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I. Introduction

Energy drinks first rose to popularity in the 1980s after the creation of Red Bull. Red Bull energy drinks were the first of its kind, opening the door to a new consumer and regulatory landscape.[1] Since Red Bull first launched, multiple companies have released countless new energy drink products. Some energy drinks, like Red Bull, contain less than 100 mg of caffeine per 8 oz can.[2] However, other energy drinks contain much higher amounts of caffeine. A 12 oz can of Celsius contains 200 mg of caffeine, and up until recently, Celsius offered a product called Celsius Heat, a 12 oz can containing 300 mg of caffeine.[3] In addition to high caffeine amounts, energy drinks often contain herbal stimulant additives, vitamin and mineral mixtures, and sugar. There is very little information available on the long-term effects of these stimulant mixtures on the body.

Although many consumers purchase energy drinks because of their caffeine content, many are left in the dark when it comes to labeling transparency and are unaware of their true contents. Energy drinks are classified as dietary supplements, meaning they are not directly regulated by the FDA before hitting store shelves. Instead, energy drink labels follow the Dietary Supplement Health and Education Act (DSHEA) guidelines.[4] Under DSHEA, energy drinks face lax labeling regulations, which leaves consumers unaware of the dangers of high caffeine contents, stimulative

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[1] *See* Red Bull Company Profile, RED BULL, https://www.redbull.com/us-en/energydrink/company-profile [hereinafter Red Bull] (last visited Nov. 4, 2024).

[2] *See Red Bull Energy Drink Ingredients, Facts & Figures*, RED BULL, https://www.redbull.com/us-en/energydrink/red-bull-energy-drink-ingredients-list (last visited Nov. 4, 2024).

[3] *See Celsius Sparkling Cherry Cola Ingredients*, CELSIUS, https://www.celsius.com/products/celsius/sparkling-cherry-cola/ (last visited Nov. 4, 2024).

[4] *See* 21 C.F.R. § 101.93 (2024).

additives, proprietary blends, and excessive sugar. We will discuss the dangers of energy drinks, the current regulatory framework and the problems it causes, why these problems should be corrected, and potential policy changes to fix those problems.

II. ENERGY DRINKS: A NEW FRONTIER

A. The Rise in Popularity of Energy Drinks

Energy drinks are a relatively new product in the consumer landscape. Although stimulative beverages existed throughout the 20th century, Red Bull is credited with popularizing energy drinks, spurring an absolute explosion of consumption over the past forty years.[5] Now, dozens of options fill store aisles, the most popular being Red Bull, Celsius, Monster, and Rockstar, with more and more products being released each year. But what is an "energy drink"? The term "energy drink" is not defined by statute or regulation. The FDA understands "energy drinks" to mean a class of products in liquid form that typically contain caffeine, with or without other added ingredients. Some products of this type are marketed as beverages, which are regulated as conventional foods, but many are marketed as liquid dietary supplements.[6]

For most adults, 400 mg of caffeine per day is considered safe.[7] Most energy drinks contain 100 to 300 mg of caffeine per serving.[8] Conversely, a 12 oz can of Coca-Cola contains 34 mg of caffeine.[9] Despite having lower caffeine content, soda beverages are held to stricter regulatory standards than energy drinks. This is because soda is classified as a "beverage" under the FDA.[10] Most energy drinks are classified as dietary supplements because of their

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[5] Red Bull, *supra* note 1.

[6] *See* Letter from Jeanne Ireland, Assistant Comm'r for Legis. of the Food & Drug Admin., to Sen. Richard J. Durbin (Aug. 10, 2012) (on file with Author).

[7] *See Spilling the Beans: How Much Caffeine is Too Much?*, U.S. FOOD & DRUG ADMIN. (Sept. 7, 2023), https://www.fda.gov/consumers/consumer-updates/spilling-beans-how-much-caffeine-too-much.

[8] *See* Jamie Pronschinske, *The Buzz on Energy Drinks*, MAYO CLINIC HEALTH SYS. (Aug. 31, 2022), https://www.mayoclinichealthsystem.org/hometown-health/speaking-of-health/the-buzz-on-energy-drinks.

[9] *See* Caffeine Chart, CENTER FOR SCI. IN THE PUB. INT. (July 2023), https://www.cspinet.org/caffeine-chart.

