWN_089/WEB_DAWN_089_HTML.pdf [hereinafter DAWN REPORT] ("[E]nergy drinks are marketed to appeal to youth . . . [by] suggesting benefits such as increased energy and stamina, weight loss, and enhanced physical and/or mental performance."); *infra* Part II.C (detailing how the energy drink industry aggressively advertises to children and adolescents with alluring product names, extreme sports sponsorships, text messaging, and social media interaction).

7. *What We Do*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/WhatWeDo/default.htm (last updated Dec. 7, 2015). The "FDA is responsible for protecting the public health by assuring the safety, efficacy and security" of our nation's food supply, and for advancing the public health "by helping the public get the accurate, science-based information they need to use . . . foods to maintain and improve their health." *Id.*

conventional beverages and dietary supplements, young consumers remain unprotected from unsafe products and misleading claims.[8] Under current law, energy drink manufacturers can elect the classification of their product as either a conventional beverage or a dietary supplement by altering the product's claims and labeling.[9] Young consumers are often ignorant to the differences between the two types of products.[10] On the one hand, the FDA does not require beverage manufacturers to reveal the amount of caffeine contained in the product.[11] When the amount of caffeine is voluntarily provided on the product's label, it is often underestimated and does not account for the inclusion of herbal ingredients.[12] On the other hand, the FDA allows dietary supplement manufacturers to hide the exact amount of certain ingredients in their products by displaying all of them in a single category, as a "proprietary blend."[13] Furthermore, the FDA allows dietary supplement labels to make certain health claims concerning their product without any scientific proof of the product's efficacy.[14] As a result, energy drink

8. *See infra* Part III.A.2 (describing how the FDA's broad interpretation and application of the Food Additive Amendment prompted Congress to deregulate the dietary supplement industry, providing energy drink companies today great freedom in the ingredients included in their products).

9. *See* 21 U.S.C. § 321(ff)(1) (2012) (defining a "dietary supplement" as a product "*intended* to supplement the diet that bears or contains" an explicitly listed dietary ingredient (emphasis added)); § 321(ff)(2)(B)–(C) (requiring that dietary supplements not be "represented for use as a conventional food" and be "labeled as a dietary supplement").

10. *See Energy Drinks: Exploring Concerns About Marketing to Youth*: *Hearing Before the S. Comm. On Commerce, Sci. & Transp.,* 113th Cong. 32 (2013) (statement of Marcie Beth Schneider, Member, Am. Acad. of Pediatrics) ("[I]t [is] difficult to discern products' caffeine and other stimulant content. Nearly identical products are often marketed and represented differently to consumers, based on the distinction of whether they are categorized as beverages or dietary supplements.").

11. *Why Isn't the Amount of Caffeine a Product Contains Required on a Food Label?*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/aboutfda/transparency/basics/ucm194317.htm (last updated Mar. 4, 2016).

12. While the American Beverage Association issued a voluntary guidance for its member companies to disclose caffeine content on energy drink labels, the amounts listed have been found to underestimate the amount of caffeine per serving, and do not account for the synergistic effect that occurs when caffeine is added with other herbal stimulants. *See* AM. BEVERAGE ASS'N, ABA GUIDANCE FOR THE RESPONSIBLE LABELING AND MARKETING OF ENERGY DRINKS 1, http://ameribev.org/files/339_Energy%20Drink%20Guidelines%20(final).pdf; Sara M. Seifert et al., *Health Effects of Energy Drinks on Children, Adolescents, and Young Adults*, 127 PEDIATRICS 511, 512 (2011) (stating that actual caffeine content may exceed the amount listed due to herbal ingredients such as guarana and yerba mate not included in the calculation).

13. *See infra* notes 176–178 and accompanying text (describing how dietary supplements must indicate the amount of caffeine in the product, but do not have to indicate the amount of other herbal ingredients with similar stimulating effects).

14. *See* 21 U.S.C. §§ 342(f)(1)(B), 350b(d) (2012) (excusing "old dietary ingredients," those marketed in the United States before October 15, 1994, from the reporting requirements for "new dietary ingredients"); *infra* notes 168–91 and accompanying text

labels often mislead young consumers into believing that these products should be consumed as if they were hydrating sports drinks.[15] Unlike drugs, energy drinks require no testing before they are sold to consumers.[16] The ultimate result: uninformed adolescents and children consuming excessively stimulating products for improper, unsafe purposes that the FDA has not tested for safety.[17]

Excessive caffeine consumption represents a substantial danger to young consumers. These dangers include typical health risks that adults also experience, such as caffeine toxicity, sleeplessness, heart palpitations, hypertension, central nervous stimulation, nausea, vomiting, convulsions, irregular heartbeat, and even sudden death, but also health risks related specifically to neurological development.[18] Energy drink labels and advertisements suggest a connection with increased athletic performance, but the actual effects on athletes are mainly negative, and include insomnia, nervousness, and a risk of severe dehydration if consumed like a sports drink.[19]

While energy drink manufacturers marketing their product as a dietary supplement are required to report serious adverse events regarding the use of their products to the FDA, and while these adverse reports confirm the reality of health risks associated with energy drink consumption,[20] young consumers are still left

(describing how the burden manufacturers must satisfy for new dietary ingredients does not include actually establishing safety or efficacy).

15. *See infra* Part II.A.2.

16. 21 U.S.C. § 355 (a)–(b) (2012).

17. *See infra* Part II.D (describing the multifarious health risks involved with youth energy drink consumption).

18. *Id.*

19. *Energy Drinks*, PLAY HEALTHY, http://playhealthy.drugfree.org/facts/energy-drinks (last visited Apr. 22, 2016); *see also infra* note 64 and accompanying text (describing how energy drink companies use extreme sports sponsorships in their marketing strategies); *infra* Part II.A.2 (warning that the purpose of sports drinks is hydration while energy drinks act as a diuretic).

20. *See Voluntary and Mandatory Reports on 5-Hour Energy, Monster Energy, and Rockstar Energy Drink, Jan. 1, 2004 through Oct. 23, 2012*, U.S. FOOD & DRUG ADMIN., Nov. 15, 2012, http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/UCM328270.pdf (providing that from January 1, 2004 through October 23, 2012, the FDA received the following reports: sixteen life-threatening events and thirteen deaths associated with 5-Hour Energy; and four life-threatening events and five deaths associated with Monster Energy). *See also* DAWN REPORT, *supra* note 6, at 3 (reporting that between 2004 to 2009, 45% of energy drink related emergency room visits were made by patients aged 18 to 25, 32% of visits were made by patients aged 26 to 39, and 11% of visits were made by patients aged 12 to 17 and adults aged 40 or older). The DAWN Report also notes that there was a tenfold increase in energy drink related emergency room visits between 2005 and 2009 (1,128 visits to 13,114 visits respectively). *Id.*

unprotected due to FDA's inability to act.[21] The FDA's inaction is beginning to push this protection gap to the courts, with numerous consumers filing lawsuits against energy drink companies over the past few years.[22] In February 2016, a national consumer law firm filed lawsuits against Monster Beverage Corporation on behalf of five people claiming to have suffered serious injuries, and the firm claims to have 100 more similar suits in the works. [23] While the ultimate success of these cases remains unclear, they illustrate increasing public awareness of the dangers of energy drink consumption among adolescents and children.[24]

The need for increased regulation is not unknown. The medical community has urged for tighter regulations on the energy drink industry concerning adolescent energy drink consumption.[25] Scholars have taken notice of the problem as well, but the changes called for are too drastic to have any chance of success.[26] Recently, politicians have recommended reasonable and rational changes for the energy drink industry to protect young

---

21. *See* Part III.B (describing the aftermath of FDA regulatory authority following Congress's deregulation of the dietary supplement industry).

22. Prior to 2010, litigation addressing the health risks of caffeine was "virtually non-existent." James G. Hodge, Jr. et al., *The Consumable Vice: Caffeine, Public Health, and the Law*, 27 J. CONTEMP. HEALTH L. & POL'Y 76, 115 (2010). Since that time, however, a number of product liability, wrongful death, and class action lawsuits have been filed against energy drink companies. Mike Esterl, *Coke Says It's Ready to Let Monster In: Soda Giant Stands by Decision to Take Stake in Energy Drink, Despite Liability Suits,* WALL ST. J. (May 26, 2015, 9:10 PM), www.wsj.com/articles/coke-says-its-ready-to-let-monster-in-1432689055 (discussing numerous lawsuits filed against Monster since 2010). For example, on October 17, 2012, Wendy Crossland and Richard Fournier filed suit against Monster Beverage Corporation, claiming that consumption of two energy drinks within a twenty-four hour time period caused their fourteen-year-old daughter to die from cardiac arrest. Complaint at 2, Crossland v. Monster Beverage Corp., No. RIC 1215551 (Cal. Super. Ct. Oct. 17, 2012), 2012 WL 5007518. Paula Morris filed a wrongful death action against Monster Beverage Corporation on June 25, 2013, claiming that consumption of the drink caused her nineteen-year-old son to die from cardiac arrest while he was engaged in sexual activity. Complaint at 3, Morris v. Monster Beverage Corp., No. RG13685028 (Cal. Super. Ct. June 25, 2013), 2013 WL 3197674. These cases were settled for undisclosed amounts. Esterl, *supra*.

23. *See* Lisa Blanck, *Lawsuits Filed in Florida Against Monster Beverage Corporation*, EXAMINER, (Feb. 8, 2016, 9:19 PM), http://www.examiner.com/article/lawsuits-filed-florida-against-monster-beverage-corporation.

24. *See also infra* text accompanying note 78 ("74% to 78% of American parents believe energy drinks should not be marketed or sold to children or teens . . . .").

25. Barry Meier, *Doctors Urge F.D.A. to Restrict Caffeine in Energy Drinks*, N.Y. TIMES (Mar. 19, 2013), http://nyti.ms/1AxyGsw.

