S. HRG. 113–331

ENERGY DRINKS: EXPLORING CONCERNS ABOUT MARKETING TO YOUTH

HEARING

BEFORE THE

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION UNITED STATES SENATE

ONE HUNDRED THIRTEENTH CONGRESS

FIRST SESSION

JULY 31, 2013

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SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

ONE HUNDRED THIRTEENTH CONGRESS

FIRST SESSION

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ENERGY DRINKS: EXPLORING CONCERNS ABOUT MARKETING TO YOUTH

WEDNESDAY, JULY 31, 2013

U.S. SENATE,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, DC.

The Committee met, pursuant to notice, at 2:55 p.m., in Room SR–253, Russell Senate Office Building, Hon. John D. Rockefeller IV, Chairman of the Committee, presiding.

OPENING STATEMENT OF HON. JOHN D. ROCKEFELLER IV, U.S. SENATOR FROM WEST VIRGINIA

The CHAIRMAN. The Senate is the Senate. The person at the witness table knows that better than anybody. Are you going to do anything with those things? Is that an exhibition, or are you going to show us your—you are? OK.

All right. Let me just explain to the witnesses and to the faithful audience. It is hard to get people confirmed around here, and so it always come down to—often comes down to when a single member is missing or not findable that everything stops, and the whole world tries to get that person, find that person. And so, that is the situation we are in now.

If she is found and does vote, which I don't think will be probable, then we will—I will have to go back and do another vote, make your life even worse.

However, Senator Durbin is here, and Senator Blumenthal is here, and Senator Markey is going to be here. And what I want to do, because those three have been so incredible on this whole subject, they put out a report, the three of them, which is called "What's All the Buzz About?" And you understand what I mean by "buzz." I mean this is a different kind of buzz.

And they did this some months ago. It is a fabulous report, and it is all about targeting marketing to adolescents of things which should not be targeted or marketed to them.

So what I am going to do is make my statement and then listen to my leader, Richard Durbin, who has been working very, very strongly, as I indicated, on this. And then I am going to turn the gavel over to Senator Blumenthal. Not because I want to, but because the thought of him having the gavel, presiding over something in which he and Senator Markey have been so committed and so dedicated for so long is the only proper thing to do.

So I will fade into the distance, and you will forget that you ever heard me or saw me.

[Laughter.]

The CHAIRMAN. So my statement. Today's hearing is going to look at a product that it has been growing very rapidly in popularity in the last few years. It is not the Congress, actually, I am talking about. It is energy drinks, energy drinks.

While energy drink companies have aggressively marketed their products on television, social media, and event sponsorship, public health experts have been raising some serious, disturbing questions about these drinks. They are asking whether we should be letting our children drink energy drinks and whether energy drink companies should be able to market their products to children and to teenagers, two fairly basic questions.

In the meantime, if you watch TV, you just—every other TV ad is either about a car, which is fine, or about one of these drinks, which is less fine. I think these are important questions, and I am going to be listening to those who are asking some of them.

So here are just two facts about energy drinks. As energy drink marketing and sales to children has increased, there has been a surge in emergency room visits associated with energy drinks. And in the first 6 months of this year, poison control centers received 1,500 reports involving energy drinks, more than half of which involved children under the age of 18.

So these are two frightening statistics. Pediatricians and other medical experts have been saying that high levels of caffeine found in many of these drinks may pose health risks to young people, such as heart arrhythmias, increased blood pressure, and dehydration. And again, that is scary stuff.

In fact, a recent clinical report published by the American Academy of Pediatrics states, "Rigorous review and analysis of the literature reveal that caffeine and other stimulant substances contained in energy drinks have no place in the diet of children and adolescents." So that is what we are hearing from pediatricians.

And just last month, the American Medical Association approved a resolution endorsing a ban on marketing energy drinks to children and teens. They don't do that often. They did that on this.

That brings us to the question before us. How are companies marketing energy drinks to younger people? What are their techniques? And are energy drink companies listening to the medical experts who are increasingly worried about what these drinks may be doing to our kids? Is there any talk back and forth?

Two members of this committee, Senators Blumenthal and Markey, along with Senator Durbin, have been leading the way in examining the marketing practices of major energy drink companies for a long time. And I honor them for their work. Their investigation found that while energy drink companies say they do not market to children, adolescent consumer products are frequent targets for energy drink marketing practices. We know that.

Similarly, marketing experts at the Rudd Center on Food Policy and Obesity at Yale University have raised concerns about energy drink marketing practices that are reaching teens in high percentages relative to adults. For example, disturbingly, many energy drinks are now sold in large, nonresealable containers holding two to three servings that encourage high-volume consumption in one sitting. Clever, isn't it? Helpful, it is not.

To explore the nature and extent of energy drink marketing efforts reaching children and teens, the Committee recently requested information from leading energy drink companies about marketing practices that reach young audiences. The information we received from these companies, along with publicly available information, supports the findings of Senators Blumenthal, Markey, and Durbin, as well as other marketing experts, that a number of companies are using marketing techniques highly appealing to teens, deliberately appealing to teens.

We know that some companies sponsor athletes as young as 13 or 14 years and make them a public face for the company. These young athletes are featured wearing the logos of the company in photos and videos on the company's Website and through social media channels. The question I want us to get at in this hearing is whether this is responsible corporate behavior.

Today, we will learn more about these issues from public health and marketing experts as well as several leading energy drink companies. In the next few weeks, I understand that the Institute of Medicine, the Department of Health and Human Services, and other leading health agencies are convening public panels to review the health effects of these drinks. In my judgment, this problem is crying out for that kind of credible scientific review, and I am glad it is happening in the immediate aftermath of this hearing.

Without further pause and with the permission of Senator Blumenthal, I would like to call on Senator Richard Durbin from Illinois.

STATEMENT OF HON. RICHARD DURBIN,
U.S. SENATOR FROM ILLINOIS

Senator DURBIN. Thank you very much, Mr. Chairman.

I want to commend you, Chairman Rockefeller and Senator Blumenthal, for your leadership in convening this hearing on this important issue, and I want to thank you for allowing me to make a statement.

Ten years ago, most of the people in this room would have never heard of an energy drink. Well, times have changed. By some estimates, the sale of energy drinks has risen by 60 percent over the past 5 years. Energy drinks are now a common fixture in grocery stores, vending machines, and convenience stores.

I would really challenge anybody in this room to go to their favorite gas station and stand at the cash register, and if you cannot reach an energy drink as you stand there, I will be shocked. Throughout Illinois, whether it is Chicago or Springfield, they are as close to the register, as close to the consumer as possible.

And as the sale of energy drinks has grown, so has the alarming evidence that they pose potential health risk, and the energy drink market has grown to its current size because it is marketing to children and adolescents. Scientific studies have concluded that consuming large amounts of caffeine can have serious health risks, such as seizures, heart arrhythmias, and in some cases death.

In our audience today is Wendy Crossland. She is the mother of a 14-year-old, Anais Fournier, who died in Maryland after consuming two 24-ounce cans of Monster energy drink. I met with Mrs. Crossland. It is a heartbreaking story.

Scientific studies have concluded that consuming these drinks are dangerous. Organizations committed to the well-being of children and adolescents, such as the American Academy of Pediatrics, the American Medical Association, the National Federation of State High School Associations, and the NCAA, discourage kids from drinking energy drinks. In fact, the American Academy of Pediatrics stated that energy drinks have no place in the diet of children and adolescents.

A recent article in an official AAP journal said, "Given the unknown levels of caffeine and other poorly studied additives in energy drinks, there is significant risk associated with energy drink consumption and may outweigh the benefits in the adolescent consumer."

Warnings from AAP are echoed by a recent SAMHSA study, which found that between 2007 and 2011 emergency room visits related to the consumption of energy drinks doubled, from 10,000 to 20,000. In the first 6 months of this year, the American Association of Poison Control Centers, in the first 6 months, have already received 1,575 reports related to energy drinks; 988 of those reports—over half—involve children under the age of 18.

Many of the health concerns about energy drinks are due to their high levels of caffeine and ingredients that act as stimulants. The FDA currently limits the level of caffeine in a soda to no more than 71 milligrams of caffeine in a 12 ounce can. Compare that to 240 milligrams of caffeine in a 24 ounce can of Monster Energy.

But as we all know, most energy drinks are not sold in 12 ounce cans. They are sold in 16, 24, even 32 ounce containers. These are two, Monster and Rockstar. Twenty-four ounce cans. Just one of these cans contains 240 milligrams of caffeine.

These cans are sold in convenience stores right next to the Gatorade and soft drinks, but just one of these cans contains the same amount of caffeine as almost seven cans of soda, which we have displayed here on the table. They each contain 35 milligrams apiece. They are restricted and regulated in terms of what they can contain. But this one can contains more caffeine and is for sale right next to them.

Keep in mind that some adolescents consume more than one energy drink in a 24 hour period and that each of these drinks contain not only caffeine, but additives and stimulants, such as guarana and ginseng. I was reading the ingredients on this Monster label while we were getting ready for this hearing. It contains both of the things I just noted.

Although many of these ingredients have been used for years, energy drinks combine them in new ways and at higher doses. On top of that, energy drink companies urge people to "chug down," "throw it back," "pound it down" when it comes to their products and to consume them before, during, or after physical activity to enhance performance. As a result, younger and younger people in America are exposed to higher and higher levels of stimulants in a short window of time and in new ways, compared to how people have traditionally consumed caffeinated hot drinks or beverages.

Now let us get to the issue of marketing. Across the board, makers of energy drinks say consistently that they do not market their products to children, Senator. But then you hear about the samples

of energy drinks being distributed where teens hang out—sporting events, concerts, local parks, even SAT prep courses.

You can go to their websites and see that energy drink makers sponsor athletes as young as 10 years of age. You can't see this cover from where you are sitting, but this is a publication up here called "Red Bulletin" put out by Red Bull that makes some of these energy drinks. They are insisting to us they don't market to children. Take a look at that cover. That is a 12-year-old boy on that cover.

Enzo Lopes is a Motocross athlete. He has been signed by Red Bull to promote their product. Do you think that he appeals to older people? He appeals to kids his own age. That is what it is all about.

Some of us—Senator Blumenthal, now Senator Markey, even Senator Rockefeller—we were all veterans of the tobacco wars, fought in different theaters, but we were fighting in that same war. Remember when the tobacco companies used to tell us, oh, we are not interested in kids? We knew better. We knew if they could get them hooked early on, it would become an addiction and one hard to break.

We are getting the same run-around from these energy drink companies. They are openly, openly advertising to kids and denying it. Companies use highly effective tools to reach kids—video games on their websites, social media, flashy ads, and claims to increase attention, stamina, and help with hydration and building muscle.

Contrary to industry claims that they don't market to children, we can see they do. And sadly, sadly, it is working. According to a 2011 study, 35 percent—1 out of 3—eighth graders recently consumed energy drinks, and 18 percent drank more than 1 a day.

Here is a photo from an event sponsored by Monster Energy as part of the Monster Army Recon Tour. I think you can see that up there, which moves across the country to identify talented athletes, including children under the age of 12. This photo features kids as young as 7 years of age who won the local competition that was sponsored by this company, this Monster beverage company. It is hard to believe the claims of Monster, Red Bull, and Rockstar that they don't market to children and look at the obvious marketing that is going on right now.

When energy drink makers say they don't market to children, maybe they mean they don't market to kids under 12. This image clearly suggests marketing to children, but I want to make a separate point. I am also deeply concerned about marketing to adolescents between the ages of 12 and 18.

I have been through this battle before. We talked about tobacco. I have been through this battle with Ephedra. When a 16-year-old kid in Lincoln, Illinois, wanted to get "powered up" for a high school football game, went to his local gas station and bought some of these stimulant pills, energy pills, poor kid died from just taking pills that you can buy over the counter at a gas station that contained that chemical.

These companies know what they are doing. They have got kids with disposable income who are swayed by advertising and can get hooked on their product. Public health experts across the country

have stated concerns about the health risks of highly caffeinated beverages for adolescents.

Last month, the AMA adopted a policy supporting a ban on the marketing of energy drinks to adolescents under the age of 18. Now I have joined with Senators Blumenthal and Markey to urge energy drink makers to adopt policies prohibiting marketing to adolescents up to the age of 18.

This hearing provides an important opportunity to discuss health and marketing when it comes to these energy drinks and kids. I look forward to working with you and the public health community and even the industry, the responsible elements in this industry, to take the necessary steps to protect our children and adolescents.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Durbin, for your totally focused and intense presentation. You at your best.

Senator DURBIN. Thanks.

The CHAIRMAN. Now I want to call on Senator Thune, and then we will proceed as I indicated before.

STATEMENT OF HON. JOHN THUNE,
U.S. SENATOR FROM SOUTH DAKOTA

Senator THUNE. Thank you, Mr. Chairman.

I want to thank you for holding this hearing and want to extend a thank you to all the witnesses. I understand we are going to have seven witnesses on the panel today. I am not sure I remember a time when we have had seven witnesses on one panel. So I am sure it will be informative and lively and, with all the cans that are on the table, energetic, I would say, too.

And let me just say that ensuring the health of our children is a priority for all of us. And so, we all take that responsibility very seriously.

The energy drink industry is remarkably fast growing, with American sales of energy drinks reaching $8.6 billion in 2012, which is about 12 times their level a decade ago, according to a recent article in *The Economist.* This rapid growth, however, has contributed to closer scrutiny of the industry and its products.

Concerns about the levels of caffeine in energy drinks and the possible effects on children and adolescents who consume these products have prompted several studies and investigations. And while it is entirely appropriate to examine these issues, we should also consider the broader context regarding caffeinated products.

Caffeine has been consumed for thousands of years, and I am sure most of us on this committee and in the Senate take advantage of it once in a while to get through our days. It is found in beverages such as coffee, tea, soft drinks, and in products containing cocoa and chocolate. But when I hear that caffeine may now be added to products as diverse as potato chips and marshmallows, I have to wonder whether our fascination with caffeine has gone too far.

Some of our witnesses today will also note that certain energy drinks may contain other stimulants in addition to their caffeine content and that the combination raises additional concerns. And so, I look forward to the witnesses' discussion on this point as well.

The industry has shared with the Committee that most commonly sold energy drinks contain about half the caffeine of a similarly sized cup of coffeehouse coffee. For example, we are told that a typical 16 ounce can of one energy drink contains about 180 milligrams of caffeine. By comparison, my understanding is that a typical 16 ounce cup of coffee from a coffeehouse contains about 330 milligrams of caffeine.

According to the FDA, most healthy adults can safely consume up to 400 milligrams of caffeine per day, but children can safely only consume between 45 and 85 milligrams of caffeine per day, depending on their weight.

Few would challenge the statement that children should not be consuming highly caffeinated energy drinks. So I look forward to hearing about the steps that the companies represented here today are taking to ensure their products are safe, as well as the efforts that they are undertaking to ensure their products are marketed appropriately.

Protecting the health of our children is very important. I believe it is also important to rely on good science, careful investigation, and accurate evaluations when assessing the possible health risks of energy drinks and other products.

Given the broader context regarding the safety of caffeine and its sometimes significant use in non-energy drink beverages, it also seems appropriate that any discussion of the scientific determinations about safe levels of caffeine should examine the consumption of caffeine from a variety of products, not just energy drinks. I hope that the testimony and evidence put forward today is examined thoughtfully and within that larger context.

Mr. Chairman, thank you again for holding this hearing, and I look forward to hearing from our witnesses.

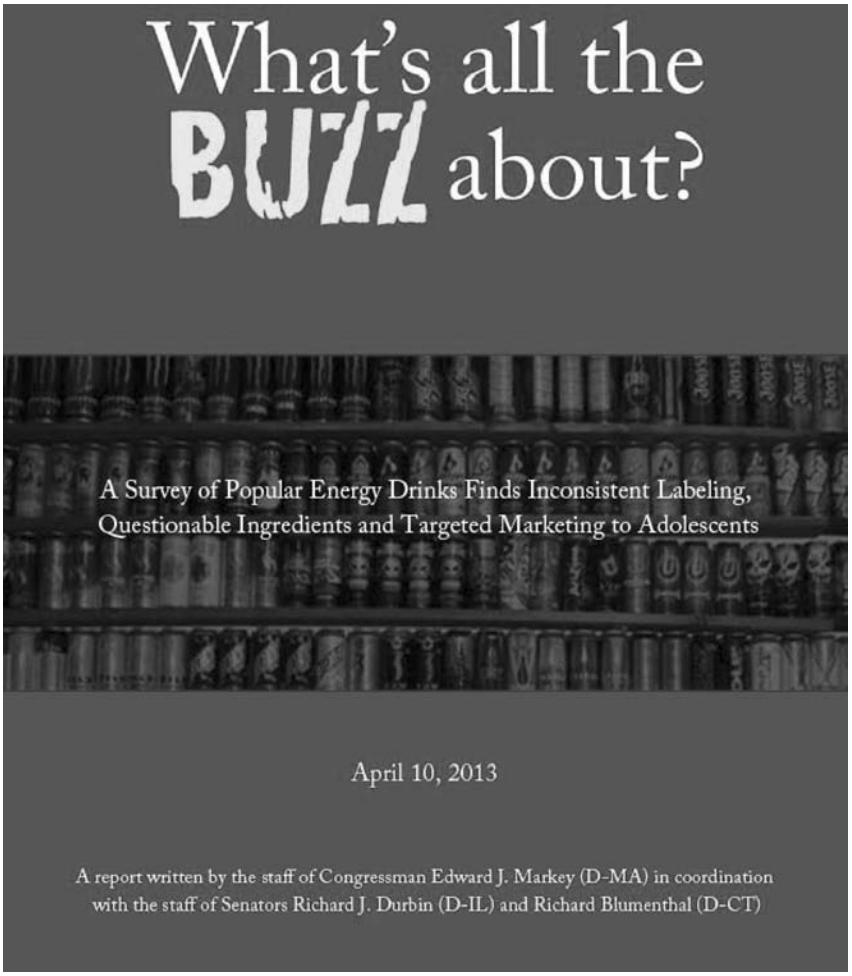
I thank the Senator from Illinois for being here.

The CHAIRMAN. Thank you. Thank you very much, Senator Thune.

I ask unanimous consent to place this [*What's All the Buzz About?* A Survey of Popular Energy Drinks Finds Inconsistent Labeling, Questionable Ingredients and Targeted Marketing to Adolescents, A report written by the staff of Congressman Edward J. Markey (D–MA) in coordination with the staff of Senators Richard J. Durbin (D–IL) and Richard Blumenthal (D–CT)] in the hearing record, and I don't hear any objections. Nor would I have heard, were there to have been any.

[Laughter.]

"Whats all the Buzz About? A Survey of Popular Energy Drinks Finds Inconsistent Labeling, Questionable Ingredients and Targeted Marketing to Adolescents"—A report written by the staff of Congressman Edward J. Markey (D–MA) in coordination with the staff of Senators Richard J. Durbin (D–IL) and Richard Blumenthal (D–CT)



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Executive Summary

The term "energy drinks" generally represents a class of products in liquid form that contains high levels of caffeine frequently combined with other stimulants and specialty ingredients. The spike in the number of energy drinks in the marketplace and the frequency in which these products are marketed to children and teens raises serious questions, both about the safety of this class of products and whether they fulfill their claims to consumers.

Recently, the Food and Drug Administration (FDA) released a series of adverse event reports of illness, injury and death allegedly linked to the consumption of products marketed as energy drinks. The FDA also is currently investigating energy drinks. The Department of Health and Human Services recently issued a report that emergency room visits related to energy drinks doubled from 10,000 to 20,000 visits between 2007 and 2011.

To address growing concerns over energy drinks, the marketing of these products to children and provide more information about the ingredients used in these products, Representative Edward J. Markey (D–MA) and Senators Richard J. Durbin (D–IL) and Richard Blumenthal (D–CT) launched an investigation into the practices of fourteen commonly sold energy drink brands. This report presents the information gathered in response to this investigation and places it in the context of the current regulatory structure for energy drink products.

Findings in Brief

- Various marketing, labeling and ingredient disclosure requirements are applied to energy drinks, sometimes inconsistently. As a result, nearly identical energy drinks can be marketed and represented to consumers differently, leading to consumer confusion and a lack of transparency.
  - Four out of the 14 companies surveyed classify and market one or more of its products as dietary supplements, as opposed to conventional beverages.

- The beverage company Arizona produces several energy drink products, but although the products come in similar sizes and caffeine concentrations, half of the products disclose caffeine concentrations on the label, while the other half do not.
- Both Monster Beverage Corporation and Rockstar Inc., recently switched classification of their energy drinks from dietary supplements to beverages, resulting in some products being marketed, represented, regulated and labeled as dietary supplements and some as conventional beverages despite their identical compositions.

- Energy products come in a range of sizes, with various amounts of caffeine that exceed what has been previously recognized as safe by the FDA for soda beverages (approximately 71 milligrams of caffeine per 12 ounces). Despite these elevated levels, concentrations of caffeine are not uniformly represented on the label of the brands evaluated.
  - Of the 14 companies, Coca-Cola's NOS energy drink product contains the most caffeine at 260 milligrams per 16 ounce can, while Target's Archer Farms energy drink contains just 70 milligrams in 16 ounces.
  - Monster's Worx Energy shot contains 200 milligrams of caffeine in just 2 ounces, but the level of caffeine is not disclosed on the label. In contrast, Arizona Energy Fast shot contains 113 milligrams of caffeine in 2 ounces and discloses the caffeine on the label.
  - Rockstar energy drink contains 240 milligrams of caffeine in 16 ounces, but because the company is undergoing a change in labeling practices, only some cans currently on the market present the amount of caffeine on the label.
- All 14 companies stated that they do not market energy drinks to children. However, there is clear evidence that adolescent consumers are frequent targets for the marketing pitches of energy drink companies. The use of unconventional marketing practices combined with product design and placement on store shelves assists in creating product images that appeal to children and teens.
  - Companies such as Monster Beverage Corporation and Rockstar Inc, focus on youth-oriented social media advertising as well as sponsoring events and athletes that cater to high school-aged students.
  - Monster Beverage Corporation produces a range of products meant to mimic frequently consumed alcoholic beverages and which appear to be intended for audiences that are not old enough to consume alcohol legally.
- Energy drink companies make a range of advertising claims related to the functional benefits of their products that are not generally evaluated or substantiated by the FDA. Some of these claims appear to be targeted to young audiences or student athletes. However, the National Collegiate Athletic Association, National Federation of High Schools, and American Academy of Pediatrics have all warned of the risks these products play, particularly for children and student athletes.
  - PepsiCo's AMP Energy Boost claims that it will help "energize and hydrate the body," while Coca-Cola's NOS promises "50 percent more focus".
  - Monster energy pledges that its products will provide a "big, bad buzz."
  - Dr. Pepper's Venom highlights its products ability to improve "up to the nanosecond performance."
  - Red Bull claims "increased concentration and reaction speed" and "stimulated metabolism."
- In addition to caffeine, energy drinks contain a myriad of specialty ingredients whose combinations and additive impacts are not thoroughly evaluated or well understood. Companies can and often do self-determine that ingredients are safe for use in energy drinks, and there is no requirement for companies to notify the FDA of this determination or the use of the ingredient. Moreover, much like caffeine, companies can choose whether they want to disclose the amount of these other ingredients on the product label.
  - Nearly all energy drinks surveyed contain taurine, an amino acid that has not been approved as a food additive by the FDA, but has been self-determined by energy drink companies to be safe for inclusion in its products.
  - In addition to caffeine, energy drinks combine other stimulants such as ginseng, guarana, green tea and, less frequently, methylated xanthine (as in 5-hour Energy), a synthetic stimulant.

Recommendations

There are a number of steps that energy drink manufacturers should take to improve transparency and representation of this class of products as well as ensure that children and teens are adequately protected from deceptive advertising practices. Energy drink manufactures should immediately:

1. Label products with a clear description of the total amount of caffeine (in milligrams) added to the product from all sources. For products that are packaged in non-resealable containers (such as pop-top cans), the label should include the amount of caffeine from all sources in the entire container, not just one serving.
2. For products that contain caffeine that has been intentionally added to the product at levels above 200 parts per million (approximately 71 milligrams per 12 fluid ounces), the level affirmed as GRAS by the FDA, display a prominent precautionary statement that at a minimum says, "This product is not intended for individuals under 18 years of age, pregnant or nursing women or for those sensitive to caffeine. Consult with your doctor before use if you are taking medication and/or have a medical condition."
3. Cease marketing of energy drink products to children and teens under the age of 18. Marketing includes use of both traditional media and social media as well as the sponsorship of events, activities and individuals that are intended for an audience comprised primarily of children or teens.
4. Report to the FDA the receipt of any serious adverse events associated with energy drink use. Serious adverse events are defined by the FDA, but reporting is currently only required by the FDA for products that are represented as dietary supplements.

Background

In the past few years, there has been an explosion in the consumption of a class of beverage products, known collectively as energy drinks, which carry a unique set of risks for adolescents. Although the term "energy drink" is not defined by the Food and Drug Administration (FDA), the primary entity responsible for the safety, labeling and ingredients present in the food supply, it generally represents a class of products in liquid form that contains high levels of caffeine and, typically also includes, additional ingredients not found in sodas and juice drinks.

Energy drinks have become a multibillion-dollar business, with steadily increasing sales that rose 16 percent in 2012 alone, amounting to a U.S. sales market worth more than $12.5 billion.[1] Consumption of energy drinks by children and teens has been a growing trend; a 2012 study of U.S. high school students revealed that energy drinks represented 8.8 percent of the sugar-sweetened beverages they consumed.[2] Another U.S. study found that 31 percent of 12–17 year olds regularly drink energy drinks, in comparison to 22 percent of 25–35 year-olds.[3]

The proliferation of energy drinks is largely related to the tailored marketing and claims made by these products, which promise outcomes such as improved athletic performance, reaction time and increased attention and alertness. Energy drink companies rely on added sugars and caffeine in the effort to fulfill these promises. However, both the high levels of caffeine and the mixture of other unique ingredients, not typically found in other beverages, call into the question the safety of these products, particularly for youth. Furthermore, the high levels of sugar (typically double the amount of soda) present serious health risks of obesity, diabetes and heart disease.

The increasing consumption of energy drinks by children and teenagers has emerged as a new public health threat for youth. Frequently these products are marketed through youth-oriented media and venues and use packaging and images that appeal to a young audience.[4] The American Academy of Pediatrics (AAP) has stated that "energy drinks have no therapeutic benefit to children" and that the properties of the ingredients of these drinks "may put some children at risk for ad-

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[1] Energy Drinks and Shots: U.S. Market Trends, Packaged Facts, Feb. 11, 2013

[2] Park, S., Blanck, H.M., Sherry, B., Brener, N. and O'Toole, T. (2012) Factors associated with sugar-sweetened beverage intake among united states high school students. Journal of Nutrition 142(2): 306–312

[3] Simon, M. and Mosher, J. (2007) Alcohol, Energy Drinks, and Youth: A Dangerous Mix. California: Marin Institute.

[4] Pomeranz, J.L., Munsell, C.R. and Harris, J.L. (2013) Energy drinks: An emerging public health hazard for youth. Journal of Public Health Policy. Advance online publication 14 March 2013

verse health events."[5] A recent survey by the U.S. Department of Health and Human Services revealed that emergency room visits related to energy drinks doubled from 10,000 to 20,000 visits between 2007 and 2011.[6] It has been previously reported that 11 percent of total emergency room visits related to energy drink consumption involved youth aged 12–17 years.[7]

The FDA recently released injury report filings, also known as adverse event reports, that were associated with several popular energy drink brands including, Rockstar, Red Bull, Monster and 5-hour Energy.[8] These reports indicated serious or life threatening injuries such as heart attacks, convulsions and, in a few instances, death. The FDA is currently investigating these reports, as the mere filing of an incident report with the FDA does not mean that a product was responsible for a death or an injury. The FDA has also announced that it intends to form a third party review panel to help determine whether energy drinks pose particular risks to teenagers or people with underlying health problems.

For consumers interested in limiting their personal consumption of caffeine or concerned about the ingredients used in energy drinks, labels on the packaging of these products can be confusing or lack necessary information regarding the quantity of caffeine and other ingredients. Manufacturers of energy drinks currently are left to their own discretion in deciding whether a product will be marketed and labeled as a conventional food (beverage) or as a dietary supplement. These two product types have different Federal requirements relating to ingredient disclosure, labeling and other FDA responsibilities. As a result, the information that is provided to consumers on a product label is inconsistent within the category of energy drink products depending on whether the product is classified as a beverage or dietary supplement. In 2009, the FDA issued draft guidance to clarify when a liquid energy drink product should be classified as a dietary supplement or a beverage, but the guidance, which is non-binding, has yet to be finalized by the agency.[9]

Investigation

To address the growing consumer concern over energy drinks, the marketing of these products toward youth and to provide more information about the ingredients used in these products, Representative Edward J. Markey (D–Mass) and Senators Richard J. Durbin (D–IL) and Richard Blumenthal (D–CT) launched an investigation into the practices of fourteen commonly sold energy drink brands (See an example of the letter in Appendix A).[10] Each company was asked to respond to a series of fourteen questions seeking information on:

- how the company determines whether its product should be represented as a dietary supplement or a conventional food;
- the ingredients used in the products;
- the levels of caffeine and serving size of the products;
- the studies performed to back up any claims made about the benefits of the products; and
- the marketing and advertising practices employed by the companies to target youth audiences.

With the exception of Sambazon and 5-hour Energy, all companies responded to the questions posed to them.[11] In instances where companies did not provide complete responses or simply did not respond to a question, supplemental information was gathered from company websites, contacting company consumer representatives

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[5] See Energy Drinks Can Harm Children, Feb. 114, 2011 *http://www.aap.org/en-us/about-the-aap/aap-press-room/pages/Energy-Drinks-Can-Harm-Children.aspx*

[6] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (January 10, 2013). The DAWN Report: Update on Emergency Department Visits Involving Energy Drinks: A Continuing Public Health Concern. Rockville, MD.

[7] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (November 22, 2011). *The DAWN Report: Emergency Department Visits Involving Energy Drinks.* Rockville, MD. Data from between 2004 and 2008.

[8] *http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/UCM328270.pdf* and *http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/UCM328525.pdf*

[9] FDA Draft Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods. (December 2009)

[10] An example of the letters sent to the companies can be found here: *http://markey.house.gov/press-release/markey-durbin-blumenthal-quiz-energy-drink-makers-products*

[11] Sambazon and 5-hour energy did not respond to the questions asked. Sambazon requested to be removed from the investigation. 5-hour energy provided a copy of its patent in lieu of responding to specific questions.

through the company's public contact telephone number, or through reviewing other publically available information, including product labels. This report presents the information gathered in response to this investigation.

Findings

FINDING #1: *Various marketing, labeling and ingredient disclosure requirements are applied to energy drinks, sometimes inconsistently. As a result, nearly identical energy drinks can be marketed and represented to consumers differently, leading to consumer confusion and a lack of transparency.*

While the FDA does have the authority to regulate both conventional foods, referred to in this report as "beverages," and dietary supplements, the requirements for ingredients, manufacturing processes, reporting of adverse events and labeling, differ depending on whether the product is marketed as a beverage or as a supplement (See Table 1). According to FDA, a manufacturer of a product in liquid form may choose *on its own* whether or not to market its product as a beverage with the required "Nutrition Facts" panel or as a liquid dietary supplement with the required 'Supplement Facts' panel.

Regardless of the category chosen by the manufacturer FDA is responsible for ensuring that the manufacturer complies with the requirements associated with beverages and dietary supplements, including how the product is represented (*i.e.,* marketed) to consumers.

TABLE 1: Key differences between the Federal regulation of dietary supplements and beverages

Conventional Food (Beverage)	Dietary Supplements
New ingredients must be approved as a food additive by the FDA, unless the ingredient is generally recognized as safe (GRAS)*	Only new ingredients not marketed in dietary supplements in the U.S. prior to October 15, 1994 require FDA preapproval. Otherwise, FDA must determine an ingredient is unsafe under conditions of use to take the product off the market
Any reporting of serious adverse events is completely voluntary	Required by law to report to the FDA any serious adverse events
Includes a "Nutrition Facts" panel on the label, with information on amount of calories, total fat, cholesterol, sodium, carbohydrates, protein, vitamin A, vitamin C, calcium and iron	Includes a "Supplement Facts" panel on the label, with information on quantities of ingredients that exceed standards or that are relevant to a product claim
Listing of ingredients in descending order of predominance is required	List the quantity of each dietary ingredient, unless the ingredient is a part of a 'proprietary blend', in which case quantities are not required
Good Manufacturing Practices (GMP) focus on ensuring safe and sanitary processing conditions	Good Manufacturing Practices (GMP) contain standards of identity to help verify that the product is what it is purported to be

*Manufacturers of a product are permitted to self-determine that an ingredient is generally recognized as safe (GRAS) without FDA affirmation

In 2009, FDA attempted to clarify the agency's views on the distinction between liquid dietary supplements and beverages by issuing a guidance document that outlines some of the factors that may cause a product to be represented as a beverage, instead of as a dietary supplement.[12] These items include the volume in which the product is intended to be consumed, the labeling of the product, the recommended conditions of use, and the packaging in bottles or cans that are similar to packaging found in other beverages like soda and bottled water. This guidance has yet to be finalized by the FDA, but the agency has indicated that it hopes that once completed the guidance will more clearly demarcate the line between beverages and liquid dietary supplements.

[12] FDA Draft Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods. (December 2009)

TABLE 2: Energy drinks, even those produced by the same company, are represented inconsistently in the market as both dietary supplements and regular beverages

Parent Company	Brand Name	Product Name	Marketed as Dietary Supplement or Conventional Food (Beverage)
Living Essentials	5-hour Energy	5-hour Energy	Dietary Supplement
Celsius	Celsius	Celsius	Dietary Supplement
Monster Beverage Corporation	Worx Energy	Worx Energy	Dietary Supplement
Monster Beverage Corporation	Monster	Monster Energy, Blue Energy, Hansen's Energy	Conventional Food (since March 2013)
Rockstar Inc.	Rockstar Energy Drink	Rockstar	Conventional Food (since January 2013)
PepsiCo	AMP Energy Boost	AMP	Conventional Food (since 2012)
Dr. Pepper Snapple Group	Venom	Venom Energy	Conventional Food
Clif Bar and Company	Clif Shot	Clif Shot Gel	Conventional Food
Red Bull	Red Bull	Red Bull	Conventional Food
Coca Cola	Full Throttle	Fuze	Conventional Food
Coca Cola	NOS	Nos	Conventional Food
Nestlé USA (until November 2012)	Jamba	Jamba Energy	Conventional Food
Sambazon	Sambazon	Sambazon	Conventional Food
Target Corp. made by third party	Archer Farms	Archer Farms Energy Drinks	Conventional Food
AriZona Beverages	Arizona	AZ Energy, RX Energy Fast Shot	Dietary Supplement
AriZona Beverages	Arizona	Caution, Joltin Joe, Rx Energy Herbal	Conventional Food

The FDA has stated that energy drinks can be lawfully marketed as either dietary supplements or as beverages as long as they satisfy the requirements for the product category which they represent. Responses from energy drink companies indicate that four of the fourteen responding companies classify and market one or more of its products as dietary supplements (See Table 2). These products include Celsius, Monster's Worx, 5-hour Energy and approximately 50 percent of the Arizona brand energy drinks (representing 5 products).

In addition, three energy drink brands, AMP Energy (owned by PepsiCo), Rockstar and Monster energy drinks have only within the last year shifted from marketing their products in the category of dietary supplements to marketing and labeling their products as beverages.[13] Until this market transition is complete, which in the case of Rockstar may take a year, consumers can expect to find identical products by Rockstar Inc., and Monster labeled with both Supplement Facts (as in dietary supplements) and Nutrition Facts (as in beverages). According to Monster Beverage Corporation, this decision was made for business purposes as well as to avoid criticism that the company was marketing their products as dietary supplements to avoid FDA oversight.

When the companies were asked to explain how they determine whether a product should be marketed as a beverage or dietary supplement, the responses indicated that the companies routinely review FDA laws and regulations and in some instances cited warning letters issued by the FDA to other companies. The companies indicated that the decisions are made on a case-by-case basis dependent on the

[13] Monster Beverage Corp. indicated in its response that all products, with the exception of Worx Energy would be transitioned to beverages and labeled with a nutrition facts panel.

intention of the product. For instance if the product is intended to primarily quench thirst, the company markets it as a beverage, but if the product is intended to be a supplement to the diet they would treat the product as a dietary supplement.

Interestingly, Monster indicated in its response that it views its products as intended to specifically supplement the diet with dietary ingredients and "not merely to be consumed ad libitum to provide refreshment and good taste." Despite this declaration, the company still transitioned its products (with the exception of Worx Energy) from dietary supplements into the beverages category. Furthermore, Arizona beverages produces several remarkably similarly packaged and sized energy drink products with comparable claims and ingredients and the company appears to arbitrarily select whether a product is classified as a dietary supplement or beverage. The blurred distinction between supplements and beverages is a source of confusion for consumers. The FDA should expeditiously ensure that energy drink manufacturers utilize a consistent approach to categorize their products.

FINDING #2: *Energy products come in a range of sizes, with various amounts of caffeine that exceed what has been previously recognized as safe by the FDA for soda beverages (approximately 71 milligrams of caffeine per 12 ounces). Despite these elevated levels, concentrations of caffeine are not uniformly represented on the label of the brands evaluated.*

The fourteen companies surveyed produce different types of energy drink products (See Table 3). In the case of Clif Shot, the product is an energy gel packaged in small squeezable packet and intended to be consumed by athletes during endurance activities. Clif Shot is marketed as a conventional food. Another product, Celsius, which is sold as a single serving packet of powder to mix with water as well as ready to drink cans and is marketed as the "ultimate fitness partner" is classified as a dietary supplement. In the case of Celsius, the product is intended to be consumed pre-exercise to help reduce body fat and improve endurance. These two companies have remarkably similar uses, but two different designations.

The remaining twelve companies produce two main energy product types, which they refer to as "drinks" and "shots" (See Table 3). The energy shots come in 2-ounce single serve containers. The energy drinks are commonly sold in 8–32 ounce packaging, many of which are packaged in large, non-resealable cans, despite the number of servings listed on the container. For example, Monster Energy and Arizona AZ Energy both produce a 24 fluid ounce canned product that contains 240 mg and 306 mg of caffeine, respectively, and more than 75 grams of sugar per container. Both companies claim that the can represents 3 servings of the product, yet the carbonated beverage is provided in a non-resealable can similar to a soda can, encouraging the product to be consumed in one sitting. For comparison, this is 7–9 times more caffeine and approximately twice as much sugar as a can of Coca-Cola Classic. Monster produces a 32 ounce non-resealable can with approximately 108 grams of sugar and 320 mg of caffeine.

The caffeine content varies widely between the energy products surveyed, and in many cases is not disclosed on the product label. In cases where it is disclosed, companies vary in the way they present this information, sometimes impairing consumers' ability to make informed decisions about caffeine levels in the products they are purchasing. For example, some products only present the amount of caffeine per recommended serving size rather than in the entire container. For products packaged in large 24 or 32 ounce non-resealable containers that are typically consumed all at once, this practice could mislead consumers about the total amount caffeine and other ingredients they are ingesting, as they may presume that there is no distinction between the recommended serving size and the serving in the container itself. While some companies provide caffeine concentration in milligrams, other companies, including 5-hour Energy and some of the Arizona energy drink products, disclose caffeine only in comparison to other products, stating on the label that the product contains "caffeine equivalent to 2 cups of coffee" or "contains caffeine comparable to a cup of the leading premium coffee." The inconsistent ways in which caffeine concentration is presented on the label may further confuse consumers.

TABLE 3: Energy drinks contain a varied amount of caffeine that is inconsistently represented on the label

Product Name	Product Type	Container Size (fl.oz.)	Total Caffeine Per Container From All Sources (mg)	Caffeine Amount Declared On The Label
Rockstar	Drink	24	360 or 240*	Transitioning to labeling caffeine on all products
Arizona AZ Energy Half&Half Iced Tea Lemonade	Drink	23	265	Yes
NOS	Drink	16	260	Yes
Rockstar	Drink	16	240 or 160*	Transitioning to labeling caffeine on all products
Monster Energy	Drink	24	240	Transitioning to labeling caffeine on all products
Worx Energy	Shot	2	200	No
Celsius	Drink, Powder	12	200	Yes
Full Throttle Fuze	Drink	16	200	Yes
Java Monster	Drink	16	200	Yes
Arizona AZ Energy	Drink	15	195	Yes
Venom	Drink	16	160	Yes
Monster Energy	Drink	16	160	Transitioning to labeling caffeine on all products
Arizona Caution	Drink	11.5	144	Yes
AMP Energy Boost	Drink	16	142	Yes
Red Bull	Drink	12	114	Yes
Arizona Rx Energy Fast Shot	Shot	2	113	No
Jamba	Drink	8.4	80	Yes
Sambazon	Drink	10.5	80	Yes
Target Archer Farms	Drink	12	70	Yes
Clif Shot	Gel	34 grams	0, 25 mg, 50 mg, or 100	Yes
5-hour Energy	Shot	2	did not answer	No

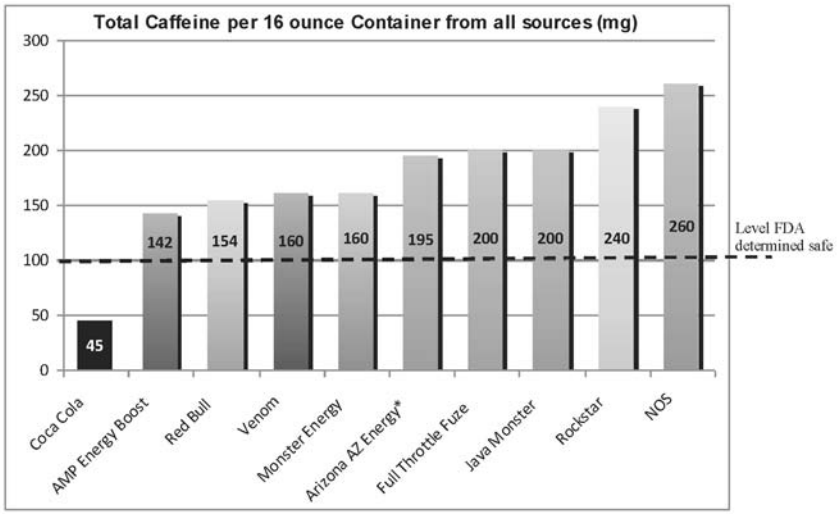
*Caffeine amount depends on specific product.

Although FDA does not require caffeine disclosure for either beverages or supplements, the American Beverage Association (ABA), the trade association that represents the non-alcoholic beverage industry in the U.S., recommends that all such energy products clearly label their products with the amount of caffeine from all sources in the product. However, not all energy products, abide by these voluntary guidelines. For example, Arizona has several energy drink products with labels that

either do not disclose the level of caffeine at all or provide a level of caffeine that is not representative of the actual caffeine content from all sources. Living Essentials 5-hour Energy, not a member of the ABA and marketed as a dietary supplement energy shot, also does not provide the amount of caffeine on the label of its product. Monster and Rockstar energy products are transitioning to labels that disclose caffeine content from all sources, in compliance with ABA's voluntary guidelines. Most caffeinated sodas also disclose the concentration of caffeine present in the container from all sources.

In general the caffeine concentration of the energy products surveyed is much higher than that of sodas for which the FDA has generally recognized as safe (GRAS) at a level of 200 parts per million of caffeine (approximately 71 mg per 12 fl oz serving). In contrast, popular energy drinks, such as NOS and Rockstar contain between 240 and 260 milligrams of caffeine per 16 ounce can and popular energy shots, such as 5-hour energy and Worx contain between 200-242 milligrams of caffeine [14] per 2 ounce bottle (See Figure 1). For 5-hour Energy and Worx, because these products are marketed as dietary supplements, there is no requirement or voluntary guidance that the amount of caffeine be listed on the product label or disclosed to the consumer in any way.

FIGURE 1: Comparison of similar sized energy drink caffeine concentrations



*Container size 15 fluids ounces

Caffeine toxicity is a concern, especially for children and adolescents, who are the frequently targeted demographic for energy drink companies. According to the American Academy of Pediatrics (AAP) "caffeine can produce harmful health effects in adolescents, including cardiovascular problems, anxiety, insomnia, digestive problems, dehydration, and others." [15] The American Academy of Pediatrics' Committee on Nutrition and the Council on Sports Medicine and Fitness recently concluded that, "rigorous review and analysis of the literature reveal that caffeine and other stimulant substances contained in energy drinks have no place in the diet of children and adolescents.[16]"

Children and teens who consume energy drinks for the promise of increased physical performance, before, during, or after physical activity are exposed to a high dose of caffeine and other ingredients in a short window of time. According to a recent

[14] Information for 5 hour Energy provided by Consumer Report Magazine (December 2012). The buzz on energy-drink caffeine.

[15] AAP, Energy Drinks Pose Health Risks to Adolescents Feb. 1, 2013.

[16] Committee on Nutrition and the Council on Sports Medicine and Fitness. Sports drinks and energy drinks for children and adolescents: Are they appropriate? *Pediatrics.* 2011; 127(6):1182–1189.

study [17], "cardiovascular effects as a result of heavy caffeine use can be a significant source of morbidity in athletes," and "given the unknown levels of caffeine and other poorly studied additives, there is significant risk associated with energy drink consumption that may outweigh the benefits in the adolescent consumer."

On average the U.S. population consumes approximately 300 milligrams of caffeine per day.[18] For healthy adults, the FDA has noted that consumption of 400 milligrams of caffeine (considered an upper limit) in a day is not associated with adverse health effects. However, the standard of 'healthy adults' does not take into account varying sensitivities to caffeine and varying capabilities of younger consumers to metabolize this stimulant.[19] Furthermore, statements made by energy drinks such as "chug it down" and "pound down" [20] encourage consumers to drink large quantities of these products rapidly, which can decrease the clearance of caffeine from the body and result in elevated caffeine blood concentrations for a sustained period of time.[21] This is especially risky for children and teen consumers, as well as consumers who have pre-existing health conditions or who are taking medications that may interfere or interact with caffeine metabolism. As the FDA has stated, smaller individuals (adolescents) are typically more sensitive to caffeine consumption. The FDA has also warned that while caffeine and other stimulants may make one feel more awake, "judgment and reaction time can still be impaired." [22]

FINIDNG #3: *Adolescent consumers are frequent targets for the marketing pitches of energy drink companies. The use of unconventional marketing practices combined with product design and placement on store shelves assists in creating product images that appeal to children and teens.*

In the course of this investigation, companies were asked whether they market energy drink products to children or teenagers. Unsurprisingly, all companies indicate that their products were not directed toward children, and several products including Venom and Red Bull, indicated that they follow the American Beverage Association (ABA) voluntary guidance for the responsible labeling and Marketing of Energy Drinks (See Table 4).[23] Monster Beverage Corp. and Rockstar indicated that the companies have recently joined the ABA. These ABA guidelines indicate that energy drinks should be labeled with the quantity of caffeine from all sources contained in the beverage, should not promote mixing with alcohol, should not be marketed as sport drinks, should contain an advisory statement [24] and should not be advertised to an audience that is comprised predominantly of children less than 12 years of age.

Not all energy drink companies adhere to ABA guidance. Furthermore, while children 12 years of age and younger may not be targeted by some companies, adolescents who are between the ages of 13 and 17 are frequently the focus for energy drink marketing practices and this population is also at risk for the detrimental impacts of energy drink consumption. For example, Monster Energy and Rockstar Energy both indicate that their target audience is young adults and as a result, these companies frequently sponsor young athletes, such as Mitchie Brusco, a skateboarder who has been sponsored by Rockstar since he was at least 14 years old. Monster also has a practice of awarding outstanding high school student athletes with the *"Monster Energy Drink Player of the Game."* As a part of this honor, photos of these teen student athletes are taken with a package of Monster Energy in each hand and other Monster paraphernalia.[25] Red Bull also engages in the sponsorship of high school sport events, including the "Red Bull Game Breakers" and "Red Bull Rookies Cup" which includes adolescents as young as 13 years old. While Monster Energy indicated in its response that it does not conduct traditional advertising through traditional media, the company, along with Rockstar Energy prod-

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[17] Blankson, K., *et al., Pediatrics in Review* Vol. 34 *No. 2* February 1, 2013 pp. 55–62

[18] Caffeine Intake by the U.S. Population, September 2009, revd. August 2010, by Laszlo P. Somogyi, Ph.D.

[19] Letter from City Attorney of San Francisco Dennis Herrera to FDA Commissioner Margaret Hamburg (March 19, 2013)

[20] See for example: *http://www.monsterenergy.com/ph/en/products/and http://originalcapsultimate.blogspot.com/2012/08/where-should-buy-8-pack-monster-energy.html*

[21] Letter from City Attorney of San Francisco Dennis Herrera to FDA Commissioner Margaret Hamburg (March 19, 2013)

[22] *http://www.fda.gov/Food/NewsEvents/ucm328536.htm*

[23] See: *http://www.ameribev.org/files/339__Energy%20Drink%20Guidelines%20%28final%29.pdf*

[24] According to ABA voluntary guidelines, labels of energy drinks should include the statement "Not (intended/recommended) for children, pregnant or nursing women,(and/or persons/those) sensitive to caffeine"

[25] Monster energy has indicated through conversations with staff that were unaware of the routine awarding "Monster Energy Player of the Game" and are investigating this practice.

ucts, relies heavily on an organized social media presence and the sponsorship of music and sports events that target young audiences. As Rockstar indicated in its response, teenagers do attend and participate in these marketing initiatives.

Recently both the National Collegiate Athletic Association (NCAA) and the National Federation of State High School Associations (NFHS) have stated that energy drinks may pose a health and safety risk for student-athletes and are particularly worrisome if consumed before or during strenuous exercise. These organizations are making a concerted effort to warn their student athletes of the risk of energy drink consumption and in the case of NCAA to also restrict the marketing advertising of these products to their athletes.

TABLE 4: Company responses on marketing practices and warning labels included on energy drink products

Company Name	Marketing Practices Relating To Kids	Precautionary Statements
5-hour Energy	Marketed and intended for adults	Do not take if you are pregnant or nursing, or under 12 years of age. If you are taking medication and/or have a medical condition, consult your doctor before use.
AMP Energy	Target demographic is the male consumer between the ages of 25 and 35	Not recommended for children, pregnant women or people sensitive to caffeine
Arizona	Company does little marketing	Recommended limits and precautionary statements are provided on 7 out of 11 of the company's energy products
Celsius	Follows American Academy of Pediatrics guidelines for marketing dietary supplements and does market to children or teens. Target demographic is 25–54	Not recommended for people who are caffeine sensitive, children under 12 or women pregnant or nursing
Clif Shot	Product is marketed to adult athletes. Company is aware that high schools occasionally offer caffeinated products to teenage athletes	Not recommended for children, pregnant or nursing women, or people sensitive to caffeine
Full Throttle Fuze	Company policy is to market only to consumers over 18 years of age and buy advertising only when 65 percent of audience is above 18 years of age.	Not recommended for individuals under 18 years of age, pregnant or nursing women or for those sensitive to caffeine. Daily caffeine consumption should be limited to 400 mg per day from all sources, this package contains 200
Jamba	Does not market to children or teenagers. The intended audience is 26–34.	Not recommended for pregnant women, children or people sensitive to caffeine
Monster Energy	Target demographic is young adults (primarily males). Brand initiatives and brand image are directed toward this population.	Not recommended for children, people sensitive to caffeine, pregnant women or women who are nursing.
NOS	Company policy is to market only to consumers over 18 years of age and buy advertising only when 65 percent of audience is above 18 years of age.	Not recommended for individuals under 18 years of age, pregnant or nursing women or for those sensitive to caffeine. Daily caffeine consumption should be limited to 400 mg per day from all sources, this package contains 260
Red Bull	Company follows American Beverage Association voluntary guidance	Not recommended for children, pregnant or nursing women, or people sensitive to caffeine
Rockstar	Messaging is designed to be aspirational for young adults. Some teenagers do participate in marketing initiatives or view them on TV or the internet	Not recommended for children, pregnant or nursing women, or people sensitive to caffeine
Sambazon	Not conventionally marketed to any groups (particularly teens and children)	None
Target Archer Farms	Not intended or marketed to children or teens. Product is designed to appeal to adults with an active lifestyle as an alternative to soda.	None
Venom	Not marketed to children or teens. Follows American Beverage voluntary guidance	Not recommended for children, pregnant or nursing women, or people sensitive to caffeine

The combination of energy drinks with alcohol is a well-recognized public health hazard, particularly for youth. In the past FDA has taken enforcement action against caffeine containing alcoholic beverages, because drinking them was considered to create risky, "hazardous and life-threatening situations."[26] While caffeine containing alcoholic beverages are no longer popularly sold, some energy drink companies have sought to fill this market void by marketing products that represent themselves similarly to commonly consumed alcoholic beverages. For example, Monster Energy produces a product known as Cuba Lima, which is compared on its website to the popular alcoholic beverage Cuba-Libre.[27] The company also makes a product with a special "brewing process" and packaged in a bottle made to look similar to a beer bottle. Monster additionally markets a product compared to the alcohol infused whipped cream called 'Whip-it' and for which the company proudly states "it will whip you good."[28] It appears that these products and their advertising and packaging practices are intended to attract young audiences that are not of legal age to consume alcohol.