[10] *Product Categories and Products*, FDA (Sept. 4, 2014), https://www.fda.gov/product-categories-and-products.

use of herbal additives, meaning they are not directly regulated by the FDA.[11]

Approximately 90% of Americans and 80% of the global population consumes caffeine every day, making it the most popular stimulant in the world.[12] In the United States, energy drinks are an increasingly popular way to get a daily caffeine fix, becoming the second most common dietary supplement used by young people.[13] Approximately 30% of young Americans consume energy drinks on a regular basis, with young men comprising the majority of such consumers.[14]

This number could continue to grow across all ages and genders due to the current marketing strategies used by the majority of energy drink producers. Most energy drinks have bright, colorful cans or bottles with eye-catching logos, drawing the attention of younger consumers. This is problematic for several reasons. Children and young adults typically do not have high tolerances for caffeine.[15] Because children and adolescents aren't typically as accustomed to caffeine, consuming energy drinks with high caffeine content could result in caffeine overconsumption.[16] Additionally, younger consumers tend to disregard what little information is provided on energy drink labels.[17] In one study, college students were largely unaware of the caffeine content in typical energy beverages.[18] Instead, they were often motivated by price rather than health information when purchasing their desired energy drink products.[19] Caffeine consumption is also linked to risky behavior in young adults.[20]

In one study, researchers found that among groups of children ranging from ten to fourteen years old, energy drinks were

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[11] *See* Chad J. Reissig et al., *Caffeinated Energy Drinks--A Growing Problem*, 99 DRUG & ALCOHOL DEPENDENCE 1, 2 (2009).
[12] *See* Cyril Willson, *The Clinical Toxicology of Caffeine: A Review and Case Study*, 5 TOXICOLOGY REPS'. 1140, 1140 (2018).
[13] *See* Ahmed A. Alsunni, *Energy Drink Consumption: Beneficial and Adverse Health Effects*, 9 INT'L J. HEALTH SCIS'. 468, 469 (2015).
[14] *See id.*
[15] *See Spilling the Beans*, *supra* note 7.
[16] *See id.*
[17] *See* Caitlin K. Kelly & J. Roxanne Prichard, *Demographics, Health, and Risk Behaviors of Young Adults Who Drink Energy Drinks and Coffee Beverages*, 6 J. CAFFEINE RSCH. 73, 79 (2016).
[18] *See id.*
[19] *Id.* at 79.
[20] *Id.* at 74.

consumed in a variety of public and private places.[21] Their consumption was generally linked to social activities, sports, and computer gaming.[22] The child participants demonstrated strong brand awareness that was linked to preferences to taste and perceived value for money.[23] Key factors included the low price of energy drinks, their widespread availability, and their gendered branding and marketing.[24] The outcome of this study demonstrates an urgent need for a more defined regulatory framework. Moreover, the problem seems to be getting worse. With influencers now dipping their toes into the energy drink market, such as YouTuber Logan Paul's PRIME energy drink,[25] children are becoming even more exposed to dangerously high levels of caffeine without knowing the true consequences, while parents are being left in the dark.

B. Energy Drinks & Health Risks

Children and young adults are not the only consumers that can be affected by overconsumption. Anyone can experience the negative side effects associated with excessive caffeine intake. Excessive caffeine intake can cause palpitations, tremors, agitation, and gastrointestinal issues.[26] In more extreme cases, caffeine overconsumption can cause serious cardiovascular, neurological, psychological, metabolic, renal events, and death.[27] For example, atrial fibrillation and myocardial infarction has been reported after high energy drink ingestion in otherwise healthy teenage boys.[28] Energy drinks may also contribute to ischemic stroke and lead to seizures.[29] Studies also suggest that energy drinks can contribute to obesity and Type 2 diabetes.[30]

Caffeine sources in energy drinks are commonly derived from guarana, green tea extract, yerba mate, or are synthetically

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[21] Shelina Visram et al., *Children and Young People's Perception of Energy Drinks: A Qualitative Study*, 12 PLOS ONE e0188668, at 1 (2017).
[22] *Id*.
[23] *Id*.
[24] *Id*.
[25] Drink Prime, https://drinkprime.com/collections/energy (last visited Nov. 9, 2024).
[26] Sara M. Seifert et al., *Health Effects of Energy Drinks on Children, Adolescents and Young Adults*, OFFICIAL J. OF THE AMERICAN ACAD. OF PEDIATRICS 511, 518 (2011).
[27] *See id.* at 517.
[28] *See* Alsunni, *supra* note 13, at 469.
[29] *See* Seifert et al., *supra* note 26 at 519.
[30] *Id*.

