Worker Health Risk from Energy Drinks

by

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ABSTRACT

Little research has been done on the effects of energy drinks on workers, and their ingredients as a whole are not well understood. However, the circumstantial evidence has moved medical communities, politicians, parents, and worker health and safety professionals to begin to question their safety. Policies to protect workers are now being instituted by various work sectors but a general lack of awareness could prove catastrophic. New research is now emerging in the occupational health sector that demonstrates a likely link with energy drinks and ill health effects in workers. Occupational and environmental health nurses can develop prevention, intervention, and advocacy programs to assist in preventing the toxic effects of energy drinks among workers.

*Keywords:* Energy Drinks, Synergistic and Additive Effects, Worker Health and Safety
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CHAPTER I
INTRODUCTION

Energy drinks are a largely unrecognized health danger for workers. The drinks are consumed to increase energy and performance by a wide and ever changing demographic but the reports of serious health effects are mounting. The drinks are now being implicated in both acute and chronic health issues, psychological disorders, and deaths. Often the ill effects are blamed on the high levels of caffeine in the drinks but little research has been done to assess the effects of the high amounts of each ingredient or the specific combinations of ingredients used in energy drinks. Combining the adverse health effects of energy drinks, both physical and psychological, with workplace dangers is a recipe for a potential catastrophic health and safety event. Workers who consume the drinks containing toxic levels and combinations of stimulants, sugar, vitamins, and herbs are at-risk for side effects that directly affect their fitness for duty. Occupational and environmental health nurses (OEHNs) play a key role in raising awareness, advocating for public health safety, and preventing deleterious health consequences in individuals from consuming energy drinks.

The Problem

Energy drinks were frequently in news reports in the United States (U.S.) in late 2012 because of the suspected association with illness, injury, and deaths. A host of ill effects such as exacerbations of gouty arthritis, psoriasis, and other inflammatory illnesses to more serious ailments such as cardiac dysrhythmias and death have been reported (Laino, 2010; Seifert, Schaechter, Hershonin, & Lipschultz, 2011). In addition, behavioral health issues have also been
associated with the liquid supplements but not proven in cases of substance co-dependence, aggression, anxiety disorders, and exacerbation of mental health conditions (Bronstein et al., 2011; Jackson et al., 2011; Seifert et al., 2011; Substance Abuse and Mental Health Services Administration [SAMHSA], 2013). The health ailments have become so prevalent that the U.S. Poison Control Centers began recording data under the title – “energy drinks” – for the first time in 2010 to track ill effects (American Association of Poison Control Centers [AAPCC], 2011). According to the AAPCC (2013), the reports involving energy drinks have increased from 672 reports in 2010 to 3,150 in 2012. The symptoms reported to poison control centers in the U.S. include minor to severe health problems (Table 1.1). According the AAPCC (2013) there were 3150 reports of ill health after exposure to energy drinks reported to U.S. Poison Control Centers. Approximately 41% of those reporting symptoms were individuals over the age of 18. The symptoms reported range from minor to major and are included in the list.

Emergency department visits related to energy drinks, by age, have increased as well (Figure 1.1). From 2007 to 2011 the number of emergency room visits from the effects of energy drinks has risen. In 2011 the rate of ED visits doubled to 20,783 from 10,068 in 2007. Another significant rise was in the 40 or older group from 14% in 2007 to 25% of the visits in 2011, a 279% increase. An indicator of the widening demographic of consumers with health ailments related to the drinks.

Energy drinks, sold in the beverage sections of supermarkets and convenience stores, contain substantial amounts of stimulants, vitamins, herbs, sugar or sugar substitutes, and amino acids making them very different from sports drinks (AAPCC, 2013). For example, some energy drink supplements contain as much as 8,333% of the Recommended Daily Intake (RDI) of
TABLE 1.1
2012 AAPCC: REPORTED SYMPTOMS FROM ENERGY DRINKS

<table>
<thead>
<tr>
<th>Minor Symptoms</th>
<th>Moderate to Severe Symptoms</th>
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<tbody>
<tr>
<td>Nausea</td>
<td>Sweating</td>
</tr>
<tr>
<td>Vomiting</td>
<td>Diarrhea</td>
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<tr>
<td>Nervousness</td>
<td>Withdrawal</td>
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<tr>
<td>Tremors</td>
<td>Increased Heart Rate</td>
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<tr>
<td>Mood Changes</td>
<td>Delirium</td>
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<tr>
<td>Insomnia</td>
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</tr>
<tr>
<td>Restlessness</td>
<td>Altered Heart Rhythm</td>
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<tr>
<td>Headache</td>
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<td></td>
<td>Chest Pain</td>
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<tr>
<td></td>
<td>Dehydration</td>
</tr>
<tr>
<td></td>
<td>Kidney Problems(kidney stones, renal failure)</td>
</tr>
<tr>
<td></td>
<td>Death</td>
</tr>
</tbody>
</table>

**Source (Table adapted from):** AAPCC, 2013
FIGURE 1.1
ENERGY DRINK-RELATED EMERGENCY DEPARTMENT (ED) VISITS,
BY AGE GROUP: 2007 AND 2011

Source: SAMHSA, 2013

* The difference between the number of visits in 2007 and 2011 was statistically significant at the .05 level among patients aged 40 or older. Source: 2011 SAMHSA Drug Abuse Warning Network (DAWN).
vitamin B12 ("5-Hour Supplement Facts," 2013) and more caffeine in a single dose than is recommended for safe consumption. Energy supplements are most frequently consumed as an energy drink though many versions have evolved. Capsules, flavored melts – placed on the tongue, energy shots, enhanced coffee creamers and fruit juices, to name a few, are also joining in the profitability of these supplements causing similar ill effects.

The explanation for the high rate of interest in these supplemental drinks is complex. The young person looking for a thrill, a chronically fatigued society looking for a quick pick-me-up, an athlete looking for a performance edge, an older worker trying to keep up, or substance dependent individual seeking a legal drug of abuse are reasons for consumption (Seifert et al., 2011).

Two recent studies assessed the effects of energy drinks on firefighters (Abbott, 2010) and military personnel (Toblin, Clarke-Walper, Kok, & Sipos, 2012). Though the two studies were small, they identified intracellular dehydration, sleep disturbances, increased stress, and sleepiness while on duty in workers who consumed energy drinks. The firefighter study was a double blind crossover study that used vital signs, urinary output, and bioimpedence analysis to assess intracellular hydration (Abbott, 2010). The military study was a cluster sample survey of 1,000 military personnel stationed in Afghanistan during military operations. The studies suggest the impact of energy drink complications are likely unrecognized in the work setting.

Lost productivity caused by energy drinks can include presenteeism, work stoppage to care for an ill or injured employee on a job, increased work injury, increased Workers’ Compensation claims, potential workplace violence, low employee morale, and damage to the company reputation (Kaiser Permanente, 2010; SAMHSA, 2013). Additionally, self-insured
companies risk financial losses when funding healthcare for employees who develop chronic health conditions from the beverages. The health damages caused by energy drinks are an entirely preventable public health problem that has not been recognized to the fullest degree.

**History of Energy Drinks**

A self-made millionaire named Chaleo Yoovidhya from Thailand had been making a product called “Krathing Daeng”, meaning “Red Bull” since 1960. Yoovidhya met an Austrian named Dietrich Mateschitz attempting to create an energy supplement, and they combined forces in the 1980s to reformulate the supplement and co-found “The International Red Bull” brand. In 1987 the newly formulated Red Bull was re-introduced in Austria, gained in popularity, and was then introduced in the U.S. in 1997 as a supplement not a beverage (Red Bull, n.d.; The Associated Press, 2012). Reformulations of the drinks in the U.S. have included the elimination of ephedra in 2004 and alcohol in 2010 by mandate of the U.S. Food and Drug Administration (U.S. FDA) due to health safety concerns (Bottemiller, 2010; Kapner, 2004).

Since the introduction of supplemental drinks, the numbers of brands and sales have proliferated around the world. In 2012 the energy drinks sold over $10 billion and another $2.5 billion in energy shots in the U.S. alone (Figure 1.2) (BevNet, 2012; Energy Fiend, 2013). U.S. market sales are impressive but another interesting note is Red Bull International’s net profit in 2012 was $406 million, and for the third quarter of 2012 alone the Monster Beverage Corporation’s net profit was $86.4 million despite a less than predicted increase in profits for the quarter ("Red Bull 2012 Profits," 2012; Reuters, 2012). Though energy drinks are still mostly consumed by young white males, who have been the initial target market, changes in marketing
FIGURE 1.2

TOP MARKET SALES IN U.S. BY BRAND OF ENERGY DRINK

Source: Graph adapted from Energy Fiend, 2013
strategies are beginning to elicit sales in new groups (National Policy and Legal Analysis Network to Prevent Childhood Obesity [NPLAN], 2011).

The recommendations for labeling of energy drinks published by the FDA have done little to encourage manufacturers to accurately describe the contents of their products on the labels. The FDA can regulate how much caffeine a soda contains and can remove supplements from the market if they are found to be dangerous. However, energy drinks fit into neither category because they have not yet been defined by the FDA nor have they been determined to be the definitive cause in any deaths (Carpenter, 2012). Attempts to ban or regulate energy drinks have failed in the U.S. though some politicians are still trying to pursue improvements in labeling and further research of energy drinks.

Definitions

**Functional beverages:** beverages that proclaim a health benefit; included in this category are both energy and sports drinks (American Beverage Association [ABA], n.d.).

**Energy drinks:** functional drinks not yet defined by the FDA or U.S. Department of Agriculture (USDA). The ABA characterizes them as “novelty refreshment beverages” (ABA, 2013, “Energy Drinks”) and Centers for Disease Control and Prevention (CDC) describe them as “beverages that typically contain caffeine, other plant-based stimulants, simple sugars, and other additives” (2010, para. 4). Some examples of energy drinks include Amp, Monster, Red Bull, Full Throttle, VitaminWater Energy and VitaminWater Attention, Venom, Cocaine, Rev, Rip It, and Rock Star.

**Sports drinks:** functional drinks used to assist with replenishment of electrolytes, calories, and fluids lost during heavy physical activity and have no amino acids or caffeine

**“Nutritional Facts” panel:** required by the FDA on containers of foods or beverages with ingredients that have designated RDIs, such as vitamins A, B, and C. The FDA also dictates the information contained within those panels.

