

AMERICA’S FAVORITE STIMULANT: AN ARGUMENT FOR FDA REGULATORY CONTROL OVER CAFFEINATED PRODUCTS LABELED AS DIETARY SUPPLEMENTS UNDER THE FDCA

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I. INTRODUCTION

Americans tend to characterize themselves as “go-getters.” Our history indicates nothing less than an infatuation with perseverance, resolve, and accomplishment. At the very least, the drive to pursue and overcome obstacles persists in the lives of Americans. A common aid utilized in accomplishing said goals is the consumption of caffeinated beverages and other miscellaneous products. More than ninety percent of Americans consume caffeine every day.¹ As caffeine intake continues to rise amongst Americans, the World Health Organization (“WHO”) has determined that caffeine dependence should be considered a clinical disorder.² This should be a cautionary tale for those who consume high amounts of caffeine on a frequent, mindless basis. What seems to be a sociologically acceptable habit has the true potential to impair one’s cognitive function.³ While caffeine is widely popular and consumed by millions each day, there should be more consideration given to the negative impact caffeine can have on both individuals and society in the modern age.⁴ This Note argues that the lack of regulation surrounding highly caffeinated products, coupled with the lack of awareness surrounding health implications of chronic caffeine consumption, serve as a detriment to individuals and society as a whole. Specifically, the lack of regulation for caffeinated dietary supplements may have an impact on higher rates of consumption, children and adolescents included. The implications spurred by automatic, consistent consumption of caffeine at high levels are numerous and can result in long-term health consequences. Nonetheless, rather than opting to prohibit caffeine use by consumers and businesses through regulation, a more reasonable and pertinent approach would involve revealing that unmonitored consumption of high levels of caffeine over time can have a harmful effect on an individual’s health and well-being.

A proper avenue to address this issue is through proposing an amendment to the Federal Food, Drug, & Cosmetic Act (“FDCA”) enabling the Federal Drug Administration (“FDA”) to assert control over the regulation of caffeinated products defined as dietary supplements under the statute.⁵ The FDA, if granted

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1. Steven E. Meredith et al., *Caffeine Use Disorder: A Comprehensive Review and Research Agenda*, 3 J. CAFFEINE RSCH. 114, 114 (2013).

2. *Id.*

3. *Id.*

4. Jon Kelly, *Coffee Addiction: Do People Consume Too Much Caffeine?*, BCC NEWS MAG. (May 23, 2013), <https://www.bbc.com/news/magazine-22530625> [<https://perma.cc/W4KJ-6CCE>].

5. 21 U.S.C. §§ (301)-(399)(i) (1938).

authority, could have a significant impact on educating consumers, enabling them to determine which products are best for them and to obtain a greater understanding of their relationship with caffeine and caffeinated beverages. This might be accomplished through requiring companies to list total amounts of caffeine on their products, caution against consumption for children and adolescents, and highlight the potential for detrimental health effects to arise due to chronic consumption via educational labeling. Through the adoption of an amendment to the FDCA, the FDA can play a leading role in evaluating the safety of highly caffeinated products on the market, and accordingly regulate while furthermore broadening society's understanding of the relationship between caffeine consumption and overall well-being.⁶

Section II provides relevant background relating to the tradition of caffeine consumption and its striking significance for the development of society across history, including its influence on both the Industrial and American Revolutions. Section III discusses positive and negative repercussions of caffeine consumption on the human brain. Section IV highlights the current status of the FDA's regulatory authority over caffeinated products labeled as food and as dietary supplements under the FDCA. Section V outlines a proposal for amending the FDCA to expand the FDA's regulatory deference over such products and emphasizes the potential benefits of broader regulation for American society.

II. HISTORICAL BACKGROUND

Michael Pollan, in his audiobook "Caffeine", describes in detail the frequency of usage and influence of caffeine on society throughout history while conducting an experiment in abstinence from the drug for three months.⁷ The crux of Pollan's work focuses on the question of whether caffeine has been a "boon or bane" to the human species.⁸ Pollan stipulates that the origin of caffeine can be traced back to China circa 1000 B.C., where it was commonly ingested through drinking tea.⁹ Another notable legend concerns an Ethiopian farmer who one day discovered his goats acting strangely energized after eating the berries of an arabica plant.¹⁰ The goats had eaten berries from an arabica plant which the farmer then took to a monk who is credited with producing the first cup of coffee, although it was more like a stew than a beverage.¹¹ This discovery was paramount, as a primary reason for the widespread popularity of coffee across sovereign borders in earlier times was that it was substantially safer than drinking the water of the time, which was not boiled before consumption.¹² Moreover, coffee became the antithesis of

6. *Id.*

7. MICHAEL POLLAN, *CAFFEINE: HOW CAFFEINE CREATED THE MODERN WORLD*, at 1:00-20:00 (2020) (downloaded using Audible).

8. *Id.*

9. *Id.*

10. *Id.*

11. *Id.*

12. Colleen Walsh, *How Caffeine Changed the World*, HARV. GAZETTE (Aug. 20, 2020),

alcohol, and in some instances, relieved people of the terrible impact of long term alcohol abuse while concurrently promoting a more focused, sober lifestyle.¹³

The historical significance of caffeine cannot be overstated. Rather, caffeine has played an impressive role in inspiring some of history's most impactful occurrences. Both coffee and tea were responsible for the disruption of a previous cycle of human activity, enabling humans to stay awake for longer periods of time and to engage in deep thought as a result of increased focus.¹⁴ It is beyond question that the introduction of caffeine in the forms of coffee and tea impacted the development of cultures across the globe. Even the renowned philosophies, amongst the minds of Voltaire, Isaac Newton, and Simone de Beauvoir, drank coffee throughout the day and late into the night.¹⁵

As coffee was slowly introduced to Europe, it claimed a firm grip on Western society.¹⁶ The first copycat version of the Ottoman coffeehouses appeared in Venice, Italy, and the first coffeehouse in England opened for business in the early 1650's.¹⁷ Coffeehouses like these became centers for discussion and debate in England and were coined as "penny universities" because, for a cheap price, individuals had an opportunity to gain exposure to a vast array of subjects ranging from economics and science to politics and religion.¹⁸ The consumption of tea eventually became the norm for the English working class.¹⁹ This cheap, plentiful source of caffeine altered the workforce. Employees could endure much longer shifts, despite horrific working conditions, with less distraction from hunger due to the satisfaction of sugar.²⁰ "The caffeine in tea helped create a new kind of worker, one better adapted to the rule of the machine. It is difficult to imagine an Industrial Revolution without it."²¹

Because England's societal structure was based on a strict hierarchy, the concept of attending a coffeehouse, and sitting next to people of all social classes

<https://news.harvard.edu/gazette/story/2020/08/author-michael-pollan-discusses-how-caffeine-changed-the-world/> [<https://perma.cc/E69H-7FZH>].

13. *Id.*

14. POLLAN, *supra* note 5.

15. Jessica Pearce Rotondi, *How Coffee Fueled Revolutions—And Revolutionary Ideas*, HIST. (Feb. 11, 2020), <https://www.history.com/news/coffee-houses-revolutions> [<https://perma.cc/2A6D-YSZ2>].

16. Pollan, *supra* note 5.

17. *Id.*

18. Ben Johnson, *English Coffeehouses, Penny Universities*, HISTORIC U.K., <https://www.historic-uk.com/CultureUK/English-Coffeehouses-Penny-Universities/> [<https://perma.cc/7NR8-HJT9>] (last visited Sept. 30, 2021).

19. Michael Pollan, *The Invisible Addiction: Is It Time to Give Up Caffeine?*, GUARDIAN (July 6, 2021, 1:00 PM), https://www.theguardian.com/food/2021/jul/06/caffeine-coffee-tea-invisible-addiction-is-it-time-to-give-up?campaign_id=58&emc=edit_ck_20210712&instance_id=35007&nl=cooking®i_id=42668502&segment_id=63243&te=1&user_id=a86e3dc5483352a25d1448742bdd3931 [<https://perma.cc/4WZ4-PG9N>].