With the exception of Sambazon, Target's Archer Farms Energy Drinks and some of the Arizona brand energy drink products, the remaining companies surveyed all include a precautionary statement in line with ABA voluntary guidance, that the product is not recommended for children, pregnant women or people who are sensitive to caffeine. Coca-Cola's Nos and Full Throttle Fuze brand products include an additional statement that the product is not recommended for those under the age of 18. It would be helpful for consumers if all energy drinks contained precautionary statements that were consistent across all products.

FINDING#4: *Energy drink companies make a range of advertising claims related to the functional benefits of their products that are not generally evaluated or substantiated by the FDA. Some of these claims appear to be targeted to young audiences or student athletes.*

The FDA and the Federal Trade Commission (FTC) share jurisdiction over health- and nutrient-related claims made by food and supplement manufacturers. FDA oversees labeling requirements that prohibit, among other things, food labeling that is false or misleading. FTC oversees Federal consumer protection requirements that prohibit, among other things, deceptive acts or practices in advertising, including food advertising. Under a longstanding memorandum of understanding, the two agencies agreed that FDA has primary responsibility for labeling of food, including dietary supplements and beverages, while the FTC has primary responsibility over the advertising of these products. FTC has recently emphasized in the context of energy drinks that advertising directed to youth, particularly advertising that raises safety concerns, is a priority for the Commission.[29]

The FDA categorizes health-and nutrient-related claims as follows:

- *Health claims* characterize the relationship of any substance to a disease or health-related condition (*e.g.,* diets low in sodium may reduce the risk of high blood pressure).
- *Structure/function claims* describe the role of, or characterize the mechanism by which, a nutrient affects a body structure or function (*e.g.,* calcium helps build strong bones).
- *Nutrient content claims* characterize the level of a nutrient in a food (*e.g.,* good source of vitamin C).

The survey of energy drink manufacturers found that these companies routinely use structure/function claims to convey the health benefits of their products (See Table 5). Of the 14 companies surveyed, 10 (71 percent) responded to the question that asked them to identify the types of claims their product makes. Out of these ten respondents, eight (80 percent) indicated that their product makes structure/function claims. An additional two products, AMP energy and 5-hour energy, did not answer the question regarding claim type, but do make claims both on the product label and in advertising that would be categorized as structure-function claims.

The way in which structure/function claims are validated and governed depends on whether the product is represented as a dietary supplement or beverage. If a die-

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[26] *http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm234109.htm*

[27] *http://www.monsterenergy.com/us/en/products/monster-energy/#!/products%3Acuba-lima*

[28] Monster website see *http://www.monsterenergy.com/us/en/products/monster-energy/#!/products percent3Aubermonster* and *http://www.monsterenergy.com/us/en/products/nitrous-2/#!/products percent3Ablack-ice*

[29] Letter from Chairman Jon Leibowitz to Congressman Edward J. Markey (January 2, 2013). See: *http://markey.house.gov/press-release/markey-asks-ftc-investigate-advertising-claims-energy-drinks*

tary supplement includes a structure/function claim, it must have a disclaimer on its label stating, "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease." [30] In addition, dietary supplements making a structure/function claim must notify the FDA within 30 days of first making such a claim. As a dietary supplement these claims have limitations and must also be substantiated with data.[31] However, the FDA has limited resources for oversight of dietary supplements and generally has limited information on the number and location of dietary supplement firms, the types of products currently available in the marketplace, and information about moderate and mild adverse events reported to industry.[32] As a result, many of the functional claims made about dietary supplements are not evaluated by the FDA to ensure they perform as advertised.

The limitations, disclaimers and other requirements that apply to structure/function claims made by dietary supplements do not apply to products that are classified as beverages. Instead, the structure/function claims made by beverages are subject to FDA's overall requirement that labeling *not* be false or misleading. However, as indicated by a report released by the Government Accountability Office [33], the FDA has not provided guidance on the scientific support needed to prevent false or misleading information for a structure/function claim for food or beverages. The FDA also has not given its inspectors instructions for identifying potentially false or misleading information in such claims. Furthermore, unlike dietary supplements, the FDA cannot compel food and beverage companies to turn over the data and information used to substantiate product claims. As a result, the claims made by these energy products have never been evaluated or substantiated by the FDA, or any publically accountable body.

TABLE 5: Energy drinks make a range of advertising claims relating to functional benefits

Product	Claim Type	Examples Of Claims
Sambazon	did not answer	Wake up to the energizing powers of the rainforest. Made with all organic and GMO free ingredients sustainably sourced in the Brazilian Amazon, stimulate your body and mind
AMP Energy Boost	did not answer	Caffeine and B-vitamins, Help kick you in high gear, Helps energize and hydrate the body
5-hour Energy	did not answer	Hours of energy, No crash, Helps you feel awake for hours, Power through your day, Stay bright and alert
Jamba	did not answer	All Natural (removed as of November 2012), Natural caffeine for mental alertness, A full serving of fruit per can
Celsius	Health Claims	Reduces body fat, Improves endurance, Increases metabolic rate, Burn calories (based on six clinical studies of product)
Target Archer Farms	Nutrient Content	Sugar free, Low calorie, Energy enhancing properties of ginseng
Venom	Structure/ Function	Free agent of energy, Up to the nanosecond performance for MVPs and VIPs, Instant impact
Clif Shot	Structure/ Function	Performance enhancing caffeine, Helps with motivation and mental alertness during activity, Clean essential energy and hydration, Fast muscle recovery, Fast acting energy source, Essential electrolytes
Red Bull	Structure/ Function	Increases endurance, Increases concentration and reaction speed, Improves performance during stress and strain, Gives you wings, Improves vigilance, Stimulates metabolism, Makes you feel more energetic and improves your overall well-being

[30] The Dietary Supplement Health and Education Act of 1994

[31] Dietary supplement structure function claims must also either: (1) claim a benefit related to a classical nutrient deficiency disease and disclose the prevalence of such disease in the United States, (2) describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, (3) characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or (4) describe general well-being from consumption of a nutrient or dietary ingredient

[32] FDA Needs to Reassess Its Approach to Protecting Consumers from False or Misleading Claims GAO–11–102, Jan 14, 2011

[33] *Ibid.*

TABLE 5: Energy drinks make a range of advertising claims relating to functional benefits—Continued

Product	Claim Type	Examples Of Claims
Full Throttle Fuze	Structure/ Function	Help you get the job done, Feel the energy at work, Easy drinking energy
NOS	Structure/ Function	Enhanced mental focus, High performance energy, Get focused, Get 50 percent more focused, React faster
Rockstar	Structure/ Function	Bigger, faster, and stronger that other energy drinks, Provides energy and hydration
Monster Energy	Structure/ Function	Rehabilitate with a killer mix, Gives you hydration and energy you need, Quenches thirst, Fires you up and brings you back after a hard night, No 'whip it' but it will whip you good, Delivers a big bad buzz, Unleash the beast, Packs a powerful punch
Arizona	Structure/ Function and Nutrient Content	Extreme performance, Loaded with antioxidants, Lasts for hours, Natural energy, Invigorating blend

FINDING #5: *In addition to caffeine, energy drinks contain a myriad of specialty ingredients whose combinations and additive impacts are not thoroughly evaluated or well understood. Companies can and often do self-determine that ingredients are safe for use in energy drinks, and there is no requirement for companies to notify the FDA of this determination or the use of the ingredient.*

Caffeine and added carbohydrates (usually in the form of natural or synthetic sugars) are the primary ingredients energy drinks rely on to fuel claims of "increased energy". However, these drinks also contain other ingredients for purported health benefits, most commonly high levels of certain B-vitamins, ginseng, guarana, inositol, taurine, and other amino acids (See Table 6). The combined health impacts of these ingredients as well as some less commonly used exotic ingredients, such as methylated xanthines (a stimulant), raise significant concerns for consumers, particularly youth. With the exception of the B-vitamins, the quantities of many of these other ingredients are not required to be disclosed on the label. Similarly to caffeine, some companies[34] choose to voluntarily disclose the amount of some of the more commonly used ingredients, such as guarana and taurine. However, frequently these ingredients are merely labeled without corresponding quantities.

From a regulatory perspective, ingredients that are used in energy drinks are treated differently dependent on whether the energy product is represented as a dietary supplement or a beverage. If a dietary supplement manufacturer opts to use a "new dietary ingredient"—an ingredient that was not marketed in the United States before October 15, 1994—the company may be required to notify the FDA before marketing the product, depending on the history of use of the ingredient. For the most part, FDA relies on post-market surveillance efforts—such as monitoring adverse event reports it receives from companies, health care practitioners, and individuals, as well as reviewing consumer complaints and conducting facility inspections—to identify potential safety concerns related to dietary supplements. Even once a safety concern is identified, FDA must demonstrate that the dietary supplement presents a significant or unreasonable risk under its specified conditions of use—a high threshold to meet—before it can remove the product from the market.[35]

For energy drinks classified as beverages, the FDA handles the oversight of ingredients differently. Generally, an ingredient added in a food product must either be generally recognized as safe (GRAS) or go through FDA's review and approval process as a food additive.[36] In order for an ingredient to be considered GRAS there must be a "reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."[37] However, the burden to determine whether an ingredient is GRAS is typically left to the manufacturer and a manufacturer can make this determination on its own, and use the ingredient in a product, without informing the FDA. As a result not only would the FDA potentially not know when a company has made an unsupported or incorrect determina-

[34] See for example the label of AMP energy.
[35] FDA Needs to Reassess Its Approach to Protecting Consumers from False or Misleading Claims GAO–11–102, Jan 14, 2011
[36] Substances that were in use prior to 1958 can be determined GRAS based on its common use in food.
[37] 21 C.F.R 170.3(i)

tion about whether an ingredient is GRAS, the FDA would have no knowledge whether an ingredient was even being used or the frequency of its use. In the event that FDA was aware that an unapproved additive was being used in a product and the ingredient was not GRAS for its intended use, the FDA would consider this product to be adulterated, making marketing or selling of the product illegal.

TABLE 6: Ingredients commonly used in energy drink products

Brand Name	Ingredients Related To Functional Claims Made* (not including natural or synthetic sugars)
Arizona	Caffeine, guarana extract, L-carnitine, ginseng extract, eleuthero root, schisandara, green tea extract, B-vitamins
Venom	Caffeine, taurine, guarana, L-carnitine, ginseng extract, inositol, maltodextrin, B-vitamins (niacinamide, B6, riboflavin, B12)
Clif Shot	Caffeine, green tea extract, guarana, maltodextrin
Red Bull	Caffeine, taurine, glucuronolactone, inositol, B-vitamins (niacinamide, B–12, pantothenic acid, pyridoxine)
Full Throttle Fuze	Caffeine, B-vitamins (niacinamide pantothenic acid, pyridoxine)
NOS	Caffeine, guarana, taurine, L-theanine, B-vitamins (B6, B12)
Jamba	Caffeine, green tea extract
Sambazon	Caffeine, yerba matte, green tea extract, guarana
Target Archer Farms	Caffeine, panax ginseng root, guarana, taurine, vitamin B6 and B12
AMP Energy	Caffeine, choline, theanine, maltodextrin, panax ginseng root extract, L-carnitine, guarana, taurine, B-vitamins (riboflavin, pantothenic acid, niacinamide)
Rockstar	Caffeine, guarana, B-vitamin niacin B–12, pantothenic acid, B6) taurine, yerba mate, green tea extract, L-carnitine, inositol
5-hour Energy	Caffeine, citicoline, L-tyrosine, L-phenylalanine, malic acid, glucuronolactone, taurine, B-vitamins (Niacinamide, pyridoxine,B12, folic acid), methylated xanthines
Celsius	Caffeine, guarana, taurine, green tea extract, glucuronolactone, ginger extract, B-vitamins (riboflavin, niacin, B6, B12, pantothenic acid)
Monster Energy	Caffeine, taurine, L-carnitine, glucuronolactone, guarana, panax ginseng extract, inositol, maltodextrin

*ingredients may vary dependent on product

The FDA has raised concerns that some ingredients that have been present in the food supply for many years are now being added to energy drinks at levels in excess of how they are traditionally used.[38] This trend raises questions regarding whether these higher levels and other new conditions of use are safe. For example, guarana is a FDA approved additive for flavor, but is commonly and intentionally added to energy drinks as an extra source of caffeine stimulant, sometimes at higher levels than what would be used if guarana was only being added for flavor. Taurine, an amino acid, is another frequently added ingredient in energy drinks. It has never been affirmed as GRAS by the FDA, nor has it been approved as a food additive. However, taurine is considered GRAS by the Flavor and Extract Manufacturers Association of the United States for flavor use. The European Commission (EC), assessed the use of taurine in energy drinks and couldn't conclude taurine concentrations used in energy drinks are safe.[39] Furthermore, caffeine is universally added to energy drinks at levels that are far beyond what has been affirmed as GRAS by the FDA for use in cola-type beverages (approximately 71 mg per 12 ounces).[40]

Recently, the City Attorney of San Francisco wrote a letter to FDA Commissioner Margaret Hamburg, challenging the GRAS determination energy drink companies

[38] FDA Draft Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods. (December 2009)

[39] *http://ec.europa.eu/food/fs/sc/scf/out22_en.html*

[40] 21 CFR 182.1180

have made to use levels of caffeine beyond what is typically found in cola-type beverages. According to the city attorney's letter, which was supported by 18 independent scientific experts, the addition of caffeine in the amounts used in energy drinks is not safe based on scientific evidence, and as such, the FDA should enforce limits in energy drinks that are comparable to what is commonly found in cola-type beverages. Historically, the FDA has not challenged the use of caffeine in other beverages at levels that are comparable to the GRAS level for cola beverages. However, the use of caffeine in energy drinks far surpasses that which is found in common sodas. The FDA should use its current authority to evaluate whether the levels of caffeine and other ingredients commonly used in energy drinks is in fact GRAS and revise its regulations accordingly. The FDA should also set limits for the use of these ingredients for single serve containers.

Conclusions and Recommendations

Energy drinks are a relatively new product category that is rapidly growing in the marketplace and may serve as an emerging public health risk, particularly for adolescents. Energy drinks universally contain high levels of intentionally added caffeine, sugar and other novelty ingredients that are often advertised and marketed toward young people or presented in youth-oriented media and venues. The use of these ingredients and their combinations have largely not been assessed for safety by the FDA, but recent indications of adverse events and increased hospitalizations that may be associated with consumption of energy drinks call into question both the safety and the claims made by these companies.

The inconsistency in the way these products are represented to consumers, marketed, and labeled poses unique challenges to Federal regulation and oversight. Furthermore, because of the way energy drinks are regulated, ingredients are often not presented on the label in a manner that enables consumers to make an informed decision about quantities of caffeine and other ingredients they purchase and consume. The lack of transparency in the labeling practices of energy drinks combined with the inconsistent way in which they are presented in the market and the advertising claims and marketing practices of these companies have the capability of eroding consumer confidence in the safety of all FDA-regulated products.

We call on all manufacturers of energy drink products, whether they are marketed as dietary supplements or conventional foods (beverages) to take the following steps to improve transparency and representation of its products and ensure that children and teens are adequately protected from deceptive advertising practices:

1. Label products with a clear description of the total amount of caffeine (in milligrams) added to the product from all sources. For products that are packaged in non-resealable containers (such as pop-top cans), the label should include the amount of caffeine from all sources in the entire container, not just one serving.
2. For products that contain caffeine that has been intentionally added to the product at levels above 200 parts per million (approximately 71 milligrams per 12 fluid ounces), the level affirmed as GRAS by the FDA, display a prominent precautionary statement that at a minimum says, "This product is not intended for individuals under 18 years of age, pregnant or nursing women or for those sensitive to caffeine. Consult with your doctor before use if you are taking medication and/or have a medical condition."
3. Cease marketing of energy drink products to children and teens under the age of 18. Marketing includes use of both traditional media and social media as well as the sponsorship of events, activities and individuals that are intended for an audience comprised primarily of children or teens.
4. Report to the FDA the receipt of any serious adverse events associated with energy drink use. Serious adverse events are defined by the FDA, but reporting is currently only required by the FDA for products that are represented as dietary supplements.

The CHAIRMAN. Senator Blumenthal, would you come forward, please, and chair? And the list of witnesses, you have. And I am very proud of the work you have done.

Senator DURBIN. Mr. Chairman, thank you very much for allowing me to testify.

The CHAIRMAN. Thank you, Senator Durbin.

[Pause.]

STATEMENT OF HON. RICHARD BLUMENTHAL,
U.S. SENATOR FROM CONNECTICUT

Senator BLUMENTHAL [presiding]. I would like the witnesses to come forward, if you would, please?

Dr. Marcie Beth Schneider. Dr. Schneider is a Pediatrician who is here on behalf of the American Academy of Pediatrics.

Dr. Jennifer Harris. Dr. Harris is from Yale University's Rudd Center on Food Policy and Obesity.

Dr. William R. Spencer. Dr. Spencer is a Legislator from Suffolk County, New York, and he is originally from Welch, Virginia.

Mr. Rodney Sacks. Mr. Sacks is the Chairman and Chief Executive Officer of Monster Beverage Corporation.

Ms. Amy E. Taylor. Ms. Taylor is Vice President and General Manager of Red Bull North America.

Ms. Janet Weiner. Ms. Weiner is Chief Financial Officer and Chief Operations Officer for Rockstar, Incorporated.

And Dr. James R. Coughlin. Dr. Coughlin is the President of Coughlin & Associates Consultants in Food/Nutritional/Chemical Toxicology and Safety.

We welcome you. We are very, very grateful to you each for being here today. This hearing is another step in the efforts that Senator Durbin, now Senator Markey, and I have led to call attention to the health risks associated with energy drinks.

I began my own involvement with energy drinks that combined alcohol with their product and, when I was Attorney General, led a group of my colleagues to successfully urge the FDA to ban alcoholic energy drinks for the obvious reasons that they resulted essentially in energized drunks. The effort to call attention to the potential health risks involves the marketing practices. You have heard them described here. I will have questions about them.

And clearly, we are concerned, and I know that the panel will address, each of the witnesses will address these issues. Not only the health risks that result from huge amounts of caffeine in these drinks that endanger particularly young people with problems ranging from cardiac arrest to liver and kidney damage and result in the doubling of emergency room visits that are related to energy drinks, but also the marketing and promotion practices that involve, as you have heard, the use of adolescent athletes and sometimes children in promotions and pictures as well as Websites and social media, making use of children, making use of video games and other activities designed to appeal to children, as well as buses and vans at SAT test preparation and a variety of activities that seem very problematic.

And so, I am not going to go on at this point with what I think the panel will be discussing, but simply to call attention to a number of the areas that we think are important and that are for this panel to assess. But I would just finish this part of my statement by saying we really do appeal to the more responsible elements in this industry, the more responsible companies to set a model and provide an example because voluntary compliance, for example, with the American Beverage Association standards and practices would be a good step. And if further action is necessary, certainly we would consider it.

I want to thank both of my colleagues, Senator Durbin and Senator Markey, for their work on this issue. And most particularly, now Senator Markey for the report, "What's All the Buzz About?" which has been entered into the record, a very important and compelling document that we worked on together.

And I want to ask Senator Markey if he has any remarks at the opening of our hearing?

STATEMENT OF HON. EDWARD MARKEY,
U.S. SENATOR FROM MASSACHUSETTS

Senator MARKEY. Thank you, Senator, very much and thank you for your work.

And I thank Senator Rockefeller and Senator Thune for having this very important hearing here today.

Over the last few years, a class of caffeine-laced beverages popular with teens and known collectively as "energy drinks" has taken the marketplace by storm. These products promise improved athletic performance, more energy, better hydration, increased concentration, and enhanced alertness that collectively "zap the nap" and make consumers better at life, athletics, and performance.

But energy drinks have been linked to severe adverse health effects. In fact, between 2007 and 2011, the number of emergency room visits related to the consumption of energy drinks has doubled. This data is particularly troubling when examining the way energy drink companies market these beverages, especially to teenagers.

Earlier this year, Senator Blumenthal, Senator Durbin, and I held up this issue for examination. And we believe that the spotlight belongs on this issue. Senator Blumenthal has referred to this report, "What's All the Buzz About?" And this goes right to the heart of this issue, this focus on teenagers, focus on younger people.

Senator Durbin made reference to smoking. It is right on the money. That is exactly what is happening, and we can't kid ourselves about the direct correlation that exists between the marketing practices and the increased use by younger people of these beverages.

We surveyed the practices of the makers of 14 of the most commonly sold energy drink brands, including the 3 companies here today. Our report found that while many of these products do not engage in traditional marketing through TV, print, and radio, they are very active in social media and sponsorship of sporting, music, and gaming events that promote brand recognition in a way that clearly appeals to young people and often promotes unhealthy and quick consumption.

These companies are adamant that their target market consists of adults, but with their heavy use of promotion through Facebook, Instagram, Twitter, and other teen favorites, they are, in fact, marketing to every single teenager in this country. That is what this hearing is all about.

Senator Blumenthal and Senator Durbin and I are going to continue to focus on this issue because we do think that there has to be a dramatic change in the marketing practices of this industry, and I thank you, Senator.

Senator BLUMENTHAL. Thank you, Senator Markey.

Let us begin with you, Dr. Schneider, and then we will just go across the table.

STATEMENT OF MARCIE BETH SCHNEIDER, MD, FAAP, ON BEHALF OF THE AMERICAN ACADEMY OF PEDIATRICS

Dr. SCHNEIDER. Good afternoon, Chairman Rockefeller, Ranking Member Thune, Senator Blumenthal, and members of the Senate Commerce Committee, and thank you so much for inviting me to speak this afternoon.

My name is Dr. Marcie Schneider, and I am honored to provide testimony on behalf of the 60,000 members of the American Academy of Pediatrics, or the AAP. I am a physician boarded in the specialty of pediatrics and in the subspecialty of adolescent medicine in private practice in Greenwich, Connecticut. I am an incoming Executive Committee member of the AAP Section on Adolescent Health.

While serving on the Committee on Nutrition, I coauthored the clinical report entitled "Sports Drinks and Energy Drinks for Children and Adolescents: Are They Appropriate?" The AAP published its 2011 report to raise awareness of the dangers of energy drink consumption in children and adolescents by educating pediatricians who could, in turn, educate parents and kids about the risks of consuming energy drinks.

We also took action, recognizing widespread confusion between energy drinks and sports drinks. After an extensive review of the research and scientific data available, the conclusion within the AAP's clinical report was, "Energy drinks have no place in the diets of children and adolescents." Another area of concern was that marketing played a significant role in the rising use and abuse of energy drinks.

What distinguishes an energy drink is that they all contain caffeine, an addictive stimulant with many side effects. These include cardiac side effects—elevated heart rate, elevated blood pressure, cardiac arrhythmias—sleep disturbances, anxiety, irritability, restlessness, high speech rate, motor activity, increased attentiveness. Stomachs secrete more fluid. People get dehydrated, and temperatures rise.

Energy drinks have been implicated in seizures. We know that stimulants restrict blood flow to the entire body, including the heart, including the brain, and particularly the impact of a developing neurological system of a child or a teenager is of grave concern.

Children and adolescents are also at risk for physical dependence and addiction, and in fact, in schoolchildren, caffeine withdrawal has been shown to be associated with decreased reaction and attention for up to a week after cessation of caffeine use.

In addition to caffeine, energy drinks contain other stimulant substances, such as the protein taurine and the plant extract guarana, both of which make the caffeine more potent. Other nonstimulant ingredients in energy drinks also have been noted to have negative side effects. L-carnitine has been associated with some nausea, vomiting, abdominal pain, and diarrhea. Ginseng has

been associated with vaginal bleeding, headache, dizziness, mania, and yohimbine with a rapid heartbeat.

The adverse health effects of energy drinks are increasingly bringing consumers to the emergency room. From 2007 to 2011, SAMHSA reported an increase in those emergency room visits involving energy drinks. They have doubled from 10,000—over 10,000 in 2007 to over 20,000 in 2011. And almost half of those were among patients from 12 to 25 years old. In addition, the Poison Control Exposure Report skyrocketed from 672 in 2010 to over 3,000 in 2011 and 2012.

Energy drinks are reportedly consumed by 30 to 50 percent of young adults, and you have also heard this afternoon that 18 percent of eighth graders are using these, more than one energy drink a day. The public needs to fully understand the potential for addiction, overconsumption, intoxication, and death.

The marketing and labeling of energy drink products also plays a significant role in increasing health risks for young people. First, the marketing of these products aims to entice young people through social media and entertainment without appropriate information about the product's risks.

Second, labeling is very confusing. Some energy drink labels delineate the amount of caffeine, taurine, and guarana. Others simply lump the stimulants together under an umbrella of an "energy blend."

Third, the association of energy drinks with sports and physical activity results in confusion and poses great safety risks. Sports drinks provide energy through carbohydrates, through electrolytes, and are used to replace the fuel lost during physical exertion. Stimulant substances have no nutritive value and can put athletes at risk of overheating, dehydrating, and having caffeine toxicity.

As an adolescent medicine specialist, I have encountered numerous parents who inadvertently encouraged their teen athletes to consume energy drinks and were shocked to learn of the health risks. As I conclude, I would like to submit the following five recommendations.

First, caffeine in energy drinks should be actively and strongly discouraged for young people. Children and adolescents are not little adults. Their bodies are growing. Their bodies are developing. Their minds are growing and developing.

Sleep and a well-balanced diet are really all that young bodies need to perform their daily tasks. This message really needs to be reinforced and especially at physician visits.

Second, given the health risks, public education is necessary. Caffeine, in combination with other stimulant ingredients, is what makes these energy drinks a grave concern.

Third, energy drinks' ingredients should be clearly labeled and should provide information on the cumulative total of all caffeine and other stimulants.

Fourth, given the rise in adverse health effects associated with energy drinks that include high doses of caffeine often in combination with other stimulants with unknown safety profiles, research is urgently needed.

And last, stronger Federal guidance is necessary. The AAP is very pleased that the FDA took action in response to the health

concerns associated with other caffeinated products. Ultimately, policymakers in the Federal Government should work together to advance and address the rising health and safety incidents associated with energy drinks.

Again, it is an honor to provide testimony today on behalf of the AAP. I would be happy to answer any questions that you might have.

Thank you.

[The prepared statement of Dr. Schneider follows:]

PREPARED STATEMENT OF MARCIE BETH SCHNEIDER, MD, FAAP, ON BEHALF OF THE AMERICAN ACADEMY OF PEDIATRICS

Good afternoon Chairman Jay Rockefeller, Ranking Member John Thune and members of the Senate Commerce Committee, thank you for inviting me to speak this afternoon and for your leadership on this important issue. My name is Dr. Marcie Schneider and I am honored to provide testimony on behalf of the 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists of the American Academy of Pediatrics (AAP). The AAP is committed to the health and well-being of all infants, children, adolescents, young adults, and their families. I am a physician boarded in the specialty of Pediatrics and in the subspecialty of Adolescent Medicine.

I was a member of the American Academy of Pediatrics Committee on Nutrition from 2005—2011, am a current member of the Executive Committee of the American Academy of Pediatrics Section on Adolescent Health, and a private practitioner of adolescent medicine in Greenwich, Connecticut. While on the Committee of Nutrition, I coauthored the clinical report entitled "Sports Drinks and Energy Drinks for Children and Adolescents: Are They Appropriate?" published in *Pediatrics* in June 2011.

Concerns About Energy Drinks

The AAP published its clinical report on energy drinks and sports drinks due to a persistent need to educate parents, physicians and the public about these products. Many of our colleagues within the medical field and numerous families we encountered in our practices were confused about product usage, ingredients and most importantly, safety. After extensive review of the research and scientific data on energy drinks, our conclusion as was presented in the AAP's clinical report was that "Energy drinks have no place in the diet of children and adolescents." I will summarize the data.

First, what distinguishes an energy drink from other sports beverages is that they contain caffeine, a stimulant substance. Stimulant substances have no nutritive value nor does the body have any need for them in our diets. When consumed, caffeine has a stimulant drug effect on the entire body, head to toe. When consumed frequently or in large quantities, that effect is magnified and poses greater risks.

Overall, the risks to children and adolescents from consuming energy drinks include increased heart rate, increased blood pressure, increased anxiety, sleep disturbances, physical dependence and addiction to caffeine, effects on the developing neurologic system, precipitation of arrhythmias (irregular heartbeats), and even death. Because these drinks and beverage products are considered dietary supplements, they are not strongly regulated by the Food and Drug Administration (FDA), and there is no limit to their caffeine levels, which produces additional risk for smaller sized, physiologically and developmentally immature children and adolescents.

Health Risks of Energy Drinks

Caffeine is commonly consumed in the United States in beverages including coffee, tea, and soft drinks and this has contributed to confusion with the safety of energy drinks. However, there is growing concern over caffeine consumed in the form of "energy drinks." Although the term "energy drink" lacks a statutory definition, they are generally accepted to include beverages and liquid dietary supplements that are marketed to boost energy, decrease fatigue, enhance concentration, and increase mental alertness. They typically contain variable amounts of caffeine, and often contain one or more additional stimulant substances (such as guarana and taurine). Energy drink manufacturers are not required to disclose caffeine content on drink labels, so it is difficult for consumers to identify how much caffeine is being

consumed. The total amount contained in some products can exceed 500mg (equivalent to 14 cans of common, caffeinated soft drinks).

There are many known physiologic effects of caffeine consumption.[1] Caffeine is absorbed by all body tissues, and can have variable effects on the brain, heart, endocrine, gastrointestinal, musculoskeletal, renal and other body systems.[2] Even when consumed at low levels, some effects of caffeine include increases in speech rate, motor activity, attentiveness, gastric secretion, dehydration, and temperature. It can cause sleep disturbances and can increase anxiety in those with anxiety disorders. It can cause numerous cardiac effects including elevated heart rate, blood pressure and cardiac arrhythmias in susceptible individuals.[3]

Additional concerns specific to caffeine use in children include its effects on the developing neurologic and cardiovascular systems and the risk of physical dependence and addiction. Symptoms of caffeine withdrawal can include headache, fatigue, decreased alertness, drowsiness, difficulty concentrating, irritability, depressed mood, muscle pain or stiffness, and nausea or vomiting. In school age children, caffeine withdrawal has been shown to be associated with decreased reaction and attention for up to one week after cessation of caffeine use.[4]

When consumed in higher doses, caffeine intoxication can occur.[5] Heavy caffeine consumption has been reported to cause serious consequences including seizures, mania, stroke, hallucinations, increased intracranial pressure, cerebral edema, paralysis, altered consciousness, arrhythmias, and even sudden death.[5] Effects on children are less well studied, but evidence is mounting that children experience many similar and some unique adverse health impacts compared to adults. Caffeine effects also are dose dependent so the same amount of caffeine consumed by a child or adolescent who is smaller than the average adult will lead to increased risk of toxicity.

Consumption of caffeine in the form of energy drinks by children and adolescents is a growing public health problem. Energy drinks are reportedly consumed by 30 percent to 50 percent of adolescents and young adults.[5] In addition to the negative health effects associated with consuming large amounts of caffeine, young people are experiencing additional adverse effects of energy drink consumption. Guarana, a plant that naturally contains large amounts of caffeine, can boost the effects of added caffeine. Taurine, an amino acid, potentiates the effects of caffeine as it affects the heart in a similar fashion. Ingredients in energy drinks other than caffeine have also been associated with negative health effects, such as nausea, vomiting, abdominal pain, and diarrhea (L-Carnitine); vaginal bleeding, headache, vertigo, mania, hypertension, rash, insomnia, irritability (Ginseng); and tachycardia (Yohimbine).[5]

The adverse health effects of energy drinks are increasingly bringing consumers to the emergency room: from 2007 to 2011, the Substance Abuse and Mental Health Services Administration (SAMHSA) reports the number of emergency department visits involving energy drinks doubled from 10,068 visits in 2007 to 20,783 visits in 2011.[6] Over 7,000 visits were made by young adults aged 18 to 25 years in 2011; 1,499 visits were made by adolescents aged 12 to 17.

In addition, the number of energy drink exposures reported to poison control centers has skyrocketed from 672 reports in 2010 to over 3152 reports in 2011 and 2012.[7]. Clearly, energy drink use and abuse is becoming a public health problem with significant costs and burdens to the health care system.

Energy drink consumption has also been linked to other unhealthy behaviors in adolescents. Among college students, energy drink consumption has been linked to

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[1] American Academy of Pediatrics, Committee on Nutrition and the Council on Sports Medicine and Fitness. Clinical Report: Sports Drinks and Energy Drinks for Children and Adolescents: Are They Appropriate? *Pediatrics.* 2011 Jun; 127(6):1182–1189.

[2] Kabagambe EK, Wellons MF. Benefits and risks of caffeine and caffeinated beverages. In: UpToDate, Rose BD (Ed), UptoDate, Waltham, MA, 2013.

[3] Giardina EG. Cardiovascular effects of caffeine. In: UpToDate, Rose BD (Ed), UpToDate, Waltham, MA, 2013.

[4] Bernstein GA, Carroll ME, Dean NW, *et al.,* Caffeine withdrawal in normal school-age children. J Am Acad Child Adolesc Psychiatry 1998; 37:858–65.

[5] Seifert, S. M., Schaechter, J. L., Hershorin, E. R., & Lipshultz, S. E. (2011). Health effects of energy drinks on children, adolescents, and young adults. *Pediatrics, 127*(3), 511–528.

[6] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (January 10, 2013). *The DAWN Report: Update on Emergency Department Visits Involving Energy Drinks: A Continuing Public Health Concern.* Rockville, MD.

[7] American Association of Poison Control Centers, accessed online at *http://www.aapcc.org/alerts/energy-drinks/*

marijuana use, sexual risk-taking, fighting, smoking, drinking, and misuse of prescription drugs.[8,9]

Mixing Caffeine and Alcohol

Mixing caffeine and alcohol is dangerous and potentially life-threatening, particularly for adolescents. In 2010, FDA took regulatory action against caffeinated alcoholic beverages. The FDA outlined the health concerns about dual use of caffeine and alcohol to include behavioral effects, diminished motor coordination or slower visual reaction times and reduced perception of intoxication. The agency also highlighted concerns about the risk that consumption of pre-mixed products containing added caffeine and alcohol may result in higher amounts of alcohol consumed per drinking occasion, a situation that was particularly dangerous for underage drinkers.[10]

The American Academy of Pediatrics agreed with the concerns of the FDA about the combined use of alcohol and caffeine. The agency's actions also represented an example of effective governmental intervention in response to demonstrated health and safety risks. However, despite FDA's regulatory action, research has demonstrated the continuing prevalence of alcohol and energy drink mixing behaviors by adolescents.

Concerns About Energy Drink Marketing

Perhaps one of the AAP's greatest concerns during the course of our research was the realization that marketing plays a significant role in the rising use and abuse of energy drinks. It is increasingly clear that children and adolescents are targets as well as victims of marketing aimed to encourage frequent, repetitive use of energy drinks without any attempt to provide education as to potential risks by the beverage manufacturers.

The manner in which energy drinks are packaged, the sizes as well as the poor product content labeling only serve to exacerbate the health concerns associated with youth consumption of energy drinks. While the AAP has concluded that stimulant containing energy drinks have no place in the diet of children and adolescents, current energy drink marketing significantly targets youth with considerable effectiveness.

Industry marketing practices and inconsistent Federal guidelines contribute to consumer confusion and a lack of information from which to properly make informed decisions. Children and adolescents are frequently exposed to advertising for these products, contributing to the public health problem of youth energy drink consumption. One of our recommendations to this committee is to support and advocate for widespread education and detailed product labeling so that consumers may be better informed as they make choices for beverage consumption.

The U.S. energy drink market has grown rapidly and in 2012, sales rose 16 percent percent and totaled $12.5 billion.[11] At the same time, adolescents consume energy drinks more regularly than other groups, with 31 percent of 12–17 year olds regularly consuming energy drinks, compared with 22 percent of the 25–35 year old age range.

Much of the growth in adolescent consumption is attributable to marketing, which frequently targets youth through youth-oriented media and packaging and images geared toward a young audience. In 2010, energy drink advertisements reached 18 percent more teens than adults via television and 46 percent more teens than adults via radio.[12] This marketing is increasing as well, as teens saw 20 percent more television ads for energy drinks in 2010 than in 2008. The practices energy drink manufacturers use to sell these products associate them with sports and physical activity.[13] Frequently, companies sponsor young athletes and high school sporting

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[8] Miller, K. E. (2008). Energy drinks, race, and problem behaviors among college students. *Journal of Adolescent Health, 43*(5), 490–497.

[9] Thombs, D. L., O'Mara, R. J., Tsukamoto, M., Rossheim, M. E., Weiler, R. M., Merves, M. L., & Goldberger, B. A. (2010). Event-level analyses of energy drink consumption and alcohol intoxication in bar patrons. *Addictive Behaviors, 35*(4), 325–330.

[10] FDA: Background Information Caffeinated Alcoholic Beverages: *http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/UCM190372.pdf*

[11] Staff of Congressman Edward J. Markey (D–MA), in coordination with the staff of Senators Richard J. Durbin (D–IL) and Richard Blumenthal (D–CT). What's all the buzz about? A Survey of Popular Energy Drinks Finds Inconsistent Labeling, Questionable Ingredients and Targeted Marketing to Adolescents. April 10, 2013.

[12] Harris, Jennifer *et al.,* Yale Rudd Center for Food Policy and Obesity. Sugary Drink F.A.C.T.S.: Evaluating Sugary Drink Nutrition and Marketing to Youth. October 2011. Accessed July 17, 2013. *http://www.sugarydrinkfacts.org/resources/SugaryDrinkFACTS__Report.pdf*

[13] *Pediatrics.* 2011 Jun; 127(6):1182–1189.

events, and these advertisements promise things such as improved athletic performance and increased attention and alertness.[14]

Teen exposure to advertising for energy drinks is significant. Recent research by the Yale Rudd Center for Food Policy and Obesity found that in 2010, energy drinks ranked high in the list of sugar-sweetened beverage advertisements viewed by teens. Out of the top 28 beverages by teen advertisement exposure, three were for energy drinks: 5-Hour Energy ranked number one overall, Red Bull ranked 9th, and PepsiCo's Amp ranked 19th.

All three of these beverages had a ratio of teens to adults targeted by the ad that were above 1.0.[15] In addition, energy drink companies target and reach an adolescent market through significant social media marketing. Yale's Rudd Center found that in 2011, Red Bull had over 150 million YouTube upload views and over 20 million Facebook fans. Rockstar also had 11 million Facebook fans.[16]Young people commonly use social media, with over half of all teens accessing social media daily and 22 percent of teens visiting their favorite social media site over 10 times per day.[17] These tools reach a disproportionately young audience, and we know that advertisements influence the behavior of children and adolescents. A study has found that the amount of time watching television correlates with requests for specific foods and caloric intake, and children are more likely to request high caloric foods with low nutritional values after viewing commercials.[18]

The claimed association of energy drinks and ergogenic and performance enhancing effects of the stimulants in energy drinks has not been adequately studied in adolescents, who are more susceptible to the negative health effects and who do not need stimulants to support physical activity.[19] Notably, adolescents surveyed do not differentiate between "sports drinks" and energy drinks, highlighting the same benefits for both product categories.[20]

A "sports drink" is a beverage that helps young athletes rehydrate and replenish carbohydrates, electrolytes, and water during prolonged and vigorous activity. The "energy" from a sports drink is from carbohydrates which the body needs. However, the body never needs the "energy" in the form of a drug stimulant like caffeine. Regardless, heavy marketing and the association of energy drinks with sports and physical activity equates the two types of products and results in confusion about their uses.[21] After all who doesn't want more "energy"? Youth athletes are susceptible to these marketing practices and are consuming larger quantities of energy drinks in association with sports activities, putting them at risk for adverse health outcomes.

As an adolescent medicine specialist, I have encountered numerous parents who inadvertently encouraged their teens to consume energy drinks to enhance sports performance and were confused or surprised when informed about the health risks. This is due in large part to advertising practices that associate energy drinks with health, nutrition and physical activity without appropriate information about the products' effects. In addition, products that use the terms "organic" and "all natural" also appeal to many young people's desire to embrace healthier lifestyle options.

Packaging and Discerning Stimulant Content

The marketing and packaging of energy drinks also makes it difficult to discern products' caffeine and other stimulant content. Nearly identical products are often marketed and represented differently to consumers, based on the distinction of whether they are categorized as beverages or dietary supplements. Because this is a distinction companies choose, they are able to decide which regulatory rules under FDA govern their products.[22] These inconsistencies result in a dearth of information

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[14] Staff of Congressman Edward J. Markey (D–MA), in coordination with the staff of Senators Richard J. Durbin (D–IL) and Richard Blumenthal (D–CT). What's all the buzz about? A Survey of Popular Energy Drinks Finds Inconsistent Labeling, Questionable Ingredients and Targeted Marketing to Adolescents. April 10, 2013.

[15] Harris, Jennifer *et al.,* Yale Rudd Center for Food Policy and Obesity. Sugary Drink F.A.C.T.S.: Evaluating Sugary Drink Nutrition and Marketing to Youth. October 2011. Accessed July 17, 2013. *http://www.sugarydrinkfacts.org/resources/SugaryDrinkFACTS_Report.pdf*

[16] *Ibid.*

[17] O'keefe, Gwenn Schurgin; Clarke, Kathleen; American Academy of Pediatrics Council on Communications and Media. The Impact of Social Media on Children, Adolescents, and Families. *Pediatrics.* 2011 March. 127(4): 800–804.

[18] American Academy of Pediatrics, Committee on Communications. Policy Statement: Children, Adolescents, and Advertising. *Pediatrics.* 2006 Jun; 118(6): 2563–2569.

[19] *Ibid.*

[20] *Pediatrics.* 2011 Jun; 127(6):1182–1189.

[21] *Ibid.*

[22] Staff of Congressman Edward J. Markey (D–MA), in coordination with the staff of Senators Richard J. Durbin (D–IL) and Richard Blumenthal (D–CT). What's all the buzz about? A Survey

for consumers to make informed choices about how much caffeine and other stimulants they are consuming. While products classified as beverages list caffeine content, supplements do not have to, or can include vague quantities comparing the product to a number of cups of coffee.[23] Additionally, even when caffeine content is listed, it can be per serving in a container containing multiple servings and the stimulant effect of additional ingredients is not quantified, providing an incomplete estimate of total stimulant content.[24]

Regulation of Conventional Foods and Supplemental Products

Although soft drinks and energy drinks seem similar, the two products are regulated in different manners. Soft drink beverages are classified as a conventional "beverage" and, as such, are regulated by the *Federal Food, Drug, and Cosmetic Act* (FFDCA), which limits the amount of caffeine in soft drinks to no more than 71 mg per 12 fl. oz.[25]

Energy drinks can be categorized as either conventional "beverages" or "dietary supplements." Many energy drink manufacturers claim their products are "dietary supplements," which allows them to fall under regulation by the *1994 Dietary Supplement Health and Education Act* (DSHEA) instead of the FFDCA. DSHEA allows herbal or other natural products to be classified as dietary supplements rather than food or drugs, and does not place limits on the amount of caffeine that can be included in products.[26]

The requirements related to caffeine labeling for conventional beverages and dietary supplements are also different. Beverages containing caffeine must include the included amount on the product label; dietary supplements must include caffeine in the list of ingredients, but there is no requirement that the amount of caffeine be listed.

Caffeine is considered by the FDA as a Substance Generally Recognized as Safe (GRAS), which allows it to be added to conventional foods and beverages without preapproval from the FDA. In the case of dietary supplements, caffeine is considered to be a "dietary ingredient," which allows it to similarly be used without FDA preapproval. This means in both beverages and dietary supplements, manufacturers can add caffeine to their products without FDA approval.

Adverse events associated with use of dietary supplements are required to be reported to the FDA by the 2006 *Dietary Supplement and Nonprescription Drug Consumer Protection Act.*[27] Specifically, dietary supplement manufacturers, packers, and distributors must notify FDA if they receive reports about serious adverse events in connection with the use of their products. This law defines a serious adverse event as an adverse health-related event that is associated with the use of a dietary supplement and that results in death, a life threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity, a congenital anomaly or birth defect, or that requires, based on reasonable medical judgment, a medical or surgical intervention to prevent one of those outcomes. The requirement to report serious adverse events to FDA applies only to dietary supplements and not to conventional beverages, other conventional foods, or cosmetics.

FDA has prepared draft guidance on the subject of differentiating between whether a product ought to be classified as a beverage or a dietary supplement.[28] First prepared in December 2009, this guidance would provide significant clarity to manufacturers about precisely the standards a product should meet to be classified as one category or the other. Additionally, this guidance would outline standards for the use of novel ingredients or novel quantities of previously used ingredients, to ensure that they meet GRAS and those consumers, particularly children, who are more susceptible to the effects of caffeine and other stimulants, are not exposed to unsafe products.

In addition, proposals have been introduced in Congress to establish FDA authority to regulate or mandate new labeling for energy drinks, including a mandatory warning label requirements for dietary supplement ingredients that the Secretary

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of Popular Energy Drinks Finds Inconsistent Labeling, Questionable Ingredients and Targeted Marketing to Adolescents. April 10, 2013.

[23] *Ibid.*

[24] *Pediatrics.* 2011 Jun; 127(6):1182–1189.

[25] FDA GRAS Notices, *http://www.accessdata.fda.gov/scripts/fcn/gras_notices/grn000347.pdf*

[26] FDA, *http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/ucm148003.htm*

[27] FDA, "Energy Drinks" and Supplements: Investigation into Adverse Event Reports, *http://www.fda.gov/Food/NewsEvents/ucm328536.htm*

[28] FDA: Guidance Document *http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm196903.htm*

determines to cause potentially serious adverse events, drug interactions, contraindications, or potential risks to subgroups to subgroups such as children and pregnant or breastfeeding women.

Recommendations

The American Academy of Pediatrics submits the following recommendations for consideration by the Committee:

- *Caffeine and Energy Drinks Should Be Actively and Strongly Discouraged for Young People.* Due to the potentially harmful health effects of caffeine, dietary intake should be discouraged for all children. Because the actual stimulant content of energy drinks is hard to determine, energy drinks pose an even greater health risk than simple caffeine. Therefore, energy drinks are not appropriate for children and adolescents and should never be consumed.
- *Public Education is Necessary.* Parents should be advised on nutrition and sleep needs of children and adolescents to reduce the need for stimulant seeking behaviors. Also, parents and adolescents should understand the risks of consumption and overconsumption of caffeinated beverages and energy drinks as well as the dangers of consuming alcohol with energy drinks. The health risks of these products also reinforce the need for increased media literacy as recommended by the AAP.[29]
- *Voluntary Consumer Product Labeling Would Benefit the Public.* Energy drink packaging should provide information on the cumulative total of all caffeine and other stimulants, and it should be per package for non-resealable packaging. In the absence of strong voluntary standards, mandatory requirements would help consumers make informed choices and better protect public health and safety.
- *More Research Is Needed.* Given the health effects of energy drinks due to the high doses of caffeine, often in combination with other stimulant ingredients with unknown safety profiles, research on energy drinks and the ingredients they contain, is urgently needed. Additional poison control data would certainly be helpful in identifying areas of concern.
- *Stronger Federal Guidance is Necessary.* The AAP is pleased the FDA took action to protect public health and safety in response to concerns and adverse incidences regarding caffeinated alcoholic beverages, inhalable caffeine products and the introduction of caffeinated gum and processed foods. The FDA should finalize its 2009 guidance for industry to ensure that beverage products are classified appropriately based on their composition and intended use. Furthermore, additional efforts are needed to examine potential safety standards for GRAS ingredients that are generally regarded as safe but with demonstrated health and safety risks for children or other vulnerable populations or when consumed in excess amounts. Finally, Congress should eliminate all unnecessary requirements that delay or inhibit the work of the Interagency Working Group on Food Marketed to Children.

Conclusion

It is an honor to provide testimony on behalf of myself and the over 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists of the American Academy of Pediatrics. I appreciate the opportunity to discuss this very important national issue and would be happy to answer your questions.

[29] Pediatrics, Vol. 118 No. 6 December 2006, pp 2563–2569

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Clinical Report—Sports Drinks and Energy Drinks for Children and Adolescents: Are They Appropriate?

COMMITTEE ON NUTRITION AND THE COUNCIL ON SPORTS MEDICINE AND FITNESS

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Guidance for the Clinician in Rendering Pediatric Care

Clinical Report—Sports Drinks and Energy Drinks for Children and Adolescents: Are They Appropriate?

abstract

FREE

Sports and energy drinks are being marketed to children and adolescents for a wide variety of inappropriate uses. Sports drinks and energy drinks are significantly different products, and the terms should not be used interchangeably. The primary objectives of this clinical report are to define the ingredients of sports and energy drinks, categorize the similarities and differences between the products, and discuss misuses and abuses. Secondary objectives are to encourage screening during annual physical examinations for sports and energy drink use, to understand the reasons why youth consumption is widespread, and to improve education aimed at decreasing or eliminating the inappropriate use of these beverages by children and adolescents. Rigorous review and analysis of the literature reveal that caffeine and other stimulant substances contained in energy drinks have no place in the diet of children and adolescents. Furthermore, frequent or excessive intake of caloric sports drinks can substantially increase the risk for overweight or obesity in children and adolescents. Discussion regarding the appropriate use of sports drinks in the youth athlete who participates regularly in endurance or high-intensity sports and vigorous physical activity is beyond the scope of this report. *Pediatrics* 2011;127:1182–1189

Sports and energy drinks are a large and growing beverage industry now marketed to children and adolescents for a variety of uses. Marketing strategies for sports drinks suggest optimization of athletic performance and replacement of fluid and electrolytes lost in sweat during and after exercise, and marketing strategies for energy drinks purport a boost in energy, decreased fatigue, enhanced concentration, and mental alertness. Sports drinks are different products than energy drinks; therefore, the terms should not be used interchangeably. Sports drinks are flavored beverages that often contain carbohydrates, minerals, electrolytes (eg, sodium, potassium, calcium, magnesium), and sometimes vitamins or other nutrients. Although the term "energy" can be perceived to imply calories, energy drinks typically contain stimulants, such as caffeine and guarana, with varying amounts of carbohydrate, protein, amino acids, vitamins, sodium, and other minerals.

With children and adolescents, careful consideration is necessary when selecting a beverage to hydrate before, during, or after exercise and outside of physical activity to prevent excessive sugar and caloric intake that may encourage dental erosion, overweight, and obesity.[1]

COMMITTEE ON NUTRITION AND THE COUNCIL ON SPORTS MEDICINE AND FITNESS

KEY WORDS
sport drinks, energy drinks, obesity, caffeine

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Pediatric athletes can benefit from using sports drinks that contain carbohydrates, protein, or electrolytes[2]; however, for the average child engaged in routine physical activity, the use of sports drinks in place of water on the sports field or in the school lunchroom is generally unnecessary. Stimulant-containing energy drinks have no place in the diets of children or adolescents.[3] Excessive regular consumption of carbohydrate-containing beverages increases overall daily caloric intake without significant additional nutritional value. Therefore, frequent consumption adversely affects the appropriate balance of carbohydrate, fat, and protein intakes needed for optimal growth, development, body composition, and health. This report defines and categorizes selected popular sports and energy drinks, reviews their contents, and examines the evidence for and against the use of sports and energy drinks in children and adolescents. Recommendations are provided for counseling patients, parents, government policy-makers, and administrators who run both school programs and youth sports organizations with regard to appropriate use of sports drinks. It is not intended to be a guide for the use or effectiveness of these drinks in children and adolescents involved in competitive endurance, repeated-bout sports (such as tournaments in which the athlete may have prolonged exposure to a hot, humid environment or be subjected to prolonged, repetitive exercise, often without adequate recovery time in between competitions), or other prolonged vigorous physical activities, because these uses have been reviewed elsewhere.[4]

DEVELOPMENT OF THIS REPORT

The American Academy of Pediatrics Committee on Nutrition (CON) and Council on Sports Medicine and Fitness (COSMF) conducted a thorough review of the literature from 2000 to 2009. Various approaches were used, including numerous PubMed searches. Reference lists from related studies, reviews, editorials, and position statements from other professional organizations were used. Search terms included sports drinks, energy drinks, children, and adolescents. The recent Institute of Medicine report on school health[3] and position statements on this subject from the American Dietetic Association and American College of Sports Medicine[2] were reviewed for this report. Comments were solicited from committees, sections, and councils of the American Academy of Pediatrics; 7 entities responded. For recommendations for which high levels of evidence are absent, the expert opinions and suggestions of the CON, the COSMF, and other groups/authorities consulted were taken into consideration in development of this clinical report.

DEFINITION AND CATEGORIZATION OF SPORTS DRINKS VERSUS ENERGY DRINKS

Sports drinks are beverages that may contain carbohydrates, minerals, electrolytes, and flavoring and are intended to replenish water and electrolytes lost through sweating during exercise. In contrast, the term "energy drink" refers to a very different type of beverage. Today's energy drinks also contain substances that act as nonnutritive stimulants, such as caffeine, guarana, taurine, ginseng, L-carnitine, creatine, and/or glucuronolactone, with purported ergogenic or performance-enhancing effects. Tables 1 and 2 list some popular commercially available sports drinks and energy drinks and their respective contents.

