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## Giving You Wings: Should the Food and Drug Administration Investigate the Safety of Red Bull and So-Called Energy Drinks?

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**Giving You Wings: Should the Food and Drug Administration Investigate the  
Safety of Red Bull and So-Called Energy Drinks?**

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**This paper is submitted in satisfaction of both the course requirement and the third year  
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**Abstract Summary:** This paper examines the necessity of Food and Drug Administration regulation of Red Bull and other energy drinks. First, the paper generally discusses energy drinks such as Red Bull that are currently on the market. Next, the paper discusses the FDA's ability to ban the products or to require warnings on them based on the FDA's regulatory ability specifically under DSHEA. The paper then discusses the approaches used by various other nations regarding regulation of energy drinks. The paper also discusses some of the specific ingredients in Red Bull, namely caffeine and taurine. The safety of Red Bull and other energy drinks in conjunction with their normal uses are then addressed. Finally, the paper addresses the propriety of warnings generally for Red Bull and other energy drinks.

## I. Introduction: Red Bull, Energy Drinks and American Culture

Einstein was wrong. Energy does not equal mass multiplied by the speed of light squared. Rather, energy equals caffeine plus lots of sugar and unproved nutritional additives. At least this is what the makers of so-called "energy drinks" would have consumers believe. Neither soft drinks nor sports drinks, these trendy products occupy an increasingly growing sector of the beverage market in the United States and abroad.

The consumer market is inundated with new products that promise to do much more than to quench thirst: there are elixirs marketed as energy drinks, sports drinks, functional foods, and smart drinks. As the Food and Drug Administration's approach to the regulation of nutritional supplements is under attack following another ephedra related death, should the agency also be concerned about the status of energy drinks? In other countries, warnings are required on certain energy drinks following deaths associated with the drinks when consumed in combination with exercise or alcohol. Thus the question is raised:

Is it time for the FDA to investigate into the safety of so-called energy drinks, particularly the market leader Red Bull?

A closer look into the energy drink industry, particularly into Red Bull, illustrates some of the most important issues currently facing the Food and Drug Administration. For example, the debate over energy drinks focuses on the problems that the FDA has encountered because of the strict limits of the Dietary Supplement

Health and Education Act (DSHEA). Additionally, the sale of energy drinks illustrates the manner in which marketing products with health-like properties can allow skirting of limits placed on similar products. Third, the debate over Red Bull illustrates the complexity of making decisions on food additives when scientific studies are largely inconclusive and criticisms are often based on isolated incidents.

Furthermore, the debate surrounding energy drinks exposes one of the more fundamental issues surrounding regulations in the United States. To what extent should the FDA be paternalistic and prevent marketing of products or require warnings on products that if used moderately will have no negative impact?

### **Outline of the Paper**

Section II of this paper will begin by discussing energy drinks generally: their ingredients, their functions, and their market. Next, this section will compare energy drinks with other products such as sports drinks. Then the section will focus more specifically on Red Bull, the market leader of the energy drinks and the general focus of the paper.

In Section III, the paper will look at the possibility of regulation of energy drinks in the United States and will discuss relevant statutory constraints on such regulation. Then this section will examine foreign regulations of Red Bull and other energy drinks; it will also examine studies done abroad regarding the efficacy of claims made by energy drinks and their safety in general.

The fourth section of the paper will analyze the safety of the main components of Red Bull, the market leader

in energy drinks, and it will consider the most significant research on these substances: first the section will examine caffeine; then the section will discuss taurine. Finally the section will briefly discuss ephedra, a component of some energy drinks such as Ripped Force.

Section five will analyze information regarding the safety of Red Bull in various common manners of consumption of the product. First the section will examine the use of Red Bull and other energy drinks in conjunction with alcohol and other drugs. Then the section will examine the use of energy drinks in conjunction with sports or exercise. Third, this section will discuss the safety of consumption of Red Bull and other energy drinks by children. Finally, Section V will examine the marketing of Red Bull for these specific consumption habits.

The sixth section of the paper will discuss the necessity of warnings on Red Bull and similar energy drinks. Finally, in Section VI, the paper will conclude with a recommendation as to what the FDA should do with energy drinks such as Red Bull.

## **II. Energy Drinks and Red Bull: General Product Overview**

Because of the proliferation of energy products on the market, from smart drinks to energy tonics, from functional foods to stimulant drinks, this section begins by attempting to define the term energy drink and by differentiating this product from others on the market such as sports drinks. Additionally, this section introduces the most popular energy drink on the market, Red Bull.

### **A. What is an Energy Drink?**

When it originated a century ago, Coca-Cola was marketed as an energy tonic.<sup>1</sup> Like early Coke ads that spoke of a secret formula with invigorating power and mysterious ingredients,<sup>2</sup> today energy drinks that contain caffeine and sugar as their main ingredients offer varying promises of providing energy to the consumer. These advertisements stay clear of actual medical claims that could push the drinks into the drug category of regulation under the Food Drug and Cosmetic Act and instead promise to “give you wings” or “make you fire on all cylinders” or “thunder through your workouts” with “radical energy in liquid form.”<sup>3</sup> The American market is flooded with such drinks promising to boost energy. The current group of energy drinks includes Red Bull, Solstis, Burn, and Lipovitan<sup>4</sup> as well as KMX, 180, Jones WhoopAss, SoBe and Niagara.<sup>5</sup> The success of Red Bull has been so great that beverage companies who have had success in other arenas have entered into the energy market. The producers entering the energy drink realm include Anheuser-Busch (180), Coke (KMX), Pepsi (Adrenaline Rush and Amp).<sup>6</sup>

Almost any drink that calls itself an energy drink contains caffeine and sugar and most contain high levels of both; additionally most contain some sort of herbal substance found in dietary supplements and traditional herbal medicines, some of which may not be effective, or even safe.<sup>7</sup> Such herbal supplements added to energy drinks include ginkgo biloba, kava kava, and taurine; other energy drinks also contain ma huang, also known as ephedra, and guarana, a seed extract which itself contains caffeine.<sup>8</sup> The FDA has never approved of many of the herbs and other substances in the new products as allowable additives, but it has not sough

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<sup>1</sup>See Tim Dowling, *Wake-up call: A Student who robbed a supermarket at knifepoint blamed the 11 cans of Red Bull he'd drunk. So what exactly do energy drinks do to you?* THE GUARDIAN (London), Nov 9, 2001, § Features, at 6 [hereinafter Dowling].

<sup>2</sup>See Rob Walker, *Bull Marketing*, AUSTRALIAN FINANCIAL REVIEW, Aug. 31, 2002, § Observer, at 41[hereinafter Walker].

<sup>3</sup>See Todd Morman, *Jacking Up Junior*, WEEKLY PLANET TAMPA, June 27, 2002. [hereinafter Morman]

<sup>4</sup>See Dowling, *supra* note 1.

<sup>5</sup>See Maureen McDonald, *Energy drinks: Too much of a jolt?; Health experts urge moderation when consuming fad drinks that give a lift*, THE DETROIT NEWS, Aug 29, 2001, § H, at 6 [hereinafter McDonald].

<sup>6</sup>See James F. Sweeney, *Energy Drinks Pack Real Punch*, THE TIMES-PICAYUNE (New Orleans), Aug. 4, 2002, § Living, at 4 [hereinafter Sweeney].

<sup>7</sup>See Julian E. Barnes & Greg Winter, *Stressed Out? Bad Knee? Relief Promised in a Juice*, NEW YORK TIMES, May 27, 2001, §1, at 1 [hereinafter Barnes].

<sup>8</sup>See Dowling, *supra* note 1.



to ban them.<sup>9</sup>

## A Workable Definition

A study in the European Union defined energy drinks as soft drinks containing substances such as caffeine, taurine, glucuronolactone and others at high levels.<sup>10</sup> Alternatively, energy drinks may be referred to as smart drinks<sup>11</sup> or stimulant drinks.<sup>12</sup> Energy drink may be a misnomer for these elixirs as the term may suggest that the products are helpful in the sporting context; a major Irish study rejected the term “energy drink,” in favor of the term “stimulant drinks” in a report on the drinks.<sup>13</sup> Stimulant drinks were defined as “beverages, which typically contain caffeine, taurine and vitamin(s), and may contain an energy source (e.g. carbohydrate), and/or other substance(s), marketed for the specific purpose of providing real or perceived enhanced physiological and/or performance effects.”<sup>14</sup> This is the definition of the term “energy drink” adopted by this paper.

Consumers purchase and consume energy drinks for a variety of reasons. They are used as mixers with alcohol, hangover cures, mid-afternoon pick-me-ups and performance boosters.<sup>15</sup> The consumption of such drinks continues to grow: sales of these drinks doubled in the United States in 2000 and again in 2001.<sup>16</sup> The

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<sup>9</sup>See Barnes, *supra* note 7.

<sup>10</sup>*Energy Drinks Follow-Up Letter*, Food Standards Agency, United Kingdom, Mar. 21, 2002, available at <http://www.foodstandards.gov.uk/multimedia/webpage/energydrink2>.

<sup>11</sup>See Victor Lambert, *Using Smart Drugs and Drinks May Not be Smart*, FDA CONSUMER, Apr. 1993, available at <http://www.fda.gov/government/bbs/topics/CONSUMER/CON00207.html> (“Smart drinks are made with amino acids, such as phenylalanine, choline, L-cysteine, and taurine, which are blended into juices and other nonalcoholic beverages. They are promoted as a way to increase energy, improve memory and boost intelligence.”).

<sup>12</sup>See Ireland Food Safety Promotions Board (Safefood), *A Review of the Health Effects of Stimulant Drinks, Final Report*, J.J. Strain, chairman, Stimulant Drinks Committee, Mar. 2002, at 3, available for download at [http://www.safefoodonline.com/news/n\\_190302.asp](http://www.safefoodonline.com/news/n_190302.asp) (stating that stimulant drinks are generally packed in visually attractive slimline cans and belong to a new class of food known as ‘functional foods’) [hereinafter Safefood].

<sup>13</sup>See Safefood, *supra* note 12, at 3.

<sup>14</sup>See *id.*

<sup>15</sup>See Sweeney, *supra* note 6.

<sup>16</sup>*Id.*

advertising of these drinks focuses primarily on the ever sought after market of young, active consumers.<sup>17</sup> The makers of energy drinks make bold claims about the effects of their drinks such as increased concentration, stamina and reaction speed.<sup>18</sup> However, according to a survey in Ireland of a representative sample of 11 – 35 year olds, the most common location of consumption of energy drinks was pubs and clubs; the drinks were also consumed with friends, at home, before or after sport and occasionally in association with study or work.<sup>19</sup> Stimulant drinks were most frequently consumed as mixers with alcohol, particularly vodka.<sup>20</sup> The stimulant drink consumers in the survey reported strong or moderate agreement for consumption of stimulant drinks with the following reasons: (1) to perk themselves up when tired; (2) on big nights out; (3) to perk themselves up if they have too much to drink; (4) with alcohol to enable them to drink more in an evening.<sup>21</sup>

Stimulant drinks manufacturers, due probably both to the newness of the products and the immense competition in the market, spend a great deal on advertising. Their ads speak about “the ultimate high” or “improv[ing] psychological performance”; the advertisements generally do not make any specific health or nutritional claims in their promotion, prompting a concern about their advertising and marketing methods.<sup>22</sup> However, certain products do make claims about real physical effects of the products, such as claims about metabolism, in their labeling.<sup>23</sup>

The market for products that promise health benefits beyond their inherent nutritional value, known as functional foods, has nearly doubled in the recent years.<sup>24</sup>

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<sup>17</sup>See Morman, *supra* note 3.

<sup>18</sup>See Dowling, *supra* note 1 (stating that there is no evidence to suggest that these drinks do any better than a cup of coffee in providing these effects).

<sup>19</sup>See Safefood, *supra* note 12, at *v* (stating additionally that very few reported drinking stimulant drinks in association with driving).

<sup>20</sup>*Id.*

<sup>21</sup>*Id.*

<sup>22</sup>*Id.* at 43.

<sup>23</sup>See Can of Red Bull (stating on label “Stimulates the Metabolism”); see generally discussion of such claims below, in § X.

<sup>24</sup>See Barnes, *supra* note 7.

## What is a functional food?

Functional foods are those foods that purport to target and to affect favorably particular functions of the body.<sup>25</sup> A functional food is a food that claims to have health benefits beyond basic nutrition<sup>26</sup> or one of a broad range of foods that is specifically formulated or touted for its special properties having a beneficial effect on the consumer's overall health and well being.<sup>27</sup> Functional foods include those that have an added ingredient to provide a particular health benefit, such as calcium-fortified orange juice, or foods that inherently may contain an ingredient that has become associated with a particular health benefit.<sup>28</sup>

Certain foods have been traditionally used for their functional properties, like coffee or tea to combat fatigue.<sup>29</sup> The United States does not have any specific regulations pertaining to functional foods; they may be regulated as foods, dietary supplements, drugs, medical foods or food for special dietary use.<sup>30</sup> Energy drinks are functional foods that are regulated as foods, but it is unclear if they are regulated as foods with additives or as liquid dietary supplements.<sup>31</sup>

In July 2000, the General Accounting Office criticized the FDA for providing limited assurances of the safety of functional foods containing dietary supplements.<sup>32</sup> Even if consumers had been hurt by these herbal substances, the FDA would not necessarily be aware of these harms because there are no requirements for the food companies to disclose any harm as long as they determine to their own satisfaction that the ingredients they put in their food are safe.<sup>33</sup>

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<sup>25</sup> See Safefood, *supra* note 12, at 3.

<sup>26</sup> See Ilene Ringel Heller, *Functional Foods: Regulatory and Marketing Developments*, 56 FOOD DRUG L.J. 197, 197 (2001) [hereinafter Heller].