20. *Id.*

21. *Id.*

while engaging in invigorating discussions on controversial subjects was considered radical in comparison to the status quo.²² In a sense this open-minded atmosphere fostered an initial manifestation of the essence of democracy, at least among men.²³ Embarrassingly, women were forbidden from such environments.²⁴ Discussion of revolutionary ideas deliberately put the structures of government and society at risk for intense change.²⁵ A primary example of this potential is rooted in the origins of the American Revolution, during which coffee became the staple beverage of the colonists.²⁶ Beforehand, however, drinking tea was more commonplace as it was established early on by English colonizers.²⁷ Due to the monarchy's grant of a monopoly to the East India Company on the sale and importation of tea, legislative measures such as the Stamp Act of 1765 and the Townshend Acts of 1767 were imposed to collect taxes from the colonies.²⁸ Even though both the Stamp Act and the Townshend Acts were eventually repealed, the monarchy refused to back down on its imposition of the tax on imported tea, which served as a symbol of English control over the colonists.²⁹ Subsequently, many colonists began refusing to drink tea out of principle, and others resorted to smuggling Dutch tea due to its cheaper quality.³⁰ In response, King George III imposed the Tea Act of 1773 in a bold attempt to bail the East India Company out of bankruptcy.³¹

An initial wave of unity amongst the thirteen colonies manifested after the famous Boston Tea Party, as most colonists refused to drink tea and used coffee as the substitute.³² Over time it was considered brutally unpatriotic to drink tea.³³ Even John Adams, in a letter to his wife, mentioned that he loved drinking tea, but needed to quit the habit and switch to drinking coffee instead as a true expression of his support for the colonies in their fight for freedom.³⁴ This popular trend continued on throughout the birth of the United States, as an early rendition of the Declaration of Independence was given at the Merchant Coffee

22. MARKMAN ELLIS, *THE COFFEE HOUSE: A CULTURAL HISTORY* 150, 154 (2004).

23. POLLAN, *supra* note 5.

24. *Id.*

25. *Id.*

26. Lydia Zuraw, *How Coffee Influenced The Course Of History*, NAT'L PUB. RADIO (Apr. 24, 2013, 3:24 AM), <https://www.npr.org/sections/thesalt/2013/04/24/178625554/how-coffee-influenced-the-course-of-history> [<https://perma.cc/96K2-C45Z>].

27. Beth Carver Wees, *Coffee, Tea, and Chocolate in Early Colonial America*, METRO. MUSEUM ART (Oct. 2003), https://www.metmuseum.org/toah/hd/coff/hd_coff.htm [<https://perma.cc/NM94-VAUH>].

28. *Id.*

29. *Tea Act*, HIST., <https://www.history.com/topics/american-revolution/tea-act> [<https://perma.cc/MN6L-82TU>] (last updated Sept. 25, 2019).

30. *Id.*

31. Wees, *supra* note 25.

32. Zuraw, *supra* note 24.

33. *Id.*

34. *Id.*

House in Philadelphia.³⁵ Moreover, George Washington was one of the first farmers to grow coffee in the United States, at his own home in Mount Vernon.³⁶ Indeed, caffeinated drinks have been pervasive in their influence on history throughout the world, and the United States is no exception. This influence continues in the modern age, although it is evident that its scope has significantly expanded.³⁷ By the time World War II began, Americans were consuming more coffee than ever before as consumption levels increased to about twenty pounds per year for every adult.³⁸ American servicemen were drinking coffee at even higher rates, around thirty-two pounds of coffee per capita per year.³⁹ As the Army Quartermaster Corps attempted to vacuum-seal roasted ground coffee to be shipped to service men overseas, the government back home fluctuated back and forth between different levels of rationing for civilians.⁴⁰ “In April 1942, the U.S. government limited coffee roasters to seventy five percent of the previous year’s supply. In September the quota was cut to sixty five percent. Finally, the Office of Price Administration found it necessary to ration coffee for civilians beginning November 29, 1942.”⁴¹ Every five weeks civilians were given only one pound of coffee, which emphasizes the strain American soldiers would have endured if they were unable to imbibe on the battlefield.⁴² Caffeine continued to have a daily impact on the lives of Americans through World War II, the rest of the twentieth century, and well into the twenty first century.⁴³ Coffee consumption may only be at half the level of the 1940’s, but this can be explained by the various kinds of carbonated, caffeine-heavy drinks that have been popularized since the late twentieth and early twenty first centuries.⁴⁴ Regardless

35. *Sip Sip Hurrah! How Coffee Shaped Revolutionary America*, AM. BATTLEFIELD TR., <https://www.battlefields.org/learn/head-tilting-history/sip-sip-hurrah-how-coffee-shaped-revolutionary-america> [<https://perma.cc/A33Q-N4WE>] (last updated Apr. 15, 2021).

36. *Id.*

37. Trenton David, *Return to Regulation: FDA, Energy Drinks, and Our Youth*, 53 Hous. L. Rev. 1401, 1402-03 (2016).

38. Brian Lokker, *U.S. Coffee Rationing in World War II*, COFFEE CROSSROADS, <https://www.coffeecrossroads.com/coffee-history/u-s-coffee-rationing-in-world-war-ii#:~:text=The%20wartime%20rationing%20regulations%20cut%20the%20amount%20of,a%20year%2C%20to%20everyone%20over%2015%20years%20old> [<https://perma.cc/W8T5-UPH9>] (last updated June 22, 2020).

39. Michael Haft & Harrison Suarez, *The Marine’s Secret Weapon: Coffee*, N.Y. TIMES (Aug. 16, 2013), <https://atwar.blogs.nytimes.com/2013/08/16/the-marines-secret-weapon-coffee/> [<https://perma.cc/6EJV-YHZZ>].

40. *Id.*

41. Lokker, *supra* note 36.

42. Cirrelia Thaxton, *History of Coffee in America*, STUDY.COM, <https://study.com/academy/lesson/history-of-coffee-in-america.html> [<https://perma.cc/TBA7-9T6S>] (last visited Feb. 7, 2021).

43. *Id.*

44. Jean C. Buzby & Stephen Haley, *Coffee Consumption Over the Last Century*, U.S. DEP’T. AGRIC. (June 1, 2007), <https://www.ers.usda.gov/amber-waves/2007/june/coffee-consumption-over-the-last-century/> [<https://perma.cc/BB6Q-GWQZ>].

the source, it is apparent that caffeine has impacted history in remarkable ways as humans continue to consume the drug daily and oftentimes mindlessly, without fully understanding the true depth of the health repercussions that may present when consumption of caffeine goes unmonitored.

III. CAFFEINE'S INFLUENCE ON THE BRAIN

Caffeine's chemical label is 1, 3, 7 trimethylxanthine.⁴⁵ Commonly confused as a nutrient, caffeine is simply a dietary component that operates as a stimulant upon ingestion.⁴⁶ The chemical is completely absorbed into water and fat molecules within a matter of about forty-five minutes.⁴⁷ Caffeine transcends the blood-brain barrier rather easily, resulting in antagonism of adenosine receptor subtypes and thus inducing caffeine's stimulating effects.⁴⁸ Absorption through the small intestine in particular enables quick entry into the bloodstream, explaining the felt sense of caffeination.⁴⁹ The quick hit of dopamine alongside increased levels of mental focus from caffeine are primary reasons for its popularity, especially among groups like employees, students, and adolescents in general.⁵⁰

Although caffeine is extremely popular, research indicates that chronic consumption of caffeine debilitates the central nervous system through the modulation of neuronal pathways.⁵¹ Common adverse effects associated with caffeine range from mild to severe, with some of the milder effects being insomnia, anxiety, irritability, and increased urination.⁵² Some of the more severe adverse effects of chronic caffeine consumption include hallucinations, psychosis, arrhythmias, seizure, and disorientation, not to mention a plethora of withdrawal effects in the event that one ceases consumption after perpetuating the habit over long periods of time.⁵³

Caffeine's grip on society is as strong, if not stronger, than in the early years

45. *Caffeine*, HARV. T.H. CHAN. SCH. OF PUB. HEALTH, <https://www.hsph.harvard.edu/nutritionsource/caffeine/> [https://perma.cc/3DCH-G7LT] (last visited Oct. 6, 2021).

46. *Dietary Guidelines for Americans 2015-2020*, U.S. DEP'T HEALTH & HUM. SERV. (Dec. 2015), https://health.gov/sites/default/files/2019-09/2015-2020_Dietary_Guidelines.pdf [https://perma.cc/URX4-22WK].

47. *Caffeine*, *supra* note 43.

48. Justin Evans et al., *Caffeine*, STATPEARLS, <https://www.ncbi.nlm.nih.gov/books/NBK519490/> [https://perma.cc/FP5Q-4HPC] (last updated Dec. 4, 2021).

49. Jena Hilliard, *Caffeine and Caffeine Addiction*, ADDICTION CTR., <https://www.addictioncenter.com/stimulants/caffeine/> [https://perma.cc/R65R-ZYM4] (last updated Sept. 30, 2021).

50. Caroline R. Mahoney et al., *Intake of Caffeine From All Sources and Reasons for Use by College Students*, 38 CLINICAL NUTRITION 668, 669 (2019).

51. Fawaz Alasmari, *Caffeine Induces Neurobehavioral Effects Through Modulating Neurotransmitters*, 28 SAUDI PHARMACY J. 445, 446 (2020).