COMPONENTS OF SPORTS AND ENERGY DRINKS AND THEIR INDICATIONS

Water

Water is an essential part of the daily diet. Adequate hydration is necessary for maintaining normal cardiovascular, thermoregulatory, and many other physiologic functions during exercise and routine daily activity. In children, maturation and body size are the primary determinants of the necessary daily water intake. The quantity of water needed to maintain a euvolemic state is influenced by a number of fac-

TABLE 1 Contents of a Sampling of Sports Drinks per Serving (240 mL [8 oz])

Product	Manufacturer	Calories	Carbohydrate, g	Sodium, mg	Potassium, mg	Vitamins	Other
All Sport Body Quencher	All Sport, Inc	60	16	55	60	C	—
All Sport Naturally Zero	All Sport, Inc	0	0	55	60	B_3, B_5, B_6, B_{12}	—
Gatorade	PepsiCo Inc	50	14	110	30	—	—
Gatorade Propel	PepsiCo Inc	10	3	35	—	B_3, B_5, B_6, B_{12}, C, E	—
Gatorade Endurance	PepsiCo Inc	50	14	200	90	—	Calcium, magnesium
Gatorade G2	PepsiCo Inc	20	5	110	30	—	—
Powerade Zero	Coca-Cola Company	0	0	100	25	B_3, B_6, B_{12}	—
Powerade	Coca- Cola Company	78	19	54	—	—	Iron
Powerade Ion4	Coca-Cola Company	50	14	100	25	B_3, B_6, B_{12}	—
Accelerade	Pacific Health Laboratories, Inc	80	15	120	15	E	Calcium, protein

Selection of the specific sports drinks listed was based on the most commonly available products at the time this report was under development.

TABLE 2. Contents of a Sampling of Energy Drinks per Serving (240 mL [8 oz])

Product	Manufacturer	Calories	Carbohydrate, g	Sodium, mg	Potassium, mg	Caffeine, mg	Calcium, mg	Vitamins	Taurine, mg	Guarana, mg	Other
Java Monster	Hansen Natural Corporation	100	17	340	240	*	180	A, B_3, B_5, B_6, B_{12}, C, D	1000	*	Inositol, ginseng, L-carnitine, glucuronolactone, phosphorus
Java Monster Lo-Ball	Hansen Natural Corporation	50	6	230	60	*	90	B_3, B_5, B_6, B_{12}, C, D	—	—	Inositol, ginseng, L-carnitine, glucuronolactone, phosphorus
Monster Energy	Hansen Natural Corporation	100	27	180	—	*	—	B_3, B_5, B_6, B_{12}, C	1000	*	Inositol, L-carnitine, ginseng, glucuronolactone
Monster Low Carb	Hansen Natural Corporation	10	3	180	—	*	—	B_3, B_5, B_6, B_{12}	1000	*	Inositol, L-carnitine, ginseng, glucuronolactone
Red Bull	Red Bull GmbH	106	27	193	—	77	—	B_3, B_5, B_6, B_{12}	*	—	Inositol, glucuronolactone
Red Bull Sugar Free	Red Bull GmbH	9 6	3	193	—	77	—	B_3, B_5, B_6, B_{12}	*	—	Inositol, glucuronolactone
Power Trip Original Blue	Power Trip Beverages, Inc	100	26	190	—	105	—	B_3, B_5, B_6, B_{12}, C	1000	23	Inositol, glucuronolactone
Power Trip "O"	Power Trip Beverages, Inc	5	0	190	—	105	—	B_3, B_5, B_6, B_{12}, C	1000	23	Inositol, glucuronolactone
Power Trip the Extreme	Power Trip Beverages, Inc	110	30	130	—	110	—	B_3, B_5, B_6, B_{10}, C	1300	30	Inositol, glucuronolactone
Rockstar Original	Rockstar, Inc	140	31	40	—	80	—	B_3, B_5, B_6, B_{12}	1000	25	Ginseng, inositol, ginkgo, L-carnitine
Rockstar Sugar Free	Rockstar, Inc	10	0	125	—	80	—	B_3, B_5, B_6, B_{12}	1000	25	Ginseng, inositol, ginkgo, L-carnitine
Full Throttle	Coca-Cola Company	110	28	85	—	*	—	B_3, B_5, B_6, B_{12}	—	—	—

Selection of the specific energy drinks listed was based on the most commonly available products at the time this report was under development.
* The amount was not specified on the nutritional content label.

tors such as diet, medications, illnesses, and chronic health conditions. With exercise, daily water needs can increase quickly and dramatically on the basis of environmental conditions (eg, heat, humidity, sun exposure), exercise time and intensity, heat-acclimatization state, and individual sweat rates. Therefore, a deliberate increase in water intake is frequently required during exercise to avoid significant dehydration and related health consequences such as heat illness.[5]

Dehydration is caused by a mismatch between body water loss (through sweating, respiration, urine production, and fecal loss), and water intake. Significant dehydration can be associated with premature fatigue, impaired sports performance, cognitive changes, possible electrolyte abnormalities (sodium deficit), and increased risk of heat illness.[6,7] Effective management of hydration, which optimizes performance and minimizes risk of heat illness in the setting of prolonged vigorous sports participation, is complex and beyond the scope of this report. Children and adolescents should be taught to drink water routinely as an initial beverage of choice as long as daily dietary caloric and other nutrient (eg, calcium, vitamins) needs are being met. Water is also generally the appropriate first choice for hydration before, during, and after most exercise regimens. Children should have free access to water, particularly during school hours.[1,2]

Carbohydrates

Carbohydrates are the most important source of energy for an active child or adolescent. However, daily carbohydrate intake must be balanced with adequate intake of protein, fat, and other nutrients. In general, there is little need for carbohydrate-containing beverages other than the recommended daily intake of fruit juice and low-fat

milk. However, for youth who exercise with prolonged vigorous intensity, blood glucose becomes an increasingly important energy source as muscle glycogen stores decrease and the use of circulating (blood) carbohydrates rises, which results in a need to supply an ongoing carbohydrate energy substrate to avert fatigue and maintain performance. The use of a carbohydrate-containing beverage by a child or adolescent in this situation is the most appropriate use of a commercial sports drink. The carbohydrate content of sports and energy drinks varies widely. Sports drinks contain 2 to 19 g of carbohydrates (glucose and fructose forms) per serving (240 mL [8 oz]), and the carbohydrate content of energy drinks ranges from 0 to 67 g per serving. The caloric content of sports drinks is 10 to 70 calories per serving, and the caloric content of energy drinks ranges from 10 to 270 calories per serving (Tables 1 and 2). Excessive intake of carbohydrate-containing beverages beyond what is needed to replenish the body during or after prolonged vigorous exercise is unnecessary and should be discouraged.[8] Sports and energy drinks are not indicated for use during meals or snacks as a replacement for low-fat milk or water. Excessive caloric intake can result from routine dietary intake of carbohydrate-containing beverages such as sports drinks, energy drinks, or soft drinks. This excessive caloric intake can substantially increase the risk for overweight and obesity in children and adolescents and should be avoided.[1,2]

Caffeine and Other Stimulants

Many children and adolescents perceive the need to increase or boost energy levels. The body's need for energy in the form of carbohydrate and other dietary fuel sources is best provided through balanced nutrition. Energy drinks often provide carbohydrate, but the primary source of energy in these drinks is caffeine—one of the most popular stimulants taken today. It is unfortunate that many young people knowingly ingest large amounts of caffeine in a variety of forms despite the fact that regular intake has many noted negative health effects.

Caffeine has been shown to enhance physical performance in adults by increasing aerobic endurance and strength, improving reaction time, and delaying fatigue.[9–11] However, these effects are extremely variable, dose dependent, and, most importantly, have not been studied in children and adolescents. Ergogenic effects have been reported with doses of 3 to 6 mg/kg. Some athletes who desire to achieve performance enhancement may voluntarily reach daily caffeine intakes of up to 13 mg/kg of body weight.

Caffeine is absorbed by all body tissues. It is structurally similar to adenosine and, thus, can bind in its place to cell membrane receptors, which results in a subsequent block of adenosine's actions. The effects of caffeine on various organ systems include increases in heart rate, blood pressure, speech rate, motor activity, attentiveness, gastric secretion, diuresis, and temperature. Sleep disturbances or improved moods are considered variable and individualized effects.[12–17] Caffeine can increase anxiety in those with anxiety disorders,[17] and it is known also to play a role in triggering arrhythmias.[18]

There is heightened awareness of the risks of caffeine use, abuse, and even toxicity in children and adolescents.[19,20] In 2005, the American Association of Poison Control Centers reported more than 4600 calls received for questions regarding caffeine. Of these calls, 2600 involved patients younger than 19 years, and 2345 patients required treatment, although the number of pediatric patients who required treatment was not defined.[21,22] Energy drinks contain large and varied amounts of caffeine, often much more per serving than cola. Parents and children should be cautioned about the difficulties in being aware of how much caffeine is ingested depending on the product and the serving size, as differentiated from the product size. The actual caffeine content for many energy drinks is not easily identified on product packaging or via the Internet. The total amount of caffeine contained in some cans or bottles of energy drinks can exceed 500 mg (equivalent to 14 cans of common caffeinated soft drinks) and is clearly high enough to result in caffeine toxicity.[23] A lethal dose of caffeine is considered to be 200 to 400 mg/kg.[24]

Additional concerns regarding the use of caffeine in children include its effects on the developing neurologic and cardiovascular systems[14] and the risk of physical dependence and addiction. Because of the potentially harmful adverse effects and developmental effects of caffeine, dietary intake should be discouraged for all children.[14,20] Avoidance of caffeine in young people poses a great societal challenge because of the widespread availability of caffeine-containing substances and a lack of awareness of potential risks. The primary dietary source of caffeine for children is soft drinks, which contain approximately 24 mg per serving (240 mL [8 oz]).[25] Ellison et al[26] reported that children 6 to 10 years old ingested caffeine on an average of 8 of 10 days. Other authors have reported variable caffeine intakes of up to 16 mg/day by 7- to 8-year-olds, 24 mg/day by 9- to 10-year-olds, and 37.4 mg/day by 5- to 18-year-olds.[27] Symptoms of caffeine withdrawal include headache, fatigue, decreased alertness, drowsiness, difficulty concentrating, decreased desire to socialize, flulike symptoms, irritability, depressed

mood, muscle pain or stiffness, and nausea or vomiting.[28]

Guarana

Guarana is a plant extract that contains caffeine.[29] It is marketed to increase energy, enhance physical performance, and promote weight loss. One gram of guarana is equal to approximately 40 mg of caffeine.[30] Thus, the presence of guarana in an energy drink is a cause for concern, because it increases the total caffeine level in the beverage.[31]

Electrolytes

Electrolytes (primarily sodium and potassium) are often found in sports and energy drinks (Tables 1 and 2). Sodium content varies from approximately 25 to 200 mg, and potassium content generally ranges from 30 to 90 mg per serving (240 mL [8 oz]). For most children and adolescents, daily electrolyte requirements are met sufficiently by a healthy balanced diet; therefore, sports drinks offer little to no advantage over plain water.[32] During or after participation in short training or competition sessions, athletes generally do not need supplemental electrolyte replacement. However, caution should be taken with athletes who are inappropriately restricting their dietary sodium or who drink excessive amounts of water, because they may be more susceptible to serious electrolyte abnormalities. Electrolyte-replacement requirements in the setting of prolonged vigorous exercise or in excessively hot or humid conditions vary widely because of large variations in sweat rates. Severe electrolyte abnormalities that occur in each of these settings are serious and potentially life-threatening situations and are discussed in detail elsewhere.[5,32]

Amino Acids/Protein

Specific amino acids are added to some sports and energy drinks (Table 2). Protein has been shown to enhance muscle recovery when ingested promptly after exercise; accordingly, a small subset of sports drinks that contain protein or amino acids are often marketed as "muscle-recovery drinks." The ingestion of protein (the major source of amino acids) should occur throughout the day as part of a normal diet to allow the body free access to necessary amino acids. Most children and adolescents who eat a well-balanced diet easily get their recommended daily allowance of protein (1.2–2.0 g of protein per kg), even those who are engaged in regular sports activities.[33] If a food source of protein is unavailable, an amino acid–containing sports drink can be used immediately after prolonged vigorous exercise for muscle recovery. Low-fat milk is a good option for use as a postexercise protein-recovery drink. The optimal ratio of carbohydrate/protein intake is likely individual and is affected by personal tolerance, dietary practices, metabolism, and exercise type and duration.

Additional, heavily marketed effects of specific amino acids in sports and energy drinks have not been supported by appropriate clinical trials. Enhanced immune function (glutamine), vasodilatation (arginine), enhanced lipolysis (L-carnitine, which is not technically an amino acid), and caffeine-potentiating effects (taurine) are among the most commonly described.[34–36] Taurine does have an inotropic effect on cardiac muscle similar to that of caffeine.[24] Like caffeine, taurine has physiologic effects on the intracellular calcium concentration in smooth muscles that may cause coronary vasospasm.[37] In general, the use of amino acids in energy drinks in place of traditional dietary sources is not supported by the scientific literature and, therefore, is discouraged for children and adolescents. Use of stimulant-containing energy drinks with or without amino acid supplementation is always discouraged.

Vitamins and Minerals

Many sports and energy drinks contain several B vitamins, vitamin C, calcium, and magnesium. There is no advantage to consuming these vitamins and minerals in drinks, because they can be easily obtained from a well-balanced diet. For further details, see the *Pediatric Nutrition Handbook*.[1]

HARMFUL DENTAL EFFECTS OF SPORTS AND ENERGY DRINKS

Dental Erosion

Dental erosions from sports and energy drinks are of concern in children and adolescents. Bartlett et al[38] found enamel erosion in 57% of 11- to 14-year-olds in a cluster sample of adolescents. Most sports and energy drinks have a pH in the acidic range (pH 3–4). A pH this low is associated with enamel demineralization.[39] Citric acid is frequently included in sports and energy drinks and has been found to be highly erosive, because its demineralizing effect on the enamel continues even after the pH has been neutralized.[40]

Extent of Use and Misuse

Sports and energy drink consumption by children and adolescents is widespread and continues to grow. O'Dea[41] studied 78 adolescents and found that 56.4% used sports drinks and 42.3% consumed energy drinks during the 2 weeks before the survey. Adolescents consumed these products for various reasons including good taste, quenched thirst, and extra energy needed to improve sports performance. Most notably, the adolescents did not differentiate between sports and energy drinks and cited the same benefits for both beverages. None of the adolescents surveyed mentioned potential problems referable to the

consumption of these beverages, and they did not distinguish use on the basis of the degree of athletic participation.[41]

Physically active children and adolescents and their parents are often unaware of the additional nutrient and fluid needs relative to exercise. Sports drinks have an important, specific role in the diet of young athletes who are engaged in prolonged vigorous sports activity—primarily to rehydrate and replenish carbohydrate, electrolytes, and water lost during exercise.[2] However, confusion about energy by young people can lead to unintentional ingestion of energy drinks when their goal is simply to rehydrate and replenish carbohydrate, electrolytes, and water with sports drinks. Using energy drinks instead of sports drinks for rehydration can result in ingestion of potentially large amounts of caffeine or other stimulant substances and the adverse effects previously described. Of additional concern is the intentional use of energy drinks by adolescents who desire stimulant effects to combat fatigue and increase energy during sports and school activities. Advertisements that target young people are contributing to the confusion rather than effectively distinguishing between sports and energy drinks. Furthermore, marketing fails to identify appropriate sources and amounts of energy substrate that should be consumed by children and adolescents.[42]

ASSESSMENT OF USE/MISUSE IN THE OFFICE

As part of each yearly checkup, it is important for pediatric health care providers to review a patient's nutritional status (food and fluid intake) and quantify physical activity. Routine questions that specifically address the use of sports and energy drinks are recommended. Parents may be unaware of their use, or they may, in fact, promote their use, which opens the door to provide education about these drinks for both patients and their parents. Frequent consumption of energy drinks may identify students at risk of substance use and/or other health-compromising behavior.[43] Education on proper dietary and sleep habits may help combat fatigue in adolescents and may decrease the common "stimulant-seeking behaviors."

Stimulant toxicity should be reported to local poison control centers. The ability to use tracking methods for sources of stimulant substances, such as energy drinks, will improve our understanding of dietary habits and facilitate the development of appropriate public health measures to prevent misuse and abuse.[19]

Given the current epidemic of childhood overweight and obesity, we recommend the elimination of calorie-containing beverages from a well-balanced diet, with the exception of low-fat or fat-free milk, because it contains calcium and vitamin D, which are particularly important for young people.

SPORTS AND ENERGY DRINKS ARE NOT INDICATED AS NORMAL FLUID CONSUMPTION IN SCHOOLS

Sales of sports and energy drinks in schools are increasing. Having agreed voluntarily to phase out full-calorie sodas from schools by the 2009–2010 school year, beverage manufacturers are heavily promoting sports drinks as a healthier alternative. In 2006, sports drinks were the third-fastest growing beverage category in the United States, after energy drinks and bottled water, according to the trade journal *Beverage Digest*.[44] The trade group representing beverage manufacturers reported that sports drinks increased their market share in schools from 14.6% in 2004 to 20% in the 2006–2007 school year. During the same period, the market share for full-calorie sodas decreased from 39.9% to 29.8%.[44]

A few school districts have already fought policy battles over sports drinks, and Connecticut became the first, and so far only, state to have passed legislation barring sports drinks and enhanced waters in schools.[45] Bills have been introduced in the US Congress to set new nutritional standards for the foods and drinks that schools sell to students outside cafeterias.[45]

In April 2007, the Institute of Medicine published a report titled *Nutrition Standards for Foods in Schools*,[5] in which it recommended a healthier eating environment for children and adolescents in this country. Relevant to sports and energy drinks, its recommendations for schools included:

- limit sugars in food and drink;
- have water available at no cost;
- restrict carbonated, fortified, or flavored waters;
- restrict sports drinks to use by athletes only during prolonged, vigorous sports activities;
- prohibit energy drink use, even for athletes; and
- prohibit the sale of caffeinated products in school.

CLINICAL IMPLICATIONS: GUIDANCE FOR THE PEDIATRICIAN

Regarding consumption of sports and energy drinks by children and adolescents, the pediatrician is encouraged to:

- Improve the education of children and adolescents and their parents in the area of sports and energy drinks. This education must highlight the difference between sports drinks and energy drinks and their associated potential health risks.

- Understand that energy drinks pose potential health risks primarily because of stimulant content; therefore, they are not appropriate for children and adolescents and should never be consumed.
- Counsel that routine ingestion of carbohydrate-containing sports drinks by children and adolescents should be avoided or restricted. Intake can lead to excessive caloric consumption and an increased risk of overweight and obesity as well as dental erosion.
- Educate patients and families that sports drinks have a specific limited function for child and adolescent athletes. These drinks should be ingested when there is a need for more rapid replenishment of carbohydrates and/or electrolytes in combination with water during periods of prolonged, vigorous sports participation or other intense physical activity.
- Promote water, not sports or energy drinks, as the principal source of hydration for children and adolescents.

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Clinical Report—Sports Drinks and Energy Drinks for Children and Adolescents: Are They Appropriate?

COMMITTEE ON NUTRITION AND THE COUNCIL ON SPORTS MEDICINE AND FITNESS

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Senator BLUMENTHAL. Thank you, Dr. Schneider.
Dr. Harris?

STATEMENT OF JENNIFER L. HARRIS, PH.D., MBA, SENIOR RESEARCH SCIENTIST, DIRECTOR OF MARKETING INITIATIVES, RUDD CENTER FOR FOOD POLICY & OBESITY, YALE UNIVERSITY

Dr. HARRIS. Thank you, Senator Blumenthal, Chairman Rockefeller, and members of the Committee, for inviting me to participate in this important hearing on energy drinks and youth.

My name is Dr. Jennifer Harris, and I am Senior Research Scientist and Director of Marketing Initiatives at the Rudd Center for Food Policy and Obesity at Yale University. I have been studying food marketing to children and teens for the past 10 years, and I also have an MBA and 20 years of experience as a marketing executive and consultant.

Today, I will describe how energy drink companies reach and target teens, why beverage industry marketing guidelines do not address public health concerns, and how companies could protect minors from the harm caused by their products. I would also like to refer you to my extensive written testimony.

In 2010, we began to study youth-targeted marketing of soda, fruit drinks, and other sugary drinks. But what we learned about energy drinks stunned us. Energy drink brands, such as 5-Hour Energy shots and Red Bull, spend more on advertising than any other category of sugary drinks except soda, and their TV ads often appear on teen-targeted networks, like MTV and Adult Swim.

In fact, teens see more energy drink ads than adults do on TV. All brands are active in social media that teens share virally with their friends, including Facebook, Twitter, and YouTube. Red Bull and Monster Energy are the number 5 and the number 12 most popular brands on Facebook.

Energy drink brands often promote teen athletes and musicians and sponsor local events, where they provide free samples, including to minors. And most energy drinks are sold in convenience stores, where special displays encourage impulse purchases, and minors can easily buy them without parents' consent.

We recently updated our marketing analysis and found that these practices continue unabated and have become worse. New products are being advertised. Several brands doubled their advertising spending in 2 years, and social media fans increased by 2 to 10 times.

And this marketing is very effective. While sales of most other beverage categories have declined, energy drink sales increased by 19 percent in 2012, reaching $8 billion. You have heard that pediatricians are concerned, and so are parents. Three quarters of parents agree that energy drinks should not be marketed or sold to teens under 18.

The American Beverage Association and energy drink manufacturers have responded to these concerns. Today, you will probably hear from members of the panel that caffeine is safe for all ages and that manufacturers comply with ABA guidelines for responsible labeling and marketing of energy drinks.

But many energy drink manufacturers do not belong to the ABA, and not all members comply with these guidelines. Further, the FDA has not determined that the concentration of caffeine and the other stimulants in most energy drinks and shots are safe for the food supply.

You will probably also hear that these companies do not market their products to children. But the only marketing the ABA guidelines specifically prohibit is advertising on children's television programs like Nickelodeon and marketing in elementary schools. The policy does not address advertising to children 12 years and older or most common types of energy drink marketing, including social media and sponsorships.

The ABA also suggests that energy drinks not be marketed as sports drinks. But companies continue to sponsor sporting events and high school athletics, hire athletes as brand Ambassadors, and explicitly encourage use during physical activity.

Clearly, more needs to be done to protect teens. At a minimum, energy drink manufacturers should not advertise in media that are more likely to be seen by teens than by adults, and they should establish age requirements to access digital content whenever possible. They should not engage in marketing, including YouTube videos and smartphone apps, which disproportionately appeal to teens. They should not distribute free samples to minors, and they should comply with their own guidelines to not market energy drinks as sports drinks.

But teens represent a significant growth opportunity for energy drink companies. Teens are highly vulnerable to marketing influence, especially when it exploits their peer relationships and their desire to appear cool, daring, and grown-up, making them an easy target.

If energy drink manufacturers continue to evade the issue of marketing to teens, the FDA, the FTC, policymakers, and attorneys general have the authority to establish and enforce restrictions on energy drink ingredients, labeling, retail placement, and sales to minors. Such regulations would be widely supported by parents, the medical community, and others who advocate for children's health.

Thank you, and I look forward to answering your questions.

[The prepared statement of Dr. Harris follows:]

PREPARED STATEMENT OF JENNIFER L. HARRIS, PH.D., MBA, SENIOR RESEARCH SCIENTIST, DIRECTOR OF MARKETING INITIATIVES, RUDD CENTER FOR FOOD POLICY & OBESITY, YALE UNIVERSITY

Thank you for the opportunity to address this committee. I am Jennifer Harris, Director of Marketing Initiatives and Senior Research Scientist at the Rudd Center for Food Policy and Obesity at Yale University. I also have twenty years experience as a marketing executive and consultant. The Rudd Center seeks to improve the world's diet, prevent obesity, and reduce weight stigma by establishing creative connections between science and public policy, carrying out research that addresses key questions in nutrition policy, and serving as an information resource to leaders around the world on matters of food and nutrition. For the past five years, I have been conducting research to document the amount and impact of food marketing to children and teens and identify opportunities to reduce its harmful effects on children's diets and health.

In 2011, I led a team of researchers at the Rudd Center to evaluate the nutritional quality and marketing of sugary drinks, including energy drinks, to children and teens. Soda and fruit drinks were our primary concern when we started. Nu-

merous research studies have shown that young people consume these products in large quantities, contributing to obesity and other diet-related diseases, such as type 2 diabetes and cardiovascular disease. However, as we gathered our data, we soon became alarmed by what we were learning about energy drink products—including energy drinks such as Red Bull and Monster Energy, and energy shots such as 5-Hour Energy—and how they are marketed. Key findings include:

- *Most energy drinks contain unhealthy levels of sugar, sodium, and caffeine for young people.*[1] Sugar and calories in energy drinks are comparable to sugar-sweetened sodas, but sodium levels are three times as high. The median amount of caffeine in energy drinks is 80 mg per 8 ounces—comparable to one cup of coffee. However, energy drinks often come in large, non-resealable cans (that must be consumed at one time), which contain up to 325 mg of caffeine,[2] while energy shots contain as much as 280 mg of caffeine per 2.5-ounce bottle.[3] These amounts are six to seven times the caffeine in a can of cola.
- *Information about caffeine content and other ingredients in energy drinks can be difficult to find.*[4] Just over half of products fully disclosed caffeine and other ingredients on the labels. Even after repeated calls to company customer helplines, researchers were unable to obtain caffeine content for 46 percent of energy drinks, including 5-Hour Energy and Monster products.
- *Energy drink brands spent more on media advertising in 2010 than all other sugary drink brands except soda.*[5] Spending on media advertising for energy drinks and shots, including 5-Hour Energy, Red Bull, and Amp, totaled $165 million, an increase of 36 percent from 2008 and comparable to the $189 million spent on fruit juices.
- *Both children and teens often are often exposed to energy drink advertising on TV.* In 2010, all children (ages 6–11) in the United States viewed on average more than one energy drink advertisement per week.[6] They saw more ads for 5-Hour Energy than for any brand of sugary drink, except Capri Sun children's fruit drink. And teens (defined by advertisers as 12- to 17-year-olds) see even more. They viewed 124 energy drink ads on average in 2010—more ads than any other drink category including soda, fruit drinks, and sports drinks.
- *While sales of most other categories of sugary drinks are decreasing, sales of energy drinks continue to grow.* From 2007 to 2012, gallon sales of energy drinks increased by 53 percent, compared with a decline of 9 percent for carbonated soft drinks.[7] In 2010, U.S. energy drink sales equaled approximately $20 per capita, surpassing sales of both sports and fruit drinks and approximately half of sugar-sweetened soda sales.[8] Total sales of energy drinks reached $6.9 billion in 2012, an increase of 19 percent over the previous year, and sales of energy shots increased by 9 percent to reach $1.1 billion.[9]
- *Despite risks and concerns about energy drink consumption by youth under age 18, teens appear to be an important target market for many energy drink brands.* Our research shows that many energy drink brands reach teens through targeted media and marketing messages that disproportionately appeal to this age group.[10]

Targeted marketing of energy drinks to teens

Our research utilizes syndicated market research data (including Nielsen and comScore) and other publicly available information to measure where companies place their advertising, as well as age and other demographic information about individuals who see or hear this advertising. Advertisers use these same data to measure the effectiveness of their own campaigns and monitor those of their competitors. While our analysis did not include proprietary industry documents detailing companies' marketing strategies, our findings are comparable to results of a recent Con-

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[1] Harris JL, Schwartz MB, Brownell KD, *et al.,* (2011). Sugary Drink FACTS: Evaluating fast food nutrition and marketing to youth. Retrieved from *http://www.sugarydrinkfacts.org/resources/SugaryDrinkFACTS_Report.pdf.*
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[3] *SKEnergyShots.com*
[4] Harris *et al.,* (2011).
[5] *Ibid.*
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[10] Harris *et al.,* (2011).

gressional investigation.[11] Responses by fourteen energy drink companies confirmed that adolescents are frequent targets of their marketing efforts.

The following summarizes our findings on teen-targeted marketing by energy drink brands in 2010,[12] and Exhibit 1 provides examples of their marketing communications.

- *Energy drink ads frequently appeared on cable networks with more teen viewers than adults,* including Adult Swim (80–90 percent more teen viewers), MTV and MTV2 (88–199 percent more teen viewers), and Comedy Central (20–30 percent more teen viewers).[13] Overall, teens viewed 18 percent more TV ads for energy drinks than adults viewed, even though they spend 25 percent less time watching TV.[14]
- *Energy drink brands have been early adopters of social media marketing,* with a strong presence on Facebook, Twitter, and YouTube.[15] Red Bull had more than 20 million Facebook fans in 2011 and Monster had 11 million; Coca-Cola was the only sugary-drink brand with a larger fan base (31 million). Teens comprised 38 percent of unique visitors to Monster's Facebook page and 11 percent of Red Bull's visitors.[16] 5-Hour Energy and Red Bull tweeted more frequently than any other sugary drink brand: 42.1 and 32.5 times per week, respectively. Red Bull posted an astounding 447 videos to its YouTube channel in 2010 and received 158 million views by June 2011. Monster Energy's YouTube channel was also popular with 121 videos uploaded and almost 11 million views. Teens and even children under age 12 are frequent users of these social media.[17]
- *Energy drink brands offered popular smartphone applications and advertised on mobile websites.*[18] Red Bull offered 18 different smartphone apps, primarily games and music, and teens under 18 represented 25 percent to 41 percent of individuals who downloaded three of these apps. Amp was a frequent advertiser on mobile websites, including VH1 Mobile and MTV Mobile.
- *Energy drink brands were active sponsors of local events,* primarily music concerts and extreme sports, such as Monster Energy AMA Supercross, AMP World Extreme Cagefighting, and Red Bull rallycar jumping.[19] Monster Energy, Rockstar, Red Bull and Amp all aired advertising on local television to support their sponsorships, and sponsorships were featured prominently on company websites and YouTube videos. Of note, there are typically no age restrictions on who may attend these events and energy drink sponsors often provide free samples to spectators.
- *Messages on energy drink websites frequently targeted young males and often contained highly questionable messages.*[20] For example, MonsterEnergy.com included references to extreme sports, alcohol and drug use, and sexual objectification of women, and Rockstar69.com featured scantily clad women in sexually suggestive poses. RedBull.com focused on extreme sports and youth culture. MonsterEnergy.com had the most teen visitors (averaging 23,300 per month), followed by 5HourEnergy.com (13,200) and RedBull.com (11,800). Teens were 2.5 times more likely to visit MonsterEnergy.com than adults and 1.7 times more likely to visit *Rockstar69.com.*
- *Retail practices encourage impulse purchases and provide easy access for minors.* The majority of energy drinks (79 percent) are sold in convenience stores.[21] They typically are stocked in coolers together with sugary drinks or alcoholic beverages. This placement implies that these products are similar to sodas and

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[11] Markey EJ, Durbin RJ, Blumenthal R. (2013). What's all the buzz about? A survey of popular energy drinks finds inconsistent labeling, questionable ingredients and targeted marketing to adolescents. Retrieved from *clerk.house.gov/member__info/vacancies__pr.aspx?pr=house&vid=83*

[12] Harris *et al.,* (2011).

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[14] Harris *et al.,* (2011).

[15] *Ibid.*

[16] Pomeranz, JL, Munsell CR, and Harris JL (2013).Energy drinks: an emerging public health hazard for youth. *J. PublicHealthPolicy, 34,* 254–271.

[17] Harris *et al.,* (2011); Harris JL (2013). The new hidden persuaders: The digital world of food marketing to children and teens. In A Place at the Table, 106–P Pringle (Ed), 106–122, Public Affairs: NY.

[18] Harris *et al.,* (2011).

[19] Harris *et al.,* (2011).

[20] *Ibid.*

[21] *Ibid.*

other non-alcoholic beverages and may encourage their consumption with alcohol. Energy shots often are featured in free-standing displays near the checkout counter, and 79 percent of sales occurred in stores with special displays of these products.

Why energy drinks should not be marketed to teens

Increasing consumption of high-sugar energy drinks and potential effects on obesity and other diet-related diseases in young people is an obvious concern. However, concerns extend far beyond excess sugar consumption, as evidence of severe immediate adverse effects of energy drink consumption by minors grows. Emergency room visits involving energy drinks increased tenfold from 2005 to 2009, and 11 percent of ER visits related to energy drink consumption involved 12-to 17-year-olds, mostly due to energy drink intake alone.[22] The U.S. Food and Drug Administration (FDA) is investigating adverse effects related to the intake of energy drinks and shots, including deaths.[23]

The medical community and parents do not believe that children under 18 should consume these products.

- In 2008, 100 scientists and physicians wrote a letter to the FDA requesting increased regulation of energy drinks due to the risk of caffeine intoxication and alcohol-related injuries when consumed by youth.[24]
- The American Academy of Pediatrics (AAP) concluded in 2011 that "energy drinks have no place in the diet of children and adolescents" due to their "stimulant content."[25] An article in *Pediatrics in Review* counsels pediatricians to screen teenagers for energy drink use and provide appropriate counseling due to heavy energy drink consumption among some patients that can cause significant morbidity.[26]
- The American Medical Association (AMA) adopted a policy to support a ban on the marketing of energy drinks and shots to adolescents under age 18. According to an AMA board member, "Energy drinks contain massive and excessive amounts of caffeine that may lead to a host of health problems in young people, including heart problems, and banning companies from marketing these products to adolescents is a common sense action that we can take to protect the health of American kids."[27]
- The Institute of Medicine (IOM) will hold a two-day workshop next month to "examine cardiovascular and central nervous system (CNS) effects and other important health hazards of caffeine that may arise in at-risk populations consuming varied amounts of caffeine" including in dietary supplements or conventional foods, "alone or in combination with other substances in products commonly referred to as 'energy products.'"[28]
- The Rudd Center conducted a survey of 985 parents of children under age 18 in 2011.[29] The majority of parents agreed that energy drinks should not be marketed or sold to children and adolescents (78 percent and 74 percent, respectively). In addition, 86 percent supported caffeine disclosures and 85 percent supported warnings on labels about potential adverse effects. Almost half of

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[22] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality (2011, November 22). The DAWN Report: Emergency Department Visits Involving Energy Drinks. Rockville, MD.

[23] Food and Drug Administration [FDA] (2012, November 16). Energy "drinks" and supplements: Investigations of adverse event reports. Retrieved from *www.fda.gov/Food/NewsEvents/ucm328536.htm.*

[24] Weise E (2008, October 22). Petition calls for FDA to regulate energy drinks. *USA Today.* Retrieved from *Usatoday30.usatoday.com/news/health/2008-10-21-energy-drinks__N.htm.*

[25] American Academy of Pediatrics [AAP]. (2011). Sports drinks and energy drinks for children and adolescents: Are they appropriate? *Pediatrics, 127*(6), 1182–1189.

[26] Blankson KL, Thompson AM, Ahrendt DM, Patrick V (2013). Energy drinks: What teenagers (and their doctors) should know. *Pediatrics in Review, 34*(2),55–62.

[27] American Medical Association [AMA]. (2013, June 18). AMA adopts new policies on second day of voting at annual meeting. Press release. Retrieved from *www.ama-assn.org/ama/pub/news/news/2013/2013-06-18-new-ama-policies-annual-meeting.page*

[28] Institite of Medicine, National Academies of Sciences (2013). Planning committee for a workshop on potential health hazards associated with consumption of caffeine in food and dietary supplements. *www.iom.edu/Activities/Nutrition/PotentialHazardsCaffeineSupplements.aspx.*

[29] Yale Rudd Center for Food Policy & Obesity. (2012) Parents' attitudes about energy drinks. Retrieved from *www.yaleruddcenter.org/resources/upload/docs/what/policy/SSBtaxes/SSB__Parent__Attitudes__Energy__Drinks.pdf*

parents (48 percent) agreed that youth under 18 should not be allowed to consume energy drinks.

How energy drink companies have responded

Energy drink manufacturers and the American Beverage Association (ABA) have responded to the AAP, the Rudd Center, and others who have raised concerns about their products with statements such as "We do not market our products to children and other caffeine sensitive people" (Red Bull, June 2011)[30] or "Caffeine is safe for all ages and is among the most studied ingredients in the food supply today" (ABA, October 2011).[31] The ABA has produced guidelines for its members on the responsible labeling and marketing of energy drinks.[32] In its guidance document, the ABA encourages its members who produce and market energy drinks to disclose caffeine content and include a warning, "Not (intended/recommended) for children, pregnant or nursing women (and/or persons/those) sensitive to caffeine" on product labels. It also encourages members to not market energy drinks as sports drinks and not market them to children "as set forth in ABA's commitment to the Global Policy on Marketing to Children."

However, these statements fail to address most concerns about energy drink products and their marketing practices.

- *Not all energy drink companies belong to the ABA, and all products on the market do not abide by their guidelines.* Labeling across energy drinks is inconsistent,[33] and products labeled as supplements (including energy shots) are not subject to these requirements.[34] In Presently, Coca-Cola, PepsiCo, Dr Pepper Snapple Group, Red Bull, Monster, and Rockstar are ABA members.[35]
- *Most energy drinks contain caffeine in higher concentrations than has been determined to be safe.* In 1977, the FDA determined that caffeine is Generally Recognized as Safe (GRAS) for "cola-type beverages" in quantities up to .02 percent (71 mg per 12 ounces),[36] significantly less caffeine than contained in most energy drinks.[37] Caffeine's GRAS status was granted 40 years ago at a time when the food supply was very different, and energy drinks did not exist in the marketplace.
- *Energy drinks often contain ingredients, such as guarana and taurine, which energy drink companies have self-determined to be safe.* [38] If an ingredient added to beverages has not been designated as GRAS by the FDAs, companies may self-determine its GRAS status, as long as the FDA is notified.[39] Further, beverages are not required to disclose the amount of these ingredients on product packages.
- *The ABA's policy on marketing to children does not address marketing to children 12 years and older.* The International Food & Beverage Alliance (IFBA) Global Policy on Marketing and Advertising to Children, to which the ABA guidance document refers, only limits advertising to children under 12 years old and commercial communication to students in primary schools.[40] IFBA defines advertising to children as "advertising to media audiences with a majority of children under 12 years." In effect, the only marketing guidance the ABA has

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[30] BeverageDaily.com (2011, June). Red Bull denies child marketing claims in new study. Retrieved from *http://www.beveragedaily.com/Regulation-Safety/Red-Bull-denies-child-marketing-claims-in-new-study.*

[31] American Beverage Association. (2011, October 31). Beverage Industry Responds to Latest Rudd Report. Press release. Retrieved from *www.ameribev.org/files/news/253__ABA%20Responds%20to%20Rudd%20Report.pdf.*

[32] American Beverage Association. ABA Guidance for the Responsible Labeling and Marketing of Energy Drinks. Retrieved from *www.ameribev.org/files/339__Energy%20Drink%20Guidelines%20%28final%29.pdf*

[33] Harris *et al.,* (2011).

[34] Pomeranz *et al.,* (2013).

[35] American Beverage Assocation. Active Members. Retrieved from *www.ameribev.org/members/active-members/.*

[36] Food and Drug Administration [FDA] (2003). Substances generally recognized as safe. Code of Federal Regulations. Title 21 volume 3, Sec. 182.1180. Retrieved from *www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=182.1.*

[37] Reissig CJ, Strain EC, and Griffiths RR. (2009). Caffeinated energy drinks—A growing problem. Drug and Alcohol Dependence, *99*(1–3), 1–10; Markey *et al.* (2013).

[38] Pomeranz, Munsell, & Harris (2013); Markey, Durbin, & Blumenthal (2013).

[39] Markey, Durbin, & Blumenthal (2013).

[40] International Food and Beverage Alliance. (2010). IFBA Global Policy on Marketing and Advertising to Children. Retrieved from *www.ifballiance.org/sites/default/files/IFBA%20Global%20Policy%20on%20Marketing%20and%20Advertising%20to%20Children%20%28June%202010%29.pdf.*

provided its members is to encourage them not to advertise on children's television programs (*e.g.,* Nickelodeon, Cartoon Network) or in elementary schools. These guidelines do not even cover children's websites (including Nickelodeon.com and CartoonNetwork.com)[41] or most food-company child-targeted websites (including HappyMeal.com and FrootLoops.com) because their audiences consist of 30 percent or fewer children under 12.[42] Further, marketing that occurs in non-measured media—including social media, mobile devices, local events and signage, retail displays and product packaging—are not covered by the IFBA policy.

- *Despite ABA guidelines, marketing for many energy drinks implies that they are appropriate for use in connection with sports.*[43] For example, companies commonly feature sports themes in advertising, sponsor sporting events and high school athletics, hire professional athletes as brand ambassadors, and explicitly encourage consumption during physical activity.[44] One Coca-Cola brand (NOS) recently introduced an energy drink sub-brand called "Active" which resembles a traditional sports drink in packaging and presentation.[45] Apparently many energy drink companies have chosen not to comply with the ABA's "encouragement" in this regard.

Recent developments in energy drink marketing to teens

We recently updated our data on energy drink marketing practices from 2011 through early 2013 to evaluate how energy drink manufacturers' marketing practices have changed following increased attention to potential dangers of their products. Exhibit 2 (Rudd Report, *Energy Drink Marketing to Teens: 2010 to 2103*) details many of these findings.[46]

We found a few positive developments.

- *ABA-member energy drinks now disclose caffeine content on product labels.* Visits to convenience stores and other retail outlets indicate that all ABA companies also are compliant with the guideline to include warning labels on cans. However, the problem of inadequate disclosure and inconsistent labeling from non-ABA companies, including 5-Hour Energy and smaller energy drink brands, remains.
- *A few brands significantly reduced marketing in 2012.*[47] Two products, Venom (Dr Pepper Snapple Group), and Full Throttle (Coca-Cola), appear to have stopped most marketing practices observed in 2010. In addition, Amp (PepsiCo) reduced traditional advertising, although the brand remains active on social media.

However, we found significantly *more* cause for continued concern. Two new energy products have been introduced since 2010 that present significant risks for youth consumption.

- *Street King Energy* "was founded to fight childhood hunger, using the SK Energy Shots brand as a launch pad to unite the world's best athletes and performers and prove that energy, health, and philanthropy can exist in one amazing package."[48] SK Energy is promoted by sports figures, such as Erin Andrews (Fox Sportscaster) and pro football and basketball players. The company spent $6 million on advertising in 2012 and also maintains Facebook, Twitter, and YouTube pages. The product is touted as "a better source of energy" because it does not contain "controversial industry ingredients like taurine, guarana and ginseng" and because "We added in beneficial ingredients like antioxidants and Vitamins A, B6, B12, C and E." However, the product also contains a very high 280 mg of caffeine in one 2.5-oz shot and directly claims to help improve sports performance.

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[41] Harris JL, Speers SE, Schwartz MB, Brownell KD. (2012). U.S. food company branded advergames on the internet: Children's exposure and effects on snack consumption. *Journal of Children and Media, 6*(1), 51–68.

[42] Ustjanauskas AE, Harris JL, Schwartz MB (2013). Food and beverage advertising on children's websites. *Pediatric Obesity.* [published online ahead of print]. Retrieved from *http://onlinelibrary.wiley.com/doi/10.1111/j.2047-6310.2013.00185.x/pdf.*

[43] Harris et al (2013); Markey, Durbin, & Blumenthal (2013).

[44] Red Bull. Q&A. Retrieved from *http://energydrink.redbull.com/when-to-consume.*

[45] NOS. Energy Drink Products. Retrieved from *http://www.drinknos.com/products.do.*

[46] Rudd Report (2013). Energy drink marketing to teens: 2010 to 2013. Available at *yaleruddcenter.org/energydrinks.*

[47] *Ibid..*

[48] SK Energy. Retrieved from *www.skenergyshots.com.*

- Kraft Foods introduced *Mio Energy* "drops" as part of its Mio drink mix line to be added to other beverages.[49] The company spent $16 million to advertise in 2012. Consumers are instructed to use one "squirt" of Mio in 8 ounces of liquid. Although one drop contains a relatively small amount of caffeine (60 mg), each bottle contains 18 servings totaling 1,080 mg of caffeine, and consumers may purposely or inadvertently use more than one drop. The product also contains B vitamins, taurine, guarana, and ginseng. Further, Mio Energy is stocked in the drink mix aisle with non-caffeinated Mio products—together with Kool-Aid, lemonade, and iced tea mixes—creating the risk of consumer confusion and inadvertent caffeine intake.

Further, most leading energy drink manufacturers have not taken any actions to reduce teens' exposure to their marketing messages. On the contrary, they appear to have increased marketing in venues where young people are highly likely to view them.

- *Advertising spending on all energy drink brands combined totaled $282 million in 2012, an increase of 71 percent versus 2010 and 2.5 times 2008 spending.* [50] Three existing brands increased advertising spending in 2012 over 2010 levels. Spending on 5-Hour Energy reached $194 million, an increase of 82 percent versus 2010 and almost 4 times the amount spent in 2008. Red Bull spent $56 million, more than twice its spending in 2010. NOS spent significantly less than the others ($5.2 million), but this was twice the amount spent in 2010.
- *Teens' exposure to energy drink advertising on TV increased by 33 percent in 2012 compared with 2010.*[51] In addition to TV advertising for new products, teens viewed 8 percent more ads for 5-Hour Energy, twice as many ads for Red Bull, and three times as many NOS ads in 2012 than they had in 2010. Teens also saw 31 percent more ads for Red Bull than adults saw and 44 percent more ads for Street King. Examination of the networks where these ads appeared confirms that 5-Hour Energy, Red Bull, and Street King placed a high proportion of advertising on programs viewed significantly more often by teens than adults.
- *Some brands increased teen-targeted marketing on the internet.*[52] Average monthly teen visitors to 5HourEnergy.com and RedBull.com increased by 47 percent and 7 percent, respectively. Teen visitors to DrinkNOS.com increased 4.5-fold, and teens were 50 percent more likely to visit the site compared with adults. Three brands that had not used display advertising in 2010 began to advertise on other websites, including NOS, Monster, and Street King; Facebook was the most common site where these ads appeared. Although Full Throttle reduced display advertising in 2012, 27 percent of these ads were placed on youth-targeted websites.
- *But most energy drink brands shifted their Internet marketing focus to social media,* evidenced by enormous growth in Facebook, Twitter, and YouTube reach across the board.[53] For example, the number of Facebook likes for Red Bull and Monster doubled to 39 million and 23 million, respectively. These two brands rank #5 and #12 in number of likes for corporate brands on Facebook.[54] Red Bull and Monster also have approximately 1 million followers on Twitter. Red Bull tweets 68 times per day and 53 percent of tweets are retweeted by its followers. These numbers are comparable to Twitter followers of Coca-Cola (1.2 million) and McDonald's and Subway (1.4 million each). Red Bull dominates corporate-sponsored videos on YouTube. Its videos have been viewed on YouTube 598.6 million times; this number does not include videos viewed on other websites. One Red Bull video, "Felix Baumgartner's supersonic freefall from 128k'," has been viewed 34.5 million times since it was posted in October 2012. The company posted 520 new videos to its YouTube channel from January to July 2013.
- *Energy drink brands continued to be active sponsors of extreme sports and music events in many local markets.* Events with teenage athletes include Street League 2013 Skateboarding World Tour (Monster Energy), 27th Annual U.S. Open Snowboarding Championships (Amp Energy), and Vans U.S. Open Surfing and X Games (Red Bull). One Rockstar-sponsored event, Nautique WWA

[49] MiO Liquid Water Enhancer. MiO Energy. Retrieved from *www.makeitmio.com/mio-energy.*
[50] Rudd Report (2013).
[51] *Ibid.*
[52] *Ibid.*
[53] *Ibid.*
[54] Fan Page List. Top Corporate Brands on Facebook. Retrieved from *Fanpagelist.com/category/corporate__brands/.*

Wakeboard National Championships, has a junior competition for boys aged 9 and under.

- *Red Bull introduced eleven new smartphone apps since 2010 and Rockstar introduced five.* One Red Bull game app (Kart Fighter) includes a parental advisory: "This game has cool stuff to purchase with your iTunes account." Rockstar apps include one for its Mayhem Festival and three Grand Theft Auto apps with ratings asking users to be 17 to download. 5-Hour Energy introduced one app that asks users to confirm that they are 17 before downloading.

Regulating energy drinks marketed and sold to youth

Recent developments in energy drink marketing practices clearly indicate that current industry self-regulatory guidelines are inadequate to protect teens from exposure to marketing of these potentially dangerous products. We support recommendations by Congressman Markey and Senators Durbin and Blumenthal that energy drink manufactures immediately take steps to provide additional information and warnings on product labels, report all serious adverse events to the U.S. Food and Drug Administration (FDA) (which is not currently required for products labeled as beverages), and cease marketing to teens under age 18.[55]

Effective self-regulation of energy drink marketing would require manufacturers to acknowledge that energy drink consumption by children under 18 is much more dangerous than consumption of soda. There are many options to substantially reduce energy drink marketing to teens, with minimal effects on brands' access to adult consumers.

- *Discontinue advertising in teen-targeted media.* At a minimum, energy drink manufacturers should not advertise in media with an audience of 30 percent or more children and teens (approximately 50 percent more youth viewers than the average television and Internet audience) or with large audiences of children and teens. Alcohol industry self-regulation does not allow advertising in media with an audience comprising more than 30 percent minors under 21.[56] The National Research Council (NRC) and IOM,[57] and 19 state attorneys general[58] have recommended tighter regulatory standards for the alcohol industry, but these standards are significantly more restrictive than ABA guidelines that limit energy drink advertising only in media where the majority of the audience (*i.e.,* >50 percent) is children under 12.
- *Discontinue other marketing practices that disproportionately appeal to children under 18.* For example, energy drink companies could block Facebook users under 18 from accessing energy drink pages. Cap'n Crunch currently does this, and alcohol manufactures do so for minors under 21. They could require age verification for visitors to energy drink websites and downloads of mobile apps. They also could cease sponsorship of athletic events that include teenage participants.
- *Comply with ABA guidelines to not market energy drinks as sports drinks,* including ABA members and non-members.
- *Agree to independent review of marketing practices.* The NRC and IOM have recommended establishing an independent review board to monitor alcohol marketing practices.[59] Independent review would verify that energy drink marketing does not encourage consumption of energy drinks by children under 18.

Given that effective limits on teen-targeted marketing of energy drinks would restrict a successful strategy for continued sales growth and conflict with companies' obligations to shareholders and private owners, government regulation may be required. My colleagues and I recently examined the regulatory structure for energy drinks in the United States and present a number of possible strategies to protect

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[55] Markey, Durbin, & Blumenthal (2013).

[56] Federal Trade Commission [FTC] (2008). Marketing Food to Children and Adolescents. A Review of Industry Expenditures, Activities, and Self-Regulation. *A report to Congress.* Retrieved from *www.ftc.gov.*

[57] National Research Council [NRC] & Institute of Medicine [IOM]. (2004). *Reducing Underage Drinking: A Collective Responsibility.* R.J. Bonnie and M.E. O'Connell, eds. (Washington, D.C.: The National Academies Press.

[58] National Association of Attorneys General Youth Access to Alcohol Committee. (2006, May 8). RE: Alcohol reports: Paperwork comment RE: FTC file no. P064505. Washington, D.C.: Federal Trade Commission. Retrieved from *http://www.ftc.gov/os/comments/alcoholmanufacadstudy/522852-01287.pdf*

[59] NRC & IOM (2004).

young consumers from these potentially dangerous products (see Exhibit 3).[60] Following is a summary of our recommendations.

- *Revise GRAS.* The FDA should reevaluate GRAS standards, add limitations on problematic ingredients in energy drinks, and take enforcement action against manufacturers that add unapproved ingredients.
- *Update labeling.* The FDA should update regulations for the Nutrition Facts Label. The update should include establishing daily reference values for caffeine and added sugar and disclosures of caffeine, added sugar, and novel ingredients (*e.g.,* taurine, guarana) on all energy drinks and shots. In addition, FDA should mandate labeling for all energy products, requiring more explicit warnings on labels and compliance with the Nutrition Labeling and Education Act of 1990 (NLEA), and taking enforcement action against products mislabeled as dietary supplements.
- *Enforce marketing regulations.* The Federal Trade Commission (FTC) could take enforcement action against marketing of mislabeled products or products with false or deceptive claims.
- *Establish age limits.* The U.S. Congress, state or local governments could require age limits for purchase of energy products and establish excise taxes on products with sugar and/or caffeine.
- *Establish sales restrictions.* State and local governments could restrict where energy products may be located in retail establishments (*e.g.,* separated from other alcoholic and non-alcoholic beverages or behind the counter) and prohibit the sale of the most problematic products.
- *Enforce consumer protections.* Attorneys general also could take many of these actions under state consumer protection laws.
- *Establish monitoring of energy drink consumption* among youth to provide the public health community with the necessary tools to address this crisis. For example, the U.S. Centers for Disease Control and Prevention (CDC) could include consumption of energy drinks and shots in its Youth Risk Behavior Surveillance System[61] and obtain separate results for energy drink consumption in the National Health and Nutrition Examination Survey (NHANES).[62] Current NHANES questionnaires combine sports drinks and energy drinks in the "Energy drinks" category.

In conclusion

Energy drink products are dangerous for children and teens to consume, but many manufacturers continue to aggressively market these products to teens, and sales are growing rapidly. While the industry has initiated some modest improvements in product labeling, they have evaded the issue of marketing to teens and in fact seem to be increasing teen-targeted marketing. It is clear that the current self-regulatory efforts on the part of energy drink companies are insufficient. Unless such efforts are strengthened, federal, state, and local government efforts aimed at limiting the sales and marketing of energy drinks to children under 18 may be warranted. And such oversight would be supported by parents, the medical community, and others who advocate for children's health.