<sup>27</sup> See Steven B. Steinborn & Kyra A. Todd, *The End of Paternalism: A New Approach to Food Labeling*, 54 FOOD DRUG L.J. 401, 401 (1999).

<sup>28</sup> See Heller, *supra* note 26, at 197.

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> See Garret Condon, *Energy Drinks, Straight Up or Mixed, Stir Debate*, LOS ANGELES TIMES, Jan. 21, 2002, at S3.

<sup>32</sup> Gen. Acct. Off. Rep. No. RCED-00-156, at 16-17 (July 11, 2000), available at <http://www.gao.gov/archive/2000/rc00156.pdf>; see generally Barnes, *supra* note 7.

<sup>33</sup> See generally Barnes, *supra* note 7.

## Energy Drinks Versus Sports Drinks

Despite the similarity in name, energy drinks should not be mistaken for sports drinks such as Gatorade or Powerade. Sport drinks provide two major functions: first, they aid in the maintenance of fluid balance and electrolyte concentration; second, they provide energy for use either during exercise or in recovery from exercise.<sup>34</sup> Sports drinks do not normally contain the same ingredients as energy drinks, like caffeine, taurine or glucuronolactone; the International Olympic Committee currently considers caffeine to be a stimulant that can result in athlete disqualification.<sup>35</sup>

Sports drinks contain fewer calories than energy drinks; they also contain electrolytes like potassium and sodium that can prevent muscle cramps.<sup>36</sup> The combination of dehydration and exercise can itself be dangerous.<sup>37</sup>

## B. The Bull Market: Leader of the Energy Drink Market, Red Bull

Red Bull, touted by constant television commercials featuring cartoons with the common theme of “giving you wings,” holds the dominant market position for performance enhancing health drinks in the United States.<sup>38</sup> Red Bull controls a little under 70% of the energy drink niche.<sup>39</sup>

The sales of Red Bull continue to grow. Sales of Red Bull are over one billion cans a year in the United

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<sup>34</sup> See Safefood, *supra* note 12, at 3; see *infra* Part V.B (providing more detailed discussion of the propriety of consumption of energy drinks in combination with exercise or sports activity).

<sup>35</sup> See Safefood, *supra* note 12, at 3.

<sup>36</sup> See Sweeney, *supra* note 6.

<sup>37</sup> See Morman, *supra* note 3.

<sup>38</sup> See *Red Bull Mystique Undergoes Scrutiny Over Health, Safety*, HOUSTON CHRONICLE, Aug 28, 2001, § Business, at 10 [hereinafter *Red Bull Mystique*].

<sup>39</sup> See Barb Berggoetz & Michael J. Rochon, *Popular Drink Mixer Boosts Partiers but Worries Officials*, THE INDIANAPOLIS STAR, Dec 3, 2001, § A, at 1 [hereinafter Berggoetz].

States alone.<sup>40</sup> In 2001, Red Bull grossed \$184 million and held more than two-thirds of the energy drink market.<sup>41</sup> Additionally in 2001, Red Bull sold an estimated 1.6 billion cans in 62 countries.<sup>42</sup> In 2001, Red Bull held 8<sup>th</sup> place in U.S. market share with just 0.1% compared to Coca-Cola's 43.7%.<sup>43</sup> Red Bull was introduced in Europe over fifteen years ago.<sup>44</sup> Much of its success is related to the mystique surrounding what is a "perfectly ordinary drink" that was sold in Thailand for many years before it was "discovered" by Austrian Dietrich Mateschitz and turned into a highly successful marketing concept.<sup>45</sup>

Though the FDA does not regulate it as a drug, Red Bull is certainly not popular because of its phenomenal taste or flavoring. It is fizzy, straw-colored and sickly sweet; most consumers believe that Red Bull tastes horrible and is meant to because it is an energy tonic and not a soft drink.<sup>46</sup> The taste is described as "bitter"<sup>47</sup> or "medicinal."<sup>48</sup> The popularity of Red Bull must, rather, be based on its actual or perceived benefits besides its taste.

Unlike other energy drinks, Red Bull does not contain multiple stimulants. The only stimulant present is 80 milligrams of caffeine, which is about the amount present in a cup of coffee.<sup>49</sup> Red Bull, like other energy drinks, primarily appeals to people who require a great deal of energy and want to perform their best: athletes, long-distance drivers, and especially college students cramming for tests.<sup>50</sup> It is especially popular

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<sup>40</sup> See *Red Bull Mystique*, *supra* note 38.

<sup>41</sup> See Stephen A. Crockett, *Cocktail and Bull Story: D.C.'s New Drink Fad*, WASHINGTON POST, June 20, 2002, § C, at 1 [hereinafter Crockett].

<sup>42</sup> See Sweeney, *supra* note 6.

<sup>43</sup> *Id.*

<sup>44</sup> See *Red Bull Mystique*, *supra* note 38.

<sup>45</sup> *Id.*

<sup>46</sup> See *i.e.* Dowling, *supra* note 1 (stating that Red Bull's advertisements don't risk making any unsubstantiated claims about its palatability).

<sup>47</sup> See McDonald, *supra* note 5.

<sup>48</sup> See Berghoetz, *supra* note 39.

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*; see *infra* Part II.A (regarding when Red Bull or other energy drinks are actually consumed).

with college students and night clubbers, and the company aggressively targets these lucrative markets.<sup>51</sup>

The huge success of Red Bull may be partly attributed to the mystique involved in its marketing. For example, Red Bull has been falsely rumored to contain a mystery stimulant, namely testosterone derived from bull's semen.<sup>52</sup> Perhaps because of this mystique – but also due to its intense marketing strategies - Red Bull has passed into pop-culture status; it is regularly used in TV shows and magazines as shorthand for getting “legally jacked.”<sup>53</sup>

The most public advertising tactic for Red Bull, beyond the simple cartoon commercials, is to associate its product with extreme sports.<sup>54</sup> Sport is the main focus of the sponsorship program of Red Bull, with an emphasis on emerging and established “extreme” sports. This sponsorship program occurs in all markets of Red Bull; analysis indicates that the strategy adopted by the manufacturer is designed to support both the functionality positioning of the product and the personality of the brand.<sup>55</sup> Much of the Red Bull website is devoted to the coverage of extreme sports sponsorship.<sup>56</sup> Red Bull also advertises itself to night clubbers and dancers with its Red Bull Music Academy focusing on electronic music.<sup>57</sup>

Red Bull is available in supermarkets, in convenience stores and in bars and nightclubs. It is packaged in a slim line silver can. Red Bull breaks away from the formula of traditional soft drinks by its use of chemicals such as a nonessential amino acid: taurine. The company then touts this ingredient and makes claims of increased endurance. The front of the can reads: “With Taurine. Vitalizes body and mind.” At the top of the back of the can it says:

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<sup>51</sup> See Walker, *supra* note 2; see generally <http://www.redbull.com>.

<sup>52</sup> See *Red Bull Mystique*, *supra* note 38; see *infra* Part IV.B (providing greater discussion of taurine).

<sup>53</sup> See Morman, *supra* note 3.

<sup>54</sup> See Walker, *supra* note 2; see *infra* Part V.B (discussing generally discussion regarding Red Bull's association with extreme sports).

<sup>55</sup> See Safefood, *supra* note 12, at 44.

<sup>56</sup> See <http://www.redbull.com/sports/sportshighlight/index.html>.

<sup>57</sup> See <http://www.redbullmusicacademy.com>.

RED BULL Energy Drink · Improves performance especially during times of increased stress or strain · Increases endurance · Increases concentration and improves reaction speed · Stimulates the metabolism.<sup>58</sup>

Despite regulations on its sale in several European countries, Red Bull officials say its product is safe and has been examined by health officials.<sup>59</sup> As of September 2002, the Food and Drug Administration had not filed any complaints regarding Red Bull.<sup>60</sup> Based on the applicable food and drug laws, many commentators suggest that the Food and Drug Administration's "hands" are to a large extent tied.<sup>61</sup>

### **Something to Hide?**

Recent deaths in Europe have raised awareness about potential safety concerns posed by Red Bull in conjunction with sports or alcohol.<sup>62</sup> Red Bull is certainly aware of the controversy surrounding its product. However, the company stands by the safety and effectiveness of its product. The website, featuring the same cartoon-like characters from the popular television ads, runs a feature called FAQ or Frequently Asked Questions. These questions cover many topics from the propriety of Red Bull for vegetarian consumers to the recommended number of Red Bull energy drinks to consume daily. However, the scope of the FAQ's, or the information on the website generally, has changed over time.

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<sup>59</sup>See McDonald, *supra* note 5; see also <http://www.redbull.com/faq/index.html> (lacking any examination of questions to the safety of Red Bull or discussion of the deaths that have been linked to this product).

<sup>60</sup>See Justin Henning, *Controversy Swirls over Red Bull*, UNIVERSITY DAILY KANSAN, Sept. 9, 2002 via University Wire [hereinafter Henning].

<sup>61</sup>See *infra* Part III.A.3 (regarding DSHEA and the constraints caused by it as well as the free reign of sale of nutritional supplements).

<sup>62</sup>See generally Colman Cassidy, *Little Known About Red Bull Effects*, THE IRISH TIMES, July 13, 2001, at 9.

For example, an article dated June 2002 found a question on the Red Bull website regarding the drinks appropriateness for children: ‘Is Red Bull suitable for young people?’ answered with a confident ‘Yes! For young people who drink coffee, Red Bull is harmless.’<sup>63</sup> As of January 2003, the website no longer provided an answer to this question.<sup>64</sup> Likewise, in an article dated September 2002, the Red Bull website contained a statement regarding mixing Red Bull with alcohol: “You can mix it with alcohol, however, the positive effects of Red Bull might be impaired by alcohol.”<sup>65</sup> However, as of January 2003, this information was no longer listed on the web site.<sup>66</sup> While the disappearance of these questions from the web-site may just reflect that they are no longer frequently asked,<sup>67</sup> a more likely explanation is that Red Bull feared that the answers to those questions either were not true or did not wish to answer those questions in light of future potential litigation.

The number of lawsuits that Red Bull has faced in the United States, if any, is unclear. However, at least one suit, brought by the widow of an athlete whose football player husband had used Red Bull in conjunction with herbal supplements is in its initial stages in Utah.<sup>68</sup>

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<sup>63</sup> See Morman, *supra* note 3.

<sup>64</sup> See <http://www.redbull.com/faq/index.html>.

<sup>65</sup> See Henning, *supra* note 60.

<sup>66</sup> See <http://www.redbull.com/faq/index.html>.

<sup>67</sup> See *id.* (stating that any questions not addressed in the frequently asked questions portion of the website could be answered via email).

<sup>68</sup> See Dawn House, *Athlete’s Widow Presses Lawsuit Against Nutrition Products’ Makers*, THE SALT LAKE TRIBUNE, Aug. 24, 2002, available at <http://www.sltrib.com/2002/aug/08242002/utah/764735.htm>.



### III. Regulation of Energy Drinks – In the United States and Abroad

#### A. The Possibility of Regulation of Energy Drinks At Home and the Statutory Limits on FDA Action

##### 1. Introduction

Regulation of foods and drugs in the United States falls under the guidance of the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act (FDCA).<sup>69</sup> Functional foods, like energy drinks, may be regulated as foods, dietary supplements, drugs, medical foods or food for special dietary use.<sup>70</sup> Though energy drinks have many of the same qualities as soft drinks, which are regulated as foods, they are regulated differently because the functional beverage industry is part of the trend of “nutraceutical foods” that occupies the gray area between food and dietary supplements.<sup>71</sup> Dietary supplements<sup>72</sup> are generally characterized as foods, despite their drug-like properties and their lack of testing on the market.

This section will discuss generally the different classifications of foodstuffs by the FDA. Then the section

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<sup>69</sup>Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. §§ 301 et seq. (1994)).

<sup>70</sup>See Heller, *supra* note 26, at 197; see § II A above For general discussion of functional foods.

<sup>71</sup>See Morman, *supra* note 3.

<sup>72</sup>21 U.S.C. § 321 (ff) (“The term 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);

2) means a product that . . . (B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and (C) is labeled as a dietary supplement. . . .

3) . . . except for purposes of section 201(g) [definition of a drug] a dietary supplement shall be deemed a food within the meaning of this Act.”).

addresses the FDA's approach to the regulation of dietary supplements such as those found in energy drinks. Next the section will analyze the ability of products that are under FDA regulation to make health claims. This section will then suggest possible ways that energy drinks could be regulated and walls against regulations under DSHEA.

## 2. Classification under FDCA

The FDA has differing rules for regulations of products based on their fitting within specific categories such as foods, drugs, medical foods, and medical devices. The line between food and drug regulation is important because of the amount of regulation that goes into the product based on its category. Foods enjoy more freedom from FDA regulation. Foods that have added ingredients that are considered GRAS,<sup>73</sup> or generally recognized as safe, are subject to even less regulation than other foods containing additives.

Some commentators have argued that the FDA does not adequately ensure the safety of substances added

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<sup>73</sup>21 CFR 182.1 § 182.1 "Substances that are generally recognized as safe.

(a) It is impracticable to list all substances that are generally recognized as safe for their intended use. However, by way of illustration, the Commissioner regards such common food ingredients as salt, pepper, vinegar, baking powder, and monosodium glutamate as safe for their intended use. This part includes additional substances that, when used for the purposes indicated, in accordance with good manufacturing practice, are regarded by the Commissioner as generally recognized as safe for such uses.

(b) For the purposes of this section, good manufacturing practice shall be defined to include the following restrictions:

(1) The quantity of a substance added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritional, or other technical effect in food; and

(2) The quantity of a substance that becomes a component of food as a result of its use in the manufacturing, processing, or packaging of food, and which is not intended to accomplish any physical or other technical effect in the food itself, shall be reduced to the extent reasonably possible.