52. Evans et al., *supra* note 46.

53. *Id.*

of the United States. It naturally exists in coffee, teas, and chocolate, and yet technology has provided ways to insert caffeine into all kinds of beverages and foods as an additive, including but not limited to sports drinks, dietary regulation supplements, alcoholic beverages, soda, bottled water, chewing gum, and protein bars.⁵⁴ The FDA, in a statement concerning the magnitude of caffeine consumption in the United States, admonished Wrigley for manufacturing packs of gum which contained an amount of caffeine equal to that of half a cup of coffee, which is an interesting yet potentially harmful development.⁵⁵ The most common caffeine-containing beverages in North America are coffee and soda, but the United States consumed the most caffeine in the forms of soda, sports drinks, and energy drinks per capita than any other country listed in the Euromonitor Passport Global Market Database in 2018.⁵⁶ Moreover, children as well as adults partake in large amounts of caffeine consumption.⁵⁷ Because of the popularity of caffeine, many Americans may be partaking without recognizing it and find it difficult to avoid the substance completely.⁵⁸

Generally, the FDA has noted that 400mg of caffeine per day is an amount that is not associated with dangerous side effects for healthy adults.⁵⁹ Considering that four or five cups of coffee measures up to that limit, depending on the particular size of each cup, there is about 95mg of caffeine on average present in one cup of coffee.⁶⁰ For context, in a 2014 study where caffeine intake in the United States was estimated based on the weekly caffeine diaries of over 30,000 subjects, consumption was measured at 380 mg/day at the 90th percentile for all ages combined.⁶¹ A more comprehensive understanding of this daily 400mg recommendation is necessary. Despite the relevant and positive intentions of such a recommendation, 400mg of caffeine intake per day may result in detriments to one's health depending on an individual's sensitivity to caffeine.⁶² For instance, many energy drinks including popular brands like Celsius, Reign, Bang, and

54. James G. Hodge et al., *The Consumable Vice: Caffeine, Public Health, and the Law*, 27 J. CONTEMP. HEALTH L. & POL'Y 76, 77 (2010).

55. Kelly, *supra* note 4.

56. Celine M. Reyes & Marylin C. Cornelis, *Caffeine in the Diet: Country-Level Consumption and Guidelines*, 10 NUTRIENTS 1772, 25 (2018).

57. Jennifer L. Temple, *Caffeine Use in Children: What We Know, What We Have Left to Learn, and Why We Should Worry*, 33 NEUROSCIENCE & BIOBEHAVIORAL REV. 793, 793 (2009).

58. Hodge et al., *supra* note 52.

59. *Spilling the Beans: How Much Caffeine is Too Much?*, FED. DRUG ADMIN. (Dec. 12, 2018), <https://www.fda.gov/consumers/consumer-updates/spilling-beans-how-much-caffeine-too-much> [<https://perma.cc/6JE3-LVLQ>].

60. *Food Data Central Search Results*, U.S. DEP'T OF AGRIC. (April 1, 2019), <https://fdc.nal.usda.gov/fdc-app.html#/food-details/171890/nutrients> [<https://perma.cc/X7XN-UJ2E>].

61. Diane C. Mitchell et al., *Beverage Caffeine Intakes in the U.S.*, 63 FOOD & CHEM. TOXICOLOGY 136, 136 (2014).

62. *Spilling the Beans: How Much Caffeine is Too Much?*, FED. DRUG ADMIN. (Dec. 12, 2018), <https://www.fda.gov/consumers/consumer-updates/spilling-beans-how-much-caffeine-too-much> [<https://perma.cc/6JE3-LVLQ>].

Rockstar already consist of 300mg in one serving or one can.⁶³ Thus, drinking a product with 30mg of caffeine alongside a cup of coffee or even another energy drink later in the day pushes one well above the 400mg limit.

Many consumers may be under the impression that their daily caffeine intake is at a safe level simply because nothing bad has ever occurred to them as a result. Instead, they may focus on the captivating and energizing effects of caffeinated products and are able to subtly disregard the FDA's daily intake recommendation. However, these patterns are unhealthy and dangerous and are exacerbated when consumer ignorance is factored into the equation.⁶⁴ A primary issue with such a recommendation is that it is misleading to consumers. A daily caffeine intake of 400mg may not result in dangerous side effects for average adults, but this observation undermines other circumstances that play a significant role in influencing whether or not negative health implications arise. One such relevant circumstance is the time of day when people choose to consume caffeine. Ingesting 400mg of caffeine before noon would have different implications than 400mg of caffeine consumed after three o'clock in the afternoon.⁶⁵ The 400mg itself may not be inherently dangerous, but caffeine consumed in the afternoon hours will likely result in a lack of quality sleep. A prolonged pattern of such a habit, compounded by cravings and numerous withdrawal symptoms, is a recipe for a detrimental effect on daytime functioning.⁶⁶

It would be facetious to say that caffeine does not provide any benefits whatsoever. Indeed, moderate consumption of caffeine will yield hardly any negative side effects short-term.⁶⁷ The potential health detriments posed by caffeine present themselves when one's frequency and volume of consumption increase over a longer period of time, especially if these patterns are unbeknownst to or ignored by the consumer.⁶⁸ Similarly, even small amounts of pure caffeine powder can prove to be fatal.⁶⁹ Rather than saying that caffeine alone is harmful, it would be more accurate to say that unchecked, consistent consumption of higher amounts of caffeinated products can result in consequences that

63. James Foster, *Energy Drinks With the Most Caffeine*, CAFFEINE INFORMER, <https://www.caffeineinformer.com/energy-drinks-caffeine> [<https://perma.cc/4SNR-DPEV>] (last updated Feb. 15, 2022).

64. *Risks of Energy Drinks*, SUTTER HEALTH, <https://www.sutterhealth.org/health/nutrition/risks-of-energy-drinks> [<https://perma.cc/QP4L-XXHD>] (last visited Nov. 10, 2021).

65. Christopher Drake et al., *Caffeine Effects on Sleep Taken 0, 3, or 6 Hours Before Going to Bed*, 9 J. CLINICAL SLEEP MED. 11, 1196 (2013).

66. *Id.* at 1198.

67. *24 Remarkable Caffeine Consumption Statistics*, HEALTH RSCH. FUNDING, <https://healthresearchfunding.org/remarkable-caffeine-consumption-statistics/> [<https://perma.cc/ZXS3-G62K>] (last visited Oct. 6, 2021).

68. Hilliard, *supra* note 47.

69. *Pure and Highly Concentrated Caffeine*, FED. DRUG ADMIN., <https://www.fda.gov/food/dietary-supplement-products-ingredients/pure-and-highly-concentrated-caffeine> [<https://perma.cc/P3UC-6NSX>] (last updated Mar. 30, 2021).

unfortunately put one's physical and mental health at risk.⁷⁰

Accordingly, it becomes understandable why energy drinks are so popular amongst adolescents; they are ingesting a large amount of caffeine comparable to two or three cups of coffee in one sitting when they purchase such beverages. This produces a rush of energy far more gripping than the typical cup of coffee would provide. Furthermore, these energy drinks are often supplemented with other ingredients meant to work together with caffeine to further stimulate consumers.⁷¹ In addition to caffeine, energy drinks may also contain guarana, taurine, glucuronolactone, and other various additives to heighten the stimulant effect of the product.⁷² "When higher doses of caffeine are combined with these other substances currently blended in EBs (energy beverages), the subsequent effect cannot always be predicted; adverse effects have been reported, including cardiac arrest."⁷³ Thus, the recommendation of 400 mg of caffeine daily by the FDA more realistically serves as an indication that consumers should probably stop ingesting caffeine once they have hit the 400mg mark if they do not want to flirt with the possibility of developing caffeine toxicity or even death. This recommendation may give consumers a false sense of security in the face of products that include other ingredients which enhance the effects of caffeine, as well as a general lack of awareness surrounding one's individual relationship with caffeine and its impact on one's overall cognitive function.

A major way that caffeine can inhibit cognitive function is through its anti-tiring effects on the brain.⁷⁴ Although caffeine can help one stay awake and simultaneously focus for longer periods of time, ingesting it later in the day can cause a plethora of issues related to hindered sleep quality.⁷⁵ Ingesting caffeine in the afternoon or evening hours ". . . results in you getting fewer hours of sleep, leading you to drink more coffee to make up for your tiredness the next day, creating a vicious cycle that can leave you more fatigued than ever."⁷⁶ Although caffeine is the most popular drug in the United States as well as the rest of the world, sleep may be the strongest performance enhancer that many disregard.⁷⁷ In fact, over sixty six percent of adults across the globe refrain from sleeping the recommended amount of eight hours per night.⁷⁸ Furthermore, because the number of Americans who get fewer than six hours of sleep per night has

70. Hilliard, *supra* note 47.

71. John P. Higgins et al., *Energy Beverages: Content and Safety*, 85 MAYO CLINIC PROC. 1033, 1034 (2010).

72. *Id.* at 1034.

73. *Id.*

74. *Is Caffeine Boosting or Sabotaging Your Productivity?*, ENTREPRENEUR (June 12, 2017), <https://www.entrepreneur.com/article/295232> [<https://perma.cc/8C7M-D5AC>].

75. Matthew Walker, *The Best Thing You Can Do for Your Health: Sleep Well*, GUARDIAN (Feb. 9, 2019), <https://www.theguardian.com/lifeandstyle/2019/feb/09/best-thing-you-can-do-for-your-health-sleep-well> [<https://perma.cc/5YUV-388S>].

76. ENTREPRENEUR, *supra* note 72.

77. *See* Walker, *supra* note 73.