I thank the Committee for this opportunity to share our research and increase awareness of the dangers posed by continued aggressive marketing of energy drinks to children. I also would like to thank my colleagues at the Rudd Center and Berkeley Media Studies Group who conducted much of this research and the Robert Wood Johnson Foundation and the Rudd Foundation for their funding of our research.

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[60] Pomeranz, Munsell, & Harris (2013).

[61] Centers for Disease Control and Prevention [CDC]. Adolescent and School Health: Youth Risk Behavior Surveillance System. Retrieved from *www.cdc.gov/HealthyYouth/yrbs/index.htm.*

[62] Centers for Disease Control and Prevention [CDC]. National Health and Nutrition Examination Survey. Retrieved from *www.cdc.gov/nchs/nhanes.htm.*

EXHIBIT 1

Exhibit 1

YALE RUDD CENTER
FOR FOOD POLICY & OBESITY

Energy drinks and shots: Current marketing practices

Prepared by Jennifer L. Harris, PhD, MBA
Director, Marketing Initiatives
July, 2013

5-Hour Energy (Innovation Ventures)

Marketing FACTS

Advertising spending (2012): $194.6 mill (+82% vs. 2010)

TV advertising (2012)

- Av'g ads viewed by children: 47
- Av's ads viewed by teens: 133 (+8% vs. 2010)
- Ads viewed by teens vs. adults: +2%

Internet advertising (2012)

- Av'g monthly teen website visitors: 19,400 (+47%)
- Teen composition index: 102

Social media (July, 2013)

- Facebook likes: 73,200 (+127% vs. 2011)
- Twitter followers: 6,400 (+327%)

TV ads

LATEST 5-HOUR ENERGY® COMMERCIALS

LATEST 5-HOUR ENERGY® COMMERCIALS

5HourEnergy.com

Red Bull (Red Bull GMBH)

Marketing FACTS

Advertising spending (2012): $56.1 mill (+116% vs. 2010)

TV advertising (2012)

- Av'g ads viewed by children: 11
- Av'g ads viewed by teens: 29 (+100% vs. 2010)
- Ads viewed by teens vs. adults: +31%

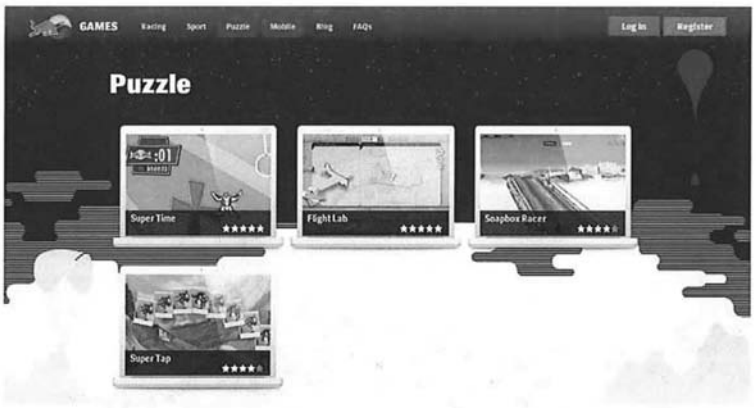
Internet advertising (2012)

- Av'g monthly teen website visitors: 12,600 (+7% vs. 2010)
- Teen composition index: 73
- Av'g monthly ads viewed on third-party websites: 65.1 mill (-86% vs. 2010; 28% on Facebook)

Social media (July, 2013)

- Facebook likes: 39.3 mill (+92% vs. 2011)
- Twitter followers: 1.1 mill (+385%)
- YouTube upload views: 598.6 mill (+278%)

RedBull.com



Sponsored events with teen artists and athletes

Facebook page (#5 most popular brand on Facebook)

iPhone applications

Monster Energy (Hansen Beverage)

Marketing FACTS

Advertising spending (2012): $0

Internet advertising (2012)

- Av'g monthly teen website visitors: 19,500 (-16%)
- Teen composition index: 107
- Av'g monthly ads viewed on 3rd-party websites: 1.9 mill (no 2010 ads; 37% on Facebook)

Social media (July, 2013)

- Facebook likes: 23.3 mill (+108% vs. 2011)
- Twitter followers: 758,000 (+904%)
- YouTube upload views: 53.7 mill (+398%)

About

Most companies spend their money on ad agencies, TV commercials, radio spots, and billboards to tell you how good their products are. Instead, we support the scene, our bands, our athletes and our fans!

Mission

At Monster, all of our guys walk the walk in action sports, punk rock music, partying, hangin' with the girls, and living life on the edge. Monster is way more than an energy drink. Led by our athletes, musicians, employees, distributors and fans, Monster is a lifestyle in a can!

Company Overview

Most companies spend their money on ad agencies, TV commercials, radio spots, and billboards to tell you how good their products are. At Monster, we choose none of the above. Instead, we support the scene, our bands, our athletes and our fans. We back athletes so they can make a career out of their passion. We promote concert tours, so our favorite bands can visit your home town. We celebrate with our fans and riders by throwing parties and making the coolest events we can think of a reality.

Facebook (#12 brand) and YouTube

Mio Energy (Kraft Foods)

Marketing FACTS

Advertising spending (2012): $16.3 mill (new product)

TV advertising (2012)

- Av'g ads viewed by children: 6
- Av'g ads viewed by teens: 14.1
- Ads viewed by teens vs. adults: -28%

No Internet or social media advertising for Mio Energy alone

Street King (SK Energy Shots)

Marketing FACTS

Advertising spending (2012): $6.2 mill (new product)

TV advertising (2012)

- Av'g ads viewed by children: 2
- Av's ads viewed by teens: 8
- Ads viewed by teens vs. adults: +44%

Social media (July, 2013)

- Facebook likes: 524,000
- Twitter followers: 38,300
- YouTube upload views: 168,000

About

Voted #1 in Energy.
Used by the World's Best Athletes.

Mission

Create energy shot that's better for you and better for the world.

Company Overview

SK Energy Shots are a new breed of energy shots. SK is a better source of energy. We have beneficial ingredients like antioxidants and Vitamins A, B6, B12, C and E and 100% natural flavors. And we left out common, controversial ingredients like taurine, guarana and ginseng. SK is a smooth rush of energy that tastes great and really works. SK is for performers, those that care about working harder and smarter, and beating the competition. We promise energy that gives them the boost they need to be their best. And the best part? SK gives back, and we're on a mission to fight hunger and poverty. Make the switch to a better source of energy today.

Description

SK is a better source of energy.

What we put in: We added in beneficial ingredients like antioxidants and Vitamins A, B6, B12, C and E. Made with 100% natural flavors and no artificial flavors, sugar, carbs or calories.

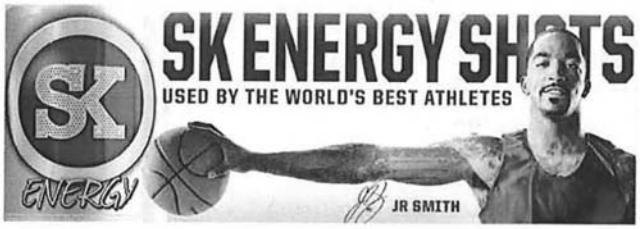
What we left out: We left out common, controversial industry ingredients like taurine, guarana and ginseng. And we have no sugars or calories, so you never feel the jitters or crash.

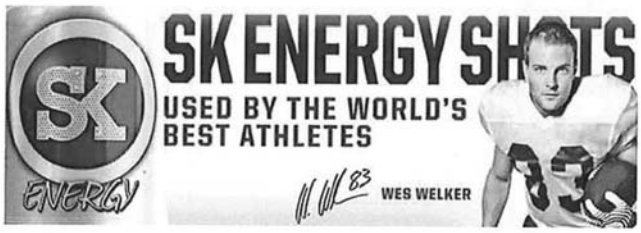
Best taste: Preferred in 9 out of 10 taste tests, available in 100% natural Berry, Grape and Orange flavors.

SK gives back: Every energy shot sold provides a meal to a hungry child through the United Nations World Food Programme (WFP).

LEGALESE: www.skenergyshots.com/facebookterms

Athlete endorsements





Facebook page

NOS (Coca-Cola)

Marketing FACTS

Advertising spending (2012): $5.2 mill (+185% vs. 2010)

TV advertising (2012)

- Av'g ads viewed by teens: 1 (+200% vs. 2010)
- Ads viewed by teens vs. adults: -58%

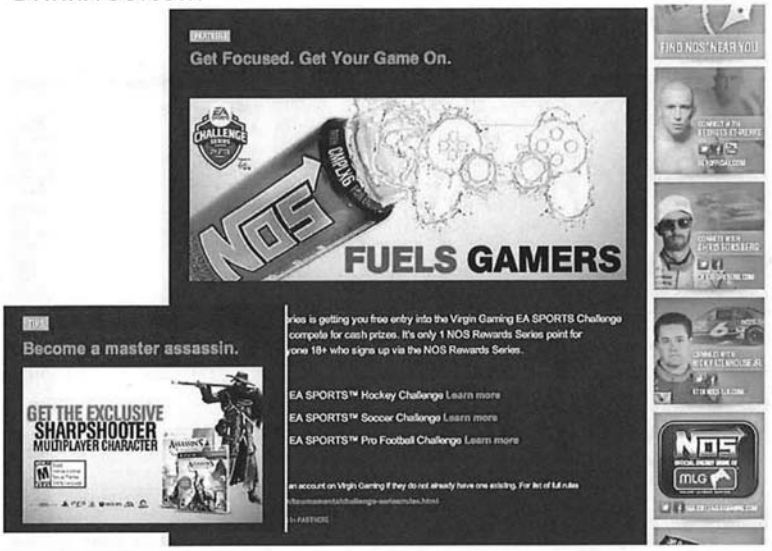
Internet advertising (2012)

- Av'g monthly teen website visitors: 9,300 (+447%)
- Teen composition index: 154
- Av'g monthly ads viewed on third-party websites: 16.9 mill (no 2010 ads; 60% on Facebook)

Social media (July, 2013)

- Facebook likes: 176,300 (+204% vs. 2011)
- Twitter followers: 5,500 (no 2010 acct)
- YouTube upload views: 3.0 mill (+331%)

DrinkNOS.com



Rockstar (Rockstar)

Marketing FACTS

Advertising spending (2012): $0

Internet advertising (2012)

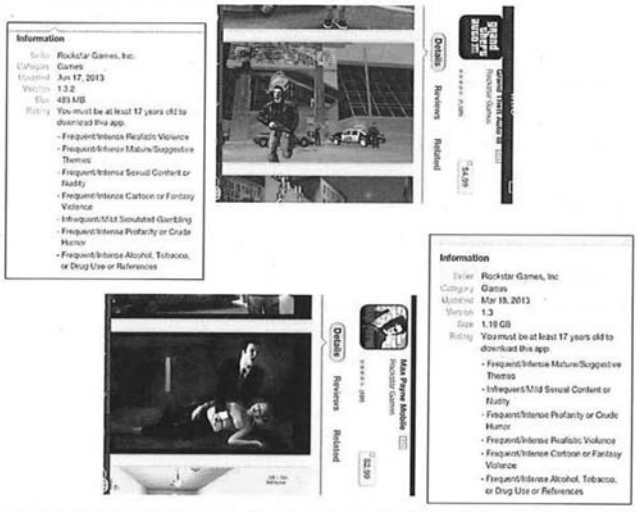
- Av'g monthly teen website visitors: 3,200 (-37%)
- Teen composition index: 95

Social media (July, 2013)

- Facebook likes: 2.0 mill (+114% vs. 2011)
- Twitter followers: 114,300 (+539%)
- YouTube upload views: 4.9 mill (no 2011 channel)

Facebook page

iPhone applications



Facebook page

Amp (PepsiCo)

Marketing FACTS

Advertising spending (2012): $1.4 mill (-90% vs. 2010)

Internet advertising (2012)

- Av'g monthly ads viewed on third-party websites: 2.5 mill (-99% vs. 2010; 74% on Facebook)

Social media (July, 2013)

- Facebook likes: 543,800 (+160% vs. 2011)
- Twitter followers: 15,500 (+96%)
- YouTube upload views: 904,000 (+173%)

Facebook page

AMP Energy

Don't get side-swiped with low energy. Plan ahead and take it w/Vita!

AMP Energy shared AMP Energy's photo.
May 17

It's the very last day to get your scores on the PowerDash leaderboard. The top player with the overall score on the leaderboard at 11:59:59 will win a VIP Dale Jr. race weekend! Woohoo!

Play AMP Energy PowerDash. Drive like Dale Jr. and win big. Download: www.amppowerdash.com/

Like · Comment · Share 40 2

Nascar sponsor

Trevco Dale Earnhardt, Jr. Amp Energy Uniform Driver Suit Kids' (4-10)

by Direct Authentics

Be the first to review this item

Size: Select

The Southern Peanut Growers will sponsor the Talladega Superspeedway Kid's Zone during the AMP Energy 500 weekend. New for the Kids Zone will be an expanded inflatable activities area, 'peanut field, ticket-tag toss, information stations with recipe cards, and of course, free samples of delicious pen'uts.

"We are excited to welcome the Southern Peanut Growers to Talladega Superspeedway," said President Rick Humphrey. "They have a lot of great activities planned for the kids and are a great addition to the Kids Zone. We look forward to welcoming our youngest race fans to the AMP Energy 500."

The Talladega Superspeedway Kids Zone is located next to the display area, behind the frontstretch grandstands.

Families will find great deals on attending Talladega's Friday and Saturday events as well. Children 11 and under are admitted free of charge to the General Admission grandstands with a paid adult.

There will be numerous activities for children during the HALLOW-DEGA festivities as well. A costume contests, pumpkin seed-spitting contest, haunted maze and hall of mirror are just a few of the many activities.

Tickets are still available for the Oct. 30 – Nov. 1 AMP Energy 500 weekend. To purchase, call 1-877-GO2-DEGA or visit www.talladegasuperspeedway.com.

In 2009, Talladega Superspeedway proudly celebrates forty years of the most competitive racing in NASCAR. While the track has seen changes made to the cars that circle its high-banks, the surface that they race on and the grandstands that thousands of fans fill twice a year, one constant remains: Talladega Superspeedway is supreme NASCAR racing at its finest.

AMP Energy presents the Zac Brown Band and Southern Ground Records artists Levi Lowrey, Nic

References

For additional information and description of methods see:

Harris, Schwartz, Brownell, et al. (2011). Sugary Drink FACTS: Evaluating sugary drink marketing to youth. Available at www.sugarydrinkfacts.org

Rudd Center (2013). Update on energy drink marketing to teens: 2010 to 2013. Available at yaleruddcenter.org/energydrinks

EXHIBIT 2

"ENERGY DRINK MARKETING TO TEENS: 2010–2010"

A report submitted by Yale Rudd Center

YALE RUDD CENTER
FOR FOOD POLICY & OBESITY

ENERGY DRINK MARKETING TO TEENS: 2010 TO 2013

July 29, 2013

In 2011, researchers at the Rudd Center for Food Policy & Obesity conducted a comprehensive analysis of beverage marketing, *Sugary Drink FACTS: Evaluating Sugary Drink Nutrition and Marketing to Youth*.[1] That study identified significant amounts of energy drink marketing targeted to teens (ages 12-17). Due to recent evidence of substantial health hazards for teens who consume energy drinks,[2,3] the American Medical Association adopted a policy to support a ban on marketing of high stimulant/caffeine drinks to adolescents under age 18.[4] This report examines data on energy drink marketing to teens in 2012 and early 2013[5] and compares them to findings from the 2011 report to determine whether companies have changed their marketing practices in light of these concerns.

Advertising spending in all media

Advertising spending on all energy drink brands totaled $281.8 million in 2012, an increase of 71% versus 2010 and 2.5 times 2008 spending. Three existing brands increased spending – 5-Hour Energy, Red Bull, and NOS – and two new brands advertised in 2012. Kraft Foods introduced Mio Energy "drops" as part of its Mio drink mix line to be added to other beverages.[6] Although one drop contains a relatively small amount of caffeine (60 mg), each bottle contains 18 servings totaling 1,080 mg of caffeine. Another new product, Street King Energy, is touted as "a better source of energy," but contains a very high 280 mg of caffeine in one 2.5-oz shot.[7]

Advertising spending by energy drink brands: 2008 to 2012

		Advertising spending ($000)			% change
Company	**Brand**	**2008**	**2010**	**2012 (% TV)**	**2010-2012**
Innovation Ventures	5-Hour Energy (shots)	$51,545	$107,010	$194,620 (96%)	+82%
Red Bull GMBH	Red Bull	$41,719	$25,974	$56,086 (94%)	+116%
Kraft Foods	Mio Energy (drink mix)	--	--	$16,347 (99%)	New product
Street King LLC	Street King	--	--	$6,239 (99%)	New product
Coca-Cola	NOS	$79	$1,828	$5,218 (99%)	+185%
PepsiCo	Amp	$18,882	$13,608	$1,389 (0%)	-90%

Source: Nielsen, 2013

Other brands with less than $1 million in TV advertising in 2012 include: Zipfizz (Enfission Inc., $603k); Full Throttle (Coca-Cola Co, $588k), Hydrive (Inov8 Beverage Co, $434k); Monster (Hansen Beverage Co, $158k); Rockstar (Rockstar Inc, $56k); RevHoney (RevHoney Inc, $45k); and Turbo Power Energy (Biorite Nutritionals, $10k).

Advertising on television

Teens' total exposure to energy drink advertising on TV increased by 33% in 2012 compared with 2010. In addition to advertising for new products, teens viewed more ads for 5-Hour Energy, Red Bull, and NOS in 2012 than they had in 2010. Teens also saw 31% more ads for Red Bull than adults saw, 44% more ads for Street King, and approximately the same number of 5-Hour Energy ads, even though teens watch 25% less television than adults do.

Teen exposure to TV advertising for energy drink brands: 2008 to 2012					
	Avg # ads viewed by teens (12-17 years)			% change	Teen:adult[8] ratio
Brand	**2008**	**2010**	**2012**	**2010-2012**	**2012**
5-Hour Energy	60.3	104.6	113.2	+8%	1.02
Red Bull	22.5	14.5	29.0	+100%	1.31
Mio Energy	--	--	14.1	New product	.72
Street King	--	--	7.7	New product	1.44
NOS/Full Throttle	--	0.2	0.6	+200%	.42

Source: Nielsen, 2013

Children's (ages 2-11) total exposure to TV ads also increased in 2012 versus 2010. Children saw on average 47 ads for 5-Hour Energy, 11 ads for Red Bull, 6 ads for Mio Energy, and 2 ads for Street King.

Examination of the networks where energy drink ads appeared confirms that 5-Hour Energy, Red Bull, and Street King continued to place a high proportion of advertising on programs viewed by most by teens, including Adult Swim, MTV, and MTV2.

Youth exposure to TV advertising for energy drink brands by distributor in 2012[9]					
		Ads viewed			
Brand	**Distributor[10]**	**2-11 years**	**12-14 years**	**15-17 years**	**Teen:adult ratio[11]**
5-Hour Energy	Total	45.9	104.6	121.5	1.02
	Adult Swim	13.5	33.6	31.6	2.33
	MTV	2.3	11.4	14.3	2.04
	20th Television (syndicated)	5.2	11.3	13.1	1.10
	Comedy Central	1.5	7.8	11.9	1.20
	MTV2	0.9	4.0	5.2	2.26
	Spike	2.2	3.7	4.8	0.73
	BET	1.6	3.3	4.0	1.23
	TBS	1.2	2.8	3.7	0.72
	ESPN	1.4	2.2	3.6	0.51
	Warner Brothers (syndicated)	1.7	3.0	3.3	0.67
	NBC	0.8	1.1	2.3	0.40
	History Channel	1.1	1.9	2.2	0.56
	FX	0.7	1.4	1.9	0.76
	TRU	0.9	1.8	1.8	0.81
	USA	1.4	2.1	1.7	0.90
	NBC Universal (syndicated)	0.8	1.3	1.6	0.51
	ESPN2	0.6	0.8	1.4	0.37
Red Bull	Total	10.6	26.4	31.1	1.31
	20th Television (syndicated)	2.8	6.0	6.1	1.36
	Adult Swim	2.6	6.0	5.4	2.39

	MTV	0.7	3.8	4.9	1.93
	MTV2	0.5	2.0	3.3	2.14
	TBS	0.7	1.9	2.6	0.93
	Comedy Central	0.3	1.2	1.8	1.18
	ESPN	0.5	0.8	1.3	0.58
Mio Energy	Total	6.2	12.2	15.9	0.72
	FX	0.6	1.1	1.7	0.84
	MTV	0.3	1.1	1.5	1.12
	Spike	0.6	1.0	1.5	0.69
Street King	Total	1.8	6.8	8.5	1.44
	MTV	0.6	2.4	2.8	2.02
	Comedy Central	0.2	1.5	2.2	1.34
	MTV2	0.2	1.0	1.2	2.44

Source: Nielsen, 2013

Advertising on the internet

Average monthly teen visitors to 5HourEnergy.com, RedBull.com, and DrinkNOS.com increased from 2010 to 2012, while teen visitors to MonsterEnergy.com and Rockstar.com declined. Teens were 50% more likely to visit DrinkNOS.com compared with adults and also more likely to visit MonsterEnergy.com and 5HourEnergy.com.

Teen visitors to energy drink websites: 2010 to 2012

		Avg # unique visitors per month (12-17 years)			
Company	**Website**	**2010**	**2012**	**% change 2010-2012**	**Composition index: Teens**
Hansen Beverage Co.	MonsterEnergy.com	23.3	19.5	-16%	107
Innovation Ventures	5HourEnergy.com	13.2	19.4	+47%	102
Red Bull GMBH	RedBull.com	11.8	12.6	+7%	73
Coca-Cola Co	DrinkNOS.com	1.7	9.3	+447%	154
Rockstar	Rockstar69.com	5.1	3.2	-37%	95

Source: comScore, 2013

Numbers of children (2-11 years) visiting these websites were low, averaging 1,200 unique child visitors per month (to MonsterEnergy.com) or less. RedBull.com had the highest number of average monthly visits per visitor (1.4), while MonsterEnergy.com had the highest average minutes per visit (4.8).

Three brands that had not used display advertising in 2010 began to advertise on other websites: NOS, Monster, and Street King. However, all brands that had advertised on third-party websites in 2010 reduced their display advertising, and Venom eliminated internet advertising altogether. Although Full Throttle reduced display advertising in 2012, 27% of these ads were placed on youth-targeted websites.

Display advertising for energy drink brands on third-party websites: 2010 to 2012						
		Avg # ad views per month (000)		% change	% ads viewed in 2012 on	
Company	Brand	2010	2012	2010-2012	Youth websites[12]	Facebook
Red Bull GMBH	Red Bull	456,915	65,088	-86%	2%	28%
Coca-Cola	NOS	--	16,869	No 2010 ads	0%	60%
PepsiCo	Amp	186,667	2,460	-99%	0%	74%
Hansen Beverage Co	Monster	--	1,915	No 2010 ads	1%	37%
Coca-Cola	Full Throttle	8,683	1,314	-85%	27%	0%
SK Energy Shots	Street King	--	198	New product	--	--
Dr Pepper Snapple Group	Venom	20,938	--	-100%	--	--

Source: comScore, 2013

One-third of all display advertisements for energy drinks (averaging 31.2 million per month) appeared on Facebook. ESPN.com was the second most common placement for energy drink ads (averaging 7.8 million per month), followed by Google sites, including YouTube.com (averaging 6.4 million per month).

Social media marketing

Most energy drink brands have shifted much of their internet marketing to social media, evidenced by enormous growth in Facebook, Twitter, and YouTube reach for all brands. In all three social media, Red Bull was by far the most active, followed by Monster.

Social media activity for energy drink brands: 2011 to 2013						
	Facebook likes (000)			Twitter followers (000)		
Brand	June, 2011	July, 2013	% growth	June, 2011	July, 2013	% growth
Red Bull	20,462.1	39,291.4	+92%	223.5	1,082.9	+385%
Monster	11,238.5	23,331.4	+108%	75.5	758.3	+904%
Rockstar	924.7	1,975.2	+114%	17.9	114.3	+539%
Amp	209.1	543.8	+160%	7.9	15.5	+96%
Street King	--	524.3	New product	--	38.3	New product
NOS	57.9	176.3	+204%	--	5.5	No 2010 acct
5-Hour Energy	32.3	73.2	+127%	1.5	6.4	+327%
Full Throttle	--	--	--	--	5.8	No 2010 acct
	YouTube upload views (000)			YouTube videos posted		
Brand	June, 2011	July, 2013	% growth	2011	2012	2013
Red Bull	158,344.0	598,593.5	278%	n/a	528[13]	520
Monster	10,776.9	53,693.7	398%	241	36	14
Rockstar	--	4,914.2	No 2010 site	116	102	44
Amp	330.7	903.7	173%	3	28	9
Street King	--	168.3	New product	2	6	0
NOS	699.2	3,011.2	331%	7	6	3
5-Hour Energy	199.3	40,268.7	20,100%	8	15	14
Full Throttle	--	166.3	No 2010 site	104	0	0

*Source: Analysis of social media websites as of July, 2013

Energy drink brands posted to their Facebook pages on average 244 times each from January 1 to July 15, 2013 (1.3 times per day). The most active Facebook pages were Monster (437 posts), Rockstar (389 posts), and 5-Hour Energy (345 posts), whereas Street King and NOS posted just twice per week (62 and 70 posts, respectively). Most brands were more active on Twitter. From June 16 to July 15, 2013, Red Bull tweeted 2,040 times (68 tweets per day); Rockstar, 5-Hour Energy, and Monster each tweeted 5 to 8 times per day; and all others tweeted 2 to 3 times daily. Of note, Full Throttle has not tweeted since November 2012.

Conclusion

Energy drinks and shots can be dangerous for children and teens to consume, but many manufacturers continue to aggressively and inappropriately market these products. In fact, many brands appear to have increased marketing in venues where teens are likely to view them. Regulations to limit the sales and marketing of energy drinks to children under 18 may be warranted, and such oversight would be supported by parents, the medical community, and others who advocate for children's health.[14]

This document was prepared by Jennifer L. Harris, PhD, MBA. The research was funded by grants from the Robert Wood Johnson Foundation and the Rudd Foundation.

Endnotes

[1] Harris JL, Schwartz MB, Brownell KD, Javadizadeh J, Weinberg M, et al. (2011). Sugary Drink FACTS: Evaluating sugary drink marketing to youth. Available at www.sugarydrinkfacts.org.
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[3] American Academy of Pediatrics (2011). Sports drinks and energy drinks for children and adolescents: Are they appropriate? *Pediatrics*, 127(6), 1182-1189.
[4] American Medical Association (2013, June 18). AMA adopts new policies on second day of voting at annual meeting. Press release. Available at http://www.ama-assn.org/ama/pub/news/news/2013/2013-06-18-new-ama-policies-annual-meeting.page.
[5] Data were obtained and analyses conducted using the same methods as the 2011 Sugary Drink FACTS report. For a detailed description of these methods, please refer to pp. 19-31 of that report. Available at www.sugarydrinkfacts.org.
[6] www.makeitmio.com/mio-energy
[7] www.skenergyshots.com
[8] Ads viewed by teens (12-17 years)/Ads viewed by adults (18-49 years)
[9] For details of the methods used in this analysis, please refer to the Yale Rudd Center for Food Policy & Obesity fact sheet, Adolescent-targeted television advertising for energy drinks. Available at yaleruddcenter.org/resources/upload/docs/what/advertising/TVAdvertising_EnergyDrinks_2010.pdf
[10] Includes all distributors with >1.25 ads viewed (125 GRPs) by individuals in any youth age group
[11] Ads viewed by teens (12-17 years)/Ads viewed by adults (18-49 years)
[12] Youth websites met one of two conditions: 1) comScore identified it as an entertainment website for youth (2-17 years) during the first three quarters of 2012; or 2) the proportion of youth visitors to the website exceeded the total percent of youth visitors to the internet in the given month.
[13] Due to the high number of videos on Red Bull's YouTube channel, the site only listed videos uploaded in the past year (since July, 2012).
[14] Pomeranz et al. (2013).

Original Article

Energy drinks: An emerging public health hazard for youth

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Abstract Energy drinks are emerging as a public health threat and are increasingly consumed by youth internationally. Energy drinks contain high levels of caffeine, sugar, and novel ingredients, and are often marketed through youth-oriented media and venues. We review these practices and the current inconsistent state of labeling. We also examine international support for regulation of these products, including a survey showing that 85 per cent of United States parents agreed that regulations requiring caffeine content disclosure and warning labels on energy drinks are warranted. We then examine the regulatory structure for energy drinks in the United States, analyzing legal and self-regulatory strategies to protect consumers, especially youth, from these potentially dangerous products. Recommended government interventions include revised labeling requirements, addressing problematic ingredients, and enacting retail restrictions. We conclude by identifying areas for future research.

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Keywords: child and adolescent health; energy drinks; marketing; regulation; law

Introduction

The consumption of sugary beverages is an established public health concern,[1] with *energy drinks* emerging as a unique and independent risk for youth. Sales of energy drinks are rising at a steady pace.[2] In 2011, they increased by 12.5 per cent overall, and by 15–30 per cent for the category leaders, Red Bull and Rockstar.[3] In a study of 600 nationally advertised beverage products in the United States, the sale of energy drinks surpassed that of either sports or fruit drinks.[4]

The products in this category typically have the word 'energy' in the product name and contain high levels of caffeine plus additional ingredients not found in sodas and juice drinks. (Energy drinks differ from sports drinks which are marketed to accompany physical activity and contain electrolytes.) The energy drink category includes two types of products: drinks and shots. Drinks are sold in 8–32 oz. containers. Many are available in large, non-resealable cans that produce one serving, despite the number of servings listed on the container.[4,5] Shots come in 2–2.5 oz. single serving containers.[4] Because there are few data on youth consumption of energy shots, this article focuses primarily on energy drinks.

A recent study of US high school students revealed that energy drinks represented 8.8 per cent of sugar-sweetened beverages they consumed, and more than 10 per cent of drinks consumed by males and Hispanic students.[6] Another US study indicated that 31 per cent of 12–17 year olds regularly consume energy drinks.[7] Similarly, a study of German adolescents found that 53 per cent tried energy drinks and 26 per cent of adolescents consumed them regularly.[8] Internationally, Thailand was reported to be the highest per capita consumers of energy drinks in 2007, with the United States, Austria, Ireland, New Zealand, Slovenia, and Kuwait rounding out the top seven countries.[9]

Energy drink consumption is a potential health hazard for the general population and especially alarming for youth due to high levels of caffeine and novel ingredients not normally found in the food supply.[10,11] The American Academy of Pediatrics (AAP) stated that 'energy drinks have no place in the diet of children and adolescents' due to their 'stimulant content',[12] but energy drink manufacturers continue to advertise directly to adolescents in media also viewed by children.[12] A study by the US Department of Health and Human Services revealed that emergency room (ER) visits involving energy drinks (alone or mixed with other substances) increased tenfold from 2005 to 2009.[13]

The mixing of energy drinks with alcohol is an obvious public health concern,[14] but adolescent consumption of energy drinks alone also poses considerable health risks. Eleven per cent of total ER visits related to energy drink consumption involved youth aged 12–17 years and 75 per cent of those visits were due to energy drink intake alone.[13] Similarly, calls to the Australian poison information center revealed increasing reports of caffeine toxicity from energy drink consumption among adolescents. The median age of callers was 17 years and more than half of all calls were due solely to energy drink consumption.[15]

The first part of this article builds on previous research about negative health effects of energy drink consumption among youth,[7,9] by discussing the potential health effects of problematic ingredients, inconsistent labeling practices, and the marketing of energy drinks to adolescents. Then it describes international support for increased regulation of energy drinks; we also report on a survey of US parents that indicates such support to protect youth. We review current regulatory structure for energy drinks and analyze legal strategies to protect consumers, especially youth, from these potentially dangerous products. We conclude by identifying areas for future research, in particular the need for more information about energy shot consumption and its effects.

Inconsistent Labeling

US Food and Drug Administration (FDA) regulations contain certain requirements for beverage labels but not all manufacturers of energy drinks designate their products as 'beverages', thus labels are inconsistent across companies. Manufacturers that label energy drinks as beverages comply with the Nutrition Labeling and Education Act of 1990 (NLEA). Others mislabel their products as dietary supplements and comply with labeling required by the Dietary Supplement Health and Education Act of 1994 (DSHEA). However, DSHEA has significantly more lax requirements and manufacturers can list ingredients on *supplement facts panels* that would not be permitted under the NLEA.[16] If there are no macronutrients in a product, manufacturers of dietary supplements can eliminate disclosure of the macronutrient list on the supplements fact panel, unlike beverage manufacturers who must list the amount as zero.[17]

The Food, Drug, and Cosmetic Act (FDCA) does not require caffeine disclosure for beverages or supplements. American Beverage Association (ABA) member companies and some independent ones disclose caffeine voluntarily,[18] but as many manufacturers do not, consumers would have to call these companies directly to obtain information about the caffeine content.

Ingredients and Health Risks

Energy drinks are generally composed of sugar and/or artificial sweeteners, caffeine, and additional ingredients, many of them in high

quantities or novel for beverages, such as guarana and taurine. Under the FDCA, ingredients added to beverages are considered food additives, and must be pre-approved by the FDA if they have not already gained status as *GRAS* (Generally Regarded as Safe).[19] If a food additive is not proven safe by the entity seeking to introduce it into the food supply, beverages containing such additives are considered 'adulterated' and may be condemned by the FDA.[20] Conversely, manufacturers of dietary supplements are responsible for determining their products' safety without any DSHEA requirement to obtain pre-approval for an ingredient unless it is new. Thus, ingredients not designated GRAS are found in some energy drinks labeled as dietary supplements.

Owing to these labeling issues, it is difficult to determine amounts of many ingredients contained in energy drinks. Table 1 summarizes calorie, sugar, caffeine, and sodium content of prominent, nationally advertised sugar-sweetened energy drinks identified in a 2010 study.[4] On the basis of the labels of these products, the most common additional ingredients are sodium compounds, guarana, panax ginseng, and taurine.

Sugar and sugar substitutes

A comprehensive study of energy beverages reported that the median sugar content of sugar-sweetened energy drinks was 27 g per 8 oz. serving, comparable to sodas and fruit drinks, and higher than sports drinks and flavored water.[4] With one exception, all energy drinks in this analysis were available in large, non-resealable containers, providing excessive sugar and calories in a single serving. Sixty-nine per cent of energy products also contained artificial sweeteners in lieu of or *in addition* to sugar.[4] More than half of these were not labeled as diet products; diet labels would normally alert consumers to the presence of artificial sweeteners.

Consumption of sugary beverages is associated with increased risk for dental caries, weight gain, overweight, obesity, diabetes, and heart disease.[21] In 2008, sugary beverages made up 31 per cent of added sugar in the diet of 6–11 year olds and 44 per cent of the added sugar consumed by 12–17 year olds in the United States.[22] Although added sugar intake derived from sugary beverages in total, such as soda, has decreased since 1999, added sugar intake from energy drinks has increased.[22] Consistent with sales data, youth may be substituting energy drinks for other sugary beverages.[2,3]

Table 1: Caffeine, calorie, sugar, and sodium content of common sugar-sweetened energy drinks[a]

Product[b]	*Additional varieties*[c]	*Manufacturer*	*ABA member company*	*Can size (oz.)*	*Caffeine per can (mg)*	*Calories per can (kcal)*	*Sugar per can (g)*	*Sodium per can (mg)*
Amp Energy	4	PepsiCo	X	16	142	220	58	140
AZ Energy	3	Arizona	–	15	188	188	49	20
Full Throttle (Red Berry)	2	Coca-Cola	X	16	200	230	58	160
Monster Energy	24	Hansen Beverage Company	–	16	160	200	54	180
Monster Energy	24	Hansen Beverage Company	–	24	240	300	81	270
Monster Energy	24	Hansen Beverage Company	–	32	320	400	108	360
NOS	4	Coca-Cola	X	16	260	210	54	410
Red Bull	0	Red Bull	X	8.4	80	110	27	99
Red Bull	0	Red Bull	X	12	114	160	39	142
Red Bull	0	Red Bull	X	16	154	220	54	189
Red Bull	0	Red Bull	X	20	192	275	68	237
Rockstar	11	Rockstar	–	8	80	140	31	40
Rockstar	11	Rockstar	–	16	160	280	62	80
Rockstar	11	Rockstar	–	24	240	420	93	120
Venom Energy (Black Mamba)	3	Dr. Pepper Snapple	X	16.9	170	250	57	320

[a]Nutrition information as of September 2012 for each available can size for nationally advertised energy drink brands identified in the 2011 Sugary Drink FACTS report from the Rudd Center for Food Policy & Obesity.
[b]Information given for original variety of drink brand. For those brands that do not have an original variety, the flavor is specified.
[c]Number includes additional sugar-sweetened unique flavor varieties within each listed brand, not including multiple can sizes.

Caffeine

Energy drinks are touted for high caffeine content, but manufacturers do not always report the amount in each container. In the 2010 study of sugary drinks, 54 per cent of 83 total energy drink products reported their caffeine content with a median of 80 mg per 8 oz. serving or shot, more than double the median caffeine in 8 oz. of soda.[4] Two products contained extreme levels and were available in 20 oz. containers, providing 245 mg and 325 mg of caffeine.[4] Another study found that energy drinks may contain up to 505 mg of caffeine per container.[9]

Caffeine toxicity is a concern for youth. In 2007, there were 5448 caffeine overdoses reported in the United States and a striking 46 per cent of them occurred in persons younger than 19 years.[8] The AAP raised additional concerns for children because of caffeine's effect on developing neurological and cardiovascular systems, plus a risk of physical dependence and addiction.[12] Caffeine binds to cell membranes in place of adenosine, an inhibitory neurotransmitter, causing changes in normal physiological processes. Specific effects of caffeine consumption include disturbed sleep, increased body temperature and gastric secretions, increased blood pressure and heart rate, as well as a risk of physical dependence and addiction. This is especially problematic for youth because they are still growing. The AAP specifically cautioned that dietary intake of caffeine can produce harmful adverse effects in youth and should be 'discouraged for all children'.[12]

Sodium and other ingredients

Energy drinks contain surprisingly high levels of sodium. In the 2010 study, the median sodium level was 123 mg per 8 oz. serving or shot, more than three times the amount in soda.[4] Several energy drinks had even more extreme levels, with one containing 340 mg per 8 oz. serving.[4] Diets high in sodium can result in high blood pressure and increased risk for heart disease and stroke.[23]

Energy drinks often contain *specialty* ingredients with purported health benefits, but that can have negative effects on young people. Table 2 provides information on three of the most common ingredients: guarana, taurine, and panax ginseng. Many of the same novelty ingredients found in energy drinks are also ingredients in over-the-counter diet drugs.[27] As consumption of energy drinks increases, these ingredients raise

Table 2: Common energy drink ingredients

Ingredient	*Intended effects*[8]	*Generally recognized as safe (GRAS)*	*Comments from the American Academy of Pediatrics clinical report*[24]	*Other notes*
Guarana	Stimulant (caffeine-containing)	Yes	Guarana is concerning for youth because it increases the total amount of caffeine in the product	Contains 40 milligrams of caffeine per gram
Taurine	Amino acid believed to assist with cell metabolism, thought to improve athletic performance	No	Amino acids in energy drinks should be discouraged in children	Mayo Clinic study found no evidence that it produces advertised benefit[25]
Panax ginseng	Thought to improve athletic performance	No	Not Available	Potential negative side effects include insomnia, menstrual problems, increased heart rate, and blood pressure disturbances[26]

significant concerns because it is unclear what combined health impact they may have on consumers, especially youth.

Marketing

A comprehensive analysis of marketing practices and youth exposure to this marketing in the United States confirmed that several energy drink manufacturers market their products using media and techniques aimed at adolescents.[4] In 2010, US adolescents saw on average 124 television ads for energy drinks and shots, which is the equivalent of one ad every 3 days.[4] This is similar to adolescents' viewing of regular soda ads (122), and more ads for energy drinks and shots than seen by adults.[4] Adolescents viewed 9–16 per cent more ads than adults for three energy drink brands.[28] The majority of energy drink ads viewed by adolescents appeared on youth-targeted cable networks including Adult Swim (80–90 per cent more adolescent than adult viewers), MTV and MTV2 (88–199 per cent more adolescent viewers), and Comedy Central (20–30 per cent more adolescent viewers).[28]

Energy drink brands also sponsor extreme sports competitions and are prominent in digital media that disproportionately appeals to adolescents. Adolescents were approximately twice as likely to visit the Monster and Rockstar energy drink websites compared to adults,[4] and youth under age 18 often visited Facebook pages of popular energy drinks, comprising 11 per cent of unique visitors for Red Bull and 38 per cent to Monster's page.[29] Although it does not appear that energy drink companies directly market to children less than 12 years of age, many children view the same media as adolescents. As a result, children in the United States saw on average 62 energy drink and shot ads in 2010, which is on par with the number of ads they saw for the children's drinks Capri Sun and Kool-Aid.[4]

Support for Regulation

In 2008, scientists and physicians wrote to the FDA requesting increased regulation of energy drinks because their high caffeine content puts youth at risk for caffeine intoxication and alcohol-related injuries.[30] France, Denmark, and Norway attempted to ban Red Bull because of concerns about excessive caffeine and other novel ingredients in the product,[31] but the European Court of Justice found it to be an improper trade restriction.[32]

In 2011, Canada officially designated energy drinks as subject to regulation as food; they established specific criteria, including composition restrictions and labeling requirements.[33] Canada determined the maximum amount of caffeine permitted per single-serve container to be 180 mg and designated all non-resealable containers *one serving*.[33] Canada also requires labels to disclose the amount of caffeine per serving and to include warnings for use by children and certain sensitive adults.[33]

The Rudd Center for Food Policy & Obesity conducted a nationally representative online survey of 985 US parents of 2–17 year olds in 2011, seeking to understand attitudes about energy drinks, beliefs about appropriateness of these drinks for their children, feelings regarding caffeine and other common ingredients, and attitudes toward energy drink labeling and regulation.[34] They found that 67 per cent of parents were concerned about the caffeine content of beverages for their children, 78 per cent agreed that energy drinks should not be marketed to children and adolescents, and 74 per cent agreed these drinks should not be sold to children or adolescents. In addition, 85 per cent of parents

agreed that regulations requiring reporting of caffeine and warning labels were warranted for energy drinks.

In 2012, US Senators Durbin and Blumenthal asked the FDA for increased regulation of energy drinks, including clarifying labeling requirements, directly regulating the amount of caffeine permitted in products, and an FDA determination of the safety of other additives and ingredients.[35]

Regulatory Recommendations

The FDA has primary authority over the safety, labeling, and ingredients of energy drinks.[36] Federal law preempts state and local governments from addressing issues in the FDA's domain. State and local governments (collectively states), via their legislatures and agencies, can, however, exercise authority over public health and safety to regulate the sale of these products and protect consumers.[37] If a government entity determines that increased regulation of energy drinks is warranted, several options are available, summarized in Table 3 and discussed below.

Designation as beverages

The FDA issued a non-binding draft guidance document in 2009 distinguishing beverages from liquid dietary supplements,[16] and the agency is currently finalizing the guidance document.[35] The FDA has explained that even if a manufacturer characterizes a product as a dietary supplement, it may be a beverage for regulatory purposes. Beverages can be distinguished by packaging, volume, advertising, name, and similarity to other beverages (for example, soda),[16] whereas a dietary supplement is defined as 'a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet'.[16] According to the FDA, energy drinks labeled as supplements are mislabeled.

Ingredients

The FDA expressed concern that energy drinks contain some GRAS ingredients 'at levels in excess of their traditional use levels', which 'raises questions regarding whether these higher levels and other new conditions of use are *safe*'.[16] The FDA granted GRAS status to added sugar[38] and caffeine (at levels of 0.02 per cent of the product) in the

Table 3: Potential interventions to reduce underage consumption of liquid energy products

Topic	*Intervention*	*Actor*
Ingredients	• Reconsider GRAS status for problematic ingredients (including caffeine, sugar, and guarana), especially in large quantities	FDA
	• Add limitations to permissible amounts of GRAS ingredients	FDA
	• Take enforcement action against manufacturers that add unapproved ingredients	FDA, AGs
Labeling	• Require caffeine disclosures on all products regulated by FDA	FDA
	• Establish Daily Reference Value (DRVs) for caffeine and added sugar	FDA
	• Require warning labels for liquid energy products	FDA
	• Require liquid energy products comply with the NLEA	FDA
	• Take enforcement actions against products mislabeled as dietary supplements	FDA, AGs
	• Take enforcement action against the marketing of mislabeled products or products with false or deceptive claims	FTC, AGs
Retail	• Require age limits for purchase	Congress, State, Local
	• Establish location restrictions in retail establishments	State, Local
	• Prohibit the sale of the most problematic products	State, Local, AGs
	• Establish excise taxes on highly sugared products	Congress, State, Local (to extent authorized)
Marketing	• Stop marketing to adolescents, including on programming and in events that appeal to them	ABA, Manufacturers
Research	• Measure population caffeine consumption and youth consumption of energy drinks and shots	Public Health Community
	• Identify best practices to reduce sales to underage consumers	Policy Advocates

1970s.[39] During the approval process, the Select Committee on GRAS substances recognized potential health hazards associated with consuming added sugar at levels higher than at that time and caffeine in doses larger than used in cola-type beverages.[38,40] Energy drinks contribute to high *added sugar* consumption, which exceeds the levels at the time of GRAS approval, and they contain far more caffeine than cola-type beverages.[22] Further, although the stimulant guarana is GRAS up to a specified amount, it is unclear exactly how much guarana is in energy drinks and how much would be considered safe when it is added to an already highly caffeinated product.

The FDA has the authority to revise GRAS status for sugar, caffeine, and guarana and to regulate the amount of each ingredient permitted to be added to beverages. The agency can mandate maximum levels of these ingredients in single-serving containers.

The FDA also expressed concern that other ingredients in energy drinks are not GRAS and are not being used in accord with existing food additive regulations.[16] Taurine and panax ginseng, among other potential ingredients, are not approved for use in beverages. The FDA has the authority to designate these products as *adulterated* and unsafe for the food supply.[16] The agency can reprimand manufacturers or condemn the products outright.

Labeling

The US government has several labeling options that should be considered to protect and inform consumers about the ingredients and risks associated with energy drinks. Congress can amend the FDCA and the FDA can issue binding regulations that energy drinks must be labeled as beverages and that caffeine content must be disclosed on all products under the FDA's purview.[41]

Some or all energy drinks should contain warnings about caffeine toxicity and the introduction of ingredients not normally found in the food supply. Today, when caffeine is added to stimulant drug products, the package must bear a specific warning label stating that the product is for 'occasional use only' and not intended for children under 12 years of age.[42] US law requires a warning when 'foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings' and the omission of such a warning 'renders the product not reasonably safe'.[43] ER data from visits involving energy drinks, show these products may be regarded as not reasonably safe without warnings.

Consumer protection actions

The Federal Trade Commission (FTC) and state attorneys general (AGs) have authority to institute consumer protection actions to address labeling and ingredient violations identified above. The FTC can bring an action against manufacturers for unfair and deceptive marketing practices. The state AGs have similar authority over questionable marketing and

labeling and can additionally bring actions to protect citizens from particularly problematic products.[44] In 2012, for example, New York's Attorney General started an investigation into whether energy drink manufacturers were misleading consumers about caffeine content and potential health risks.[45]

Retail restrictions

State governments in the United States may enact retail regulations. Seventy-nine per cent of energy drinks are sold from convenience stores, and thus subject to a variety of potential regulations.[4] States can, for example, restrict the sale of energy drinks to youth under a certain age; an option supported by parents. In 2010, a New York county legislator proposed a ban on the sale of energy drinks to minors younger than 19 years.[46] Lawmakers can determine which age is appropriate. Implementation would be straightforward, because retail outlets are already legally required to verify the age of customers purchasing alcohol and tobacco.

Another option would be to regulate the location of problematic products in the retail environment, akin to state requirements that tobacco be sold from behind the counter. Energy drinks are generally offered in a refrigerator case near alcoholic or other sugary beverages. This placement may imply that they are similar to sugary beverages and/or encourage consumers to mix them with alcohol. Research might help determine how revised placement of drinks could have a positive impact on public health by discouraging purchases and the mixing with alcohol. Research can answer the question whether the top shelf of coolers or aisles, the back of the store, or behind the counter would help protect consumers.[21]

Another retail restriction would ban the sale of certain energy drinks, such as those in large non-resealable containers or with the highest caffeine content. A bill proposed in Oregon sought to ban sale of 'high-calorie' beverages in single-serving containers larger than 12 oz.[47] The same type of restriction could be placed on the sale of highly caffeinated products in large containers.

Finally, it is noteworthy that an excise tax placed on sugary beverages would surely apply to sugary energy drinks. The underlying rationale and potential benefits of such a tax have been discussed elsewhere; the goal is to decrease consumption.[1] Both federal and state governments can institute excise taxes. Local jurisdictions can sometimes also enact

taxes or fees – to the extent permitted by the state's laws governing localities.[21]

Marketing restrictions

Tighter regulations on the marketing of energy drinks to adolescents are warranted, but in the United States a substantial barrier exists to government enacting such regulations. The Supreme Court has interpreted the First Amendment of the Constitution to protect marketing, or *commercial speech*, from government interference. Thus, the United States has focused on self-regulation, hoping to maintain some control over marketing directed at youth.

The ABA established guidelines for the sale and marketing of energy drinks, under which member companies agree to refrain from marketing products to children (ages 2–11) and selling them in schools (grade levels K–12).[18] The guidelines also state that energy drinks should not be promoted as sports drinks or in connection with alcohol consumption. In response to criticism of marketing that promotes energy drinks to youth, both Red Bull[48] and the ABA,[49] as a spokes-organization for its member companies, reiterated that they do not market energy drinks to children under age 12. But these self-regulatory pledges do not prohibit marketing targeted directly to adolescents and, as noted, despite these restrictions, children and adolescents continue to be exposed to large numbers of advertisements for energy drinks.

Self-regulation of alcohol marketing to minors (20 years and younger) provides a potential blueprint for reducing energy drink marketing to youth. The FTC has recommended a self-regulatory approach to reduce underage exposure to alcohol marketing. Major alcohol suppliers agreed that they would not advertise in media with an audience comprising more than 30 per cent minors and have largely complied.[50] The National Research Council (NRC), Institute of Medicine (IOM),[51] and 19 state AGs[52] recommended tighter self-regulatory standards, including no alcohol advertising in media with an underage audience share of 15 per cent (approximately their share of the US population) and restrictions on marketing practices with substantial underage appeal. The NRC and IOM also recommended establishment of an independent review board to monitor alcohol marketing practices. A similar protocol would work well for energy drinks.

Companies that belong to the ABA currently comply with their self-regulatory commitments, but this program has limitations. Several of the highest selling energy drink brands do not belong to the ABA. At a minimum, these companies should agree to abide by ABA guidelines. However, to address the majority of youth-targeted marketing of energy drinks, all energy drink manufacturers should also agree to discontinue their marketing practices that disproportionately appeal to adolescents, including advertising on television programming with a higher-than-average proportion of youth in the audience and the use of social media and sponsored events.

Discussion and Conclusion

Existing evidence points to significant public health issues arising from youth consumption of energy drinks, but further research and analysis are needed:

- More comprehensive measurement of youth consumption of caffeine and energy drinks, separate from other sugary beverages. Because energy drinks are relatively new products in the American marketplace, ongoing dietary measurement panels do not adequately monitor and report on these products.
- Research to determine consumer understanding of ingredients and claims on energy drink labels would help us understand the extent to which current practices mislead or deceive.
- Studies of *energy shots* are also warranted. We know little about energy shot consumption by youth; but 82 per cent of the energy product ads viewed by children and adolescents promoted one shot: 5-Hour Energy.[4] Of all products examined in the 2010 study, a 2.5 oz. shot had the highest per-serving caffeine content overall, 200 mg.[4] Manufacturers designate energy shots as dietary supplements so they are located with other dietary supplements in pharmacies, which may send an unwarranted health message to consumers. In other retail outlets, shots are often located in free-standing displays at the check-out[4] further encouraging purchase. The FDA should pay particular attention to categorization and labeling of shots because companies market them in media viewed by youth and they contain extreme levels of caffeine that could be dangerous for children and adolescents.

- To identify best policies, research might help local jurisdictions determine the best location in retail establishments to require problematic products to be placed to discourage purchase by youth. Alternatively, locales can experiment with product placement restrictions to determine which locations work best.

* * *

Consumption of energy drinks is a public health concern especially for young people. Increased regulation is warranted to inform and protect consumers by addressing problematic ingredients, clarifying labeling requirements, and restricting youth access. At a minimum, increased self-regulatory efforts should be instituted to protect youth from marketing. Energy drinks are a unique beverage and should be regulated accordingly.

About the Authors

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Senator BLUMENTHAL. Thank you.
Dr. Spencer?

STATEMENT OF WILLIAM R. SPENCER, M.D.,
SUFFOLK COUNTY LEGISLATOR

Dr. SPENCER. Thank you.

Good afternoon, Honorable Senators, members of the Committee, ladies and gentlemen. Thank you for allowing me this opportunity to testify on the marketing and sale of energy drinks.

