You Are What You Drink—a Rockst*r or a Monster?: An Enviga-rating Regulatory Question

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This paper briefly examines the regulation of caffeine in energy drinks. The FDA does not have specific regulations pertaining to the use of caffeine in energy drinks. Caffeine is generally safe, but may pose dangerous health risks to children, pregnant women, and people with caffeine sensitivities. I suggest that the Food and Drug Administration require energy drink companies to list the amount of caffeine on the product labels of energy drinks to facilitate informed product comparison.
INTRODUCTION

To caffeinate or to hibernate? The impending doom of “crunch time” before finals forces this choice on many law students. The fear of another dreadful “case of the Mondays” drops this loaded decision on many nine-to-fivers. The draining hours of strength and endurance training thrusts this dilemma on many a teenage and adult athletes. Often, when my eyes want most to close and my body wants most to repose, I ignore them in favor of a sleep-defeating cup of coffee. When I develop a resistance to coffee, I turn to a Rockstar or a Monster energy drink; I choose an energy drink so that I may feel more like a rockstar. But, what if I unknowingly choose poorly, making myself feel more like a monster? I have felt like both a rockstar and a monster after consuming energy drinks. For a while, my energy drink of choice was Enviga. It tasted great and drinking only one can made me feel sufficiently energized. Shortly after I fell in love with Enviga, I stopped finding it in the school cafeteria and in my local grocery store. During a recent “crunch time,” I desperately needed caffeine to stay awake another twenty-four hours. I couldn’t rely on Enviga, so I turned to Monster. I drank one can, but did not feel as alert as I felt after drinking one can of Enviga, so I drank a Rockstar. Hours later, feeling like I had to push sleep off longer than I originally thought, I drank some coffee, followed by a 5-hour energy shot and some more coffee. By the end of my energy drink marathon, I was afraid to go to sleep; something was not right. I had overdosed on caffeine; or had I? The truth is I had no way of knowing because I did not know how much caffeine was in each of the energy drinks I had consumed.

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1 OFFICE SPACE (Twentieth Century Fox Film Corporation 1999).
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We are living in an energy crisis. People want endless energy, but not at the expense of feeling like a monster. In order for people to make informed choices about the type and amount of energy drinks they consume, they need to know how much caffeine is in the products they are comparing. This paper examines the regulation of energy drinks, and recommends that the Food and Drug Administration (FDA) require listing caffeine amounts and health warnings on energy drink labels to better inform the consumer and to prevent a loss of energy from becoming a loss of health.

THE ENERGY DRINK MARKET

Energy drinks have been on the market for at least forty years.² There are thousands of energy drinks on the market. The U.S. market for energy drinks in 2006 was approximately $5.4 billion,³ and sales are expected to reach over $9 billion by 2011.⁴ Red Bull alone sold 3.5 billion cans in 2007.⁵ In fact, annual per capita consumption of energy drinks in North America was

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about 5 liters in 2008, up from 0.5 liter in 2005. The global presence of energy drinks and the variety of energy drinks produced likely contributes to the growth in the energy drink market. Rockstar has about 13 different products and is available in: the United States, Canada, Australia, New Zealand, Japan, Germany, Switzerland, Finland, Spain, The Netherlands, and throughout the United Kingdom.

WHO’S IN CHARGE?

Neither the FDA nor the United States Department of Agriculture (USDA) recognizes the term “energy drink.” Companies in the beverage industry created the term, which “refers to beverages that contain caffeine in combination with other ingredients such as taurine, guarana, and B vitamins, and that claims to provide its consumers with extra energy.” In 1959, the FDA designated caffeine as “generally recognized as safe” (GRAS), but only in soft-drinks up to 200

10 Id.
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parts per million.\textsuperscript{11} “Caffeine. (a) Product. Caffeine. (b) Tolerance. 0.02 percent. (c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used in cola-type beverages in accordance with good manufacturing practice.”\textsuperscript{12} The FDA once considered removing caffeine’s GRAS status.\textsuperscript{13} The Select Committee on GRAS Substances Review reviewed caffeine’s GRAS status in the 1970s. The review was concerned with “caffeine as commercially added to food commodities[, of which] [c]ola beverages comprise the largest and only significant source of caffeine….\textsuperscript{14} The date of the review is 1978 (but updated in 1996), years before products like Monster and Rockstar came on the market. The report concludes:

A. While no evidence in the available information on caffeine demonstrates [sic] a hazard to the public when it is used in cola type beverages at levels that are now current and in the manner now practiced, uncertainties exist requiring that additional studies be conducted. B. It is inappropriate to include caffeine among the substances generally recognized as safe (GRAS).\textsuperscript{15}


\textsuperscript{12} 21 C.F.R. § 182.1180 (2010).