78. *Id.*

increased from thirteen to twenty percent, caffeine consumption affecting this dangerous cycle may influence widespread social implications such as increased anxiety, depression, irritability, and chronic fatigue.⁷⁹ Research indicates that fatigue in the morning hours may result in higher caffeine consumption, ultimately disrupting subsequent sleeping patterns.⁸⁰ Thus, although caffeine is known to enhance cognitive function and memory in the short term, daily consumers may develop the antithesis of those benefits when their consumption disrupts their sleep cycle each night.⁸¹ Caffeine can impact how quickly one is able to fall asleep and can furthermore constrict the length of sleep as well as its quality.⁸² Caffeine additionally reduces the amount of slow-wave sleep experienced through the night.⁸³ This slow-sleep stage is associated with deep rest that tends to promote a felt sense of refreshment in the morning hours.⁸⁴ The habit of relying on caffeine in the morning and throughout the day can develop into a dangerous pattern where one relies on caffeine to keep themselves awake while sacrificing the deep rest provided by sleep which is all the more required for efficient and unhindered cognitive function.⁸⁵ “Caffeine-interrupted sleep can lead to sleep deprivation the following day, which is characterized by fatigue and problems with learning, memory, problem-solving, and emotion regulation.”⁸⁶ A 2013 study confirmed that caffeine consumption up to as much as six hours before bedtime can decrease time spent asleep throughout the night.⁸⁷ Furthermore, “. . . study participants reported sleeping problems when consuming caffeine at least three hours before bed, but they did not realize their sleep was also disrupted when consuming caffeine six hours before bed.”⁸⁸ This study indicates that many may misunderstand the relationship they have with caffeine, and in turn how their caffeine consumption impacts the quantity and quality of their sleep.

The unhealthy pattern of relying on caffeine for alertness and higher levels of functionality comes with other potential ramifications, such as an increased risk for Alzheimer’s and dementia.⁸⁹ A 2021 study broadened the understanding

79. Francis O’Callaghan et al., *Effects of Caffeine on Sleep Quality and Daytime Functioning*, 11 RISK MGMT. & HEALTHCARE POL’Y 263, 266 (2018).

80. *Id.* at 265.

81. *Id.*

82. Danielle Pacheco, *Caffeine and Sleep*, SLEEP FOUND. (Jan. 22, 2021), [https://www.sleepfoundation.org/nutrition/caffeine-and-sleep#:~:text=In%20This%20Article%20%20%20Beverage%20%20,of%20tea%20%20%2014%20%E2%80%93%2060mg%20\[https://perma.cc/88WQ-FVVC\]](https://www.sleepfoundation.org/nutrition/caffeine-and-sleep#:~:text=In%20This%20Article%20%20%20Beverage%20%20,of%20tea%20%20%2014%20%E2%80%93%2060mg%20[https://perma.cc/88WQ-FVVC]).

83. *Id.*

84. *Id.*

85. *See* Walker, *supra* note 73.

86. *Id.*

87. Christopher Drake et al., *Caffeine Effects on Sleep Taken 0, 4, or 6 Hours Before Going to Bed*, 11 J. CLINICAL SLEEP MED. 1195, 1198 (2013).

88. Pacheco, *supra* note 80.

89. *See* Severine Sabia et al., *Association of Sleep Duration in Middle and Old Age with*

of the relationship between the two, confirming based on a large subject pool that those who sleep less than six hours per night in midlife increase their chances of developing late-onset dementia.⁹⁰ Although caffeine may not be the single source of sleep deprivation amongst the general population, it is worth noting that the link between increased caffeine consumption and lack of quality sleep has the potential to wreak havoc on one's well-being long term.

Another negative consequence of daily caffeine intake concerns increased risk for the development of anxiety and panic attacks.⁹¹ This is, of course, ironic in the context of students who use caffeine as a source of stress management, and to endure many hours of study and exam preparation, et cetera. A notable pop-culture moment which references the risks of caffeine abuse stems from an episode of *Saved by the Bell*, where a student develops an addiction to caffeine pills to meet the demands of her hectic schedule, resulting in a mental breakdown.⁹² In contrast to scientific evidence which points towards the dangers of repetitious caffeine consumption, this television episode highlights just how easy it is for children and adolescents to repeat the dangerous pattern of relying on caffeine. In 2018 alone, ninety-two percent of students claimed to consume caffeine on a regular basis.⁹³ Popular reasons for doing so include “to feel awake (79%); enjoy the taste (68%); the social aspects of consumption (39%); improve concentration (31%); increase physical energy (27%); improve mood (18%); and alleviate stress (9%).”⁹⁴ Moreover, according to a study utilizing dietary recall data from 1999-2010, seventy-three percent of children ranging from ages 2-22 consume caffeine on a daily basis.⁹⁵ More specifically, “. . . the percentage of consumers increased from 63% among two-to-five-year-old children to ~75% among the older age groups.”⁹⁶ This is striking, especially considering the broad access children have to caffeinated products like sodas and other energy drinks that tend to be loaded with sugar and additives for the purpose of enhancing the product's stimulating effects.⁹⁷ An additional study highlighting the relationship between caffeine and cognitive function of children determined that greater

Incidence of Dementia, 12 NATURE COMMUN'S 1, 1 (2021).

90. *Id.*

91. ENTREPRENEUR, *supra* note 72.

92. Mara Reinstein, *How “I’m So Excited” Became the Most Ridiculous—and Iconic—‘Saved by the Bell’ Moment*, RINGER (Nov. 24, 2020), <https://www.theringer.com/tv/2020/11/24/21611425/saved-by-the-bell-jessies-song-im-so-excited-history-reboot> [<https://perma.cc/E6RD-KJ9D>].

93. Mahoney et al., *supra* note 48.

94. *Id.*

95. Amy M. Branum et al., *Trends in Caffeine Intake Among U.S. Children and Adolescents*, 133 PEDIATRICS 386, 386 (2014).

96. *Id.*

97. William R. Perlman, *Childhood Caffeine Exposure May Negatively Affect Cognitive Functioning*, NAT'L INST. ON DRUG ABUSE (April 19, 2021), <https://www.drugabuse.gov/news-events/nida-notes/2021/04/childhood-caffeine-exposure-may-negatively-affect-cognitive-functioning> [<https://perma.cc/4UHL-J7CF>].

caffeine consumption was associated with worse performance on several cognitive measures, including vocabulary comprehension, inhibitory control, working memory, processing speed, and cognitive flexibility.⁹⁸ Thus, the assumption amongst children and adolescents that caffeine will enable them to perform more efficiently in the face of intense schedules and high demands due to surges of dopamine and energy could be characterized as delusion.

Mindless and unregulated repetition of caffeine binging can lead to disastrous outcomes stemming from caffeine abuse, which may ultimately lead to outright dependence.⁹⁹ There seems to be a certain controversy in the scientific community regarding whether or not caffeine is an addictive substance. While caffeine does mimic the effects of amphetamines and cocaine through inducing surges of dopamine in the brain, some scientists claim that it does not induce a large enough disruption in the reward-system balance to be considered addictive.¹⁰⁰ However, scientists cannot deny the potential for those who consume caffeine on a consistent basis to develop a dependency on the substance, which can occur rather quickly.¹⁰¹ Once an individual begins to consume caffeine on a regular basis, they develop a tolerance.¹⁰² This may result in a conditioned habit of caffeine intake in the morning, producing a noticeable wake-up effect.¹⁰³ As one's tolerance increases, the larger the amount of caffeine necessary to spark that semi-euphoric state of mind which forces us out of morning grogginess.¹⁰⁴ If one were to suddenly cease consumption after increasing their tolerance, they would experience an onslaught of withdrawal symptoms and cravings similar to any other potentially addictive substance.¹⁰⁵ Withdrawal symptoms can occur within just a few hours after missing one's regular date with caffeine in whatever form and can be severe for those who consistently ingest high doses.¹⁰⁶ These symptoms may include headaches, fatigue, irritability, muscle stiffness, lack of concentration, and insomnia.¹⁰⁷ Dealing with these symptoms makes it much more difficult for those attempting to quit or change their caffeine routine, resulting in relapse back to their familiar habits despite health concerns linked to chronic caffeine use.¹⁰⁸ Although the American Psychiatric Association does not characterize caffeine addiction as a substance use disorder, it does label caffeine

98. *Id.*

99. Hilliard, *supra* note 47.

100. *Id.*

101. *Id.*

102. *Id.*

103. *Id.*

104. *Id.*

105. *Id.*

106. *Caffeine: How to Hack It and How to Quit It*, CLEV. CLINIC, <https://my.clevelandclinic.org/health/articles/15496-caffeine-how-to-hack-it-and-how-to-quit-it> [<https://perma.cc/JA8E-H4CH>] (last updated Dec. 23, 2020).