26. Some of these drastic changes include requiring FDA approval similar to pharmaceutical drugs and an outright repeal of DSHEA. *See* Peter J. Cohen, *Science, Politics, and the Regulation of Dietary Supplements: It's Time to Repeal DSHEA*, 31 AM. J.L. & MED. 175, 213 (2005) (calling for an outright repeal of DSHEA); Hodge, *supra* note 22, at 113–14 (recommending that the FDA apply the caffeine standard for sodas to all beverages and that age restrictions should apply to the sale of beverages containing caffeine above this amount).

consumers from the danger of excessive caffeine intake, but without FDA and legislative action, young consumers remain unprotected.[27]

While adoption of these recommendations would be a significant step towards better protecting children and adolescents from the health risks of energy drinks, the FDA should implement two similar and overlapping changes to ensure the long-term safety of these products: (1) requiring caffeine content labels to include not only added caffeine, but also the content of herbal ingredients that provide a stimulant-like effect and may interact with caffeine; and (2) reforming the Adverse Event Reporting System to provide the FDA with pertinent information.[28] Part II of this Comment describes the types of energy products currently on the market and the increasing consumption of these products, as well as the health risks associated with adolescent consumption. Part III examines the FDA's regulatory authority over these products. Specifically, this Part will explore (1) the history of the FDA's treatment of caffeinated beverages; (2) the deregulation of the dietary supplement industry through the Dietary Supplement Health and Education Act; and (3) recent congressional attempts to better protect consumers through implementation of an Adverse Events Reporting System. Part IV outlines various strategies the FDA should implement outside of legislative action to better protect children and adolescents.

## II. ENERGY DRINKS AND SOCIETY

Before deciding on the proper direction and scope for regulatory reform in the energy drink industry, it is important to keep in mind that the purpose of such reform should be, first and foremost, protecting the public from unsafe products.[29] To this end,

---

27. *See* EDWARD J. MARKEY, RICHARD J. DURBIN, & RICHARD BLUMENTHAL, BUZZ KILL 5 (2014), http://www.markey.senate.gov/imo/media/doc/2014-12-30-Report_BuzzKill_EnergyDrinks_ScreenV.pdf [hereinafter BUZZ KILL]. The report by Senators Markey, Durbin, and Blumenthal contains the following recommendations: (1) energy drink manufacturers should cease marketing energy drinks to children under the age of 18 and cease selling energy drinks in K–12 school settings; (2) energy drink manufacturers should cease marketing energy drinks as intended to be consumed for hydration purposes; (3) the FDA should release guidance to the industry on voluntary reporting of adverse events; and (4) the FDA should define what constitutes an energy drink. *Id.* On February 10, 2015, Senator Robert Menendez reintroduced the Safe Play Act, which would allow multiple federal agencies to develop information about energy drink ingredients and recommend guidelines for the safe use of energy drink consumption by young consumers. Safe Play Act, S. 436, 114th Cong., § 6 (2015) (initially introduced as S. 2718, 113th Cong. (2014)).

28. Currently, the FDA does not require medical records or even the age of the affected person to be submitted. *Infra* Part III.B.

29. *See* Christopher C. DeMuth & Douglas H. Ginsburg, *Rationalism in Regulation*, 108 MICH. L. REV. 877, 879–80 (2010) (book review) ("The purpose of [regulatory reforms]

this Part begins by examining the types of caffeinated products currently on the market and compares them with other non-caffeinated products that consumers often get confused. Next, this Part examines the recent market trends in the energy drink market. Finally, this Part describes the aggressive marketing strategies employed to reach young consumers and concludes with a grim look into the looming health crisis that will result if excessive consumption is not curtailed.

### *A. Caffeinated Products*

People have consumed caffeine for centuries through the natural properties of the seeds, leaves, and fruit of cocoa, guarana, kola nuts, yerba mate, and more than sixty other plants.[30] Over the past 500 years, consumers have found their caffeine fix mainly through coffee and tea.[31]

During the early twentieth century, carbonated soft drinks emerged, often containing kola nut (with manufacturers claiming the inclusion of caffeine was to enhance flavor).[32] Today, consumers purchase products that contain caffeine extracted from natural sources and injected with synthetic sources through conventional foods, beverages, dietary supplements, over-the-counter drugs, and pharmaceutical drugs.[33] Common

---

is to make regulation more effective and productive—to counter the influence of narrow interest groups in bending rules to their selfish advantage . . . .). *But see The Dietary Supplement Health and Education Act of 1994 (DSHEA)*, COUNCIL FOR RESPONSIBLE NUTRITION, http://www.crnusa.org/leg.html (last visited Apr. 22, 2016) (quoting the White House press release following the signing of the Dietary Supplement Health and Education Act as stating: "we have finally reformed the way Government treats consumers and supplements in a way that encourages good health").

30. Regan L. Bailey et al., *Estimating Caffeine Intake from Energy Drinks and Dietary Supplements in the United States*, 72 NUTRITION REVIEWS (SPECIAL ISSUE) 9, 9–10 (2014); LASZLO P. SOMOGYI, CAFFEINE INTAKE BY THE U.S. POPULATION 4 (2010), http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/UCM333191.pdf.

31. Bill J. Gurley, Susan C. Steelman & Sheila L. Thomas, *Multi-Ingredient, Caffeine-Containing Dietary Supplements: History, Safety, and Efficacy*, 37 CLINICAL THERAPEUTICS 275, 275 (2015); Bertil B. Fredholm, *Notes on the History of Caffeine Use*, in 200 HANDBOOK OF EXPERIMENTAL PHARMACOLOGY 1, 3–6 (F.B. Hofmann ed., 2011); *see also* GOODMAN AND GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS, *supra* note 1, at 727 ("The basis for the popularity of all caffeine-containing beverages is the ancient belief that they have stimulant and antisoporific actions that elevate mood, decrease fatigue, and increase capacity for work.").

32. Gurley, Steelman & Thomas, *supra* note 31, at 275. While the flavor-enhancing justification for adding caffeine to sodas has since been debunked, the argument allowed soda manufacturers to avoid stricter regulation on multiple occasions. *See infra* notes 126–51 and accompanying text (describing how Coca Cola was able to avoid strict regulations by relying on the precedent of a settlement reached with the FDA where Coca Cola argued that the purpose of caffeine's presence was only to enhance flavor).

33. Bailey, *supra* note 30, at 9–10, 12–13.

products on the market today containing varying amounts of caffeine include coffee, tea, soft drinks, energy drinks and shots, chocolate, certain medications (headache relief and painkillers), dietary supplements, and over-the-counter stimulants.[34] Of these products, energy drinks in particular are widely available and marketed extensively to children and adolescents.[35]

*1. Energy Drinks Defined.* Energy drinks are beverages that contain varying amounts of caffeine, along with other additives such as vitamins, taurine,[36] theanine, carnitine, herbal supplements, and guarana,[37] a plant product that contains concentrated caffeine.[38] Energy drinks typically contain large doses of these stimulant-rich herbal extracts, which interact with the caffeine in the product.[39] These additional ingredients act in synergy with the caffeine to provide a greater stimulant effect.[40]

While soda and energy drinks are often thought to be similar products, energy drinks contain greater levels of caffeine than soda because the FDA's caffeine limits for sodas do not apply to energy drinks.[41] Additionally, even if these limits did apply to energy drinks, they still do not account for the synergistic effect that occurs when caffeine is combined with stimulant-rich herbal

---

34. Elvira Gonzalez de Mejia & Marco Vinicio Ramirez-Mares, *Impact of Caffeine and Coffee on Our Health*, 25 TRENDS IN ENDOCRINOLOGY & METABOLISM 489, 489 (2014). *See* Gurley, Steelman & Thomas, *supra* note 31, at 276 (stating that purified caffeine can be found in over-the-counter drugs such as NoDoz and Excedrin).

35. *See* Kavita M. Babu, Richard James Church & William Lewander, *Energy Drinks: The New Eye-Opener for Adolescents*, 9 CLINICAL PEDIATRIC EMERGENCY MED. 35, 35 (2008), https://com-emergency.sites.medinfo.ufl.edu/files/2013/02/energy-drinks.pdf (stating that energy drinks are widely available and can be found in grocery stores, convenience stores, and school bookstores).

36. Taurine is an amino acid that enhances the effect of caffeine. SOMOGYI, *supra* note 30, at 4.

37. Guarana typically contains more caffeine than coffee beans and contains other stimulants such as theobromine and theophylline. *Id.*

38. Densie Webb, *The Truth About Energy Drinks*, 15 TODAY'S DIETITIAN, Oct. 2013, at 62, http://www.todaysdietitian.com/newarchives/100713p62.shtml.

39. Janet Thorlton, David A. Colby & Paige Devine, *Proposed Actions for the US Food and Drug Administration to Implement to Minimize Adverse Effects Associated with Energy Drink Consumption*, 104 AM. J. PUB. HEALTH 1175, 1175 (2014); Seifert, *supra* note 12, at 512; Margaret Hamburg, FDA Comm'r, Remarks to a Meeting of the Institute of Medicine, Caffeine in Food and Dietary Supplements: Examining Safety (Aug. 5, 2013), http://www.fda.gov/NewsEvents/Speeches/ucm363925.htm.

40. SOMOGYI, *supra* note 30, at 5.

41. Chad J. Reissig, Eric C. Strain & Roland R. Griffiths, *Caffeinated Energy Drinks—A Growing Problem*, 99 DRUG & ALCOHOL DEPENDENCE 1, 2 (2009); Thorlton, Colby & Devine, *supra* note 39, at 1175–76; *see also* Hodge, *supra* note 22, at 114. (arguing that the FDA's caffeine limits for soda should "apply to all beverages that are lawfully sold and consumed by children and adolescents under the age of twelve"). The current limit set for caffeine is 0.02%, which in cola-type beverages is approximately 71 milligrams per 12 fluid ounces. 21 C.F.R. § 182.1180(b) (2015); Reissig, Strain & Griffiths, *supra*.

extracts.[42] The ways in which the various ingredients in energy drinks interact with eachother and are metabolized are largely underexplored.[43] Similar to energy drinks, energy shots are a concentrated form of caffeine and herbal extracts, usually sold in two-ounce containers, but which normally contain the same amount of caffeine as larger energy drinks.[44] In comparison, sports drinks, which do not contain caffeine, are wholly dissimilar to energy drinks, yet energy drink companies often market their products as if the two accomplished similar goals.

*2. Sports Drinks Compared.* Companies often market energy drinks and sports drinks to adolescents and children as if they were similar products, but these products should not be confused.[45] Sports drinks contain electrolytes to rehydrate the consumer, but the main ingredient of energy drinks, caffeine, is a diuretic, resulting in a loss of fluid from the body.[46]

The National Collegiate Athletic Association advises student athletes in its Sports Medicine Handbook that "[f]luids containing electrolytes and carbohydrates are a good source of fuel and rehydration[,]" but "[f]luids (e.g., energy drinks) containing questionable supplement ingredients and high levels of caffeine or other stimulants . . . may be detrimental to the health of the competitive athlete and are not effective forms of fuel or hydration."[47]

Nonetheless, the overlap between the marketing of sports drinks and energy drinks continues to grow, creating potential confusion and unintended misuse.[48] A report developed by

---

42. *See* 21 C.F.R. § 182.1180(c) (2012); *see also* Thorlton, Colby & Devine, *supra* note 39, at 1176 ("Synergistic effects can result when consumers unknowingly combine caffeinated beverages with other stimulants.").