**“Supplemental Facts” panel:** describes on a container the amounts of supplements that have no designated RDI, such as gingko and ginseng. This information is recommended but not required to be listed and is not regulated by the FDA (U.S. FDA, 2012).
CHAPTER II
LITERATURE REVIEW

Reasons for Use

Long work hours, personal lives filled with demands, an aging workforce, and a world that is active around the clock all lead to fatigue - the bane from which workers and others seek relief. Approximately 40% of American adults sleep less than seven hours per night (CDC, 2012), and according to the National Sleep Foundation (2011) most adults need seven to nine hours of sleep per night to function well and be healthy. Lack of sleep and fatigue have been linked to increased pain (Buxton & Sorensen, 2012), work-related accidents (Hallowell, 2012; McGuire, 2008; Powell & Copping, 2010; Spengler, Browning, & Reed, 2004), and over all ill health. Shift-work is a common cause of sleep disorders and fatigue from the disruption to the cyclic nature of the body’s physiology (Lombardi, Folkard, Willetts, & Smith, 2010). Workers around the world seek relief from the drowsiness and fatigue caused by the epidemic of sleeplessness, a common threat to a person’s wellbeing, with stimulants such as coffee and energy drinks.

The toxic jock syndrome, described as risk taking and aggressive behaviors by athletes, often includes substance abuse including energy drinks (Duchan, Patel, & Feucht, 2010; Miller, 2008; Wimer & Levant, 2013). Competition in sports events has a long tradition of creating the toxic jock mentality and substance use that led to the ruin of outstanding athletes such as Lance Armstrong, Sammy Sosa, Mark McGwire, and the deaths of Korey Stringer, Steve Bechler and others (Atkinson, 2011; Banks, 2003; Miller, 2008; "Sosa Says," 2013). Manufacturers of energy
drinks are often sponsors of sporting events and advertise a product that offers legal energy or performance enhancing benefits, a tempting offer for participants who consume them hoping for an edge in the fierce competition.

Workplaces that require shift work, long hours, and have stressful environments contribute to fatigue among workers. According to the U.S. Department of Labor Statistics (BLS), “Manufacturing sector productivity increased 0.5 percent in the fourth quarter of 2012” (2013a, para. 5); the “doing more with less” environment at work continues. In 2012 roughly one-third of the adult working population is 50 years old or older in the U.S (BLS, 2013b).

The increased demands for productivity at work and an aging work force encourage older workers to seek relief, often from food supplements, to boost energy and health. Energy drinks containing herbs and vitamins thought to be healthy are mistakenly becoming one of the supplements used to aid in keeping up.

Long hours of gaming, studying for exams, and the active social calendars in teens and young adults lead to lack of sleep. This combined with the thrill seeking desire for increased energy, and experimentation with substances in this age group can also lead to use of energy drinks (Bender, 2006; Buchanan, 2012; "Teens-Despite the Risks," 2012). Teens and young adults remain the largest consumer group for energy drinks (SAMHSA, 2013) and are more susceptible to the advertising campaigns employed by the manufacturers of energy drinks such as receiving free products (Heckman, Sherry, & Gonzalez de Mejia, 2010).

**Changing Demographics**

The ages targeted by energy drink manufacturers marketing campaigns are changing to expand profitability (ABA, 2012; NPLAN, 2011). Initially athletes were the intended marketing
target in the U.S.; the market expanded to extreme sports and included mostly young, white, males. As the marketing bracket titled “youth” grew more ethnically diverse and became saturated, new groups were targeted with marketing campaigns (ABA, 2012; Heckman et al., 2010). More mature adults and working groups are now being targeted and the rate of consumption along with the episodes of health-related problems from the drinks are rising in this demographic (SAMHSA, 2013). The ABA says, “… Energy drinks are being created with many different formulations geared to meeting the tastes and demands of different consumers – everyone from college students to corporate executives” (ABA, 2012, para. 3). Rivet Energy Drink packaged its product to look like a container that “…any handyman or construction worker would want to keep attached to his tool belt” as a marketing strategy to widen the demographics of consumers (Roblin, 2011, p. 2).

While packaging is still designed to attract teens and young adults, it is changing. Packaging Digest announced that in 2012, energy drink use by adults of a mature age increased from 13 to 17% of the market with 5% of mature adults consuming energy drinks 5 to 7 times a month and 2% consuming energy drinks 10 or more times per month. They also indicate those mature adults using five or more energy drinks per month are considered “heavy users” (Lingle, 2013).

**Current News**

Because of lawsuits and new regulations in other countries, energy drinks began appearing in headlines in 2011. Canadian Health Minister Leona Aglukkaq changed the classification of energy drinks from “health products” to “foods” so that more stringent regulations could be applied to caffeine and other ingredients in 2011 (Fitzpatrick, 2011). Charlie
Davies of the D.C. United’s soccer team sued a nightclub and Red Bull in 2011 for $20 million claiming they were responsible for a car crash that caused the death of a co-passenger and damage to his career (Gresko, 2011; The Associated Press, 2011). In October 2012, a settlement was reached for an undisclosed amount and details were not released (Goff, 2012). Stories of energy drinks and the destruction they create were posted in many news reports and blog discussions in 2012 describing the side effects of energy drinks with titles as frightening as “Did I almost die? A look at energy drinks from a survivor’s perspective” (Cooper, 2012). Another frightening report announced in 2012 was that research is advancing a new technology to make ginseng, a stimulant with many side effects, more bio-available and less expensive to help boost profits in the functional food and beverage markets (Watson, 2012). Ginseng is among the ingredients in question in the recent health scare issues and a more bio-available version may lead to more adverse health events. This is not the direction medical professionals are working towards.

Energy drinks were also on the political news fronts in 2012. Senators Dick Durbin and Richard Blumenthal urged action by the FDA regarding the energy drinks even though many attempts to regulate or ban the supplements have failed in the past (Young, 2012). The FDA responded to the requests in August 2012. In December 2012, both senators released a news statement indicating they felt the FDA is taking their concerns seriously ("Blumenthal Press Release," 2012; "Durbin Press Release," 2012). Appendix A contains a copy of the letter from the FDA to Senator Durbin and Appendix B contains a copy of the press release from Senator Blumenthal. Other political figures involved in efforts to regulate energy supplements in 2012 included the New York Attorney General, the Attorney for the City of San Francisco, and a
Chicago Alderman; they requested a ban on sales to those under the age of 21. Among those currently being challenged to provide documentation of proof their products are safe are the makers of Monster, 5-Hour Energy, and Amp (Gormley, 2012; Meier, 2012b; Spielman, 2012). Despite their efforts the FDA still feels they do not have enough evidence to determine energy drinks are unsafe or need further regulation but are considering convening an expert panel for assistance ("Blumenthal Press Release," 2012).

The fortunes created by energy drinks led to news reports of name changes for manufacturers and legal scandal for an heir of the Red Bull co-founder. To demonstrate the dominance of the Monster sales within the company, The Hansen Natural Company changed their name to “Monster Beverage Corporation” on January 5, 2012 (Monster Beverage Corporation, 2012). Chaleo Yoovidhya, the co-founder of Red Bull International, died in March 2012. Later in 2012 an heir to Yoovidhya and the Red Bull fortune was involved in a cover up scandal after killing a police officer with his car in Bangkok ("Red Bull Heir Arrested," 2012). The health reports were more frequent in 2012 and energy drinks were named in lawsuits due to heart attacks, spontaneous abortions, deaths, along with numerous reports to the FDA of other ill effects (Meier, 2012a, 2012b, 2012c). Many lawsuits have pending decisions within the courts (Meier, 2012a, 2012b) and may have contributed to the slightly lower than expected profits in the third quarter of 2012 for the Monster Beverage Corporation (Reuters, 2012).

Industries were beginning to educate workers about the health risks of energy drinks through publications directed to the workers and their families long before the news stories started. In 2006 a Texas AgriLife Extension Service article detailed the need for caution with energy drinks especially when working in hot environments and suggests fruits, fruit juice, milk,
seltzer water, and lemonade as alternatives for hydration (Pollard, Rice, & Anding). In 2011 Major and Minor League Baseball teams stopped providing energy drinks to players, educated players about the risks of consuming them, and banned the drinks for players in the minor leagues. Major League Ball clubs have discouraged but have not banned energy drink use because of collective bargaining agreements with the players (Nightengale, 2011). In Australia, the mining industry has discussed energy drink concerns with workers and issued educational cautions or outright bans on the drinks due to risks for dehydration, episodes of panic, and lack of fitness for duty when consuming the energy drinks (Ekert, 2012).

In 2012, teachers and parents were also among the occupations educated about the risk of energy drink consumption through an article in the Weekly Reader: Current Health Kids publication (Flam, 2012). Oilfield companies, International Brotherhood of Electrical Workers Union, and construction companies are beginning to educate workers about the risks associated with energy drinks through safety talks, newsletters, and banning of energy drinks (Gonzalez, 2012; Quinn, 2012; "Toolbox Talk," n.d.). A pleasant ray of hope was a professional nursing article in The Journal of Nursing for Women’s Health that addressed the increased risks with energy drinks for nurses themselves and their patients (Guilbeau, 2012).

Focus on Caffeine Not Combination of All Ingredients

The news media coverage and the medical reports in 2012 have focused on the caffeine and sugar content of energy drinks. Poison control centers recorded the adverse events that occurred from energy drink consumption under caffeine toxicity until 2010 though little research has been done to assess what causes the ill effects from energy drinks. In 2010 energy drinks were given their own category to track adverse events. However, the assigned categories by
poison control centers still focus heavily on caffeine in the drinks even though the synergistic or additive effects of the entire list of ingredients are not known (AAPCC, 2011; Seifert et al., 2011). Sugar is another ingredient in energy drinks getting blame for side effects. However, no explanations in any literature addressed why similar ill effects occurred with use of sugar free energy drinks or sodas.

Ingredients commonly used in energy drinks for their stimulant and mental focus enhancement effects include caffeine, guarana, taurine, ginseng, glucuronolactone, and others. At one time energy drinks contained the now banned stimulant called ephedra that has been linked with deaths in athletes, namely Korey Stringer and possibly Steve Bechler. Other athletes have died after consuming energy supplements and the deaths in these individuals came immediately after a strenuous workout such as training or playing a game. Many energy drinks currently bear cautions for their use and have ingredients that interact with various medications or other herbs in prescribing resources such as Medline Plus. The following is a list of characteristics of some of the notable ingredients.

**Caffeine and Guarana**

Caffeine is a food, beverage, and medication additive that functions mostly as a central nervous and respiratory system stimulant (U.S. FDA, 2008). Caffeine, an addictive substance, comes in both synthetic and natural forms, is added in large doses to energy drinks, and can create symptoms of withdrawal (Seifert et al., 2011). Guarana comes from the seeds of a shrub in Venezuela and rainforest of Brazil and contains caffeine that is more concentrated than found in coffee beans. The drug interactions with caffeine include ephdra or ephedrine, anticoagulants - aspirin, Coumadin, Ticlid, Plavix, and monoamine oxidase inhibitors (MAOI) antidepressants –
Nardil or Parnate. Caffeine should be used with caution in people who have heart disease, diabetes, hypertension, epilepsy, hyperthyroidism, anxiety, insomnia, kidney disease, pregnancy, and anyone taking any of the above medications (AAPCC, 2011; Clauson, Shields, McQueen, & Persad, 2008; Seifert et al., 2011).