107. *Id.*

108. Hilliard, *supra* note 47.

withdrawal symptoms as clinical conditions.¹⁰⁹ Furthermore, the World Health Organization recognized caffeine addiction as a clinical disorder in 2012.¹¹⁰ Although scientists argue about the technicalities of what constitutes as an addictive substance, it cannot be denied that caffeine dependence in its own right is easily developed and potentially dangerous to one's health and well-being given the broad access consumers have to highly caffeinated products.

The facts of various court cases indicate the dangers of unmitigated consumption of products with a high caffeine content. In *Lemley v. Red Bull of North America*, the mother of William Jacob Wade brought multiple claims against Red Bull when her son consumed an unspecified amount of the product.¹¹¹ William Wade eventually suffered cardiac arrhythmia, aortic dissection, hypertension, and other cardiovascular problems that ultimately led to his death.¹¹² Multiple wrongful death claims have been pursued against Monster Beverage, including two separate cases in 2013.¹¹³ Anais Fournier, at fourteen years old, suffered and eventually died from cardiac arrhythmia upon consuming at least two 24oz. Monster energy drinks.¹¹⁴ In this case, Dr. Ana Rubio opined that Anais died of caffeine toxicity upon her completion of the autopsy.¹¹⁵ Dr. Stephen Lipshultz, a world renowned cardiologist, believed that Monster energy drinks substantially contributed to the conditions which led to Anais' death.¹¹⁶ Another complaint, filed in the same year, concerned the death of nineteen-year-old Alex Morris, who suffered from cardiac arrest after supposedly drinking two cans of Monster every day for three years before his death, including the day he died.¹¹⁷ Cases against Monster Beverage Corp. have led to scrutiny surrounding the company, but have failed to enforce accountability for their elusive marketing tactics geared towards children and adolescents.¹¹⁸

An additional relevant court case concerns the death of Logan Stiner, an eighteen-year-old high school student who passed away after ingesting pure caffeine powder advertised as a workout supplement on Amazon.¹¹⁹ As previously discussed, one teaspoon of powdered caffeine may contain up to

109. *Id.*

110. *Id.*

111. *Lemley v. Red Bull N. Am., Inc.*, No. 4:16-CV-080, 2016 WL 7197442 at *1 (S.D. Ga. Dec. 9, 2016).

112. *Id.*

113. Jason Gewirtz, *Second Wrongful Death Suit Filed Against Monster Beverage*, CNBC, <https://www.cnbc.com/id/100843412> [<https://perma.cc/88BT-JQAM>] (last updated June 26, 2013).

114. Pls.' Opp'n to Defs.' Mot. for Summ. J. at 1, *Crossland v. Monster Beverage Corp.*, No. RIC 1215551, 2015 WL 5162521 (Cal. Super. July 7, 2015).

115. *Id.*

116. *Id.*

117. *Monster Energy Drink Linked to Another Teen's Death, Lawsuit Filed*, CBS NEWS (June 26, 2013), <https://www.cbsnews.com/news/monster-energy-drink-linked-to-another-teens-death-lawsuit-filed/> [<https://perma.cc/AS6W-73BX>].

118. *Id.*

119. *Stiner v. Amazon.com, Inc.*, 164 N.E.3d 394, 396 (Ohio 2020).

twenty-eight cups of coffee's worth of caffeine; products touted to be "pure" caffeine are highly concentrated, potent, and can result in serious health consequences.¹²⁰ The Court of Appeals held that Amazon was not liable as a supplier or seller of caffeinated products.¹²¹ A more recent instance concerns the death of twenty-one year-old Lachlan Foote, who put caffeine powder advertised as a dietary supplement in his protein shake after a workout.¹²²

These cases display the potential dangers involved in consuming high amounts of caffeine, or even small amounts of powdered caffeine at a substantially higher potency than the typical dosage present in a soda or a cup of coffee. One 2018 study tallied ninety-two cases where caffeine was established as the only cause of death, and although death due to caffeine intoxication or caffeine toxicity is rare, ". . . unintentional caffeine abuse due to excessive intake of caffeine is relatively frequent and responsible for classical clinical manifestations of overstimulation."¹²³ It is worth noting that a third of the reported deaths from this study were considered to be suicides, which emphasizes the fact that those who did consume caffeine as a vehicle for suicide knew that the amount consumed in those instances would render their bodies unable to function, resulting in their death.¹²⁴ This ominous result stems from a process known as ventricular fibrillation, which occurs when the heart's lower chambers begin to vibrate instead of maintaining their regular contractions, leading to cardiac arrest.¹²⁵ Typically, ingesting up to eighty milligrams of caffeine per liter will likely put one at high risk for ventricular fibrillation and subsequent fatality.¹²⁶

Caffeine, although generally safe for ingestion, can have a remarkable impact on an individual's state of mind and overall well-being considering all relevant circumstances, most notably caffeine's influence on our dopaminergic systems.¹²⁷ Caffeine is one of the most commonly studied drugs to this date by scientists and medical professionals due to its history as a commonly consumed drug, previously in the forms of coffee and tea.¹²⁸ Although this research has yielded a greater understanding of caffeine's chemical breakdown in the body in comparison to other substances, an approach tainted with complacency has

120. *Pure and Highly Concentrated Caffeine*, FED. DRUG ADMIN., <https://www.fda.gov/food/dietary-supplement-products-ingredients/pure-and-highly-concentrated-caffeine> [https://perma.cc/P3UC-6NSX] (last updated Mar. 30, 2021).

121. *Stiner*, 164 N.E.3d at 396.

122. Maggie O'Neill, *Caffeine Powder Overdose Leaves 21-Year-Old Dead- Here's What to Know*, HEALTH, <https://www.health.com/nutrition/caffeine-powder-overdose> [https://perma.cc/YK77-23QY] (last updated Jan. 8, 2020).

123. Simone Cappelletti et al., *Caffeine-Related Deaths: Manner of Deaths and Categories at Risk*, 10 NUTRIENTS 611, 615 (2018).

124. Claire Sissons, *Can You Overdose on Caffeine?*, MED. NEWS TODAY (Jan. 16, 2019), <https://www.medicalnewstoday.com/articles/322933> [https://perma.cc/2QH2-MQWU].

125. *Id.*

126. *Id.*

127. Alasmari, *supra* note 49.

128. Pollan, *supra* note 5.

become the norm for most individuals. A significant amount of clinical studies show that despite an individual's knowledge surrounding chronic caffeine use, many are unable to refrain from habits related to caffeine ingestion.¹²⁹ This can result in a seemingly automatic habit that can persist for long periods of time and can additionally serve as a detriment to one's health long-term.¹³⁰ Expanding awareness surrounding one's own relationship to caffeine can correspondingly result in a potential decrease of negative health implications and a greater sense of well-being for society.

IV. SCOPE OF CAFFEINE REGULATION

The Federal Administration and the Drug Enforcement Agency both play unique roles in the regulation of caffeine, amongst all other substances, foods, and beverages. Congress has given both agencies a specified amount of deference to regulate substances through statutes. The FDA is responsible for the enforcement of the Federal Food, Drug, and Cosmetic Act ("FDCA"),¹³¹ which "prohibits the introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded."¹³² The essence of the FDCA centers on protecting consumers from accessing unsafe drugs and various other health products via interstate commerce.¹³³ However, determining the practical effect of legislation is exponentially difficult. The FDCA is no exception, as it regulates caffeine as both a drug and a food source.¹³⁴

The definition of "drug" in the FDCA is quite broad and thus encompasses a wide array of products. For purposes of the FDCA, the term "drug" includes articles listed in the United States Pharmacopeia, the official Homeopathic Pharmacopeia of the United States, or official National Formulary or any of their supplements.¹³⁵ Furthermore, the definition includes articles used to diagnose, cure, mitigate, treat, or prevent disease in man or other animals, as well as articles other than food intended to affect the structure or any function of the body of man or other animals.¹³⁶ Interpretations of FDCA language concerning the definition of "drug" are potentially unlimited in comparison to the FDCA definition of "food", which includes articles used for food or drink for man or other animals, chewing gum, and articles used for components of other articles of food or

129. Meredith et al., *supra* note 1.

130. *Id.*

131. 21 U.S.C. §§ (301)-(399)(i) (1938).

132. *Id.*

133. Joanna R. Lampe, *The Controlled Substances Act (CSA): A Legal Overview for the 117th Congress*, CONG. RSCH. SERV. (Feb. 5, 2021), <https://crsreports.congress.gov/product/pdf/R/R45948> [<https://perma.cc/D83W-LPSW>].

134. Gwendolyn Prothro, *The Caffeine Conundrum: Caffeine Regulation in the United States*, 27 CUMB. L. REV. 65, 75 (1997).

135. 21 U.S.C. § 321(g)(1) (1938).