derived, all of which may yield variations in how they are metabolized within the body.[31] However, it is unlikely that caffeine content alone is solely responsible for the potential for adverse events or safety concerns.[32] In addition to caffeine, a majority of energy drinks also contain B-vitamins, sugar, taurine, ginseng, tyrosine, L-carnitine, and electrolytes.[33] The mixed ingredient combination of vitamins, various herbal extracts, and amino acids—collectively or in combination with caffeine—may be a major contributor to adverse effects associated with energy drink consumption.[34] There is minimal research regarding the long-term effects of high amounts of caffeine interacting with herbal stimulants.[35]

III. FDA REGULATION OF ENERGY DRINKS

A. The Birth of DSHEA

In 1994, Congress enacted the Dietary Supplement Health and Education Act (DSHEA).[36] At the time of DSHEA's enactment, improving the health status of United States citizens ranked at the top of the Federal government's national priorities, and the use dietary supplements grew in popularity.[37] The benefits of dietary supplements to health promotion and disease prevention were documented increasingly in scientific studies.[38] In addition to the growing interest in public health, Congress believed that consumers should be empowered to make choices about their health, and that dietary supplements were a major part of that decision-making process.[39]

With this background in mind, DSHEA had two primary goals: "to ensure the continued consumer access to a wide variety of dietary supplements and to provide consumers with more information about the intended use of dietary supplements."[40]

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[31] *See* Andrew R. Jagim et al., *Prevalence and Amounts of Common Ingredients Found in Energy Drinks and Shots*, 14 NUTRIENTS Jan. 13, 2022, at 8.
[32] *See id*. at 7.
[33] *See id*. at 2.
[34] *See id*.
[35] *See id*.
[36] *See* 21 U.S.C. §321.
[37] *See* Annette Dickinson, *History and Overview of DSHEA*, 82 FITOTERAPIA 5 (2011); *see also* Jessie L. Bekker et al., *Re-Regulating Dietary Supplements*, 19 J. FOOD L. & POL'Y 1, 5 (2023).
[38] *See id.*
[39] *Id.*
[40] *Id*.

DSHEA defined the term dietary supplement to mean "a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary supplements: a vitamin, mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the aforementioned ingredients."[41]

Before DSHEA and its definition of dietary supplements, there was the 1958 Food Additives Amendment[42] to the Food, Drugs, and Cosmetics Act.[43] In this amendment, Congress aimed to protect consumer health by requiring food additive manufacturers to conduct pre-tests of any potentially unsafe substances that were to be added to food and to advance food technology by permitting food additive use at safe levels.[44] This amendment reclassified several added ingredients, including caffeine and other common supplement ingredients, as food additives.[45] "Food additive" is defined by statute 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."[46] Companies are required to list these ingredients on product labels. The FDA does not require testing or pre-market approval for foods that do not qualify as food additives; there is a presumption of safety unless the government proves otherwise.[47] On the other hand, foods that qualify as food additives require FDA approval before entering the market.[48] This method of classification caused conflict between the FDA and manufacturers until Congress passed DSHEA.

Before the enactment of DSHEA, the FDA frequently contested products with dietary supplement ingredients, deeming them adulterated due to the inclusion of ingredients not authorized

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[41] Janet Rehnquist, OFFICE OF INSPECTOR GEN., DEP'T. OF HEALTH & HUMAN SERVS., OEI-01-01-00120, DIETARY SUPPLEMENT LABELS: KEY ELEMENTS, https://oig.hhs.gov/oei/reports/oei-01-01-00120.pdf. (2003).
[42] *See* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified throughout 21 U.S.C. §§ 301-399f (2012)).
[43] *See* 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)). .
[44] H.R. REP. NO. 85-2284, at 1 (1958).
[45] S. REP. NO. 103-410, at 21 (1994).
[46] 21 U.S.C. § 321 (2022).
[47] S. REP., *supra* note 45, at 22.
[48] Joyce A. Generali, *Energy Drinks: Food, Dietary Supplement, or Drug?*, 48 HOSPITAL PHARMACY 5, 5 (2013).

under food additive regulations.[49]The FDA interpreted the food additive provision expansively, indicating that incorporating any food ingredient into another ingredient would subject the product to more stringent regulatory standards for food additives.[50] Many considered the FDA's interpretation of "food additives" to be too broad, leading to the creation of DSHEA.[51]