43. Thorlton, Colby & Devine, *supra* note 39, at 1178.

44. Leah S. Rosenfeld et al., *Regulatory Status of Caffeine in the United States*, 72 NUTRITION REVIEWS (SPECIAL ISSUE) 23, 28 (2014); *Energy Drinks & Energy Shots*, HUM. PERFORMANCE RESOURCE CTR., http://hprc-online.org/dietary-supplements/files/Monograph_EnergyDrinks.pdf (last visited Apr. 22, 2016).

45. Comm. on Nutrition & the Council on Sports Med. & Fitness, *Clinical Report—Sports Drinks and Energy Drinks for Children and Adolescents: Are They Appropriate?*, 127 PEDIATRICS 1182, 1182, 1186–87 (2011); *see also* note 64 and accompanying text (discussing the use of athletes in energy drink marketing campaigns).

46. Babu, Church & Lewander, *supra* note 35, at 38.

47. NAT'L COLLEGIATE ATHLETIC ASS'N, 2014–15 NCAA SPORTS MEDICINE HANDBOOK 49 (2014), http://www.ncaapublications.com/productdownloads/MD15.pdf.

48. *See Kids Should Not Consume Energy Drinks, and Rarely Need Sports Drinks, Says AAP*, AM. ACAD. OF PEDIATRICS (May 30, 2011), http://www.aap.org/en-us/about-the-aap/aap-press-room/pages/Kids-Should-Not-Consume-Energy-Drinks,-and-Rarely-Need-Sports-Drinks,-Says-AAP.aspx ("[A]dolescents are often unaware of the differences in these products." (quoting Marcie Beth Schneider, a member of the AAP Committee on Nutrition)).

Senators Edward Markey, Richard Durbin, and Richard Blumenthal found that three major energy drink companies (Monster Energy, Rockstar, and Coca Cola) currently market caffeinated beverages for rehydration purposes similar to sports drinks.[49] Because of this growing issue, the report recommends, and this Comment agrees, that the FDA should issue definitions and guidance concerning "sports drinks," "energy drinks," "hydration," and "electrolytes."[50]

### *B. Substantial Increase in Energy Drink Consumption*

While coffee remains the leading contributor of caffeine consumption in the American diet by a large margin,[51] the increasing consumption of energy drinks, especially in adolescents and children, is cause for alarm.[52] Approximately seventeen years ago, energy drinks entered the U.S. market, with athletes as the initial consumers.[53] New subclasses of consumers have emerged since then, including shift workers, body builders, military personnel, and, most startling, adolescents.[54]

Recently, the market for energy drinks in the United States grew substantially, with 60% growth from 2008 to 2012, and projections of becoming a $21.5 billion industry by 2017.[55] Approximately half of the energy drink market consists of children (less than twelve years old), adolescents (twelve to eighteen years old), and young adults (nineteen to twenty-five years old).[56] One self-reported study found that up to 50% of children, adolescents, and young adults have consumed energy drinks.[57] The report also found that 28% of twelve to fourteen year olds, 31% of twelve to

49. BUZZ KILL, *supra* note 27, at 17.

50. *Id.* at 18.

51. Gonzalez de Mejia & Ramirez-Mares, *supra* note 34, at 489. On the other hand, the leading contributors of caffeine to the diets of children and adolescents are caffeinated soft drinks and tea. *Id.*

52. *See infra* Part II.D (warning of the health risks of youth consumption of energy drinks, most notably the possibility of disrupting brain development). Another alarming statistic is that a recently conducted survey reported that 43% of children from two to five years of age have consumed caffeine. LESLIE PRAY, ANN L. YAKTINE & DIANA PANKEVICH, CAFFEINE IN FOOD AND DIETARY SUPPLEMENTS: EXAMINING SAFETY 15 (2014), http://www.nap.edu/catalog/18607/caffiene-in-food-and-dietary-supplements-examining-safety-workshop-summary.

53. Thorlton, Colby & Devine, *supra* note 39, at 1176.

54. *Id.*

55. *Energy Drink Sales Will Skyrocket to $21 Billion by 2017*, NAT. PRODS. INSIDER (Feb. 4, 2013), http://www.foodproductdesign.com/news/2013/02/energy-drink-sales-will-skyrocket-to-21-billion-b.aspx.

56. Seifert, *supra* note 12, at 512.

57. *Id.* at 514–15.

seventeen year olds, and 34% of eighteen to twenty-four year olds reported regularly consuming energy drinks.[58] Overall, energy drinks constitute the fastest growing segment of the beverage market in the United States, and are extremely popular among adolescents.[59] The FDA admitted that "the proliferation of these [caffeine-containing products] in the marketplace is very disturbing[,]" but has taken little action.[60] The rapid growth of this new class of products, their popularity among children and adolescents, the industry's efforts at marketing to young people, and the known and unknown health risks of consumption by children and adolescents should motivate the FDA to implement changes to the regulatory scheme to better protect this vulnerable class of consumers.[61]

### *C. Aggressive Marketing to Minors*

Energy drink companies aggressively market their products to young consumers.[62] These companies primarily target young males through alluring product names, attempting to tap into the consumer's sense of masculinity.[63] In an attempt to establish a relationship with the consumer at a young age, these companies use "'grassroots' level marketing strategies, . . . [including] extreme sports sponsorships, Internet interactions, text messaging, and communication among users on [social media sites]."[64] The remarkable presence of energy drink companies on social media sites such as Facebook and Twitter, where many

58. *Id.* at 514.

59. Gurley, Steelman & Thomas, *supra* note 31, at 287.

60. *FDA to Investigate Added Caffeine*, U.S. FOOD & DRUG ADMIN. (May 3, 2013), http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm350570.htm (quoting Michael R. Taylor, deputy commissioner for foods and veterinary medicine at the FDA).

61. *See infra* Part II.C (explaining how energy drink companies attempt to establish long term relationships with consumers by aggressively targeting them at an early age); *infra* Part II.D (warning of the known risks of caffeine consumption by adolescents and children and describing the lack of medical studies concerning the risks of herbal stimulant consumption).

62. *FDA to Investigate Added Caffeine*, *supra* note 60; *see also* Kevin I. Goldberg, *Dangerous Drinks*, TRIAL, Mar. 2013, at 28, 28 ("Energy drink companies target their marketing to teenagers and young adults just as cigarette companies did in the 1980s and 1990s . . . .").

63. Reissig, Strain & Griffiths, *supra* note 41, at 4. The top selling energy drink brands in 2015, Red Bull, Monster, Rockstar, NOS, Amp, and Full Throttle, demonstrate this marketing effort. *Top Selling Energy Drink Brands*, *supra* note 4.

64. MICHELE SIMON & JAMES MOSHER, ALCOHOL, ENERGY DRINKS, AND YOUTH: A DANGEROUS MIX 1 (2007), http://www.alcoholjustice.org/images/stories/Energy DrinkReport.pdf; *see also* Sarah McNew Razzaque, *Monster Energy: Social Media Breakdown*, SOCIAL TOASTER (June 24, 2013), http://www.socialtoaster.com/blog -entry/monster-energy-social-media-breakdown ("Monster Energy does a great job of connecting with its teen and young adult audience through social media marketing.").

users are under the age of seventeen, further fuels increasing adolescent consumption.[65]

Senators Markey, Durbin, and Blumenthal recognize this issue in their report concerning adolescent consumption of energy drinks and recommend that age restrictions be placed on companies' websites.[66] One energy drink company, Xenergy, has already done this by requiring users to indicate that they are eighteen years old before they can access the company's website.[67] While this change could help protect young consumers from targeted advertising, it does not address the underlying issue: the substantial health risks associated with adolescent consumption.

### *D. Health Risks of Energy Drink Consumption*

Recently, numerous families of deceased consumers filed wrongful death lawsuits against energy drink companies; this is an increasing trend, and it illustrates the urgent need for federal intervention.[68] While research and studies show that moderate consumption by adults of products containing naturally occurring sources of caffeine is generally safe, children face an increased risk for possible health effects by consuming these products.[69]

Excessive amounts of caffeine can lead to significant toxic effects, including headaches, nausea, anxiety, vomiting, tachycardia, severe hypertension, arrhythmia, seizures, restlessness and even death.[70] Other effects of high caffeine intake include hyperglycemia and hypokalemia, which could contribute to ventricular arrhythmias and sudden death.[71] Carnitine, a common ingredient in energy drinks, is linked to the development of atherosclerosis (a buildup of plaque in the arteries), which is the

---

65. YALE RUDD CTR. FOR FOOD POLICY & OBESITY, ENERGY DRINKS FACT SHEET, NOVEMBER 2011 (2011), http://www.yaleruddcenter.org/resources/upload/docs/what/policy/SSBtaxes/SSB_EnergyDrinks.pdf (reporting that as of 2011, 59% of Facebook users were between ten and seventeen years old and 18% of Twitter users were between twelve and seventeen years old); *see Red Bull*, FACEBOOK, https://www.facebook.com/redbull (last visited Apr. 22, 2016) (reporting the number of "likes" received for Red Bull at 44.9 million); *Monster Energy*, FACEBOOK, https://www.facebook.com/MonsterEnergy (last visited Apr. 22, 2016) (reporting the number of "likes" received for Monster Energy at 24 million).

66. BUZZ KILL, *supra* note 27, at 12.

67. *Id.*

68. *See supra* note 22 and accompanying text (describing multiple settled wrongful death cases against Monster Beverage Corporation and recently filed lawsuits that indicate an increasing trend of similar suits).

69. Hamburg, *supra* note 39.

70. Gonzalez de Mejia & Ramirez-Mares, *supra* note 34, at 490; Gurley, Steelman & Thomas, *supra* note 31, at 276.

71. Gurley, Steelman & Thomas, *supra* note 31, at 278.

usual cause of heart attacks and strokes.[72] The possible synergistic effect of combining caffeine with other dietary ingredients often included in energy drinks exacerbates these risks.[73] Furthermore, other synergistic effects can occur when consumers unwittingly combine energy drinks with other stimulants, such as medications for attention deficit disorder.[74]

Excessive caffeine consumption can be extremely dangerous to children and adolescents still in the neurological development stage of life.[75] The American Academy of Pediatrics unequivocally stated that "[e]nergy drinks pose potential health risks because of the stimulants they contain, and should never be consumed by children or adolescents."[76] The National Collegiate Athletic Association, the International Olympics Committee, and the National Federation of High Schools also caution of the risks associated with energy drink consumption.[77] These arguments are beginning to convince the general public, with a recent survey reporting that 74% to 78% of American parents believe energy drinks should not be marketed or sold to children or teens, and 85% support regulations requiring caffeine content disclosure and warning labels.[78]

Perhaps the most alarming possible effect on children and adolescents is the impact on brain development. Although few studies exist on caffeine's effect on sleep in children and adolescents, studies in adults show that caffeine consumption reduces the time spent in deep sleep and REM sleep, both of which play critical roles in learning and memory consolidation.[79] Recent studies show that energy drinks increase the risk of hyperactivity

---

72. HEART & VASCULAR INST., 2012 OUTCOMES 94 (2013); *What is Atherosclerosis?*, WEBMD, http://webmd.com/heart-disease/what-is-atherosclerosis (last visited Apr. 22, 2016).