(3) The substance is of appropriate food grade and is prepared and handled as a food ingredient. Upon request the Commissioner will offer an opinion, based on specifications and intended use, as to whether or not a particular grade or lot of the substance is of suitable purity for use in food and would generally be regarded as safe for the purpose intended, by experts qualified to evaluate its safety.

(c) The inclusion of substances in the list of nutrients does not constitute a finding on the part of the Department that the substance is useful as a supplement to the diet for humans.

(d) Substances that are generally recognized as safe for their intended use within the meaning of section 409 of the act are listed in this part. When the status of a substance has been reevaluated, it will be deleted from this part, and will be issued as a new regulation under the appropriate part, e.g., affirmed as GRAS under part 184 or 186 of this chapter; food additive regulation under parts 170 through 180 of this chapter; interim food additive regulation under part 180 of this chapter; or prohibited from use in food under part 189 of this chapter."

to food.<sup>74</sup> Under the original FD&C Act, the FDA possessed broad responsibility but comparatively weak regulatory authority over such substances.<sup>75</sup>

### **Brief Overview: Food Additives**

The term “food additive” means 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, if such substance is not generally recognized to be safe under the conditions of its intended use.”<sup>76</sup> At the most basic level, this definition applies to a substance whenever the manufacturer or food processor knows or should know that it will become a component or otherwise affect the characteristics of any food.<sup>77</sup> Another persistent increasingly relevant issue in food and drug law is how to differentiate between food additives and food itself; the FDA has at times challenged specific supplements as drugs and as food additives, both of which require pre-market approval.<sup>78</sup>

According to the courts, only components that somehow affect the final food may be regulated as food additives.<sup>79</sup> If a substance can be classified as a “dietary supplement” or as an ingredient in such a supplement, it is excluded by statute from the definition of the term “food additive.”<sup>80</sup> Food producers have become increasingly frustrated with lengthy delays in the review process, and public interest groups vocally criticize approved additives as unsafe.<sup>81</sup> The FDA is caught between these competing factions and the interests they

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<sup>74</sup>See Lars Noah & Richard A. Merrill, *Starting from Scratch?: Reinventing the Food Additive Process*, 78 B.U.L. REV. 329, 330, Apr. 1998 [hereinafter Noah & Merrill].

<sup>75</sup>See *id.*, at 332.

<sup>76</sup>See *id.*, at 341.

<sup>77</sup>See *id.*, at 342.

<sup>78</sup>See *id.*, at 346.

<sup>79</sup>See Noah & Merrill, *supra* note 73, at 346.

<sup>80</sup>See *id.*, at 346.

<sup>81</sup>See *id.*, at 443.

represent, while at the same time struggling to do more with fewer resources.<sup>82</sup>

### **How this affects Energy Drinks**

Energy drinks do not neatly fit within one of these categories based on the rules established by DSHEA that provide general rules for governing dietary supplements. Taurine, the highly touted ingredient in Red Bull, and many substances present in other energy drinks such as ephedra or ginseng fall into this dietary supplement category. Because they fall under the FDA's more limited governing power under DSHEA, energy drinks are more immune from FDA attack even if they are found to have some potential negative effects. The next section will discuss DSHEA and dietary supplement regulation more specifically.

## **3. DSHEA**

The lack of Food and Drug Administration investigation into the safety of energy drinks exemplifies the treatment of nutritional supplements under the Dietary Supplement Health and Education Act<sup>83</sup> (DSHEA). Congress passed DSHEA in 1994 following heavy lobbying by herbal supplement companies.<sup>84</sup> As a result of DSHEA, the FDA exempted certain substances like guarana, kava kava and ma huang – substances frequently found in energy drinks - from the stricter regulation that had occurred in the past.<sup>85</sup> This occurred despite evidence linking some of these substances such as ma huang to serious medical problems like heart attacks

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<sup>82</sup>See *id.*, at at 443.

<sup>83</sup>Pub. L. No. 103-417, 108 Stat. 4325 (codified at 21 U.S.C. § 301 note (1994)).

<sup>84</sup>See Morman, *supra* note 3.

<sup>85</sup>See *id.*

and death.<sup>86</sup> Under DSHEA foods marketed as dietary supplements are not subject to as strict requirements as other foods, drugs and devices.

Recently, the difficulties in regulation prompted by DSHEA have come under great fire. Some critics suggest that companies are selling functional foods as dietary supplements to avoid FDA regulation.<sup>87</sup> As of 2001, the FDA had issued only a handful of its Warning Letters to manufacturers of functional food products containing herbal ingredients that it did not believe to be GRAS for use in food.<sup>88</sup>

One important controversy in this debate is the regulation of ephedra. Prompted by recent high profile sports deaths, many have called into question the intelligence of the hands off characteristics of DSHEA. Perhaps the recent outrage over ephedra regulation will result in amendments to the provisions of DSHEA.

## **Purpose of DSHEA**

The purpose of DSHEA is to promote consumer health, to encourage preventive health measures, and to reduce national healthcare costs.<sup>89</sup> DSHEA prevents the FDA from taking restrictive regulatory actions; therefore it provides consumers with greater access to dietary supplements and information regarding their health benefits.<sup>90</sup>

The underlying premises of DSHEA are that dietary supplements are safe and that the dietary supplement

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<sup>86</sup> *See id.*

<sup>87</sup> *See* Heller, *supra* note 26, at 210

<sup>88</sup> *Id.* at 212.

<sup>89</sup> *See* DSHEA, Pub. L. No. 103-417, 2(15)(A), 108 Stat. 4325, 4326 (1994) (stating that “legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness”); *see also* DSHEA, Pub. L. No. 103-417 2(1)-(6)(B), 108 Stat. 4325, 4325-26 (1994) (noting improvements of the “health status of the United States citizens ranks at the top of the national priorities of the Federal Government,” and the reduction of long-term health care costs is paramount). *See generally*, Meghan Colloton, Comment, *Dietary Supplements: A Challenge Facing the FDA in Mad Cow Disease Prevention*, 51 AM. U.L. Rev. 495 (providing detailed discussion and analysis of DSHEA in context of potential regulation of BSE) [hereinafter Colloton].

<sup>90</sup> *See* DSHEA, Pub. L. No. 103-417, 12, 108 Stat. 4325, 4332-33 (1994); *see generally* Colloton, *supra* note 88, at 524-25.

industry will continue to produce safe products.<sup>91</sup>

DSHEA has a benevolent intent: “to provide dietary supplements that may help augment daily diets and provide health benefits to Americans.”<sup>92</sup> Prior to the enactment of DSHEA, the FDA regulated many herbal substances as food additives, restricting their availability.<sup>93</sup> With the passage of DSHEA, Congress amended the definition of dietary supplements to counteract the FDA’s regulatory practices and to make dietary supplements readily available to Americans.<sup>94</sup> Congress intended for DSHEA to meet the concerns of consumers and manufacturers and to help assure that safe and appropriately labeled products remain available to those who want to use them.<sup>95</sup>

## **Result of DSHEA**

The result of DSHEA, however, has not been so benevolent. The enactment of DSHEA has had the effect of deregulating the dietary supplement industry. Furthermore, DSHEA expanded the definition of dietary supplements to include herbs, amino acids and any other “dietary substance for use by man to supplement the diet by increasing the total dietary intake.”<sup>96</sup> As a result, the act prevents the FDA from classifying those substances as drugs.<sup>97</sup>

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<sup>91</sup> See DSHEA, Pub. L. No. 103-417, 2(14), 108 Stat. 4325, 4326 (1994) (stating that “dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare”); see also Dietary Supplement Health and Education Act: Is the FDA Trying to Change the Intent of Congress? Before the House Comm. on Government Reform, 106<sup>th</sup> Cong. 8 (1999) (opening statements of Hon. Dan Burton) (“It is more likely that you will be struck by lightning and die in this country than it is that you will die from using a dietary supplement”); see generally Colloton, *supra* note 88 at 525.

<sup>92</sup> See Tod L. Stewart, Note, *Getting High with a Little Help from the Feds: Federal Regulation of Herbal Stimulants*, J. PHARMACY & LAW 101, 101, 1996 [hereinafter Stewart].

<sup>93</sup> *Id.* at 101.

<sup>94</sup> *Id.*

<sup>95</sup> *Id.*

<sup>96</sup> 21 U.S.C. 321 (ff) (1994) (defining dietary supplement).

<sup>97</sup> See Health Research and Health Services Amendments of 1976, Pub. L. No. 94-278, sec. 501(a), 411, 90 Stat. 401, 410 (1976) (Amending the FDCA and forbidding the classification of dietary supplements as drugs); see also S. Rep. No. 103-410, at 20 (1994) (showing the need to make the definition of dietary supplements clear because of attempts by FDA to regulate

DSHEA prevents dietary supplements from being subject to the approval requirements applied to food additives.<sup>98</sup> The law also makes it more difficult for the Food and Drug Administration to remove an unsafe or potentially unsafe product from the market because DSHEA shifts the burden of proof away from the manufacturer and onto the FDA.<sup>99</sup> DSHEA requires the FDA to establish that the product “presents a significant or unreasonable risk of injury”<sup>100</sup> under ordinary use or that it poses an imminent hazard to public health or safety” before regulation can occur.<sup>101</sup>

DSHEA severely limited the FDA’s regulatory ability by placing the burden of proving dietary supplement safety on the FDA alone.<sup>102</sup> Prior to DSHEA, manufacturers of dietary supplements often bore the burden of proving that their products met safety standards.<sup>103</sup> The new standards of DSHEA decrease the likelihood of success in actions brought by the FDA against supplement manufacturers.<sup>104</sup> Additionally, under DSHEA, the FDA is not authorized to perform pre-market review or required to approve of dietary supplements.<sup>105</sup>

## **Aftermath of DSHEA**

Can the FDA, under the sharp rules of DSHEA, adequately protect consumers from possible health threats of dietary supplements?<sup>106</sup> By forbidding classification of dietary supplements as food additives and by not regulating them as drugs, DSHEA has closed two normal avenues for the FDA to determine if products are

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such supplements as drugs despite the Proxmire Amendment); *see generally* Colloton, *supra* note 88, at 525.

<sup>98</sup> *See* Heller, *supra* note 26, at 198.

<sup>99</sup> *Id.* at 199.

<sup>100</sup> 21 U.S.C. § 342(f)(1)(A)&(B).

<sup>101</sup> *Id.* § 342(f)(1)(C); *See* Gary Mihoces, *Legal Issue Murky without Tough Laws*, USA TODAY, Nov. 8, 2001, at 3C.

<sup>102</sup> *See* DSHEA, Pub. L. No. 103-417, sec. 4, 402(f)(1), 108 Stat. 4325, 4328 (1994) (“In any proceeding under this subparagraph the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated.”); *see generally* Colloton, *supra* note 88, at 527.

<sup>103</sup> *See* Colloton, *supra* note 88, at 527.

<sup>104</sup> *Id.* at 527-28.

<sup>105</sup> *See* S. Rep. No. 103-410, at 21 (1994); *see generally* Colloton, *supra* note 88, at 528.

<sup>106</sup> *See generally* Colloton, *supra* note 88 at 528 (discussing ability of FDA to protect against BSE in dietary supplements).

safe.<sup>107</sup> Furthermore, the FDA's adverse event reporting for dietary supplements is not mandatory, and it does not require supplement manufacturers to report adverse events of which they are aware.<sup>108</sup> As a result, it is estimated that less than one percent of adverse reactions to dietary supplements are reported to the FDA.<sup>109</sup>

As a practical matter, this burden on the FDA requires that the agency first build a convincing case of substantial harm to public health based on the supplement and then prevail in court before it can do anything about the product, a process that often takes years.<sup>110</sup> As a result, the agency has resorted in most cases to merely issuing public warnings about hazardous supplements.<sup>111</sup>

As a result of DSHEA, Congress removed much of the FDA's authority to regulate dietary supplements, including vitamins, minerals, and herbs as drugs. As a result manufacturers began to produce drinks like Black Lemonade, Herbal XTC, Brain Wash, Cloud 9, Euphoria, Rave Energy, Herbal Ecstasy, Ultimate Xphoria, and Legal Weed to name a few.<sup>112</sup> These products generally contain ephedra or other more controversial ingredients than those found in energy drinks like Red Bull.

There have been hundreds of reports of bad reactions, including at least 17 deaths, that may be attributed to herbal products containing ephedrine; this has caused recent legislative attempts to target herbal supplements that contain products that claim to produce a "high."<sup>113</sup> These ephedra containing products are marketed towards college students and younger people.<sup>114</sup> The manufacturers advertise the products cost effectively by using the Internet in addition to showy brochures and placements in magazines such as Penthouse, Rolling

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<sup>107</sup> See *id.* at 528-529.

<sup>108</sup> See *id.* at 530.

<sup>109</sup> See *Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and "Functional Foods*, Gen Acct. Off. Rep. No RCED-00-156, July 11, 2000, at 16-17 (citing 1999 survey in which 11.9 million consumers of dietary supplements reported some adverse reaction compared to the 2,797 reports of adverse events reported to the FDA from 1993 to 2000), available at <http://www.gao.gov/archive/2000/rc00156.pdf>; see generally Colloton, *supra* note 88, at 530.

<sup>110</sup> See Heller, *supra* note 26, at 199.

<sup>111</sup> *Id.* at 199.

<sup>112</sup> See Stewart, *supra* note 91, at 101.

<sup>113</sup> *Id.* at 102; see also *infra* Part IV.C (discussing safety of ephedra more generally).

<sup>114</sup> See Stewart, *supra* note 91, at 103.



Stone, and High Times.<sup>115</sup> The products are intended to get the buyer high: the claims that the products are safe, natural, and tested invite misuse and abuse by young people who purchase the product.<sup>116</sup> The proliferation of such products is the aftermath of DSHEA.