B. DSHEA & Energy Drink Labels: A Dangerous Lack of Transparency

As a result of Congress' attempt to reduce FDA overreach, DSHEA contains vague requirements for dietary supplement labels. Under DSHEA, labels must contain

> "(1) a statement of identity; (2) net quantity of contents (e.g., 60 capsules); (3) nutrition information; (4) net weight of proprietary blend (if it contains a proprietary blend) and a list of ingredients in the blend; (5) the part of the plant used, if an herb or botanical; (6) the name and place of business of the manufacturer, packer, or distributor; (7) a complete list of ingredients by their common or usual names; (8) safety information that is considered "material" to the consequences that may result from the use of the supplement; and (9) a disclaimer that "this statement has not been evaluated by the FDA ..."[52]

At first glance, these labeling requirements may seem like a valid effort to keep consumers informed. However, DSHEA does not require energy drink labels to contain specific amounts of *each* ingredient, just the net quantity.[53] For example, if added caffeine is an ingredient comprising part of a proprietary blend, then the label must indicate only the total amount of the entire blend.[54] Thus, proprietary blends can have many different ingredients of undisclosed amounts, resulting in wide possibilities of the true

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[49] Trenton David, *Return to Regulation: FDA, Energy Drinks, and Our Youth*, 53 HOUS. L. REV. 1401, 1421 (2016).
[50] *Id.*; *see also* United States v. An Article of Food, 678 F.2d 735, 738-39 (7th Cir. 1982).
[51] David, *supra* note 49, at 1421.
[52] Rehnquist, *supra* note 41, at 4; *see also* 21 U.S.C. §101.36.
[53] *Id*.
[54] *Id*.

number of stimulants within them.[55] Further, there is no definition on what "material" means in a safety context.[56] This is concerning because energy drinks can contain dozens of ingredients, all of which can interact with one another. From a consumer standpoint, there is no way to tell how much of each ingredient you are consuming.

Transparent labels are crucial to keeping consumers safe. Labels can play a role in helping consumers to select an appropriate supplement, or in this case, energy drink, by providing information about the purposes of the supplement, the conditions for which the supplement should be taken, and the contents and manufacture of the supplement. When consumers are unknowingly looking at vague or incomplete labels, it negatively affects their ability to choose a product that best fits their needs, which directly conflicts with DSHEA's stated purpose.[57]

C. Insufficient Solutions: The FDA & the Post-Market Failure

One of the major changes under DSHEA was the exclusion of dietary supplement ingredients from the food additive category and its pre-market approval requirement.[58] As a result, the FDA does not require dietary supplement manufacturers to establish a product's safety before entering the market.[59] The FDA can only intervene after the product is sold to the public, creating a post-market review system.[60]

Manufacturers are responsible for making sure a product is safe before it hits the market. In order to alert the FDA of potentially unsafe products entering the market, DSHEA includes a notification requirement for "new dietary ingredients."[61] "The market entry date for the ingredient determines the burden the

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[55] *Id*.
[56] *Id*.
[57] 21 U.S.C. §321.
[58] *See* Anthony L. Young & I. Scott Bass, *The Dietary Supplement Health and Education Act of 1994*, 50 FOOD & DRUG L.J. 285, 286-290. (1995).
[59] *See Questions and Answers on Dietary Supplements*, U.S. FOOD & DRUG ADMINISTRATION (2024), https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements.
[60] *See* Rachel Harrison, *How a Legal Loophole Allows Unsafe Ingredients in U.S. Foods*, NYU (Aug. 8, 2024), https://www.nyu.edu/about/news-publications/news/2024/august/legal-loophole-unsafe-ingredients.html.
[61] 21 U.S.C. § 350b.

manufacturer must satisfy."[62] If the ingredient was marketed in the United States before October 15, 1994, the manufacturer is not required to notify the FDA of its use, because it has been classified as an "old ingredient."[63] This framework creates an issue that is unique to energy drinks: because energy drinks often contain a mixture of these "old ingredients," their manufacturers are technically not required to report them to the FDA.[64]

However, mixing these "old ingredients" is a relatively new practice, and there is very little research on how these ingredients interact with each other, much less their long term effects on the body.[65] Even if a manufacturer did include "new" ingredients in their products or considered the blends of "old" ingredients as "new" and notified the FDA, it would not make much of a difference in safety efforts because manufacturers are not required to prove that a product is safe or effective.[66] Additionally, there is no list of what is considered to be an "old ingredient," so manufacturers face blurred lines when determining what is "new" and what's not.[67]

If an unsafe product does make its way into the market, the FDA has the burden of proof to show that a supplement presents a significant or unreasonable risk of illness or injury if taken as instructed on the label or is otherwise adulterated.[68] The FDA also has the burden of proof to show that label information is misleading or untrue.[69] To establish proof, the FDA conducts field exams, tests supplement ingredients, and reviews label claims.[70] This is a good effort in theory, but the review process is tedious. Additionally, the FDA typically conducts these post-market reviews only if there have been adverse events, meaning that if a product is under FDA review, somebody has already fallen ill or died from consuming the product.