I am Suffolk County legislator Dr. William Spencer, a pediatric otolaryngologist from Huntington, New York. I was elected to the legislature in 2011, and I am part of a legislative body that represents 1.5 million people. I currently serve as Chair of the legislature's Health Committee and am a Member of the Suffolk County Board of Health.

The powerful energy drink industry generates over $7 billion of revenue a year and spends over $100 million per year in advertising here in the United States. Due to the growing reports of adverse effects in our county related to energy drinks, the board requested that I look for potential avenues of legislative action.

A poor public health message has become pervasive. Recent ads that you mentioned earlier include the catch phrase "zap the nap." The message to children, who are frequently overscheduled and under constant pressure to succeed, is to ignore the body's natural signals of fatigue and hunger and use a stimulant instead. These beverages are marketed as a quick and easy way to relieve fatigue and improve performance. Their illusion of energy is high-dose caffeine acting as a stimulant to the central nervous system.

These marketing tactics and messages are embedded throughout our children's lives, even in the early Sunday morning cartoons. Over the years, we have seen that marketing has doubled recently, as indicated by the Yale Rudd report.

In our 24/7 social media world, commercials, sampling directed at children have taken the power of control away from parents and made our children vulnerable to an industry with a cool, seductive message. I discovered that an unlevel playing field existed and most parents did not know about the dangers associated with ingesting energy drinks.

In fact, many parents think energy drinks are akin to sports drinks. I have personally witnessed a parent dispensing an energy drink to her 10-year-old child at a swim meet, and she had assumed incorrectly that she was helping her child to hydrate.

There has been a lot of action around the country, as you have indicated. We know in 2012, Manatee County, Florida, banned the sale of energy drinks in its schools, indicating that the drinks made the children restless and unable to concentrate in class.

It also has been reported by some of the other members that there has been a dramatic increase in emergency room visits. So far, what I have reported is what I have read and heard, but I would like to share with you what I have personally seen in Suffolk County.

Energy drink companies sponsor local events for children as young as 10 years old. Samples are being distributed to local theaters in my legislative district to children standing in line as young

as 12. Energy drink displays are positioned next to video games in local department stores. And most recently, along Memorial Day, after our legislation was passed, we saw energy drinks being distributed at a parade in Sayville, New York.

Finally and probably the most egregious act was that direct mail of an energy drink with a sample packet was sent to one of my colleagues on the legislature's 16-year-old child.

I believe we have a responsibility to protect the public and our vulnerable children. I believe in the importance of free commerce and the right of businesses to conduct business in an unfettered way, but they cannot be allowed to imperil the public, especially our most vulnerable, children.

After an exhaustive effort in Suffolk County, we passed the first in the Nation modest regulations prohibiting the marketing and advertising of stimulant drinks to minors, prohibiting the distribution of stimulant drinks to minors in our county parks, and also embarked upon an educational campaign. This, for me, is about protecting our children. Some children, as many as 1 in 100, have underlying heart defects that may make them susceptible to life-threatening conditions when exposed to even a recommended sample of energy drink.

There are responsible members of the industry that I have met with. But in conclusion, although they may be responsible, there are a lot of members who are not part of the American Beverage Association that may act on their own.

What I am asking today is that if the products are labeled not recommended for use in children, then we should not allow them to be marketed to children. Please consider restricting the marketing to children under 18 years old and until we can find that these drinks are safe and not habit forming.

Thank you for this opportunity.

[The prepared statement of Dr. Spencer follows:]

PREPARED STATEMENT OF WILLIAM R. SPENCER, M.D., SUFFOLK COUNTY LEGISLATOR

Good afternoon ladies and gentlemen. Thank you for allowing me the opportunity to testify today on the marketing and sale of energy drinks to children.

I am Suffolk County Legislator William Spencer from New York. I am also a board-certified, fellowship-trained, pediatric otolaryngologist in Huntington, New York. I am currently the Vice President for the Suffolk County Medical Society, a delegate to the New York State Medical Society, and a member of the AMA. I have attached my CV for your review.

For the purposes of this presentation I will be referring to the products as "energy drinks." I want you to know that I disagree with the characterization of these products as "energy drinks" and in fact, in my legislation, I refer to them as "stimulant drinks" because they do not provide energy, they stimulate.

In November 2011, I was elected to the Suffolk County Legislature. I am one of 18 legislators in the County's legislative body that represent over 1.5 million people. As the first physician to serve on the Suffolk County Legislature, I was appointed to serve as Chairman of the County's Health Committee and to serve on the County Board of Health. The Board of Health is charged with formulating public health policy and administering the sanitary code.

Suffolk County has a proud history of passing consumer protecting, visionary legislation that have gone on to be adopted at both the state and Federal levels. Prohibiting the use of cell phones while driving and most recently the ban on the use of the carcinogen bisphenol A (BPA) are resolutions that began as Suffolk County resolutions.

In 2010, my colleague Legislator Lynn Nowick introduced two resolutions regarding energy drinks, one to alert customers to the health risks associated with energy drinks and the other that would have banned the sale of energy drinks to minors

in our county. Her efforts received national and even worldwide attention. Lobbyists and industry representatives opposed any restrictions on their products claiming they were safe. They believed the legislation was misguided and that any bans would hurt commerce.

The powerful energy drink industry generates over 7 billion dollars per year in revenue, and spends hundreds of millions of dollars per year in marketing and advertising here in the United States.

Eventually, under pressure from the industry, Legislator Nowick was able to fashion a compromise. Some major manufacturers of energy drinks and the American Beverage Association agreed to include a warning on their labels that stated "these products are not intended for children, pregnant or nursing women or those sensitive to caffeine." In addition, they agreed to disclose the total caffeine content on the product label. Additionally, funding was promised for an educational campaign to teach youth about the risks of excessive caffeine ingestion.

With this compromise in hand, Legislator Nowick allowed her resolutions to expire without any further action being taken. In light of the enormous lobbying effort against her position, my colleague's efforts were considered by most a huge win against a powerful industry and a victory for protecting our children's public health.

Two years later, I was elected and started my tenure on the Board of Health. Due to the growing reports of adverse incidents related to energy drinks, the board requested that I revisit the issue for potential legislative action. During the summer of 2012, I began to research and discuss the issue with my colleagues and peers in the medical field.

Much had changed since the compromise with Legislator Nowick.

A poor public health message had become pervasive. The idea delivered in advertisements was that if you are tired, just drink an energy drink. Recent ads included the catch phrase "zap the nap". The message to our children, who are frequently over scheduled and under constant pressure to succeed, is to ignore your body's natural signals of fatigue or hunger and override those signals with stimulants. These beverages are marketed as a quick and easy way to relieve fatigue and improve performance. Their illusion of energy is high-dose caffeine acting as a stimulant to the central nervous system.

These deceptive marketing tactics and messages are imbedded throughout our children's lives, supported by popular stars, influential athletes and are directed at the very young, even in early morning cartoons. Recent data reveals that the marketing of these products to children and young people has doubled in recent years.

A Yale Rudd Center for Food Policy and Obesity study showed that "on average, preschoolers viewed 44 energy drink ads per year in 2010, children viewed 54 ads, and adolescents viewed 124 ads. From 2008 to 2010, exposure increased 47 percent among preschoolers, 23 percent among children, and 22 percent among adolescents. In 2010, adolescents viewed 18 percent more ads for energy drinks compared to adults."

In our 24/7, high tech social media world, a shift of influence has occurred away from parents. Commercials, sponsorships and sampling directed at our children have taken the power of control away from parents and made our children vulnerable to an industry with a cool seductive message. I discovered that an un-level playing field existed and that most parents did not know about the dangers associated with ingesting energy drinks or the enticing advertising their children had been exposed to as they watched television, played video games, and even competed on their local soccer field. In fact, many parents think energy drinks were akin to sports drinks.

I have personally witnessed a parent dispensing an energy drink to her 10-year-old child at a swim meet. She had assumed incorrectly that she was helping her child hydrate and that the caffeine would boost her child's performance. Other parents I have spoken with have witnessed their peers supplying their children with energy drinks before track, soccer and lacrosse meets.

While I was contemplating this issue, others were starting to express concern as well:

> In April 2012, The Honorable Senator Durbin sent a letter to the FDA "expressing concern about the potential safety issues associated with the consumption of so-called "energy drinks and requested they take certain actions in response to these issues . . ." Most of his issues dealt with how the industry defines their product.
>
> In July 2012, the School Board of Manatee County in Florida banned the sale of energy drinks in its schools and would no longer allow students to bring them from home, citing the drinks make students to restless to concentrate in class. The director of elementary schools, Joe Stokes was quoted as saying "we know

a significant number of students who have increased energy followed by decreased energy can have agitation. Caffeine affects how the brain works."

In August 2012, closer to my home, NYS Attorney General Schneiderman began investigating energy drinks, specifically whether the multibillion-dollar energy drink industry is deceiving consumers with misstatements about the ingredients and health value of its products. According to reports, the subpoenas asked for "information on the companies' marketing and advertising practices."

In October 2012, strict new regulations and taxes were imposed on the sale of energy drinks in Mexico to deter new brands from entering the market. The Mexican Senate eventually banned the sale of energy drinks to anyone under the age of 18.

In November 2012, the FDA announced that it was investigating reports of five deaths that may have been associated with Monster Energy Drink since 2009. The family of Anais Fournier, a 14-year-old girl with a heart condition who died after drinking two cans of it's Monster Energy Drink in a 24-hour period had recently filed its lawsuit against the company.

It was also reported during that same time that emergency room visits attributed to caffeine toxicity had risen 10-fold between the years 2005–2008. According to a 2012 report by the Substance Abuse and Mental Health Services Administration, there were 1,128 visits to an E.R. as a result of caffeine overdoses in 2005. That number went up to 16,053 in 2008.

One last example of the changing tide, was in late October 2012, Dennis J. Herrera, the city attorney of San Francisco sent a letter to Monster Beverage, asking them to substantiate its claim that large daily quantities of Monster were safe for adolescents and adults. According to reports, Mr. Herrera cited a section of California law that makes it illegal for a company to make false or misleading advertising claims that purport to be based on fact or clinical data.

Similar conversations were taking place in Canada where Mr. James Shepherd, who lost his 15-year-old son due to an "unexplained arrhythmia" on January 6, 2008, has become a huge advocate for regulation and change in Canada. Claims are that his son was supplied an energy drink sample during a free hand out by Red Bull company representatives and several hours later collapsed and died. Canadian government officials have made strides to create a caffeine cap on these products and are working on further regulations.

Schools, colleges, cities, states, countries and even branches of the military have started to address increasing use and abuse of these products. The issue is studied and a variety of actions including banning the sale, use and marketing of the products have been taken to product consumers.

So far I have reported about what I have read, heard and researched, but this is what we have seen in Suffolk County which led my colleagues to support my three point plan to educate, protect and empower residents.

1. I heard first hand from residents and colleagues that energy drink companies were sponsoring local sporting events/lacrosse and soccer tournaments. Coupons and products with the company's logo were distributed.
2. Samples of Monster Energy Drink were distributed on several occasions out of the back of a Monster Energy truck to concert attendees, ranging from approximately 12 years old to adult, in front of the Paramount in Huntington Village. Concert attendees were give samples of the product as they waited on line for the concerts to begin. The Paramount is a very popular concert and performance venue.
3. Energy Drink marketing displays are positioned next to video games in local department stores. I heard testimony that energy drink manufacturers imbed logos or references to their products in video games and cartoons. One drink even "gives you wings . . ." which are particularly attractive to children when they are playing in a competitive arena.
4. One of my colleagues called to report that energy drink samples were handed out at a traditional small town Memorial Day parade in Sayville, Long Island. Apparently, there was an energy drink truck with company representatives handing out products with their logo and coupons to parade attendees and there were no obvious attempts at ensuring that children didn't receive these samples. This activity took place a month after Suffolk made it illegal to do so.
5. Finally and probably the most egregious was that a direct-mail sample packet was sent to one of my colleague's 16-year-old son at his home. The product was

clearly marked not for use by anyone under 18 but was sent directly to a 16-year-old who had come home from school hours before his parents, and could have added the small packet to water and ingested it, without his parent's knowledge.

I believe the government has a responsibility to protect the public, particularly the most vulnerable, our children. I also believe in the importance of free commerce, capitalism and the right of businesses to conduct business in an unfettered way. But they cannot be allowed to imperil the public, especially our most vulnerable.

In the fall of 2012, I began meeting with industry leaders, health officials and educators, constituents and my colleagues. Rather than implementing an outright ban on the sale of the products in Suffolk County as our Board of Health advocated, I worked to create a balanced, comprehensive plan.

After getting word that the minor son of my colleague received a sample and coupons in the mail from a local energy drink company, I filed *IR 1085–2013, A Local Law to Protect Minors From Direct Mail Stimulant Drink Advertising and Samples.* The product that was clearly marked "Not for Use by Children" was sent directly to a minor through the mail. Despite vehement claims by the industry that they didn't market to children, there was enormous proof to the contrary.

To address the concerns expressed by the Suffolk County Board of Health, my colleagues supported the compromise position stated in my *IR 1086–2013, A Local Law to Prohibit the Sales and Distribution of Stimulant Drinks to Minors in County Parks.* If the County Board of Health, supported by much research and reliable data, was concerned about the harmful effects of energy drinks on children, then we should not be allowing those products to be sold or distributed on County property.

Finally, but actually the first and most widely supported resolution was *IR 1920–2012, Establishing "The Truth About Stimulant Drinks" Public Education Campaign to Increase Awareness of the Side Effects Associated with Stimulant Drink Consumption.* This campaign would educate junior high and high school students about stimulant drinks and encourages their participation in a public safety announcement (PSA) competition. The winning PSA would be aired on local cable television to strengthen awareness about these drinks annually. We have begun to meet with the Department of Health and school officials to get this program off the ground and have met with excitement and support.

In April 2013, after an exhaustive effort, Suffolk County became the first municipality in the United States to pass legislation that would modestly regulate the industry and educate consumers. We had fashioned a comprehensive energy/stimulant education and protection plan to address the health risks associated with energy/stimulant drinks. Again, this historic three-pronged approach included:

- Prohibiting the marketing and advertising of stimulant drinks to minors.
- Prohibiting the distribution and sale of stimulant drinks to minors in County parks.
- Educating Suffolk's youth about the health risks associated with stimulant drinks.

This plan addresses the issue from an educational, medical and practical way without stifling business or infringing on anyone's constitutional rights.

These bills were approved, in spite of the industry's efforts to stop any legislation which included constant lobbying, letters, repeated phone calls. Political pressure was placed on legislators by calls to other elected officials, county leaders and even calls to the NYS governor's staff to stop the legislation.

Most of the industry's arguments against legislation were well-worn and repetitive. The same players showed up to testify, using the arguments as they had when the Suffolk County Legislature debated Legislator Nowick's resolutions in 2010. Their arguments against legislation include the following points with responses as numbered below include:

1. "Caffeine is a natural substance. It is safe. Why try to regulate it?" Poppies use to make heroin are also a natural substance but that does not make their use safe.
2. "FDA fully regulates energy drinks, their ingredients and labeling." Substances designated as "Food" products, have to list their exact ingredients but don't have to report adverse reactions or side effects. But dietary supplements don't have to list exact ingredients but must report adverse reactions. Most energy drinks are now regulated as foods.
3. "Some caffeine is safe for children, why limit their access to it." Although children can tolerate some caffeine there is no benefit to caffeine in a child's diet.

4. Many energy drinks contain as much caffeine as much as large cups of coffee why not ban or restrict coffee? Coffee has a considerably higher volume and is hot which slows the ingestion of caffeine.
5. Industry leaders insist repeatedly that they do not market their products to children and teens. When in fact, according to one pediatrician, Dr. Kwabena Blankson, "They market in places kids like to go—on their X-boxes, at the X-games . . ." This point can be broadened. Energy drink manufacturers market to children during cartoons, during sporting events, in video games and movies. Products are available everywhere children go, except for school but that change was recent and not welcomed by the industry. They send samples to minors using team rosters and market research. They hand out coupons and samples at concert venues. They sponsor teams, athletes, and popular video gamers. They give drinks trendy, cool names, put them in attractive packaging and offer appealing, desirable performance enhancement abilities. *There is overwhelming proof that there is direct marketing to children and adolescents.*
6. "Ingredients are considered safe." Yes, this may be the case when they are consumed individually but what they cannot prove is that their ingredients in combination are safe. Energy drinks often include, vitamins, supplements (Guarine, Taurine, Guarana) and other ingredients that potentiate stimulating effects of caffeine. If multiple drinks are consumed, the effects are multiplied. The AMA, with members across the Nation have expressed concern that these ingredients, taken together may not be safe for children under 19.
7. "There are warnings on the bottles or cans . . ." This labeling had been part of the compromise originally negotiated by my colleague two years prior!! *If the industry agrees that their "products are not intended for children, pregnant or nursing women or those sensitive to caffeine" then why allow them to market to children?*

Important Points to Consider

Potentially as many as 1 out of 100 children have underlying congenital heart anomalies that may go undetected but under the right circumstances in combination with stimulants and extreme physical activity like competing in a sport event, running or etc. may potentially cause heart arrhythmias or possibly death possibly after one ingestion of a normal serving of a energy drink.

Currently without caffeine caps of guidelines new products are being introduced to the market place upping the ante including highly concentrated caffeinated products like gum, patches, tongue tabs electronic cigarettes with no limits to caffeine concentration.

Energy/stimulant drinks can be a gateway to addiction to alcohol and drugs by altering vulnerable chemistry of the brain by starting a cycle of dependence.

There are some responsible members of the industry who do not do all of the above but do allow marketing divisions broad discretion to get their message out.

With the support of my colleagues in the Suffolk County Medical Society, I brought my resolution to annual convention of the New York State House of Delegates of the Medical Society of the State of New York. The bill was to temporarily ban the marketing of energy drinks to children until the FDA could investigate the products and deem them safe. It was approved overwhelmingly. A delegation from MSSNY brought the same resolution before the American Medical Association, where it was strengthened, changes were made and it was also approved.

In conclusion, my desire is to protect our kids. That is what this is about. I am going to paraphrase my colleague Legislator Lou D'Amaro, who summed up our debate so eloquently. . . . Our kids are bombarded by all kinds of advertising. Some things are worse than others. There is always a matter of degree, but the fact of the matter is that energy drinks, just by the name alone, are a misnomer because they don't give you energy. But, yet, that is the message that's being directed at our children, telling them that as we live in a more and more hectic world, and it becomes more and more difficult to find the time to do everything you want to do in a day, here's the quick solution. Have an energy drink, you'll feel great and you'll just keep on going.

It is even more egregious for athletes, kids in schools, kids that are in school playing, maybe even high school sports, to believe that energy drinks somehow will make you a better athlete, because they will not. But, yet, this industry insists on calling their products energy drinks. They are not energy drinks. They give you a caffeine high and a sugar high and then you crash. They reduce your performance and add to fatigue. We are talking about children. They should not be drinking caffeine no matter if the amount is equivalent to a cup of coffee. I will not advise any parents to give their child one cup of coffee, and never multiple cups. This is about

telling our children at a very young age that it's okay to drink these products because you're going to feel great. These seemingly benign stimulants can be a precursor and gateway to using other drugs and alcohol as teenagers look for that next and better high. For the vulnerable person, the jolt from caffeine or an energy complex, changes the chemistry, tricks the brain and leaves it seeking more chemical stimulation. If caffeine is stopped, the body and brain do experience withdrawal symptoms, no matter the quantity ingested. Hundreds of thousands of physicians across this nation, as indicated by the AMA resolution, agree that these products have the potential to harm our children. The deceptive marketing practices of the industry are placing children in peril, contributing to addiction cycles of those who are vulnerable and taking away parents' power to make educated decisions about what their children should and can ingest.

Please, consider restricting the marketing to children under 18 unless or until the products are proven to be safe and not habit forming. Also, let's embark on an education campaign to empower parents to make educated decisions for their children and even teach adults about the potential side effects they may experience as a result of choosing to indulge in these products.

Thank you for your time and attention to this matter. I am honored to have been given this opportunity. Thank you again.

BIOGRAPHY OF WILLIAM ROBERT SPENCER, JR.

Dr. William Robert Spencer, Jr. received his early education in Welch, West Virginia, a small town near Charleston. He was named a "West Virginia Scholar", graduated with honors from high school and went on to receive his higher education at Wesleyan University, Middletown, CT; Connecticut Missionary Baptist Association; and University of Connecticut School of Medicine, Farmington, CT. He moved on to St. Vincent's Hospital and Medical Center, New York City where he completed his Internship and Residency in Surgery. His residency in Otolaryngology was completed at New York Eye and Ear Infirmary, New York City and he studied at the University of Miami in Miami, FL under a Fellowship in Pediatric Otolaryngology in 1999–2000.

He is a Diplomate of the American Board of Otolaryngology, a Diplomate of the National Board of Medical Examiners, a Fellow of the American Academy of Pediatrics, and a Fellow of The American Academy of Otolaryngology Head and Surgery. He is a member of the Suffolk County Medical Society, and the American Medical Association and is licensed to practice in the State of Florida and the State of New York. In 2000 he started his own private practice, Long Island Otolaryngology & Pediatric Airway, P.C. at 25 E. Carver Street, Huntington, NY.

Dr. Spencer has been involved in research in various areas of his field at the University of Miami; New York Medical College in Valhalla, NY; New York Eye and Ear Infirmary in New York City; Wesleyan University, Middletown, CT; University of Connecticut Department of Pulmonology in Farmington, CT; and New England Nuclear Medicine Society where he was granted a fellowship for research in a particular area.

Dr. Spencer has at least 16 articles to his credit that have been published in Journals pertaining to his area of specialty, as well as chapters that have been contributed to books on the subject. He has made oral presentations in Texas; Washington, D.C.; Florida; New York; Ohio; Connecticut; and in Paris, France and Cancun, Mexico.

Academic Appointments include Stony Brook University, Department of Otolaryngology, Assistant Professor Voluntary Clinical Faculty; New York Eye and Ear Infirmary, Department of Otolaryngology, Associate Adjunct; Huntington Hospital, Department of Surgery/Otolaryngology, Attending Staff; Otolaryngology—Head and Neck Surgery Journal, San Antonio, TX, Editorial Review Panel; University of Miami, Department of Otolaryngology, Miami, FL, Clinical Instructor; Jackson Memorial, Department of Otolaryngology, Miami, FL, Attending Staff; Bascom Palmer Eye Institute, Department of Surgery, Miami, FL, Attending Staff.

In addition to being a West Virginia Scholar his awards and honors include West Virginia Bar Association Award, Leadership and Academic Excellence; Psi Upsilon Achievement Prize, Outstanding Community Service; University of Connecticut Surgical Scholar; Sigma Xi Research Honor Society, Outstanding Medical Research; J. Swift Hanley Award, New York Eye and Ear Infirmary, Excellence in Resident Research.

During his school years Dr. Spencer served as a Residential Health Advisor at Wesleyan University; Steward of Psi Upsilon Fraternity; Chemistry and Physics

Laboratory Instructor; Medical/Dental Student Government President; and an Anatomy Teaching Assistant. He also taught at the University of Miami

With his father, Rev. William Robert Spencer, Sr., as his role model Rev. Spencer, Jr. has been serving God since he was a youngster. At St. James Missionary Baptist Church where his father was Pastor, he served as Superintendent of Sunday School from 1978–1989 and also as Jr. Deacon and Lay Minister. It was there that he became a Licensed Minister in 1986. At Shiloh Missionary Baptist Church in Middletown, CT he served as their first Youth Pastor and expanded the Youth Ministry from 6 to 75 children. He served also as Assistant Pastor from 1986–1993. It was there that he became an Ordained Minister in 1993 and was accepted as such by The Connecticut Missionary Baptist Association. At Metropolitan Duane Methodist Church in New York City he attended services as Lay Minister and delivered the Sunday morning message periodically from 1995–2000. He has served as an Evangelist preaching at various worship services and revivals throughout the East Coast, by invitation, from 1986 to the present.

Rev. Spencer is a Licensed Private Pilot, having achieved that goal after his first year of college. In l987, combining his interest in flying and his compassion for children, he received some first-hand missionary experience when he flew, seated in the cockpit with the commercial pilot, to Haiti to deliver medicine, supplies, and food to the children of that country. There he donned the traditional red and white suit and played Papa Noel to thousands of children in streets, schools, and hospitals for the five days that he was there.

In 1997 Rev. Spencer began his affiliation with Huntington Hospital and when he asked employees there about a church that he might visit, he was referred to the little white church across the street, up on the hill. Once he visited Bethel, he decided to make it his church home. He was a member at Bethel for many years taking part regularly in morning Worship Services. He delivered the Sunday morning message periodically and was of great assistance to the pastor in whatever capacity he has been called upon to serve. Once a month there is a time devoted to "Children's Talk" and Rev. Spencer was called upon periodically to deliver that message, as well. He loves working with the children and has spoken to our YPD and also arranged for them to add Huntington Hospital to their Christmas caroling list last year.

He attended the A.M.E. Ministers' Institute, and completed his studies to become an Itinerant Elder in the African Methodist Episcopal Church. He conducts services in his home regularly and continues to minister to a modest congregation of the faithful.

Legislator William R. Spencer

This multi-talented gentleman now lives with his wife, Rachel, and three young children, Robbie and Hannah, and Ava in Centerport. He is committed to bettering the community in which he lives and has, accordingly, become active in the Town's political structure. He was elected to serve as the Suffolk County Legislator in the 18th Legislative District and is serving the second of his two-year term.

His freshman-year accomplishments are impressive. As the first physician to serve in the Suffolk County Legislature since its inception in 1960, he was selected to serve as the chairman of the Legislature's Health Committee. Working closely Commissioner James Tomarken of the Health Department, Legislator Spencer helped to streamline the department with a priority on maintaining good public health for all County residents.

Since January, 2012, Legislator Spencer sponsored more than 35 resolutions with almost 1/3 of them related to health and safety issues. One of the first was a request for money from a dedicated fund to improve the Wastewater Treatment Collection System in Northport thus ensuring that the beaches, harbors and fisheries become healthy again. Trying to find new and more efficient sewage treatment technologies has become another priority of his in an effort to protect our drinking water and health.

Over the years, it has been proven that the effects of secondhand smoke pose a serious threat to the health, safety and welfare of all citizens. It was difficult to understand why our County parks and beaches, which provide our residents with easy access to the beauty of nature and recreational activities, permitted smoking. Fortunately, a majority of his colleagues in the Legislature agreed and as a result of his sponsored resolution, smoking is no longer permitted there.

Legislator Spencer believes public education campaigns are also an effective vehicle for getting important messages out to our most vulnerable residents. Working with AT&T and Harborfields School District, he declared 9/19 "Don't Text and Drive Awareness Day" in Suffolk County and developed an assembly program to teach students that no text is worth dying for—"It can Wait!" Furthermore, he also intro-

duced legislation recently to establish "The Truth About Energy Drinks" public education campaign to increase awareness of the potentially dangerous side effects associated with caffeine toxicity.

Opiate addiction has become an epidemic among our young people on Long Island and overdoses are on the rise. Some estimates say we lose one resident per day to the horrendous effects of drug use. Narcan is a narcotic antagonist which prevents or reverses the effects of narcotics within minutes of being administered. Earlier this year, another legislator introduced legislation to pilot a Narcan program in three of our Suffolk County Police Precincts. This pilot program has already saved 42 lives. Seeing the abundant results of the trial program, he proposed a resolution to expand it to all of our precincts which passed unanimously. Narcan is now available to police emergency responders in the Second Precinct.

Super Storm Sandy, the looming fiscal cliff, and the bleak economy, have added dramatically to the burdens Suffolk County residents face. In his first year, he fought hard to hold the line on no tax increase in the General Fund and he continues to ensure taxpayers get the services they need and are paying for.

William R. Spencer, Jr. is a rare combination of scholar, medical doctor, active Reverend and Suffolk County Legislator and he allows these components to interact in his own life and in the lives of others with whom he comes in contact.

ATTACHMENT 1

Intro. Res. No. 1920–2012 Laid on Table 9/13/2012
Introduced by Legislators Spencer and Anker

RESOLUTION NO. 187–2013, ESTABLISHING "THE TRUTH ABOUT STIMULANT DRINKS" PUBLIC EDUCATION CAMPAIGN TO INCREASE AWARENESS OF SIDE EFFECTS ASSOCIATED WITH STIMULANT DRINK CONSUMPTION

WHEREAS, stimulant drinks are increasingly popular beverages, particularly among young people; and

WHEREAS, caffeine is not a source of energy but a stimulant and therefore subsequent reference will be made to "stimulant" drinks and not "energy" drinks.

WHEREAS, stimulant drinks can contain up to 800 milligrams of caffeine, the equivalent of eight cups of coffee, but manufacturers are not obligated to disclose such amounts to consumers; and

WHEREAS, stimulant drinks also contain a number of herbal supplements, including, but not limited to, ginkgo, guarana, taurine and St. John's Wort, with no requirement for manufacturers to report a drink's exact contents; and

WHEREAS, consumption of stimulant drinks has been associated with significant adverse health effects, including aggravating heart conditions, headaches, rapid heartbeat, nervousness, irritability, sleeplessness, dehydration, abnormal heart rhythms, and stomach upset; and

WHEREAS, the County of Suffolk should take all possible steps to increase public awareness of the health effects associated with consuming stimulant drinks; now, therefore be it

1st RESOLVED, that the Office of the Presiding Officer of the County Legislature shall conduct an annual "The Truth About Stimulant Drinks" campaign in high schools throughout the County of Suffolk, inviting students to participate in a contest creating a video public service announcement incorporating the student's interpretation on the negative health effects associated with consuming stimulant drinks; and be it further

2nd RESOLVED, that each Legislator shall send letters and a copy of the stimulant drink effects pamphlet, published pursuant to the 5th RESOLVED clause of this Resolution, to the Superintendents of public school districts, located within their pertinent legislative district, advising the school as to the contest; and be it further

3rd RESOLVED, that each Legislator shall judge entries made by high schools and recommend one (1) winner from each school as a finalist. A Legislator from each district shall then recommend to the Presiding Officer of the County Legislature one (1) public service announcement to represent their legislative district; and be it further

4th RESOLVED, that the deadline for submitting eligible public service announcements shall be May 1st of each year beginning with the year 2013; the Legislative Office of Budget Review shall then select the winning public service an-

nouncement, which shall be announced by the Presiding Officer at the first regularly scheduled meeting of the Legislature in June each year; and be it further

5th RESOLVED, that any student requesting to participate in said contest shall be furnished with a pamphlet from the Suffolk County Department of Health Services regarding energy drinks and the health effects of consuming same, as well as information from any other relevant organization dedicated to reducing the use of energy drinks by minors; and be it further

6th RESOLVED, that said pamphlet shall be disseminated by the County Department of Health Services no later than January 31st each year; and be it further

7th RESOLVED, that this Legislature, being the State Environmental Quality Review Act (SEQRA) lead agency, hereby finds and determines that this resolution constitutes a Type II action pursuant to Section 617.5(c)(20), (21) and (27) of Title 6 of the NEW YORK CODE OF RULES AND REGULATIONS (6 NYCRR) and within the meaning of Section 8–0109(2) of the NEW YORK ENVIRONMENTAL CONSERVATION LAW as a promulgation of regulations, rules, policies, procedures, and legislative decisions in connection with continuing agency administration, management and information collection, and the Suffolk County Council on Environmental Quality (CEQ) is hereby directed to circulate any appropriate SEQRA notices of determination of non-applicability or non-significance in accordance with this resolution.

DATED: March 19, 2013

APPROVED BY:

/s/ DENNIS M. COHEN
Chief Deputy County Executive of Suffolk County
Date: April 4, 2013

ATTACHMENT 2

Intro. Res. No. 1085–2013 Laid on Table 2/5/2013
Introduced by Legislators Spencer and Anker

RESOLUTION NO. 188–2013, ADOPTING LOCAL LAW NO. 16–2013, A LOCAL LAW TO PROTECT MINORS FROM DIRECT MAIL STIMULANT DRINK ADVERTISING AND SAMPLES

WHEREAS, there was duly presented and introduced to this County Legislature at a meeting held on February 5, 2013, a proposed local law entitled, "*A LOCAL LAW TO PROTECT MINORS FROM DIRECT MAIL STIMULANT DRINK ADVERTISING AND SAMPLES";* now, therefore be it

RESOLVED, that said local law be enacted in form as follows:

LOCAL LAW NO. 16–2013, SUFFOLK COUNTY, NEW YORK

A LOCAL LAW TO PROTECT MINORS FROM DIRECT MAIL STIMULANT DRINK ADVERTISING AND SAMPLES

BE IT ENACTED BY THE COUNTY LEGISLATURE OF THE COUNTY OF SUFFOLK, as follows:

Section 1. Legislative Intent.

This Legislature hereby finds and determines that so-called "energy drinks" are very popular, particularly among young people.

This Legislature also finds that these drinks contain very high amounts of caffeine, though the exact amounts are not disclosed by their makers as nutrition information.

This Legislature finds that caffeine is not a source of energy but a stimulant and, therefore, these beverages are more accurately described as "stimulant drinks" and are referred to as such in this law.

This Legislature finds that stimulant drinks also contain herbal supplements, vitamins and amino acids, including, but not limited to, guarana, taurine, vitamins B6 and B12, yerba mate, bitter orange, ginkgo, St. John's Wort and ginseng. The exact blend of these ingredients is not disclosed by manufacturers.

This Legislature determines that consumption of stimulant drinks by minors has been associated with hyperactivity, lack of concentration, poor nutrition and dental problems. Consumption of stimulant drinks can also cause significant adverse health effects, including: aggravating heart conditions, headaches, rapid heartbeat, nervousness, irritability, sleeplessness, dehydration, abnormal heart rhythms, and

stomach upset. These effects may be exacerbated in minors and occur after consuming smaller quantities of caffeine or other stimulants.

This Legislature notes that many stimulant drinks are labeled by their own manufacturers as "Not Recommended for Children".

This Legislature also finds that although there is general consensus that it is not advisable for minors to consume stimulant drinks, some manufacturers and distributors of stimulant drinks advertise their products at extreme sporting events, concerts, and in video games and gaming networks, all of which are popular with adolescents.

This Legislature further determines that some stimulant drink manufacturers provide free samples of their products at public events that attract young people; mail free samples of liquid and powdered stimulant drinks to minors at their homes; and provide coupons to minors for free or discounted samples of stimulant drinks.

This Legislature concludes that given the health risks associated with consumption of stimulant drinks by minors, it is reasonable and appropriate for the County of Suffolk to exercise its police powers to prohibit certain advertising and marketing practices that put stimulant drinks in the hands of minors.

Therefore, the purpose of this law is to prohibit the distribution of free samples of stimulant drinks or coupons for free or discounted stimulant drinks to minors within the County of Suffolk.

Section 2. Definitions.

As used in this law, the following terms shall have the meanings indicated:

"STIMULANT DRINK" shall mean a beverage or powdered drink mix that contains 75 or more milligrams of caffeine per 8 fluid ounces and generally includes a combination of other supplements such as methylxanthines, B vitamins, herbal ingredients and other ingredients which are advertised as being specifically designed to provide or improve energy.

"PERSON" shall mean any natural person, individual, corporation, unincorporated association, proprietorship, firm, partnership, joint venture, joint stock association or other entity or business organization of any kind.

Section 3. Prohibitions.

No person shall provide free samples of stimulant drinks or coupons for free or discounted stimulant drinks to any individual under the age of eighteen (18) in the County of Suffolk. This prohibition shall apply to the direct mailing of free samples or coupons for free or discounted stimulant drinks to County residents under the age of eighteen (18).

Section 4. Penalties.

A. Violation of this law shall be punishable by a civil fine of up to five hundred dollars ($500.00) for a first violation, with subsequent violations punishable by a fine of up to one thousand dollars ($1,000.00).

B. A civil penalty shall only be assessed by the Commissioner of the Department of Health Services following a hearing at which an alleged violator has the opportunity to be heard.

Section 5. Enforcement.

A. This law shall be enforced by the Department of Health Services.

Section 6. Authority to Promulgate Rules and Regulations.

The Commissioner of the Department of Health Services is hereby authorized and empowered to promulgate such rules and regulations as he or she deems necessary to implement this law.

Section 7. Applicability.

This law shall apply to actions occurring on or after the effective date of this law.

Section 8. Severability.

If any clause, sentence, paragraph, subdivision, section, or part of this law or the application thereof to any person, individual, corporation, firm, partnership, entity, or circumstance shall be adjudged by any court of competent jurisdiction to be invalid or unconstitutional, such order or judgment shall not affect, impair, or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph, subdivision, section, or part of this law, or in its application to the person, individual, corporation, firm, partnership, entity, or circumstance directly involved in the controversy in which such order or judgment shall be rendered.

Section 9. SEQRA Determination.

This Legislature, being the State Environmental Quality Review Act (SEQRA) lead agency, hereby finds and determines that this law constitutes a Type II action pursuant to Section 617.5(c)(20), (21), and/or (27) of Title 6 of the NEW YORK CODE OF RULES AND REGULATIONS (6 NYCRR) and within the meaning of Section 8–0109(2) of the NEW YORK ENVIRONMENTAL CONSERVATION LAW as a promulgation of regulations, rules, policies, procedures, and legislative decisions in connection with continuing agency administration, management and information collection. The Suffolk County Council on Environmental Quality (CEQ) is hereby directed to circulate any appropriate SEQRA notices of determination of non-applicability or non-significance in accordance with this law.

Section 10. Effective Date.

This law shall take effect on the sixtieth (60) day upon filing in the Office of the Secretary of State.

DATED: March 19, 2013

APPROVED BY:

/s/ STEVEN BELLONE
County Executive of Suffolk County

Date: April 19, 2013

After a public hearing duly held on April 2, 2013
Filed with the Secretary of State on May 3, 2013

ATTACHMENT 3

Intro. Res. No. 1086–2013 Laid on Table 2/5/2013
Introduced by Legislators Spencer and Anker

RESOLUTION NO. 189–2013, ADOPTING LOCAL LAW NO. 17–2013, A LOCAL LAW TO PROHIBIT THE SALE AND DISTRIBUTION OF STIMULANT DRINKS TO MINORS IN COUNTY PARKS

WHEREAS, there was duly presented and introduced to this County Legislature at a meeting held on February 5, 2013, a proposed local law entitled, *"A LOCAL LAW TO PROHIBIT THE SALE AND DISTRIBUTION OF STIMULANT DRINKS TO MINORS IN COUNTY PARKS";* now, therefore be it

RESOLVED, that said local law be enacted in form as follows:

LOCAL LAW NO. 17–2013, SUFFOLK COUNTY, NEW YORK

A LOCAL LAW TO PROHIBIT THE SALE AND DISTRIBUTION OF STIMULANT DRINKS TO MINORS IN COUNTY PARKS

BE IT ENACTED BY THE COUNTY LEGISLATURE OF THE COUNTY OF SUFFOLK, as follows:

Section 1. Legislative Intent.

This Legislature hereby finds and determines that the County of Suffolk is dedicated to protecting the health and safety of its residents, and pays special attention to children's health.

This Legislature further finds and determines that so-called "energy drinks" are very popular, particularly among young people.

This Legislature finds that these drinks contain very high levels of caffeine, though the exact amounts are not disclosed by their makers as nutrition information.

This Legislature finds that caffeine is not a source of energy but a stimulant and, therefore, these beverages are more accurately described as "stimulant drinks" and shall be referred to as such in this law.

This Legislature finds that in addition to caffeine stimulant drinks contain a variety of herbal supplements, vitamins and amino acids, such as guarana, taurine, vitamins B6 and B12, yerba mate, bitter orange, ginger, ginkgo, St. Johns Wort and ginseng.

This Legislature determines that consumption of stimulant drinks can cause significant adverse health effects: aggravating heart conditions, headaches, rapid heartbeat, nervousness, irritability, sleeplessness, dehydration, abnormal heart rhythms and stomach upset.

This Legislature also finds that consuming stimulant drinks can be particularly harmful to young people. Consumption of stimulant drinks may interfere with medications prescribed for certain conditions, including attention deficit disorder, allergies, asthma, and birth control pills.

This Legislature notes that many stimulant drinks are labeled by their own manufacturers as "Not Recommended for Children".

This Legislature further finds that given the health risks associated with the consumption of stimulant drinks by minors, it is reasonable and appropriate for the County of Suffolk to exercise its police powers to prohibit the sale and distribution of stimulant drink products at its own parks and beaches..

Therefore, the purpose of this law is to prohibit the sale or distribution of stimulant drinks to minors in County parks.

Section 2. Amendments.

Chapter 643 of the SUFFOLK COUNTY CODE is hereby amended as follows:

Chapter 643. PARKS AND PARK FACILITIES.

ARTICLE I. Rules and Regulations.

****

§ 643–2. Definitions.

As used in this article, the following terms shall have the meanings indicated:

****

PERSON—Any person, firm, partnership, association, corporation, company or organization of any kind.

STIMULANT DRINK—a beverage that contains 75 or more milligrams of caffeine per 8 fluid ounces and generally includes a combination of other supplements such as methylxanthines, B vitamins, herbal ingredients and other ingredients which are advertised as being specifically designed to provide or improve energy.

****

§ 643–4. Prohibited acts.

A. No person in a County park shall:

****

(25) sell or offer for sale, provide or otherwise distribute stimulant drinks to persons under the age of eighteen.

****

Section 3. Exemptions.

(A) This prohibition shall not apply to individuals who bring stimulant drinks into a County park solely for personal consumption.

(B) This law shall not apply to persons operating a concession in a County park who are expressly authorized by their agreement with the County of Suffolk to sell or distribute stimulant drinks.

Section 4. Future Concession Licenses

All concession licenses and license renewals entered into by the Suffolk County Department of Parks, Recreation and Conservation on or after the effective date of this law shall contain a provision barring the sale or distribution of stimulant drinks to persons under the age of eighteen.

Section 5. Applicability.

This law shall apply to all actions occurring on or after the effective date of this law.

Section 6. Severability.

If any clause, sentence, paragraph, subdivision, section, or part of this law or the application thereof to any person, individual, corporation, firm, partnership, entity, or circumstance shall be adjudged by any court of competent jurisdiction to be invalid or unconstitutional, such order or judgment shall not affect, impair, or invalidate the remainder thereof, but shall be confined in its operation to the clause, sen-

tence, paragraph, subdivision, section, or part of this law, or in its application to the person, individual, corporation, firm, partnership, entity, or circumstance directly involved in the controversy in which such order or judgment shall be rendered.

Section 7. SEQRA Determination.

This Legislature, being the State Environmental Quality Review Act (SEQRA) lead agency, hereby finds and determines that this law constitutes a Type II action pursuant to Section 617.5(c)(20), (21), and/or (27) of Title 6 of the NEW YORK CODE OF RULES AND REGULATIONS (6 NYCRR) and within the meaning of Section 8–0109(2) of the NEW YORK ENVIRONMENTAL CONSERVATION LAW as a promulgation of regulations, rules, policies, procedures, and legislative decisions in connection with continuing agency administration, management and information collection. The Suffolk County Council on Environmental Quality (CEQ) is hereby directed to circulate any appropriate SEQRA notices of determination of non-applicability or non-significance in accordance with this law.

Section 8. Effective Date.

This law shall take effect on the sixtieth (60th) day following its filing in the Office of the Secretary of State.

____ Underlining denotes addition of new language

DATED: March 19, 2013

APPROVED BY:

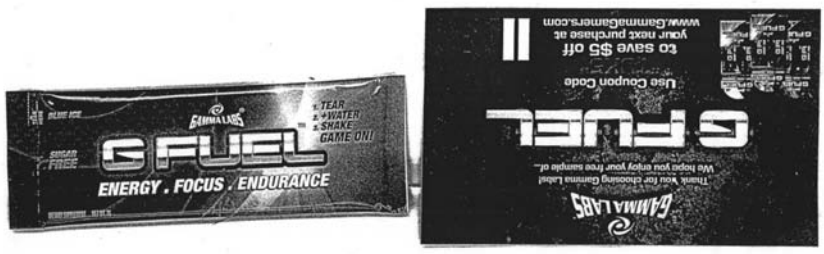
/s/ STEVEN BELLONE
County Executive of Suffolk County

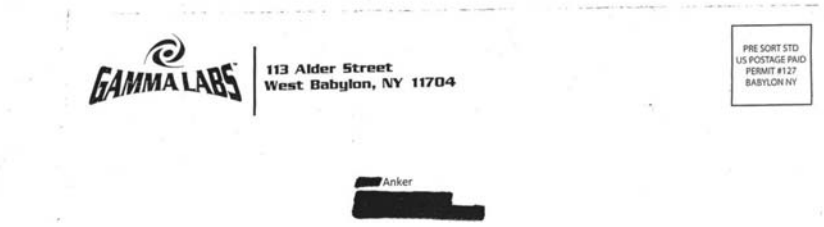
Date: April 19, 2013

After a public hearing duly held on April 2, 2013
Filed with the Secretary of State on May 3, 2013

ATTACHMENT 4

Copy of envelope and sample sent to Legislator Sarah Anker's 16-year-old son





Suffolk County Department of Health Services Brochure

What's So Bad About Caffeine?

Caffeine is a natural chemical found in many common foods and drinks, and in moderation it's not harmful to most people.

Caffeine is a stimulant and can be addictive.

It will stimulate your brain and central nervous system, making you more alert, and energetic.

But too much caffeine may lead to:

- ⇒ irritability
- ⇒ dangerously rapid or irregular heart beat
- ⇒ restlessness/ sleeplessness
- ⇒ excitability
- ⇒ dizziness
- ⇒ headaches
- ⇒ concentration lapses
- ⇒ stomach/intestine pain
- ⇒ dehydration

STEVEN BELLONE
SUFFOLK COUNTY EXECUTIVE

Suffolk County Department of Health Services

JAMES L. TOSKES, MD, MPH, MBA, MSW
Commissioner

Adding Alcohol to the mix...

If the side effects of energy drinks alone aren't bad enough, adding alcohol worsens the negative effects. Injuries and fatalities have occurred from dehydration, organ failure, coma-induced state, or car crashes due to false sense of sobriety.

The feeling of being drunk is reduced from the combination of stimulant and depressant.

The results of a study from Wake Forest, NC showed that students who consumed alcohol with energy drinks were twice as likely to:

- be hurt or injured
- require medical attention
- ride with an intoxicated driver
- be taken advantage of sexually
- take advantage of someone else sexually

In November of 2010, New York State banned the sale of alcoholic energy drinks.

References & Resources

- www.marininstitute.org
- www.fda.gov
- www.camy.org
  (The Center on Alcohol Marketing and Youth)
- www.cspinet.org
  (The Center for Science in the Public Interest)

SCDHS

Suffolk County Department of Health Services
Office of Health Education

What's in That Energy Drink and What Can it Do to You?

Fast Facts:

- Energy drinks are currently unregulated in the United States, and they don't all contain the same ingredients.
- The main ingredients in many of these drinks are sugar, herbal stimulants and large amounts of caffeine.
- The Food and Drug Administration (FDA) requires beverage manufacturers to list the presence of caffeine on the label, but not the amount of caffeine in the product.

Read on to find out more about these products.

You may be surprised to learn...

Can Sugar be That Bad?

Energy drinks high in **sugar** stimulate your nervous system quickly, which usually makes you feel more energetic at first.

Sugar causes your energy levels to come crashing down once it leaves the bloodstream. The person is left feeling more fatigued than they were to begin with.

If your drink contains high amounts of **sugar**, regular consumption may lead to dental health problems such as cavities.

Cane sugar and **fructose** can also have laxative effects.

And remember, **sugar** provides a lot of unwanted calories, and can lead to obesity and diabetes.

What About Other Ingredients?

In addition to caffeine and sugar, some energy drinks contain many ingredients which have not been tested for safety or effectiveness. Some may cause harmful side effects when consumed in high quantities or combinations.

Other Ingredients...

Creatine is an organic acid which causes muscles to draw water from the rest of your body. In energy drinks, it may cause greater dehydration.

Because **creatine** causes the muscles to hold water, many people who use it gain weight.

Overuse of **creatine** may contribute to:

- irregular heartbeat
- stomach pain
- nausea
- diarrhea
- muscle cramping

When taken in high doses, there is concern that **creatine** could harm the kidneys, liver, or heart.

Ginseng root is widely used in traditional Asian Medicine. It mainly acts as a stimulant.

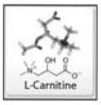
The most common side effects of **ginseng** over-use are headache, sleep disturbance and gastro-intestinal problems.

Guarana is a stimulant which acts just like caffeine. Its side effects can include:

- insomnia
- trembling
- anxiety
- rapid heartbeat
- frequent urination
- hyperactivity

L-Carnitine is an amino acid which the body naturally makes. Possible side effects of overusing it are:

- insomnia
- headaches
- restlessness
- nausea/vomiting
- diarrhea
- rapid heartbeat
- increase in blood pressure



ATTACHMENT 5

COUNTY OF SUFFOLK—DEPARTMENT OF HEALTH SERVICES
Great River, NY, December 3, 2012

Hon. Presiding Officer WILLIAM J. LINDSAY,
Suffolk County Legislature,
Hauppauge, NY.

Dear Presiding Officer,

The Suffolk County Board of Health has been concerned about energy drinks for the past two years beginning when the Suffolk County Legislature requested the Board of Health to review proposed legislation regarding limiting the sale of energy drinks and promoting educational activities. In 2011, recommendations were made to the you as Presiding Officer of the Suffolk County Legislature.

Since 2011, the energy drink industry has continued and expanded its marketing of its products to young adults and children. Recent alleged associations of deaths related to energy drinks and the increase in emergency room visits due to illnesses attributed to these beverages has added to the concerns of the Board.

The use of energy drinks for children and young adults sends a negative nutritional message to this population. The use of these supplements to compensate for fatigue, lack of energy and to experience higher levels of physical and mental functioning is not only inappropriate for this population but may be dangerous to their health.

As a result, the Board recommends the following:

1. Regulation at the Federal level to limit the access to energy drinks by restricting the sale to individuals less than 19 years of age.
2. Regulation at the county (Suffolk) level to limit the access to energy drinks by restricting the sale to individuals less than 19 years of age.
3. Promote a multi-component educational program for the schools, the general public and especially parents so they are aware of the ingredients in energy drinks and their potential dangers, including the total caffeine content from all sources.
4. Labeling of all the ingredients in energy drinks and their components, in milligrams per container (mg/container), should be required on the packages. The label should be on the front of the can, easily visible by consumers, utilizing a color that stands out and a font size that is easily distinguishable.
5. Consideration should be given to the placement of energy drinks in commercial establishments.
6. Propose a local law requiring that a WARNING sign be posted at the point of sale of energy drinks in all establishments in Suffolk County.

The warning is the following:

ENERGY DRINKS WARNING

CONSUMPTION OF ENERGY DRINKS MAY BE HARMFUL TO CHILDREN, PREGNANT WOMEN AND PEOPLE SENSITIVE TO CAFFEINE. ENERGY DRINKS MAY AGGRAVATE HEART CONDITIONS, CAUSE HEADACHES, RAPID HEARTBEAT, DEHYDRATION, DISRUPTION OF SLEEP PATTERNS AND CONCENTRATION, AND IN RARE CASES, DEATH. THESE EFFECTS MAY BE MAGNIFIED IN CHILDREN UNDER AGE 19. ENERGY DRINKS MAY CONTAIN LARGE QUANTITIES OF CAFFEINE AND OTHER INGREDIENTS, INCLUDING HERBAL SUPPLEMENTS, AMINO ACIDS AND VITAMINS. THE INGREDIENTS IN THESE DRINKS MAY INTERFERE WITH CERTAIN PRESCRIPTION MEDICATIONS FOR ATTENTION DEFICIT DISORDER, ASTHMA, ALLERGIES, BIRTH CONTROL AND OTHER CONDITIONS. MIXING ENERGY DRINKS WITH ALCOHOL OR OTHER DRUGS MAY POSE ADDITIONAL HEALTH RISKS.