## 4. Health Claims

Another way for regulation of food products by the FDA has to do with the health claims or structure function claims of products. Energy drinks make claims like “giving you wings” that fly under the FDA radar because they are not specific enough to be considered as health or structure function claims.

Health claims are governed under the Nutrition Labeling and Education Act of 1990 (NLEA).<sup>117</sup> The approach of the United States to dietary supplements is unique; it is the only country to allow health claims for dietary supplements.<sup>118</sup> Whether this is a result of a more hands off approach in the United States toward business or a result of the strength of the lobbying power of makers of dietary supplements in Congress is unclear.

Manufacturers may now make health claims for foods and dietary supplements based on authoritative statements published by a scientific body of the U.S. government about the relationship between a nutrient and a disease or health related condition to which the claim refers.<sup>119</sup> However, health claims for functional foods may not be used on products that FDA has determined contain excessive levels of fat, saturated fat,

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<sup>115</sup>*Id.* at 104.

<sup>116</sup>*Id.*

<sup>117</sup>Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified as amended at 21 U.S.C. §§ 301, 321, 337, 343, 343-1, 345, 371 (1994)) (stating strict guidelines for labeling food products).

<sup>118</sup>*See* Heller, *supra* note 26, at 199.

<sup>119</sup>21 U.S.C § 343(r)(3)(C). *See* Heller, *supra* note 26, at 200.

cholesterol, sodium or other substances specified in FDA regulations.<sup>120</sup>

Health claims are not permitted for products that do not contain, prior to any nutrient addition, at least 10% of the Reference Daily Intake or Reference Daily Value of vitamin A, vitamin C, calcium, protein, or fiber per reference amount customarily consumed.<sup>121</sup> Therefore, health claims for functional soft drinks, chewing gum, bottled waters and other foods of low nutritional value would not be permitted under what has been nicknamed the “Jelly Bean Rule.”<sup>122</sup> Additionally, health claims are prohibited for both foods and dietary supplements if the claim relates to a substance that does not contribute taste, aroma, or nutritive value, or does not perform a technological function on the food itself.<sup>123</sup> This definition of the word “substance” is problematic because many herbs are not considered to be nutritional substances: they do not have nutritive value.<sup>124</sup>

Much controversy has arisen over the fine line separating structure/function claims, which do not require FDA pre-market approval, from health claims, which do require such approval.<sup>125</sup> A structure/function claim “describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, and characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function.”<sup>126</sup> Some companies make structure/function claims to avoid the rules placed on health claims.

Some commentators suggest that the FDA should require that foods making structure/function claims, similar to those making health claims, must meet specified nutrient levels.<sup>127</sup> Although Red Bull and other energy drinks do not make what are technically “health claims” like those prohibited by the Jelly Bean Rule,

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<sup>120</sup> See Heller, *supra* note 26, at 201.

<sup>121</sup> 21 C.F.R. § 101.14(e)(6). See Heller, *supra* note 26, at 201 (stating that Red Bull does not contain any of these nutrients); see generally *infra* note 58 (quoting ingredient list of Red Bull).

<sup>122</sup> See Heller, *supra* note 26, at 201.

<sup>123</sup> *Id.* at 202.

<sup>124</sup> *Id.* at 206.

<sup>125</sup> *Id.* at 206.

<sup>126</sup> *Id.* at 206.

<sup>127</sup> See Heller, *supra* note 26, at 219.

this rule does emphasize the skepticism in the food and drug market generally over claims about junk foods. Red Bull clearly carries much more in common with a soft drink than a bowl of Total. Yet, Red Bull makes claims about stimulating metabolism.<sup>128</sup>

Though “give you wings” does not approximate a structure/function claim, some of the claims on an actual can of Red Bull may be more problematic. Certainly, beyond removing Red Bull from the market or requiring warnings on the cans themselves, the FDA can make sure that the present labeling of cans of Red Bull are truthful. For example, England has challenged claims that the drink “increases metabolism” – making sure that the claims on the cans of Red Bull are truthful is an important area where regulation can be done in the US.<sup>129</sup>

## 5. So how can energy drinks be regulated in the United States?

When there are problems with the safety of foods or drugs, the FDA has several regulatory options: it can issue warnings letters about products. It can require warnings on products. It can take dangerous products off the market. It can monitor negative reports made about products, and it can issue warnings to the public about specific products. But there are many limits to what the FDA can do, specifically under the rule of DSHEA. Additionally, states may impose their own regulations on certain dietary supplements as has been done with ephedra.<sup>130</sup>

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<sup>128</sup> See Can of Red Bull (stating that Red Bull “Stimulates the metabolism”).

<sup>129</sup> See ASA Adjudication, available at [http://www.asa.org.uk/adjudications/show\\_adjudication.asp?adjudication\\_id=29616&from\\_index=show](http://www.asa.org.uk/adjudications/show_adjudication.asp?adjudication_id=29616&from_index=show) (British advertising challenge to claims made by Red Bull and responses by the company with reports regarding the effects of caffeine (not taurine) as the reason for the claims on the can regarding metabolism, alertness, and reaction speed.).

<sup>130</sup> See Vignuolo, *supra* note X, at 228; see also Morman, *supra* note 3 (stating that high schools in Burbank, California have banned the substance).

Exaggerated claims of health benefits by energy drink manufacturers and other herbal food manufacturers were so common in 2001 that the FDA issued a letter to the entire industry reminding companies they were expected to follow “longstanding legal requirements” governing food products.<sup>131</sup> Red Bull avoids the problem by staying away from ephedrine and guarana and sticking with caffeine and taurine with FDA approval.<sup>132</sup>

Pondering the possibility of FDA regulation of Red Bull and other energy drinks, one should consider the regulatory actions taken in other countries.

## **B. How does FDA’s approach to Red Bull square with regulatory approaches abroad?**

The U.S. Food and Drug Administration has not conducted any serious investigations into the safety of energy drinks. As dietary supplements, energy drinks are subject to much less stringent regulations than other foodstuffs. Abroad, however, drinks like Red Bull have been subject to more rigorous testing and controversy. Certain nations limit the locations that can sell energy drinks, including Red Bull. Other countries require warning labels on individual cans of energy drinks. Still other countries have issued national statements regarding their safety. Some countries, such as Canada, have not yet approved Red Bull for sale.<sup>133</sup> The ingredients in Red Bull may not be uniform throughout the world based on more particularized governmental restrictions.<sup>134</sup> However, the key ingredients in Red Bull, namely, sugar, taurine, and caffeine,

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<sup>131</sup> See Morman, *supra* note 3.

<sup>132</sup> *Id.*

<sup>133</sup> See *i.e.* Sweeney, *supra* note 6. (stating that Red Bull is smuggled in to Canada).

<sup>134</sup> See generally <http://www.redbull.com/faq/index.html>.

remain the same.<sup>135</sup>

The approaches to regulation and warnings on Red Bull and other energy drinks in several countries are worth note:

## **Ireland**

On November 14, 2000, an inquest was held into the death of an 18-year-old male student in Ireland.<sup>136</sup> The inquest heard evidence that the student collapsed and died during an interval at a basketball tournament. Though the jury found the death was related a rare syndrome, witnesses had described having seen the young man consume up to three cans of a stimulant drink during the tournament, and a rider to the jury verdict called for immediate research into the safety of energy drinks in the Irish market.<sup>137</sup>

The Stimulant Drinks Committee of Ireland's Food Safety Promotions Board (Safefood) reviewed Irish consumption of Red Bull in 2002.<sup>138</sup> Following their report, the board made recommendations for additional warnings on the product's label indicating that energy drinks are unsuitable for pregnant women; additionally the board found that people should be cautious when these drinks are used with alcohol and that the drink should not be used in association with sport and exercise as a thirst quencher because the drinks are unsuitable as rehydration agents.<sup>139</sup> Ireland has also conducted research into the safety of Red Bull's banner ingredient, taurine; though the effects of taurine have not been extensively researched, this Irish study found that the amino acid could have negative physical impact such as causing dilation of blood vessels around the heart.<sup>140</sup>

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<sup>135</sup> See *id.*; see generally Safefood, *supra* note 12.

<sup>136</sup> See Safefood, *supra* note 12, at 1.

<sup>137</sup> *Id.*

<sup>138</sup> See generally Safefood, *supra* note 12.

<sup>139</sup> See Dick Ahlstrom, *Stimulant Drinks Report Welcomed*, THE IRISH TIMES, Mar. 22, 2002, at 2.

<sup>140</sup> See *Red Bull Mystique*, *supra* note 38.

The intense research in Ireland over the safety of energy drinks is not an exception. Several other countries have much more real concerns about the safety of energy drinks and have looked into the products in much greater detail than has the United States.

### **Austria**

Austria, the nation where Red Bull is produced, requires stringent safety regulations on cans of the energy drink. For example, Austria is the only country where Red Bull cans are required to carry a warning on their labels against mixing the drinks with alcohol.<sup>141</sup> Furthermore, labels in Austria warn that children should not consume Red Bull.<sup>142</sup>

### **Thailand**

Likewise Thailand, the country where Red Bull was “discovered” as well as the nation where the holder of 51% of the patent of Red Bull resides, imposes certain regulations on the energy elixir. For example under regulation from the Thai Food and Drug Administration in 2003, Red Bull marketers can no longer use famous singers, sports stars or actors as presenters in TV commercials for the substance.<sup>143</sup> Furthermore, energy drink commercials must contain warnings to consumers that they should not drink more than two

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<sup>141</sup> See Sweeney, *supra* note 6.

<sup>142</sup> See Dave Newbart, The So-Called Energy Drink, One Ad Boasts, Gives You Wings, Chicago Sun-Times, Jan. 22, 2002, at 14 [hereinafter Newbart].

<sup>143</sup> See Somluck Srimalee, *Energy-drink Marketing Strategies to Take New Directions*, NATION (Thailand). Dec 19, 2002.

bottles a day.<sup>144</sup> Furthermore, the Thai government was urged by educators, senators and activists to take action preventing more children from becoming addicted to energy drinks.<sup>145</sup> The regulations in Thailand, however, demonstrate what is possible in a regulation system unlike the United States where equivalents of the FTC and the FDA are combined.

## Sweden

Sweden, too, provides for much more stringent regulation of the energy elixir than the United States. Three very public deaths occurred in Sweden that were linked to the consumption of Red Bull. Two of these deaths involved Red Bull and alcohol and the third death involved Red Bull in conjunction with exercise.<sup>146</sup> Following these deaths, Sweden's National Food Administration (NFA) issued a warning to the public: Red Bull should not be combined with alcohol or used after exertion.<sup>147</sup>

## Italy

In Italy, as a result of growing concern about the safety of Red Bull, the Italian Health Superior Council Study performed a study regarding the health effects of high levels of caffeine and taurine.<sup>148</sup> As a result of the study, the Council recommended additional labeling regarding caffeine content to advise children, pregnant

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<sup>144</sup>*Id.*; see <http://www.redbull.com/faq/index.html> (answering the question as the appropriate number of cans of Red Bull to drink per day: the answer is the same as the number of cups of coffee that someone would feel comfortable drinking).

<sup>145</sup>See *Thai Government Urged to Prevent Children From Energy Drinks*, XINHUA GENERAL NEWS SERVICE, Nov 25, 2002.

<sup>146</sup>See Cassidy, *supra* note 62.

<sup>147</sup>See *Red Bull Mystique*, *supra* note 38.

<sup>148</sup>See Safefood, *supra* note 12, at 5; *Study on Nutritional, Health and Ethical Claims in European Union* (2000), prepared by Hill & Knowlton for European Commission Directorate General for Health and Consumer Protection, at 292, *available at* <http://europa.eu.int/comm./consumers/policy/developments/envi=clai03=en.pdf>.

women, and caffeine sensitive individuals about possible dangers.<sup>149</sup> Furthermore, the study concluded that any claims on the beneficial effects of these energy drinks that cannot be adequately documented should not be included on the label.<sup>150</sup> Additionally, the Italian study recommended that exposure to alcohol and tobacco with the drinks should be avoided.<sup>151</sup>

### Australia and New Zealand

Australia and New Zealand have also instituted new rules concerning energy drinks.<sup>152</sup> Under the new standards governing the labeling of stimulant drinks, they must carry advisory statements that the products contain caffeine and are not recommended for children, for pregnant or breastfeeding women or for individuals who are sensitive to caffeine.<sup>153</sup> Despite these warnings in New Zealand and Australia, these countries have found no scientific link between the consumption of energy drinks and adverse health effects.<sup>154</sup>

### **Other Studies of Safety of Red Bull and Energy Drinks**

The negative effects of Red Bull may be different for different age levels of the population. A study in the European Union concluded that the caffeine levels found in Red Bull and other energy drinks were not suitable for children.<sup>155</sup> In February 2002, European Union member states agreed to change labeling

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<sup>149</sup>See *Study on Nutritional, Health and Ethical Claims in European Union* (2000), prepared by Hill & Knowlton for European Commission Directorate General for Health and Consumer Protection, at 292, available at <http://europa.eu.int/comm/consumers/policy/developments/envi=clai03=en.pdf>.

<sup>150</sup>See Safefood, *supra* note 12, at 5.

<sup>151</sup>*Id.*

<sup>152</sup>Australian and New Zealand Food Standards Council, Standard 2.6.4. (2001), available at <http://www.anzfa.gov.au/foodstandardscodecontents/standard264.cfm>.

<sup>153</sup>*Id.*

<sup>154</sup>See Safefood, *supra* note 12, at 6.