\textsuperscript{15} \textit{Id.}
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The proposal to revoke caffeine’s GRAS status was eventually dropped when a district court dismissed a consumer group’s suit to ban caffeine immediately.\(^\text{16}\)

Currently, the FDA does not regulate the caffeine content in energy drinks.\(^\text{17}\) The amount of caffeine a food product contains is not required on a food label, because caffeine is not a nutrient. It must be listed on the label as an ingredient if it is added to a food, but not the actual amount added.\(^\text{18}\) The FDA does, however, regulate “over-the-counter stimulants in which caffeine is the active ingredient.”\(^\text{19}\) These products are regulated as drugs,\(^\text{20}\) unlike food products.\(^\text{21}\) When caffeine is added to soft drinks, the FDA “does not regulate the product as a drug even if the manufacturer promotes the food’s high level of caffeine and its ‘energizing’ qualities.”\(^\text{22}\)

\(^{16}\) See Hutt et al., supra note 11, at 417, 420 (citing Federation of Homemakers, Inc. v. Harris, Food Drug Cosm. L. Rep. (CCH) ¶38,100 (D.D.C. 1981)).


\(^{18}\) FDA, Why Isn’t the Amount of Caffeine a Product Contains Required on a Food Label?, http://www.fda.gov/AboutFDA/Basics/ucm194317.htm (last visited Apr. 4, 2010).

\(^{19}\) Hutt et al., supra note 11, at 34.

\(^{20}\) 21 U.S.C. § 321(g)(1) (2010) (“The term ‘drug’ means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, … is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.”).

\(^{21}\) 21 U.S.C. § 321(f) (2010) (“The term ‘food’ means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.”).

\(^{22}\) Hutt et al., supra note 11, at 34 (“Apparently, in FDA’s view, such products fall within the food exception to the structure/function drug definition in section 201(g)(1)(C).”)}
The FDA also regulates dietary supplements. Energy drinks and energy shots, like 5-hour energy, are regulated by the FDA as dietary supplements and must comply with the Dietary Supplement Health and Education Act of 1994 (DSHEA). DSHEA defines both "dietary ingredient" and "new dietary ingredient" as components of dietary supplements. FDA regulations require that certain information appear on dietary supplement labels. Information that must be on a dietary supplement label includes: a descriptive name of the product stating that it is a "supplement"; the name and place of business of the manufacturer, packer, or

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23 21 U.S.C. § 321(ff) (2010) ("The ‘dietary supplement’ (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)…").


25 In order for an ingredient of a dietary supplement to be a "dietary ingredient," it must be one or any combination of the following substances: “a vitamin, a 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 (e.g., enzymes or tissues from organs or glands), or a concentrate, metabolite, constituent or extract.” FDA, Overview of Dietary Supplements, http://www.fda.gov/Food/DietarySupplements/ConsumerInformation/ucm110417.htm#what (last visited Apr. 4, 2010) [hereinafter Overview of Dietary Supplements].

26 HUTT ET AL., supra note 11, at 267 (“A product may be represented as either a dietary supplement or a conventional food depending on the labeling. A dietary supplement must be designated as such on the principal display panel and bear a Supplement Facts box. A conventional food bears a Nutrition Facts box.”). The FDA has authority to regulate labeling for food, while the Federal Trade Commission (FTC) retains authority to regulate advertising. Id. at 98. The FTC prohibits food advertisement, other than labeling, which is “misleading in a material respect.” FTC, Enforcement Policy Statement on Food Advertising (1994), http://www.ftc.gov/bcp/policystmt/ad-food.shtm (citing 15 U.S.C. §§ 45, 52, 55 (1980)).

27 21 U.S.C. § 321(k) (“The term ‘label’ means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.”); 21 U.S.C. § 321(m) (“The term ‘labeling’ means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.”).
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distributor; a complete list of ingredients; and the net contents of the product. In addition, each
dietary supplement (except for some small volume products or those produced by eligible small
businesses) must have nutrition labeling in the form of a "Supplement Facts" panel. This label
must identify each dietary ingredient contained in the product.\(^{28}\) DSHEA also requires the
dietary supplement manufacturer to bear responsibility “for ensuring that a supplement is safe
before it is marketed….”\(^{29}\) Other than the manufacturer's responsibility to ensure safety, there
are no rules that limit a serving size or the amount of a nutrient in any form of dietary
supplements. This decision is made by the manufacturer and does not require FDA review or
approval.\(^{30}\) DSHEA effectively creates a loophole so people can reclassify foods or drugs as
dietary supplements to escape regulations.

ENVIGA PROBLEM

The FDA labeling regulations appeared to be at the root of my initial discouragement
with the disappearance of Enviga. On February 1, 2007, the Center for Science in the Public
Interest (CSPI)\(^{31}\) sued Coca-Cola and Nestlé for misbranding and false advertising.\(^{32}\) In a

\(^{28}\) Overview of Dietary Supplements, supra note 25.
\(^{29}\) Aaronson v. Vital Pharm., Inc., 2010 U.S. Dist. LEXIS 14160 (noting that the FDA is also
responsible for taking action against an unsafe supplement after it reaches the market); Dietary
Overview of Dietary Supplements, supra note 25.
\(^{30}\) Overview of Dietary Supplements, supra note 25.
\(^{31}\) Through education and advocacy, CSPI seeks to “[fight] for government policies and
corporate practices that promote healthy diets, prevent deceptive marketing practices, and ensure
that science is used to promote the public welfare.” About CSPI,
http://www.cspinet.org/about/index.html (last visited Apr. 4, 2010).
\(^{32}\) Center for Science in the Public Interest, Watchdog Group Sues Coke, Nestlé For Bogus
Enviga Claims]; Sheila Marikar, Drink Enviga, Burn Calories, Lose Weight? Not So Fast, ABC
warning letter to Coca-Cola and Nestlé, CSPI warns the companies that “Enviga is ‘misbranded’ in violation of both the Federal Food, Drug, and Cosmetic Act [FD&C Act], and state food and drug laws…” 33 The FD&C Act describes the process for determining whether labeling or advertising is misleading:

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual. 34

Enviga “boasted” negative calories from the combination of caffeine and epigallocatechin gallate (EGCG), an antioxidant found in green tea. 35 As of the date of the CSPI warning letter, the Enviga website claimed, “Enviga results in negative calories, because you burn more calories


35 Marikar, supra note 32.
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than you consume.’ . . . ‘There is a calorie burning effect from a single can.’”\textsuperscript{36} The label on the front of an Enviga can described Enviga as “the Calorie Burner;”\textsuperscript{37} the side panel contained other claims:

- Enviga ‘increases your metabolism to gently increase calorie burning.’
- Enviga gives ‘your body a little extra boost.’
- The caffeine and EGCG in Enviga ‘invigorate your metabolism to burn calories.’
- The caffeine alone ‘stimulates your body to enhance the calorie burning process.’\textsuperscript{38}

On the back of the can Enviga includes the following statements:

- Three cans per day of Enviga have been shown to increase calorie burning by 60–100 calories in healthy normal weight 18–35 year olds.
- Enviga burns calories but is not by itself a guaranteed weight loss solution.
- Remember, weight loss requires a reduced calorie diet and regular exercise. Individual results may vary. Drinking more than three cans per day will not have an additional effect.”\textsuperscript{39}

\textsuperscript{37} Bogus Enviga Claims, supra note 32.
\textsuperscript{38} CSPI Enviga Letter, supra note 33.
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These statements are on the back of the can, but the product is marketed as a calorie-burning beverage; what good is that? In New York City, outdoor advertising included the following statement: “‘Be positive. Drink negative.’”

Coca-Cola and Nestlé justified these negative calories by explaining that Enviga was high in the antioxidant EGCG. Coca-Cola also purportedly encouraged drinking three cans per day to achieve the desired effect, and that three 12-ounce cans of Enviga—each containing five calories—would burn 60–100 calories in healthy adults aged 18–35. They attempted to substantiate their claims with a study. In the “72-hour Nestlé-funded study[, ] 31 people [ ] were given a drink containing amounts of EGCG and caffeine equivalent to three cans of Enviga. On average, those subjects expended more energy, according to an abstract of the unpublished study.” The subjects’ caloric expenditure increased an average of 106 kilocalories per day, with “no adverse side effects on heart rate or blood pressure.”

Even though Coca-Cola’s chief scientist added a disclaimer to the study, stating that Enviga was “not a magic bullet,” Enviga was still attacked for having misleading labeling and

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40 CSPI Enviga Letter, supra note 33.
41 Bogus Enviga Claims, supra note 32.
42 CSPI Enviga Letter, supra note 33.
44 Bogus Enviga Claims, supra note 32. The study was conducted by Nestlé and researchers at the University of Lausanne in Switzerland. Enviga FAQS, http://www.enviga.com/#FAQs (last visited Apr. 4, 2010).
45 Enviga Clinical Study, http://www.enviga.com/#Science (last visited Apr. 4, 2010); Clinical Study, supra note 43, at 352 (noting that the subjects all ate a set diet in a metabolic chamber).
46 Stanford, supra note 43.
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advertising practices. The CSPI noted that the study used “unrealistically large doses” of caffeine and EGCG, and that the study “produced inconsistent results.”\(^\text{47}\) Additionally, none of the 31 subjects were overweight or obese.\(^\text{48}\) According to scientists at the CSPI, “Enviga is just a highly caffeinated and over-priced diet soda, and is exactly the kind of faddy, phony diet aid it claims not to be.”\(^\text{49}\) Coca-Cola and Nestlé claimed Enviga was not marketed\(^\text{50}\) as a weight loss product, but “some doctors and consumer advocates say that looking at the ads, it's hard to think of anything else.”\(^\text{51}\) People accused Coca-Cola and Nestlé of “putting marketing hype ahead of science.”\(^\text{52}\) A European study found that the combination of caffeine and EGCG did not induce weight loss; whereas a Japanese study by a tea company found that this combination did produce the weight-loss and calorie-burning effects that Enviga claimed.\(^\text{53}\) Coca-Cola and Nestlé eventually agreed to pay $650,000 to settle and “to add disclosures that disclaim any suggestion that the drink inherently has weight-loss benefits.”\(^\text{54}\)

THE SAFETY AND SIDE EFFECTS OF CAFFEINE AND ENERGY DRINKS

\(^\text{47}\) Id.; CSPI Enviga Letter, \textit{supra} note 33.

\(^\text{48}\) Bogus Enviga Claims, \textit{supra} note 32. The 31 subjects had a mean weight 65.3. Clinical Study, \textit{supra} note 43, at 352.