7. Ban the distribution of samples of energy drinks in Suffolk County to individuals less than 19 years of age.

Respectfully submitted,

JAMES L. TOMARKEN, MD,
MPH, MBA, MSW, FRCPC, FACP,
Commissioner & Chair Health Committee.

cc: Honorable William Spencer, MD, Chair, Health Committee, Suffolk County Legislature

ATTACHMENT 6

MEDICAL SOCIETY OF THE STATE OF NEW YORK 2013 HOUSE OF DELEGATES

Report of: Reference Committee on Public Health and Education

Presented by: Daniel Young, MD, Chair

Mister Speaker and Members of the House of Delegates:

Your Reference Committee recommends the following consent calendar for acceptance:

RECOMMENDED FOR ADOPTION

(1) Resolution 154—Require Third Party Payer Coverage of Follow Up Exams for Patients with Dense Breast Tissue

(2) Resolution 163—Committees of Specialty Societies to Eliminate Health Care Disparities

(3) 2013 Public Health & Education Sunset Report

RECOMMENDED FOR ADOPTION AS AMENDED OR SUBSTITUTED

(4) Resolution 152—Violent Acts of Youth and Violent Acts Upon Youth

(5) Resolution 153—Immunization in Hamilton County Children

(6) Resolution 155—Legislation Requiring 90 day Supply of all Chronic Medications

(7) Resolution 157—Oppose Legislature Approval of Smoked Medical Marijuana

(8) Resolution 158—Farm Use of Antibiotics

(9) Resolution 159—Regulation of Tattoo Procedures

(10) Resolution 160—Statewide "Don't Text and Drive Initiative"

[(11) Resolution 161—Banning Marketing and Sale of "High-Energy/Stimulant Drinks" to Children Under the Age of 19**]**

(12) Resolution 162—STI Elevation Myocardial Infarction

(13) Resolution 165—Opposition to Mandatory Maintenance of Certification

And

Resolution 168—Opposition of Mandatory Maintenance of Certification (MOC)

(14) Resolution 166—Opposition to Maintenance of Licensure

And

Resolution 167—Opposition to Maintenance of Licensure

(15) Resolution 169—Transparency and Accountability for Specialty Boards and MOC

(16) Resolution 170—Expanding Participation of Asthmatic Children in Physical Education Or Exercise Programs

(17) Resolution 171—Public Health Implications of Natural Gas Extraction Using Hydraulic Fracturing

(18) Resolution 172—Partner Delivered Therapy for STIs

(19) Resolution 173—Sudden Closure of Residency Programs

RECOMMENDED NOT FOR ADOPTION

(20) Resolution 150—Pathology Specimen

Reference Committee agrees with the intent of the sponsor, but did believe it was more appropriate for MSSNY to encourage that the county medical societies become involved in these types of initiatives. Additionally, your Reference Committee offered up the substitute resolution to more accurately reflect the current status of the federal, state and local efforts on this matter. Your Reference Committee recommends adoption of the substitute resolution.

(11) Resolution 161 Banning Marketing and Sale of "High-Energy/Stimulant Drinks" to Children Under the Age of 19

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that the *FOLLOWING SUBSTITUTE RESOLUTION 161 BE ADOPTED IN LIEU OF RESOLUTION 161:*

RESOLVED, that the Medical Society of the State of New York support a temporary ban on the marketing of "high stimulant/caffeine drinks" to children/adolescents under the age of 18; and be it further

RESOLVED, that the temporary marketing ban for children/adolescents under age 18 be kept in place until such time as the scientific evidence regarding the possible adverse medical affects that stimulant drinks may have on children and adolescents is determined; and be it further

RESOLVED, that a copy of this resolution be forwarded to the American Medical Association for consideration at its next House of Delegates meeting.

RECOMMENDATION B:

Mister Speaker, your Reference Committee recommends that *A TITLE CHANGE BE MADE TO RESOLUTION 161 TO READ AS FOLLOWS;*

Banning Marketing and Sale of "High-Energy/Stimulant Drinks" to Children/Adolescents Under the Age of 18

Resolution 161 says that in recognizing the adverse health effects which "stimulant" drinks can have on children and adolescents, including but not limited to insomnia, agitation, anxiety, cardiac arrhythmias, and even death, that the Medical Society of the State of New York support legislation or regulation to place a temporary ban on the marketing of these "high stimulant/caffeine drinks" at youth-related sporting activities, as well as prohibiting the sale and direct distribution by industry of these stimulant drinks to children under the age of 19; and that the above ban, sales, and direct distribution prohibition be kept in place until such time as the scientific evidence regarding the adverse medical affects these stimulant drinks have on children and adolescents have been disproven.

Your Reference Committee heard testimony in support of this resolution. Your Reference Committee applauds the effort of Suffolk County physician and county legislator, Dr. William Spencer, in bringing this matter forward to the House of Delegates. Your Reference Committee agreed that this resolution is meritorious, but felt that the substitute resolution more clearly defined a more balanced approach until such time as the FDA acts on these drinks. The FDA is currently investigating the health consequences of energy drinks. The substitute also provides MSSNY with a position should such legislation come before the NYS Legislature for action. There were some questions received in testimony regarding the age, and your Reference Committee agrees that 18 is the appropriate age for the temporary marketing ban. The resolution also request that a copy of the resolution be forwarded to the AMA for its consideration as this is also a Federal issue as the FDA is involved. Your Reference Committee believes the substitute creates an appropriate balance and urges adoption.

Your Chairperson is grateful to the Committee members, namely David M. Jakubowicz, MD; Sonya Sidhu-Izzo, MD; Brian Meagher, MD; David Y. Zhang, MD and Stephen Coccaro, MD.

Your Reference Committee Chairman also wishes to express his appreciation Pat Clancy, Barbara K. Ellman, and Terri Holmes for their help in preparation of this report.

Respectfully submitted,

Daniel Young, MD, Chair; David M. Jakubowicz, MD, Bronx County; Sonya Sidhu-Izzo, MD, Schenectady County; Brian Meagher, MD, Cautauqua County; David Y. Zhang, MD, Queens County; Stephen Coccaro, MD, Suffolk County

ATTACHMENT 7

L-Carnitine is an amino acid which the body naturally makes. Possible side effects of overusing it are:

- insomnia
- headaches
- restlessness
- nausea/vomiting
- diarrhea
- rapid heartbeat
- increase in blood pressure

Adding Alcohol to the mix worsens the effects...

Injuries and fatalities have occurred from dehydration, organ failure, coma-induced state, or car crashes due to false sense of sobriety.

The feeling of being drunk is reduced from the combination of stimulant and depressant.

The results of a study from Wake Forest, NC showed that students who consumed alcohol with energy drinks were twice as likely to:

- be hurt or injured
- require medical attention
- ride with an intoxicated driver
- be taken advantage of sexually
- take advantage of someone else sexually

In November of 2010, New York State banned the sale of alcoholic energy drinks.

Reminder to SADD advisors... In order to communicate and share upcoming events, the SCDHS, Office of Health Education needs to keep your contact information up to date. If you have not already done so, please e-mail Bonnie Anderson at: bonnie.anderson@suffolkcountyny.gov with an e-mail address you routinely check.

References & Resources

- www.marininstitute.org
- www.fda.gov
- www.camy.org (The Center on Alcohol Marketing and Youth)
- www.cspinet.org (The Center for Science in the Public Interest)

SADD Newsletter: *Decisions*

Suffolk County Department of Health Services
Division of Preventive Medicine

Featured in This Issue:
What's in Those Energy Drinks?

FALL 2012

Fast Facts About Energy Drinks:

- Energy drinks are currently unregulated in the United States.
- The main ingredients in many of these drinks are sugar, herbal stimulants and large amounts of caffeine.
- The Food and Drug Administration (FDA) requires beverage manufacturers to list the presence of caffeine on the label, but not the amount of caffeine in the product.

STEVEN BELLONE
SUFFOLK COUNTY EXECUTIVE

Suffolk County Department of Health Services

JAMES L. TOMARKEN, MD, MPH, MBA, MSW
Commissioner

What's So Bad About Caffeine?

Caffeine is a natural chemical found in many common foods and drinks, and in moderation it's not harmful to most people.

Caffeine is a stimulant and can be addictive. It will stimulate your brain and central nervous system, making you more alert, and energetic.

But too much caffeine may lead to:

⇒ irritability
⇒ dangerously rapid or irregular heart beat
⇒ restlessness/ sleeplessness
⇒ excitability
⇒ dizziness
⇒ headaches
⇒ concentration lapses
⇒ stomach/intestine pain
⇒ dehydration
⇒ excess sweating

Can Sugar be That Bad?

Energy drinks high in **sugar** stimulate your nervous system quickly, which usually makes you feel more energetic at first.

Your energy levels come crashing down once sugar leaves the bloodstream. You are left feeling more fatigued than you were to begin with.

If your drink contains high amounts of **sugar**, regular consumption may lead to dental health problems such as cavities.

Cane sugar and **fructose** can also have laxative effects.

And remember, **sugar** provides a lot of unwanted calories, and can lead to obesity and diabetes.

What About Other Ingredients?

In addition to caffeine and sugar, some energy drinks contain many ingredients which have not been tested for safety or effectiveness. Some may cause harmful side effects when consumed in high quantities or combinations. Some of these ingredients include:

> Guarana *> Creatine*
> Gensing *> L-carnitine*

Guarana is a stimulant which acts just like caffeine. Its side effects can include:

- insomnia
- trembling
- anxiety
- rapid heartbeat
- frequent urination
- hyperactivity

Ginseng root is widely used in traditional Asian Medicine. It mainly acts as a mental stimulant. The most common side effects of **ginseng** over-use are headache, sleep disturbance and gastro-intestinal problems.

Creatine is an organic acid which causes muscles to draw water from the rest of your body. In energy drinks, it may cause greater dehydration.

Because **creatine** causes the muscles to hold water, many people who use it gain weight.

Overuse of **creatine** may contribute to:

- irregular heartbeat
- stomach pain
- nausea
- diarrhea
- muscle cramping

When taken in high doses, there is concern that **creatine** could harm the kidneys, liver, or heart.

ATTACHMENT 8

(14) RESOLUTION 409 – BANNING MARKETING AND SALE OF "HIGH-ENERGY/STIMULANT DRINKS" TO CHILDREN/ADOLESCENTS UNDER THE AGE OF 18

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that Resolution 409 be amended by deletion in the first resolve to read as follows:

RESOLVED, That our American Medical Association support a ~~temporary~~ ban on the marketing of "high stimulant/caffeine drinks" to children/adolescents under the age of 18 (New HOD Policy); and be it further

RECOMMENDATION B:

Mr. Speaker, your Reference Committee recommends that Resolution 409 be amended by deletion of the second resolve.

~~RESOLVED, That the temporary ban on marketing for children/ adolescents under age 18 be kept in place until such time as the scientific evidence regarding the possible adverse medical affects that stimulant drinks may have on children and adolescents is determined. (New HOD Policy)~~

RECOMMENDATION C:

Mr. Speaker, your Reference Committee recommends that Resolution 409 be adopted as amended.

HOD ACTION: Resolution 409 adopted as amended.

Resolution 409 asks that our American Medical Association (1) support a temporary ban on the marketing of "high stimulant/ caffeine drinks" to children/ adolescents under the age of 18 and (2) that the temporary ban on marketing for children/adolescents under age 18 be kept in place until such time as the scientific evidence regarding the possible adverse medical effects that stimulant drinks may have on children and adolescents is determined.

Your Reference Committee received favorable testimony for this resolution. Testimony acknowledged the increasing number of health events presenting in emergency departments as a result of energy drink consumption, particularly by youth. It was noted that our AMA already has policy in support of a ban on marketing "beverages that contain alcohol and caffeine and other additives to produce alcohol energy drinks" (D-60.973) to youth, and felt this resolution was in line with current policy. Your Reference Committee is very concerned about the potential effects of marketing such products to an impressionable, young audience, and therefore amended the language in the first resolve to take a stronger position with the removal of the word "temporary". The second resolve was deleted to avoid confusion and redundancy. Your Reference Committee recommends that Resolution 409 be adopted as amended.

(15) RESOLUTION 410 – PHYSICIANS AND THE PUBLIC HEALTH ISSUES OF GUN SAFETY

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that Resolution 410 be amended by addition and deletion to read as follows:

RESOLVED, That our American Medical Association request that the U.S. Surgeon General develop a report and campaign aimed at reducing gun-related injuries and deaths ~~by one half by the year 2020, and that such report and~~

ATTACHMENT 9

MONSTER ENERGY DRINK STORE DISPLAY

Senator BLUMENTHAL. Mr. Sacks?
Thank you.

STATEMENT OF RODNEY SACKS, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, MONSTER BEVERAGE CORPORATION

Mr. SACKS. Thank you.

Good afternoon, Mr. Chairman, Ranking Member Thune, and members of the Committee. My name is Rodney Sacks, and I am the Chairman and Chief Executive Officer of Monster Beverage Corporation.

Monster is and has always been committed to ensuring that all of the ingredients in its energy drinks, including caffeine, are safe and in regulatory compliance for their intended use. The formulations of our energy drink line have been and continue to be overseen by our chief scientific officer, a professor of pharmacology at a major university who has been part of our team from the outset.

Indeed, we have extensively and continually analyzed the scientific and medical literature relating to the safety of caffeine and other ingredients in our products. Since 2002, more than 9 billion cans of Monster energy drinks have been sold and safely consumed worldwide, including 8 billion in the United States.

The safety of caffeine and other ingredients in Monster energy drinks is well established by an overwhelming body of generally accepted scientific literature published by reputable third parties, including major governmental and other authoritative, scientific, and medical bodies.

Mr. Chairman, the level of caffeine in Monster energy drinks is about half the caffeine per ounce of coffeehouse-brewed coffee. Monster Energy's 16-ounce cans, which represent more than 80 percent of Monster energy drinks sold, contain approximately 160 milligrams of caffeine from all sources per can.

A 16-ounce medium cup of coffee from Starbucks contains approximately 330 milligrams of caffeine, more than twice as much. Dunkin' Donuts, Caribou, Pete's, Seattle's Best, all have more caffeine per ounce than Monster, as do many iced coffees and other cold coffee beverages.

The presence of energy drinks in the U.S. marketplace has not increased the consumption of caffeine by teenagers and young adults. Consumption data from the USDA shows that caffeine consumption in the U.S. has remained relatively stable over the past decade, despite the introduction of energy drinks.

These conclusions have been confirmed by subsequent research, including a study commissioned by the FDA in 2009–2010, which showed that teens and young adults, ages 14 to 21, do not consume high amounts of caffeine and that their source of caffeine is mainly from coffee, soft drinks, and tea. The FDA study noted a prior survey that concluded that only about 0.9 percent of 14-to 21-year-olds are regular energy drinkers.

A study released this year by researchers at Penn State University further confirmed that coffee, tea, and soft drinks are the most significant caffeine sources in younger age groups, not energy drinks.

While the company believes that its products are safe for all consumers, the company does not market Monster to children and has

never done so. From Monster's introduction in 2002, the company has included an advisory statement on every can that Monster is not recommended for children. Monster was the first energy drink company to ever include such an advisory statement in its labeling.

Monster considers the primary demographic of consumers of its energy drinks to be young adults, primarily males. And its brand initiatives and brand image are directed towards this population. The company does not focus its brand initiatives on young teenagers. To do so would undermine the credibility of the brand image in the eyes of young adults.

It has long been the company's policy not to sample Monster at K through 12 schools. The company has also told its network of independent distributors to refrain from any marketing activities for Monster that target children or K through 12 schools.

The company sponsors a variety of athletes, music artists, events, tours, and shows to promote Monster. The company's primary marketing involves motor sports that are aligned with Monster's brand image, such as NASCAR, Supercross, Motocross, MotoGP, off-road truck racing, Formula 1, and the Dakar Rally. The primary demographic for such motor sports is adults, not children or young teenagers.

For 2012, one of the company's most significant marketing commitments was to NASCAR, which has a median viewership age of over 50. Other sponsorships include smaller commitments to action sports, such as athletes who compete in events like the X Games. The average age of X Games viewers is in the early 30s.

The company shares your commitment to protecting the health and safety of consumers, including children and teenagers. The company strives to be a responsible corporate citizen, and we believe that our marketing practices reflect that.

I appreciate the opportunity to appear before you today to discuss the safety and marketing of our products.

Thank you. I look forward to any questions you may have.

[The prepared statement of Mr. Sacks follows:]

PREPARED STATEMENT OF RODNEY SACKS, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, MONSTER BEVERAGE CORPORATION

Good afternoon, Mr. Chairman, Ranking Member Thune, and members of the Committee. My name is Rodney Sacks, and I am the Chairman and Chief Executive Officer of Monster Beverage Corporation. Based in Corona, California, Monster Beverage Corporation and its subsidiaries is a leading marketer and distributor of alternative beverages and energy drinks, including Monster Energy® ("Monster"). I appreciate the opportunity to appear before you today to discuss the safety of our products and our marketing practices.

Monster Beverage Corporation traces its origins to the 1930s, when it was founded as a business selling fresh juices under the brand name Hansen's® in Los Angeles. In 1992, a group headed by my co-founder Hilton Schlosberg and I acquired the struggling Hansen's® brand. We have worked hard to grow the business, and we are proud of what the Company has accomplished. Today the Company employs more than 2,100 people, including more than 1,200 full-time workers, and supports the employment of tens of thousands more at packaging plants, warehouses, distributors and retailers all across the country. *Forbes* magazine has named us the "Best Small Company" in America and the Company has similarly been recognized by other prestigious publications and institutions over the years.

Monster is, and has always been, committed to ensuring that all of the ingredients in its energy drinks (including caffeine) are safe and in regulatory compliance for their intended use. The formulations of our energy drink line have been and continue to be overseen by our chief scientific officer, a professor of pharmacology at

a major university who has been part of our team from the outset. Indeed, we have extensively and continually analyzed the scientific and medical literature relating to the safety of caffeine and other ingredients in our products.

Since 2002, more than 9 billion cans of Monster energy drinks have been sold and safely consumed worldwide, including 8 billion in the United States. The safety of caffeine and other ingredients in Monster energy drinks is well established by an overwhelming body of generally accepted scientific literature published by reputable third parties, including major governmental and other authoritative scientific and medical bodies. This body of literature includes literally hundreds of studies on caffeine over many decades, as caffeine is one of the most widely studied ingredients in the food supply. Attached to this statement is a letter submitted to the FDA on behalf of the Company discussing the relevant scientific literature and the safety of Monster energy drinks.

The level of caffeine in Monster energy drinks is about *half* the caffeine per ounce of coffeehouse brewed coffee. Monster Energy's 16-ounce cans, which represent more than 80 percent of Monster energy drinks sold, contain approximately 160 mg of caffeine from all sources per can. A 16-ounce medium cup of coffee from Starbucks contains approximately 330 mg of caffeine—more than twice as much. See Attachment 1. Dunkin' Donuts, Caribou, Peet's, Seattle's Best—all have more caffeine per ounce than Monster, as do many iced coffees and other cold coffee beverages. See Attachments 2–3.

The presence of energy drinks in the U.S. marketplace has not increased the consumption of caffeine by teenagers and young adults. Consumption data from the USDA shows that caffeine consumption in the U.S. has remained relatively stable over the past decade, despite the introduction of energy drinks. These conclusions have been confirmed by subsequent research, including a study commissioned by the FDA in 2009–2010, which showed that teens and young adults (ages 14–21) do not consume high amounts of caffeine and that their source of caffeine is mainly from coffee, soft drinks and tea. The FDA study noted a prior survey that concluded that only about 0.9 percent of 14–21 year olds are regular energy drink consumers. A study released this year by researchers at Penn State University on behalf of International Life Sciences Institute of North America (ILSI) further confirmed that coffee, tea, and soft drinks are the most significant caffeine sources in younger age groups—not energy drinks. The study also concluded that the percentage of energy drink users is low (less than 10 percent) and that these energy drinks are minor contributors to overall caffeine intakes in all age groups.

While the Company believes that its products are safe for all consumers, I would like to emphasize that the Company does *not* market Monster to children, and has never done so. From the time that Monster was first introduced into the marketplace in 2002, the Company has included an advisory statement on every can that Monster is not recommended for children. The label currently states: "*CONSUME RESPONSIBLY: Not recommended for children, people sensitive to caffeine, pregnant women or women who are nursing.*"[1] Monster was the first energy drink company to ever include such an advisory statement in its labeling, and years later, many peer companies have done the same.

Monster considers the primary demographic of consumers of its energy drinks to be young adults (primarily males), and its brand initiatives and brand image are directed toward this population. The Company does not focus its brand initiatives on young teenagers. To do so would undermine the credibility of the brand image in the eyes of young adults. It has long been the Company's policy not to sample Monster at K–12 schools. The Company has also told its network of independent distributors to refrain from any marketing activities for Monster that target children or K–12 schools.

Like many other popular food and beverage companies, the Company sponsors a variety of athletes, music artists, events, tours, and shows to promote Monster. The Company's primary marketing involves motor sports that are aligned with Monster's brand image, such as NASCAR, Supercross, Motocross, MotoGP, off-road truck racing, Formula 1 racing, and the Dakar Rally. The primary demographic for such motor sports is young adults over the age of 18, not children or young teenagers. For 2012, one of the Company's most significant marketing commitments was to NASCAR, which typically attracts an older population of viewers and attendees, by sponsoring one of its leading teams. Other sponsorships include smaller commitments to action sports, such as athletes who compete in events like the X Games. The X Games is open to athletes and spectators that span a broad range of ages,

[1] The original label was amended a few years ago to include the reference to women who are nursing.

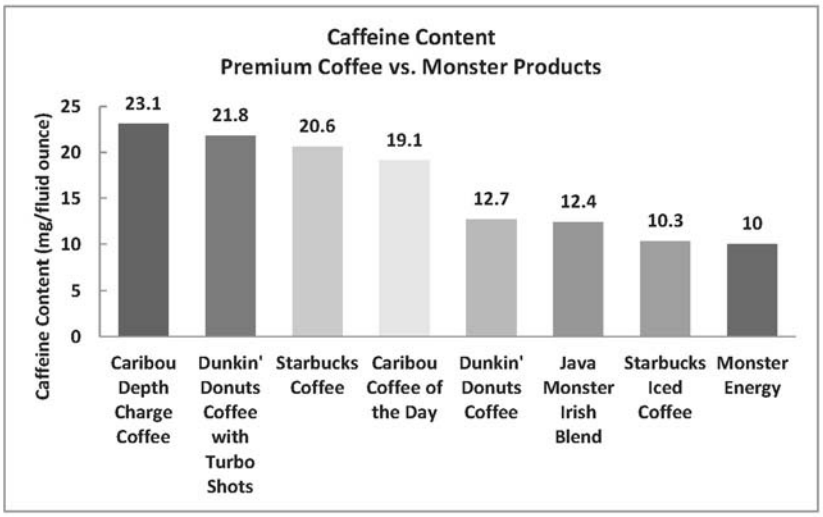
but is primarily attended or watched by persons who are 18 years of age or older. As reported by Nielsen, the average age of X Games viewers is in the early thirties.

The Company shares your commitment to protecting the health and safety of consumers, including children and teenagers. The Company strives to be a responsible corporate citizen, and we believe that our marketing practices reflect that. I appreciate the opportunity to appear before you today to discuss the safety and marketing of our products, and also your willingness to review objectively and in an evidence-based manner the body of scientific literature and other information we have provided to the Committee.

Thank you. I look forward to any questions you may have.

ATTACHMENT 1

ATTACHMENT 2



ATTACHMENT 3

Table 1. Caffeine Content of Select Foods Available in the U.S.

Product	Amount	mg of Caffeine[1]	mg of Caffeine per fl. oz. or per oz.
Caribou Depth Charge	16 fl. oz.	370	23.1
Dunkin' Donuts with Turbo Shots	20 fl. oz.	436	21.8
Starbucks Coffee (Grande/Medium)	16 fl. oz.	330	20.6
Caribou Coffee of the Day	16 fl. oz.	305	19.1
Panera Frozen Mocha	16.5 oz.	267	16.2
Dunkin' Donuts Coffee (Medium)	14 fl. oz.	178	12.7
Starbucks Iced Coffee	16 fl. oz.	165	10.3
Pepsi Max	12 fl. oz.	69	5.8
Mountain Dew (Regular or Diet)	12 fl. oz.	54	4.5
Mountain Dew Big Gulp	52 fl. oz.	234	4.5
Brewed tea	8 fl. oz.	30-80	3.75
Coca-Cola, Coke Zero, or Diet Pepsi	12 oz.	35	2.9
Mio (by Kraft)	1 squirt (1/2 tsp.)	60 per serving; 1080 per 1.62 fl. oz. bottle	
Hershey's Special Dark Chocolate Bar	1.45 oz.	31	21.4
Ben & Jerry's Coffee Heath Bar Crunch Ice Cream	8 oz.	84	10.5
Ben & Jerry's Coffee Flavored Ice Cream	8 oz.	68	8.5

Table 2. Caffeine Content of Energy Drinks Available in the U.S.

Energy Drink	Can Size (oz.)	Caffeine Per Serving (mg)	Caffeine Per Container (mg)[2]	Caffeine (mg) per oz.
Amp Energy (by Pepsi)	16	71	142	8.9
Red Bull	8.4	80-83	80-83	9.5-9.9
Monster Energy	16	80	160	10
Rockstar	16	80	160	10
Full Throttle (by Coca-Cola)	16	100	200	12.5
NOS Energy (by Coca-Cola)	16	112	224	14

[1] Source: *Caffeine Content of Food & Drugs*, Center for Science in the Public Interest ("CSPI") (Dec. 2012), http://www.cspinet.org/new/cafchart.htm, and public industry information including www.cariboucoffee.com. This chart includes values from the CSPI chart currently on the website, as well as previous versions of the page.

[2] Source: *The Buzz on Energy-Drink Caffeine*, CONSUMERREPORTS.ORG (Dec. 2012), http://www.consumerreports.org/cro/magazine/2012/12/the-buzz-on-energy-drink-caffeine/index.htm; *Caffeine Content of Food & Drugs*, CENTER FOR SCIENCE IN THE PUBLIC INTEREST (CSPI) (Dec. 2012), http://www.cspinet.org/new/cafchart.htm; and public industry information.

ATTACHMENT 4

COVINGTON & BURLING LLP
Washington, DC, July 29, 2013

MARGARET A. HAMBURG, MD
Commissioner of Food and Drugs,
Food and Drug Administration,
Silver Spring, MD.

RE: MONSTER BEVERAGE CORPORATION RESPONSE TO THE LETTER BY ARRIA, ET AL.

Dear Dr. Hamburg:

This letter reflects the response of Monster Beverage Corporation (Monster or the Company) to the March 19, 2013, letter (the Letter) to you from 18 healthcare professionals and researchers of various backgrounds (the Authors) concerning the safety of caffeine as an ingredient in energy drinks.[1] Monster fully endorses the American Beverage Association's (ABA's) response to the Letter but has also prepared its own response to provide additional information specific to the Company's products, to address some of the points in greater detail, and to reinforce the evidence-based response of the ABA documenting the safety and regulatory compliance of caffeine in energy drinks. We hope this information is useful to FDA as the agency considers the evidence regarding the safety of energy drinks and other caffeinated foods and beverages.

I. Introduction

Monster is committed to ensuring that the caffeine and all ingredients in its energy drinks are safe and in regulatory compliance for their intended use. Indeed, Monster has extensively analyzed and continues to analyze the scientific and medical literature relating to the safety of caffeine and other ingredients in its products, and has done so since prior to the formulation and initial marketing of Monster Energy® Drinks. Contrary to the assertion of the Authors that "the best available scientific evidence demonstrates a robust correlation between the caffeine levels in energy drinks and adverse health and safety consequences, particularly among children, adolescents, and young adults,"[2] the wealth of peer-reviewed published scientific and medical literature, including studies conducted by governmental and other authoritative bodies and data on consumption of caffeine from energy drinks and other sources, establishes that caffeine in energy drinks is both safe and generally recognized as safe (GRAS) for its intended use in energy drinks.

This body of literature includes literally hundreds of studies on caffeine over many decades, as caffeine is one of the most widely studied ingredients in the food supply and is certainly not new, novel, or unknown. Regrettably, the Authors appear to have focused primarily on their own research in characterizing the "best available scientific evidence," rather than on this overarching body of well-established literature, as nearly a third of the articles cited in the Letter were drafted by the Authors themselves.[3] The articles cited by the Authors stand at odds with the large and reputable body of scientific and medical literature confirming the safety of caffeine at the level at which it is used in Monster Energy Drinks (and most other energy drink brands). Monster therefore takes this opportunity to summarize that full body of reliable scientific and medical literature establishing the safety and GRAS status of caffeine in its energy drinks.

It is also helpful to put these issues into context. Energy drinks are not new, nor have they suddenly emerged on the marketplace. Tens of billions of energy drinks have been sold and safely consumed worldwide for more than 25 years, and have been marketed in the United States since 1997. Since 2002, more than 9 billion cans of Monster Energy products alone have been sold globally, of which more than 8 billion have been sold in the United States. Moreover, energy drinks are subject to ample regulatory oversight and review. Food safety authorities in Europe, where energy drinks were first marketed in 1987, have evaluated the safety of energy drinks on numerous occasions over the course of more than a decade and concluded they

[1] Letter from Amelia M. Arria, Ph.D., *et al.,* to the Honorable Margaret A. Hamburg, M.D., Commissioner, FDA at 1 (Mar. 19, 2013) (Letter).

[2] *Id.*

[3] A significant limitation of the Letter is the fact that the greater part of the Authors' expertise, as evidenced by their professional biographies and peer-reviewed publications, lies in behavioral-related aspects of consumption of caffeine/energy drinks combined with alcohol (such as addiction and risk-taking) and in prevention of childhood obesity. The Authors with cardiology expertise do not appear to have expertise (*i.e.,* few if any studies or publications) on the cardiovascular effects of caffeine/energy drink consumption.

are safe. The FDA has likewise been actively evaluating the safety of energy drinks for a number of years and has not identified evidence establishing a cause for concern. This significant history of safe consumption of so many billions of servings of energy drinks, in conjunction with the wealth of scientific evidence supporting the safety of caffeine at the levels used in these products, negates speculative allegations of potential harm from energy drinks.

II. Monster Energy Drinks Are Not "High" in Caffeine, and Contain Half The Caffeine of Starbucks Coffee

At the outset, it is important to clarify that Monster Energy Drinks are not "high" in caffeine, contrary to the assertion in the Letter that energy drinks contain "high levels of added caffeine."[4] The amount of caffeine in Monster Energy Drinks is comparable to standard brewed coffee and other foods, and is about *half* the amount of caffeine found in the same volume of premium coffee such as Starbucks (Table 1 and Figure 1). Monster Energy Drinks sold in cans 8 ounces or larger generally contain approximately 10 mg of caffeine (from all sources) per ounce. The typical 16-ounce Monster Energy can, which represents more than 80 percent of Monster Energy Drinks sold, contains approximately 160 mg of caffeine from all sources (including guarana, which contributes only approximately 2 mg caffeine per 16-ounces)—half the caffeine contained in a medium cup of Starbucks coffee. This amount is comparable to, and in some cases, lower than, the caffeine in other major energy drink brands (Table 2).

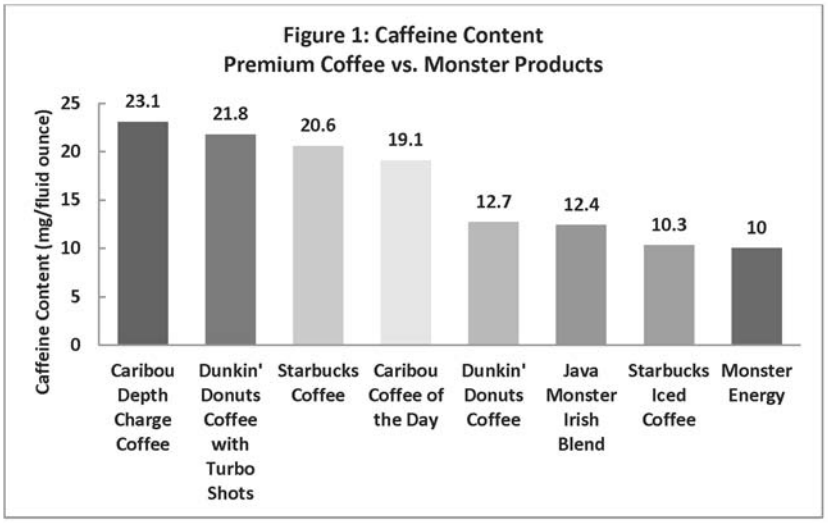


Table 1.—Caffeine Content of Select Foods Available in the U.S.

Product	Amount	Caffeine (mg)[5]	Caffeine (mg) per fl. oz. or per oz.
Caribou Depth Charge	16 fl. oz.	370	23.1
Dunkin' Donuts with Turbo Shots	20 fl. oz.	436	21.8
Starbucks Coffee (Grande/ Medium)	16 fl. oz.	330	20.6
Caribou Coffee of the Day	16 fl. oz.	305	19.1
Panera Frozen Mocha	16.5 oz.	267	16.2
Dunkin' Donuts Coffee (Medium)	14 fl. oz.	178	12.7

[4] *See, e.g.,* Letter at 1.

Table 1.—Caffeine Content of Select Foods Available in the U.S.—Continued

Product	Amount	Caffeine (mg)[5]	Caffeine (mg) per fl. oz. or per oz.
Starbucks Iced Coffee	16 fl. oz.	165	10.3
Pepsi Max	12 fl. oz.	69	5.8
Mountain Dew (Regular or Diet)	12 fl. oz.	54	4.5
Mountain Dew Big Gulp	52 fl. oz.	234	4.5
Brewed tea	8 fl. oz.	30–80	3.75
Coca-Cola, Coke Zero, or Diet Pepsi	12 oz.	35	2.9
Mio (by Kraft)	1 squirt (1/2 tsp.)	60 per serving; 1080 per 1.62 fl. oz. bottle	
Hershey's Special Dark Chocolate Bar	1.45 oz.	31	21.4
Ben & Jerry's Coffee Heath Bar Crunch Ice Cream	8 oz.	84	10.5
Ben & Jerry's Coffee Flavored Ice Cream	8 oz.	68	8.5

Table 2.—Caffeine Content of Energy Drinks Available in the U.S.

Energy Drink	Can Size (oz.)	Caffeine Per Serving (mg)	Caffeine Per Container (mg)[6]	Caffeine (mg) per oz.
Amp Energy (by Pepsi)	16	71	142	8.9
Red Bull	8.4	80–83	80–83	9.5–9.9
Monster Energy	16	80	160	10
Rockstar	16	80	160	10
Full Throttle (by Coca-Cola)	16	100	200	12.5
NOS Energy (by Coca-Cola)	16	112	224	14

As shown in Table 1 and Figure 1, numerous foods and beverages contain caffeine at levels comparable to or greater than that in Monster Energy Drinks (and many other brands). These foods have a long history of safe consumption in the U.S. and globally by persons of all age groups. It is therefore clear that energy drinks do not introduce new or alarming levels of caffeine into American diets. While the Letter states that "many energy drinks and related products containing added caffeine exceed the caffeine concentration of even the most highly caffeinated coffee,"[7] the data in Table 1 and Figure 1, showing the caffeine content of coffee, and in Table 2, which reflects approximately 95 percent of the range of caffeine content in the energy drink category, make clear that this statement is not correct.

To provide consumers with additional information about caffeine content and to dispel false assertions that Monster Energy Drinks are "high" in caffeine, Monster Energy Drink labels produced beginning in the spring of 2013 declare the total caffeine content from all sources. Contrary to the Letter's assertion that energy drinks fail to disclose caffeine content, most energy drink brands now bear a declaration of caffeine content on their labels, on both a per-serving and a per-container basis. This caffeine declaration is in addition to the advisory statements that have ap-

[5] Source: *Caffeine Content of Food & Drugs,* Center for Science in the Public Interest ("CSPI") (Dec. 2012), *http://www.cspinet.org/new/cafchart.htm,* and public industry information including *www.cariboucoffee.com.* This chart includes values from the CSPI chart currently on the website, as well as previous versions of the page.

[6] Source: *The Buzz on Energy-Drink Caffeine,* CONSUMERREPORTS.ORG (Dec. 2012), *http://www.consumerreports.org/cro/magazine/2012/12/the-buzz-on-energy-drink-caffeine/index.htm; Caffeine Content of Food & Drugs,* CENTER FOR SCIENCE IN THE PUBLIC INTEREST (CSPI) (Dec. 2012), *http://www.cspinet.org/new/cafchart.htm;* and public industry information.

[7] Letter at 2.

peared for years on Monster Energy Drinks directing consumers to consume the drinks responsibly and advising that the products are not recommended for children, pregnant or nursing women, or people sensitive to caffeine. These advisory statements convey meaningful information to help consumers enjoy Monster Energy Drinks safely and responsibly. In contrast, coffee marketers generally include no such advisories regarding consumption on their products.

The Authors of the Letter suggest a distinction between "naturally occurring" caffeine in coffee and "added" caffeine, implying that "added" caffeine is somehow different and more problematic.[8] There is no scientific basis for this assertion. The caffeine molecules of "added" caffeine and "naturally occurring" caffeine are chemically identical, and the body metabolizes "added" caffeine, from any source, in the same way that it metabolizes "naturally occurring" caffeine in foods and beverages. Moreover, Monster's leading products contain 100 percent natural caffeine derived from coffee beans.

Importantly, food manufacturers like Monster who add caffeine to their products can control the caffeine content of their foods to a far greater extent than producers or marketers of food in which caffeine is "naturally occurring." Monster can ensure with a high degree of precision that its products contain the amount of caffeine declared on their labels. By contrast, the caffeine content of coffee products varies widely due to many factors, such as brewing method, origin and growing conditions of the bean, degree of roasting, and other attributes. Indeed, one study found that the caffeine content of one specific coffee (Starbucks Breakfast Blend) at a single coffee shop varied by hundreds of milligrams (from 259 to 564 mg in a 16-oz cup) over the course of six consecutive days.[9]

The Authors also distinguish energy drinks from coffee by saying that "coffee is typically served hot, tastes bitter, and is consumed slowly by sipping. By contrast, energy drinks are typically carbonated, sweetened drinks that are served cold and consumed more rapidly."[10] No data are offered to support these statements, which are selective characterizations that fail to account for the fact that many, if not most, consumers sweeten their coffee and add milk and drink it quickly enough to avoid it becoming cold. Perhaps even more relevant in the context of the Authors' focus on children and adolescents, these statements do not account for cold or iced coffee beverages, which are typically sweetened and are quite popular among younger consumers. The volume of liquid in energy drinks is also self-limiting. With energy drinks containing about half the caffeine content of premium coffee on a mg/oz basis (see Table 1 and Figure 1), even if a consumer took twice as long to drink coffee as he or she takes to drink an energy drink, the amount of caffeine delivered in a given time period would be the same.

Moreover, the unproven assumption that energy drinks are consumed in a considerably shorter time than coffee is not clinically significant. Given the pharmacokinetic parameters of caffeine, oral administration of equal doses of caffeine over a short window (five minutes, for example) as opposed to a longer window (15 minutes, for example) would have a negligible effect on serum levels.[11] Further, the human body absorbs, distributes, metabolizes and excretes (ADME) caffeine in the same manner whether it is delivered to the stomach cold or hot.[12] For example, one study conducted specifically to examine any differences in the absorption and subjective effects of caffeine from coffee vs. cold cola found no such effects.[13] This randomized, double-blind, placebo-controlled within-subjects study compared the absorption and subjective effects of 400 mg caffeine from coffee and cola (as well as capsules) and found no differences in peak caffeine absorption, time to peak absorption, and subjective effects of caffeine from the cola vs. coffee vehicle. This study confirms earlier research concluding that temperature does not influence caffeine absorption.

In sum, the foregoing data and information document that Monster Energy Drinks are not "high" in caffeine content, and there is no meaningful difference between the caffeine in coffee or other foods and the caffeine in energy drinks.

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[8] *See* Letter at 2.

[9] R.R. McCusker *et al., Caffeine Content of Specialty Coffees,* 27 J. ANALYTICAL TOXICOLOGY 520, 522 (2003).

[10] Letter at 2.

[11] *See* M. Arnaud, *Pharmacokinetics and Metabolism of Natural Methylxanthines in Animal and Man,* METHYLXANTHINES, 200 HANDBOOK OF EXPERIMENTAL PHARMACOLOGY 33, 35–41 (B. Fredholm ed., 2011).

[12] M.J. Arnaud, *The Pharmacology of Caffeine,* 31 PROGRESS IN DRUG RESEARCH 273, 276–77 (1987).

[13] A. Liguori *et al., Absorption and Subjective Effects of Caffeine from Coffee, Cola and Capsules,* 58 PHARMACOLOGY BIOCHEMISTRY AND BEHAVIOR 721 (1997).

III. Consumption Data Confirm that Children and Adolescents Are Not Frequent Consumers of Energy Drinks or Caffeine

Having established that Monster Energy Drinks are not "high" in caffeine content and do not expose consumers to caffeine in a manner that is meaningfully different from coffee, we next discuss the consumption data demonstrating the relative contribution of energy drinks to the total caffeine intake of children, adolescents, and adults. These consumption data, including from studies performed or sponsored by the U.S. government, show that consumption of energy drinks by younger consumers is low and has not increased their overall caffeine intake. Therefore, the availability of energy drinks and the limited consumption of these food products by younger people is simply not a cause for alarm.

U.S. caffeine consumption data obtained from the United States Department of Agriculture (USDA) National Health and Nutrition Examination (NHANES) surveys shows that caffeine consumption in the U.S. has remained essentially stable over the past decade. Data from NHANES show that caffeine intake remained steady across all age groups from 2001–2010 despite the growth of the market for energy drinks and caffeinated water during this time. In direct contrast to the allegations of the Authors, the level of caffeine consumption for children and young adults has remained stable or *decreased* between 2001–2010, despite the availability of energy drinks (Table 3 and Figure 2).

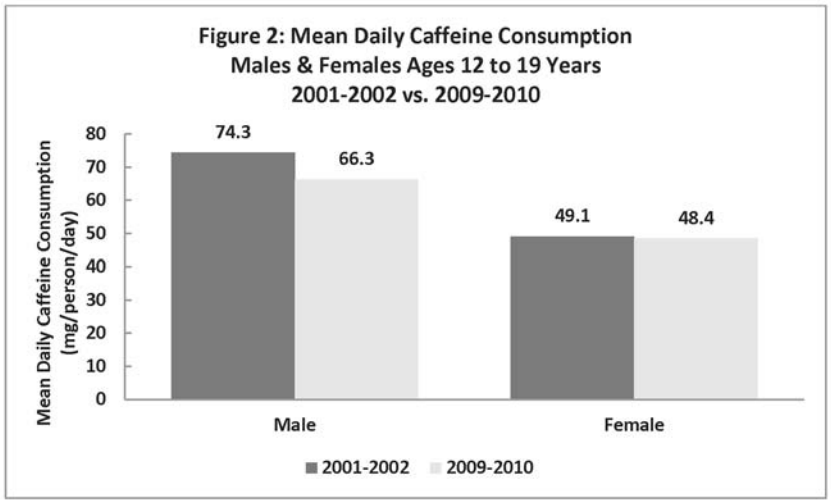

Table 3.—Caffeine Intakes From Beverages and Foods (NHANES 2001–2010) *

Age (years)	Caffeine (mg)/person			
	2001–2002 [1]	2005–2006 [2]	2007–2008 [3]	2009–2010 [4]
Males				
2–5	15.2	8.4 ± 0.72	7.8 ± 0.80	6.0 ± 0.70
6–11	26.1	19.7 ± 2.74	29.9 ± 3.59	18.2 ± 1.78
12–19	74.3	69.5 ± 6.70	73.6 ± 10.18	66.3 ± 11.12
20–29	151.9	133.4 ± 14.46	139.6 ± 14.39	124.0 ± 13.82
30–39	215.0	201.1 ± 12.21	187.8 ± 18.29	187.9 ± 18.79
40–49	240.1	263.6 ± 14.78	259.6 ± 20.99	253.3 ± 22.34
50–59	243.0	295.6 ± 26.51	273.4 ± 22.40	282.0 ± 19.41
60–69	203.8	228.0 ± 16.17	228.3 ± 17.81	220.5 ± 15.75
70 and over	160.1	156.9 ± 12.81	162.7 ± 8.23	174.8 ± 15.93
20 and over	207.7	216.1 ± 8.23	211.0 ± 10.78	208.6 ± 10.70
Females				
2–5	12.3	6.9 ± 0.90	8.9 ± 1.63	5.7 ± 0.56
6–11	23.0	17.0 ± 1.26	19.0 ± 3.29	16.1 ± 0.99
12–19	49.1	46 6 ± 4.18	60.4 ± 4.40	48.4 ± 4.28
20–29	91.4	82.2 ± 8.14	105.8 ± 13.35	107.6 ± 7.62
30–39	168.9	165.2 ± 19.3	153.5 ± 15.04	155.8 ± 12.22
40–49	190.0	219.8 ± 10.24	194.4 ± 11.96	168.8 ± 12.22
50–59	190.6	225.3 ± 15.33	207.2 ± 32.17	186.1 ± 15.95
60–69	153.0	163.7 ± 19.05	180.7 ± 17.96	166.8 ± 14.61
70 and over	118.5	120.8 ± 7.61	139.1 ± 10.39	121.9 ± 11.93
20 and over	153.4	165.3 ± 4.91	163.8 ± 8.51	152.2 ± 7.79
Males and females				
2 and over	142.1	149.8 ± 5.27	148.8 ± 7.44	142.2 ± 6.33

* Data are reported as mean error *per* individual (*per capita*) by gender and age in United States people 2 years and over (excluding breast-fed children) unless indicated otherwise.
[1] No standard errors were reported. Does not include separate food codes for energy drinks.
[2] Includes separate food codes for one brand of energy drinks and a general food code for "Energy Drink".
[3] Includes separate food codes for ten different brands of energy drinks and a general food code for "Energy Drink".
[4] Includes separate food codes for ten different brands of energy drinks and a general food code for "Energy Drink".

In addition, the results of a study commissioned by FDA (the Somogyi study) confirm the NHANES consumption data. The Somogyi study results show that caffeine consumption in the U.S. has remained "relatively stable at approximately 300 milligrams per person per day (mg/p/d), despite the entry of 'energy drinks' into the market place."[14] The study results also confirm that U.S. consumers have not significantly modified their caffeine consumption patterns since the appearance of energy drinks on the market. As an FDA representative commented, "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."[15]

Based on the Federal data, it is clear that adolescents do not consume high amounts of caffeine. The Somogyi study reported that "teens and young adults (14–21 years of age) consume, at the mean, approximately one-third (or about 100 mg/p/d) the amount of caffeine as adults, and that their caffeine consumption is mainly from coffee, soft drinks, and tea."[16] Adolescent caffeine consumption also has remained relatively stable since 2001, *i.e.*, before Monster Energy Drinks were marketed.[17] FDA therefore concluded that "'energy drinks' contribute a small portion of the caffeine consumed, even for teens."[18]

With regard to adolescent and young adult energy drink consumption, the Somogyi study cited a survey ending in February 2010 of 2,000 nationally representative households, which concluded that 0.9 percent of 14–21 year old individuals are

[14] Letter from Michele Mital, Acting Associate Commissioner for Legislation, FDA, to the Honorable Richard J. Durbin, United States Senate at 4 (Nov. 21, 2012) ("FDA November 2012 letter"), *citing* L. Somogyi, CAFFEINE INTAKE BY THE U.S. POPULATION (September 2009, rev'd Aug. 2010) ("Somogyi").
[15] Letter from Jeanne Ireland, Assistant Commissioner for Legislation, FDA, to the Honorable Richard J. Durbin, United States Senate, at 2 (Aug. 10, 2012) ("FDA August 2012 letter").
[16] FDA November 2012 letter at 4, *citing* Somogyi, *supra* note 14.
[17] Somogyi, *supra* note 14, at 48, Table 26; *see also* Figure 2.
[18] FDA November 2012 letter at 4.

"regular energy drinkers."[19] Somogyi assumed that 2 percent of the entire population older than 10 years of age are "regular consumers" of energy drinks, though "regular consumers" was not defined. Somogyi suggested that "[r]eliable consumption data for habitual energy drinkers are unavailable" for any age group.[20] The study assumed that the 2 percent of the general population estimated to consume energy drinks consume about 1.55-16 fluid oz. servings per day (or approximately 24.8 fluid oz. per day).[21] This amount would yield caffeine exposures that are well within those accepted as safe in the published scientific literature and in statements of governmental and other authoritative bodies, as discussed herein.

These consumption data have been further confirmed by additional recent studies examining caffeine consumption in the U.S. and Canada. Researchers at Penn State University conducted a large study (over 37,000 participants) examining beverage caffeine intake across the U.S. on behalf of the International Life Sciences Institute of North America (ILSI).[22] Like NHANES and Somogyi, the researchers found that Americans consume the bulk of their caffeine from coffee and soft drinks, rather than from energy drinks. They concluded, "Coffee was the primary contributor to caffeine intakes in *all* age groups combined, but a more significant contributor in adults (>18 yrs.)."[23] The study further observed, "Carbonated soft drinks and tea beverages were also significant caffeine sources, particularly in the younger age groups."[24] Specifically with respect to energy drinks, the researchers determined, "The percentage of energy drink users was low (<10 percent) and these beverages were minor contributors to overall caffeine intakes in *all* age groups."[25] The researchers found that out of all caffeine consumers, coffee drinkers consume the most caffeine, with the highest daily mean average ingested by adults aged 50 to 64 years (223 mg/day). Only 4 percent of caffeine consumers reported consuming energy drinks. Teenagers (ages 13 to 17) in the 90th percentile of caffeine consumption ingest their caffeine from coffee at a far greater level than they do from energy drinks—132.9 milligrams/day from energy drinks versus 223.7 milligrams/day from coffee. This survey, like the NHANES data and Somogyi report, confirms that coffee is the primary source of caffeine in the U.S. for consumers of all ages, not energy drinks. As discussed above, caffeine from energy drinks presents no new or different effects from caffeine in coffee.

Researchers have found similar results when studying Canadian consumption patterns. A 2010 through 2011 survey of more than 60,000 Quebecois teens, aged 13 to 17, found 83.8 percent of teens aged 13 to 17 rarely or never consumed energy drinks, with only 1.5 percent consuming them daily (Figure 3).[26] A 2012 study in Quebec, Canada further confirms these trends, as it found that out of 10,000 teenagers (aged 12 to 17) surveyed, 93 percent reported that they rarely or never consumed energy drinks as compared to only 1 percent of participants who consumed them daily.[27]

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[19] Somogyi, *supra* note 14, at 61; Somogyi assumed that 2 percent of the entire population older than 10 are "regular consumers" of energy drinks, though "regular consumers" was not defined.

[20] *Id.* at 2.

[21] Somogyi, *supra* note 14, at 61.

[22] D.C. Mitchell *et al., Beverage Caffeine Intakes in the U.S., Presented at Experimental Biology,* American Society for Nutrition Meeting (Apr. 22, 2013).

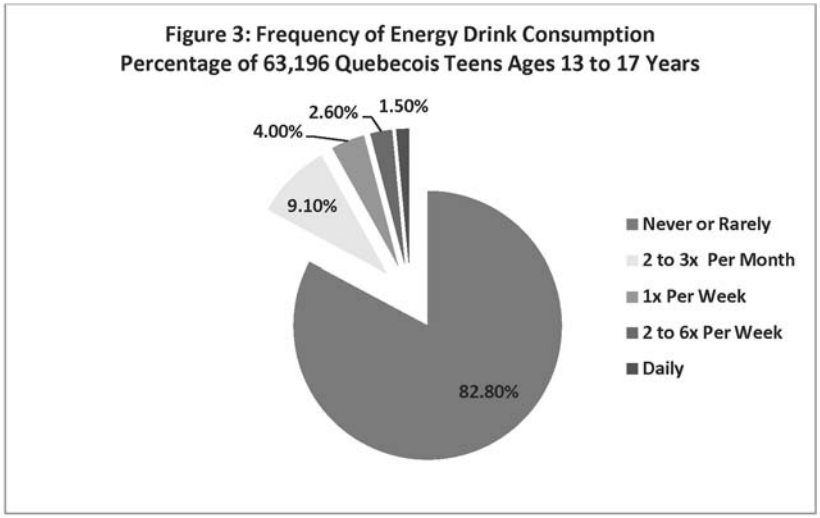
[23] *Id* (emphasis added).

[24] *Id.*

[25] *Id* (emphasis added).

[26] *See* L. PICA ET AL., INSTITUT DE LA STATISTIQUE DU QUEBEC, L'ENQUETE QUEBECOISE SUR LA SANTE DES JEUNES DU SECONDAIRE 2010–2011, VOLUME 1 (2012), *http://www.stat.gouv.qc.ca/publications/sante/pdf2012/EQSJS_tome1.pdf.*

[27] J. H., RESEAU DU SPORT ETUDIANT DU QUEBEC, JUNK FOOD MARKETING SURVEY: 10,000 QUEBEC TEENAGERS SPEAK OUT (2012), *http://rseq.ca/media/27863/rapport_d_enquete-anglais_final.pdf.*



A 2012 study conducted at the request of the European Food Safety Authority ("EFSA Study") observed similar trends in children and adolescents in the European Union ("EU"), where energy drinks have been marketed for at least a decade longer than in the United States.[28] The EFSA Study found that 68 percent of adolescents (defined as consumers ages 10–18) consumed at least one energy drink in 2012, although energy drink contribution to their total caffeine exposure was limited. For adolescents who identified themselves as energy drink consumers, just 23.5 mg, or 12.7 percent, of their total average daily caffeine intake came from energy drinks; with "high chronic energy drink consumers," this level rose to only 75.08 mg caffeine, or 15.7 percent of the total daily caffeine intake.

For children (defined as consumers ages 3–10) who were energy drink consumers, mean total caffeine exposure from all sources for energy drink consumers and high chronic energy drink consumers was 51.38 milligrams/day and 90.24 milligrams/day respectively. For each group, their total caffeine intake was primarily from sources other than energy drinks. Accordingly, as in the United States, children and adolescents in the EU receive the majority of their daily caffeine from a source other than energy drinks, and their total daily caffeine intakes remain within levels accepted as safe.

These robust and recent consumption data from governmental and other sources, reflecting tens of thousands of consumers surveyed, belie the allegations of the Authors suggesting that adolescents are regular consumers of high amounts of energy drinks. First, the Authors conflate consumption by adolescents and young adults, stating, for example, that "65 percent of energy drink consumers are 13- to 35-year-olds" and that "[M]ore recent reports show that 30 to 50 percent of adolescents and young adults consume energy drinks."[29] Such statistics provide no information

[28] S. Zucconi et al, External Scientific Report: Gathering Consumption Data on Specific Consumer Groups of Energy Drinks (European Food Safety Authority (EFSA) Supporting Publications 2013).