Signs and symptoms of caffeine toxicity include agitation, tremors, confusion, psychotic behavior, headache, abdominal pain, nausea and vomiting, seizures, hypertension, tachycardia, cardiac dysrhythmias, cardiac ischemia, heart failure, rhabdomyolysis, and death (Clauson et al., 2008; Seifert et al., 2011; U.S. FDA, 2008). Caffeine toxicity for adults occurs at doses of caffeine above 400 milligrams (mg) per day though the effects vary from person to person and some individuals have symptoms at much lower levels. Pregnant women are recommended to consume no more than 200 mg per day. Acute toxicity is described as toxicity that occurs at approximately 1000 mg per day. Patients with acute caffeine toxicity may present with the symptoms listed above or seizures, cardiovascular instability, and death (Seifert et al., 2011; U.S. FDA, 2008; Yew & Tarabar, 2011). The literature briefly addresses the speed at which an energy drink is consumed when discussing the ill effects from energy drinks. Energy drinks are a cold gulped drink versus a hot beverage that is sipped slowly. Again, no discussion was present about why cold sodas do not cause the same ill effects and are consumed in much the same fashion. Warnings on some of the containers to avoid consuming too much of the energy drinks within a short time suggest speed of consumption may play a part in toxicity or side effects.

The FDA limits caffeine content in sodas to a maximum of 71 mg per 12 ounce soda (Substances Generally Recognized as Safe, 2012) but no limit exists for energy drinks or other energy supplements to date. Regular brew coffee contains approximately 100 to 150 mg of
caffeine in 5 to 8 ounces (Consumers Reports, 2012; Seifert et al., 2011; U.S. FDA, 2008); caffeine content that is similar to energy drinks. Again this fact leads one to wonder about the synergistic or additive effects of the other ingredients in energy drinks.

**Taurine**

Taurine, also known as L-taurine, is an organic acid that functions in the liver to form bile acids for use in metabolism of fats. Taurine also has some anti-dysrhythmia effects as well as the ability to increase heart rate and contractility of the heart. It can be used in medications to promote eye and biliary health, prevent congestive heart failure through its cardiac contractility effects, decrease sympathetic nervous system stimulation, and alter calcium stores in heart muscle. Taurine comes from meat, eggs, fish, and dairy products in the diet and is also synthetically produced. Side effects include either diarrhea or constipation, and starting at doses of 1500 mg - nausea, headache, dizziness, and difficulty with walking. At doses of 2000 mg or more of taurine - intense itching and psoriasis outbreak can occur (Clauson et al., 2008; Seifert et al., 2011). The estimated dietary daily intake of taurine is 400 mg per day but some energy drinks have 1000 mg per serving.

**Ginseng**

Ginseng is from an herbal root and has been used in Asian health remedies for years to treat a wide scope of health issues. The role of ginseng in energy drinks is purported to assist with energy but research has led to many contradictory health findings. In light of the confusing research results, the effect of ginseng in energy drinks is unclear and could be unsafe especially with other stimulants. Side effects of use include insomnia, breast discomfort, vaginal bleeding or amenorrhea, tachycardia, palpitations, hypertension, edema, headache, vertigo, euphoria and
mania, diarrhea, irritability, erythema multiforme and rashes, as well as agranulocytosis. Interactions include Coumadin, Nardil – an MAOI, estrogen, corticosteroids, digoxin, and antidiabetic medications (Clauson et al., 2008; Kiefer, 2010; Seifert et al., 2011; Therapeutic Research Faculty, 2013).

Ginseng is considered safe for use when taken for no longer than a few months and the dose is usually 200 mg to 400 mg per day of a 4% ginsenoside. Doses in energy drinks are not always listed because they are often included in the proprietary blends called “energy blends” that are the supposed distinction between the effects of each brand of supplement. Energy drinks are reported to contain anywhere from 8 to 400 mg per serving.

**Glucuronolactone**

Glucuronolactone is an organic metabolite of glucose formed in the liver and is also found in plants. The ingredient used as part of the “energy blends” in energy drinks has not been researched in humans and the reason for its use is unclear. Red Bull (2010) says “Glucuronolactone is a carbohydrate derivative, which is a natural constituent of the human body. It is also present in human nutrition such as red wine and grain” (p. 28) but no explanation for its use is offered. Side effects include disorientation, dizziness, tachycardia, and kidney disease. No safe or requirement dose has been determined (European Food Safety Authority [EFSA], 2009).

**Inositol**

Inositol, sometimes called vitamin B8, is a vitamin like carbohydrate found in plants and animals that assists in neurological impulse transmission and is purported to boost energy and mental alertness. Medical uses include the treatment of neuropathy, polycystic ovary disease,
respiratory distress in newborns, and psoriasis (WebMD, 2009). Again this is an ingredient that is often part of the proprietary energy blends and content is often not listed on the label. Side effects can include dizziness, headache, tiredness, nausea, and diarrhea. Overdose causes anaphylaxis, vomiting, psychological disorders, stomach upset and ulcers, angina, diabetes, gallbladder disease, gout, kidney and liver disease, and sensitivity to niacin. Up to 12 to 18 mg per day have been used to treat various psychiatric disorders and that is considered maximum dosing (Benjamin et al., 1995; Kirkland Science Lab, 2013; WebMD, 2009).

**Citric Acid**

Another ingredient worth noting is citric acid. Citric acid found in citrus fruit is used as a preservative and flavor enhancer in beverages but it erodes tooth enamel. Dietary supplementation has not been found to be effective. The oral pH takes approximately 30 minutes after drinking an energy drink to balance back out and this leads to excessive enamel loss and tooth decay. In addition to the enamel erosion, citric acid has been associated with decreased bone mass and kidney stones (Jain, Hall-May, Golabek, & Agustin, 2012). The amount contained in energy drinks is often not revealed on the label.

**Labeling**

Adding to the confusion over the healthfulness of the drinks is some energy drinks have a “Supplemental Facts” label while other energy drink products have a “Nutritional Facts” panel. One explanation for the difference in the labels may be the attempt by manufacturers to garner all corners of the market. The beverage manufactures realize that government food subsidies (food stamps) can be used to buy energy drinks if they contain the nutritional facts label but not if they have a supplemental facts label (USDA, 2013).
Monster brand drinks have a “Supplemental Facts” label with nutritional data such as calories, vitamins, sodium, and others included. However, AMP has a “Nutrition Facts” label with a list of ingredients followed by supplement ingredient information with the milligrams listed (information taken from product containers). Neither nutritional or supplement information for energy drinks is required, evaluated, or regulated thus is often inaccurate. Consumer Reports (2012) concluded in a report published in December 2012 that nearly half of 27 energy drinks tested for verification of caffeine content in their lab did not list caffeine content on the labels. Of the 16 that had the information, nearly one-third actually contained 20% more caffeine than indicated on the label. Often the manufacturers list the proprietary “energy blend” ingredients without specific content information and no testing to determine which ingredients or the level contained in energy drinks was discovered in this review.

**Health Effects**

The EFSA (2009) ruled the doses of specific elements in energy drinks were without harm though other studies disagree. However, energy drink formulas from European nations differ from those in the U.S. and the formulas vary from year to year, brand to brand, and flavor to flavor within the same company’s products in the U.S. (Reissig, Strain, & Griffiths, 2008). Since their introduction in the U.S. in 1997, energy drinks have been associated with health and safety risks for consumers and troublesome health effects in young people began shortly after their introduction. Now adverse events are widely reported by health professionals and poison control centers for all ages (AAPCC, 2011, 2013; Breus, 2012; McCarthy, 2009; Reissig et al., 2008; SAMHSA, 2013; Seifert et al., 2011). Reissig et al. (2008) point heavily to the caffeine inexperienced nature of young people as the sole reason for health effects with energy drinks.
Curiously all three stated conflicts of interest for the article including that each held stock in one or more of the following companies: PepsiCo, Starbucks, and Coca-Cola. The health effects reported include cardiac dysrhythmias, hypertension, tachycardia, heat illness - heat stroke or heat exhaustion, cerebral vascular accidents, dehydration, severe psoriasis exacerbation, severe gout, spontaneous abortion, renal failure complications, seizures, co-addictions, physical injury due to risk taking behaviors, as well as deaths (McMillin, Richards, Mein, & Nelson, 1999; Meier, 2012b, 2012b; Reissig et al., 2008; SAMHSA, 2013; Seifert et al., 2011; Suliman, Barany, Divino Filho, Lindholm, & Bergstrom, 2002).

**Cardiovascular**

Energy drinks are hypertonic solutions that cause fluid shifts leading to vascular and intracellular dehydration (Abbott, 2010). Cohen and Townsend (2006) found caffeine increases sympathetic activity and blocks adenosine receptors leading to vasoconstriction and resultant hypertension. The rates of hypertension were higher in individuals drinking energy drinks when compared with drinks having the same caffeine doses but no other stimulants. This led Cohen and Townsend to conclude the high rates of hypertension were likely caused by the synergism and additive effects of ingredients rather than by caffeine alone. Steinke, Lanfear, Dhanapal, and Kalus (2009) found when energy drinks are combined with alcohol, the hypertensive and dehydration effects were more pronounced than consuming either one separately. Shah, Dargush, Lacey, Riddock, and Lee (2013) found that consuming just one to three energy drinks immediately caused elevated blood pressure as well as prolonged QT intervals on electrocardiograms in study participants. Prolonged QT intervals are associated with sudden
cardiac arrest. Shah et al. also note that the blood pressure increase detected in this study was similar to those found in a medication study in 2006 that caused the halt of that study.

Other researchers believe the speed at which a cold energy drink can be consumed versus a hot caffeinated beverage is also considered a possible explanation for the ill effects from energy drinks (Heckman et al., 2010). Some energy drinks contain as much as 30% of the RDI of sodium which is considered high content by the U.S. FDA (2010) and associated with hypertension. Studies also found energy drinks aggravated the impaired baroreflex buffering— the central nervous systems control mechanism for arterial pressure in cardiac patients, leading to hypertension (Steinke et al., 2009). The extremely large amounts of the B vitamins in energy drinks can lead to cardiac dysrhythmias, clotting or bleeding disorders and interference with anticoagulation therapy, rapid re-occlusion of cardiac stents, hypertension, as well as non-cardiac conditions such as gout and dermatologic lesions (Heckman et al., Mayo Clinic, 2012a, 2012b).