73. *See* SOMOGYI, *supra* note 30, at 5 (explaining how certain dietary ingredients such as taurine and guarana may enhance the stimulating effects of caffeine); Seifert, *supra* note 12, at 512 (stating that over-consumption can occur because actual caffeine content exceeds that listed on product labels due to herbal ingredients such as guarana and yerba mate not included in the calculation).

74. Thorlton, Colby & Devine, *supra* note 39, at 1175–76. Adolescent consumption of energy drinks may even contribute to the onset of attention deficit disorder. *See* Rahul Srinivas, *Are Energy Drinks Harming Your Children? Study Links ADHD to Sweetened Energy Drinks*, INQUISITR (Feb. 10, 2015), http://www.inquisitr.com/1830823/are-energy-drinks-harming-your-child-study-links-adhd-to-sweetened-energy-drinks/.

75. Gonzalez de Mejia & Ramirez-Mares, *supra* note 34, at 490.

76. AM. ACAD. OF PEDIATRICS, *supra* note 48.

77. Thorlton, Colby & Devine, *supra* note 39, at 1177.

78. Judith A. Owens, Jodi Mindell & Allison Baylor, *Effect of Energy Drink and Caffeinated Beverage Consumption on Sleep, Mood, and Performance in Children and Adolescents*, 72 NUTRITION REVIEWS (SPECIAL ISSUE) 65, 69 (2014).

79. Owens, Mindell & Baylor, *supra* note 78, at 67.

and inattention in children and adolescents, attention deficit disorder symptoms are strongly correlated with "poor academic outcomes, greater difficulties with peer relationships, and increased susceptibility to injuries."[80] Although the energy drink industry's voluntary acquiescence not to target children and adolescents would be ideal, increasing consumption trends and accessibility indicate that more drastic FDA measures are required.

## III. FDA REGULATION OF ENERGY DRINKS

Energy drinks are a relatively new class of products that contribute to the already substantial caffeinated beverage industry.[81] Throughout its history, the FDA has grappled with regulating soda beverages.[82] In 1994, Congress deregulated the dietary supplement industry after FDA overreach, leaving the FDA ill-equipped to handle the substantial increase of new caffeine-containing products, including energy drinks, with questionable caffeine combinations and levels. While Congress attempted to implement an adverse reporting system to better protect the public from unsafe dietary supplements, the system is insufficient and does not address the underlying safety issues concerning energy drinks. These events are addressed in turn.

### *A. History of the FDA's Regulatory Authority*

From humbled beginnings, the evolution of the FDA's regulatory authority is commendable. In 1906, Congress transformed the FDA's principle regulatory function from completing chemical analysis studies of agricultural goods to protecting consumers from unsafe foods and drugs.[83] During the late twentieth century however, the FDA overreached in its authority to regulate dietary supplements.[84] The congressional action that followed has left the public unprotected from excessively caffeinated energy drinks.

---

80. Michael Greenwood, *Energy Drinks Significantly Increase Hyperactivity in Schoolchildren*, YALENEWS (Feb. 9, 2015), http://news.yale.edu/2015/02/09/energy-drinks-significantly-increase-hyperactivity-schoolchildren.

81. Polis, *supra* note 3.

82. *See infra* Part III.A (discussing multiple battles the FDA has had with Coca Cola over its caffeine content and the eventual promulgation of a regulation limiting the amount of caffeine in sodas).

83. *History*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm (last visited Apr. 22, 2016).

84. *See infra* Part III.A.2 (detailing the judicial and congressional reprimands of the FDA following the Administration's abuse of the Food Additive Amendment).

*1. Early Concern over Caffeinated Beverages.* In 1906, Congress passed the Pure Food and Drugs Act,[85] a monumental legislative accomplishment that transformed the FDA's principle regulatory function into protecting consumers from unsafe adulterated or misbranded food and drugs.[86] Even at this early stage of the FDA's regulatory history, contention existed over caffeinated products. With Coca Cola gaining popularity,[87] the FDA became concerned with the safety of caffeine and sought to remove it from the product's formula.[88] In the FDA's lawsuit against Coca Cola, the Supreme Court held that caffeine was in fact an additive but remanded the case to determine whether the added ingredient qualified as injurious to consumers' health.[89] During the litigation of the case, Congress introduced two bills to amend the Act by adding caffeine to the list of "habit-forming" and "deleterious" substances, but Coca Cola killed both bills.[90] Eventually, Coca Cola settled with the government, agreeing to reduce the amount of caffeine in its product.[91]

A health crisis in 1937[92] motivated Congress to pass the 1938 Federal Food, Drug, and Cosmetic Act (FDCA),[93] overhauling the earlier legislation and expanding the FDA's regulatory authority.[94] The FDCA greatly enhanced the FDA's

85. Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768, *repealed by* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

86. *History*, *supra* note 83.

87. By 1895, Coca Cola was being consumed in every state in the United States. *The Chronicle of Coca-Cola: The Candler Era*, COCA-COLA CO. (Jan. 1, 2012), http://www.coca-colacompany.com/stories/the-chronicle-of-coca-cola-the-candler-era.

88. United States v. Coca Cola Co., 241 U.S. 265, 270–71 (1916) ("The allegation of adulteration was, in substance, that the product contained an added poisonous or added deleterious ingredient, caffeine, which might render the product injurious to health.").

89. *Id.* at 284–85. One of the main arguments Coca Cola offered was that caffeine is added to the product to enhance its flavor. *Id.* at 272. In order for the FDA to deem a food adulterated under the Pure Food and Drugs Act of 1906, the FDA had to prove it contained an "added poisonous or other added deleterious ingredient" which rendered the product "injurious to health." Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, § 7, 34 Stat. 768, 769–70 (repealed 1938).

90. MARK PENDERGRAST, FOR GOD, COUNTRY AND COCA-COLA 121–22 (1993).

91. Morris B. Hoffman, *The Drug Court Scandal*, 78 N.C. L. REV. 1437, 1455 n.68 (2000).

92. The Elixir Sulfanilamide crisis of 1937, when over 100 people died from consuming a new antibiotic that contained diethylene glycol, a component of antifreeze, prompted lawmakers to provide the FDA with stronger regulatory capabilities to better protect the public from unsafe products. J. Richard Crout et al., *FDA's Role in the Pathway to Safe and Effective Drugs*, *in* FDA: A CENTURY OF CONSUMER PROTECTION 159, 162 (Wayne L. Pines ed., 2006).

93. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified throughout 21 U.S.C. §§ 301–399f (2012)).

94. Michael A. McCann, *Dietary Supplement Labeling: Cognitive Biases, Market Manipulation & Cognitive Biases, Market Manipulation & Consumer Choice*, 31 AM. J.L. &

purpose and regulatory power by providing expanded definitions of and regulations for two types of products: "foods"[95] and "drugs."[96] The FDCA placed stricter regulations on drugs.[97] While the FDCA was a monumental step towards better protecting the public from unsafe foods and drugs, the Act limited the FDA's authority to actually keep these products from entering the market.[98]

Some of the difficulties the FDA faces in regulating dietary supplements today remain the same, despite the increased complexity of dietary supplements.[99] The difficulties in regulating dietary supplements during the first half of the twentieth century stemmed from the problem of properly classifying these products as either a food or a drug.[100] The FDCA expanded the definition of "drugs" to include all substances, other than food, intended to affect the structure and function of the body as well as substances intended for use in the cure, mitigation, treatment or prevention

---

MED. 215, 234 (2005). FDCA remains good law and subsequent legislation, including Congress's direct attempt at regulating the dietary supplement industry, DSHEA, are amendments and additions to FDCA. *See generally* 21 U.S.C. § 301 (2012) (chronicling various amendments to FDCA); *infra* Part III.B.1.

95. 21 U.S.C. § 321(f) (2012); *see* McMann, *supra* note 94, at 232–34 (comparing the regulatory authority of the FDA under the Pure Food and Drugs Act of 1906 with that under the Food, Drug, and Cosmetic Act of 1938). Section 321(f) defines "food" as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." 21 U.S.C. § 321(f).

96. 21 U.S.C. § 321(g)(1) (2012). Section 321(g)(1) defines "drug" as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body . . . ." *Id.*

97. *See* Katharine A. Van Tassel, *Slaying the Hydra: The History of Quack Medicine, the Obesity Epidemic and the FDA's Battle to Regulate Dietary Supplements Marketed as Weight Loss Aids*, 6 IND. HEALTH L. REV. 203, 220–25 (2009) (demonstrating that the FDCA, while not perfect, was an improvement over the Pure Food and Drugs Act of 1906 in that it required minimal procedures prior to a drug being sold on the market).

98. *See id.* at 224–25 (stating that if the FDA objected to the product's release, the manufacturer was only required to produce "a comparatively small amount" of medical expert opinion based on anecdotal evidence). After the FDA refused to approve a new drug, manufacturers would normally appeal to the courts, and the FDA still carried the burden of proving that the product was unsafe or ineffective at trial. *Id.* at 225.

99. *See* Peter Barton Hutt, *FDA Statutory Authority to Regulate the Safety of Dietary Supplements*, 31 AM. J.L. & MED. 155, 158 (2005) (discussing the history of the dietary supplement industry and stating that at the time, dietary supplements were not complex, consisting mainly of vitamins, nutrients, and other common food constituents). Cod liver oil (containing vitamins A and D) was possibly the first dietary supplement. *Id.*

100. Hutt, *supra* note 99, at 158–59. While caffeine may not seem to be applicable to this categorization controversy, caffeine has been compared to a drug throughout its history. *See* WEINBERG & BEALER, *supra* note 1, at xii ("Although the chemical substance caffeine remained unknown until the beginning of the nineteenth century, both coffee and tea were always recognized as drugs.").

of disease.[101] This expanded definition captured under the drug category some, but not all, dietary supplement products.[102]

While the Act did not require any proof of efficacy, it did provide consumers protection from insufficient labels, requiring that foods claiming to have "special dietary uses" be deemed misbranded "unless its label bears [certain] information concerning its vitamin, mineral, and other dietary properties . . . necessary in order fully to inform purchasers as to its value for such uses."[103]

Additionally, the fact that a particular product was a special dietary food did not preclude the product from also qualifying as a drug under the statute.[104] Ultimately, in close cases, how a company marketed a particular product seemingly determined its classification as either a food or a drug.[105] The historical difficulties of establishing stricter regulation for caffeinated sodas and the problems with self-identification of special dietary foods foreshadowed the looming shortcomings of energy drink regulation.