136. *Id.*

drink.¹³⁷

Speculation and concern regarding the implementation of numerous chemicals in food products has been apparent since at least the 1950s. As a result, Congress passed the Food Additives Amendment to the FDCA in 1958.¹³⁸ This amendment defined a “food additive” generally as “any substance the intended use of which results or may reasonably be expected to result . . . in its becoming as component or otherwise affecting the characteristics of any food.”¹³⁹ This amendment created a scientifically based safety standard which demanded that food additive producers show to a reasonable certainty that no harm will result from an additive’s intended use.¹⁴⁰ Upon the FDA’s evaluation of an additive and the subsequent finding that said additive is safe, it will promulgate regulation procedures which describe how the additive may be used in a safe manner.¹⁴¹ These regulation procedures outline how companies are able to utilize additives in their products on an everyday basis in such a way that even though absolute safety of an additive cannot be fully established, their use in various products can be determined as generally safe for the public.¹⁴² Another relevant statutory development for caffeine regulation is the GRAS provision, outlined in Section 348 of the FDCA.¹⁴³ GRAS, or “generally recognized as safe”, is an acronym used to designate exceptions to the definition of food additives.¹⁴⁴ This designation applies to substances that would not require formal premarket approval because its safety has already been determined by “. . . a long history of use in food or because the nature of the substances, their customary or projected conditions of use, and the information generally available to scientists about the substances precluded the need for a formal review.”¹⁴⁵ The provision also allows for a GRAS classification based on scientific procedures.¹⁴⁶ GRAS determination further requires qualified experts to evaluate each substance for its intended use and to ensure that information used in its safety evaluation is available to the public in some forum, the most common and frequent being the Internet.¹⁴⁷

Indeed, the FDCA does not consider the definitions of “food” and “drug” to be exclusive.¹⁴⁸ Accordingly if a substance is sold and used a food as well as for treatment or prevention of disease, that substance falls under the umbrella of both “food” and “drug” and is controlled by substantive legislative requirements for

137. 21 U.S.C. § 321(f) (1938).

138. Leah S. Rosenfeld et al., *Regulatory Status of Caffeine in the United States*, 72 NUTRITION REV. 23, 24 (2014).

139. 21 U.S.C. § 348 (2018).

140. Rosenfeld et al., *supra* note 135, at 24.

141. Rosenfeld et al., *supra* note 135.

142. *Id.* at 24.

143. 21 U.S.C. § 348 (2018).

144. Rosenfeld et al., *supra* note 135.

145. *Id.*

146. *Id.*

147. *Id.*

148. Prothro, *supra* note 131, at 75.

both definitions.¹⁴⁹ If a company markets a caffeinated soft drink as soda, it will likely be regulated as a food.¹⁵⁰ But if a company markets a product as a soft drink that helps maintain a bodily function such as lowering cholesterol, it will likely be regulated as a drug.¹⁵¹ In the case of caffeine, a feasible approach would be for a company to say that it helps boost cognitive function or enables consumers to become more alert. This is especially confusing and inconsistent for purposes of understanding exactly how caffeine is regulated. “These regulatory classifications are different with respect to ingredient regulation, labeling, and good manufacturing practices.”¹⁵²

Dietary supplement labels must display a Supplement Facts panel while foods must include a Nutrition facts panel.¹⁵³ That being said, these dietary supplement labels are not required for FDA approval, rather a company has to provide the FDA with a notification that includes the text of the structure or function claim of the product within thirty days of implementing marketing practices.¹⁵⁴ Thus, there is a split in the road where caffeine is regulated in different ways dependent upon the definition and purpose of the product in which it resides. A third framework regulates caffeine in over-the-counter pain relievers such as Excedrin, Midol, and Bayer, but is not relevant to the framework which guides regulations for caffeinated foods or dietary supplements because caffeinated over-the-counter drugs undergo the FDA’s drug approval process.¹⁵⁵ Despite the difference in regulation between caffeinated over-the-counter medications and caffeinated foods or dietary supplements, over-the-counter medications that include caffeine are a source which consumers may not consider in their daily caffeine consumption. Moreover, there are different policies and procedures utilized for regulating pure caffeine in comparison to caffeine as an additive or a dietary supplement. This is likely due to the differences in potency between pure caffeine and caffeine as an additive or dietary supplement. “A single teaspoon of pure powdered caffeine is roughly equivalent to the amount of caffeine in twenty-eight cups of coffee and a half cup of a typical liquid concentrated caffeine product contains roughly the same amount of caffeine as more than twenty cups of

149. *Id.*

150. *Id.*

151. *Id.*

152. Rosenfeld et al., *supra* note 135.

153. Tara Couch & Allen Sayler, *Dietary Supplements vs. Foods- A FSMA Regulatory Challenge*, NAT. PRODUCTS INSIDER (April 30, 2018), <https://www.naturalproductsinsider.com/legal-compliance/dietary-supplements-vs-foodsa-fsma-regulatory-challenge> [<https://perma.cc/E6CU-TD8E>].

154. Michael Shabaka, *Dietary Supplements vs. Food: FSMA Labeling Requirements for Food Manufacturers*, MANEX, <https://www.manexconsulting.com/blog/dietary-supplements-vs-food-fsma-labeling-requirements-for-food-manufacturers/> [<https://perma.cc/4DZ4-K4QB>] (last visited Feb. 10, 2022).

155. *Caffeine Chart*, CTR. FOR SCIENCE PUB. INT., <https://www.cspinet.org/caffeine-chart> [<https://perma.cc/Z45Z-D8UB>] (last visited Mar. 13, 2022).

coffee.”¹⁵⁶

Although historically coffee and tea reigned as the most commonly consumed caffeinated products, the scope has been widened as products like energy drinks, energy shots, and highly concentrated caffeine powders and liquids have made their way into the market.¹⁵⁷ “Energy drinks are flavored beverages containing varying amounts of caffeine and, typically, other additives, such as vitamins, taurine, theanine, carnitine, herbal supplements, creatine, sugars, and guarana, a plant product that naturally contains concentrated caffeine.”¹⁵⁸ All of these other additives are included to create a higher stimulant effect in addition to caffeine, constituting a clear difference between energy drinks and the typical caffeinated soda.¹⁵⁹ To the detriment of the consumer, many energy drinks that include caffeine-containing ingredients like guarana do not list the actual amount of caffeine in the beverage.¹⁶⁰ “If caffeine is listed as part of a ‘proprietary blend,’ then the amount of the blend must be listed, but not the amount of caffeine in the blend.”¹⁶¹ This is misleading to consumers, given that energy drinks already tend to have a higher caffeine content than sodas.¹⁶²

A historical precursor to the widespread popularity of energy drinks was the introduction of highly caffeinated sodas like Jolt Cola. Jolt was marketed as a high energy soda that contained twice as much caffeine as the regular can of Coke, but failed to maintain a grip on consumers as displayed by Jolt Cola filing for bankruptcy in 2009.¹⁶³ Jolt Cola was a beverage concocted by Pepsi Co. and marketed as an energy drink in the 1990s, its primary ingredient being guarana.¹⁶⁴ Although neither of these drinks remain on the market today, they were a foreshadowing of the current market where energy drink companies flourish.¹⁶⁵ In the light of rising popularity surrounding products with high amounts of caffeine or even small amounts of highly concentrated caffeine, “the potential for

156. *FDA Warns Consumers About Pure and Highly Concentrated Caffeine*, FED. DRUG ADMIN., <https://www.fda.gov/food/dietary-supplement-products-ingredients/fda-warns-consumers-about-pure-and-highly-concentrated-caffeine> [<https://perma.cc/B77F-7JMV>] (last updated Apr. 13, 2018).

157. David, *supra* note 35.

158. Denise Webb, *The Truth About Energy Drinks*, 15 TODAY’S DIETITIAN 62, 63 (2013).

159. David, *supra* note 35. See also John Higgins et al., *Energy Drinks: A Contemporary Issues Paper*, 17 CURRENT SPORTS MED. REP. 65, 65 (2018).

160. Jon Kole & Anne Barnhill, *Caffeine Content, Labeling: A Missed Opportunity for Promoting Personal and Public Health*, 3 J. CAFFEINE RES. 108, 110 (2013).

161. *Id.*

162. Webb, *supra* note 155.

163. Jamie Logie, *Jolt Cola: The Story of the Original Energy Drink*, MEDIUM, <https://bettermarketing.pub/jolt-cola-the-story-of-the-original-energy-drink-4d5b9241f9cd> [<https://perma.cc/C9FD-EQ5A>] (last visited Mar. 16, 2022).

164. *Pepsi to Widen Testing of Drink Made with Mystical Guarana Berry*, ASSOCIATED PRESS, <https://apnews.com/article/34d756298be0563975d2da80674d63a1> [<https://perma.cc/CC8G-NNA9>] (last visited Mar. 16, 2022).