[29] Letter at 1–2. The Authors cite one of their own articles to suggest that 30 percent to 50 percent of adolescents and young adults consume energy drinks. S. Seifert *et al., Health Effects of Energy Drinks on Children, Adolescents, and Young Adults,* 127 PEDIATRICS 511 (2011). The levels of consumption cited in that report do not provide any insight, however, into regular consumption. One 2007 report cited by Seifert found that 28 percent to 34 percent of teens and young adults reported "regularly consuming" energy drinks but did not define "regular consumption." Another, a German study published in 1996, referred to consumption "regularly but at a rate of < 1 can per week." *Id.* That study also found that 53 percent of adolescents had "tasted" energy drinks, 24 percent drank <1 8 oz. can per week, and 3 percent drank 1 to 7 such cans per week. *Id.* at 514. That study concluded that all young people in Germany knew about energy drinks but actually consume them moderately, and prefer cola drinks. B. Viell *et al., New Caffeinated Beverages: A Pilot Survey of Familiarity and Consumption by Adolescents in North-Rhine Westphalia and Berlin and Considerations of Consumer Protection* [in German], 35 Z. ERNÄHRUNGSWISS 378–386 (1996). While Seifert asserts that "[m]ost children in the study consumed energy drinks in moderation but a small group consumed extreme amounts," that "small

about consumption by adolescents alone, while the NHANES, Somogyi, and ILSI data specifically document that adolescents' caffeine consumption from energy drinks is low. The Authors' statement that "35 percent of eighth graders and 29 percent of both tenth and twelfth graders consumed an energy drink during the past year"[30] reflects, at most, only that such consumers tried an energy drink and says nothing about caffeine exposure from energy drinks among this population. The Authors' statement that "18 percent of eighth graders reported using one or more energy drinks every day"[31] is simply at odds with the rest of the survey literature and it is unclear how the cited survey defined "energy drinks" for the young survey respondents,[32] if the term "energy drinks" was defined at all.

In sum, the consumption data, including from studies performed or sponsored by the U.S. government, show that consumption of energy drinks by younger consumers is low and has not meaningfully increased their overall caffeine intake. The caffeine contributed to the diet by energy drinks does not push consumption of caffeine above the levels documented to be safe in the wealth of scientific and medical literature, as addressed below.

IV. The Wealth of Published, Peer-Reviewed Scientific and Medical Literature Establishes the Safety of Caffeine at Levels Delivered by Energy Drinks

Caffeine is one of the most widely studied ingredients in the food supply, and has been the subject of clinical and other research for decades. Caffeine levels significantly higher than those reasonably contributed by Monster Energy Drinks have been documented to be safe in the published literature, including up to 600 mg per day in the Institute of Medicine (IOM) study described below.[33] Specifically, the weight of the scientific and medical literature demonstrates, contrary to the Authors' assertions in the Letter, that caffeine does *not* cause cardiovascular complications or seizures in healthy people, and that it is virtually impossible for a healthy person to consume a fatal dose of caffeine from food or beverages.

A. Cardiovascular Effects

The Authors allege that several adverse cardiac effects are associated with consumption of energy drinks, such as elevated blood pressure, altered heart rates, and severe cardiac events. In support of their conclusions, the Authors cite only eight studies, five of which were authored by the Authors, one of which concluded only that consumption of energy drinks before or during exercise "might be linked" to an increased risk for myocardial ischemia.[34]

In stark contrast, several renowned, peer-reviewed studies and a number of substantial reviews of the scientific literature on caffeine and cardiac effects conducted by governmental and other authoritative organizations and reputable scientific experts find no scientifically valid relationship between caffeine consumption at the levels reported in the consumption data discussed above and heart disease or cardiac arrhythmias, nor does the evidence document significant or long-term effects on blood pressure. Representative peer-reviewed scientific studies are summarized below:

- In perhaps the best clinical study of its kind, the Framingham Study (a landmark longitudinal study initiated in 1948 to identify cardiovascular risk factors) examined whether there was any relationship between various dietary factors, including caffeine, and the incidence of atrial fibrillation, the most commonly encountered cardiac arrhythmia in clinical practice.[35] The well-known Framingham Study included 4526 individuals who had undergone 9640 clinical examinations and were prospectively followed for four years. A multivariate anal-

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group" appears to have been comprised of just three out of 1265 survey participants who said they consumed 32 oz. of energy drinks a day, for a total of 320 mg of caffeine, which is not "extreme amounts." Seifert at 514–15. In sum, these data provide little insight into current patterns of energy drink consumption in the U.S., and are far less relevant than the recent U.S. consumption figures recorded in the study commissioned by the FDA.

[30] Letter at 2.

[31] *Id.*

[32] *See* the December 14, 2011 Monitoring the Future survey report at 8 (quoting the survey question as, "About how many [energy drinks] do you drink per day on average?" (brackets in original)), available at: *http://www.monitoringthefuture.org/pressreleases/11drugpr_complete.pdf* (accessed July 23, 2013).

[33] IOM, CAFFEINE FOR THE SUSTAINMENT OF MENTAL TASK PERFORMANCE: FORMULATIONS FOR MILITARY OPERATIONS (2001).

[34] J.P. Higgins and K.M. Babu, *Caffeine Reduces Myocardial Blood Flow During Exercise,* 126 AM. J. MED. 730 (2013).

[35] J. Shen, *Dietary Factors and Incident Atrial Fibrillation: the Framingham Heart Study,* 93 AM. J. CLIN. NUTRITION 261, 261 (2011) ("Framingham Study").

ysis was performed to account for nine important confounding factors including age, gender, and body-mass index. Individuals were divided into four quartiles based on daily caffeine intake. Compared to individuals with the lowest daily caffeine intake (median 23 mg/day, range 0 to 82 mg/day), the individuals with the highest daily caffeine intake (median 452 mg/day, range 366 to 1203 mg/day) were at no higher risk for atrial fibrillation (hazard ratio: 0.98, 95 percent confidence interval: 0.70–1.39).[36] The authors concluded that consumption of caffeine "was not significantly associated with [atrial fibrillation] risk."[37]

- The 2001 IOM study of caffeine for the military concluded: "The preponderance of evidence indicates that the use of caffeine by the military would not place personnel at increased risk of cardiovascular disease."[38] That report stated further that, "[d]espite numerous studies attempting to show a relationship between caffeine and serum lipoproteins, blood pressure, cardiac arrhythmias, and risk of coronary heart disease, results have failed to show a consistent adverse effect of ingestion of moderate amounts of caffeine."[39] The IOM characterized up to 600 mg/day as moderate caffeine consumption.[40] Additional independent studies support the IOM conclusion that 600 mg or more caffeine per day (bolus or acute) is safe.[41]
- The Organisation for Economic Co-operation and Development (OECD) reported in 2002: "Though consumption of caffeine (eight cups of regular coffee corresponding to 500 mg caffeine per day) may exhibit acute increases in blood pressure, the long-term effects appear to be minimal. After one to four days of regular consumption a tolerance develops, with blood pressure returning to previous levels."[42] The OECD also cites several studies demonstrating that "caffeine doses up to 500 mg/day do not affect cardiac rhythm in normal subjects and patients."[43] The 2002 OECD report also concludes that although studies before the mid-1970s suggested an association between consumption of more than six cups of coffee and coronary heart disease, retrospective and prospective studies conducted since have consistently failed to demonstrate an association between caffeine and heart disease.[44] It also cites repeated dose toxicity rodent studies of caffeine that showed the average No Observable Adverse Effect Levels (NOAELs) were 160 mg for each kilogram of body weight of the rat per day and 170 mg/kg bw/day (highest dose tested) in mice.[45]
- A thorough review of the scientific literature on caffeine consumption examining the supposed causal connection between caffeine and heart disease concludes that the body of relevant scientific literature fails to show that the consumption of caffeine in moderate quantities results in an increased risk of coronary heart disease or arrhythmias. In particular, the review notes that more recent and better-conducted research undermines earlier erroneous assumptions that caffeine consumption has a significant, long-term impact on cardiovascular health.[46] With respect to cardiac arrhythmias, the authors conclude that "moderate ingestion of caffeine does not increase the frequency or severity of cardiac arrhythmias."[47] The authors of this review conclude, "Contrary to common belief, the published literature provides little evidence that coffee and/or caffeine in typical dosages increases the risk of infarction, sudden death or arrhythmia."[48] While this review was published in 1994, more recent evidence (see, for instance, the discussion immediately below) supports the paper's basic conclusions.

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[36] *Id* at 264.
[37] *Id.* at 261, 265.
[38] IOM REPORT ON CAFFEINE, *supra* note 33 at 12, 59.
[39] *Id.* at 51.
[40] *Id.* at 55.
[41] *See, e.g.,* W. Killgore, *Effects of Dextroamphetamine, Caffeine and Modafinil on Psychomotor Vigilance Test Performance After 44 H of Continuous Wakefulness,* 17 J. SLEEP RES. 309 (2008); W. Pasman *et al., The Effect of Different Dosages of Caffeine on Endurance Performance Time,* 16 INT. J. SPORTS MED. 225 (1995); L. Spriet, *Caffeine and Performance,* 5 INT. J. SPORT NUTR. S84 (1995); and N. Wesensten *et al., Performance and Alertness Effects of Caffeine, Dextroamphetamine, and Modafinil During Sleep Deprivation,* 14 J. SLEEP RES. 255 (2005).
[42] OECD, CAFFEINE 16 (2002).
[43] *Id.* at 16.
[44] *Id.* at 15.
[45] *Id.* at 24.
[46] T. Chou and N. Benowitz, *Caffeine and Coffee: Effects on Health and Cardiovascular Disease,* 109 COMP. BIOCHEM. PHYSIOL. 173, 185–186 (1994).
[47] *Id.* at 185.
[48] *Id.* at 173.

- A 2011 article by researchers at Northwestern University examined eleven clinical studies that were performed to investigate whether caffeine had any effect on cardiac arrhythmias.[49] The researchers concluded that human studies examining the effect of caffeine on cardiovascular endpoints are consistent in finding "minimal to no effect of caffeine on coronary artery disease or stroke."[50] With respect to cardiac arrhythmias, the researchers found that even studies on men with heart disease or known arrhythmias show no effect up to 450 mg/day caffeine on heart rhythm, and concluded "that in most patients, even those with known or suspected arrhythmia, caffeine in moderate doses is well tolerated and there is therefore no reason to restrict ingestion of caffeine."[51]
- A 2010 article on a prospective study of caffeine consumption by women concluded that increased consumption was not associated with an increased risk of atrial fibrillation.[52] The study was part of the large Women's Health Study, with 33,638 women followed prospectively for incident atrial fibrillation between 1993 and March 2, 2009.[53] Multivariable analyses were performed to account for potential confounding factors such as age, body-mass index, smoking, and history of diabetes.[54] In follow-up observations, participants in the study comprising the highest quintile of caffeine consumption (median daily caffeine intake: 656 mg/day, range: 561–778 mg/day) were found to have a risk of incident atrial fibrillation similar to their counterparts in the lowest quintile (median daily caffeine intake: 22 mg/day, range: 9–44 mg/day) of caffeine consumption (multivariable-adjusted relative risk: 0.89, 95 percent confidence interval: 0.73–1.09).[55] The researchers discovered that women in the third quintile of caffeine consumption (median daily caffeine intake: 285 mg/day, range: 217–326 mg/day) were found to have a significantly lower risk of incident atrial fibrillation (multivariable-adjusted relative risk: 0.78, 95 percent confidence interval: 0.64–0.95), which possibly "suggested that the consumption of small to moderate amounts of caffeine may even be beneficial," and may have a "small but significant protective effect on the occurrence of [atrial fibrillation]."[56]
- A meta-analysis of eleven prospective, longitudinal cohort studies was performed to investigate whether there was any association between coffee consumption and coronary heart disease.[57] The investigators concluded, "No association between increasing coffee consumption and the development of [coronary heart disease] was evident."[58] Compared to consumption of 1 cup of coffee per day or less, the consumption of 6 or more cups of coffee per day did not result in a significantly different risk of coronary heart disease (odds ratio: 1.09, 95 percent confidence interval: 0.97–1.22).[59]
- A prospective cohort study—part of the well-known Nurses' Health Study (NHS)—that followed 85,747 U.S. women for ten years found no association between coffee and caffeine consumption and the risk of subsequent coronary heart disease.[60] Multivariate analyses were performed to account for potential confounding factors such as body-mass index and smoking history.[61] Compared to individuals who consumed 0 cups of coffee a day, those who consumed 6 or more cups of coffee per day did not have a significantly different risk for coronary heart disease (multivariate-adjusted relative risk: 0.95, 95 percent confidence interval: 0.73–1.26). Similarly, when the highest quintile of total caffeine intake from all sources (median daily caffeine intake: 816 mg/day) was compared to the lowest quintile of total caffeine intake (median daily caffeine

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[49] D. Pelchovitz and J. Goldberger, *Caffeine and Cardiac Arrhythmias: a Review of the Evidence,* 124 AM. J. MED. 284, 286 (2011).
[50] *Id.* at 285.
[51] *Id.* at 288.
[52] D. Conen *et al., Caffeine Consumption and Incident Atrial Fibrillation in Women,* 92 AM. J. CLIN. NUTR. 509, 512 (2010).
[53] *Id.* at 509–10.
[54] *Id.* at 511, Table 2.
[55] *Id.* at 511–12, Table 2.
[56] *Id.* at 511, 513, Table 2.
[57] M. Myers and A. Basinski, *Coffee and Coronary Heart Disease,* 152 ARCH INTERN. MED. 1767 (1992).
[58] *Id.* at 1769.
[59] *Id.*
[60] W. Willett *et al., Coffee Consumption and Coronary Heart Disease in Women: a Ten-Year Follow-Up,* 275 JAMA 458 (1996).
[61] *Id.* at 460.

intake: 51 mg/day), there was no significant difference in the relative risk of coronary heart disease.[62]

- More than a decade later, Lopez-Garcia and colleagues followed up with women from the NHS as well as men from the Health Professionals Follow-Up Study and again found no evidence that coffee consumption increases the risk of coronary heart disease or mortality rate.[63] In addition, based on eighteen years of follow up with 41,736 men and twenty-four years of follow up with 86,214 women, the authors concluded that there may even be a positive benefit of coffee consumption on all-cause and cardiovascular disease mortality.[64]
- In addition to showing that coffee consumption is not a risk factor for heart disease, the NHS has also revealed that coffee consumption is not associated with increased risk of stroke, another disease involving the cardiovascular system. A study of 83,076 thousand women over twenty-four years revealed that long-term coffee consumption is not associated with an increased risk of stroke in women.[65]
- One recent meta-analysis study examined 13 retrospective case-control studies and 10 prospective cohort studies for evidence of an association between coffee consumption and coronary heart disease. Interestingly, while a significant association was found among the retrospective case-control studies, no significant associations emerged from the long-term follow-up prospective studies. This difference was attributed, in part, to the greater vulnerability of retrospective studies to bias and confounding, especially recall bias.[66]
- The findings from these large and long-term studies in the United States have been replicated in similar studies conducted in countries with traditionally high levels of caffeine exposure. For example, a 2005 study of 47,979 Danish men and women, showed that caffeine consumption is not associated with risk of atrial fibrillation or ventricular arrhythmias.[67] A nine-year follow-up study of 37,315 Swedish men found that high coffee consumption is not associated with increased rates of heart failure hospitalization.[68] A prospective cohort study of 59,490 Finnish men and women found that coffee consumption does not increase the risk of heart failure in men or women, and that with women there is an inverse association between moderate coffee consumption and the risk of heart failure.[69] A prospective cohort study in Italy, involving 11,231 Italian patients with a recent myocardial infarction found no association with coffee consumption and cardiovascular events in post-myocardial infarction patients.[70]

The foregoing summary clearly demonstrates that the Authors' allegations of harmful cardiac effects from caffeine consumption are largely speculative and unsupported by the best available medical and scientific evidence.

B. Seizures

In support of their conclusion that seizures have been "attributed to energy drink consumption," the Authors cite a handful of individual case reports.[71] The Authors do not cite any human clinical studies or animal studies. Case reports are inherently anecdotal and have significant limitations that do not permit the establishment of any causal link between seizures and the consumption of energy drinks. Most of the patients had a past history of seizures, had consumed other high caffeine sources such as diet pills, had a past history of stroke, or had neurological or

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[62] *Id.* at 461, Figure 1.

[63] Lopez-Garcia *et al., Coffee Consumption and Coronary Heart Disease in Men and Women: a Prospective Cohort Study,* 113 CIRCULATION 2045 (2006); Lopez-Garcia *et al., The Relationship of Coffee Consumption With Mortality,* 148 ANNALS INTERNAL MED. 904 (2008).

[64] Lopez-Garcia *et al.,* (2008), *supra* note 63.

[65] Lopez-Garcia *et al., Coffee Consumption and Risk of Stroke in Women,* 119 CIRCULATION 1116 (2009).

[66] F. Sofi *et al, Coffee Consumption and Risk of Coronary Heart Disease: a Meta-Analysis,* 17 NUTR. METAB. CARDIOVAS. 209 (2007).

[67] L. Frost and P. Vestergaard, *Caffeine and Risk of Atrial Fibrillation or Flutter: the Danish Diet, Cancer, and Health Study,* 18 AM. J. CLINICAL NUTRITION 578 (2005).

[68] H.N Ahmed *et al., Coffee Consumption and Risk of Heart Failure in Men: an Analysis from the Cohort of Swedish Men,* 158 AM. HEART J. 158 (2009).

[69] Y. Wang *et al., Coffee Consumption and the Risk of Heart Failure in Finnish Men and Women,* 97 HEART 44 (2011)

[70] M.G. Silletta *et al., Coffee Consumption and Risk of Cardiovascular Events After Acute Myocardial Infarction: Results from the GISSI (Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto miocardico)-Prevenzione Trial,* 116 CIRCULATION 2944 (2007).

[71] Letter at 5.

other disorders.[72] For example, in one case report the patient had a history of prior stroke, past heroin and cocaine consumption, and an abnormal CAT scan revealing chronic vascular encephalopathy with subcortical atrophy but no acute cerebrovascular lesions.[73] In another case report, the patient reported she only had seizures when she consumed both an energy drink along with diet pills, but the patient was uncertain as to the ingredients in the diet pills, and the case report does not include the quantity of diet pills the patient consumed.[74]

In contrast to the anecdotal reports cited by the Authors, the largest and best study on this subject found that moderate-to-high intake of caffeine was not associated with risk of seizures or epilepsy.[75] For its analysis of caffeine, the Nurses' Health Study followed 105,941 study participants for a total of 1,440,850 person-years of follow up. A multivariate analysis was performed to take into account important potential confounding factors. Compared to individuals with a long-term average caffeine intake of < 200 mg/day, individuals with a long-term average caffeine intake of ≥ 400 mg/day did not have a greater risk of seizures or epilepsy (seizure relative risk: 0.77, 95 percent confidence interval: 0.41–1.47; epilepsy relative risk: 0.97, 95 percent confidence interval: 0.57–1.67). In addition, there was no linear relationship between increasing caffeine intake and seizure or epilepsy risk (seizure relative risk: 0.95, 95 percent confidence interval: 0.80–1.11, p = 0.5; epilepsy relative risk: 0.97, 95 percent confidence interval: 0.85–1.11, p = 0.6).[76]

The weight of the evidence clearly establishes that caffeine in the amounts delivered by energy drinks does not cause seizures.

C. Caffeine "Overdose"

The Authors state that there is a "risk for energy drink overdose" due to marketing activities of energy drink companies.[77] A fatal acute dose of caffeine in adult humans is estimated to be between 10 and 14 g (between 142 and 200 mg per kg body weight).[78] In children, 3 g of caffeine (183 mg caffeine/kg body weight) was shown to be fatal for a 16.4 kg child.[79] An adult would need to consume over 62.5 16-ounce cans (7.8 gallons of fluid) and a small child would need to consume over 18 16-oz cans (2.3 gallons of fluid) of Monster Energy Drinks *acutely, i.e.,* in a single sitting, to ingest a lethal dose of caffeine. This volume is in gross excess of what can reasonably be consumed, even for individuals with high consumption patterns. Accordingly, a caffeine "overdose" is impossible to achieve through beverage sources of caffeine.

D. Alleged Fatalities and Injuries

In support of their conclusion that energy drinks are the cause of fatalities and injuries, especially in children, the Authors reference several adverse event reports (AERs) submitted to FDA that cite energy drinks. FDA has repeatedly emphasized that AERs associated with a consumer product are not reports by FDA and do not establish any causal link between a product and the reported event.[80] In a recent interview, FDA Commissioner Margaret Hamburg stressed that AERs related to energy drinks do not suggest a causal effect: "Frankly, many of the reports, when examined with a real look at the science and the potential for a causal relationship, are not very compelling."[81]

The Authors identify the case of 14-year-old Anais Fournier who died of a cardiac arrhythmia to try and establish a link between Monster Energy Drinks and the fatality. Ms. Fournier's medical records, however, establish that Ms. Fournier had a

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[72] *See, e.g.,* S. Iyadurai and S. Chung, *New-Onset Seizures in Adults: Possible Association With Consumption of Popular Energy Drinks,* 10 EPILEPSY BEHAV. 504–508 (2007); D. Trabulo *et al., Caffeinated Energy Drink Intoxication,* 28 BMJ CASE REP. 712–714 (2011).

[73] *See* D. Trabulo *et al., supra* note 72, at 712–714.

[74] *See* S. Iyadurai and S. Chung, *supra note* 72, at 504–508.

[75] B. Dworetzky *et al., A Prospective Study of Smoking, Caffeine, and Alcohol as Risk Factors for Seizures or Epilepsy in Young Adult Women: Data from the Nurses' Health Study II,* 51 EPILEPSIA 198 (2009).

[76] *Id.*

[77] Letter at 2.

[78] IOM, *supra* note 33, at 5.

[79] V.J.M. Dimaio and J.C. Garriott, *Lethal Caffeine Poisoning in a Child,* 275 FORENSIC SCIENCE 275 (1974).

[80] FDA, *Energy "Drinks" And Supplements: Investigations Of Adverse Event Reports* (Nov. 16, 2012), *http://www.fda.gov/Food/NewsEvents/ucm328536.htm.* In a statement that accompanied FDA's November 16, 2012 release of AERs pertaining to energy drinks, FDA explained, "The existence of an adverse event report does not necessarily mean that the product identified in the report actually caused the adverse event. FDA assesses the relationship, if any, between a product or ingredient and the reported adverse event."

[81] C. Choi and M. Jalonick, *Monster Hits Back at Lawsuit Over Teenager's Death,* YAHOO! NEWS (Mar. 4, 2013), *http://news.yahoo.com/monster-hits-back-lawsuit-over-160836281.html.*

known, pre-existing heart condition, which was most likely the cause of her death. It is alleged that Ms. Fournier consumed two 24-ounce cans of Monster Energy Drink 24 hours apart. She drank the first can without incident. According to the body of scientific and medical literature on normal caffeine metabolism, the caffeine from the first beverage would have dissipated by the time she drank the second beverage 24 hours later. The medical records reflect that no caffeine blood level test was performed at the hospital. The Maryland Medical Examiner who performed the autopsy on Ms. Fournier conducted a toxicology test and the results came back negative for caffeine.

Despite reference to "caffeine toxicity" in her autopsy report, the Maryland Medical Examiner testified under oath that there is no evidence Ms. Fournier had any caffeine in her body at the time of her cardiac arrest. She further testified that there is no medical or scientific evidence that Ms. Fournier's cardiac arrest was due to caffeine. The Maryland Medical Examiner also testified that she could not say to a reasonable degree of medical certainty that Ms. Fournier's cardiac arrest was due to her consumption of a Monster Energy Drink.

The Maryland Medical Examiner requested the expertise of a world-renowned cardiac pathologist, Dr. Renu Virmani of CV Path Institute, in analyzing Ms. Fournier's heart. Following a microscopic analysis of Ms. Fournier's heart tissue, Dr. Virmani found that Ms. Fournier's heart had several structural abnormalities, including (1) mitral valve prolapse; (2) cardiomegaly (enlarged heart); (3) fibrosis (scarring); and (4) inflammation. Dr. Virmani testified under oath that each of Ms. Fournier's heart conditions is known causes of cardiac arrhythmia and sudden death. Although Dr. Virmani had been told Ms. Fournier drank a Monster Energy Drink three hours before her cardiac arrest, Dr. Virmani did not find that Ms. Fournier's cardiac arrest was due to caffeine and made no reference to caffeine in her final diagnosis.

Dr. Virmani testified that she is not aware of any evidence that Ms. Fournier had any caffeine in her system at the time of her cardiac arrest. She further testified that she cannot say to a reasonable degree of medical certainty that Ms. Fournier's cardiac arrest was due to caffeine or due to consuming a Monster Energy Drink. Instead, Dr. Virmani testified that it was very plain and clear that Ms. Fournier had mitral valve prolapse, and that condition, along with the scarring (fibrosis), were the likely causes of Ms. Fournier's cardiac arrest.

The Authors also reference a paper, of which one of the Authors was a co-author, in support of the conclusion that there has been a greater incidence of accidental ingestion of caffeine from energy drinks than other forms of caffeine in children under 6 years of age.[82] Certainly, no one has ever recommended that children under 6 years of age consume energy drinks. To the contrary, all major energy drink marketers label their products as not recommended for children and highlight the caffeine content in the products, so parents and caregivers can ensure that children do not consume them. The accidental ingestion of substances by young children is not grounds for concluding that the substances themselves are unsafe for their intended use.

E. Emergency Room Visits

The Authors cite to the oft-mischaracterized report on so-called energy drink-related emergency room (ER) visits (the Drug Abuse Warning Network (DAWN) report)[83] in an attempt to establish an increase in energy-drink related ER visits. The DAWN report, however, has many limitations, and therefore does not establish an association between energy drink consumption and ER visits.[84]

For example, the report did not track the energy drinks brands consumed or provide estimates of amounts of caffeine consumption. The report is based on ER visits involving use of drugs, where drugs are defined as alcohol, cocaine, heroin, marijuana, pharmaceuticals, nutritional supplements, vitamins, and caffeine products. In more than half of the visits in which energy drinks were reportedly consumed by 18- to 25-year olds, the subjects also reported using alcohol and other drugs (and this figure is likely an underestimate given that alcohol and drug use was self-reported and thus likely underreported). The DAWN report did not provide patient

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[82] S.M. Seifert *et al., Energy Drink Exposures in the American Association of Poison Control Centers (AAPCC) National Poison Data System (NPDS) Database.* Paper presented at: Annual Meeting of the North American Congress of Clinical Toxicology; 2012; Las Vegas, NV.

[83] *See* Substance and Abuse Mental Health. Servs. Admin., Ctr. for Behavioral Health. Statistics and Quality, *The DAWN Report Update on Emergency Department Visits Involving Energy Drinks* (Jan 10, 2013).

[84] An analysis of the DAWN public use data also reflects that the number of emergency room visits related to numerous other products, including infant formula, vitamins and laxatives, substantially exceeded those where energy drink consumption was reported.

outcomes. Where energy drink consumption was reported, the report did not include the amount of energy drink consumed or the amount of other sources of caffeine consumed. The DAWN report, therefore, does not contain sufficient information to determine the nature of patients' complaints, the amount of caffeine consumed from all sources (including coffee, sodas, etc., either independently of or in conjunction with energy drinks), or whether there was any causal connection between the complaints and the consumption of energy drinks. Moreover, the report concludes that while ER visits doubled, "[v]isits among adolescents aged 12 to 17 remained stable" during a period in which energy drink consumption increased substantially.[85]

In contrast to the limitations of the DAWN Report, the International Society of Sports Nutrition's (ISSN's) 2013 position statement on energy drinks, which is based on a thorough review of the scientific literature and 224 medical and clinical studies, states, "the rate of adverse events [associated with energy drinks] appears low in the population of consumers" and the current evidence "suggests that consumption of [energy drinks] and [energy shots] are safe in healthy populations and similar to ingesting other foods and beverages containing caffeine."[86] In fact, the ISSN concluded, based on its extensive comprehensive literature search, that consuming an energy drink 10–60 minutes before exercise can improve mental focus, alertness, aerobic performance, and/or endurance performance.[87]

F. Caffeine Metabolism

The Authors express concern that metabolism of caffeine appears to be non-linear at "high doses," selectively quoting from or interpreting the study by Kaplan, *et al.*[88] The Authors cite the Kaplan study for the proposition that metabolism of caffeine at high doses (500 mg) was non-linear as compared to a 250 mg dose. While the understanding that caffeine does not follow linear kinetics at high concentrations has been documented since at least 1990, this very property of non-linearity kinetics may play a role in the self-regulating nature of caffeine. The Authors do not address the fact that the Kaplan study cites cognitive and performance improvement at the 250 mg dose with some unpleasant effects at the higher dose. Importantly, Kaplan and colleagues conclude that "the unfavorable and somatic effects, as well as performance disruption, from high doses of caffeine may intrinsically limit the doses of caffeine used in the general population."[89] The Kaplan study thus reflects what caffeine consumers know from their consumption experience: caffeine in low to intermediate doses produces favorable effects, while higher doses may produce some unpleasant effects and are not associated with consistent enhancement of performance which, in turn, results in self-regulation of intake. The Authors did not acknowledge the Kaplan study's comments on this self-limiting effect of higher amounts of caffeine.

The Letter also asserts that the accumulation of caffeine metabolites could compound the "negative effects of caffeine at high blood levels."[90] This would only be the case in situations of overt caffeine overdose (for example, purposeful caffeine tablet overdose). Caffeine is known not to accumulate in any body tissues. Additionally, accumulation of metabolites has not been demonstrated under normal metabolic conditions, as the three primary metabolites paraxanthine, theobromine, and theophylline are themselves metabolized and excreted via multiple pathways. The Letter also describes the metabolites as stimulants themselves. With normal caffeine ingestion, the metabolites are present at small levels, and do not accumulate. While they may have stimulant properties similar to caffeine, they are not the source of the primary stimulant effect of caffeine-containing beverages.[91]

G. Combining Energy Drinks with Alcohol

The Letter concludes that energy drinks, when mixed with alcohol, pose unique dangers. Monster does not market or recommend its energy drinks for use with alcohol. Any such abuse by consumers does not mean that energy drinks themselves are unsafe. Monster supports education of consumers about the appropriate and responsible consumption of energy drinks.

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[85] DAWN Report at 3.

[86] B. Campbell *et al., International Society of Sports Nutrition Position Stand: Energy Drinks,* 10 J. INT'L SOC. SPORTS NUTR. 1, 10 (2013).

[87] *Id.* at 1.

[88] Letter at 3, citing G.B. Kaplan *et al., Dose-Dependent Pharmacokinetics and Psychomotor Effects of Caffeine in Humans,* 37 J CLIN. PHARMCOL 693 (1997).

[89] Kaplan, *supra* note 88, at 693.

[90] Letter at 3.

[91] M. Arnaud, *supra note* 11, at 35–36.

V. Children and Adolescents Are Not at a Unique Risk for Health Effects From Energy Drink or Caffeine Consumption

The majority of the Letter discusses the alleged "health complications associated with the consumption of energy drinks"[92] by children and adolescents. As detailed herein, the wealth of relevant scientific literature does not substantiate the alleged correlation between caffeine levels in energy drinks and adverse health effects, nor does it show that children and adolescents are more susceptible to caffeine effects. To the contrary, the weight of the evidence supports the conclusion that consumption of caffeine from Monster Energy Drinks is not associated with such health risks and that children and adolescents experience no unique effects from caffeine.

Perhaps most notably, FDA itself confirmed the safety of caffeine for teenagers at levels even higher than those in Monster Energy Drinks in approving caffeine as safe for use in over-the-counter (OTC) drug products at levels up to 200 mg caffeine every 3 to 4 hours for consumers ages 12 and older.[93] The agency made no distinction between adolescents and adults and concluded that these acute and repeated caffeine consumption levels were safe for both age groups. These levels of caffeine are comparable to or higher than that found in Monster Energy Drinks. FDA's conclusions in this monograph (which went through a 1975 proposed rule, 1978 tentative final order, and 1988 final rule, all published in the Federal Register allowing for public comment) establish that caffeine at the levels present in Monster Energy Drinks is safe for adolescents as well as adults.

European food safety authorities have likewise confirmed the safety of caffeine in energy drinks for younger consumers. As noted above, energy drinks have been reviewed by European food safety authorities on three occasions spanning a decade, and have been found to be safe, including for young consumers. In a 1999 opinion, the European Commission Scientific Committee on Food (SCF) expressed no safety concerns with consumption of energy drinks formulated with a caffeine content comparable to that in Monster Energy Drinks.[94] SCF also addressed consumption of energy drinks by children and reported no safety concerns from the exposure of young people to the caffeine in these products. SCF revisited energy drinks again in 2003 and estimated mean chronic, high chronic, and acute consumption of energy drinks by regular consumers of such drinks to be 125, 350, and 750 ml/day, respectively, concluding that its 1999 opinion on the safety of caffeine and energy drinks remained unchanged.[95] In 2009, the European Food Safety Authority (EFSA), SCF's successor entity, evaluated new data on taurine and glucuronolactone in caffeinated energy drinks and did not identify any safety concerns.[96]

A. No Unique Effects of Caffeine on Children and Adolescents

The substantial body of scientific and medical literature demonstrates that children and adolescents experience no particular or unique safety effects from caffeine, that dose response is a function of body weight (mg/kg), not age, and that any behavioral or other effects that children and adolescents may experience from caffeine are the same as those experienced by adults.[97] For these reasons, many of the analyses in the scientific literature refer to safe levels of caffeine in terms of mg/kg body weight per day, either in addition to or instead of an absolute amount.

Dr. Alan Leviton, of Harvard Medical School and Children's Hospital in Boston, Massachusetts published a paper, which he also presented at the Annual Meeting of the American Academy of Pediatrics (AAP), documenting the finding that after infancy, neither caffeine's absorption, its excretion, nor its half-life are age-dependent.[98] In addition, articles reviewing the relative caffeine amounts in particular bodily fluids or tissues reflected no appreciable differences in children's and adults' caffeine pharmacokinetics.[99] "A mean distribution volume of 0.7 L/kg (0.5–0.8 L/kg)

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[92] Letter at 3.

[93] 21 C.F.R. § 340.50. FDA's approved OTC monograph for stimulant drug products includes the following directions for use: "Adults and children 12 years of age and over: Oral dosage is 100 to 200 milligrams not more often than every 3 to 4 hours." *Id.* § 350.50(d). FDA noted that caffeine from other sources should be taken into account. *Id.* § 350.50(c)(1).

[94] *See* SCF, *Opinion on Caffeine, Taurine, and D-Glucurono-γ-Lactone as Constituents of So-Called "Energy" Drinks* (1999), available at *http://ec.europa.eu/food/fs/sc/scf/out22_en.html.*

[95] SCF, OPINION OF THE SCIENTIFIC COMMITTEE ON FOOD ON ADDITIONAL INFORMATION ON "ENERGY" DRINKS at 2–3, 12 (2003).

[96] EFSA, *The Use of Taurine and D-Glucurono-γ-*Lactone as Constituents of the So-Called "Energy" Drinks, 935 THE EFSA JOURNAL 1, 23 (2009).

[97] A. Leviton, *Behavioral Correlates of Caffeine Consumption by Children,* 31 CLIN. PEDIATR. 742, 743 (1992). *See also* M. Arnaud, *supra* note 11, at 35.

[98] Leviton, *supra* note 97.

[99] M. Arnaud, *supra* note 11 at 36–37.

was found in newborn infants, adult subjects, or aged subjects. The pharmacokinetics of caffeine in healthy young men aged 20.5 ± 2.0 years and in healthy elderly men aged 71.2 ± 3.9 years showed that Tmax, Cmax, and caffeine bioavailability were essentially identical."[100] Therefore, as in adults, the amounts of caffeine that distribute to a child's or adolescent's tissues appear to be a result of the individual's caffeine intake in relation to his or her weight, rather than of any differences in the rate and extent of children's and adults' caffeine metabolism.

Accordingly, there are no scientific grounds for safety concerns about consumption of caffeine or energy drinks simply based upon the consumer's chronological age, as caffeine effects are a function of body weight. For example, the term "teenagers" captures 13- to 19-year-olds, yet a 13-year-old typically weighs considerably less than a 19-year-old. Recent data (2007–2010) reported by the Centers for Disease Control and Prevention (CDC) reveal that for adolescent males, mean weight ranges from 59.2 kg for 13-year-olds to 79.5 kg for 19-year-olds.[101] For adolescent females, mean weight ranges from 56.8 kg for 13-year-olds to 68.0 kg for 19-year-olds.[102] These data also reveal that even the youngest teenagers are, on average, not particularly small.

In support of their conclusion that energy drinks should not be consumed by adolescents, the Authors reference statements in a review article by the American Academy of Pediatrics' Committee on Nutrition and the Council of Sports Medicine and Fitness, which states that "caffeine and other stimulant substances contained in energy drinks have no place in the diet of children and adolescents" and "are not appropriate for children and adolescents and should never be consumed."[103] At the outset, we note that the authors of that article expressed concern about "large and varied amounts of caffeine" in energy drinks stating that the "total amount of caffeine contained in some cans or bottles of energy drinks can exceed 500 mg (equivalent to 14 cans of common caffeinated soft drinks)."[104] As noted in Table 2, above, reflecting approximately 95 percent of the energy drink category, virtually all energy drinks have less than half this amount. Thus, it appears the view of these authors may have been skewed by a misperception of the caffeine content of typical energy drinks.

The first statement in the AAP Committee article quoted above cites to a 2007 IOM report on nutrition standards for foods in schools in support.[105] That 2007 IOM report concluded that "[a]lthough there may be some benefits associated with caffeine consumption among adults," the IOM Committee on Nutrition Standards for Foods in Schools did not support offering caffeinated beverages in schools because of the potential for effects such as physical dependency and withdrawal.[106] This recommendation related to *all* caffeinated beverages except those with trace amounts of naturally occurring caffeine substances. That is, this recommendation applied to coffee, tea, and caffeinated sodas, and not solely to energy drinks. Further, the potential effects described, such as physical dependence and withdrawal, were not unique to children and adolescents but were the same as those experienced by adults. Thus, this citation does not establish any unique health effects of caffeine on youth.

The second statement is not associated with a particular citation, but is reflective of an overall cautious tone, which, while not inappropriate for the AAP Committee, does not reflect evidence of a different effect of caffeine on children and adolescents. Notably, the authors of that article acknowledge that caffeine has been shown to enhance physical performance in adults by increasing aerobic endurance and strength, improving reaction time, and delaying fatigue, though they state that these effects have not been studied in children and adolescents.[107] They note a number of effects of caffeine that have been addressed herein, such as increases in blood pressure, increases in attentiveness, withdrawal effects and sleep disturbances, but these effects are neither unique to children nor documented to pose genuine health risks. The AAP Committee article states that caffeine is "known also to play a role in triggering arrhythmias," but relies for this proposition only on an experimental

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[100] *Id.* at 45.

[101] Centers for Disease Control and Prevention, *Anthropometric Reference Data for Children and Adults: United States, 2007–2010,* 11 VITAL HEALTH STAT. 1, 7–9 (2012).

[102] *Id.*

[103] Committee on Nutrition and the Council on Sports Medicine and Fitness, *Sports Drinks and Energy Drinks for Children and Adolescents: Are They Appropriate?* PEDIATRICS 1185 (2011).

[104] PEDIATRICS 2011, *supra* note 103, at 1185.

[105] IOM, NUTRITION STANDARDS FOR FOODS IN SCHOOLS: LEADING THE WAY TOWARD HEALTHIER YOUTH (2007).

[106] *Id.* at 134.

[107] PEDIATRICS 2011, *supra* note 103, at 1185.

study in dogs with a review of the literature,[108] which stands at odds with the comprehensive analyses discussed above refuting the alleged association of caffeine and arrhythmias.

The AAP Committee discourages dietary intake of caffeine by children—from *all* sources, not just energy drinks—"[b]ecause of the potentially harmful adverse effects and developmental effects of caffeine."[109] Such potential developmental effects are the only effects alleged to be particular to children, but the apparent source cited in support is equally cautious and speculative. That source, a review article by Nawrot, *et al.,* noted behavioral effects of caffeine in children and adolescents comparable to those discussed below, as well as reports of beneficial effects such as improvements in attention.[110] The review included discussion of some studies that did not reveal any deleterious effects, including a meta-analysis of nine studies showing "no significant deleterious acute effects on behavior or cognition in children."[111] Nawrot *et al.* acknowledged the mixed evidence in children by stating, "In conclusion, it is unknown if long-term daily consumption of caffeine would produce effects similar to those observed in the studies reviewed above."[112] Nawrot *et al.* later opine that, "[o]wing to these findings [of behavioral effects], as well as the fact that the nervous system in children is continually developing and the lack of available information on the longer-term effects of caffeine in this population, a cautious approach is warranted."[113] Thus, the reference to potential developmental effects is a cautionary one—not one grounded in definitive evidence of such an effect or conclusive evidence of an impact of caffeine on children that is qualitatively different from that on adults.

Relevant to the question of the theoretical potential of caffeine to affect neurodevelopment in children and adolescents is the fact that caffeine, and other methylxanthine derivatives such as theophylline and theobromine, have a long-history of safe use for pediatric treatment of apnea and attention deficit disorder in children and infants. Under placebo controlled settings, the administration of caffeine (5 to 10 mg/kg body weight) to infants within the first 10 days of life for a median duration of 37 days, for treatment of apnea of prematurity, did not affect motor function, cognition, behavior, general health or other developmental measures (*e.g.,* deafness, blindness) during a 5-year follow-up period.[114] Meta-analyses of controlled studies (21 studies) evaluating the effects of caffeine on development and behavior in children and adolescents administered caffeine, or the structurally similar methylxanthine theophylline, for treatment of asthma or attention-deficit hyperactivity disorder, do not support an association between methylxanthine use and adverse effects on cognition or behavior in these individuals.[115] Accordingly, the actual relevant evidence strongly supports the conclusion that dietary exposure to caffeine is not a risk for potential adverse effects on neurodevelopment in children. Similarly, there is no evidence within the scientific and medical literature to suggest that dietary exposure to caffeine in energy drinks among adolescents has the potential to adversely affect neurodevelopment in this population.

B. Childhood Obesity

The Authors state that energy drinks "have [ ] been shown to contribute to youth obesity due to their high calorie and sugar content" and cite to the AAP Committee article discussed above to conclude that "the consumption of excessive carbohydrate calories from energy drinks increases risk for pediatric overweight."[116] Certainly, "excessive" consumption of calories from any food or beverage increases the risk of obesity for any person, and "excessive" consumption of sugary foods in general should be avoided. Monster produces and sells many energy drinks that have

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[108] *Id.,* citing A. Mehta, *et al., Caffeine and Cardiac Arrhythmias: an Experimental Study in Dogs With Review of the Literature,* 52 ACTA CARIOL. 273 (1997).

[109] PEDIATRICS 2011, *supra* note 103, at 1185.

[110] P. Nawrot *et al., Effects of Caffeine on Human Health,* 20 FOOD ADDIT CONTAM. 1 (2003).

[111] *Id.* at 10 (discussing a study by Stein *et al.*).

[112] *Id.* at 10.

[113] *Id.* at 23.

[114] B. Schmidt *et al., Caffeine Therapy for Apnea of Prematurity,* 254 NEW ENGLAND J. MED. 2112 (2006); B. Schmidt *et al., Long-Term Effects of Caffeine Therapy for Apnea of Prematurity [Caffeine for Apnea of Prematurity Trial Group],* 357 NEW ENGLAND J. MED. 1893 (2007); B. Schmidt *et al., Survival Without Disability to Age 5 Years After Neonatal Caffeine Therapy for Apnea of Prematurity [Caffeine for Apnea of Prematurity (CAP) Trial Investigators],* 307 J. AM. MED. ASS'N, 275 (2012).

[115] S. Lindgren *et al., Does Asthma or Treatment With Theophylline Limit Children's Academic Performance?,* 327 NEW ENGLAND J. MED. 926 (1992); Stein *et al., Behavioral and Cognitive Effects of Methylxanthines: a Meta-Analysis of Theophylline and Caffeine,* 150 ARCH. PEDIATRICS AND ADOLESCENT MED. 284 (1996).

[116] Letter at 5.

no sugar or are low in sugar. In fact, almost half of Monster Energy Drink sales come from these products.

C. Behavioral Effects

The Authors assert that caffeine consumption is associated with several negative behavioral effects in "youth."[117] The evidence, however, establishes that caffeine effects on behavior are largely dependent upon the amount of caffeine a person normally consumes, and are not unique for young consumers. This body of evidence includes the work of Judith L. Rapoport, M.D., Chief, Child Psychiatry Branch, and colleagues at the National Institute of Mental Health, National Institutes of Health. As early as 1984, their review of the literature led to the conclusion that "[t]here is no clear behavioral toxicity from caffeine in normal children. Those self-selecting high caffeine diets generally do not seem to get negative effects."[118] An earlier study by Rapoport even found no negative outcomes when 19 children were given 3 mg/kg or 10 mg/kg caffeine (500 mg for a 110-pound child).[119] Rapoport and another NIH colleague reviewed the literature again in 2002, and described the results of seven studies performed with hyperactive children and eight in normal children.[120] The authors concluded that "[t]he effects of caffeine in children seem to be modest and generally innocuous."[121] Notably, the authors reported that the administration to children habituated to caffeine of 10 mg/kg bw/day produced no significant behavioral effects.[122] The review concludes that in children (as with adults), the amount of caffeine a person normally consumes is very important in determining their behavioral response to caffeine. The behavioral effects that were observed in children not habituated to caffeine were the same as those observed in adults, thereby indicating no unique effects on children. Similar conclusions have been reached by medical researchers studying the effects of caffeine on a wide range of children.[123]

VI. Concerns About "Sensitive Consumers" Are A Matter of Labeling, Not General Safety or GRAS Status

The Authors assert that a safety standard for caffeine should take into consideration that "individuals have varying sensitivities to caffeine," rather than be based on only "healthy" individuals.[124] Further, the Authors state that the consumption of "highly caffeinated" energy drinks is associated with adverse cardiac events "especially [for] those with underlying cardiovascular diseases."[125] Many of the studies addressed above found no increased risks from caffeine consumption by consumers with underlying cardiovascular diseases or conditions, such as preexisting arrhythmias or prior myocardial infarctions,[126] but in any case, the sensitivity of consumers with underlying diseases or conditions to a particular food ingredient does not detract from the GRAS status of that ingredient. Such sensitivities are typically addressed through labeling. For example, commonly consumed foods such as milk, wheat, and peanuts are highly dangerous, and even fatal, to consumers who are allergic or sensitive to them, but these foods are not deemed unsafe. Rather, the issue is addressed through labeling. Congress enacted the Food Allergen Labeling and Consumer Protection Act of 2004, requiring the clear label declaration of the eight

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[117] *Id.*

[118] J. Rapoport and M. Kruesi, *Behavior and Nutrition: A Mini Review,* 51 J. DENT. CHILD. 451 (1984). *See also* J. Rapoport *et al., Behavioral Effects of Caffeine in Children,* 41 ARCH. GEN. PSYCHIATRY 1073 (1984); T. Zahn and J. Rapoport, *Acute Autonomic Nervous System Effects of Caffeine in Prepubertal Boys,* 91 PSYCHOPHARMACOLOGY (BERL.) 40 (1987).

[119] J. Rapoport *et al., Behavioral and Autonomic Effects of Caffeine in Normal Boys,* 3 DEV. PHARMACOL. THER. 74 (1981).

[120] F. Castellanos and J. Rapoport, *Effects of Caffeine on Development and Behavior in Infancy and Childhood: a Review of the Published Literature,* 40 FOOD CHEM. TOXICOL. 1235 (2002).

[121] *Id.* at 1242.

[122] *Id.* at 1241.

[123] *See, e.g.,* G. Bernstein *et al., Caffeine Effects on Learning, Performance, and Anxiety in Normal School-Age Children,* 33 J. AM. ACAD. CHILD ADOLESC. PSYCHIATRY 407 (1994); H. Barr and A. Streissguth, *Caffeine Use During Pregnancy and Child Outcome: a 7-Year Prospective Study,* 13 NEUROTOXICOL. TERATOL. 441 (1991); R. Baer, *Effects of Caffeine on Classroom Behavior, Sustained Attention, and a Memory Task in Preschool Children,* 20 J. APPL. BEHAV. ANAL. 225 (1987); R. Elkins *et al., Acute Effects of Caffeine in Normal Prepubertal Boys,* 138 AM. J. PSYCHIATRY 178 (1981).

[124] Letter at 3.

[125] Letter at 4.

[126] *See, e.g.,* Pelchovitz and Goldberger, *supra* note 49; Silletta *et al., supra* note 70. *See also* T.B. Graboys *et al., The Effect of Caffeine on Ventricular Ectopic Activity in Patients With Malignant Ventricular Arrhythmia,* 149 Arch. Int'l Med. 637 (1989) (study of 50 patients with malignant arrhythmia found no evidence that caffeine is arrhythmogenic, even among patients with life-threatening arrhythmia).

major food allergens, after finding that "each year, roughly 30,000 individuals require emergency room treatment and 150 individuals die because of allergic reactions to food."[127] Likewise, sulfites, to which sensitive consumers may have serious, and even fatal reactions, are not deemed unsafe food additives but rather are required to be disclosed in labeling where present over 10 ppm.[128]

Similarly, the fact that some consumers may be sensitive to caffeine does not render caffeine unsafe or not GRAS for use in energy drinks. Rather, these concerns should be addressed through labeling, consistent with FDA's approach to other foods to which some consumers may be sensitive. Monster has done so by labeling its energy drinks with the caffeine content (per-serving and per can) and with the statement, *"Not recommended for children, people sensitive to caffeine, pregnant women or women who are nursing."*

VII. Conclusion

The scientific and medical literature clearly refutes the Letter's ultimate conclusion that there is no general consensus among qualified experts that the addition of caffeine in the amounts used in energy drinks is safe under its conditions of intended use. As plainly and thoroughly set forth above, the body of scientific and medical evidence and actual consumption data establishes that caffeine effects are a function of body weight and habituation, not age, and that caffeine levels such as those delivered by Monster Energy Drinks are safe for children, adolescents, and adults.

FDA has made clear, and courts have confirmed, that the consensus of expert opinion needed to establish GRAS status does not require unanimity among qualified experts,[129] and that "mere conflict among experts is not enough to preclude a finding of general recognition."[130] The conclusions of the Authors and selective citations in their Letter—including in large part to their own work—do not undermine the GRAS status of caffeine for use in Monster Energy Drinks. Rather, the great weight of the scientific and medical literature, including that by governmental and other authoritative bodies, establishes the safety and GRAS status of caffeine as used in Monster Energy Drinks.

Very truly yours,

/S/ MIRIAM J. GUGGENHEIM,
Counsel to Monster Beverage Corporation.

cc: Michael Taylor
Michael Landa

Senator BLUMENTHAL. Thank you, Mr. Sacks.

Ms. Taylor?

STATEMENT OF AMY TAYLOR, VICE PRESIDENT AND GENERAL MANAGER, RED BULL NORTH AMERICA, INC.

Ms. TAYLOR. Mr. Chairman, Ranking Member Thune, and members of the Committee, my name is Amy Taylor. I have been with Red Bull for 14 years and responsible for Red Bull's marketing strategy and initiatives in North America for much of that time.

Let me thank the Committee for the chance to appear and testify today on behalf of Red Bull North America about our marketing policies and practices.

First, let me say something about our company and product. Red Bull created the modern energy drink category in Europe in 1987 and launched it in the U.S. in 1997. Red Bull is now sold in more

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[127] Food Allergen Labeling and Consumer Protection Act of 2004, 21 U.S.C. 343 note (1)(B).
[128] 21 C.F.R. § 101.100(a)(4).
[129] FDA Proposed Rule, "Substances Generally Recognized as Safe," 62 Fed. Reg. 18938, 18939 (April 17, 1997) ("Unanimity among experts regarding safety of a substance is not required.") (citing *United States* v. *Articles of Drug *** 5,906 boxes,* 745 F.2d 105, 119 n. 22 (1st Cir. 1984); *United States* v. *An Article of Drug *** 4,680 Pails,* 725 F.2d 976, 990 (5th Cir. 1984); *Coli-Trol 80,* 518 F.2d 743, 745 (5th Cir. 1975); *Promise Toothpaste,* 624 F.Supp. 776, 782 (N.D. Ill. 1985).
[130] 62 Fed. Reg. at 18939 (citing *Coli-Trol 80, supra* note 129, at 745).

than 165 countries. Health and regulatory bodies all over the world have concluded that Red Bull is safe to consume.

It is worth noting that our 8.4-ounce can of Red Bull contains 80 milligrams of caffeine, which, despite perceptions, is about the same amount that a cup of coffee has in a home-brewed situation and half as much of that of a typical coffeehouse coffee. Red Bull is the small can product in the energy drink category, with 85 percent of our business comprised of the sale of 8 and 12 ounce cans, making us unique within the category.