*2. A New Era of Stricter FDA Regulation.* With food manufacturers increasing the complexity of their products, Congress gave the FDA greater authority to regulate ingredients

---

101. 21 U.S.C. § 321(g)(1) (2012).

102. *See* 78 CONG. REC. 8960 (1934) (statement of Sen. Copeland) (providing that the expanded "structure and function" definition would not encompass "preparations intended to reduce excessive weight.").

103. 21 U.S.C. § 343(j) (2012). In 1977, the FDA promulgated regulations defining "special dietary uses" as:

> [U]ses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, . . . . [u]ses for supplying particular dietary needs which exist by reason of age, . . . . [and u]ses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral or other dietary property . . . . regardless of whether such food also purports to be or is represented for general use.

21 C.F.R. § 105.3 (2015). The FDA also promulgated regulations establishing minimum daily requirements and labeling standards for certain vitamins and minerals, including Vitamin A, Vitamin B (thiamine), Vitamin C (ascorbic acid), Vitamin D, Riboflavin, calcium, phosphorous, iron, and iodine. 21 C.F.R. § 125.3–.4 (1941).

104. Mark A. Kassel, *From a History of Near Misses: The Future of Dietary Supplement Regulation*, 49 FOOD & DRUG L.J. 237, 252 (1994); *see also* United States v. Kordel, 164 F.2d 913, 914, 916–17 (7th Cir. 1947), *aff'd,* 335 U.S. 345 (1948) (affirming the conviction of a distributor of "health-food" products, including a beverage and mineral tablet product, for the introduction into interstate commerce of misbranded drugs because of claims in literature accompanying the products describing their health benefits).

105. Gwendolyn Prothro, *The Caffeine Conundrum: Caffeine Regulation in the United States*, 27 CUMB. L. REV. 65, 76–77 (1997) ("Thus, if one markets a caffeinated soft drink as just a soft drink, it will likely be regulated as a food. But if one markets it as a soft drink to help maintain 'blood energy, muscular activity, sound teeth and gums,' it will likely be regulated as a drug . . . ." (quoting *Kordel*, 164 F.2d at 916)).

added to foods with drug-like characteristics by passing the 1958 Food Additive Amendment. However, the FDA abused this power in regulating dietary supplements, motivating congressional deregulation of the entire industry. This deregulation has left the FDA incapable of adequately addressing the health concerns associated with energy drink consumption.

*a. The Definition of Food Additive.* In 1958, Congress passed the 1958 Food Additives Amendment, amending the FDCA by creating a new subcategory of food—"food additives."[106] With this amendment, Congress set out "(1) [t]o protect the health of consumers by requiring manufacturers of food additives and food processors to pretest any potentially unsafe substances which are to be added to food; and (2) to advance food technology by permitting the use of food additives at safe levels."[107]

To accomplish this, the Amendment reclassified many ingredients added to products, including caffeine and other dietary supplement ingredients, as food additives.[108] The Food Additive Amendment defined a "food additive" as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food."[109] Companies must list these ingredients on the product's label.[110] On the other hand, the FDA does not require testing or pre-market approval for foods not qualifying as food additives; a presumption of safety attaches unless the government proves otherwise.[111] Under this amended version of the FDCA, which remains in place today, substances meeting this definition require FDA approval before entering the market, as do drugs, unless the substance falls within

106. Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (codified as amended at 21 U.S.C. §§ 321, 331, 342, 346, 348 (2012)).

107. H.R. REP. NO. 85-2284, at 1 (1958).

108. *See* S. REP. NO. 103-410, at 21 (1994) (describing the FDA's history of treating dietary supplements as "food additives"); United States v. 45/194 Kg. Drums of Pure Vegetable Oil, 961 F.2d 808, 813 (9th Cir. 1992) (holding that Evening Primrose Oil, a dietary supplement ingredient, falls under the broad definition of "food additives").

109. 21 U.S.C. § 321(s) (2012).

110. 21 U.S.C. § 348 (2012). Since the passage of the Kefauver-Harris Amendment in 1962, pharmaceutical drugs now must obtain pre-market approval from the FDA based on scientific testing (clinical studies) concerning the product's safety and effectiveness. McCann, *supra* note 94, at 220 (citing 21 U.S.C. § 355 (2000)). Over-the-counter drugs do not require pre-market approval but manufacturers must provide the FDA with evidence of both safety and efficacy in order to show that their benefits outweigh the risks of consumption. Dana Ziker, *What Lies Beneath: An Examination of the Underpinnings of Dietary Supplement Safety Regulation*, 31 AM. J.L. & MED. 269, 272 (2005).

111. S. REP. NO. 103-410 at 22 (1994).

a statutory exemption.[112] This method of classification caused strife between manufacturers and the FDA until Congress passed the Dietary Supplement Health and Education Act of 1994 (DSHEA).[113] Among the food additive exemptions from stricter regulation are substances found by qualified scientific experts to be "generally recognized as safe" (GRAS) for their intended use based on scientific procedures and common use in food prior to 1958.[114]

For a substance to qualify for GRAS treatment, there must be "common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food."[115] Unlike food additive substances, GRAS substances do not require an FDA regulation categorizing the substance before it may be used in food, although the FDA may promulgate a regulation for clarity.[116] Thus, companies are legally allowed to make their own GRAS determinations without notifying the FDA.[117] Nonetheless, a GRAS determination is not necessarily permanent because the FDA has the authority to "remove the substance from food products or require the manufacturer to conduct studies to evaluate the newly raised concern" if new evidence suggests the substance may not be safe.[118]

For food additive substances that do not qualify for GRAS treatment, the FDA must first approve their use by issuing a food additive regulation before companies may add the substance into products.[119] Companies wishing to use the substance may file a food additive petition with the FDA to prompt a regulation, but

---

112. *Compare* 21 U.S.C. § 348(a)–(c) (2012) *with* 21 U.S.C. § 355(a)–(b), (d) (2012).

113. *See* Stephen H. McNamara, *Dietary Supplements of Botanicals and Other Substances—A New Era of Regulation*, 50 FOOD & DRUG L.J. 341, 341 (1995) ("Many members of the House of Representatives and Senate stated that they had received more mail, phone calls, and constituent pressure on [deregulating the dietary supplement industry through DSHEA] than on anything else . . . .").

114. 21 U.S.C. § 321(s) (2012). In 1994, Congress accomplished its deregulation of the dietary supplement industry by passing DSHEA, adding dietary ingredients as another exemption from the "food additive" category, and exacerbating the problem of classification of caffeine-containing products. 21 U.S.C. § 321(s)(6) (2012).

115. 21 C.F.R. § 170.30(a) (2012).

116. Cassandra A. Soltis, *Between a Rock and a Hard Place: FDA's Regulation of Dietary Ingredients in Dietary Supplements*, 2 J. FOOD L. & POL'Y 11, 15 (2006); *see also* 21 C.F.R. § 182.1(a) (2012) (stating that it would be "impracticable to list all substances that are generally recognized as safe for their intended use.").

117. Soltis, *supra* note 116, at 15.

118. Carol Rados, *GRAS: Time-Tested, and Trusted, Food Ingredients*, FDA CONSUMER, Mar./Apr. 2004, at 20, 21, http://www.foodsafety.wisc.edu/assets/pdf_Files/GRAS.pdf.

119. 21 U.S.C. §§ 342(a)(2)(C), 348(a) (2012).

this is potentially costly and time consuming.[120] The petition must provide technical evidence of "reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."[121] The status of caffeine in cola beverages under this scheme was settled in 1961 when the FDA promulgated a GRAS regulation.

*b. The GRAS Regulation of Caffeine*. In 1961, the FDA promulgated a regulation classifying caffeine used in sodas as GRAS, solidifying the psychoactive substance's status as a commonplace ingredient in food and beverages.[122] The regulation permits manufacturers of cola-type beverages to add caffeine up to a certain amount, approximately 71 mg per 12 fluid ounces.[123] The regulation does not address other possible uses of caffeine in food.[124] In 1980, the FDA recognized this regulatory leniency and attempted to tighten the reins on caffeine-containing beverages, but to no avail.[125]

In 1980, after reviewing the substances listed in the regulations as GRAS, the FDA determined that unresolved safety issues remained concerning caffeine consumption.[126] Citing these unresolved issues, the FDA proposed a rule to remove caffeine from the list of GRAS substances, to restrict the use of caffeine as an added ingredient in foods to current uses and levels, and to require that the presence of caffeine be reflected on product labels.[127] Manufacturers responded, as they did during the FDA's attack on Coca Cola under the Pure Food and Drugs Act,[128] that they added caffeine to beverages only as a flavor enhancer.[129] Although extensive research now debunks this argument,[130] the

120. *See* S. REP. NO. 103-410, at 21 (1994) ("The cost to a manufacturer to prepare a food additive petition can run to $2 million. FDA approval of a food additive petition typically takes from 2 to 6 years.").

121. 21 C.F.R. § 170.3(i) (2012).

122. 26 Fed. Reg. 938, 940 (Jan. 31, 1961) (codified at 21 C.F.R. § 182.1180(c) (2012)).

123. *See* 21 C.F.R. § 182.1180 (2012) (limiting caffeine to .02% of cola-type beverages, which equals approximately 71 milligrams per 12 fluid ounces).

124. Rosenfeld, *supra* note 44, at 26.

125. *Infra* notes 126–51 and accompanying text; *see also FDA to Investigate Added Caffeine*, *supra* note 60 (quoting Michael R. Taylor, the deputy commissioner for foods and veterinary medicine at the FDA, as saying that the "[e]xisting rules never anticipated the current proliferation of caffeinated products").

126. Caffeine; Deletion of GRAS Status, Proposed Declaration That No Prior Sanction Exists, and Use on an Interim Basis Pending Additional Study 45 Fed. Reg. 69,817, 69,818 (Oct. 21, 1980).

127. *Id.*

128. *Supra* notes 88–89 and accompanying text.