165. Logie, *supra* note 160.

adverse health consequences should be considered and may be cause for preemptive regulatory action.”¹⁶⁶ The FDA, however, has minute regulatory power over energy drinks and other miscellaneous products as they are labeled by the FDCA as “dietary supplements” as opposed to “beverages” and thus are not subject to the heightened regulation that typical beverages that fall under the FDCA’s definition of “food”.¹⁶⁷ According to the FDA, food additives are meticulously monitored and studied.¹⁶⁸ “Federal regulations require evidence that each substance is safe at its intended level of use before it may be added to foods. Furthermore, all additives are subject to ongoing safety review[.]”¹⁶⁹

Yet, there is a stark difference in the FDA’s approach to dietary supplement regulation requirements. “Federal law does not require dietary supplements to be proven safe to FDA’s satisfaction before they are marketed.”¹⁷⁰ Rather, after health concerns have presented themselves, the FDA evaluates safety for consumption via research and adverse event monitoring.¹⁷¹ Products like energy drinks, energy shots, and highly concentrated caffeine powders and liquids fall under the periphery of the “dietary supplement” label.¹⁷² Generally, dietary supplements are defined as “a product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet [.]”¹⁷³ Regulatory classifications for food versus dietary supplements differ from one another in respect to labeling, manufacturing, and ingredient regulation.¹⁷⁴ The basis for product classification as a dietary supplement or food is a particular product’s intended use.¹⁷⁵ “Classification determinations often are determined by information which the manufacturer provides on a specific product’s label or otherwise in accompanying

166. Chad J. Reissig et al., *Caffeinated Energy Drinks - A Growing Problem*, 99 DRUG & ALCOHOL DEPENDENCE 1-3, 2 (2009).

167. Joseph G. Hoflander, *A Red Bull Instead of a Cigarette: Should the FDA Regulate Energy Drinks*, 45 VAL. U. L. REV. 689, 690 (2011).

168. *Overview of Food Ingredients, Additives, & Colors*, FED. DRUG ADMIN., <https://www.fda.gov/food/food-ingredients-packaging/overview-food-ingredients-additives-colors#how> [<https://perma.cc/NJD3-4CNE>] (last updated Feb. 6, 2018).

169. *Id.*

170. *FDA 101: Dietary Supplements*, FED. DRUG ADMIN., <https://www.fda.gov/consumers/consumer-updates/fda-101-dietary-supplements> [<https://perma.cc/H4DL-YBGR>] (last updated July 15, 2015).

171. *Is It Really ‘FDA Approved’?*, FED. DRUG ADMIN., <https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved> [<https://perma.cc/YB4P-BATR>] (last updated Jan. 17, 2017).

172. 21 U.S.C. § 321 (1938).

173. 21 U.S.C. § 321 (1938).

174. Rosenfeld et al., *supra* note 135.

175. *Background Information: Dietary Supplements*, NAT’L INST. HEALTH, <https://ods.od.nih.gov/factsheets/DietarySupplements-Consumer/> [<https://perma.cc/VT2B-B6MP>] (last updated Mar. 11, 2020).

literature.”¹⁷⁶ Therefore, there is a lack of urgency by the FDA in terms of oversight for dietary supplements. The FDA’s Center for Food Safety and Applied Nutrition (“CFSA”) is the primary vehicle for regulatory oversight.¹⁷⁷ The “FDA’s efforts to monitor the marketplace for potential ‘illegal’ products (products that may be unsafe or make false or misleading claims) include obtaining information from inspections of dietary supplement manufacturers and distributors, the Internet, consumer and trade complaints, occasional laboratory analyses of selected products, and adverse events[.]”¹⁷⁸ Simply put, the FDA may not attempt to enforce regulation of such products unless the agency becomes aware of potential danger through its own research or an issue becomes apparent via the news, et cetera.

V. PROPOSAL FOR FDCA AMENDMENT ENABLING REGULATION BY THE FDA

The categorization of highly caffeinated products as dietary supplements may be an impediment to securing a safer market for consumers that could ultimately diminish the levels and subsequent ramifications of chronic caffeine consumption. The FDA is not the only government organization responsible for the regulation of certain products, however, as the Drug Enforcement Administration (“DEA”) is given some authority to regulate certain substances in its own right. The DEA is given its regulatory deference codified in the Controlled Substances Act (“CSA”).¹⁷⁹ The CSA regulates certain drugs that are deemed to pose a risk of abuse and dependence.¹⁸⁰ “[T]he Act simultaneously aims to protect public health from the dangers of controlled substances while also ensuring access to controlled substances for legitimate purposes.”¹⁸¹ A primary function of the CSA regards the scheduling of controlled substances which are listed out across categories labeled as “schedules”.¹⁸² There are five schedules in total, each indicating the level of restriction on production, possession, and distribution as well as consequences for improper handling of a controlled substance.¹⁸³ Accordingly, Schedule I substances are controlled the most while Schedule V substances are minimally restricted.¹⁸⁴ There are numerous avenues available to schedule a substance under the CSA. The easiest option requires the action of Congress, which is not subject to procedural requirements of

176. *Id.*

177. *Questions and Answers of Dietary Supplements*, FED. DRUG ADMIN., <https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements> [<https://perma.cc/8FM8-A5JQ>] (last updated July 22, 2019).

178. *Id.*

179. 21 U.S.C. §§ (801-904) (1970).

180. *See Lampe, supra* note 130.

181. *Id.*

182. *Id.*

183. *Id.*

184. *Id.*

administrative scheduling.¹⁸⁵ Congress can pass legislation to place a substance under control, alter a substance's classification, or remove it from a schedule completely.¹⁸⁶ Administrative scheduling involves an intricate, complex process that includes input from other federal agencies as well as the public.¹⁸⁷ The DEA can schedule a substance on its own accord, upon request from Health and Human Services, or upon "the petition of any interested party[.]"¹⁸⁸ However, scheduling caffeine as a controlled substance would effectively diminish its ability for sale in the market and thus does not present as a suitable means for accomplishing the goal of expanding awareness of caffeine-related health risks. Recognizing the difficulties apparent with expanding regulation of highly caffeinated products via the CSA and its drug scheduling processes, a more reasonable avenue towards expanding consumer awareness surrounding would be to expand the FDA's regulatory authority over caffeinated products marketed as dietary supplements through amending the FDCA.¹⁸⁹

The regulatory framework for caffeinated products is complex. Given its worldwide popularity in addition to evidence of various short-term benefits from low to moderate caffeine consumption, it would be unreasonable to suggest regulating caffeine to a point where it is in complete control of the government or even strictly regulated by a federal agency. Caffeine is entirely too popular and widely accepted to be controlled in such a restrictive way. However, explicit health consequences due to chronic caffeine consumption warrant some sort of oversight. This Note argues that the best avenue for establishing the research-based narrative that caffeine could be a detriment to one's health when consumed mindlessly is for Congress to amend the FDCA to give the FDA control over the regulation of caffeinated dietary supplements, with the potential result being a greater awareness surrounding individual relationships with caffeine.

A shift in regulatory procedure that could create a safer market for consumers would be for the FDA to require companies selling caffeinated dietary supplements to gain their approval before putting their products on the market as opposed to the current regulatory requirements, which do not include formal FDA approval. This process would at least ensure that products meet the safety standards of the FDA for consumers and could potentially diminish consumption which could lead to major health consequences. Specifically, the FDA could follow a similar approach to dietary supplements that it takes in approving food additives. This process includes an initial step taken by companies to provide the FDA with relevant information that shows that additives are safe for consumption.¹⁹⁰ FDA experts subsequently review test results conducted by companies to confirm that additives are safe for their intended use.¹⁹¹ In the case

185. *Id.*

186. *Id.*

187. *Id.*

188. 21 U.S.C. § 811(a) (1970).

189. *See Lampe, supra note 130.*

190. FED. DRUG ADMIN., *supra note 136.*

191. *Id.*

of highly caffeinated dietary supplements, requiring companies to submit tests regarding the safety of substances used in combination with caffeine such as taurine would help mitigate the risk that consumers would be exposed to products that put them in harm's way.

Another significant avenue through which the FDA could regulate these products is through requiring discrete, educational labeling. Scientists have considered the health detriments associated with chronic caffeine consumption and furthermore have proposed a more functional labeling system which effectively communicates to the consumer just what exactly they are consuming.¹⁹² Dr. Naoshi Ogawa and Dr. Hirufumi Ueki, through their research on caffeine dependence and abuse, propose specific guidelines which they believe would broaden awareness surrounding not only the caffeine content of products but also the health consequences involved with chronic consumption.¹⁹³ These guidelines include clearly listing the full amount of caffeine in certain products, cautioning against consumption by infants, children, and adolescents, and stating that chronic caffeine consumption can lead to health risks.¹⁹⁴

Congress, through the Dietary Supplement Health and Education Act of 1994 ("DSHEA") delegated to the FDA the authority to require current good manufacturing practice requirements for dietary supplements.¹⁹⁵ Otherwise called GMP's, these manufacturing practice requirements establish minimum standards for manufacturing, packaging, and labeling to ensure the quality of products through the manufacturing process.¹⁹⁶ GMP's, labeling, and adverse event reporting processes for foods differ from processes required for dietary supplements.¹⁹⁷ For instance, manufacturers of energy drinks are generally free to market their products either as food or as a dietary supplement.¹⁹⁸ This sort of freedom highlights the concern that manufacturers are advertising their products as dietary supplements in order to bypass the regulatory processes required for products advertised as food under the FDCA.¹⁹⁹ The leeway afforded to manufacturers in this context may allow them to circumvent regulation, but this issue can be supplemented with additions to GMP labeling requirements geared towards effectively informing the consumer. Specifically, listing the full amount of caffeine in caffeinated dietary supplements, warning against consumption of caffeine by infants, children, and adolescents, and stating that consistent consumption for long periods of time can result in certain health risks addresses

192. Naoshi Ogawa & Hirofumi Ueki, *Clinical Importance of Caffeine Independence and Abuse*, 61 PSYCHIATRY & CLINICAL NEUROSCIENCES 263, 263 (2007).