<sup>155</sup>2002 O.J. L. 191, European Commission Directive 2002/67/EC of 18 July 2002 on the labeling of foodstuffs containing quinine, and of foodstuffs containing caffeine, Art. 2, § 1 (“Where a beverage which is intended for consumption without modification, or after reconstitution of the concentrated or dried product, contains caffeine, from whatever source, in a proportion



regulations and require drinks with caffeine contents greater than 150mg.l to carry special labels.<sup>156</sup> These drinks must be labeled “high caffeine content” and the amount of caffeine present must be stated; this new regulation goes into effect in July 2004.<sup>157</sup> Labels of Red Bull and other energy drinks – as well as soft drinks – in the United States do not normally contain any indication on the label of the exact amount of caffeine they contain.<sup>158</sup>

Other countries, including Denmark, Norway and France place limitations on the sale of energy drinks; all three countries limit the sale of Red Bull to pharmacies where the purchasers of the drink are more likely more monitored.<sup>159</sup> France, in addition, has commissioned studies about the substances present in Red Bull, namely taurine and glucuronolactone; these studies concluded that they could not guarantee with certainty that the substances contained within the product did not present any health risks.<sup>160</sup> In Greece, health officials recommended in July 2002 that it should not be mixed with alcohol or used in conjunction with exercise.<sup>161</sup>

### **Less Restrictive Countries**

The news for manufactures of Red Bull and other energy drinks is not all bad. Other countries view any threat posed by Red Bull as minor. For example, the Food Standards Agency of Great Britain issued a

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in excess of 150 mg/l, the following message must appear on the label in the same field of vision as the name under which the product is sold: High caffeine content); *see generally* Newbart, *supra* note 142.

<sup>156</sup> *See* Newbart, *supra* note 142.

<sup>157</sup> *Id.*; *see generally* Safefood, *supra* note 12, at *iv*.

<sup>158</sup> *See infra* Part IV.A (regarding regulations on caffeine generally).

<sup>159</sup> *See* Walker, *supra* note 2; Sweeney, *supra* note 6 (stating Red Bull is banned from all other shops and classified as a medicine); *See generally* *Death Spur Study into Red Bull*, THE EVENING POST (Wellington). July 13, 2001, § N, at 3 [hereinafter *Death Spur*].

<sup>160</sup> *See* Safefood, *supra* note 12, at 5; Agence Francaise de Securite Sanitaire des Aliments (2001). AFSSA Opinion on Stimulant Drinks, available at <http://www.afssa.fr/ftp/basedoc/2000SA0191.pdf>.

<sup>161</sup> *See* Henning, *supra* note 60.

statement upholding the safety of Red Bull when consumed by adults in moderation.<sup>162</sup> A commission meeting of the members of the Food Standards Agency (Great Britain, France, Germany, the Netherlands, France, Denmark, Italy, Greece) view energy drinks as normal foodstuffs.<sup>163</sup> The agencies of other countries that play roles similar to the U.S. Food and Drug Administration, such as New Zealand's Ministry of Health, have issued statements that they are monitoring the overseas investigation into Red Bull.<sup>164</sup> Currently there is no European Union legislation pertaining specifically to stimulant drinks; like other soft drinks, they are subject to general EU labeling directives and applicable horizontal legislation.<sup>165</sup>

Foreign regulations and warnings regarding energy drinks, as well as government sponsored studies regarding the safety and efficacy of the significant ingredients of Red Bull and other energy drinks, are a large contrast to the approach to regulation of energy drinks in the United States. These regulations illustrate a potential need for FDA involvement with the energy drink market. Furthermore, these regulations call into question the intelligence of the stringent prohibitions of regulation of dietary supplements under DSHEA. Additionally, these foreign regulations as well as the combined research of the European Union, suggest that in the increasingly global economy, the FDA may be able to learn a lot from the regulations imposed by other nations. However, the foreign regulations also illustrate cultural differences that may guide the regulatory regimes of these countries: the United States may prefer to leave decisions regarding the propriety of energy drinks to the consumer and to refrain from legislating regarding improper uses of a product.

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<sup>162</sup>Statement on Red Bull, British Food Standards Agency, July 12, 2001, *available at* <http://www.foodstandards.gov.uk/news/pressreleases/redbullstate> ("Independent scientific experts have looked at the safety of energy drinks such as Red Bull. Based on current evidence The Food Standards Agency believes they are as safe as any other drinks for adults to consumer in moderation. Red Bull, in line with the Agency's recommendation, does carry a label informing people who may be sensitive to caffeine about its caffeine content. If the investigations by the Swedish authorities reveal any new information about Red Bull and the safety of its consumption the Food Standards Agency will review its position. Energy drinks like other foods must be safe and comply with the provisions of the Food Safety Act of 1990.").

<sup>163</sup>*Id.*

<sup>164</sup>*See Death Spur, supra* note 134.

<sup>165</sup>*See Safefood, supra* note 12, at 4.

## IV. A Deeper Look Into the Ingredients of Energy Drinks

Red Bull gains its energy producing qualities mainly from two ingredients: sugar and caffeine. Additionally, the product significantly touts the value of one additive: taurine. This section will first examine the efficacy and safety of the caffeine and taurine in Red Bull and other energy drinks. Additionally, this section will briefly examine another nutritional additive to energy drinks that has been the subject of more controversy: ephedra or ma huang.

### A. Regulation of Caffeine

Much of the “lift” provided by energy drinks such as Red Bull is actually based upon the effect of the caffeine and sugar rather than on the much-touted nutritional additives like taurine.<sup>166</sup> Even Red Bull, in the face of questions regarding the efficacy of its labeling claims, admits that caffeine is the key ingredient regarding greater alertness and other emphasized features of the drink.<sup>167</sup>

Caffeine is frequently described as the most widely used psychoactive substance in the world: it is also one of the most comprehensively studied food ingredients.<sup>168</sup> Surely, Americans have long relied on the pick-me up quality of caffeine through the ingestion of coffee, tea, and soda. So what are the real effects of caffeine?

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<sup>166</sup>See generally Gwendolyn Prothro, *The Caffeine Conundrum: Caffeine Regulation in the United States*, 27 CUMB. L. REV. 65 (1996/1997) (detailing regulation of caffeine by the Food and Drug Administration, its history as a GRAS substance, and its potential negative effects and recommending that products containing caffeine have labels that detail the amount of caffeine in the product in terms of the number of cups of coffee that would be equivalent).

<sup>167</sup>See ASA Adjudication, available at [http://www.asa.org.uk/adjudications/show\\_adjudication.asp?adjudication\\_id=29616&from\\_index=sho](http://www.asa.org.uk/adjudications/show_adjudication.asp?adjudication_id=29616&from_index=sho) (regarding British advertising challenge to claims made by Red Bull and responses by the company with reports regarding the effects of caffeine (not taurine) as the reason for the claims on the can regarding metabolism, alertness, and reaction speed.).

<sup>168</sup>See Safefood, *supra* note 12, at 9.

Caffeine raises the heart rate and blood pressure.<sup>169</sup> Although caffeine is regarded as only mildly addictive and safe in all but extremely high doses, some evidence suggests that in the long term it can be a contributing factor in high blood pressure and heart disease.<sup>170</sup> Other side effects of caffeine include nervousness and headaches.<sup>171</sup> Some studies show that caffeine may boost athletic performance briefly; however, it is unlikely to help the casual athlete.<sup>172</sup> Because caffeine is a diuretic, it can interfere with the absorption of water or even force the drinker to need to take a bathroom break.<sup>173</sup>

Additionally, high caffeine consumption has been linked to pregnancy problems, osteoporosis, insomnia and other ailments.<sup>174</sup> Despite the great number of adverse effects of caffeine, it is often difficult for consumers to know how exactly much caffeine they are getting in different foods or drinks.<sup>175</sup> The amount of caffeine in a can of Red Bull is not listed on the can; the information, however, is found on the website.<sup>176</sup> In the abstract the number of milligrams of caffeine in a product may not be all that useful; a consumer may find a comparison of the amount of caffeine in a substance with the amount of caffeine in a cup of coffee to be more useful.<sup>177</sup>

The FDA does not regulate the amount of caffeine in sodas, but it considers a caffeine level of .02 percent by volume or 68 milligrams in 12 ounces to be safe.<sup>178</sup> Caffeine is regulated as a drug when it is in a form like

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<sup>169</sup> *Death Spur*, *supra* note 134.

<sup>170</sup> *See* Dowling, *supra* note 1.

<sup>171</sup> *See* Sweeney, *supra* note 6.

<sup>172</sup> *Id.*

<sup>173</sup> *Id.*

<sup>174</sup> *See* Morman, *supra* note 3.

<sup>175</sup> *Id.*

<sup>176</sup> *See* can of Red Bull; *see also* <http://www.redbull.com/product/history/index.html>.

<sup>177</sup> *See generally* Prothro, *supra* note 166 (suggesting that foods containing caffeine should be labeled with their caffeine content, listed in terms comparing the content to a certain number of cups of coffee).

<sup>178</sup> *Id.*

No Doz.<sup>179</sup> These pills carry a warning that they contain as much caffeine as a certain amount of cups of coffee, a warning that some suggest should be on all caffeinated products.<sup>180</sup>

Caffeine is a GRAS substance, meaning that it is *generally recognized as safe* by the Food and Drug Administration.<sup>181</sup> In 1987, an attempt to remove caffeine from the GRAS list was unsuccessful; even had caffeine been removed from the GRAS list, its use in soft drinks would have been acceptable as a prior sanction.<sup>182</sup>

The lack of concern over caffeine consumption in the United States is evident in the marketing of Stay Alert Caffeine Supplement Gum. The company labeled the product as a dietary supplement, even though the name of the product includes the name of a conventional food, gum, and even though the product looks like and is marketed in stores next to other chewing gums.<sup>183</sup> Though caffeine is approved for food use only in cola-type beverages<sup>184</sup> and is otherwise considered a drug covered by FDA regulations for nonprescription stimulants,<sup>185</sup> the FDA has taken no enforcement action related to Stay Alert gum.<sup>186</sup> The FDA's approach to this gum demonstrates the pervasiveness of caffeine in American culture as well as the premise that it is safe.

Though adults in the United States consume it in abundance, caffeine may pose special problems when guzzled by children or pregnant women or when it is consumed with alcohol.

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<sup>179</sup>21 C.F.R. § 340.10; *See also* Prothro, *supra* note 166.

<sup>180</sup>*See generally* Prothro, *supra* note 166.

<sup>181</sup>21 CFR 182.1180

(“§ 182.1180 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.”).

<sup>182</sup>52 Fed Reg 18,923, May 20, 1987.

<sup>183</sup>*See* Heller, *supra* note 26, at X.

<sup>184</sup>21 C.F.R. § 182.1180.

<sup>185</sup>*Id.* § 340.10

<sup>186</sup>*See* Heller, *supra* note 26, at 212.

### **Caffeine and Children**<sup>187</sup>

There is conflicting data regarding the safety of caffeine consumption by children. Caffeine in excessive levels appears to cause subjective effects such as nervousness, jitteriness, stomachaches and nausea in children who normally consumed little caffeine.<sup>188</sup>

### **Caffeine and Pregnancy**

Furthermore, caffeine is thought to be dangerous for women who are pregnant and nursing; as a result, some countries require warning labels on Red Bull regarding use of the product by pregnant women.<sup>189</sup>

### **Caffeine and alcohol**<sup>190</sup>

Coffee and other caffeinated drinks have traditionally been consumed following or in combination with alcohol intake; many people believe that caffeine can ameliorate some of the effects of alcohol or that it has a potential sobering effect.<sup>191</sup> There is some research on the “acute behavioral and cardiac effects” of alcohol and caffeine, administered alone and in combination in humans.<sup>192</sup> When given in combination with alcohol, caffeine partially decreases the disruptive behavioral effects of alcohol; however, this combination does not

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<sup>187</sup>See *infra* Part V.C (discussing consumption of Red Bull and other energy drinks by children).

<sup>188</sup>See Safefood, *supra* note 12, at 13.

<sup>189</sup>See Australian and New Zealand Food Standards Council, Standard 2.6.4. (2001), *available at* <http://www.anzfa.gov.au/foodstandardscodecontents/standard264.cfm>.

<sup>190</sup>See *infra* Part V.A (discussing in detail use of Red Bull and other energy drinks in combination with alcohol).

<sup>191</sup>See Safefood, *supra* note 12, at 14.

<sup>192</sup>*Id.*

significantly alter breath alcohol levels or heart rate levels of those who ingested both caffeine and alcohol.<sup>193</sup> Red Bull’s promotional brochure in Ireland states: “Red Bull does not contain alcohol, but there is no reason why it shouldn’t. Adding alcohol to Red Bull does not change Red Bull’s properties.”<sup>194</sup> This suggests that Red Bull manufacturers do not believe there are any concerns regarding combining high caffeine content with alcohol.

Caffeine, however, is not the ingredient in Red Bull or other energy drinks that is emphasized as the “energy-giving” component.

## B. Red Bull: Taurine

### **Taurine: What does it do?**

Gazing at the front of a can of Red Bull, one cannot help but think that the “energy” of this “energy drink” comes from taurine. Of all its ingredients, only taurine is featured on the front of the can: “With taurine. Vitalizes Body and Mind.”<sup>195</sup> None of the other ingredients, for example caffeine or sugar or glucuronolactone, is mentioned until the ingredients list on the back of the can. With this prime billing, comes the question: What is taurine?

The name of the herbal substance itself probably provides the motivation for the name of the product Red Bull. In fact, the similarity between taurine and “Taurus” may have helped fuel popular rumors as to its

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<sup>193</sup> *Id.*

<sup>194</sup> *Id.* at 44.