\(^\text{49}\) Bogus Enviga Claims, \textit{supra} note 32.

\(^\text{50}\) Beverage Partners Worldwide (BPW) marketed Enviga. CSPI Enviga Letter, \textit{supra} note 33.

\(^\text{51}\) Marikar, \textit{supra} note 32.

\(^\text{52}\) Id. (quoting Dr. David Katz).

\(^\text{53}\) Bogus Enviga Claims, \textit{supra} note 32.

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The main benefits of energy drinks are the energy boost and multivitamins that they provide, however there is debate over whether energy drinks have a net positive effect. Generally consumption of up to 300 mg of caffeine per day poses no physical problems, according to the American Dietetics Association. The amount of caffeine in a standard cup of coffee may be harmless to most people, but energy drinks contain far more caffeine than a standard cup of coffee. For example, a 24-ounce can of Rockstar “has as much caffeine as three espressos, and as much sugar as six large doughnuts.” Rockstar Zero Carb, Rockstar Punched, and Rockstar Roasted products each have 120 mg of caffeine per serving (2 servings in a 16-ounce can). Rockstar Energy Shots are only 2.5 fluid ounces, but each container packs 200 mg of caffeine.

Consumption of multiple energy drinks or one energy drink and a cup of coffee may lead to excessive caffeine intake. The causal relationship between energy drinks and health problems (e.g., seizures, kidney failure, cardiac dysrhythmia) is uncertain, but such problems

56 Reissig et al., supra note 6, at 4.
57 Heaner, supra note 55; see Sheri Zidenberg-Cherr and Anna Jones (eds.), University of California Davis, Setting the Record Straight on Caffeine and Health, 31 Nutrition Perspectives 2 (2006); Heneman and Zidenberg-Cherr, supra note 9, at 1 (“[C]onsumption of up to 400 mg caffeine daily by healthy adults is not associated with adverse effects.”).
62 Heneman and Zidenberg-Cherr, supra note 9.
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have been reported after consumption of energy drinks. There have been other cases reported of people who suddenly died after drinking energy drinks. An Irish man died after drinking four cans of Red Bull and playing in a basketball game; caffeine was also an “ambient factor” in the club death of a twenty year old in the United Kingdom. Energy drinks can also exacerbate pre-existing health issues like obesity and sleep deprivation. When mixed with alcohol—a common practice among partygoers—energy drinks “lessen[] the impression but not the effects of drunkenness….”

A director of sports nutrition at the University of Pittsburgh Medical Center maintains that, “[c]affeine is not safe for everyone especially in larger quantities.” In fact, “Caffeine

68 Nordqvist, supra note 65 (pointing out the popular club drink Red Bull and vodka).
70 Marikar, supra note 32; Heneman and Zidenberg-Cherr, supra note 9, at 1 (internal citations omitted) (“Adolescents should limit caffeine consumption, as intakes greater than 100 mg/day has been associated with elevated blood pressure.”).
Intoxication” is included in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR):

The essential feature of Caffeine Intoxication is recent consumption of caffeine and five or more symptoms that develop during, or shortly after, caffeine use (Criteria A and B). Symptoms that can appear following the ingestion of as little as 100 mg of caffeine per day include restlessness, nervousness, excitement, insomnia, flushed face, diuresis, and gastrointestinal complaints. Symptoms that generally appear at levels of more than 1 g/day include muscle twitching, rambling flow of thoughts and speech, tachycardia or cardiac arrhythmia, periods of inexhaustibility, and psychomotor agitation.71

Caffeine can increase anxiety, panic attacks, stomach problems, and cardiac arrhythmias. 72 It is addictive, and withdrawal can cause symptoms such as headaches, irritability and lethargy. 73

Physical activity or alcohol may amplify the adverse effects of the already high levels of caffeine

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71 Caffeine Intoxication, DSM-IV-TR, Diagnostic and Statistical Manual of Mental Disorders – 4th Ed. (DSM-IV-TR™, 2000). The DSM-IV-TR also includes a separate entry for “Caffeine-Related Disorder[s]”. Additional Information on Caffeine-Related Disorder, DSM-IV-TR, Diagnostic and Statistical Manual of Mental Disorders – 4th Ed. (DSM-IV-TR™, 2000) (“Typical patterns of caffeine intake have not been consistently associated with other medical problems. However, heavy use is associated with the development or exacerbation of anxiety and somatic symptoms such as cardiac arrhythmias and gastrointestinal pain or diarrhea. With acute doses exceeding 10 g of caffeine, grand mal seizures and respiratory failure may result in death. Excessive caffeine use is associated with Mood, Eating, Psychotic, Sleep, and Substance-Related Disorders, whereas individuals with Anxiety Disorders are likely to avoid this substance.”).