129. Reissig, Strain & Griffiths, *supra* note 41, at 2.

130. *See* Roland R. Griffiths & Ellen M. Vernotica, *Is Caffeine a Flavoring Agent in Cola Soft Drinks?*, 9 ARCH. FAM. MED. 731 (2000) (concluding that despite contrary claims,

precedent from the FDA's deal with Coca Cola at the beginning of the twentieth century prevented this proposed rule from becoming a reality.[131] Thus, despite efforts to increase regulation of caffeine as an added food ingredient, the earlier regulation remains unchanged.[132] While the existing caffeine limitations set forth by FDA regulation do help protect the public from excessively caffeinated sodas, DSHEA completely changed the dynamic.

*c. Regulatory Revolt: Food Additive Overreach.* Prior to DSHEA, the FDA commonly challenged products containing dietary supplement ingredients as adulterated because they contained ingredients not authorized by a food additive regulation.[133] The FDA broadly interpreted the food additive provision to say that the addition of *any* food ingredient to another ingredient subjected the product to the stricter regulatory requirements for food additives.[134] This overly broad interpretation of the food additive definition came to a head in litigation in the First and Seventh Circuits over the use of black currant oil in dietary supplements, ultimately motivating the passage of DHSEA.[135]

The manufacturers in these cases wanted to market black currant oil capsules in which the only ingredients were black currant oil, glycerin, and the gelatin capsule, with the single active

caffeine plays a relatively minor role as a flavoring agent in cola soft drinks); Russell S.J. Keast & Lynnette J. Riddell, *Caffeine as a Flavor Additive in Soft-Drinks*, 49 APPETITE, 255, 257 (2007) (concluding that test subjects were unable to discriminate the difference between caffeinated and non-caffeinated soft drink samples).

131. *See* Rosenfeld et al., *supra* note 44, at 27 (stating that the proposed actions were dependent on no prior sanction existing for caffeine and that because evidence of a prior sanction involving Coca Cola was submitted, the FDA could not regulate caffeine as a food additive); *see also* Reissig, Strain & Griffiths, *supra* note 41, at 2 ("If caffeine had not been accepted as a flavor enhancer, but had been regarded as a psychoactive ingredient, soft drinks might have been regulated by the FDA as drugs.").

132. Rosenfeld et al., *supra* note 44, at 27.

133. *See, e.g.*, Nat'l Nutritional Foods Ass'n v. Kennedy, 572 F.2d 377, 389–92 (2d Cir. 1978) (holding that the FDA may regulate high-potency vitamins and minerals as food additives); United States v. Article of Food, 414 F. Supp. 793, 794 (E.D. Mo. 1976) (holding that Orotic Acid sold as a dietary supplement is a food additive).

134. *See* United States v. An Article of Food, 678 F.2d 735, 738–39 (7th Cir. 1982) (agreeing with the FDA's interpretation that the addition of *any* food ingredient to another qualifies that ingredient as a food additive, even if the ingredient is the product's principle component, and providing case law to support this conclusion).

135. United States v. 29 Cartons of *** An Article of Food, 987 F.2d 33, 34 (1st Cir. 1993); United States v. Two Plastic Drums, 984 F.2d 814, 815–16 (7th Cir. 1993). Along with the black currant oil litigation, FDA attacks on primrose oil supplements also motivated the passage of DSHEA. Stephen H. McNamara & Wes Siegner, Jr., *FDA Has Substantial and Sufficient Authority to Regulate Dietary Supplements*, 57 FOOD & DRUG L.J. 15, 15–17 (2002).

ingredient being the black currant oil.[136] The FDA argued that black currant oil was a food additive and could not be included in the product without pre-market approval.[137] The courts rejected this overly broad interpretation of the definition of food additive.[138] The Seventh Circuit reasoned that the disjunctive clause "or otherwise" in the food additive definition[139] targets only those components that "have the purpose or effect of altering a food's characteristics" and that the examples of food additives immediately following the definition describe each substance by its "function or [its] effect on food."[140] Congress passed DSHEA because of these types of FDA overreach in the regulation of dietary supplements.[141] Although the Circuits settled the definitional overreaching, Congress ultimately believed that, unless amended, the FDA would continue to use the provision in its assault on dietary supplements.[142]

### *B. Current State of the FDA's Regulatory Authority*

Congress responded to the FDA's overreach by passing DSHEA, removing dietary ingredients from the food additive definition entirely. This drastic act of deregulation has left the FDA unable to adequately address issues concerning caffeine in energy drinks.

*1. Removing FDA Authority to Regulate Dietary Supplements.* With the passage of DSHEA in 1994 came an entirely new definitional landscape that would foster the

136. *Two Plastic Drums*, 984 F.2d at 816.

137. *Id.*

138. *29 Cartons*, 987 F.2d at 37 (brandishing the FDA's interpretation of the food additive provision as "nonsensical"); *Two Plastic Drums*, 984 F.2d at 819.

139. In Section 321(s), a food additive is defined as any substance if the intended use results, or may be expected to result, "in its becoming a component *or otherwise* affecting the characteristics of any food." 21 U.S.C. § 321(s) (2012) (emphasis added).

140. *Two Plastic Drums*, 984 F.2d at 818; *see also* 21 U.S.C. § 321(s) (listing as food additive examples "any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and . . . any source of radiation intended for any such use").

141. NVE, Inc. v. Dep't of Health & Human Servs. 436 F.3d 182, 186 (3d Cir. 2006) (describing Congress's belief that the FDA had "'pursued a heavy-handed enforcement agenda against dietary supplements for over 30 years' prior to DSHEA's enactment" (quoting S. REP. NO. 103-410, at 14)); S. REP. NO. 103-410, at 22 (1994) ("FDA has attempted to twist the statute . . . in what the Committee sees as a result-oriented effort to impede the manufacture and sale of dietary supplements.").

142. S. REP. NO. 103-410, at 21 ("Although a fair reading of the current statute, as most recently interpreted by two United States courts of appeal, should make [this bill] unnecessary, the committee has heard testimony that the FDA has rejected these holdings.").

prominence of energy drinks in the years to come.[143] The purpose of DSHEA was to lessen the regulatory burdens on dietary supplement manufacturers and ensure continued access to safe products.[144] The rationale was that by freeing dietary supplement manufacturers from the stringent requirements of pre-market approval for "food additives," consumers would have more freedom to seek solutions to their health issues.[145] By exempting dietary ingredients from the food additive classification, manufacturers no longer need to demonstrate to the FDA that these ingredients are either FDA-approved food additives or generally recognized as safe substances.[146]

While remaining classified as food, the Act places dietary supplements in their own new subcategory and includes any product that contains one or more dietary ingredients such as vitamins, minerals, herbs or other botanicals, amino acids or other ingredients used to supplement the diet.[147] This definition encompasses concentrates, metabolites, constituents, extracts, and any combination of these dietary ingredients.[148] The reach of ingredients this definition covers is extraordinarily broad.[149]

Just as before DSHEA, the product's intended uses determine the classification under DSHEA, with the Act requiring that dietary supplements be "labeled as a dietary supplement" and "not represented for use as a conventional food."[150] Thus, the classification problems under the old regulatory regime persist under DSHEA because conventional foods and drugs also contain vitamins, minerals, herbs, and other dietary ingredients.[151] Ultimately, the classification of a product is based on the representations and claims made by the product and "not on the basis of the nature of the ingredients or their level of use, the

143. Pub. L. No. 103-417, 108 Stat. 4325 (1994) (codified at 21 U.S.C. §§ 301 et seq. (2012)).

144. S. REP. NO. 103-410, at 2.

145. Soltis, *supra* note 116, at 11; *see* 21 U.S.C. § 321(s)(6) (excluding dietary supplements from the definition of food additives); *The Dietary Supplement Health and Education Act of 1994 (DSHEA)*, *supra* note 29 (quoting President Clinton, who while signing DSHEA into law, stated that the bill would finally "bring common sense to the treatment of dietary supplements under regulation and law" and the White House press release, which echoed this sentiment, stating that "we have finally reformed the way Government treats consumers and supplements in a way that encourages good health").

146. Soltis, *supra* note 116, at 11.

147. 21 U.S.C. § 321(ff)(1)(A)–(E).

148. 21 U.S.C. § 321(ff)(1)(F).

149. Anthony L. Young & I. Scott Bass, *The Dietary Supplement Health and Education Act of 1994*, 50 FOOD & DRUG L.J. 285, 285 (1995).

150. 21 U.S.C. § 321(ff)(2)(B), (C).

151. Hutt, *supra* note 99, at 166.

composition of the product, its safety, or its nutritional value."[152] This self-declared classification is significant because the FDA does not subject dietary supplements to the same level of scrutiny as conventional foods and drugs with respect to labeling, efficacy, and safety.[153]

Because these products now fall under the food category, it allows manufacturers to make structure and function claims on the product's label without receiving pre-market approval from the FDA.[154] The only protection the FDA provides to prevent the public from misconstruing the product as having received the same level of regulation as a drug is that the label contain the following statement: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."[155] Although this disclaimer is meant to inform consumers of the product's intended use, "it is likely that many customers will not truly assimilate this information."[156]

Perhaps the most significant definitional change resulting from DSHEA is that it excludes dietary supplement ingredients from the food additive category and its pre-market approval requirement.[157] Under this new subcategory of food, the FDA does not require that dietary supplement manufacturers establish the product's safety before entering the market.[158] Rather, the FDA is only allowed to take action after the product has been sold to the public.[159] The manufacturer is responsible for making a pre-market determination that a dietary ingredient or product is safe for consumption.[160]

In order to alert the FDA of potentially unsafe products entering the market, DSHEA implements a notification

---

152. *Id.*

153. *See infra* notes 164, 168–69 and accompanying text (describing how under DSHEA, manufacturers are allowed to use dietary ingredients without establishing the ingredients' safety or efficacy).

154. 21 U.S.C. § 343(r)(6)(A) ("[A] statement for a dietary supplement may be made if the statement . . . describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans . . . .").

155. 21 U.S.C. § 343(r)(6)(C).

156. Cohen, *supra* note 26, at 183; *see also* Laura A.W. Khatcheressian, *Regulation of Dietary Supplements: Five Years of DSHEA*, 54 FOOD & DRUG L.J. 623, 637–38 (1999) ("This system allows manufacturers of dietary supplements to hint that a product will help a disease without actually saying so . . . .").

157. Young & Bass, *supra* note 149, at 286.

158. *Dietary-Supplements*, U.S. FOOD & DRUG ADMIN. (Aug. 16, 2011), http://www.fda.gov/Food/DietarySupplements.