<sup>195</sup> *See* Can of Red Bull.

makeup. Taurine has been rumored to contain bull semen,<sup>196</sup> bull urine,<sup>197</sup> bull testicles<sup>198</sup> and even bull testosterone.<sup>199</sup> None of these rumors about the make up of taurine is true, though they make good publicity – creating an aura of mystique and shaping the drink as an aphrodisiac that brings to its drinker the powers of the bull.<sup>200</sup>

However, taurine probably gets its bull related name from its discovery: in 1827 in ox bile<sup>201</sup> or because it is found in cattle.<sup>202</sup> Taurine is also found naturally in most meat and dairy products<sup>203</sup> as well as in breast milk,<sup>204</sup> though the taurine in Red Bull is synthetic.<sup>205</sup> Taurine is a nonessential or “conditionally essential” amino acid that is naturally synthesized by the body.<sup>206</sup> The substance is a building block of protein which some consider beneficial in small doses.<sup>207</sup> Additionally, taurine may act as a metabolizer during periods of high physical activity.<sup>208</sup>

However, the exact long-term effects of large doses of taurine, like other herbal additives to energy drinks, are unknown.<sup>209</sup> The label of a Red Bull can does not indicate the amount or the concentration of the substance in the drink. By one estimate, a can of Red Bull contains the same amount of taurine as 500 glasses of red wine.<sup>210</sup> Taurine is normally found in small amounts, like 35 milligrams in a dinner-size portion of meat.<sup>211</sup> Red Bull, however, does not disclose the amount of taurine used per can nor its concentration on its ingredient list; but the amount is listed on the website as 1000 milligrams.<sup>212</sup> There are no studies

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<sup>196</sup> See *Red Bull Mystique*, *supra* note 38; Crockett, *supra* note 41; Walker, *supra* note 2.

<sup>197</sup> See Walker, *supra* note 2; Crockett, *supra* note 41.

<sup>198</sup> See Dowling, *supra* note 1; Sweeney, *supra* note 6.

<sup>199</sup> See *Red Bull Mystique*, *supra* note 38; Walker, *supra* note 2.

<sup>200</sup> See *Red Bull Mystique*, *supra* note 38; Crockett, *supra* note 41.

<sup>201</sup> See Crockett, *supra* note 41.

<sup>202</sup> See Sweeney, *supra* note 6.

<sup>203</sup> See *id.*; Crockett, *supra* note 41.

<sup>204</sup> See *Red Bull Mystique*, *supra* note 38.

<sup>205</sup> See Dowling, *supra* note 1.

<sup>206</sup> *Id.*

<sup>207</sup> See *Death Spur*, *supra* note 134.

<sup>208</sup> See Henning, *supra* note 60.

<sup>209</sup> See Berggoetz, *supra* note 39.

<sup>210</sup> See *Debate Brewing Over Safety of ‘Energy Drinks’* USA TODAY, Dec. 12, 2001, available at <http://www.usatoday.com/news/health/diet/2001-12-20-energy-drinks.htm> [hereinafter *Debate Brewing*].

<sup>211</sup> Crockett, *supra* note 41.

<sup>212</sup> See <http://www.redbull.com/product/ingredients/ingredients03.html> (indicating that a can of Red Bull contains 1000 mg



regarding the effects of this amount of taurine on the body.<sup>213</sup>

Though few studies exist regarding taurine, an Irish study in 2000 found that the amino acid could dilate blood vessels around the heart.<sup>214</sup> The Red Bull website claims that taurine may increase alertness and mental performance, but no conclusive evidence exists to verify this claim.<sup>215</sup> A professor at Syracuse University further states that there is no evidence that taurine will do *anything* for you.<sup>216</sup> Additionally, a British study into the safety of Red Bull found insufficient scientific evidence to set of upper safe limits for levels of taurine in energy drinks or to support a ban on the use of these ingredients.<sup>217</sup> Because of a lack of research in this area, no consensus has been reached as to taurine's safety or its effects on the body. Though little is known about taurine and its effects on the body, even less is known about the effects of taurine when it is combined with caffeine as in Red Bull or when combined with alcohol<sup>218</sup> – a frequent choice of imbibers of the elixir.

A spokesperson for Red Bull says that in times of stress your taurine levels are depleted and that Red Bull replaces them.<sup>219</sup> However, there is no meaningful evidence that boosting taurine levels has any impact on your physical or mental performance.<sup>220</sup> The Red Bull spokesperson admits that taurine alone will not give the same “kick” as Red Bull: the key, according to the manufacturer, is the combination of taurine, the caffeine, and glucuronolactone, a carbohydrate.<sup>221</sup> Taurine alone is touted on the front of the Red Bull can; yet taken alone, taurine would have little effect on the “energy” of the person who ingested it.

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of taurine).

<sup>213</sup> See Crockett, *supra* note 41; see generally section *infra* (discussing DSHEA and regulation of taurine).

<sup>214</sup> See *Red Bull Mystique*, *supra* note 38.

<sup>215</sup> See McDonald, *supra* note 5.

<sup>216</sup> See Crockett, *supra* note 41.

<sup>217</sup> See *Energy Drinks Follow-Up Letter*, Food Standards Agency, UK, Mar. 21, 2002. Available online at <http://www.foodstandards.gov.uk/multimedia/webpage/energydrink2> [hereinafter *Follow-Up Letter*]

<sup>218</sup> See Berggoetz, *supra* note 39; Safefood, *supra* note 12, at 19.

<sup>219</sup> See Walker, *supra* note 2.

<sup>220</sup> *Id.*

<sup>221</sup> *Id.*

Under stimulant drink intake at the maximum level of suggested intake of Red Bull,<sup>222</sup> a drinker of the product would consume levels of taurine far in excess of that from other foods or beverages in the diet. While limited, the data available indicates no evidence of adverse effects of taurine at such intakes. For example, a recent report the EU Scientific Committee for Food (SCF) was unable to conclude that the “safety-in-use” of taurine in the concentration range reported for stimulant drinks has been adequately established; the committee concluded that further research into taurine is required.<sup>223</sup>

Certain evidence indicates that during times of severe stress, such as during intense physical exercise, the stores of the amino acids become depleted.<sup>224</sup> However, under normal physiological circumstances, taurine is very highly conserved in the adult human body and is present in large quantities.<sup>225</sup>

There is little evidence to suggest that taurine results in any sort of risk to human health at normal levels or patterns of consumption; however, there are no published studies of the effects of high intakes of taurine in healthy adults, and no studies at all in children or adolescents.”<sup>226</sup>

### **C. Compare with other substances found in energy drinks**

Energy drinks contain any variety of natural products in addition to the requisite caffeine and sugar. The ingredient lists of some energy drinks read as a veritable catalog of nutritional supplements, including such products as ginkgo biloba, ginseng, and kava kava.<sup>227</sup> One of the most controversial additives to energy drinks is ephedra: ephedra has been under increasing scrutiny as its use as an energy supplement that is popular with athletes has resulted in very publicized deaths.<sup>228</sup> One example of an energy drink containing

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<sup>222</sup> See <http://www.redbull.com/faq/index.html> (regarding recommended level of intake).

<sup>223</sup> See Safefood, *supra* note 12, at vi.

<sup>224</sup> *Id.* at 17.

<sup>225</sup> *Id.* at 17.

<sup>226</sup> *Id.* at 17.

<sup>227</sup> See Barnes, *supra* note 7.

<sup>228</sup> See also *infra* Part III.A (regarding US regulation of energy drinks).

ephedra is Ripped Force, which is sold at General Nutrition Stores and advertised as allowing the consumer to “thunder through your workouts.”<sup>229</sup>

Ephedra is an herbal extract marketed as an alternative, legal method of obtaining a drug-like high.<sup>230</sup>

Ephedra is known as ma huang; it is a Chinese herb that acts on the central nervous system in the same manner as a stimulant.<sup>231</sup> Ephedra products, marketed as alternatives to illegal street drugs, contain labels stating that the substance will produce effects similar to those illegal drugs.<sup>232</sup>

The FDA claims that the restrictions of DSHEA are responsible for their weakened reaction to the ephedra street drug crisis.<sup>233</sup> The FDA issued a public statement warning consumers of the dangers of botanical ephedrine. Additionally, several states have responded to the dangers of the product by enacting anti-ephedrine laws.<sup>234</sup> Placing the burden of proof on the FDA under DSHEA has had a detrimental impact on FDA’s attempts to regulate the marketing of ephedra, including its marketing in energy drinks, as an alternative to street drugs.<sup>235</sup>

On Feb. 28, 2003, federal officials proposed tough new labels today to warn consumers that ephedra could cause heart attack, stroke and death.<sup>236</sup> They also ordered 24 companies to stop advertising ephedra use as a way to build muscles or enhance athletic performance, saying there was no scientific evidence for the claim.<sup>237</sup>

The government has received more than 16,000 reports suggesting possible links between the use of ephedra and “adverse events” including strokes, heatstroke, heart arrhythmia and psychotic episodes.<sup>238</sup> Federal officials said the reports indicated that more than 100 people had died after using ephedra, although other

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<sup>229</sup> See Barnes, *supra* note 7.

<sup>230</sup> See Vignuolo, *supra* note 115, at 201; See also Part III.A.3 (regarding DSHEA and the blocks it places on the regulation of dietary supplements).

<sup>231</sup> See Vignuolo, *supra* note 115, at 201.

<sup>232</sup> *Id.* at 202; see also link to other portions of the paper focusing on ephedra

<sup>233</sup> See Vignuolo, *supra* note 115, at 227.

<sup>234</sup> *Id.* at 228

<sup>235</sup> *Id.* at 231

<sup>236</sup> See Robert Pear with Denise Grady, *Government Moves to Curtail the Use of Diet Supplement*, NEW YORK TIMES. March 1, 2003, at A1 [hereinafter Pear].

<sup>237</sup> *Id.*

<sup>238</sup> *Id.*

factors may have been involved in some cases.<sup>239</sup> Officials said they were not banning ephedra immediately because they wanted to obtain more evidence to show that it posed an “imminent hazard” or at least a significant, unreasonable risk of injury, the standards established by the Dietary Supplement Health and Education Act.<sup>240</sup> If it finds that no ephedra products can meet the tough standards established by DSHEA, then the FDA may ask Congress to revise the law to allow them the ability to sanction ephedra marketers.<sup>241</sup>

An examination of the main ingredients in Red Bull, namely caffeine and taurine, does not provide clear evidence of any potential harm because of energy drink consumption. Those energy drinks with other components such as ephedra pose a much more significant danger to consumers. In light of other worse ingredients in energy drinks like Ripped Force that contain ephedra, the likelihood of FDA concern or review of less imposing Red Bull seems unlikely; however, if consumer outrage over ephedra related deaths results in a Congressional response, then energy drinks may face increasing regulation.

## V. Specific Uses of Energy Drinks – Are They Safe?

The three most significant components of Red Bull are sugar, caffeine and taurine. Such ingredients are also typical of other energy drinks. While each of these substances regularly occurs in the American diet, the question arises whether the product is safe in regards to its most popular and recommended uses. This section will examine the safety of Red Bull

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<sup>239</sup> *Id.*

<sup>240</sup> *Id.*

<sup>241</sup> *See* Pear, *supra* note 236.

in three areas. First, it will examine the safety of Red Bull when used in combination with alcohol or other drugs. Second, it will discuss the safety of use of Red Bull and other energy drinks in conjunction with sports or exercise. Third, it will examine the propriety of use of Red Bull by children and adolescents. These are the three areas in which foreign regulation over the propriety of energy drinks is most often present. Finally this section will examine how advertising related to Red Bull pertains to each of these three categories.

#### A. Red Bull and Alcohol and Other Drugs:

Known by names such clever names as a “Friday Flattener,”<sup>242</sup> Red Bull and vodka has become a popular drink for bar and club patrons alike. The study conducted in 2002 by the Irish Stimulant Drinks Committee found that the most regularly named places of consumption of Red Bull or other energy drinks were pubs and clubs.<sup>243</sup> In some drinking establishments, the Red Bull manufacturer provides a logoed mini refrigerator to stock with cans of its elixir in the clear view of customers.<sup>244</sup> Yet following public deaths in Sweden related to consumption of Red Bull and alcohol,<sup>245</sup> the safety of the mixed drink has been questioned.

The Red Bull and vodka concoction is favored by bar patrons looking to dance all night – those seeking the energy to party for several hours. Such use has probably fueled popular street names for Red Bull such as liquid speed or liquid crack or liquid cocaine and a reputation for the mixture as a kind of legal speed.<sup>246</sup> Rumors circulating about the ingredients of Red Bull, such as taurine as an aphrodisiac, also may help to fuel its popularity as a mixer.<sup>247</sup>

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<sup>242</sup> See *Red Bull Mystique*, *supra* note 38.

<sup>243</sup> See Safefood, *supra* note 12, at *v.*

<sup>244</sup> See Sweeney, *supra* note 6.

<sup>245</sup> See McDonald, *supra* note 5 (stating that Red Bull denies any connection between its product and these deaths).

<sup>246</sup> *Id.*

<sup>247</sup> *Id.*

Mixing drinks laden with caffeine with others containing alcohol is no new phenomenon. Irish coffee, rum or whisky and coke, and Long Island Iced teas remain popular fixtures at any drinking establishment.<sup>248</sup> After a day at work, many happy hour patrons seek a jolt of caffeine along with their alcohol depressant. Furthermore, coffee has frequently, though ineffectively, been used as a method to sober up after a night of hard drinking, and some drinkers use Red Bull for this purpose.<sup>249</sup> Despite the popularity of the combination of the stimulant caffeine with the depressant alcohol, the question remains: is the combination safe?