**Neurologic**

Caffeine is a central nervous system stimulant that increases the speed of neurons and secretion of epinephrine to increase wakefulness and mental performance at low doses, adverse effects at high doses. However, energy drinks contain several types of stimulants, which alter whether the stimulant response is rapid with a shorter duration or a slower with a longer duration (Heckman et al., 2010). Caffeine, ginseng, guarana, and other stimulants are used in their formulations to knowingly manipulate the amount and duration of the stimulant effect. Manufacturers of energy drinks use these variations in their proprietary formulas to affect sales and claim their product causes “no caffeine crash” or “gives you a rush” in advertisements. Short
durations of high levels of caffeine may be safe for some individuals but there is a lack of research to assess the effects of high doses over long periods of time and caffeine is addictive. Seizures, agitation, tremors, cerebrovascular accidents, dizziness (no illusion of movement), and vertigo (illusion of movement) have been associated with energy drinks and the central nervous system stimulation they elicit (Heckman et al., 2010).

**Reproductive**

A recent report of spontaneous abortion after consuming a product called “5-Hour Energy Shot” is being investigated by the FDA; however, it is not yet clear the cause of the miscarriage. Several of the ingredients can cause vaginal bleeding and energy drinks usually bear some form of warning for pregnant women to avoid their use though the reason for this warning is not stated. Limiting caffeine consumption during pregnancy to less than 200 mg per day is often recommended due to the potential for teratogenic defects and more importantly the combination of ingredients in energy drinks has not been tested for safety during pregnancy (Brent, Christian, & Diener, 2011).

**Renal**

Energy drinks contain both high amounts of taurine, sugars, and excessive amounts of caffeine. Energy drinks have as much as one-fourth to one-third cup of sugar per container. Sixty-one grams of carbohydrate (sugar) equals 15.25 teaspoons equals one-third cup of sugar (Campbell, n.d.). Elevated glucose intake, as in the amounts included in energy drinks, can lead to elevated blood glucose levels, diabetes, and kidney failure (American Diabetes Association [ADA], n.d.). The dehydration produced by energy drinks discussed earlier is also caused by excessive diuresis leading to the loss of minerals, such as magnesium and calcium, via the
kidneys leading to damage (Abbott, 2010; Deuster et al., 2004; Heckman et al., 2010). Energy
drinks have also been reported in kidney failure from rhabdomyolysis, renal tubal inflammation
and necrosis, as well as kidney stones caused from the mineral excretion (Seifert et al., 2011).

**Musculoskeletal**

As with other systems, the musculoskeletal system suffers from energy drink
consumption. Gouty arthritis bouts are linked with energy drink use because of the very high
amounts of B vitamins, proteins - especially meat and seafood based-proteins such as taurine as
well as fructose sugars. Alcohol which consumers often mix with energy drinks is also linked
with gouty arthritis attacks (Crittenden & Pillenger, 2012; Heckman et al., 2010; Mayo Clinic,
2012b). Some studies found taurine was associated with decreased lactic acid build up in muscle
but it comes along with extreme muscle weakness and the mechanism is not understood
(Heckman et al., 2010; Mayo Clinic, 2012b). A more serious complication from consuming
energy drinks is rhabdomyolysis, a destruction of the skeletal muscles that can cause permanent
muscle damage, kidney failure, and can be deadly. The condition is not uncommon for the
firefighting industry especially wild fire firefighters who consume energy drinks and/or creatine
to aid in muscle and strength training (Gabbert, 2011). A common practice that body builders use
before workouts is combing energy drinks with powdered creatine mix and it can be very
dangerous due to the severe dehydration, rhabdomyolysis, and kidney failure (University of
Maryland Medical Center, 2011). Though the mechanism for the damage from energy drinks
alone or with creatine is not clearly understood in rhabdomyolysis, two theories exist. The first
theory is that the breakdown of muscle tissue is caused by the thermogenesis of herbal
stimulants, similar to the condition seen in cocaine use. The second theory is that the
sodium/potassium ion pump in skeletal muscle is altered during strenuous use and causes an additional muscle contraction that pulls the muscle while it is already contracted leading to damage (Broderick & Benjamin, 2004; Deuster et al., 2004; Hedges, Woon & Hoopes, 2009; Nabili & Shiel, n.d.; Petomatic, 2010).

**Psychological, Cognitive, and Behavioral**

Cognitive performance testing information gathered through energy drink studies is often conflicting. For example, Howard and Marczinski (2010) found some improvement in cognitive performance testing with energy drink use but Buchanan (2012) and Seifert et al. (2011) found no evidence to suggest there is an improvement in mental or physical performance. The aggression, agitation, risk taking behavior, and other behavioral issues found with energy drink use are illusive in their explanation. Ishak, Ugochukwu, Bagot, Khalili, & Zaky (2012) found the effects of energy drinks on quality of life and feelings of well-being to be unclear. However, evidence does exist that suggests genetic differences at specific adenosine receptors can lead to having restlessness and agitation after caffeine consumption when others do not and the same receptor alterations are found in patients with panic disorders (Childs et al., 2008). More than one episode of psychosis in healthy individuals has been reported after consuming large amounts of caffeine and resolved with no other treatment than a gradual withdrawal of caffeine. The episodes of psychosis in the healthy adults were thought to be from dopamine receptor and possibly the benzodiazepine neuroreceptor blockade from the caffeine (Broderick & Benjamin, 2004; Hedges et al., 2009). Of particular note when reviewing the side effects of each of the individual ingredients, agitation or restlessness is frequently cited, again pointing to the need for a review of all the ingredients for synergistic and additive effects.
Reports of frequent energy drink consumption along with the use of alcohol, non-medical use of prescription stimulants and analgesics, as well as illicit drug use are increasing (Table 2.1) and cause about 42% of emergency room visits from energy drinks (AAPCC, 2013; Arria et al., 2010; Arria et al., 2011; SAMHSA, 2013). The co-substance addictive behavior is thought to be due to the effects of the energy drinks on neurotransmitters and the synapses in the brain that elicit a paradoxical physical experience of pleasure and physical stress at the same time (Minderhout, 2011).

**Gaps in Literature**

Articles containing information about energy drink risks, research information, and recommendations for physicians exist in medical journals with regularity since 2009 but most are in pediatric medical journals. This is most likely because of the ages of the patients consuming and encountering difficulties from energy drinks. Most of the reports and research indicate more investigation is needed to understand why the energy drinks caused the health issues reported. But relatively few discussions exist on the topic in peer reviewed nursing journals and none were discovered in the occupational and environmental health nurse journals. The two recent studies to evaluate the effects of energy drinks in workers were conducted with U.S. Government funding suggesting occupational issues may have been the catalyst for seeking more information. As the diversity of the ages of those consuming energy drinks expands so too will the need for educational material across a more broad range of patient ages and types of nursing journals. The currently suspected risks associated with energy drinks should be shared with all healthcare professionals to protect public health.
TABLE 2.1
SELECTED DRUG COMBINATIONS IN ENERGY DRINK-RELATED EMERGENCY DEPARTMENT (ED) VISITS: 2011

<table>
<thead>
<tr>
<th>Drug Combination</th>
<th>Number of ED Visits</th>
<th>Percentage of ED Visits*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total ED Visits</td>
<td>20,783</td>
<td>100</td>
</tr>
<tr>
<td>Energy Drinks Only</td>
<td>12,131</td>
<td>58</td>
</tr>
<tr>
<td>Energy Drinks in Combination</td>
<td>8,652</td>
<td>42</td>
</tr>
<tr>
<td>▪ Any Pharmaceutical Combination</td>
<td>5,542</td>
<td>27</td>
</tr>
<tr>
<td>▪ Central Nervous System (CNS) Stimulants</td>
<td>1,864</td>
<td>9</td>
</tr>
<tr>
<td>▪ Any Alcohol Combination</td>
<td>2,612</td>
<td>13</td>
</tr>
<tr>
<td>▪ Any Illicit Drug Combination</td>
<td>2,047</td>
<td>10</td>
</tr>
<tr>
<td>▪ Marijuana</td>
<td>966</td>
<td>5</td>
</tr>
</tbody>
</table>

*Because multiple drugs may be involved in each visit, estimates of visits by drug may add to more than the total number of visits, and percentages may add to more than 100 percent.

Source: 2011 SAMHSA Drug Abuse Warning Network (DAWN) (as cited by SAMHSA, 2013, p. 4)
Concern among the occupational sector is rising and it is based on anecdotal reports and firsthand experience within certain professions with adverse energy drink events. Articles written by various trade leaders to educate their trade members about health risks of energy drinks are a valiant effort and should be applauded. Oilfield companies, International Brotherhood of Electrical Workers Union, and construction companies are beginning to educate workers about the risks associated with energy drinks through safety talks and newsletters (Gonzalez, 2012; Quinn, 2012; "Toolbox Talk," n.d.). However, they need the assistance of OEHNs to share the broader scope of concern, not just dehydration, and to share the correct prevention measures to assure workers are protected. In turn, OEHNs need more information resources to be on the front lines of prevention helping trade leaders to educate workers, employers, and trade school leaders.

Energy drink studies in athletics focused mostly on performance and not health effects producing conflicting results, perhaps because many were funded by the energy drink makers. Despite the conflicting evidence, the essence of the athletic research is energy drinks do little to improve performance and there is no need to recommend these drinks.

While many studies have addressed the ill effects of energy drinks most attribute the medical issues solely to the caffeine in the drinks, none have researched the possible synergistic or additive effects of the ingredients, the safety of the formulas or the effects of the high doses of ingredients. In fact, not even all of the individual ingredients have been studied and of the ones studied, no long-term exposure to high doses has been studied. Replicating in research the formulas, ingredients, doses, and patterns of current energy drink consumption by consumers is imperative to assess the safety of energy drinks.
Also missing from the journals is research looking at the low grade, chronic, long term conditions that do not involve emergency room treatment. Protocols are needed for nurses to follow for reporting low grade events. When nurses recommend follow up medical care but not emergency room treatment for a client found to have hypertension with a positive history of energy drink consumption, how should nurses report this?
CHAPTER III
ENERGY DRINKS AND INDUSTRY

Worker characteristics may make energy drink use more prevalent in some industries than others. According to SAMHSA (2012), the proportion of adults with the classification of substance dependence or abuse was highest among males, those who had not graduated from high school, and those employed part-time or unemployed. However, the same report indicates that nearly 52% of the 18.9 million adults classified with substance dependence or abuse were employed full-time in 2011. The emergency department visits related to energy drinks combined with other substances accounted for 42% of the total visits (SAMHSA, 2013). Risk-taking behaviors and substance use or abuse have been associated with energy drink use (Arria et al., 2010; Arria et al., 2011), some even consider energy drinks a possible gateway drug (Minderhout, 2011). Given the possible association, it is plausible that high rates of energy drink use will be found in industries with high rates of substance use and abuse (Arria et al., 2010; Arria et al., 2011; Jackson et al., 2011; Minderhout, 2011; SAMHSA, 2013; Seifert et al., 2011).