73 See Foreman, supra note 17.
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in energy drinks and shots.\textsuperscript{74} Large amounts of caffeine may also “increase[] the risk of miscarriages (and possibly birth defects) and inhibit[] fetal growth….\textsuperscript{75} Reports have shown that pregnant women who drank only 200 mg of caffeine “increased [their] risk of miscarriage (15\% versus 12\%) and that the corresponding risk for pregnant women with caffeine intakes of more than 200 mg was considerably higher (25\% versus 12\%).\textsuperscript{76} Some researchers worry that children and teenagers who use energy drinks might be more likely to use prescription drugs like Ritalin.\textsuperscript{77} The growth in energy drink consumption among teenagers has also led to an increase in “toxic jock” behavior, characterized by an assortment of aggressive and destructive behaviors such as substance abuse, unprotected sex, and violence.\textsuperscript{78}

\textsuperscript{74} ENERGY SHOT INTAKE, supra note 64.
\textsuperscript{75} Center for Science in the Public Interest, Chemical Cuisine: Learn About Food Additives, http://www.cspinet.org/reports/chemcuisine.htm#caffeine (last visited Apr. 4 2010); Nordqvist, supra note 65; Heneman and Zidenberg-Cherr, supra note 9, at 1 (“[C]onsumption of energy drinks by pregnant or nursing women, adolescents, and children is not recommended.”).
\textsuperscript{76} FEDERAL INSTITUTE FOR RISK ASSESSMENT, NEW HUMAN DATA ON THE ASSESSMENT OF ENERGY DRINKS, BfR Information No. 016/2008 (Mar. 2008), available at www.bfr.bund.de/.../new_human_data_on_the_assessment_of_energy_drinks.pdf; Center for Science in the Public Interest, ‘Calorie Burning’ Enviga Tea Drink a Fraud, Group Says, Dec. 4, 2006, http://www.cspinet.org/new/200612041.html (“The 300 milligrams of caffeine in the recommended three cans of Enviga per day (the caffeine equivalent of nine cans of Coke) is at the very upper limit of what experts consider safe for woman who are pregnant or may become pregnant. The FDA has urged pregnant women to avoid or minimize their intake of caffeine.”).
\textsuperscript{77} Harding, supra note 72 (“Because energy drinks are touted as performance enhancers and stimulants,… kids who use them for these reasons will likely be more open to trying prescription drugs that promise the same effects.”).
\textsuperscript{78} Tara Parker-Pope, Taste for Quick Boost Tied to Taste for Risk, NEW YORK TIMES, May 27, 2008; Kathleen E. Miller, Wired: Energy Drinks, Jock Identity, Masculine Norms, and Risk Taking, 56 J. AM. C. HEALTH 481, 482 (2008); Reissig et al., supra note 6, at 6 (“[M]ixing energy drinks with alcohol was associated with increased heavy episodic drinking and episodes of weekly drunkenness.”).
Energy drinks can generate unhealthy and undesired side effects because of the high concentration of caffeine in combination with numerous other ingredients such as taurine. The Original Rockstar drink contains the following ingredients, as listed on the label: carbonated water, sucrose, glucose, citric acid, taurine, natural and artificial flavors, sodium citrate, caffeine, caramel color, benzoic acid, sorbic acid, L-carnitine, inositol, niacinamide, calcium pantothenate, milk thistle extract, gingko biloba leaf extract, guarana seed extract, panax ginseng root extract, riboflavin, pyridoxine hydrochloride, and cyanocobalamin. Minimal scientific evidence exists to substantiate claims that some of these ingredients substantially increase endurance, mental performance and weight loss or that they have other physically beneficial effects. Additionally, insufficient scientific data exists to verify the safety of these substances, specifically taurine. Taurine is a natural human metabolite that occurs in other foods as well as in energy drinks.

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79 Heneman and Zidenberg-Cherr, supra note 9, at 4 (“[T]he safety of consuming caffeine in combination with other herbal supplements found in energy drinks prior to or during exercise has yet to be established.”).
81 Heneman and Zidenberg-Cherr, supra note 9.
82 Some health authorities link taurine with increases in neurophysiological problems. Tandy, supra note 69; Heneman and Zidenberg-Cherr, supra note 9; Energy Shot Intake, supra note 64, at 1 (“It remains to be clarified whether the interaction of caffeine with other constituents in energy drinks (e.g. taurine) or with ethanol in the alcoholic beverages consumed alongside energy shots or with physical exertion (e.g. extended, physically strenuous dancing or sports activities) could amplify the adverse effects of caffeine. An actual causal relationship between these factors has not yet been scientifically demonstrated.”).
83 European Food Safety Auth., Scientific Opinion of the Panel on Food Additives and Nutrient Sources Added to Food, The Use of Taurine and D-Gucurono-γ-Lactone as Constituents of the
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The European Food Safety Authority (EFSA) has said that exposure to taurine is not a concern at the average level of 0.5 can of energy drink per day (most people would drink the whole can). The EFSA panel “considered it possible that the health problems mentioned could be due to the well-known side effects of high caffeine intake, while the assumption of a causal relationship with taurine intake [was] lacking scientific evidence.” Nonetheless, some doctors still do not believe enough scientific evidence exists to know the effects of taurine—and thus, energy drinks as a whole—on the body and the brain.

PROONENTS OF CAFFEINE AND ENERGY DRINK REGULATION

At a 2006 FDA hearing, the CSPI pushed the FDA to adopt more stringent standards for energy drinks and other “functional foods.” Again, in 2008, scientists petitioned the FDA to tighten regulations on energy drinks by setting a limit on the amount of caffeine allowed in the product and by requiring the amount of caffeine to be listed on the label along with a warning.