193. *Id.*

194. *Id.*

195. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325.

196. *Regulation of Dietary Supplements*, CONGR. RSCH. SERV. 1, 5 <https://crsreports.congress.gov/product/pdf/R/R43062/6> [<https://perma.cc/L488-7KFV>] (last updated Dec. 16, 2014).

197. *Id.*

198. *Id.*

199. *Id.*

the issue of consumer ignorance surrounding the adverse health effects of chronic caffeine consumption.²⁰⁰

Educational labeling is a realistic option for two primary reasons. Firstly, discrete labeling with information regarding caffeine consumption does not prevent consumers from making their own decisions, rather this would serve a purely informative purpose in notifying consumers of potential risks involved with their consumption of certain products. This could be accomplished through explicitly listing the full amount of caffeine on caffeinated goods, cautioning against caffeine consumption by infants, children, and adolescents, and stating that chronic caffeine consumption can lead to health risks.²⁰¹ This would be comparable to labeling practices utilized for tobacco products, which warn against risks of certain types of cancer and other diseases.²⁰² The FDA promulgated rules in 2011 demanding stricter warning labels on smokeless tobacco products.²⁰³ Among these include the printing of statements like, “Warning: This product can cause gum disease and tooth loss”, among others.²⁰⁴ “These changes aim to increase awareness of the health risks associated with smokeless tobacco use and improve the public health.”²⁰⁵ The effectiveness of tobacco-product labels on rates of smoking is consistently debated, yet it is difficult to imagine them as obsolete.²⁰⁶ Despite this inquiry, the shift in public perception of smoking since the first half of the twentieth century is evident. Just between 2001 and 2011, Gallup polls indicate that thirty nine to fifty nine percent of polled Americans favored a smoking ban in public places in contrast to the 1980s, when smoking in these areas was commonplace.²⁰⁷ Regardless of skepticism concerning the effectiveness of educational labels, a complete lack of an approach should not be maintained while consumers may remain completely misinformed on the negative consequences of caffeine consumption.

Considering the health implications of long-term caffeine use alongside society's lack of awareness surrounding such concerns, a pertinent remedy to this issue would be for Congress to amend the FDCA. The FDCA should be amended in a way that enables the FDA to mandate that companies comply with specific procedures and requirements for caffeinated dietary supplements. Adding a subchapter to 21 U.S.C., Chapter 9 would be more fitting, especially given the

200. Ogawa & Ueki, *supra* note 189.

201. *Id.*

202. Hoflander, *supra* note 164.

203. Jason Bardi, *Cigarette Pack Health Warning Labels in US Lag Behind World*, U.C. S.F. (Nov. 16, 2012), <https://www.ucsf.edu/news/2012/11/104420/cigarette-pack-health-warning-labels-us-lag-behind-world> [<https://perma.cc/7ZLU-GBC2>].

204. *Family Smoking Prevention and Tobacco Control Act- An Overview*, FED. DRUG ADMIN., <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/family-smoking-prevention-and-tobacco-control-act-overview> [<https://perma.cc/XRS8-T3EQ>] (last updated June 3, 2020).

205. *Id.*

206. See Michael K. Cummings & Robert N. Proctor, *The Changing Public Image of Smoking in the United States: 1964-2014*, 23 *CANCER EPIDEMIOLOGICAL BIOMARKERS PREV.* 32, 3 (2014).

207. *Id.*

existence of a subchapter dedicated to regulating tobacco products. This subchapter should grant a higher level of deference to the FDA in its regulatory approach for caffeinated dietary supplements. Requiring that the FDA execute specific regulatory action may be too much to ask and would likely be dismissed by Congress. The alternative would be to simply bestow a general authority on the FDA to determine the required regulatory policies and practices for caffeinated dietary supplements. This approach is less overt and may be more appealing to members of Congress who would consider supporting such legislation. Otherwise, a bill outlining newfound, detailed regulatory practices for dietary supplements alone may never see the light of day. Below is a draft of a subchapter granting more deference to the FDA:

Subchapter XI: Caffeinated Dietary Supplements

§ 400: *FDA Regulatory Control of Caffeinated Dietary Supplements:* “Whereas a dietary supplement includes caffeine as an ingredient or additive, the FDA shall have the authority to determine the regulatory procedures of such supplements, including manufacturing, labeling, and testing requirements.”

Realistic predictions on the outcomes of new legislation are necessary in comparison to lofty, half-baked estimates. If a subchapter consistent with the draft above was implemented, the result would likely be a methodical shift in regulatory procedures for dietary supplements. Enabling the FDA to assert more control would likely result in various changes while concurrently forcing companies to comply with new policy standards. Not only would this be a long-winded process, but it would also cost resources to create a new standard for caffeinated dietary supplement regulation. Nonetheless, change has always been costly regardless of its scope. An upside to this approach is that caffeine in foods would still be considered GRAS for purposes of FDA regulation. An attempt to shift regulation for every single product containing caffeine, including food and dietary supplements, would be unwarranted. A tailored approach towards products that garner a higher risk of health implications, however, is reasonable and attainable. Adjustments must be made to adapt to an updated approach in terms of manufacturing, labeling, and safety testing requirements. If the goal of this new legislation is to create a safer market for consumers while aiming to expand awareness of their caffeine consumption habits, I postulate that these adjustments are a low price to pay in the long-term given that many may be completely unaware of the parameters of their caffeine usage.

VI. FDCA AMENDMENT PRACTICALITY CONSIDERATIONS

Realistically, Congress may not even consider such a proposal. However, given the health implications of long-term, unmitigated caffeine consumption outlined in this Note, it is clear that caffeine can play a significant role in the development of particular diseases like Alzheimer’s and dementia.²⁰⁸ The evidence of negative implications of unmonitored caffeine use is clear, yet there

208. Sabia et al., *supra* note 87.

is no dire situation at hand in which caffeine is a perpetrator of drastic health concerns large enough to spark national debate. Despite this, most individuals do not understand caffeine and its chemical properties, much less their actual relationship with the drug and how it might be negatively impacting their health and well-being given the significant role that caffeinated products play in people's lives. Caffeine consumption at high levels coupled with a lack of awareness surrounding other relevant circumstances relating to how caffeine works in the body can potentially turn into a health catastrophe if unmitigated for long periods of time.²⁰⁹ An amendment such as the one outlined above has the potential to create a more conscious consumer when it comes to patterns of caffeine ingestion.

Regulations regarding labels on caffeinated dietary supplements like energy drinks are pertinent because it would not restrict or prevent companies from selling their products. Companies would retain the same level of freedom in its ability to advertise and sell. The only difference would concern the information included on the labels. Allowing companies to retain such flexibility in a free-market economy is essential for a positive outcome in this endeavor. Otherwise, Congress would be reluctant to pass any such legislation as it could negatively impact businesses and accordingly their willingness to comply with statutory requirements. Practically, any sort of legislation that would handcuff businesses should be avoided as it may cause new problems relating to compliance with required regulatory procedures and policies. Instead, keeping in mind how essential large businesses are for the economy, it is important to keep business owners happy. An amendment to the FDCA enabling the FDA to regulate dietary supplements in this manner presents the best of both worlds for consumers and companies, allowing for expanded awareness surrounding chronic consumption of highly caffeinated products while concurrently maintaining economic flexibility for businesses. Overall, an amendment to the FDCA is the best approach because it refrains from placing too much pressure on Congress and businesses, provides the opportunity to expand consumer awareness on caffeine, and maintains a sense of accountability for manufacturers of caffeinated dietary supplements.

VII. CONCLUSION

Despite the pervasiveness and popularity caffeine has held across history and still today, research indicates a plethora of health issues that can arise if caffeine consumption, especially at high levels over long periods of time, goes unmonitored.²¹⁰ These health ramifications are exacerbated by busy schedules and various other stressful circumstances that can lead consumers into behavior patterns that are detrimental to their overall state of well-being.²¹¹

Acknowledgement of potential negative implications of caffeine consumption

209. See Meredith et al., *supra* note 1.

210. *Id.*

211. *Id.*

cannot be avoided forever. In consideration of this, a certain amount of feasible regulation is necessary if consumer safety is a goal for the United States. Amending the FDCA to allow the FDA to assert its control over the regulation of caffeinated dietary supplements can decrease the possibility for individual health catastrophes, keep companies who disregard the health of their customers in check, and ultimately broaden consumer awareness surrounding the relationship between human beings and their favorite stimulant, caffeine.