Industries At-Risk

Industries that employ mostly men such as farming, the military services, construction, oil production, and transportation could be more at-risk for energy drink use (Arria et al., 2011; SAMHSA, 2012; U.S. BLS, 2013b). These occupations also include hard physical labor and potentially long work hours, setting the perfect storm. Industries with a high number of part-time employees such as hotels, food service, and laundry facilities could be at-risk. Part-time work may have workers with fatigue from working more than one job, going to school while working,
and have financial stressors (Bender, 2006; U.S. BLS, 2013a). Food service and laundry facility workers also work in hot environments with the risk of dehydration that could be compounded by energy drinks (Abbott, 2010). Work that has high stress, long hours, high productivity demands such as emergency services personnel, medical professionals, and athletes are also industries with workers at-risk. The stimulant effect of energy drinks make industries with work conditions that include shift work, high physical performance demands, long hours, mental alertness requirements, or extreme environmental conditions a risk for energy drink use and ill effects (Abbott, 2010; Duchan et al., 2010; Lombardi et al., 2010; U.S. BLS, 2013b). Shift workers are especially at-risk for fatigue because of the disruption of the circadian rhythm and sleep disruption (Lombardi et al., 2010); energy drinks often seem like a solution.

Worker susceptibility including age and health status also plays a role in energy drink effects. However, young healthy, athletic individuals have shown negative responses to energy drink exposure suggesting good health may play only a minor part in mitigating worker susceptibility (Abbott, 2010; Duchan et al., 2010; SAMHSA, 2013; Toblin et al., 2012).

Some industries have a higher rate of substance use and abuse including the food service and construction sectors. The construction industry in a 2007 SAMHSA report had the highest percentage of heavy alcohol use at 17.8% and second highest rates of illicit drug use at 15.1% among currently employed workers (Larson, Eyerman, Foster, & Gfroerer, 2007). This coupled with the high rate of male workers, demanding physical work, and the cyclic seasonal work common among this occupation make this a particularly high risk group for energy drink use. Men tend to be risk takers, and Buchanan (2012) associated risk-taking with energy drink use. The seasonal nature of construction work also leads to periods of low physical activity alternated
with much physical activity leading some workers to seek increased endurance from energy drinks during the periods of increased demands.

Food service workers also rank high in alcohol and illicit substance use in the 2007 SAMHSA report (Larson et al., 2007). Food services workers are likely to be employed less than full-time, more apt to be young, less likely to have graduated from high school or college, work in high-demand productivity settings, and work in hot environments placing this group at increased risk. Energy drinks may offer this group the false hope of a mental pick-me-up and the energy to meet the fast pace and tiring work environment.

However, not all at-risk groups for energy drink use fall clearly into the substance use and abuse characterization. Transport workers are not listed as a high risk group in the SAMHSA report (Larson et al., 2007) but in a report to Congress the U. S. Government Accountability Office (U.S. GAO) stated this may be due to lack of detection. The GAO report says approximately 3% of motor carrier drivers were positive for illegal drugs on random testing but that many more were being missed due to drug testing protocols that do not address current substances of abuse (U.S. GAO, 2008). Because of the need to stay alert during long over-the-road transport work, drivers may also resort to energy drinks to help stay awake and alert.

**Worker Studies**

Worker studies have been few but research is slowly beginning. One worker study funded by the Federal Emergency Management Agency (FEMA) in 2010 researched the health effects of energy drinks in firefighters (Abbott, 2010). The study used vital signs, urinary output, and bioimpedence analysis to assess intracellular hydration in California firefighters (Abbott, 2010). The focus was on the high levels of sugar and caffeine in the beverages but neither was
proven as a sole cause of the ill effects found. The study showed levels of significant dehydration in firefighters consuming energy drinks and made recommendations to the California North County Fire Protection District to place energy drinks on the list of substances firefighters should consume in moderation, if at all (Abbott, 2010). Study participants who consumed energy drinks which are hypertonic solutions (Cervenka, 2012; Patlak, 1999) experienced depleted intracellular fluid (ICF) levels. Signs and symptoms of intracellular dehydration, including a decline in cognitive function, begin at a 1% loss of ICF (“Intracellular Fluid” 2013). According to Abbott, the participants who consumed energy drinks lost about 1% more ICF compared to those in the control groups regardless of their initial hydration status. An interesting note in this study was that 13% of the firefighters who took part in the study started out 2% or more deficient in ICF and 21% started out 3% or more deficient in ICF. Abbott also noted there was a reduction in blood pressure for the control group (no energy drinks) with exercise but blood pressures increased significantly for those who consumed energy drinks for the study.

Another study reviewed how energy drink consumption affected U.S. Service Members in combat deployment. The study surveyed 1,000 military personnel stationed in Afghanistan during military operations about energy drink consumption, sleep medications, personal life stressors, sleep patterns, and health issues (Toblin et al., 2012). The outcome suggests a probable connection with high consumption of energy drinks among military personnel and sleep disturbance, loss of energy, tension, and more frequent illness then those who drank little or no energy drinks (Toblin et al., 2012).
CHAPTER IV
DISCUSSION

Occupational health professionals must advocate for public health in regards to energy drinks and worker safety. In specific, OEHNs have a role as a clinical practitioner, health promotion specialist, educator, researcher, consultant, and can educate workers, employers, peers, legislators, and the public about the risks of energy drink consumption. OEHNs can develop avenues to promote assessment of energy drink use, observe for clinical signs and symptoms of complications, care for those who are afflicted, and advocate for changes in legislation to prevent this unnecessary public health risk. To institute a proactive workplace prevention plan, OEHNs should:

1. Analyze the risks from energy drinks in each work setting, such as the environmental temperature and risk for worker dehydration, how strenuous the work is being done, and the physical health and age of the workers.

2. Assess the corporate culture regarding energy drinks, including union or employment contract agreements, current corporate policies, and the acceptability of energy drinks in the work setting.

3. Develop a program with specific objectives to reduce worker risks from health and safety from energy drinks. For example, setting educational training goals that are measurable and have prevention of energy drink complications as the focus. Programs may consider monitoring energy drink use and any adverse
health effects to track health effects and improvements with the programs implementation.

4. Develop and implement policies and procedures to avoid risks from energy drinks such as limiting the use of energy drinks while on duty and offering alternative beverages at no cost to employees to prevent energy drink consumption while at work.

5. Identify and prioritize the health and safety interventions.

6. Employ excellent communication skills to share the information, risks, and health benefits of avoiding energy drinks or other highly sugared and caffeinated beverages. Each level within an organization will require information from OEHNs to establish credibility and obtain cooperation.

7. Collaborate with other disciplines to assess risks, form decisions, obtain input for the plan, determine effectiveness, and evaluate change (Rogers, 2003).

Primary Prevention Measures

OEHNs are in the perfect position to act before health events are caused by energy supplement use. Educating workers about the need for adequate rest, increased consumption of water, and a more balanced diet to increase energy and improve focus is essential. OEHNs must also acknowledge some workers will disagree with the efforts and defend their “right” to consume energy drinks even after they are aware of the risks associated with energy drinks. However, by promoting open dialog during educational events and individual worker interactions a mutually respectful relationship can be fostered and may avoid worker disagreements.
The risks for workers consuming energy drinks include:

1. Dehydration from excessive diuresis and increased risk for heat illnesses such as heat exhaustion and heat stroke, especially for workers in physically demanding work and hot or humid environments.

2. Possible cardiovascular problems such as irregular and rapid heart rhythms, heart attacks from interrupted blood flow due to vasospasm of the coronary arteries or loosened plaques, thickened blood from dehydration, interference with current medications such as anticoagulants or antihypertensives, and cardiac arrest.

3. Potential for agitation, less patience, or psychosis with high rates of consumption of energy drinks.

4. Possible association with energy drinks and other substances abuse like alcohol, prescription stimulants, or pain medications.

5. Potential for kidney failure from the large doses of glucose, caffeine, the specific combinations of stimulants, and the excessive levels of proteins – especially when energy drinks are taken with creatine.

6. Potential for minor health effects including sleeplessness, stomach upset, and extreme fatigue with muscle weakness and major health effects such as muscle breakdown, heart conditions, seizures, and death.

OEHNs also need to develop workplace education programs that teach workers and employers about how to avoid the risks and ill effects of energy drinks and by advocating more healthful alternatives such as:
1. Appropriate use of caffeine - keeping levels of consumption to less than 400 mg per day for those adults without risks, and abstinence for those with risks such as caffeine sensitivity, diabetes, kidney disease, prolonged QT syndrome, cardiac disease, hypertension, psychological disorders, and use of medications or other supplements. Remember the amount of caffeine listed on the label is often incorrect; it is usually less than what is actually contained in the beverage, and avoid consuming the entire 400 mg at one time (Mayo Clinic, 2011; Nawrot et al., 2003; Shah et al., 2013; Yew & Tarabar, 2011).

2. Adequate levels of rest – at least 6 to 8 hours per night for adults. No substitute exists.

3. Proper nutrition – including proper amounts of fluids such as water and juice. Adults need approximately 58 to 75 grams of protein, 5 servings of fruits, and 5 servings of vegetables per day to assist with replacement of fluids and nutrients lost during physical work or heat (USDA & U.S. Department of Health & Human Services [DHHS], 2010).

4. Proper levels of hydration – men need about 125 ounces of liquids and women about 91 ounces of liquids per day according to the Institute of Medicine (IOM) (2004). Consuming low sugar, non-caffeinated fluids frequently throughout the day to maintain proper hydration during physical exertion or hot environmental conditions.

5. Nutritional recommendations – when using supplements remind employees to observe nutritional requirements because no research has been conducted to see if
8333% of RDI for any water soluble vitamin, as is found in energy drinks or energy shots, is safe for long term use and there can be acute side effects of that high dose.

6. Communication – encourage open, honest communications between workers and decision makers to promote opportunities for education and exchange of ideas for workplace health initiatives involving energy drinks.

Ensuring clients understand the risks of continued exposure to energy drinks and the need to limit or eliminate their use before an illness or permanent damage occur is key. The goal of primary prevention is ensuring that further exposure is reduced or eliminated to prevent an illness. However, without regulations to rein their content or preclude their production, energy drinks will be available and workers will likely continue to consume them.