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[62] David, *supra* note 49.
[63] *See Dietary Supplement Health & Education Act (DSHEA)*, COUNCIL FOR RESPONSIBLE NUTRITION, https://www.crnusa.org/regulation-legislation/fda-ftc-regulations/dietary-supplement-health-education-act-dshea (last visited Oct. 30, 2024).
[64] *See id.*
[65] *See* 21 U.S.C. § 350b; *see also* Jagim et al., *supra* note 31.
[66] *See id.*
[67] *See Backgrounder: FDA Draft Guidance on New Dietary Ingredients for the Dietary Supplement Industry*, COUNCIL FOR RESPONSIBLE NUTRITION, https://www.crnusa.org/resources/backgrounder-fda-draft-guidance-new-dietary-ingredients-dietary-supplement-industry (last visited Oct. 30, 2024).
[68] *See id*.
[69] *See id.*
[70] 21 U.S.C. §321.

IV. POTENTIAL SOLUTIONS

A. Required Labeling of Stimulants

DSHEA's labeling requirements are extremely vague in comparison to the labeling requirements in other similar industries. One potential solution to this problem is to model energy drink labels after over-the-counter (OTC) stimulant drug labels. OTC drug stimulants have considerably stricter requirements for their labels than energy drinks do. OTC drug stimulants have several requirements, such as a statement of identity, which encompasses not only the name of the product, but identifies the product as an "alertness aid" or a "stimulant."[71] OTC stimulant drugs must also have an "indications" heading.[72] Under this heading, the product must state, "Helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness. Other truthful and non-misleading statements, describing only the indications for use that have been established and listed… may also be used."[73] There must also be a "warnings" heading.[74] The warnings must include information regarding the caffeine dosage of the product, specifically, "[t]he recommended dose of this product contains as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat."[75] The warnings must also include that the product is recommended for occasional use only, is not recommended for children under 12 years of age, and directions for consumption.[76] The recommended dosage for these drugs is "100 to 200 mg, not to be taken more often than every three to four hours."[77] In contrast, it is not unusual for energy drinks to contain more than 200 mg of caffeine, yet they do not have any of the same required safety information on their labels as OTC stimulants. If energy drink labels were modeled after OTC stimulant labels, consumers would have more information to make informed decisions about the energy drink ingredients and supplements they consume.

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[71] 21 U.S.C. §340.50(a).
[72] 21 U.S.C § 340.50(b).
[73] *Id*.
[74] 21 U.S.C § 340.50(b).
[75] *Id*.
[76] *Id*.
[77] 21 U.S.C. §340.50(d).

Another potential solution is to model our framework after other countries. The European Union mandates that energy drinks have a "high caffeine content" label.[78] Health risks associated with energy drink consumption have caused countries such as Denmark, France, Uruguay, Iceland, Norway, and Turkey to ban high caffeine and taurine drinks altogether.[79] Given the popularity of energy drinks and other caffeinated beverages in the United States, it is unlikely that they will be banned. Because of this, it is helpful to look to countries like Canada that have limits on what can be added to energy drinks. In 2011, Health Canada (the Canadian equivalent of the FDA) declared its intent to transition caffeinated energy drinks from the natural health products regulatory framework to the food regulatory framework.[80] This transition was completed in 2012. Following the transition, Health Canada set 180 mg as the maximum amount of caffeine for a single-serving container energy drink.[81]

In addition, Health Canada set specific labeling requirements for energy drinks. Health Canada banned energy drink labels from making claims that they be used for hydration or for electrolyte replacement before, during, or after physical activity; they could not contain the words "juice," "puree" or "pulp" on the label other than as required in the list of ingredients; and manufacturers were completely barred from marketing energy drinks to children.[82]