159. *Id.*

160. *Id.*

requirement for "new dietary ingredients."[161] The market entry date for the ingredient determines the burden the manufacturer must satisfy.[162] Manufacturers may use old dietary ingredients,[163] ingredients marketed in the United States before October 15, 1994, without notifying the FDA of the ingredient's use in a particular product or having any scientific backing for the ingredient's safety or efficacy.[164]

This framework has multiple shortcomings. One shortcoming is that the FDA's notification requirements for new dietary ingredients do not apply to products (energy drinks, for example) that contain differing combinations of ingredients that are technically considered old dietary ingredients, even when the particular combinations, in terms of type and amount, are actually new.[165] For ingredients not marketed in the United States before October 15, 1994, manufacturers must supply the FDA with information that the ingredient can "reasonably be expected to be safe."[166] If the manufacturer cannot satisfy this burden, the FDA will deem the product adulterated.[167]

Another shortcoming of this framework is that while this mandatory reporting requirement for new dietary ingredients does provide consumers with some protection from unsafe products, manufacturers easily satisfy the requirement because they are ultimately not required to prove that the new dietary ingredient is, in fact, safe or effective.[168] Because of this easily satisfied burden, most manufacturers do little to determine the efficacy or side effects of their products.[169] Additionally, no list

---

161. 21 U.S.C. § 350b (2012). A "new dietary ingredient" is defined by DSHEA as a "dietary ingredient that was not marketed in the United States before October 15, 1994." 21 U.S.C. § 350b(d).

162. *Before and After DSHEA*, COUNCIL FOR RESPONSIBLE NUTRITION, http://www.cmusa.org/leg_DSHEApub.html (last visited Apr. 22, 2016).

163. *See* 21 U.S.C. §§ 350b(d), 342(f)(1)(B) (excluding dietary ingredients marketed in the United States before October 15, 1994 from the notification requirements of new dietary ingredients).

164. *Before and After DSHEA*, *supra* note 162.

165. *See* 21 U.S.C. § 350b(a)(1)–(2) (describing the requirements in terms of each ingredient, not combination of ingredients).

166. 21 C.F.R. § 190.6(a) (2013).

167. 21 U.S.C. § 342(f)(1)(B); *The Dietary Supplement Health and Education Act of 1994 (DSHEA)*, *supra* note 29.

168. SHAWN M. TALBOTT, A GUIDE TO UNDERSTANDING DIETARY SUPPLEMENTS 10 (2003).

169. Lisa Milot, *Ignorance, Harm, and the Regulation of Performance-Enhancing Substances*, 5 HARV. J. SPORTS & ENT. L. 91, 105 (2014). Professor Milot goes on to state that FDA regulations have caused consumers to be completely ignorant of the product's effects. *Id.*; *see also* Ron J. Maughan, Doug S. King & Trevor Lea, *Dietary Supplements*, 22 J. SPORTS SCI. 95, 97 (2004) ("For most of these supplements, there are few supporting data—indeed, few experimental data at all.").

exists of dietary ingredients being used in the United States market prior to October 15, 1994, so the job of determining whether a dietary ingredient is "new" falls on the manufacturers themselves.[170]

Perhaps the greatest shortcoming of this new framework, though, is that basing the safety of ingredients on their market entry date does not take into account the effect of combining ingredients in different formulations, which is one of the greatest health risks to energy drink consumers.[171] Energy drink manufacturers do not indicate this possibility on their product's label and often misinform consumers by listing the amount of added caffeine without including these herbal ingredients in the calculation.

*2. The Heart of the Problem: Energy Drink Labels.* Current law requires the listing of all ingredients in conventional beverages, including caffeine, on the product's label.[172] However, the FDA only requires content labeling, the amount of each ingredient, for nutrients on food labels,[173] and caffeine is not a nutrient.[174] Thus, the FDA does not require the amount of caffeine to be labeled for conventional beverages.[175]

For dietary supplements, the FDA does require the label to indicate the amount of caffeine, but if the caffeine is part of a propriety blend, the label must indicate only the total amount of the entire blend.[176] Manufacturers can also include other dietary ingredients, including herbal stimulants, in the proprietary blend.[177] By allowing the use of proprietary blends that contain multiple caffeine and herbal stimulant sources of undisclosed

170. Stacy Hauer, *Over the Counter and Under the Radar*, TRIAL, Apr. 2011, at 22, 24.

171. *See* 21 U.S.C. § 350b(a)(1)–(2). For example, the inclusion of herbal ingredients, such as guarana and taurine, with caffeine in energy drinks may act together to increase the stimulant effect of the product. Even if this synergy does not occur, the labeled amount of caffeine, if the energy drink has one, may not take into account the inclusion of these herbal ingredients. *See supra* notes 70–74 and accompanying text (discussing the synergistic effects that may occur between caffeine and other herbal ingredients).

172. 21 C.F.R. § 101.4(a)(1) (2012).

173. 21 C.F.R. § 101.9.

174. *Why Isn't the Amount of Caffeine a Product Contains Required on a Food Label?*, *supra* note 11.

175. *See id.* (noting that caffeine must be listed as an ingredient when added to food, but that "recommended dietary information" is only required for nutrients and caffeine is not a nutrient).

176. 21 C.F.R. § 101.36(c).

177. *See id.* (requiring disclosure of proprietary blends on labels); s*ee also Energy Drink Ingredients and What They Do*, CAFFEINE INFORMER, http://www.caffeineinformer.com/energy-drink-ingredients (last visited Apr. 22, 2016) (reporting on the different energy drink ingredients and their effects).

amounts, the consumer is unable to make informed choices, and any information the FDA could collect through Adverse Event Reports about the interaction of stimulating ingredients is nullified.[178]

As discussed previously, excessive exposure to caffeine and other herbal stimulant sources represents the greatest health risk concerning energy drink consumption by adolescents and children.[179] While mandating content labeling of caffeine and dietary ingredients on energy drink labels would substantially help the FDA and consumers identify questionable products, challenges arise due to the varying amounts of caffeine in plant-based products.[180] However, without implementing a solution in the direction of quantitative labeling, adolescent consumers are left unprotected from the risks of excessive caffeine intake.[181] Since DSHEA, the FDA has increased oversight of dietary supplements, but these changes are insufficient to adequately protect consumers.

*3. Insufficient Solutions: Adverse Event Reports*. In 2006, Congress passed the Dietary Supplement and Nonprescription Drug Consumer Protection Act, which amends the FDCA by *requiring* manufactures, packers, or distributors ("responsible persons") to report any "serious adverse event"[182] that occurs due

178. *See infra* Part III.B.3 (discussing how the Adverse Event Reporting system is inherently flawed); *see also* Barry Meier, *In a New Aisle, Energy Drinks Sidestep Some Rules*, N.Y. TIMES (Mar. 19, 2013), http://nyti.ms/197hB27 (describing how Monster elected to market its energy drink as a beverage amid growing concern over reports that connected energy drinks with deaths and injuries). Before changing its labeling to qualify as a conventional beverage, a standard Monster energy drink contained an uninformative proprietary blend, an "Energy Blend," indicating that the product contained 2500mg of L-Carnitine, Glucose, Caffeine, Guarana, Inositol, Glucuronolactone, and Maltodextrine. *Id.*

179. *See supra* Part II.D (discussing the health effects of excessive caffeine consumption in children and adolescents).

180. Rosenfeld et al., *supra* note 44, at 27.

181. *But see* AM. BEVERAGE. ASS'N, *supra* note 11 (stating that the American Beverage Association and its members urge all market energy drink producers to implement certain guidelines regarding the inclusion of caffeine content on the products' labels). Voluntary labeling is inadequate to protect consumers because these labels do not provide information about the possibility of a synergistic effect occurring when caffeine is consumed with herbal stimulants, and often do not even include herbal stimulants in the caffeine calculation. *See* Seifert, *supra* note 12, at 512 (stating that over-consumption can occur due to actual caffeine content exceeding that listed on product labels due to herbal ingredients such as guarana and yerba mate not being included in the calculation).

182. A "serious adverse event" occurs when there is an adverse health-related event associated with the use of a dietary supplement that results in "death; a life-threatening experience; inpatient hospitalization; a persistent or significant disability or incapacity; or a congenital anomaly or birth defect; or requires" medical or surgical intervention to prevent the previously mentioned outcomes. 21 U.S.C. § 379aa-1(a)(2) (2012).

to the use of their products.[183] The FDA does not require responsible persons to report non-serious adverse events. However it must maintain records related to any adverse event for six years.[184] While the mandate might appear on its face to provide the FDA with ammunition to protect consumers from excessively-caffeinated energy drinks, it most likely does not for multiple reasons.

First, the mandated reporting of serious adverse events only applies to dietary supplements.[185] If a company markets its product as a conventional beverage, it is not required to report serious adverse events to the FDA.[186] Energy drink companies are able to avoid mandated reporting by merely changing how the product is marketed and labeled, because of the amorphous nature of FDA categorization.[187]

Next, because the FDA only requires reporting of "serious" adverse events, the information obtained about a product's effects is inherently limited. The Department of Health and Human Services stated, after conducting a study, that the FDA receives information regarding "less than 1 percent of all of the adverse events associated with dietary supplements."[188] The study concluded that the mandatory reporting system is "inherently limited" as a consumer safeguard, and "cannot serve as an adequate safety valve until other measures are taken that will allow FDA" to discover public health concerns.[189]

Finally, the FDA does not require responsible persons to provide the type of information that would be pertinent for further investigation.[190] Currently, the FDA does not require the harmed

183. 21 U.S.C. § 379aa-1(b)(1).

184. 21 U.S.C. § 379aa(e)(1); *see also* 21 U.S.C. § 379aa(a)–(c), (f) (establishing that, unlike other voluntary reports, serious adverse effects must be reported). Authorized Employees of the Department of Health and Human Services may access these records. 21 U.S.C. § 379aa(e)(2).

185. 21 U.S.C. § 379aa-1(b)(1).

186. *Energy "Drinks" and Supplements: Investigations of Adverse Event Reports*, U.S. FOOD & DRUG ADMIN., (Nov. 16, 2012), http://www.fda.gov/Food/RecallsOutbreaks Emergencies/SafetyAlertsAdvisories/ucm328536.htm.

187. *See supra* notes 150–53 and accompanying text (describing how the DSHEA scheme allows manufacturers to skirt food additive requirements by merely changing the marketing and labeling of the product); *see also* Meier, *supra* note 178 (discussing how in 2013 Monster decided to change its product from a dietary supplement to a conventional beverage, thereby avoiding mandatory reporting of serious adverse events).

188. OFFICE OF INSPECTOR GEN., DEPT. OF HEALTH & HUMAN SERVS., ADVERSE EVENT REPORTING FOR DIETARY SUPPLEMENTS: AN INADEQUATE SAFETY VALVE 9 (2001), http://oig.hhs.gov/oei/reports/oei-01-00-00180.pdf.