The Irish study into the safety of energy drinks specifically addressed the issue of energy drink consumption in conjunction with alcohol. The study of consumption patterns demonstrated that drinks like Red Bull were frequently consumed with alcohol, particularly vodka.<sup>250</sup> The study also found that little information exists regarding any on possible interactions between alcohol and the ingredients of stimulant drinks, such as caffeine and taurine, when these concoctions are consumed at the relatively high levels observed with some of the regular patrons of the mixed drink.<sup>251</sup> The study recommends that the absence of the research in this area warrants investigation into the effects on humans, particularly under conditions at nightclubs when such drinking normally occurs: during exercise and the consequent dehydration through sweating.<sup>252</sup>

Other information collected through the Irish study suggests that use of stimulant drinks like Red Bull may contribute to increased alcohol consumption.<sup>253</sup> For example, the study showed that some individuals consume stimulant drinks to ‘perk’ themselves up if they had had too much to drink; consuming the stimulant drink with alcohol enabled the patrons to drink more in an evening.<sup>254</sup> Such use of stimulant drinks may contribute to increased alcohol consumption. While manufacturers of stimulant drinks assert that they do

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<sup>248</sup> See Crockett, *supra* note 41.

<sup>249</sup> See Safefood, *supra* note 12, at *v*.

<sup>250</sup> *Id.* at *vii*.

<sup>251</sup> *Id.*

<sup>252</sup> *Id.*

<sup>253</sup> *Id.*

<sup>254</sup> See Safefood, *supra* note 12, at *vii*.

not encourage the consumption of the drinks with alcohol, says the Irish study, some of the promotional materials and information supplied by the manufacturers are ambiguous with regard to this and “appear to ostensibly promote the use of stimulant drinks with alcohol.”<sup>255</sup>

Because of the frequency of usage of energy drinks in conjunction with alcohol, there is large concern that the resulting behavior from the combination may be increased aggression, as well as increasing the ability of individuals to drink alcohol for longer periods of time.<sup>256</sup> The ability to drink alcohol over a greater time period causes additional concern because this may facilitate in individuals consuming larger quantities of alcohol and therefore facilitate alcohol poisoning or achievement of very dangerous blood alcohol concentrations.<sup>257</sup> According to the Irish study, there are no published reports regarding the health effects of the consumption of stimulant drinks with alcohol.<sup>258</sup>

Of all the concerns regarding the safety of energy drinks, their use as mixers with alcohol may create the most dangers. Doctors and health administrators cite several concerns regarding the mixture of energy drinks such as Red Bull with alcohol. For example, the caffeine effect of the Red Bull can mask the effects of alcohol such as drowsiness and keep people conscious for longer than they would be with just alcohol.<sup>259</sup> This in turn could lead drinkers into a false sense of security: they could then get behind the wheel or continue to drink to a level of alcohol poisoning. Therefore, the combination of alcohol and Red Bull or other energy drinks may cause those who imbibe to do more injury to both themselves and also to others.<sup>260</sup>

Additionally, health experts worry about the mixture of alcohol and caffeine because both substances are

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<sup>255</sup> *Id.*

<sup>256</sup> *Id.* at 25.

<sup>257</sup> *Id.*

<sup>258</sup> *Id.*

<sup>259</sup> See Dowling, *supra* note 1.

<sup>260</sup> *Id.*

diuretics – the combination will lead to dehydration if not consumed in combination with water or other electrolyte producing sports drinks.

Furthermore, environments where partiers are seeking to dance all night such as raves are often locations where other drugs are consumed.<sup>261</sup> For example, ecstasy is considered by many to be a rave drug. Red Bull and other energy drinks are very popular within rave culture where all night partying is the norm.<sup>262</sup> The effects of caffeine or taurine in conjunction with ecstasy – and the vast array of illegal substances that it may contain – are not known, and a study of the effects is unlikely.

Spokespersons for Red Bull do not advocate using Red Bull as a mixer; nor do orange juice manufacturers or the Coca-Cola Company promote use of their products with alcohol. However, such mixtures are bound to happen and, according to Red Bull, are completely safe.<sup>263</sup> Red Bull spokespersons also emphasize the propriety of serving Red Bull in drinking establishments where it can serve as a great alternative to alcohol for designated drivers or others who do not wish to drink but do need energy to make it through the night.<sup>264</sup> Furthermore, the Red Bull manufacturer emphasizes that although bars and clubs do purchase significant quantities of Red Bull, the biggest purchasers of the drinks are still convenient stores.<sup>265</sup>

While it is true that coffee and soda have long been mixed with alcohol, Red Bull and other energy drinks carry unique dangers. Coffee, unlike energy drinks cannot be chugged down several at once as many consumers do with Red Bull and vodka; it is also not a popular drink with club goers. Furthermore, sodas are regulated as foodstuffs by the FDA rather than as dietary supplements like energy drinks. Energy drinks contain herbal substances that have not been tested in conjunction with alcohol.

Even if Red Bull and alcohol cocktails may provide some negative consequences, is this in itself a reason

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<sup>261</sup> See <http://www.redbullmusicacademy.com> (regarding Red Bull's Red Bull Music Academy devoted to electronic music, the type of music played at raves and in some dance clubs).

<sup>262</sup> See Sweeney, *supra* at note 6 (stating that Red Bull keeps you alert and able to dance); see also Bergoetz, *supra* note 39.

<sup>263</sup> See Crockett, *supra* note 41 (quoting Red Bull representative).

<sup>264</sup> *Id.*

<sup>265</sup> See Morman, *supra* note 3 (noting that though Red Bull may not push its use as a mixer, it is routinely sold next to vodka in liquor stores; though Red Bull may not be behind this set up, they are clearly aware this is going on and could change it if they desired).



for further regulation? Alcohol itself can cause many adverse consequences: passing out, physical injury, alcohol poisoning, drunk driving accidents, and even death; alcohol already faces strict regulations from the government. Therefore, increased regulation of a product that has harmful effects when combined with alcohol may be futile. Furthermore, the very fact of advertising the danger of Red Bull with alcohol would likely encourage some to mix the two products.<sup>266</sup>

Though the verdict regarding the propriety of mixing Red Bull and other energy drinks with vodka or other types of alcohol or drugs such as ecstasy is still out, this type of consumption likely raises the greatest number of concerns about energy drinks. However, just because Red Bull may be dangerous in certain contexts does not necessarily provide the justification for warning labels or keeping it off of the market.

## **B. Red Bull and Athletics and Exercise**

Though Red Bull is touted as a performance enhancing drink that will vitalize body and mind, it is an inappropriate drink for exercise or athletics unless it is consumed in conjunction with other hydrating substances. Energy drinks, unlike athletic drinks such as Gatorade, do not contain potassium or electrolytes, the amino acids that are depleted when the body sweats from vigorous exercise.<sup>267</sup> Furthermore, the caffeine found in energy drinks such as Red Bull increases thirst: fitness trainers and dieticians caution against using caffeine for workouts because it overstimulates heart muscles.<sup>268</sup>

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<sup>266</sup> See *infra* Part VI (discussing how warnings may sometimes encourage dangerous behavior).

<sup>267</sup> See McDonald, *supra* note 5; see also section x of the paper regarding difference between sports and energy drinks.

<sup>268</sup> See McDonald, *supra* note 5.

On its website, Red Bull is touted as increasing physical endurance, stimulating metabolism and increasing concentration and reaction speed.<sup>269</sup> Red Bull is said to be appropriate for increased energy or concentration.<sup>270</sup> However, the web site also goes on to acknowledge that Red Bull is not a suitable fluid replenishing drink.<sup>271</sup>

Despite the unsuitability of the product for fluid replacement in athletes, the Red Bull manufacturer makes a name for itself through its sponsorship of new extreme sports. Red Bull hosts events such as kite-boarding and free-ride snowboarding competitions to attract a youthful demographic.<sup>272</sup> However, Red Bull would be an inappropriate drink for use by these athletes who need to maintain electrolyte levels to perform at their best athletically.

When used with exercise, Red Bull makes the heart race and dehydrates the body because of its high caffeine content.<sup>273</sup> Additionally, taurine may act as a metabolizer during periods of high physical activity.<sup>274</sup>

The Irish report on energy drinks also tackled the potential problem of the combination of the drinks with

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<sup>269</sup> See <http://www.redbull.com/product/effects/effects01.html>

(“What Are the Effects of Red Bull Energy Drink?”)

- Increases physical endurance
- Increases concentration and reaction speed
- Improves vigilance
- Stimulates metabolism

Red Bull Energy Drink is an energizer, developed particularly for periods of mental and physical stress and strain. It can be drunk in virtually any situation: during sports, at work, whilst driving and in leisure activities.”).

<sup>270</sup> <http://www.redbull.com/faq/faq03.html> (“Frequently Asked Questions about Red Bull.

When Should Red Bull Energy Drink be consumed?

Whenever you need to boost your energy or concentration! To feel its effects at best, you should drink it in times of increased mental and physical strain, for example, on long sleep-inducing motorways, during intensive working days, *prior to demanding athletic activities* or before tests and exams. . .”) [emphasis added].

<sup>271</sup> <http://www.redbull.com/faq/faq05.html> (“Frequently Asked Questions about Red Bull.

Is Red Bull Energy Drink suitable as fluid replacement?

No. Red Bull Energy Drink is an energy drink. It has not been formulated to deliver re-hydration.

Adequate fluid intake is critical during intense and long lasting physical performance. Without adequate fluid intake, intense physical activities may lead to dehydration. As Red Bull Energy Drink has not been formulated to deliver re-hydration, we encourage people who engage in sports also to drink lots of water during intense exercise.”).

<sup>272</sup> See Morman, *supra* note 3.

<sup>273</sup> See Henning, *supra* note 60.

<sup>274</sup> *Id.*

exercise and their promotion by their manufacturers for such a purpose. Caffeine, the main energy-providing ingredient in stimulant drinks, has been shown to enhance performance in some sporting activities and for this reason caffeine intake in sport is regulated by the International Olympic Committee (IOC).<sup>275</sup> Little information exists regarding the effects that the other components of energy drinks, such as taurine and glucuronolactone, have on performance during sports and exercise or whether these ingredients intensify or counteract the actions of caffeine when used in during periods of intense physical exertion.<sup>276</sup>

What is clear however, it that Red Bull and other energy drinks are not suitable for use as rehydration agents in association with exercise or other strenuous physical exertion. Unlike isotonic sports drinks that cause hydration, stimulant drinks do not meet compositional requirements with respect to osmolarity and concentration of carbohydrate and electrolytes that is recommended for such beverages to ensure optimum hydration for the athlete.<sup>277</sup> Furthermore, little is known regarding any possible adverse effects on exercise performance and fluid balance during sports or exercise that may occur from the interaction between the principal ingredients, like taurine and caffeine, contained in stimulant drinks.<sup>278</sup>

Though whether or not Red Bull actually promotes its consumption in conjunction with alcohol is unclear, it is obvious that Red Bull and other energy drinks are promoted in a manner that suggests that they may be beneficial to individuals partaking in active or high-energy pursuits.<sup>279</sup> Certain stimulant drinks, particularly Red Bull, are advertised overtly in sporting environments or with sporting overtures.<sup>280</sup>

Some studies have been done regarding the possibility of enhanced athletic performance based on consumption of energy drinks. For example, such a study has suggested that there is in fact an improved athletic

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<sup>275</sup> See Safefood, *supra* note 12, at 27.

<sup>276</sup> *Id.*

<sup>277</sup> *Id.* at vii.

<sup>278</sup> *Id.*

<sup>279</sup> *Id.* at 23.

<sup>280</sup> See Safefood, *supra* note 12, at 23.

performance based on consumption of energy drinks.<sup>281</sup> However, most of these limited small-scale studies have received endorsement from the manufacturers of the energy drinks themselves, questioning the validity or independence of the researchers.<sup>282</sup>

Other research suggests different effects of energy drinks. Qualitative research suggests that consumption of stimulant drinks is associated with effects such as disorientation, sleeplessness and increased heart rate.<sup>283</sup> Such reactions are likely not those sought by athletes attempting to improve their game. Athletes would likely be much better served by consuming water before their workouts.

### C. Red Bull and Children and Adolescents

A third usage area of energy drinks requires discussion. The popular culture placements for Energy Drinks are not limited to the college set. The drink also appeals to and is marketed to younger children. The rise in consumption of energy drinks by young people reflects a similar rise in consumption of caffeine by young people.<sup>284</sup> Some nutritionists are concerned with the rising consumption of energy drinks by children because of the negative symptoms that caffeine produces in younger individuals.<sup>285</sup> These symptoms include jitteriness, sleep disturbance and anxiety.<sup>286</sup>

The popularity of Red Bull among younger people in the United States may have dangerous consequences. A study by the European Union found that Red Bull was not suitable for children.<sup>287</sup> Yet, at one point the Red

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<sup>281</sup> *Id.* at 24.

<sup>282</sup> *Id.*

<sup>283</sup> *Id.* at 27.

<sup>284</sup> See Dowling, *supra* note 1.

<sup>285</sup> See *Drinks to carry Caffeine Warning*, THE DOMINION (Wellington). Aug. 2, 2001, § News, at 7 [hereinafter *Caffeine Warning*].

<sup>286</sup> See *Caffeine Warning*, *supra* note 285.

<sup>287</sup> See Newbart, *supra* note 142.

Bull web site stated that Red Bull was suitable for young people who drank coffee.<sup>288</sup> This statement ignores that coffee is not generally thought of as appropriate for young people. At a minimum, caffeine consumption causes anxiety and disrupts sleep, clearly negative results for growing children.<sup>289</sup> The propriety of energy drinks for children are hampered by the lack of research regarding the effects of caffeine on young people, at a time in their development when the brain is still growing.<sup>290</sup>

Until recently, coffee was thought of as an adult drink that would stunt the growth of children: now with the proliferation of Starbucks at nearly every shopping mall or on every city block in the country, younger kids routinely drink lattes.<sup>291</sup> Studies have not focused on the effects of caffeine on children; until recently children were not the subject of aggressive marketing and many parents are unaware that caffeine is a drug and needs to be accorded the respect of a drug.<sup>292</sup> However a prohibition on Red Bull by age – as is done in other countries – would be near impossible due to the pervasive penetration of caffeine in our society.<sup>293</sup>

A Center for Science in the Public Interest (CSPI) study estimates that consumption of soft drinks, including those with caffeine, has doubled among children in the last 25 years.<sup>294</sup> Additionally, many of these soft drinks contain more caffeine and come in larger sizes than they did in the past.<sup>295</sup> Red Bull and other energy drinks likely recognize the strength of this market.