OEHNs are part of a multidisciplinary team for health and safety in the occupational setting. Behavior-based safety programs based on rewards and punishment in response to an employee’s behaviors are needed in the business world and can be an effective part of a total safety culture plan within a business. However, it is often a less effective method for prevention than a safety culture that is based on mutual respect and dialogue among the company employees at all levels. A dialogue based in mutual respect and avoids assigning blame can create an environment of sincere, mutually beneficial interaction to avoid safety issues and has been shown to be more effective in improving worker compliance with safety rules and enforcement (Arthur, 2013; Schneider, 2013; U.S. Forest Service, n.d.; U.S. Nuclear Regulatory Commission [U.S. NRC], 2013). OEHNs as part of the multidisciplinary team can foster this safety culture.
OEHNs can help create multidisciplinary communication with the occupational health physicians, management, employees, safety personnel, and union leaders to discuss why removing or limiting energy drinks at worksites is important for the employees as well as the company. Phasing in a plan that employees took part in creating provides workers a chance to take part in decisions, evolve with the changes, and improves the likelihood of program success.

No U.S. Equal Employment Opportunity Commission (EEOC) or case law decisions have been made to support or oppose banning energy drinks at work. However, any work policies that ban or restrict energy drinks must abide by existing contracts negotiated with unions. The ballplayers were not happy about the ban of energy drinks proposed by the baseball leagues in 2011 and the legal issue of potential conflict with the union contracts did arise (Nightengale, 2011).

Where employees are represented by a union, energy drink or energy supplement bans may be considered a change in the working conditions and thus a subject of collective bargaining which the employer cannot unilaterally change (S. Spender, personal communication, December 20, 2012). Energy supplement bans can be part of contract negotiations and a mutual agreement to disallow them on work sites but requires education of participants and forethought to be effective, as with all efforts to promote health. Therefore bringing union employees and their leaders onboard early with the education efforts can help avoid resistance and discord with new rules or bans.

An example of a mutually agreed upon administrative rule would be requiring periodic mandatory education of employees regarding the risks of energy drinks, no energy drinks in vending machines, and moderation in energy drink consumption while at work. This has to be
based on mutual trust between management and the employees because enforcement would be difficult for an employer but could be very effective in enlisting employee cooperation.

Secondary Prevention Measures

Physical or periodic medical exams forms should include indicators for energy drink use and frequency as part of a client’s medical history. Designing screening programs, gaining employer support, executing the screening, and following up with the clients is crucial in raising awareness. Planning routine health screening events is one way to have employees voluntarily participate to detect current signs and symptoms of complications from energy drink or other substance use. Questionnaire evaluation, heart rate, blood pressure, blood sugar, mucus membrane assessment, and skin turgor are easy nursing assessments that can be done to detect health issues at each visit to detect dehydration, hypertension, elevated blood sugar, and irregular or rapid heart rates and assist in avoiding the hazards caused by energy drink complications (Rogers, Randolph, & Mastroianni, 2009; Yew & Tarabar, 2011).

Screening clients may uncover health issues from consuming energy drinks that need medical attention. Medical treatment may be urgently needed or for others it may be appropriate to arrange for care within a reasonable number of days. Ailments such as chest pain, hypertension, severe gout attacks, or severe agitation will need medical attention outside the scope of the OEHNs role and will require referral to timely and appropriate services to prevent permanent damage.

Clients who consume energy drinks are likely to have elevated blood pressure especially if taken with other prescription stimulants such as Adderall or Ritalin (Cohen & Townsend, 2006; Torpy & Livingston, 2013). Clients with systolic blood pressure at or above 160 mmHg or
a diastolic pressure at or above 100 mmHg should be referred to a primary healthcare provider
for care with instructions to avoid further energy drink consumption (Table 4.1). The blood
pressure guidelines are the same for those with energy drinks or other causes because
hypertension can lead to serious complications if not cared for appropriately. Energy drinks are
known to elevate blood pressure and heart rate to a dangerous level. Blood pressure at or above
180 mmHg systolic or 110 mmHg diastolic should be referred for urgent treatment (National
Institutes of Health, 2004). Once measured, blood pressure and heart rate need further clinical
assessment to determine if care is needed, if it is needed immediately, or if it can wait for an
appointment with their primary healthcare provider (American Heart Association, 2012; National
Health Service, 2011; National Institutes of Health, 2004). Tachycardia is also often associated
with energy drink consumption and clients with pulse rates equal to or greater than 120 beats per
minute and asymptomatic should be referred to a primary healthcare provider for evaluation and
sent for urgent treatment if symptomatic (National Health Service, 2011). Symptoms could
include dizziness, chest pain, low blood pressure, or faintness.

When individuals are found to have serious medical issues that arise after consuming
energy drinks the incidents should be reported first to the Poison Control Centers and then to the
FDA for assistance in promoting proper patient care, data collection for research, and possible
legislative interventions to prevent further health events. Documenting an accurate energy drink
use history will be critical in assisting with determining whether the ill health effects are related
to energy drinks and why. Nurses are the frontline source for gathering this information and
reporting it to the correct agencies.
TABLE 4.1  
BLOOD PRESSURE AND HEART RATE CATEGORIES  
WITH REFERRAL RECOMMENDATIONS

<table>
<thead>
<tr>
<th>Blood Pressure Category</th>
<th>Systolic mmHg</th>
<th>Diastolic mmHg</th>
<th>Referral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt; 120</td>
<td>and</td>
<td>&lt; 80</td>
</tr>
<tr>
<td>Prehypertension</td>
<td>120-139</td>
<td>or</td>
<td>80-89</td>
</tr>
<tr>
<td>Hypertension Stage 1</td>
<td>140-159</td>
<td>or</td>
<td>90-99</td>
</tr>
<tr>
<td>Hypertension Stage 2</td>
<td>&gt;160</td>
<td>or</td>
<td>&gt;100</td>
</tr>
<tr>
<td>Emergency Care Needed</td>
<td>&gt; 180</td>
<td>or</td>
<td>&gt;110</td>
</tr>
</tbody>
</table>

Heart Rate symptoms

<table>
<thead>
<tr>
<th>Heart Rate symptoms</th>
<th>Elevated</th>
<th>Refer for medical treatment based on symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 120 bpm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Based on assessment  
yr = year  
mo = month  
wk = week  
bpm = beats per minute

Source (Table adapted from): American Heart Association, 2012; National Health Service, 2011; & National Institutes of Health, 2004
Education of Healthcare Professionals

Articles have occasionally appeared in professional nursing journals such as the *American Nurse Today* and *AWHONN Journal of Nursing for Women’s Health* informing readers about the ill health effects nurses and their patients could experience if they consume energy drinks (Guilbeau, 2012; Neale, 2011). However, more work needs to be done with the information currently available to advocate for precautions until more research can enlighten the health community.

The evidence to date suggests there is at least a moderate amount of concern with energy drink use at high levels and a need for discretion in its use. Nurses need to err on the side of safety and avoid using energy drinks as well as other energy supplements. They should encourage their clients to do the same until research can prove the formulas used are safe or measures are taken to assure safe amounts of all ingredients in energy drink and supplement formulas. Sharing the gained information with other nurses will expand the likelihood of avoiding health issues in patients/clients who consume energy drinks.

Politics, Nurse Leadership, and Energy Drinks

America, a nation with the least restriction on the manufacture of energy supplements and climbing rates of ill health effects related to energy drinks, needs nurses to be political. Advocating for public safety in regard to how energy drinks are manufactured and sold in the U.S. may involve action within the political realm. By equipping elected officials with accurate health information regarding energy drinks, nurses can raise awareness and assist them in decision-making on this important health topic. Promoting development of new health policy is very much within the role of the occupational and public health nurse. Occupational and
environmental health nurses are a component of public health nursing and public health is influenced by politics. Being political is not something the nursing profession has a strong history in doing, mostly because it is unfamiliar, but it shouldn’t be (Boswell, Cannon, & Miller, 2005). Nurses are excellent communicators and educators, which is all that is required to inform an elected official regarding a health issue. Armed with knowledge, confidence, and nursing skills, OEHNs make the best advocates for public health and safety.

The best way for nurses to be an advocate on the energy supplement topic in the public health arena is to act. Public health advocacy requires willingness to act and the ability to:

1. Foster client development so they can advocate for themselves,
2. Use suitable mass media to support advocacy efforts,
3. Assume the adversarial role if appropriate, and

Nurses should report any adverse health events that occur after a patient/client has consumed energy drinks to poison control for immediate assistance and antidote information. Reporting adverse health events to the FDA is also important for research and evaluation of energy drink safety. OEHNs can contact local elected officials and encourage them support continued research and appropriate regulation of energy drinks. Resources for reporting adverse health events and contacting local government officials are listed in Table 4.2. The criteria for the information the FDA is looking for is listed in Table 4.3 but the last entry “Other Serious (Important Medical Events)” is the most important to detect the low grade events. It is crucial that nurses follow their institutional policy for reporting adverse health events and the
TABLE 4.2
CONTACT INFORMATION FOR ADVOCACY EFFORTS

1. FDA Voluntary adverse event report call 1-800-FDA-1088 or go to http://www.fda.gov/Safety/MedWatch/HowToReport/ucm085568.htm

2. Interactive government official locator: http://www.usa.gov/Contact/Elected.shtml

3. Poison Control report 1-800-222-1222

4. Senator Dick Durbin
   a. Phone: 202-224-2152
   b. Address: 711 Hart Building Washington, DC 20510

5. Senator Richard Blumenthal
   a. Phone: 202-224-2823
   b. Address: 702 Hart Building Washington, DC 20510
   c. Web (best): https://www.blumenthal.senate.gov/contact/
# TABLE 4.3

**GUIDELINES FROM THE FDA ON REPORTING AN ADVERSE EVENT**

## What is a Serious Adverse Event?

An adverse event is any undesirable experience associated with the use of a medical product in a patient. The event is serious and should be reported to U.S. FDA when the patient outcome is:

- **Death**
  - Report if it is suspected that the death was an outcome of the adverse event, and include the date if known.

- **Life-threatening**
  - Report if suspected that the patient was at substantial risk of dying at the time of the adverse event, or use or continued use, of the device or other medical product might have resulted in the death of the patient.

- **Hospitalization (initial or prolonged)**
  - Report if admission to the hospital or prolonged hospitalization was a result of the adverse event. Emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life-threatening, required intervention to prevent permanent impairment or damage, other serious medically important event).

- **Disability or Permanent Damage**
  - Report if the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions, i.e., the adverse event resulted in a significant,
persistent or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities and/or quality of life.