85 Id.

86 Scientists Close in on Taurine’s Activity in the Brain, MEDICAL NEWS TODAY, Jan. 18, 2008, http://www.medicalnewstoday.com/articles/94393.php, (“Remarkably little is known about the effects of energy drinks on the brain. We can't even be sure how much of the taurine in the drink actually reaches the brain!” Dr. Harrison says.”).


88 Weise, supra note 6; Weise, supra note 3. The fact that such concerns appear to have minimal, if any, negative impact on energy drink sales, might dissuade the government and consumer advocacy groups from pursuing more stringent regulatory policies. Daniel Palmer, France Reluctantly Lifts Ban on Red Bull, AUSTRALIAN FOOD NEWS, July 17, 2008, http://www.ausfoodnews.com.au/2008/07/17/france-reluctantly-lifts-ban-on-red-bull.html.
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The FDA limits the amount of caffeine in soft drinks like Coca-Cola, and requires over-the-counter stimulant drugs with caffeine to list the amount of caffeine on the label, however energy drinks are able to escape both of these requirements: “It is a striking inconsistency that, in the U.S. an OTC stimulant medication containing 100 mg of caffeine per tablet (e.g. NoDoz) must include …warnings, whereas a 500 mg energy drink can be marketed with no such warnings and no information on caffeine dose amount in the product.” What sense does this make? A 12-ounce can of Coca-Cola has 54 mg of caffeine, whereas a 16-ounce can of Rockstar has 160 mg of caffeine—only 40 mg less than the amount of caffeine in 1 tablet of Vivarin, an over-the-counter drug.

Regulation in Other Countries

If the FDA tightened its regulations on caffeine and energy drinks, it would not be the first to do so. France once banned energy drinks. The popular energy drink Red Bull was banned in France for twelve years “due to health authorities’ concerns about unknown consequences of the ingredient taurine, a chemical forbidden in several countries.” At first, the

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89 Harding, supra note 72.
90 Reissig et al., supra note 6, at 2 (“The FDA has been lax in regulating the caffeine content of energy drinks and does not require warning labels advising proper use or the amount of caffeine in the product, as it does for over-the-counter (OTC) caffeine-containing stimulants.”).
91 Center for Science in the Public Interest, Caffeine Content of Food & Drugs, http://www.cspinet.org/new/cafchart.htm, (last visited Apr. 4, 2010).
93 Tandy, supra note 69; Pfanner, supra note 5 (“The French authorities had long objected to one of its active ingredients, an amino acid called taurine, because of concerns that it could speed heart rates to unhealthy levels.”).
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European Court of Justice upheld the ban on Red Bull, only if France could prove the claimed health risks. The European Court’s Scientific Committee on Food thought more studies needed to be done on caffeine, taurine, and glucuronolactone. In 2008, the French government eventually legalized Red Bull, in absence of enough evidence that it is harmful.

In Germany, energy shots are marketed as dietary supplements, and manufacturers can only distribute and sell them under certain conditions. Germany’s Federal Institute for Risk Assessment (BfR) recommends detailed information on product labels:

[A]dverse effects cannot be ruled out when larger amounts of these beverages are consumed in conjunction with intensive physical activity or with the intake of alcoholic beverages[.] [B]everages of this kind, particularly when consumed in larger amounts, are not recommended for children, pregnant women, lactating women or individuals who are sensitive to caffeine.

Red Bull put warnings on cans in Austria indicating high levels of caffeine in the product and possible harmful effects for pregnant women and children. Ireland has the following regulation concerning caffeine labeling:

Article 2 (1). Where a beverage which is intended for consumption without modification,…contains caffeine, from whatever source, in a proportion in excess of 150 mg/l, the following message must appear on the label in the same field of

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94 Nordqvist, supra note 65.
95 Tandy, supra note 69; Pfanner, supra note 5 (“Though researchers in the United States have recently found links between consumption of energy drinks and risky behavior by teenagers, those concerns cannot be substantiated,” said a French Finance Ministry spokeswoman).
96 Energy Shot Intake, supra note 64.
98 Id.
99 See Tandy, supra note 69.
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vision as the name under which the product is sold: ‘High caffeine content’. …

(2). Paragraph 1 shall not apply to beverages based on coffee, tea or coffee or tea extract where the name under which the product is sold includes the term ‘coffee’ or ‘tea’.100

Based on scientific studies, the Scientific Committee on Food found it necessary for such beverages to include warning messages and indication of the amount of caffeine on the label in order to give consumers clear information.101 Bans have also been enforced in Norway, Denmark, Uruguay, and Iceland.102

In New Zealand, energy drinks are regulated as dietary supplements. The drinks must contain warning statements on the packaging indicating the level of caffeine and that they are not recommended for children, lactating women, or people with caffeine sensitivity.103 A standard