The American Medical Association has expressed worries about the sharp rise in child and adolescent caffeine

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<sup>288</sup> See Morman, *supra* note 3.

<sup>289</sup> *Id.*

<sup>290</sup> See *id.* (stating that the human brain is still wiring itself up to around age 21).

<sup>291</sup> *Id.*

<sup>292</sup> *Id.*

<sup>293</sup> See Morman, *supra* note 3.

<sup>294</sup> *Id.*

<sup>295</sup> *Id.*

use – suggesting that this rise is encouraged by a society that treats the drug very casually; CSPI petitioned in 1997 to require warning labels stating the amount of caffeine in a given product, but the FDA took no action.<sup>296</sup> In the American Psychological Association’s Monitor on Psychology in Summer 2001, the association found that “to date few studies have explored caffeine’s physical effects on children and even less attention has been paid to the drug’s psychological consequences.”<sup>297</sup>

Because Red Bull and other energy drinks are often sold on the same aisle of the supermarket as other soft drinks, parents purchasing groceries may be completely unaware that the drinks that they are purchasing for their children contain the same amount of caffeine as a cup of coffee. Furthermore, the name “energy drink” and the reference to taurine on the product’s label may confuse parents into thinking that they are purchasing a health drink for their children.

## **D. Marketing of Energy Drinks**

As discussed above, Red Bull and other energy drinks do not market their products by making health claims. Instead they make vague claims about “giving wings” and make sure to emphasize herbal or amino acid ingredients rather than sugar and caffeine. The marketing of energy drinks should be analyzed to see if the companies are promoting usage of their products in ways that are not safe.

The Food and Drug Administration also has signaled its intent to ensure that the Internet is not used as a means of circumventing FDA requirements for health claims. In a January 19, 2001 letter to Ocean Spray

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<sup>296</sup> *Id.*

<sup>297</sup> *Id.*

Cranberries, Inc., the FDA determined that references to the company's website on their product labels caused the website to be labeling.<sup>298</sup> However, the Federal Trade Commission views Internet websites as advertising and not as labeling.<sup>299</sup>

What results from the marketing strategy of Red Bull is the often criticized parenting style of "do what I say, not what I do." For example, Red Bull does not "encourage" use of its product in conjunction with alcohol, yet it strongly promotes its drink on college campuses and provides logoed mini-fridges to bars so that patrons will be aware that it is a choice. Additionally, Red Bull sponsors the Red Bull Music Academy focusing on the main type of music at raves: electronic music.<sup>300</sup>

Additionally, Red Bull – on its web site, not on the can – admits that Red Bull does not replace electrolytes and is not suitable for fluid replacements. Yet it is marketed by the confusing misnomer "energy drink" and is most visibly promoted in conjunction with extreme sports – making a very strong suggestion that the drink is suitable with exercise.

Finally, though countries abroad recommend against use of Red Bull by children, the corporation uses only cartoon type advertisements. While they are a far cry from creative a popular figure like Joe Camel, these ads, featuring cartoons and bright colors and speaking of "giving you wings," are a far cry from adult specific marketing.

Under DSHEA, the FDA is concerned with safety of a product under "normal usage." Based on the marketing strategies, Red Bull appears to market for the very usage - with alcohol or drugs, in conjunction with sports or exercise, and by children – that is most subject to scrutiny and has the possibility of the highest danger

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<sup>298</sup> See Heller, *supra* note 26, at 213.

<sup>299</sup> *Id.* at 214.

<sup>300</sup> See <http://www.redbullmusicacademy.com>.

to the consumer.

## VI. Paternalism and the Food and Drug Administration

Even if evidence conclusively demonstrated that Red Bull was not appropriate for consumption with alcohol, with exercise, or by children – and the FDCA or DSHEA provided no limitations on future regulations regarding Red Bull, would increasing regulation on the product be appropriate or desirable?

### **Warnings: are they necessary?**

What could warnings on Red Bull look like? Other countries have concluded that warnings should be placed on energy drink bottles; after its extensive study, the Committee in Ireland reporting on stimulant drinks found such warnings to be necessary. The Committee recommends that stimulant drinks should be labeled with an indication that they are unsuitable for children (under 16 years of age), pregnant women and individuals sensitive to caffeine.<sup>301</sup> The study further advised that consumption of stimulant drinks by children under 16 years should be discouraged on the basis of possible transient behavioral effects of high caffeine intake, such as increased arousal, irritability, nervousness or anxiety.<sup>302</sup> The report also concluded that consumers should be advised that caution be exercised in the consumption of stimulant drinks with alcohol and the products should carry a clear statement on the label to this effect.<sup>303</sup>

Others recommend that stimulant drinks not be consumed in association with sport and exercise as a thirst quencher and that the products should carry a clear statement on the label that they are unsuitable

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<sup>301</sup> See Safefood, *supra* note 12, at *viii*.

<sup>302</sup> *Id.*

<sup>303</sup> *Id.*



rehydration agents for use in sports and exercise.<sup>304</sup> Although the effects of Red Bull when combined with alcohol in high amounts may be harmful, they are probably not any more harmful than alcohol and coffee or alcohol in high quantities alone. Additionally, simply supplementing consumption of energy drinks with water or other hydrating agents could combat many of these adverse effects.

Coffee contains the same amount of caffeine as Red Bull, but the idea that it should not be sold to anyone without proper identification or the suggestion that it should contain a warning regarding the propriety of mixing it with alcohol or with exercise seems ludicrous. Coffee, which naturally contains caffeine, has been a popular product in our high productivity emphasizing society for hundreds of years, and restrictions such as these would likely face much more critique than removing caffeine from the GRAS list did.<sup>305</sup>

However, warning labels about the potential hazards of a product seem preferable to outright bans when the negative health implications of a product are unclear. Warnings to some extent exist on all categories of products; warnings are a preferred strategy for dealing with product risks – an inexpensive alternative to outright prohibition.<sup>306</sup>

The FDA has mandated relatively few warnings for food products since its inception.<sup>307</sup> For example, the FDA has required explicit warnings for only one food product category.<sup>308</sup> Although food product warnings are uncommon, the FDA sometimes designs food-labeling regulations to provide indirect warnings of potential health hazards.<sup>309</sup> For instance, mandatory ingredient labeling alerts consumers to the presence of substances to which they might be allergic.<sup>310</sup> So warnings are not out of the range of possible solutions to problems posed by Red Bull.

The Food and Drug Administration has taken the position that warnings on food products are appropriate

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<sup>304</sup> *Id.*

<sup>305</sup> *See* 52 Fed Reg 18,923, May 20, 1987.

<sup>306</sup> *See* Noah & Merrill, *supra* note 73, at 296.

<sup>307</sup> *Id.* at 315.

<sup>308</sup> *Id.*

<sup>309</sup> *Id.* at 316.

<sup>310</sup> *Id.* at 316.

only when based on sound scientific data with clear application to human health, stating that it “is unwilling to require a warning statement in the absence of clear evidence of a hazard.”<sup>311</sup> The proliferation of warnings may dilute the impact of truly important cautionary information; by the same token, a product inundated with caution signs may cause consumers to overreact to information about a relatively inconsequential risk.<sup>312</sup> The expense, however, of creating sound scientific data with clear evidence necessary to provide the basis for such warnings – which would require millions of dollars in experiments is not something that the FDA can shoulder.

Furthermore, some young people, especially males may actually be influenced to engage in a behavior based on seeing a warning on a product suggesting that a particular use of a product is dangerous.<sup>313</sup> Therefore, a warning that Red Bull should not be consumed with alcohol may encourage young consumers – hoping for a greater high or an increased buzz – to combine the two products.

However, Red Bull and other energy drink manufacturers may be in the best position to determine the propriety of warning labels. If they felt their product was dangerous in certain situations, and would likely result in expensive liability, then they would probably make such potential dangers known on the product labels in the same way that McDonald’s now labels its coffee as being extremely hot as a result of expensive litigation.

When the ingredients of Red Bull, looked at individually, are no different than those that could be acquired through other, perfectly legal sources, regulation or warning on this product seems pointless. As indicated by a British study<sup>314</sup> – energy drinks are safe when consumed by adults in moderation. Though moderation is something that American definitely have trouble with. It would be too easy to blame the FDA’s lack

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<sup>311</sup>See Noah & Merrill, *supra* note 73, at 317.

<sup>312</sup>*Id.* at 374-75.

<sup>313</sup>See William J. McGuire, *The Communication-Persuasion Model and Health-Risk Labeling, in Product Labeling and Health Risks*: BANBURY REPORT 6 at 299 (Louis A. Morris et. al. eds., 1980), at 109-10 (“For example, among young people (and especially young males), warning labels about the risk involved in pharmaceuticals, cigarettes, alcohol, driving styles, certain sporting equipment and practices, etc., may actually have a net positive incentive power, drawing the person to the practice (especially in public situations) rather than being a deterrent.”).

<sup>314</sup>Statement on Red Bull, British Food Standards Agency, *supra* note 162.

of action for American cultural problems of excess and laziness. Education is important but over-warning is insulting to the intelligence of individuals: this goes to cultural notions in the United States regarding individual autonomy.

Additionally, if the marketing of Red Bull – rather than the ingredients or labeling – creates the problem by promoting unhealthy consumption of the product, then the Federal Trade Commission and the judicial system may provide better answers to the concerns raised over the products. The market place itself should provide Red Bull with incentives to use appropriate warnings on its product. The role of the Food and Drug administration is to insure the safety of foods and drugs; however, once they have been approved, many products are susceptible to abuse once they end up in the hands of the consumer.

## **VII. Analysis and Conclusion: Is regulation necessary?**

Energy drinks, especially market leader Red Bull, occupy a growing segment of the beverage industry both in the United States and abroad. Foreign regulation of the products may lead to more in depth studies into the safety of the products. Such research regarding the added substances to energy drinks, such as taurine, may in the long run provide greater insight into the efficacy of the products. However, energy drinks will likely continue to be popular until the next “new” drink comes along, and then they will perhaps die out as an ill-tasting fad.

Studies regarding the safety of the main components of Red Bull, namely caffeine and taurine, do not demonstrate any need for regulation at this time. The results of the studies are largely inconclusive and can

provide no sound basis for warning labels. One area where the makers of Red Bull should be cautious is in the claims made on the Red Bull label, namely “Stimulates the metabolism” may be improper structure/function claims that should be removed from the label.

Clearly the most problematic area with regard to the safety of Red Bull is that of normal usage of the product. Although Red Bull’s website establishes that the drink does not replenish electrolytes during physical workouts, many consumers use the drink in conjunction with exercise. The advertising of the product, specifically promotion of Red Bull in the context of extreme sports, generally suggests that the product is an acceptable drink for the context of physical exertion. Additionally, though makers of Red Bull claim that they do no more to promote their product as a mixer with alcohol than the makers of Coca-Cola or orange juice do, their company does advertise by promoting the very type of music – electronic – that is popular in the rave and night club culture. Furthermore, use of “medicinal” tasting Red Bull in conjunction with alcohol is one of the most frequently mentioned uses of the product.

Although drinking Red Bull with exercise or as a mixer with alcohol has been linked to deaths in European countries, the link remains without scientific proof. Furthermore, any negative effects of dehydration because of the caffeine in the product could likely be remedied with simultaneous consumption of water. The number of products available on the market with high caffeine contents, from coffee to caffeine pills, make specific regulation of Red Bull seem all the more unnecessary.

Under the stringent guidelines of the Dietary Supplement Health and Education Act, the Food and Drug Administration has a very limited authority to police Red Bull or other similar energy drinks until more information regarding their dangers is known. Those energy drinks that are most at risk for FDA regulation are those such as Ripped Force that contain ephedra and have already been prohibited in some places. Additionally, if the current turmoil over ephedra results in changed legislation, then the manufacturers of dietary supplements may gain more responsibility for reporting adverse consequences of their products. Until

this happens, any bans or warnings on Red Bull seem impossible as well as unnecessary.

Even without the stringent limits on the FDA under DSHEA, severe regulation of energy drinks in the form of increased warnings may be inappropriate. Consumers should not be inundated with warnings on products or such warnings will lose meaning. Furthermore, warnings could in some circumstances even promote dangerous behavior by certain classes of consumers. At the same time, however, consumers should stay abreast of potential problems, and the FDA should continue to monitor studies, in the United States and abroad, regarding the health and safety of Red Bull and other energy drinks.

The FDA may not be the government body with the most effective method of controlling the problems created by Red Bull or other energy drinks either because it lacks the power or because other branches of the government, namely the FTC or the court system, would provide a more suitable remedy to the potential harms. The FTC may have more of a reason for concern than the FDA. With its marketing as an “energy drink,” Red Bull manufacturers strongly suggest that their product is more like Gatorade – that it is appropriate for use by athletes and works to replenish electrolytes. Additionally, the high liability that Red Bull would face based on the dangers posed by its product offer additional incentives for the company to conform to relevant safety guidelines.

Red Bull is about as much an energy drink as a Starbuck’s espresso or a Jolt cola. In our American business climate where increased efficiency and productivity often takes a front seat to health, the dangers posed by a high caffeine drink is unlikely to merit concern. There will always be No Doz or espresso to provide “energy” in the form of a caffeine and sugar buzz. The demand of these products by everyone from college students and long distance drivers to club-goers hoping to dance all night will continue as long as our society

puts premium on being able to get up and go. At this time, there is no need to take Red Bull or other energy drinks off of the market or to require warning labels on the cans. However, the FDA must stay aware of problems with the product and investigate structure/function claims on the labels that may be without merit.