**Congenital Anomaly/Birth Defect**

- Report if it is suspect that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.

**Required Intervention to Prevent Permanent Impairment or Damage (Devices)**

- Report if it is believed that medical or surgical intervention was necessary to preclude permanent impairment of a body function or to prevent permanent damage to a body structure is suspected to be from the use of a medical product.

**Other Serious (Important Medical Events)**

- Report when the event does not fit the other outcomes, but the event may jeopardize the patient and may require medical or surgical intervention (treatment) to prevent one of the other outcomes. Examples include allergic bronchospasm (a serious problem with breathing) requiring treatment in an emergency room, serious blood dyscrasias (blood disorders) or seizures/convulsions that do not result in hospitalization. The development of drug dependence or drug abuse would also be examples of important medical events.

**Source:** U.S. FDA, 2011
appropriate Health Insurance Portability and Accountability Act (HIPAA) guidelines. The adverse health event report to the FDA is allowed in the HIPAA Privacy Rule and Public Health report (CDC & U.S. DHHS, 2003).

Awareness and prevention are the keys to keeping workers and the public safe from the harm of energy drink and energy supplements. A peak in the adverse health events from energy drink use has likely not occurred in this under-recognized worker health problem.

**Future Research**

Nurses, especially OEHNs, should participate in research to assist with the assessment of energy drink safety. The less known about potential health risks from energy drinks, the more likely interventions will occur at the secondary or tertiary levels when disease or disorders are already present rather than at the primary level where the goal is to prevent them from occurring at all (Minnesota Department of Public Health, 2001). Making contact with a local university or hospital to conduct research, reading up on research planning in books like *Basic Steps in Planning Nursing Research: From Question to Proposal*, Seventh Edition by Marilynn Wood and Janet C. Ross-Kerr, Jones and Bartlett publisher can help formulate ideas. After reading, researching, and deciding the topic is worthy of a research project - take action! When reviewing the National Institutes of Health (NIH) and National Institutes on Drug Abuse (NIDA) research funding sites, nothing is listed for future energy drink research (NIDA, n.d.; NIH, 2012). Though this does not represent all funding avenues for energy drink research, this means no researcher has proposed any studies involving energy drinks in these two significant organizations. Unbiased determination of the health effects of each of the ingredients, at the levels contained in the drinks, over long periods of time, and the relationship these supplement beverages have with
drug abuse is imperative. Without research to determine the mechanism and effects of energy
drinks, little will be done in the way of regulation especially without political education to spur
the powers that be to action. Nurses can have a very powerful effect in the education of political
decision-makers.
CHAPTER V
SUMMARY AND RECOMMENDATIONS

Summary

The under tow of the energy drink hazards may be made of many low grade events that are likely being missed or unreported. Chronic hypertension may not cause an acute stroke but it can lead in time to kidney failure, vascular disease, and other chronic conditions that are latent for some time. An episode of heat illness on a job site that does not require emergency medical attention is unlikely to be explored for energy drink use or reported to a health agency or healthcare provider. Each episode of heat illness makes another episode in the same person more probable in the future, perhaps worse than the first (Binkley, Beckett, Casa, Kleiner, & Plummer, 2002). All of these events are possibly energy drink related events that are missed when assessing the safety of energy drinks currently on the market. It is important for nurses to screen for energy drink or supplement use. If there is a positive history and ill effects, even if not emergent, the abnormal findings should be reported to the FDA.

While manufacturers and some researchers continue to maintain that energy supplements are safe, an ever mounting accumulation of clinical evidence to the contrary would suggest otherwise. Given the vast amount of unknown information about the ingredients revved up and lurking in energy drinks coupled with the climb in the latest reports of emergency room visits related to energy drink consumption, caution should be advised. Studies in firefighters and military personnel suggest that even the most physically fit workers are susceptible to the dangerous complications that energy drinks can inflict. Most of the ingredients and the energy
drink containers include warnings for individuals with health disorders to avoid their use. Following this line of thought, older workers, who have probably accumulated a few health risks through the years, are at higher risk complications from consuming energy drinks.

OEHNs have an important role in educating, advocating, and assuring these products do not pose an unnecessary risk to the public. An obligation also exists for OEHNs to protect workers and employers from the hazards associated with these supplements. Energy drinks not only contain risk, but sales are growing at alarming rates in the beverage market with stealthily crafted advertising and manufacturing practices that leave consumers with little awareness of the risks of serious health consequences.

**Recommendations**

OEHNs should educate workers about the potential health risks of energy drinks, evaluate workers who are at-risk, and focus available resources toward the most at-risk groups to protect workers. Much more is unknown than is known about the health effects of energy drinks. By initiating a workplace plan of prevention, reporting health issues, promoting further investigation on the whole of the energy drink ingredients, and encouraging dialog with the working community, OEHNs can have the best influence in worker health and productivity. Many beverages have as much or more caffeine without the same deleterious health consequences related to energy drinks. All the ingredients and their chemical interactions need to be investigated. OEHNs should become well-versed and share the knowledge of energy drink risks to spur investigation and decrease health consequences from their consumption.
REFERENCES


Kaiser Permanente. (2010). Managing productivity: How are you addressing the high cost of lost productivity? Retrieved from https://businessnet.kp.org/health/plans/national/home/search?searchString=how+are+you+managing+productivity&search-btn=%C2%A0%C2%A0


## APPENDICES

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<tr>
<td>C. Press Release from Senator Blumenthal December 2012</td>
<td>76</td>
</tr>
</tbody>
</table>
INTRODUCTION

The chart of compiled information gathered from the labels on various energy supplement containers, which were donated by trainees at a construction trade training facility, is included to show the details found on the container. The problem is there is no way to verify that any of the nutritional or supplemental information is correct.

To follow Senators Durbin and Blumenthal along their path in seeking information from the FDA regarding the energy drink adverse health event reports, a copy of the August 2012 letter from the FDA is included here as well as a follow-up press release from Senator Blumenthal dated December 2012.
APPENDIX A

LETTER TO SENATOR DURBIN FROM THE FDA AUGUST 2012

The Honorable Richard J. Durbin
United States Senate
Washington, D.C. 20510-1304

Dear Senator Durbin:

Thank you for your letter of April 3, 2012 in which you express your concern about potential safety issues associated with the consumption of so-called “energy drinks.” You also requested that the Food and Drug Administration (FDA or the Agency) take certain actions in response to these issues.

As background, we note that the term “energy drinks” is not defined by statute or regulation. The Agency understands “energy drinks” to mean a class of products in liquid form that typically contains caffeine, with or without other added ingredients. Some products of this type are marketed as beverages (such as cola-type beverages), which are regulated as conventional foods, and others are marketed as liquid dietary supplements.

Within definitional limits set by the Federal Food, Drug, and Cosmetic Act (FD&C Act), the manufacturer of a product in liquid form may choose whether or not to label a product as a conventional food with a Nutrition Facts panel or as a liquid dietary supplement with a Supplements Facts panel. In the course of evaluating individual products on a case-by-case basis, FDA may challenge a company’s decision to label the product as one or the other. For example, in 2010, FDA issued a Warning Letter to the manufacturer of a beverage known as “Drank” that was marketed as a dietary supplement. The Agency determined that the product was a conventional food, and the Warning Letter stated that “Drank” was adulterated because it contained an unapproved food additive, melatonin. The Agency’s review of this matter is ongoing.

FDA’s December 2009 “Draft Guidance for Industry on Distinguishing Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods” (the Drinks Draft Guidance) discusses the factors that firms should consider when determining whether or not a product in liquid form is properly characterized as a dietary supplement or as a conventional food. The Agency is in the process of preparing a final guidance on this topic with the expectation that it will help both FDA and industry distinguish between beverages, on the one hand, and liquid dietary supplements, on the other.


\[1\] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm201435.htm
Any substance intentionally added to a conventional food must be used in accordance with a food additive regulation authorizing the substance for such use, unless the substance is generally recognized as safe (GRAS) among qualified experts for its use in the food, or the substance is otherwise exempt from the food additive definition. In evaluating the safety of substances added to food, FDA considers how much of the ingredient is consumed by people in the United States from all sources, and whether or not the available safety information supports such consumption.

FDA’s GRAS regulation for caffeine (21 CFR 182.1180) applies specifically to cola-type beverages. This regulation is based on a prior sanction for the then-customary uses of cola nut extracts in cola-type beverages. Over the years, the Agency has not challenged the use of caffeine in other beverages at levels comparable to the prior-sanctioned use level of 200 ppm. Although the regulation is an affirmative statement that the specified level of caffeine in cola-type beverages is GRAS, it does not automatically preclude other uses of caffeine from being considered GRAS, nor does it automatically give GRAS status to other uses. A manufacturer that has made a determination that a food ingredient is GRAS for its intended use(s) may market that ingredient without informing FDA. The Agency, however, may challenge such a determination.

There are a wide range of caffeine levels in energy drinks. The November 22, 2011, Drug Abuse Warning Network report by the Substance Abuse and Mental Health Services Administration (SAMHSA) cited levels ranging from 160 to 500 milligrams (mg) per serving. This compares with other beverages containing caffeine at the following levels:²

- brewed coffee: 135 mg per 8 ounce (oz) serving,
- coffeehouse brewed coffee: 330 mg per 16 oz serving,
- soda pop: 35 mg per 12 oz serving.

Regarding the November 2011 report, we are following up with SAMHSA regarding their source data to better assess whether any of the incidents cited in the report involved products marketed as dietary supplements and, if so, whether there were adverse event reports sent to the FDA on those incidents. We can then determine where gaps in our system may exist and how we can fill them in to best protect the public health. We will also have our medical officers review the individual reports that we are able to obtain from SAMHSA.

In response to the emergence of energy drinks as a new class of caffeinated products, FDA completed an updated assessment of the amount of caffeine that people in the United States ingest from all sources. The results show that, even when the consumption of energy drinks is considered, most of the caffeine consumed comes from what is naturally present in coffee and tea. For healthy adults, caffeine intake up to 400 mg per

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² These are approximate numbers offered only for the purpose of informing this discussion. Caffeine content can vary widely depending on the particular soft drink, and in the case of brewed coffee, depending on the beans, roasting and brewing conditions.
day (mg/d) is not associated with general toxicity, cardiovascular effects, effects on bone status and calcium balance (with consumption of adequate calcium), changes in adult behavior, incidence of cancer, or effects on male fertility. FDA recognizes, however, that some individuals may consume extraordinary amounts of caffeine as compared to those consumed by the majority of consumers in the United States.