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regulating energy drinks (as “formulated caffeinated beverages”) mandates that they contain no more than 320 mg/l of caffeine, and no more than 2000 mg (per one day quantity) of taurine.\textsuperscript{104} The Australia and New Zealand Food Authority also proposed a regulation requiring declaration of caffeine amounts on labels when the herbal supplement guarana (which contains caffeine) has been added to food.\textsuperscript{105} The labels must include the quantity of caffeine and other substances listed in the regulation, like taurine and inotosil, and warnings for pregnant women and children.\textsuperscript{106}

**State Regulation Attempts**

Some states have attempted to pass legislation regarding caffeine in energy drinks. A Louisiana senator recently proposed a ban on the sale of energy drinks (excluding coffee) to people less than 16 years old.\textsuperscript{107} The proposed legislation, currently referred to the Committee on Commerce, Consumer Protection and International Affairs,\textsuperscript{108} reads as follows:

§ 1427. Unfair trade practices; sale of energy drinks to consumers under the age of sixteen: A. It shall be an unfair trade practice for any retail business to


\textsuperscript{106}Standard 2.6.4 Formulated Caffeinated Beverages, \textit{supra} note 104.


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knowingly sell an energy drink to a consumer under the age of sixteen. B. For the purpose of this Section, ‘energy drink’ means any drink, except coffee, that contains at least five milligrams of caffeine per fluid ounce. C. Any violation of this Section shall be deemed an unfair trade practice and shall subject the violator to any and all actions and penalties provided for in this Chapter.¹⁰⁹

At least one nutritionist already supports this legislation.¹¹⁰ In September 2008, a Michigan senator proposed legislation that would require energy drinks and other bottled beverage manufacturers to list the amount of caffeine on their products: “Section 4115a. Any bottled drink not subject to section 4115 shall have indicated, upon its label, the caffeine content.”¹¹¹ A proposed bill on the Massachusetts Senate docket reads as follows:

Section 8B: (a) As used in this section, the term “energy drink” shall mean a carbonated beverage that exceeds caffeine content of 100 milligrams of caffeine per 8 ounce serving. (b) Whoever sells an energy drink to any person under the age of 18 shall be punished by a fine of not less than $100 for the first offense, not

¹¹⁰ Chris Miller, Energy Drink Ban Gets Backing of LSU Doc, WWL – AM870 | FM105.3 | News | Talk | Sports, http://www.wwl.com/pages/6613440.php? (Mar. 19, 2010, 08:30 EST) (“[Dr. Kathy] Champagne says for adults, the drinks bring a sharp energy rush, followed by a crash when the stimulants wear off. She says various energy drinks often contain other unregulated stimulants, the effects of which aren't fully known.”).
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less than $200 for the second offense and not less than $300 for the third or any subsequent offense.\textsuperscript{112}

The proposed legislation also seeks to prohibit students in primary and secondary schools from drinking energy drinks on school grounds.\textsuperscript{113}

\textbf{LABEL CAFFEINE AMOUNT}

Tightening regulations on caffeine in energy drinks may help curb the prevalence of caffeine dependence that results from “marketing campaigns promoting the use of energy drinks among adolescents.”\textsuperscript{114} According to Roland Griffiths, a psychopharmacologist and professor in the department of psychiatry and neuroscience at Johns Hopkins University, “caffeine ‘is relatively benign and is not associated with life-threatening health risks,’…[but] it is being promoted in the form of energy drinks and, alarmingly, in many cases to children and adolescents,” Griffiths said.\textsuperscript{115} Both Monster and Rockstar directly market their product to teens by sponsoring extreme sports, athletes, concerts, festivals,\textsuperscript{116} and college events.\textsuperscript{117} Monster’s website reads:

Most companies spend their money on ad agencies, TV commercials, radio spots, and billboards to tell you how good their products are. At Monster we choose

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\textsuperscript{113} Id.
\textsuperscript{114} Reissig, \textit{supra} note 6, at 5.
\textsuperscript{115} Foreman, \textit{supra} note 17.
\textsuperscript{117} See Rockstar Energy Drink: Events, http://www.rockstar69.com/events.php (last visited Apr. 4, 2010).
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none of the above. Instead, we support the scene, our bands, our athletes and our
fans. …In short, at Monster all our guys walk the walk in action sports, punk rock
music, partying, hangin’ with the girls, and living life on the edge. Monster is
way more than an energy drink. Led by our athletes, musicians, employees,
distributors and fans, Monster is... A lifestyle in a can.118

Few people probably read the “About us” section on Monster’s website, but Monster’s role as a
sponsor of athletes and “[a] life on the edge” contradict scientific reports and doctor’s messages
that energy drinks should not be consumed prior to intense physical activity,119 thereby sending
consumers an inaccurate message about the product’s safety.