189. *Id.* at iii–iv.

190. *See* GUIDANCE FOR INDUSTRY, QUESTIONS AND ANSWERS REGARDING ADVERSE EVENT REPORTING AND RECORDKEEPING FOR DIETARY SUPPLEMENTS AS REQUIRED BY THE DIETARY SUPPLEMENT AND NONPRESCRIPTION DRUG CONSUMER PROTECTION ACT, U.S.

individual's name, any known medical conditions, or the exact amount of ingredients contained in the product associated with the adverse event.[191] Thus, while in theory the Adverse Event Reporting requirements should help protect consumers in the long run, in practice the system is ineffective as a proactive measure.[192] While these changes provide the FDA with greater oversight over unsafe energy drinks, they do not go far enough and do not address the underlying issue of inadequate labeling—the main culprit behind excessive caffeine and stimulant intake in adolescent consumers.

## IV. POSSIBLE SOLUTIONS

While the emergence of the energy drink was due in large part to congressional and public reaction to the FDA's stricter dietary supplement regulation through the Food Additive Amendment,[193] public sentiment toward the FDA's role in energy drink regulation is beginning to turn. A recent survey of parents in the United States found that 74% to 78% disagreed with marketing or selling energy drinks to children or teens, and "85% supported regulations requiring caffeine content disclosure and warning labels."[194] While a change in the regulatory framework concerning energy drinks is greatly needed, the path toward that goal will not be as simple as having the FDA promulgate new regulations restricting access to energy drinks or capping caffeine levels. Because many energy drinks are classified as dietary supplements, any binding FDA regulation would have to avoid Congress's intent with passing DSHEA.[195] Without direct congressional action, a more nuanced approach is required.

---

FOOD & DRUG ADMIN. 9 Sept. (2013), http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/UCM381121.pdf [hereinafter GUIDANCE FOR INDUSTRY] (stating that the only information required is an identifiable patient, an identifiable initial reporter, the responsible person's identity and contact information, a suspect dietary supplement, and a description of the serious adverse event).

191. *Id.*

192. *See supra* Part III.B.3 (discussing the flaws in the Adverse Event Reporting system).

193. *See supra* notes 133–42 and accompanying text (describing the FDA's abuse of the Food Additive Amendment and the subsequent reaction from Congress and the public).

194. Owens, Mindell & Baylor, *supra* note 78, at 69.

195. *See* Chevron USA, Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842–43 (1984) (stating that if Congress's intent is clear and unambiguous, the statute controls). DSHEA's legislative history sufficiently demonstrates that Congress wished to better insulate dietary supplements from the FDA's "single-minded regulatory agenda." 140 CONG. REC. S1170; *see also supra* notes 141–42 and accompanying text (describing Congress's belief that DSHEA was necessary due to the FDA's pursuing a "heavy-handed enforcement agenda against dietary supplements for over 30 years" prior to DSHEA's enactment (quoting S. REP. NO. 103-410, at 14)).

In the recently released report by Senators Edward Markey, Richard Durbin, and Richard Blumenthal, the senators propose six recommendations to better protect children and adolescents, including requiring: (1) energy drink manufacturers to cease marketing energy drink products to children under the age of 18; (2) the FDA to provide suggestions for daily caffeine consumption limits for children and adolescents, as well as rules requiring the labeling of caffeine content; (3) the FDA to provide guidance to industry on voluntary reporting of adverse events; (4) the FDA to define what constitutes an energy drink and a sports drink; (5) energy drink manufacturers to cease marketing energy drinks as intended for hydration; and (6) other federal agencies, such as the USDA, to include restrictions in school-based programs for the sale of energy drinks.[196] While adoption of these recommendations would be a significant step towards better protecting children and adolescents from the health risks of energy drinks, the FDA should implement two similar and overlapping changes to ensure the long-term safety of these products: (1) requiring caffeine content labels to include not only added caffeine, but also the content of herbal ingredients that provide a stimulant-like effect and may interact with caffeine; and (2) reforming the Adverse Event Reporting System to provide the FDA with pertinent information.

### *A. Required Labeling of Stimulating Ingredients*

While the recommendation of required caffeine labeling proposed by Senators Markey, Durbin, and Blumenthal would go a long way towards better informing consumers, it misses a key nuance that differentiates energy drinks from ordinary caffeine-containing sodas: the inclusion of other herbal ingredients that also provide stimulant-like effects.[197] Caffeine content calculations do not include these ingredients even though they may produce longer-lasting stimulant effects than caffeine, a fact unknown to many consumers.[198]

The FDA should require companies to list the content of these ingredients on the product's label. This would not only provide consumers with the ability to make more informed consumption

196. BUZZ KILL, *supra* note 27, at 5. On February 10, 2015, Senator Robert Menendez reintroduced the Safe Play Act, which would allow multiple federal agencies to develop information about energy drink ingredients and recommend guidelines for the safe use of energy drink consumption by young consumers. Safe Play Act, S. 436, 114th Cong., § 6 (2015) (initially introduced as S. 2718, 113th Cong. (2014)).

197. *See* SOMOGYI, *supra* note 30, at 4–5 (describing the enhanced stimulant effects of consuming these ingredients together).

198. Thorlton, Colby & Devine, *supra* note 39, at 1177.

choices, but would also improve the information obtainable through Adverse Event Reports.

### *B. Reformed Mandatory Adverse Events Reporting System*

While well intended, the current mandatory adverse events reporting system does not provide the FDA with sufficient information to be of true practical value. Currently, DSHEA requires "responsible persons" to submit to the FDA only "serious adverse events"[199] associated with their product but does not require submission of non-serious adverse events.[200] This causes a wealth of information to go unseen by the FDA.[201] As the recent Senate report recommends, the FDA should provide guidance to industry on voluntary reporting of adverse events.[202]

But even if the FDA adopted this recommendation, the system would still be flawed, because the FDA does not require submission of pertinent information connected with adverse events.[203] Currently, the FDA only requires responsible persons to submit the following information: an identifiable patient (stating a male patient with initials T.D. would be sufficient), an identifiable initial reporter, identity and contact information for the responsible person, a suspect dietary supplement, and a serious adverse event.[204] The FDA should expand the required information to include the age of the patient, any known medical conditions, and the exact amount of ingredients contained in the suspect product that may or may not be hidden by the use of a proprietary blend.[205]

---

199. *See* 21 U.S.C. § 379aa-1(a)(2) (2012) (defining "serious adverse event" as an adverse health-related event associated with dietary supplement use that results in "death; a life-threatening experience; inpatient hospitalization; a persistent or significant disability or incapacity; or a congenital anomaly or birth defect; or requir[ing]" medical or surgical intervention to prevent the previously mentioned outcomes).

200. 21 U.S.C. § 379aa-1(b)(1).

201. OFFICE OF INSPECTOR GEN., *supra* note 188, at 9 (concluding that the FDA receives "less than 1 percent" of all adverse events). The report concluded that the reporting system, as currently structured, is "inherently limited" and "cannot serve as an adequate safety valve." *Id.* at iv.

202. BUZZ KILL, *supra* note 27, at 5.

203. *See Voluntary and Mandatory Reports on 5-Hour Energy, Monster Energy, and Rockstar Energy Drink*, *supra* note 21 (stating that an important limitation to making inferences based on adverse reports is that reports do not include all relevant data, such as whether an individual also suffered from other medical conditions).

204. GUIDANCE FOR INDUSTRY, *supra* note 190.

205. *See Energy "Drinks" and Supplements: Investigations of Adverse Event Reports*, *supra* note 186 (stating that the FDA does not always have the necessary information to determine causation, including the absence of medical records and medical histories and the concurrent use of other supplements or medications).

With this expanded knowledge, the FDA could track not only the safety of particular products, but also the safety of combinations of particular ingredients in identifiable age groups.[206] The FDA could realistically implement this balanced long-term approach to improving the regulation of the energy drink industry.

## V. CONCLUSION

The recent explosion of energy drink consumption is a market trend comparable to the emergence of sodas in the early twentieth century.[207] While the FDA succeeded in regulating caffeine-containing sodas through federal regulations, energy drinks proliferated in a deregulated environment.[208] DSHEA was above all else a statement by Congress and the public that the FDA had lost credibility through its use of the food additive provision to regulate dietary supplements.[209] That lost regulatory authority is needed now to protect vulnerable children and adolescents from excessively-caffeinated beverages and dietary supplements.[210] Although the FDA's journey to discovering its lost regulatory authority will not be easy,[211] the FDA could once again accomplish its purpose of protecting consumers from unsafe food and drugs

206. *See FDA to Investigate Added Caffeine*, *supra* note 60. ("FDA has not set a [safe caffeine] level for children . . . [and] need[s] to continue to look at what are acceptable levels.").

207. *Compare* Part II.B (detailing the recent market explosion of energy drink products) *with* note 87 and accompanying text (noting Coca Cola's rapid growth at the end of the nineteenth century to the point that in 1895 Coca Cola was being sold in every state in the country).

208. *See* Part III.B.1 (discussing how DSHEA removed dietary ingredients often found in energy drinks from the stricter requirements for food additives).

209. *See* note 141 and accompanying text (describing the congressional animosity toward what Congress saw as a heavy-handed approach to the food additive provision).

210. The reluctance of the energy drink industry to voluntarily reform their policies regarding advertising to children and adolescents demonstrates that the health risks associated with youth consumption will go unprotected until Congress acts or the FDA steps in to fulfill its purpose. *See* BUZZ KILL, *supra* note 27, at 4 (reporting that companies representing 90% of the energy drink market declined to agree voluntarily to stop marketing their products to youth under the age of eighteen); *supra* Part II.D (outlining the various health risks associated with energy drink consumption and noting that children and adolescents are particularly vulnerable to these risks).

211. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 2(15)(A), 108 Stat. 4325, 4326 (1994) (codified as amended in 21 U.S.C. § 301 (2012)) ("[L]egislative action that protects the right of access of consumers to safe dietary supplements is necessary . . . ."). On the other hand, DSHEA also states that its purpose is to empower consumers "to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements." *Id.* at §2(8). It is difficult to argue that the current state of energy drink marketing and labeling accomplishes this purpose.

through these balanced and rational changes designed to better inform the public and better protect children and adolescents from excessively-caffeinated beverages.[212]

*Trenton David*

212. *See* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000) ("Viewing the FDCA as a whole, it is evident that one of the Act's core objectives is to ensure that any product regulated by the FDA is 'safe' and 'effective' for its intended use. . . . This essential purpose pervades the FDCA." (citations omitted)).