The labels are required to contain (1) a declaration of the total caffeine content from all sources; (2) a nutrition facts panel showing details on the amount of calories and other nutrients in the product; (3) a declaration that energy drinks are not recommended for children, pregnant or breastfeeding women, or people who are sensitive to caffeine, and that energy drinks should not be mixed with alcohol; (4) a "high caffeine content" statement; (5) a "maximum number of [container(s)/servings] per day" usage

[78] Reissig et al., *supra* note 11.
[79] Kelly & Prichard, *supra* note 17.
[80] Health Canada, *Category Specific Guidance for Temporary Marketing Authorization – Caffeinated Energy Drinks* (Dec. 2013), https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/category-specific-guidance-temporary-marketing-authorization-caffeinated-energy-drinks.html#s3.1.2.
[81] *See id*.
[82] *Id*.

statement; and (6) any applicable allergen labeling.[83] Health Canada also set daily maximum levels for vitamin and nutrient additives in energy drinks.[84]

Meanwhile, in the United States, consumers can purchase Juiced Monster Mango Loco Energy Juice, an energy drink packed in an eye-catching teal and yellow can with sugar skulls, containing mango juice, 55 grams of sugar, herbal stimulative supplements that have a vague indication of daily value but no exact amount, and 150 mg of caffeine from unspecified sources. Modeling our energy drink labeling requirements after Health Canada's framework would help keep consumers informed and help prevent caffeine overconsumption, particularly in children and young adults who have lower tolerances for caffeine.

B. Comparing Caffeine & Tobacco

In 1930, Lucky Strike Cigarettes published an ad claiming, "20,679 Physicians say 'LUCKIES' are less irritating" to the throat.[85] By the late 1950s, around half of the population of industrialized nations smoked.[86] By the 1990s, it was evident that smoking cigarettes causes lung cancer and other serious health problems. In 2001, Canada became the first country to put graphic photos and warnings on cigarette packages.[87] By 2005, less than a quarter of the U.S. population smoked cigarettes. In 2020, the Centers for Disease Control and Prevention (CDC) reported that more than 480,000 deaths annually in the U.S. are caused by smoking cigarettes and secondhand smoke.[88] Also in 2020, the

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[83] Canadian Beverage Ass'n, *Energy Drinks in Canada: Know the Facts*, https://www.canadianbeverage.ca/wp-content/uploads/2014/01/Energy-Drink-Brochure-Layout-English-layout-Sept-23-to-print.pdf (last visited Nov. 11, 2024).
[84] Health Canada, *supra* note 81.
[85] Becky Little, *When Cigarette Companies Used Doctors to Push Smoking*, HISTORY (Mar. 28, 2023), https://www.history.com/news/cigarette-ads-doctors-smoking-endorsement.
[86] *See* Jason Rodriguez, *When Smoking Was Cool, Cheap, Legal, and Socially Acceptable*, THE GUARDIAN (Mar. 31, 2009), https://www.theguardian.com/lifeandstyle/2009/apr/01/tobacco-industry-marketing.
[87] *See* Heikki Hiilamo et. al., *The Evolution of Health Warning Labels on Cigarette Packs: The Role of Precedents, and Tobacco Industry Strategies to Block Diffusion*, 23 TOBACCO CONTROL e2 (2014).
[88] Centers for Disease Control & Prevention, *Tobacco-Related Mortality*, CTR. DISEASE CONTROL, https://archive.cdc.gov/#/details?url=https://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/index.htm (last visited Nov. 7, 2024).

FDA finalized the "Required Warnings for Cigarette Packages and Advertisements" rule, establishing eleven new cigarette health warning statements accompanied by color graphics depicting the negative health consequences of smoking cigarettes.[89]

The new warnings include statements like "tobacco smoke can harm your children" and "smoking reduces blood flow to the limbs, which can require amputation," among other facts about the fatal diseases that cigarettes cause.[90] The warning must comprise at least the top 50 percent of the front and rear panels of the cigarette package.[91] All eleven required warnings for packages must be randomly displayed over each 12-month period, in as equal a number of times as is possible on each brand of the product and must be randomly distributed in all areas of the United States in which the product is marketed, in accordance with an FDA-approved cigarette plan.[92] Finally, the required warnings must be indelibly printed on or permanently affixed to the cigarette package.[93]

Less than 100 years ago, cigarette companies were distributing advertisements touting physician support of their product. Today, federal law requires the same cigarette companies to place labels on their products warning consumers of fatal disease. Millions of people had to die to get these labels on cigarette packages.