The FD&C Act should be amended so that the amount of caffeine is included on the label
of all energy drink products.120 This requirement serves to protect the public health121 by
reducing consumer confusion and by allowing consumers to make healthier choices. Pregnant
women, people with minor heart conditions, and other persons sensitive to caffeine would have
difficulty choosing the best energy drink for themselves absent information on the quantity of

118 Monster Energy Drink – About Us, http://www.monsterenergy.com/web/guest/about (last
visited Apr. 4, 2010). Rockstar’s website says: “ROCKSTAR is formulated to provide an
incredible energy boost for those who lead active and exhausting lifestyles – from athletes to
visited Apr. 4, 2010).
119 See Energy Shot Intake, supra note 82.
120 Foreman, supra note 17; Reissig, supra note 6, at 7 (“Considering the variable and sometimes
very high caffeine content of energy drinks, in combination with the aggressive marketing to
youthful and inexperienced consumers, it would be prudent to require full disclosure of the
amount of caffeine and other ingredients in energy drinks on the product labeling.”).
121 The FD&C Act establishes the FDA’s mission to: “(1) promote the public health by promptly
and efficiently reviewing clinical research and taking appropriate action on the marketing of
regulated products in a timely manner; (2) with respect to such products, protect the public health
by ensuring that— (A) foods are safe, wholesome, sanitary, and properly labeled;… and (4) as
determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in
consultation with experts in science, medicine, and public health, and in cooperation with
consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated
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caffeine. The amount of caffeine in an energy drink varies greatly between products. An 8-ounce can of Monster Energy Assault has 160 mg of caffeine,\textsuperscript{122} whereas an 8-ounce can of Wired 294 Caffeine contains 294 mg of caffeine.\textsuperscript{123} According to a behavioral biology professor, some energy drinks contain the same amount of caffeine as 14 cans of Coca-Cola. He also notes that the inclusion of caffeine intoxication in the \textit{Diagnostic and Statistical Manual of Mental Disorders} and in the World Health Organization’s International Classification of Diseases should be reason enough to include caffeine amounts and warnings on product labels.\textsuperscript{124}

Including the amount of caffeine on the label might be harmful to smaller companies that would have to pay to redesign their labels. Some energy drink companies already list the amount of caffeine on some of their products, but it may be prohibitively expensive for smaller companies to do so. The American Beverage Association argues that requiring the amount of caffeine on labels creates a “‘slippery slope’ that would require coffeehouses to provide caffeine content information on their products as well.”\textsuperscript{125} But, is that such a bad thing? People will still consume caffeine because it generally does not pose a health risk to most people, but people with sensitivity to caffeine—like pregnant women—will be able to better monitor their caffeine intake if they regularly consume caffeinated beverages. Energy drink companies might argue that finding out the amount of caffeine in energy drinks is the responsibility of the consumer, not the government; the consumer can simply look at a product’s website or call the company’s 1-800

\textsuperscript{122} Heneman and Zidenberg-Cherr, \textit{supra} note 9, at 2.
\textsuperscript{123} \textit{Id.}
\textsuperscript{124} Tara Parker-Pope, \textit{Warning Labels for Caffeinated Energy Drinks}, \textit{New York Times}, http://well.blogs.nytimes.com/2008/09/25/warning-labels-for-caffeinated-energy-drinks/ (Sept. 25, 2008, 11:11 EST); Reissig, \textit{supra} note 6, at 2 (“At least 130 energy drinks now exceed 0.02% caffeine including one that contains 505 mg in a 24 oz can (the equivalent of 14 cans of a typical cola or several cups of coffee)).
\textsuperscript{125} Harding, \textit{supra} note 72.
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This argument ignores the reality that a consumer purchasing an energy drink is likely in want of energy and probably won’t stand in the grocery store aisle calling several 1-800 numbers before deciding which energy drink to purchase.

Product directions absent caffeine levels are confusing to the average consumer. Product directions for 5-hour energy recommend drinking one whole bottle for maximum energy but no more than two bottles per day. Yet, the following cautionary statement says: “Contains caffeine comparable to a cup of the leading premium coffee.” I don’t know what the “leading premium coffee” is, but I imagine that most people can drink at least two, if not more, cups of coffee per day without feeling the side effects that I felt after drinking several energy drinks. The caffeine in a cup of coffee may differ depending on the brand. Is the word “comparable” used to make the consumer think that drinking 5-hour energy is just like drinking coffee, but in a smaller container? If so, why include the warning statement recommending a daily dosage limit of two bottles? The combination of the warning and caution statements, absent any information on the quantity of caffeine in the bottle undoubtedly misleads the consumer. Even the energy drink comparison chart does not give the quantity of caffeine contained in a bottle of 5-hour energy; it merely states “yes”. It is important for consumers to know the caffeine content in their drinks; “‘armed with that knowledge, they can manage their caffeine intake.’”

126 Wajert, supra note 11.
CONCLUSION

The energy drink market is growing. Because there isn’t substantial evidence confirming the safety of energy drinks, “the potential for adverse health consequences should be considered and may be cause for preemptive regulatory action.” Other countries have taken such action. Consumers need complete information about the quantity of potentially unhealthy ingredients in energy drinks, so that they can meaningfully compare products. With so many products from which to choose, informed comparisons are all the more valuable to the consumer. Requiring energy drink manufacturers to include the amount of caffeine on the product label allows consumers to more accurately and effectively monitor their caffeine intake. I’ve debated the question any procrastinating student and midnight-oil-burner must face: To caffeinate or not? Knowing the dose of caffeine in a variety of energy drinks would allow me to choose the product that would remedy my fatigue without poisoning my body.

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130 Reissig, supra note 6, at 2.