FDA monitors the products it regulates, including “energy drinks,” by examining current scientific data, monitoring new ingredients added to products, and investigating reports of adverse events. When violations of the FD&C Act and FDA regulations are found, the Agency will pursue regulatory action, as appropriate.

In addition, FDA is conducting a review of recently published safety studies on caffeine. Although this project to identify safety studies on caffeine is still underway, the available studies do not indicate any new, previously unknown risks associated with caffeine consumption. FDA's safety evaluations are based on current scientific knowledge and do not preclude the Agency from changing its regulations if new safety information becomes available.

As your letter noted, the regulatory framework for liquid dietary supplements is somewhat different than for beverages. Under the FD&C Act, a dietary ingredient (such as caffeine or guarana) intended for use in a dietary supplement does not require premarket approval and is not required to be GRAS. To restrict the use of a dietary ingredient in a dietary supplement, FDA must demonstrate that the ingredient adulterates the product under the dietary supplement adulteration provisions of the FD&C Act; e.g., because the ingredient presents an unreasonable risk of illness or injury under the conditions of use recommended in the labeling of the supplement (see 21 United States Code (U.S.C.) 342(f)(1)(A)).

For dietary supplements, the Agency reviews adverse event reports that are submitted in accordance with the requirements in the Dietary Supplement and Nonprescription Drug Consumer Protection Act, and follows up as appropriate. Additionally, as FDA becomes aware of manufacturers, distributors, bottlers, and suppliers of liquid dietary supplements using new dietary ingredients in their products without a required premarket notification, the Agency will use the authority provided under section 413(a)(2) of the FD&C Act (21 U.S.C. 350b(a)(2)) to take regulatory action.

In your letter, you also urged FDA to clarify the definition of conventional foods, so that the distinction between dietary supplements and conventional foods will be less uncertain. In our view, a major reason for the confusion between product categories is the statutory language that distinguishes a dietary supplement from a conventional food. The Dietary Supplement Health and Education Act of 1994 (DSHEA) defined “dietary supplement,” in relevant part, as a product that is “not represented as a conventional food,” striking earlier statutory language that classified products based on whether they “simulated” conventional food. Because of this statutory change, FDA now generally must consider multiple factors to determine whether or not a product is “represented” as a conventional food. This is a more difficult standard for FDA to meet, as it necessitates a
complex evaluation of the different ways in which a product can be “represented” as a conventional food in labeling, advertising, or by other means such as packaging and product placement.

As discussed above, we expect that the Drinks Draft Guidance, once finalized, will help both FDA and industry draw a line between beverages and liquid dietary supplements. If this expectation is realized, we will consider issuing guidance on the demarcation between other types of conventional foods and dietary supplements.

You also asked that FDA investigate energy drinks that are marketed as dietary supplements to ensure that they are not in fact conventional foods and to investigate the caffeine levels in the same products. FDA has taken action on conventional foods that are unlawfully marketed as dietary supplements. In addition to the Drank Warning Letter described above, on May 23, 2012, FDA issued a Warning Letter to Rockstar, Inc.,\(^5\) stating, among other things, that the firm’s Rockstar Roasted Coffee and Energy products were represented as conventional foods and, accordingly, were not dietary supplements as defined under section 201(ff) of the FD&C Act (21 U.S.C. 321(ff)). The letter further stated that use of the term “energy supplement” on the product labels and use of a “Supplement Facts” panel for nutrition labeling did not make the products dietary supplements, because the products were represented for use as conventional foods in their labeling, packaging, and appearance. FDA evaluates products such as these to ensure that the ingredients comply with the food additive provisions of the FD&C Act.

Finally, you requested that FDA consider the safety of the use of taurine, guarana and ginseng in energy drinks, particularly in combination with caffeine, and that the Agency require manufacturers to provide evidence of the safety of these ingredients. Although FDA has not conducted a formal assessment of the safety of the use of taurine or guarana in energy drinks, we discuss the safety information we have on these ingredients below.

Taurine is an amino acid normally present in foods derived from fish and meat, and it is also produced in the human body. The European Commission (EC) assessed the use of taurine in energy drinks and, due to limited information, they were “unable to conclude that the safety-in-use of taurine in the concentration range reported for taurine in ‘energy’ drinks has been adequately established.” The EC also concluded that “[f]urther studies would be required to establish an upper safe level for daily intake of taurine.”\(^6\) FDA has not approved taurine as a food additive for use in conventional foods. However, the Flavor and Extract Manufacturers Association of the United States (FEMA) considers it to be GRAS for flavor use.

Guarana extract is derived from the plant *Paullinia cupana*. Its seeds contain caffeine as a natural component. Guarana seeds are 2 to 4.5% caffeine by weight, in contrast to coffee beans, which are 1 to 2.5% caffeine by weight. With respect to conventional foods, guarana is an approved food additive for flavor use as specified in the FDA’s

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\(^5\) [http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm309080.htm](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm309080.htm)

\(^6\) [http://ec.europa.eu/food/fs/sc/scf/out22_en.html](http://ec.europa.eu/food/fs/sc/scf/out22_en.html)
regulation on natural flavoring agents and adjuvants (21 CFR 172.510); this regulation does not provide for non-flavor uses.

When either taurine or guarana is used as a flavor, it is typically used at very low levels and in accordance with current Good Manufacturing Practices (cGMP). FDA is not aware of any GRAS determinations by FEMA or other entities for non-flavor uses of taurine or guarana. With respect to their use in dietary supplements, taurine and guarana would likely not be considered new dietary ingredients due to their probable use as dietary ingredients prior to 1994.

Finally, to provide an update regarding the untimely death of Ms. Anaïs Fournier, as Commissioner Hamburg noted in her letter to you of May 16, 2012, FDA did receive a Serious Adverse Event Report from the marketer of Monster Energy Drink. We also received a voluntary Adverse Event Report from Ms. Fournier’s family. Medical staff in FDA’s Division of Dietary Supplement Products have made multiple attempts to contact her mother, Wendy Crossland, by phone and e-mail, but have not heard from her except for one brief email. We understand it is a difficult time for Ms. Crossland, and while we will continue to pursue this matter, we will also maintain respect for the family’s wishes.

FDA has also reached out to the Maryland State Medical examiner on multiple occasions to obtain the death certificate, but we have not yet been able to obtain it. Additionally, we have consulted and received limited information from the attending physicians at Meritus Health Center, where Ms. Fournier was initially admitted, and Johns Hopkins Hospital, where she was subsequently transferred.

Thank you, again, for contacting us concerning this matter. If you have any further questions or concerns, please let us know.

Sincerely,

Jeanne Ireland
Assistant Commissioner
for Legislation
(Washington, D.C.) – After a meeting with Food and Drug Administration (FDA) Commissioner Margaret Hamburg, U.S. Senator Richard Blumenthal (D-Conn.) and U.S. Senator Dick Durbin (D-Ill.) today said they are confident that the FDA is taking their concerns about energy drinks seriously. The Senators said:

“At our meeting the FDA made it clear it is moving forward in a number of areas to protect vulnerable populations against high levels of caffeine in energy drinks. The energy drink makers are mistaken if they believe they have escaped regulatory oversight to safeguard consumer health.

“We urged the FDA to convene an expert panel, as quickly as possible but no later than early in the new year, to discuss the effects of consumption of caffeine and other stimulants by consumers. We also requested that the FDA take swift action regarding findings that a number of energy drinks contain at least 20 percent more caffeine than the products’ labels disclosed. We believe that these mislabeled products require enforcement action.

“We were heartened by the positive response by FDA officials to our points in these areas and others, such as caffeine levels, additives and labeling.”

Several agencies and organizations have conducted research on the impact of caffeine, especially on children and adolescents. A report by the Substance Abuse and Mental Health Services Administration shows that energy drinks pose potentially serious health risks. The report found that between 2005–2009, the number of emergency room visits due to energy drinks increased ten-fold from 1,128 to 13,114 visits. A major factor contributing to these hospitalizations is the exceptionally high levels of caffeine in energy drinks. According to the American Academy of Pediatrics, adolescents should not consume caffeine.

In a November letter, following reports that the Food and Drug Administration (FDA) has received 13 adverse event reports of fatalities following the consumption of 5-Hour Energy, Blumenthal and Durbin called for today’s meeting with the FDA Commissioner, Margaret Hamburg, to discuss the steps the agency is taking to ensure the safety of energy drinks.

In an October letter, after the FDA revealed an investigation into five deaths that occurred following the consumption of Monster energy drinks, Blumenthal and Durbin challenged the FDA to quickly identify and recommend remedies for weaknesses and loopholes in current law
that are exploited by energy drink manufacturers in order to avoid oversight. They also called on the FDA to investigate the interactions between caffeine and stimulants in energy drinks and to assess the health risks associated with caffeine consumption by children and adolescents.

In a September letter, Blumenthal and Durbin asked the FDA to respond to their specific concerns regarding the interaction of ingredients in energy drinks and the effect that the caffeine in energy drinks has on children and adolescents. In April, Durbin sent a similar letter to the FDA Commissioner Margaret Hamburg; however, both Senators felt that the FDA’s response did not fully address the specific concerns that were laid out.
<table>
<thead>
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<th>Ingredient</th>
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<tbody>
<tr>
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<td>0.2%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Caffeine</td>
<td>0.1%</td>
<td>0.1%</td>
</tr>
<tr>
<td>Taurine</td>
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<td>0.1%</td>
</tr>
<tr>
<td>Beta Alanine</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Vitamin B6</td>
<td>0.1%</td>
<td>0.1%</td>
</tr>
<tr>
<td>Vitamin B12</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

Values are based on a 2,000 caloric diet. The % Daily Value (DV) for different nutrients depends on your daily caloric needs. For example, if you are consuming 2,000 calories per day, 5% is equivalent to 100 calories. The DV is based on a 2,000 calorie diet. Your daily caloric needs may be higher or lower depending on your age, weight, and activity level. If you regularly consume more than 2,000 calories per day, use the higherDV for each nutrient. Energy drinks are intended to be consumed as part of a balanced diet.
<table>
<thead>
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<th>Extension</th>
<th>Length</th>
<th>Tension Force</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beam A</td>
<td>Steel</td>
<td>120 psi</td>
<td>0.02%</td>
<td>100 in</td>
<td>2400 lb</td>
</tr>
<tr>
<td>Beam B</td>
<td>Aluminum</td>
<td>80 psi</td>
<td>0.03%</td>
<td>150 in</td>
<td>1800 lb</td>
</tr>
<tr>
<td>Beam C</td>
<td>Copper</td>
<td>60 psi</td>
<td>0.04%</td>
<td>200 in</td>
<td>1200 lb</td>
</tr>
</tbody>
</table>

**Note:** The exemptions and tolerances are as per the specified standards.