We do not know the long-term health effects of proprietary blends and alternative caffeine sources in energy drinks. Although excessive consumption of energy drinks is less likely to lead to fatal diseases such as the ones caused by cigarettes, overconsumption of caffeine has already been proven to be deadly. We do not know what the long-term neurological, cardiovascular, endocrine, or

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[89] *See* Food and Drug Administration, *Cigarette Labeling and Health Warning Requirements*, FOOD AND DRUG ADMIN. (Aug. 25, 2021), https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-labeling-and-health-warning-requirements; In 2022, a U.S. District Court in Texas issued an order in the case of *R.J. Reynolds Tobacco Co. et al. v. United States Food and Drug Administration et al.*, vacating the "Required Warnings for Cigarette Packages and Advertisements" rule. However, this does not mean that cigarette packages must do away with warning labels - it applies to the photos that the FDA required under that new rule. The enactment of the new rule was postponed until Nov. 6, 2023.
[90] *Id*.
[91] *Id*.
[92] *Id*.
[93] *Id*.

metabolic effects will be. In circumstances such as these, it's better to be safe than sorry.

Energy drink labels should discourage caffeine and herbal stimulant overconsumption. They should also describe the dangers and negative health effects that can result from consuming the product. Finally, they should state that energy drinks are unsuitable for children, adolescents, and those with pre-existing health conditions that may be negatively affected by caffeine and other additives. It took the FDA and legislators far too long to regulate cigarette labels. We can still avoid a similar fate with energy drink labels. If the United States can follow Canada's lead with a stricter regulatory framework for cigarette packaging warnings, we should be able to do the same for energy drink labels.

C. Reforming the Post-Market Framework

The post-market review system is ineffective for energy drinks. It primarily relies on the manufacturers themselves reporting serious adverse events to the FDA. 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; in-patient 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.[94] The FDA does not require "non-serious" events to be reported, but does require reports to be kept for six years.[95]

The problems with this framework are two-fold. First, it only requires that "serious" adverse events are reported to the FDA. This excludes countless data points that could help determine whether a product is effective or not, let alone the potential dangers it could hold. Second, responsibility for reporting falls onto the manufacturer, yet it is in the best interests of the company to not willingly report every serious adverse event that occurs—can consumers trust multi-million-dollar corporations to do the right thing? One recent study found that the FDA receives information regarding "less than one percent of all of the adverse events associated with dietary supplements."[96] The study determined that

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[94] 21 U.S.C. § 379aa-1(a)(2).

[95] 21 U.S.C. §379aa(e)(1).

[96] Office of Inspector Gen., Dep't of Health & Human Servs., *Adverse Event Reporting For Dietary Supplements: An Inadequate Safety Valve*, (2001), http://oig.hhs.gov/oei/reports/oei-01-00-00180.pdf.

the current reporting system is "inherently limited," and "cannot serve as an adequate safety valve until other measures are taken that will allow the FDA" to discover public health concerns.[97]

The primary solution should not be a post-market review system that relies self-policing by the manufacturers of the products that cause serious adverse events. The current framework needs a complete and total overhaul. Instead of manufacturers initially placing products on the market without outside review, the FDA should examine the safety of the product and its ingredients before it reaches consumers. This could be done by doing away with the "old ingredient" versus "new ingredient" framework. If the FDA reviewed *all* ingredients before market release, despite their so-called "newness," instances of serious adverse events could decline, which may reduce the need for a robust post-market review system to begin with.

Although the current post-market review system is largely ineffective, it is still needed in some capacity. The FDA should continue to be made aware of post-market adverse events even if there was pre-market review. In addition to the above suggestions, manufacturers should not be solely responsible for reporting serious adverse events. A simpler solution may be to let the responsibility fall on distributors and consumers; they have more of an incentive to report serious adverse events because they are the ones who are directly affected by them. A more complex solution would be to create a review system within the FDA that acts as a sort of audit. Although this would require additional funding and resources, the FDA could randomly review energy drink manufacturers, test their products and ingredients, study any reports of adverse events the company may have, and conduct consumer interviews. The randomization of in-depth reviews could encourage safety compliance in manufacturers and compel greater transparency.

D. Other Considerations

Senators Edward Markey (D-MA), Richard Durbin (D-IL), and Richard Blumenthal (D-CT) released a report in 2015 that examined the dangers of energy drinks and offered solutions to improve safety. The solutions included

> "(1) all energy drink manufacturers should cease marketing of energy drink products to children

[97] *Id.*

> and teens under the age of 18 and sales of these products in K-12 school settings…; (2) the FDA should develop and release suggestions for daily caffeine consumption limits for children and adolescents, as well as rules requiring the labeling of caffeine content for all products with added caffeine; (3) the FDA should immediately develop and release guidance to industry on the voluntary reporting of adverse events associated with energy drinks and all energy drink companies should commit to providing this information to the FDA; (4) the FDA should define what constitutes an energy drink, a sports drink, or other 'functional' beverages; (5) all energy drink manufacturers should cease marketing caffeinated energy drinks as intended to be consumed for hydration or re-hydration following rigorous physical activity…; and (6) federal agencies should look to include restrictions in school-based programs for the sale of energy drinks."[98]

The Senators' attempt to form a coalition of energy drink manufacturers is similar to the Canadian Beverage Association (CBA).[99] The CBA represents Canadian non-alcoholic beverage companies and was created for the industry to take a leadership role in matters concerning the health and well-being of Canadians.[100] The CBA and its members work to encourage companies who produce energy drinks to follow the necessary health regulations and Canada's Energy Drinks Marketing Code.[101] CBA members commit to self-implemented marketing and labeling restrictions that were created with consumer protection in mind.[102]

The Senators' suggested solutions, despite being sent to various energy drink manufacturers, were never implemented or agreed upon. Adopting these solutions would create a framework that is similar to Canada's, and would hopefully reduce caffeine

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[98] S.REP., BUZZKILL: A SURVEY OF POPULAR ENERGY DRINKS FINDS THE MAJORITY OF THE MARKET UNWILLING TO MAKE COMMITMENTS TO PROTECT ADOLESCENTS (2015).
[99] Canadian Beverage Ass'n, *Energy Drinks Marketing* Code, (Mar. 2012), https://www.canadianbeverage.ca/wp-content/uploads/2016/01/CBA-Energy-drinks-Code-FINAL-English.pdf.
[100] *See id*.
[101] *See id*.
[102] *See id*.

overconsumption, increase consumer awareness, and protect American citizens' health.

E. The Ultimate Solution

The best solution to the United States' regulatory problem with energy drink labels is a mixture of all of the above suggestions. Modeling energy drink labels after OTC stimulant labels would result in a similar framework to that of Canada. It would require specific warnings on the label regarding who can safely consume the product, how much caffeine it contains, and the appropriate dosage. The United States should also require specific amounts of all ingredients to be listed and implement a maximum amount of caffeine per energy drink like Canada. The transparency of ingredients and a maximum caffeine amount paired with clear warning labels could help significantly decrease caffeine overconsumption and its associated negative health consequences. Further, a quasi-coalition of energy drink manufacturers that pledge to follow health regulations and guidelines could aid in achieving a stricter framework that would provide more transparent labels. Adopting a framework similar to Canada's is actually quite realistic—the United States already did so by requiring graphic photos on cigarette warning labels, a regulation that Canada implemented over twenty years ago.

Additionally, the post-market review system should be replaced with a pre-market approval system. All ingredients should be reviewed regardless of whether they are "new" or "old." Large manufacturers should not carry the burden of reporting adverse events to the FDA because they cannot be trusted to do so consistently or accurately. Instead, distributors and consumers should be able to make reports of adverse events of any kind, not just serious ones. To help foster an increased sense of responsibility, the FDA should adopt an audit system that randomly reviews adverse event reports, production and packaging, and specific ingredients within the manufacturing process.

Finally, Congress should grant the FDA the authority to regulate the marketing and sale of energy drinks in schools and other areas that are highly populated by children. There should also be regulations barring manufacturers from packaging energy drinks in bright, colorful containers that are appealing to children and young people.

V. CONCLUSION

Americans will never give up caffeine, that is for certain. Caffeine consumption is deeply intertwined with our economy, our culture, and our lives; but there are limits. Both Congress and the FDA need to take the initiative to regulate what has essentially become a runaway train. Energy drinks, high caffeine contents, and the vague mixtures of exotic additives are a new frontier that cannot go unaddressed. People have died because of the lack of regulations, with more likely to follow.

Labeling energy drinks appropriately can save lives, improving the health of consumers across the country while protecting children from ingesting dangerous ingredients that are harmful to both their short-term and long-term health. Other countries have adopted regulations protecting their citizens, so there is no excuse for the United States not to take similar actions. If consumers become aware of the hidden dangers of energy drinks and overconsumption of caffeine, we can push Congress and the FDA to implement a stronger regulatory regime.