We have a long history of cooperation with legislative and regulatory bodies in order to ensure the lawful marketing and safe consumption of our products. We are pleased that the FDA is looking into the safety of caffeine, as did health authorities, for example, in Canada, Europe, Australia, and New Zealand. We are participating in the FDA process and confident that it will confirm caffeine is safe for consumption, even for teens.

But we have always marketed ourselves as the adult premium product in the category. Our marketing policies and practices have evolved in the U.S. for strategic reasons. As an example, we made the decision in 2011 to focus our marketing even more narrowly at the core demographic of 18 to 34-year-olds to leverage our strengths versus our competition.

Our positioning is reflected in our can design, packaging, pricing, and core marketing messages, as well as the content, timing, and placement of our advertising and communications. While we focus on adults, no company can ensure that its marketing materials will only reach a particular audience, and people of all ages and demographics may be attracted to them.

Yesterday, we submitted a letter to this committee, which we will now respectfully ask you to include in the record.

Senator BLUMENTHAL. Without objection.

[The information referred to follows:]

RED BULL®
July 30, 2013

BY HAND DELIVERY

Hon. JOHN D. ROCKEFELLER IV,
Chairman
Committee on Commerce, Science, and Transportation,
United States Senate,
Washington, DC.

Hon. JOHN R. THUNE,
Ranking Member,
Committee on Commerce, Science, and Transportation,
United States Senate,
Washington, DC.

RE: VOLUNTARY COMMITMENTS REGARDING LABELING AND MARKETING

Dear Chairman Rockefeller and Ranking Member Thune:

Red Bull North America, Inc. (RBNA) welcomes the opportunity to participate in the Committee's investigation of the marketing and promotional practices of energy drink manufacturers. RBNA and its parent company, Red Bull GmbH (Fuschl am See, Austria), have a long history of cooperation with legislative and regulatory authorities in order to ensure the lawful marketing and safe consumption of our products. In addition, we recognize the particular concerns of the Committee and hope to be a partner in crafting a solution that sufficiently and appropriately addresses these concerns. In that spirit, RBNA is pleased to announce that it is undertaking a number of voluntary commitments relating to the labeling and marketing of its products in the United States.

Red Bull GmbH created the "modem" energy drink category, first in Europe in 1987, and then launched in the United States in 1997 through its U.S. subsidiary RBNA. Today, Red Bull® products are sold in more than 165 countries. Health authorities around the world, including Food Standards Australia New Zealand

(FSANZ), Health Canada, and European Food Safety Authority (EFSA), have concluded that Red Bull® Energy Drink is safe to consume. Indeed, since 1987, over 40 billion cans of Red Bull® products have been safely consumed and enjoyed worldwide.

We cite these facts and statistics to show that Red Bull® products are safe. An 8.4 fl. oz. can of Red Bull® Energy Drink contains about the same amount of caffeine as a cup of home-brewed coffee, and about half as much caffeine as contained in many coffee house coffees. Caffeine, a key ingredient in Red Bull® products, has been safely consumed for hundreds of years. In fact, caffeine is one of the most researched and widely consumed food ingredients throughout the world.

The vast body of science and historical use of caffeine supports the conclusion that when a teenager begins to drink coffee, tea, and caffeine-containing sodas, he/she also can consume equivalent amounts of caffeine through energy drinks. However, as a general proposition, children (12 and under) should consume less caffeine than adults and teenagers due to their lower body weight, which is why the Company does not market its products to children and does not recommend its products for consumption by children. In fact, Red Bull® product labels specifically state that the product is not intended for consumption by children.

As you may know, the Food and Drug Administration (FDA) is in the process of considering current safety data on caffeine, including data relating to caffeine-containing energy drinks. We are confident that the FDA will agree that the data support the safe use of caffeine. RBNA is supporting the FDA's evaluation by providing the FDA with Red Bull® product safety information. Beyond the FDA review, and as explained further below, in order to support public confidence in our products and the public's consumption decisions, RBNA will include additional information on its label.

Despite the safety of Red Bull® products, we recognize the public health debate surrounding caffeinated soft drink consumption. Recent public health discussions have focused on sugar-and caffeine-containing beverages and possible links to childhood and teen obesity rates, as well as excessive consumption of caffeine by teenagers. Teaching children and teenagers moderation in their consumption habits and the importance of proper exercise is an important public health goal. Finding the ideal balance is not easy, but it is the responsibility of parents to set those limits. We respect parents' choices about their children's diets and do not interfere with that control.

Since its inception in 1987 and launch in the United States in 1997, Red Bull® has always been and remains an aspirational, adult brand and a premium product positioned for and marketed to adults. This is reflected through our can design, pricing, core marketing messages, as well as the content, timing, and placement of our advertising. Over time, RBNA's marketing strategy evolved and its investments became more focused. In 2011, the Company made a strategic decision to refine its marketing activities even further to focus on adults 18–34 years of age, which always has been the Company's primary target demographic. This allowed us to leverage our positioning—our premium package design, package sizes, and pricing—and play to our strengths via differentiation from our competition within the energy drink category. Since 2012, RBNA has continued to sharpen our marketing communications and investments to reach this target demographic, recognizing, however, that no company can ensure that its marketing materials will only reach a particular audience, as people of all ages and demographics may be attracted to them.

We recognize our responsibility, along with other food and beverage companies, to play a positive role in the public health debate surrounding consumption of calories and caffeine. RBNA is committed to promoting active and healthy lifestyle choices. RBNA has supported various industry anti-obesity initiatives. Notably, Red Bull® Energy Drink contains 110 calories/8.4 fl. oz. In addition, we also are focused on supporting consumers by offering beverage choices that provide low/no sugar and low/no calorie options. Following the launch of Red Bull® Energy Drink in the United States in 1997, we introduced Red Bull® Sugarfree and Red Bull® Total Zero. Moreover, as a member of the American Beverage Association (ABA), RBNA led the energy drink sector in adopting the *ABA 's Guidance for the Labeling and Marketing of Energy Drinks,* as well as similar industry codes in other parts of the world.

In this spirit of providing adequate consumer information and in light of our focus on adult marketing, RBNA undertakes the following voluntary commitments and urges all producers of caffeine-and sugar-containing beverages to make the same commitments.

PRODUCT LABELING AND FORMULATION:

- Red Bull® energy drink products will be labeled as conventional foods/beverages and not as dietary supplements.
- Red Bull® energy drink products will declare the total caffeine content per can on the product label.

As used herein, "target" is defined as the population for whom communications/products are designed and broadcast. Marketing communications are developed to appeal specifically to the target, and are broadcast through channels most likely to reach the target.

- RBNA will not sell energy drinks with a caffeine concentration in excess of 80 mg/8.4 fl. oz.
- RBNA will not sell energy drinks with a calorie content in excess of 110 calories/8.4 fl. oz.

CLAIMS AND PROMOTION:

- RBNA's marketing will not encourage or condone excessive or rapid consumption of energy drinks.
- RBNA's marketing will not say that larger sizes, more caffeine, or higher concentrations of caffeine are better or have a better/stronger effect.
- RBNA's labeling and marketing will not make claims using language specifically targeted to those under 18.
- RBNA will not buy advertising directly targeted at audiences that are more than 35 percent under 18 years of age. This applies to TV, radio, print, and where data is available, to the Internet and mobile devices. The media buying target age for all RBNA advertising media will be 18–34.
- RBNA will not feature child-or teen-oriented animated or licensed characters in advertising or any other promotional activities.
- RBNA will not market its energy drink products in K–12 schools or any other institutions responsible for this age group. This commitment includes school related events or activities.
- RBNA will not sell (including in automated vending machines) its energy drink products in K–12 schools or any other institutions responsible for this age group. This commitment includes school-related events or activities.
- RBNA will not sample energy drink products in or within the immediate vicinity of K–12 schools or other institutions responsible for this age group. The RBNA sampling target will continue to be 18–34 year olds, with a focus on college, military, and members of the workforce.

To further promote balanced nutrition and consumer awareness, we remain open to discussing changes for the entire beverage industry. We believe that any comprehensive effort regarding child and teen nutrition should include all sugar-and caffeine-containing beverages (*e.g.,* caffeinated soft drinks, coffee, and tea). A recent caffeine consumption survey shows that within each age group (including children and teenagers), 90 percent or more do not consume energy drinks at all, and more than 93 percent of the caffeine consumption within each age group comes from sources other than energy drinks, such as caffeinated soda, coffee, and tea. This survey is consistent with an FDA-sponsored consumption survey and demonstrates that the majority of caffeine intake comes from coffee, soft drinks, and tea. Soft drinks contain about the same amount of sugar as energy drinks, but are consumed more frequently and in larger volumes. In addition, energy drinks represent only 2 percent of the total soft drink market. RBNA is ready to further advance discussions about this topic, and believes the entire industry should be engaged to make meaningful progress.

Therefore, RBNA puts forth the following voluntary commitments that it will adopt, provided other producers of sugar-and caffeine-containing beverages do the same:

CONTAINER SIZE:

- RBNA will not sell products in containers larger than 12 fl. oz. if other producers of sugar-and caffeine-containing beverages agree to abide by the same limitation.

ADVERSE EVENT REPORTING:

- RBNA is willing to report to FDA any serious adverse events (reported to the Company by consumers) that are alleged to be associated with consumption of Red Bull® energy drink products, provided that other producers of caffeine-con-

taining beverages do the same. The Company believes that any analysis of serious adverse events suspected to be linked to caffeine, should contain a review of all caffeine-containing beverages. The Company would provide the reports in a manner consistent with the serious adverse event reporting requirements applicable to dietary supplements pursuant to the Dietary Supplement and Nonprescription Drug Consumer Protection Act.

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These commitments are separate from (and do not affect) RBNA's long standing support of developing athletic talent. In "giving wings to people and ideas," RBNA supports up and coming and top potential athletes under the age of 18. Additionally, RBNA hosts and sponsors various events that are typically open to the public, and that provide a platform for skilled individuals, some under 18 years of age, to compete or perform. Finally, separate Red Bull affiliates operate independent businesses, including professional motorsports and athletic sports teams, which maintain their own marketing practices.

RBNA will regularly monitor its marketing practices to ensure it honors the commitments contained herein. Further, RBNA shall establish and conduct a recurring training program for employees and third-party contractors and consultants involved in the marketing of Red Bull® products to ensure awareness of and compliance with these commitments. These voluntary commitments shall not constitute nor be construed as an admission of any kind regarding RBNA's prior practices.

Sincerely yours,

STEFAN KOZAK,
Chief Executive Officer,
Red Bull North America, Inc.

cc: Hon. BARBARA BOXER
Hon. BILL NELSON
Hon. MARIA CANTWELL
Hon. MARK PRYOR
Hon. CLAIRE MCCASKILL
Hon. AMY KLOBUCHAR
Hon. MARK WARNER
Hon. MARK BEGICH
Hon. RICHARD BLUMENTHAL
Hon. BRIAN SCHATZ
Hon. MARTIN HEINRICH
Hon. EDWARD MARKEY
Hon. ROGER WICKER
Hon. ROY BLUNT
Hon. MARCO RUBIO
Hon. KELLY AYOTTE
Hon. DEAN HELLER
Hon. DANIEL COATS
Hon. TIMOTHY SCOTT
Hon. TED CRUZ
Hon. DEBRA FISCHER
Hon. RONALD H. JOHNSON
Hon. JEFF CHIESA
Hon. RICHARD DURBIN

Ms. TAYLOR. Thank you.

We are publicly announcing for the first time voluntary commitments relating to the labeling and marketing of our product. We make these commitments to provide more information to consumers so that they can make informed choices and to further differentiate our product as the premium adult energy drink.

Our commitments are as follows. Red Bull will continue to label its energy drinks as conventional foods, rather than dietary supplements. We will also declare the total caffeine content per can on our product label. We will not sell energy drinks with a caffeine concentration in excess of 80 milligrams per 8.4 ounces or with more than 110 calories per 8.4 ounces.

Red Bull will not encourage or condone the excessive or rapid consumption of its energy drinks. Our marketing will not say that more caffeine or larger sizes or higher concentrations of caffeine have a better or stronger effect. We will not make claims using language specifically targeted to those under 18, nor will we buy advertising targeted at audiences where more than 35 percent of viewers are under the age of 18.

We will not feature child or teen-oriented characters in our advertising and promotional activities. Red Bull will not market or sell its energy drink products in K through 12 schools or other institutions responsible for this group. And we will not sample in or within the immediate vicinity of such places.

Red Bull is also prepared to adopt two additional commitments if producers of other sugar and caffeine-containing beverages are willing to do the same. We will agree not to sell containers larger than 12 ounces, and we will agree to report to the FDA any adverse events reported to us by consumers that are alleged to be associated with the consumption of our product.

We understand that childhood and teen obesity is a major public health challenge and attracting more and more attention. To the extent that sugar and caffeine are viewed as contributors to this problem, we are interested in being a part of the solution, which includes the entire industry. The energy drink sector is only a small part of a much larger universe of caffeine and sugar-containing drinks that must be a part of any solution.

We believe that large can sizes are a primary contributor to the problem, and we think this is an area where we, together with the industry, can play a constructive role. And in closing, it is relevant to note that in every age category, including teens and children, 93 percent of caffeine consumption comes from sources other than energy drinks.

Still, we are pleased to be here to participate in these discussions. Red Bull is proud of its commitments that it is making today. They enable consumers to make informed choices, and they differentiate our product as the premium adult energy drink.

Thank you, and I would be pleased to answer any questions you may have.

[The prepared statement of Ms. Taylor follows:]

PREPARED STATEMENT OF AMY TAYLOR, VICE PRESIDENT AND GENERAL MANAGER, RED BULL NORTH AMERICA, INC.

My name is Amy Taylor. I have been employed by Red Bull North America, Inc. (RBNA) for the last 14 years. I currently serve as RBNA's Vice President & General Manager, a position I have held since November 2012. In that capacity, I am responsible for the brand's overall strategic marketing, sales and distribution throughout the eastern region. Prior to this position, I served as RBNA's Vice President of Marketing from 2008 to 2012, and led brand marketing, sports and culture marketing, digital marketing, and communications.

Company Background

Founded in 1984 by Dietrich Mateschitz, Red Bull GmbH (Fuschl am See, Austria) created the "modern" energy drink category with the launch of its Red Bull® Energy Drink, first in Europe in 1987, and then in the United States in 1997 through its U.S. subsidiary RBNA. Red Bull® Sugarfree was launched in 2003, followed by Red Bull® Total Zero in 2012, and Red Bull® Editions in 2013.

Today, Red Bull® products are sold in more than 165 countries. Health authorities around the world, including Food Standards Australia New Zealand (FSANZ),

Health Canada, and the European Food Safety Authority (EFSA), have concluded that Red Bull® Energy Drink is safe to consume. Indeed, since 1987, over 40 billion cans of Red Bull® products have been safely consumed and enjoyed worldwide.

RBNA's vision is to "give wings to people and ideas," and our brand is built on supporting the dreams and ideas of innovative individuals across sports, culture, science and technology. Red Bull® is a sophisticated, adult, aspirational brand that aims to communicate with consumers in a manner that is witty, progressive and often complex. We are the premium product in the energy drink category—as evident in our packaging, pricing, messaging, and the demographics of our consumer base.

Corporate Responsibility

RBNA always has taken an active leadership role in the public health debate surrounding the consumption of caffeinated soft drinks, including energy drinks. We recognize our responsibility, along with other food and beverage companies, to play a positive role in this discussion. RBNA is committed to promoting active and healthy lifestyle choices. We believe that teaching children and teenagers moderation in consumption habits and the importance of proper exercise is an important public health goal. Finding the ideal balance is not easy, but it is the responsibility of parents to set those limits. We respect parents' choices about their children's diets and do not interfere with that control.

We are committed to working with regulators such as the Food and Drug Administration (FDA) to ensure that there is no question about the safety of Red Bull® products. RBNA is confident that our products are just as safe to consume as the many other caffeine containing beverages, regardless whether the caffeine is naturally occurring or added. Accordingly, we remain open to discussing changes for the entire beverage industry, and believe that any comprehensive effort regarding child and teen nutrition must include all sugar-and caffeine-containing beverages (*e.g.,* caffeinated soft drinks, coffee, and tea).

Safety of Red Bull® Products

As noted above, health authorities around the world have concluded that Red Bull® Energy Drink is safe for consumption. An 8.4 fl. oz. can of Red Bull® Energy Drink contains 80 mg of caffeine—about the same amount of caffeine as a cup of home-brewed coffee, and about half as much caffeine as many coffee house coffees. Caffeine has been safely consumed for hundreds of years and is one of the most researched and widely consumed food ingredients in the world. It is a naturally occurring alkaloid that is present in the leaves, seeds, and fruits of more than 60 plants. Caffeine also can be synthetically manufactured. There is no chemical difference between synthetic caffeine and naturally sourced caffeine.

For its part, Health Canada scientists conducted an extensive review of the scientific literature on caffeine. Based on this review, in March 2010, Health Canada advised that healthy adults are not at risk for potential adverse effects from caffeine at daily consumption levels of up to 400 mg caffeine (approximately 5 mg/kg bodyweight). The FDA referred to Health Canada's conclusions in its August 10, 2012 and November 21, 2012 letters to Senator Durbin. Health Canada just published an updated risk assessment of energy drinks and reaffirmed its earlier views.

For adolescents 13 and older, Health Canada has not developed definitive advice, but concluded that daily caffeine intake of up to 2.5 mg/kg body weight would not cause adverse health effects. This dose would suggest that teenagers (with an estimated range of body weights between 40–70 kg, or 90–155 lbs) could consume 100 to 175 mg of caffeine daily, depending on the individual body weight of the teenager. Health Canada described this as a conservative approach because older and heavier adolescents may be able to consume adult doses of caffeine, recognizing the importance of body weight to an individual's metabolism of caffeine.

As you consider the safety of energy drink consumption by teenagers, it is important to note that the FDA has considered teen exposure to caffeine from all sources, including energy drinks, and found that the contribution of energy drinks is minor when compared to caffeine consumption from coffee, soft drinks, and tea. In its November 21, 2012 letter to Senator Durbin, the FDA explained:

> In an effort to better understand consumption patterns for potentially susceptible subgroups, FDA contracted for the performance of an in-depth analysis of caffeine consumption by the U.S. population, which was completed in September 2009 and revised in August 2010 (Somogyi 2010). . . .
>
> This report indicates that the mean amount of caffeine consumed by the U.S. population is consistent with past FDA estimates, remaining relatively stable at approximately 300 milligrams per person per day (mg/p/day), despite the entry of "energy drinks" into the marketplace. . . . Significantly, this report

> also indicates that teens and young adults (14–21 years of age) consume, at the mean, approximately one-third (or about 100 mg/p/d) the amount of caffeine as adults, and that their caffeine consumption is mainly from coffee, soft drinks, and tea.
>
> According to the report, "energy drinks" contribute a small portion of the caffeine consumed, even for teens. . . .

An even more recent caffeine consumption survey in the United States shows that within each age group (including children and teenagers), 90 percent or more do not consume energy drinks at all, and more than 93 percent of the caffeine consumption within each age group comes from sources other than energy drinks. As in the FDA study, among all children and teenagers, the primary source of caffeine was found to be coffee, tea, and soft drinks. Perhaps these results are not surprising because energy drinks represent only 2 percent of the total soft drink market. Thus, given the very limited consumption of energy drinks (and corresponding intake of caffeine from energy drinks), we believe that any comprehensive discussion regarding the consumption of caffeine also must include caffeinated soft drinks (which are widely consumed by children and teenagers), coffee, and tea.

Because people have different tolerance levels of caffeine, the daily consumption of Red Bull® products should conform to a person's intake of caffeine from any source. Of course, as a general proposition, children should consume less caffeine than adults due to their lower body weight, which is why we do not market our product to children and do not recommend our products for consumption by children. In fact, Red Bull® product labels specifically state that the product is not intended for consumption by children. Further, to help enable all consumers to make informed consumption decisions, our product labels will declare caffeine content.

As you may know, the FDA is in the process of considering current safety data on caffeine, including data on caffeine-containing energy drinks, and we fully expect the agency to agree with the conclusions of other health authorities regarding the safe use of caffeine in Red Bull® products. We are supporting the FDA's evaluation by providing Red Bull® product safety information to the agency.

Taurine, another ingredient in Red Bull® products, is an amino acid and a natural constituent of the human body that performs a number of useful functions. It is found in foods such as poultry, fish, and shellfish. It also is found in human breast milk, which is why it is frequently found as an additive in infant formulas. The safety of taurine consumption through energy drinks is supported by health authorities around the world. By way of example, in February 2009, the EFSA published its scientific opinion on ingredients of energy drinks and concluded that taurine does not raise any safety concerns at the levels present in Red Bull® Energy Drink. EFSA further considered the possibility of synergistic effects among the key ingredients in Red Bull® Energy Drink and concluded that the scientific data do not support the possibility of interactions between the ingredients.

The other ingredients used in Red Bull® products, which are FDA-approved food/color additives or generally recognized as safe (GRAS) substances such as sugars, inositol and B-vitamins, also satisfy the FDA's ingredient safety and regulatory standards. In fact, one 8.4 fl. oz. (250 mL) can of Red Bull® Energy Drink contains 27 grams of sugars and 110 calories. Non-diet soft drinks contain about the same amount of sugar and calories as energy drinks, but are consumed more frequently and in larger volumes.

Red Bull® is an Aspirational, Adult Brand and a Premium Product Positioned for and Marketed to Adults

Since its inception in 1987 and launch in the U.S. in 1997, Red Bull® always has been and remains an aspirational, adult brand and a premium product positioned for and marketed to adults. This is reflected through our can design, pricing, and core marketing messages, as well as the content, timing, and placement of our advertising and communications. Over time, RBNA's marketing strategy evolved and our investments became more focused. For example, in 2011, RBNA made a strategic decision to refine our marketing activities to focus further on adults 18–34 years of age, which always has been our primary target demographic. This allowed us to leverage our positioning—our premium package design, package sizes, and pricing—and play to our strengths via differentiation from our competition within the energy drink category. Since 2012, RBNA has continued to sharpen our marketing communications and investments to reach this target demographic, recognizing, however, that no company can ensure that its marketing materials will only reach a particular audience, as people of all ages and demographics may be attracted to them.

To be clear, RBNA has never targeted our marketing to children and we will not do so in the future. Regarding teenagers, RBNA believes that the underlying science and historical product use support the conclusion that Red Bull® products may be safely consumed by teenagers in the same way as coffee, tea, or caffeinated soft drinks. However, because teenagers younger than 18 do not represent our target demographic, we do not focus our marketing activities on them.

To further promote balanced nutrition and consumer awareness, we remain open to discussing changes for the entire beverage industry. Caffeine consumption surveys commissioned by both the FDA and the food industry demonstrate that the primary dietary contributors of caffeine in all age groups (including teens and youth) are coffee, tea and soft drinks. Caffeine from energy drinks represents a very small contribution to the overall daily intake. Indeed, some major soft drink companies are marketing products such as juices and waters with caffeine in them as well. The broader solution to excessive consumption of calories and caffeine must go beyond energy drinks, which are a niche product representing only 2 percent of the total soft drink market.

Conclusion

We are committed to empowering consumers to make informed choices about the amount of caffeine they consume and to differentiating ourselves from our competitors by positioning Red Bull® as the premium, adult energy drink brand. Red Bull® products are safe for teenagers and adults to consume, but we agree that children should consume little or no caffeine, including from caffeinated sodas, coffees, teas, or energy drinks. We are therefore interested in being a leader in a broad, industry-wide solution to the public health concerns surrounding sugar-and caffeine-containing beverages.

Thank you again for inviting RBNA to testify. We look forward to partnering with you on these issues going forward.

Senator BLUMENTHAL. Thank you very much.

Ms. Weiner?

STATEMENT OF JANET WEINER, CHIEF OPERATIONS OFFICER AND CHIEF FINANCIAL OFFICER, ROCKSTAR, INC.

Ms. WEINER. Good afternoon, Senator Blumenthal, Senator Markey, and——

Senator BLUMENTHAL. You might want to turn on your——

Ms. WEINER. Oh, I am sorry.

Senator BLUMENTHAL. Push the button.

Ms. WEINER. Aha, thank you. OK.

Good afternoon, Senator Blumenthal, Senator Markey, and Ranking Member Thune, and members of the Committee. My name is Janet Weiner. I am the Chief Operations Officer and Chief Financial Officer for Rockstar, Inc., the manufacturer of Rockstar energy drink products. I am also co-owner of the company.

I thank the Committee for inviting Rockstar to speak at today's hearing, and I welcome this opportunity to discuss Rockstar's commitment to the safety of our products and the responsibility of our brand marketing practices.

I believe Rockstar represents a model of entrepreneurial enterprise that has grown from an ambitious idea into an American success story. Energy drinks like ours are an extremely popular and growing product category, having sold more than 34 billion units in the United States since 2000. I would like to speak about Rockstar's commitment to consumer safety.

Rockstar's commitment to consumer safety is the company's number one priority. The use and levels of caffeine within our energy drink formulations have been determined, based upon the consensus of an independent, highly qualified expert panel led by Dr. John Doull of the University of Kansas Medical Center, to be gen-

erally recognized as safe—the acronym is GRAS—under FDA standards.

In addition to caffeine, Rockstar contains other ingredients that have been determined to be GRAS, consistent with FDA guidance, and safe for consumption. The expert panel commissioned by our company has concluded that there is no expected safety concern associated with these ingredients alone or in combination from consumption of Rockstar energy drink products.

At either 160 milligrams per 16 ounces or 240 milligrams per 16 ounces, depending on the product, Rockstar contains far less caffeine than a 16-ounce cup of Starbuck's Pike Place roast, their house blend, which contains 330 milligrams, according to the Starbuck's website.

The difference in caffeine levels are important to keep in mind insofar as coffee and tea, rather than energy drinks, are the most significant sources of caffeine for Americans, including teens and children. The FDA-commissioned Somogyi report on caffeine consumption among the U.S. population indicated that teens and young adults aged 14 to 21 years consume on average approximately one third the amount of caffeine as people over 21, a level of consumption that has remained constant even as energy drinks gain in popularity.

Further, the report found that energy drinks contributed only a small portion of caffeine consumed by teenagers and that the most significant source of caffeine for both children aged 2 to 13, as well as teens aged 14 to 17, was coffee, tea, and soft drinks. Researchers at Penn State and the Diet Assessment Center likewise found that energy drinks were minor contributors to overall caffeine intakes in all age groups.

As outlined in greater detail in my prepared statement, recent analyses have called into question two of the most cited sources alleging energy drink risks. For example, a July 25, 2013, report commissioned by the American Beverage Association, Pinney Associates noticed that the Drug Abuse Warning Network, SAMHSA DAWN—referred to as the DAWN report, this is the emergency room report—findings rely upon extrapolated sample data, which can skew the reported national statistics regarding emergency room visits associated with energy drinks.

Additionally, as the ABA has recently noted, the authors of the Arria letter paint an inaccurate picture of caffeine use and safety, ignoring the vast body of robust and reliable scientific evidence that has for decades established the safety of caffeine at the levels present in energy drinks, including for younger consumers. A copy of both the Pinney Associates' analysis of the DAWN report and the ABA's response to the Arria letter have been submitted with my prepared statement to the Committee.

I would like to speak about Rockstar's labeling and marketing practices. Rockstar takes pride in the fact that its product labeling is as transparent and clearly defined as possible. On its product labels, Rockstar has for many years included the following information—ingredients in our products, including caffeine, vitamins, sugars, and amino acids; the amount of total caffeine per serving, as well as the total caffeine from all sources per container.

A consumer advisory statement that reads "Not recommended for children, pregnant or nursing women, or those sensitive to caffeine." An example of Rockstar energy drink's label is attached to my prepared statement to the Committee.

Like other foods and beverages, Rockstar energy drink products comply with FDA regulations relating to consumable products, and as part of its commitment to consumer safety, Rockstar has voluntarily committed to provide serious adverse events to the FDA reported to us by consumers that are alleged to be associated with consumption of Rockstar products.

Rockstar has long committed to refrain from marketing its products to children under 12. In addition to our clearly labeled consumer advisory that Rockstar energy drinks are not recommended for children, we also do not promote our products to children via our company website, nor does Rockstar currently market or sell its products in K to 12 schools, including high schools.

Rockstar's target demographic is persons 18 to 35 years of age. Rockstar engages in marketing activities including event and athlete sponsorship and promotion in action sports, motor sports, and live music events that target the 18 to 35 age group.

In conclusion, I wish to thank the Chair and the members of the Committee for providing Rockstar with this opportunity to discuss our commitment to product safety and responsible marketing practices, and I look forward to answering any questions you may have.

[The prepared statement of Ms. Weiner follows:]

PREPARED STATEMENT OF JANET WEINER, CHIEF OPERATIONS OFFICER AND CHIEF FINANCIAL OFFICER, ROCKSTAR, INC.

Chairman Rockefeller, Ranking Member Thune, and members of the Committee, my name is Janet Weiner, I am the Chief Operations Officer and Chief Financial Officer for Rockstar, Inc., the manufacturer of Rockstar Energy Drink products. I am also co-owner of the company.

I thank the Committee for inviting Rockstar to speak at today's hearing, and I welcome this opportunity to discuss with this esteemed panel Rockstar's commitment to the safety of our products and the responsibility of our brand marketing practices.

Rockstar represents a model of entrepreneurial enterprise that has grown from an ambitious idea into an American success story, from a small drink manufacturer to a major force in the beverage industry.

Founded in 2001 with a single product, the Rockstar Energy Drink portfolio now consists of over 20 flavors and is currently sold in more than 30 geographies around the world including the United States, Canada, Europe, Asia, Australia, and the Middle East. Rockstar's current market share in the United States is roughly 15 percent of the overall energy drink market.

Energy drinks are an extremely popular and growing product category, having sold more than 34 billion units in the United States since 2000. As such, energy drinks are very much a mainstream product with broad participation from a range of companies within the beverage industry. Following on the next page is chart showing a sample of energy drinks marketed by some of the largest beverage manufacturers in the U.S., which are all in addition to the products manufactured by the companies present here today.

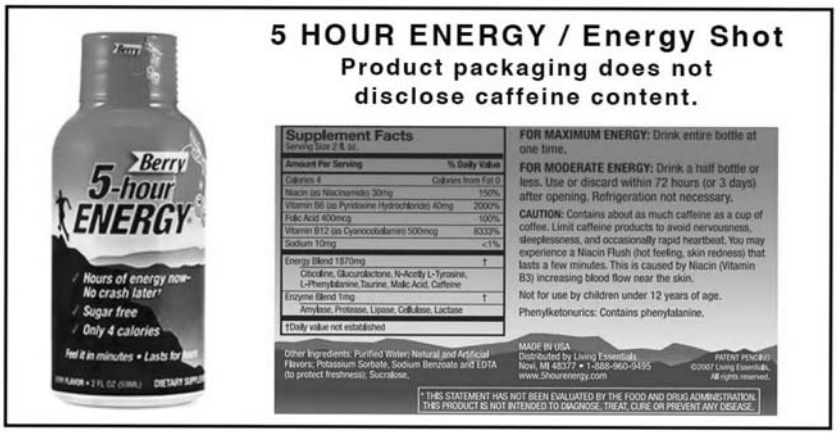
ENERGY DRINKS FROM THE COCA-COLA COMPANY

ENERGY DRINKS FROM PEPSICO

ENERGY DRINKS FROM STARBUCKS CORPORATION

ENERGY DRINKS FROM DR PEPPER SNAPPLE GROUP

The energy drink market is made more competitive by concentrated "energy shots," such as 5-Hour Energy and similar products. These products account for approximately 11 percent of the energy market.[1]



Rockstar's commitment to consumer safety is the company's number one priority, and I will outline for the Committee the steps we have taken to insure this objective.

Before I do that, I would like to make the following assertions, which are based upon a recent Rockstar submission to the U.S. Food and Drug Administration ("FDA"),[2] and which address certain inaccurate or questionable claims regarding the safety of the use of caffeine in our energy drinks products and, specifically, such claims regarding the health of children and teenagers.

First, the use of caffeine within our energy drink formulations has been determined, based upon the consensus of a highly qualified expert panel (hereinafter "GRAS panel"),[3] to be Generally Recognized as Safe ("GRAS") under FDA standards. As part of this determination, the panel specifically considered the effect of caffeine on children.

As we stated in our recent letter to the FDA:

> Various sub-populations were considered during the GRAS determination including evaluation of age or sex specific effects of caffeine. The effect of caffeine on children was considered, and it was determined, based on limited studies, that there is no evidence to support the conclusion that children display increased sensitivities to dietary caffeine. For example, as reported by Tema Nord, the Nordic Council of Ministers Working Group on Food Toxicology and Risk Evaluation, "Studies on caffeine dependency and withdrawal symptoms in children and adolescents, although few, draw the same picture of the physical and psychological findings as in adults" (Meltzer *et al.,* 2008). Dietary exposure to caffeine in children and the corresponding potential to affect neurodevelopment in children was considered. Studies conducted under placebo controlled settings using large populations of healthy children with asthma or attention deficit disorder demonstrate that consumption of large dietary quantities of caffeine on a daily basis (*i.e.,* 5 to 10 mg/kg body weight per day) for extended durations is without adverse effects on various developmental measures (*e.g.,* motor function, cognition, behavior, general health, deafness, blindness) (Lindgren *et al.,* 1992; Stein *et al.,* 1996; Schmidt *et al.,* 2006, 2007, 2012). Although the current published information provides no evidence that children display increased sensitivities, Rockstar notes that caffeinated Rockstar energy drinks are not intended for use by children . . ., nor are Rockstar products di-

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[1] *See* Food and Drug Administration, Laszlo P. Somogyi, *Caffeine Intake by the U.S. Population* 2 (updated Dec. 2012) (hereinafter "Somogyi Report").

[2] Letter from Kathleen M. Sanzo, on behalf of Rockstar, Inc. to Michael M. Landa, Director, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration (June 18, 2013) (hereinafter "Landa Letter").

[3] Rockstar's GRAS panel was comprised of the following individuals: Dr. John Doull Ph.D., M.D. (University of Kansas Medical Center); Dr. Stanley M. Tarka Ph.D. (Consultant); Dr. John A. Thomas Ph.D. (University of Indiana School of Medicine).

> rectly marketed to this population group. Caffeinated energy drinks manufactured by Rockstar are clearly labeled not recommended for children. . . . It was therefore concluded that the intended use of caffeine within Rockstar energy drinks does not represent a risk to children under the age of 12 as this population group is not an intended user of Rockstar energy drink products.[4]

Second, case reports purporting to link energy drink consumption with severe adverse effects do not demonstrate a causal relationship between caffeine and the effects that were reported. As explained in our June 18, 2013 letter to the FDA:

> During the GRAS determination, Rockstar, and the Expert Panel, recognized the increasing concerns expressed by the media and scientific community pertaining to the safety of caffeinated energy drinks. It was determined that these concerns were exclusively driven by various case reports in which the consumption of an energy drink was associated with severe adverse reactions and alleged death in some individuals. A critical review of published case-reports documenting incidences of severe adverse effects in association with energy drink consumption was conducted during the GRAS determination. It was concluded that case-reports do not represent cause-effect relationships as such information is subject to many other significant confounding events/information (*e.g.,* lack of information on exposures, the presence of pre-existing or undiagnosed conditions, or improper and falsely documented use patterns of the drink and/or other substances such as drugs and alcohol). This view was supported by the U.S. FDA as reflected within the statement on the Agency CAERs database (for which reports of energy drink associated adverse effects have been documented) that "the adverse effect report itself about a particular product only reflects information AS REPORTED [FDA's emphasis] and does not represent any conclusion by FDA regarding a causal relationship or association with the product or ingredient." The potential for confounding that is implicit within these types of case report studies is significant, and this limitation has in many instances not received proper consideration.[5]

Additionally, as I will discuss at greater length below, a report released on July 25, 2013, by Pinney Associates further calls into question the reliability of certain data that has been cited to suggest a causal link between energy drinks and emergency room visits.[6]

I. Rockstar's Commitment to Consumer Safety

Rockstar Energy Drink products contain levels of caffeine that are GRAS under FDA standards. In August 2012, the FDA stated that for healthy adults, caffeine intake up to 400 milligrams per day is not associated with general toxicity, cardiovascular effects, effects on bone status and calcium balance, changes in adult behavior, incidence of cancer, or effects on male fertility.

In addition to caffeine, Rockstar contains other ingredients that are consistent with FDA GRAS guidance and are safe for consumption. These other ingredients include B-Vitamins, Ginseng, Milk Thistle, L-Carnitine, Inositol, and Taurine. The caffeine contribution to the finished drinks from the inclusion of Guarana is less than 1 milligram per serving. Taurine is an amino acid that is naturally present in human flesh, and is in meat, mother's breast milk, and popular baby formulas. As explained in an April 25, 2013 scientific white paper signed by John Doull, Ph.D., M.D., a Professor in the Department of Pharmacology at the University of Kansas Medical Center, addressing the safety of Rockstar's products—a copy of which is attached to this statement as Attachment 1—the expert panel commissioned by our company has concluded that under the conditions of intended use in Rockstar Energy Drink products, the combination of ingredients as used in Rockstar is safe for consumption and GRAS based on scientific procedures.[7]

The caffeine content in Rockstar Energy Drink products is well below this threshold and considerably lower than that contained in a sixteen ounce cup of premium brand coffee.

For example, a sixteen ounce can of Rockstar Energy Drink will contain either 160 milligrams of caffeine or 240 milligrams of caffeine, depending on the product.

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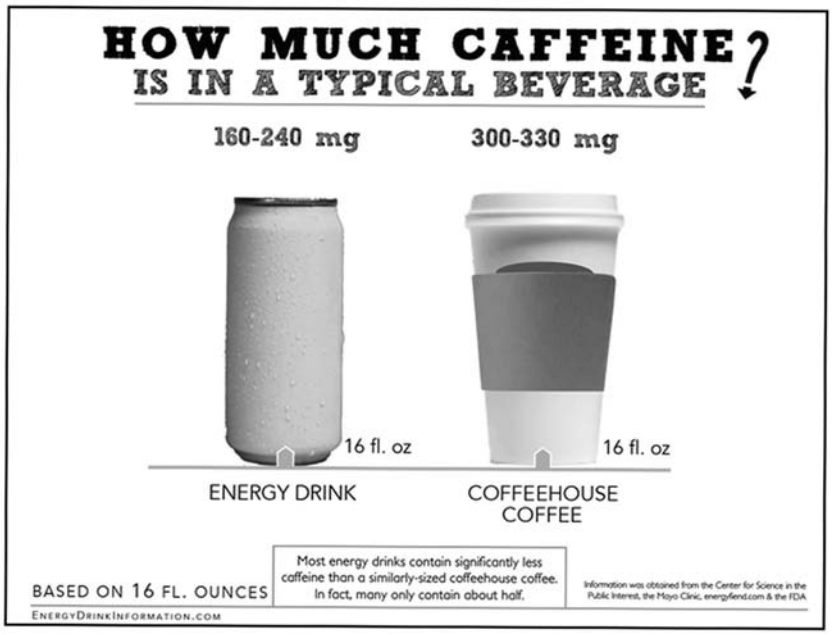
[4] Landa Letter at 7.

[5] *Id.* at 5–6.

[6] Pinney Associates, *Emergency Department Visits Involving Energy Drinks and Limitations of the Drug Abuse Warning Network (DAWN)* (July 25, 2013) (hereinafter "Pinney Report").

[7] Intertek Cantox, Scientific White Paper: Summary of Data Supporting the Safety of Rockstar Energy Drinks 3, 21–23 (April 25, 2013) [hereinafter Scientific White Paper].

By contrast, the same sixteen ounces of Starbuck's Pike Place coffee is identified on the company's website as containing 330 milligrams of caffeine.[8]



Coffee and tea, rather than energy drinks, are the most significant sources of caffeine for Americans, including teens and children. A FDA-commissioned report authored by Laszlo P. Somogyi on caffeine consumption among the U.S. population in 2009, and then updated in 2010 and again in 2012, indicated that teens and young adults ages 14 to 21 years consume, on average, approximately one-third the amount of caffeine as people over 21—about 100 milligrams per day. Importantly, the 2012 report also showed that the average amount of caffeine consumed has remained constant. Further, the report found that "'energy drinks' contributed only a small portion of caffeine consumed by teenagers." and that the most significant source of caffeine for both children aged 2 to 13 and teens aged 14 to 17 was coffee, tea, and soft drinks.[9]

Based on data gathered from 2009 through 2010, the U.S. National Center for Health Statistics' National Health and Nutrition Examination Surveys ("NHANES") reported very low energy drink consumption among adolescents, including just 1.1 percent consumption of energy drinks among adolescent girls and 4.5 percent among adolescent boys. A similar conclusion was reached by researchers at Pennsylvania State University and the Diet Assessment Center, who found that the percentage of energy drink users reported in the Kantar Worldpanel Beverage Consumption Survey was low, and that energy drinks "were minor contributors to overall caffeine intakes in all age groups."[10]

According to the National Coffee Association, "[t]he teenage years are the key entry point into the coffee market."[11] Of Americans who drink coffee, 52 percent reported that they began consuming coffee one time per week or more between the ages of 13 and 19, with another 8 percent that began to consume coffee regularly before they turned 13.[12]

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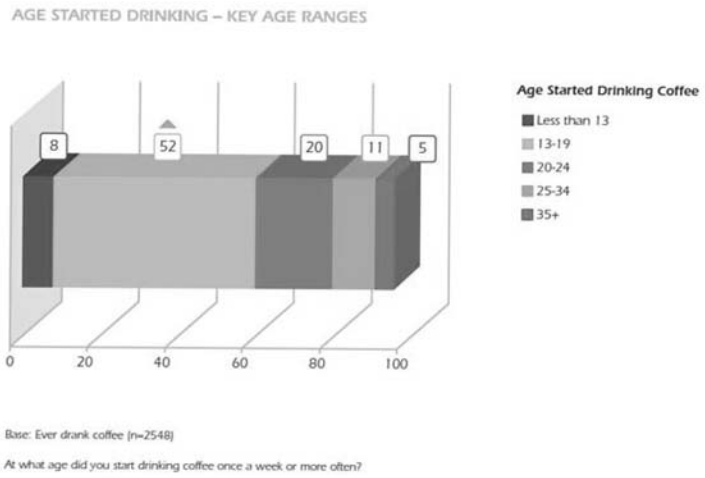
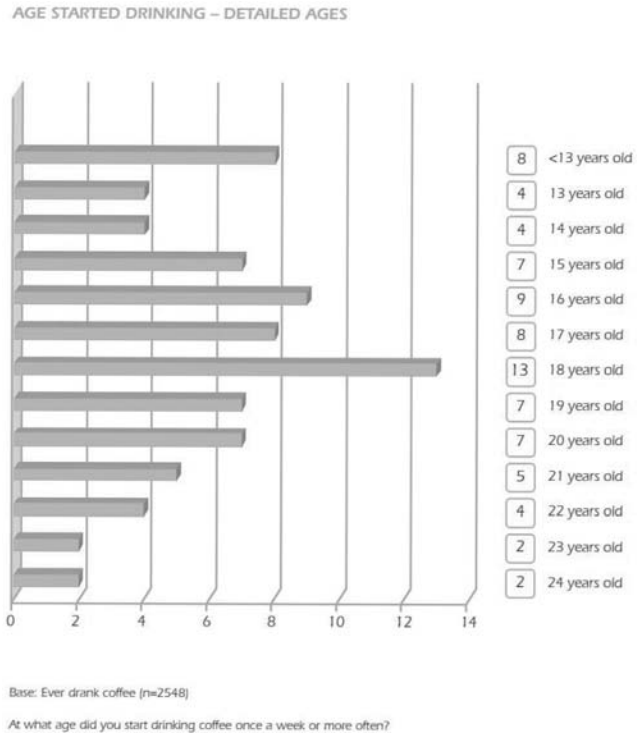
[8] Starbucks Corp., Pike Place Roast Nutritional Information, *http://www.starbucks.com/menu/drinks/brewed-coffee/pike-place-roast* (last visited July 28, 2013).
[9] Somogyi Report at Dec. 2012 update.
[10] Diane C. Mitchell, *et al., Beverage Caffeine Intakes in the U.S.* abstract (April 2012).
[11] National Coffee Assoc., *2012 National Coffee Drinking Trends* 52 (2012).
[12] *Id.* at 52–53 (2012).



Source: National Coffee Assoc., *2012 National Coffee Drinking Trends* at 52.

Looking at the years in greater detail, the National Coffee Association found that the ages of "16–18 emerge as the most important—34 percent of coffee consumers began drinking coffee weekly or more often in those years."[13] Factoring in all ages, the mean age at which consumers started drinking coffee is 19 years old.



Source: National Coffee Assoc., *2012 National Coffee Drinking Trends* at 53.

[13] *Id.* at 52.

Rockstar has been extremely distressed by the proliferation and amount of inaccurate information that has appeared in the media based upon erroneous reports and manipulated data. We hope that this hearing will help to debunk the misinformation that has been unfortunately perpetuated by the media, by questionable methodology in reports prepared by the Drug Abuse Warning Network ("DAWN"), and by the distorted information presented in the "Arria Letter." Although the DAWN report has attracted significant attention, careful analysis of the report and the public data relied on by the authors, does not appear to be consistent with a signal of substantial medical harm.

As identified in a recent analysis by Pinney Associates, commissioned by the American Beverage Association ("ABA"), reports of energy drink-related Emergency Department ("ED") visits need to be viewed in a broader context, as an analysis of DAWN public use data indicates that drug-related ED visits have also increased (both by a similar proportion and absolute magnitude as compared to energy drinks) for a number of other products, including infant formula, vitamins, and laxatives. In 2011, energy drink-related visits were estimated to comprise only 0.41 percent of all drug-related ED visits.[14]

Further, Pinney Associates noted the DAWN report's findings rely on extrapolated sample data which can distort the estimate and skew the reported national statistics regarding emergency room visits associated with energy drinks.[15]

Additionally, as the ABA has recently noted, the Authors of the Arria Letter paint a distorted and highly inaccurate picture of caffeine use and safety, ignoring the vast body of robust and reliable scientific evidence that has, for decades, established the safety of caffeine at the levels presented in energy drinks, including for younger consumers.

A copy of both the ABA-commissioned Pinney Report analysis of the DAWN report and the ABA's response to the Arria letter have been submitted with these statements for the Committee's hearing record as Attachments 2 and 3, respectively.

The opportunity to discuss the ABA and Pinney Report's recent findings regarding the DAWN report and the Arria Letter would not only be welcomed, but is imperative, as these two documents call into question the majority of recent reports in the media that claim there is a discernible pattern of adverse effects related to energy drink consumption and caffeine consumption patterns by adolescents.

In considering such claims, it is important to note again that an ordinary cup of coffeehouse coffee, such as Starbucks' Pike Place blend, contains more caffeine than our products. Moreover, setting quantity aside, the caffeine contained in our products is the same in terms of benefits and effects as the caffeine contained in ordinary coffee. It is important to recognize that caffeine is a well-studied, widely-used, and safely consumed ingredient.

II. Rockstar's Labeling and Marketing Practices

Rockstar Energy Drink product labels clearly state the ingredients in our products, including caffeine, vitamins, sugars, and amino acids.

In addition to clearly listing ingredients, Rockstar Energy Drink products also list the amount of total caffeine per serving and the total caffeine from all sources per container. We take pride in the fact that Rockstar product labeling is as transparent and clearly defined as possible.

Further, Rockstar Energy Drink product labels contain the consumer advisory statement *"Not recommended for children, pregnant or nursing women, or those sensitive to caffeine."*

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[14] Pinney Report at 4 (citing Substance Abuse and Mental Health Services Administration ("SAMHSA") extrapolated estimates that energy drink related visits totaled 20,783 in 2011 whereas all drug related visits totaled 5.1 million for the same year).

[15] PinneyAssociates specifically found that:

DAWN projects to a national estimate of cases based on combining results from two sources: approximately 183 hospitals in 13 major metropolitan areas, and approximately 50 supplementary hospitals in 2011. Although the metropolitan hospitals actually report more cases, the supplementary hospitals actually exert greater influence on the projected national estimate. On average, one case in the supplementary sample represents 135 weighted cases, whereas one case in any of the 13 main metropolitan areas represents, on average, fewer than 5 weighted cases. Therefore, a single case from a supplementary hospital can count 27 times more than a case from one of the metropolitan hospitals that report data to DAWN. This can distort the estimate. For example, a small 'outbreak' at a community hospital could potentially skew the national statistics; a single case of energy drink use presenting to a hospital in the supplementary sample could be counted as though it were 863 cases (the maximum weight for a single case in 2011), possibly seriously skewing the national statistics and resulting in misleading trend data.

Pinney Report at 9.

Below is an example of a label from a Rockstar Energy Drink, which demonstrates the full range of information that is stated clearly on each container of our product:

Like other foods and beverages, Rockstar Energy Drink products are regulated by the FDA. Rockstar complies with applicable laws and regulations related to the manufacture, labeling, sale, and distribution of consumable products. Additionally, as part of its commitment to consumer safety, Rockstar has voluntarily committed to report to the FDA any serious adverse events reported to us by consumers that are alleged to be associated with consumption of Rockstar products Rockstar conforms to the adverse reporting system and will continue to do so.

As a member of the ABA, Rockstar has also committed to refrain from marketing its products to children under 12. In addition to our clearly-labeled consumer advisory that Rockstar Energy Drinks are not intended for children, we also do not promote our products to children via our company website. Simply put, Rockstar does not market products to children under 12 years of age. Similarly, as a member of the ABA, Rockstar has committed not to market or sell its products in K–12 schools, including high schools.

Rockstar's target demographic is persons 18 to 35 years of age. Rockstar engages in marketing activities, including event and athlete sponsorship and promotion in action sports, motor sports, and live music events that target the 18 to 35 age group.

III. Conclusion

In conclusion, I reiterate that Rockstar Energy Drink products are safe for consumers and fully compliant with FDA regulations. According to a review conducted by Professor John Doull of the University of Kansas Medical Center, the combination of ingredients contained in Rockstar is safe for consumption. Moreover, contrary to certain inaccurate allegations, our products contain *less* caffeine than Starbucks ordinary house blend, on a per ounce basis, and our products clearly display the caffeine content from all sources per container. Finally, the target audience for Rockstar's marketing initiatives is persons 18 to 35 years of age.

I thank the Chair and members of the Committee for providing Rockstar the opportunity to discuss our commitment to product safety and responsible marketing practices, and I look forward to answering any questions you may have.

ATTACHMENT 1

April 25, 2013

SCIENTIFIC WHITE PAPER: SUMMARY OF DATA SUPPORTING THE SAFETY OF ROCKSTAR ENERGY DRINKS

Prepared for: ROCKSTAR, INC.; *Prepared by:* INTERTEK CANTOX

SUMMARY OF DATA SUPPORTING THE SAFETY OF ROCKSTAR ENERGY DRINKS

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SUMMARY OF DATA SUPPORTING THE SAFETY OF ROCKSTAR ENERGY DRINKS

Executive Summary

Energy drinks have been targeted in the U.S. media recently in response to reported adverse events—which have been inaccurately reported by the media—and the fact that two U.S. Senators have requested that the U.S. Food and Drug Administration (FDA) investigate the energy drink category. In response to these concerns, Rockstar, Inc. (manufacturer of Rockstar energy drink products) would like to report that an independent Expert Panel has reviewed key ingredients and use levels in Rockstar energy drink products and concluded that the intended use of the key ingredients in all Rockstar products is "Generally Recognized As Safe" (GRAS) based on scientific procedures. The Expert Panel evaluation was provided under the guidance of Dr. John Doull Ph.D., M.D., also the signatory of this White Paper, while the GRAS process was conducted by Dr. Ashley Roberts (Ph.D.) of Intertek Cantox. Intertek Cantox is a global leader in providing regulatory, scientific, and toxicology consulting services specific to the areas of food safety and nutrition. For over 25 years, Intertek Cantox experts have successfully resolved complex scientific issues, developed effective regulatory compliance plans, and facilitated global regulatory approvals for new products.

The safety of Rockstar energy drink products is further supported on the basis that:

1. Rockstar energy drink products contain either 160 mg or 240 mg of caffeine per 16 ounce can, depending on product, which is less than that of the following Starbucks® coffee:

   Starbucks® "Pike Place® Roast" (standard house blend) 16 ounce Grande coffee contains 330 mgs of caffeine. (*source: Starbucks®* website—web link here)
2. Rockstar fulfills all requirements stipulated by the FDA to sell products labelled as either Conventional Foods or as Dietary Supplements.
3. Rockstar energy drink products indicate the total amount of caffeine from all sources on all product labels.
4. Rockstar energy drink products include the following statement on all product labels: *"Not recommended for children, pregnant or nursing women, or those sensitive to caffeine."*
5. A Panel of independent experts qualified by training and experience to assess the safety of food and food ingredients (the Expert Panel) has critically evaluated the intended conditions of use including use levels and estimated dietary intakes of caffeine in Rockstar energy drink beverages. The Expert Panel applied the requisite safety standard, *i.e.,* there must be a reasonable certainty of no harm under the conditions of intended use of the substance. The Expert Panel unanimously concluded that such use of caffeine is safe and GRAS based on scientific procedures.
6. The Expert Panel also evaluated the intended conditions of use including use levels and estimated daily intakes of taurine, L-carnitine and inositol in Rockstar energy drink products. The Expert Panel unanimously concluded that such uses are safe and GRAS based on scientific procedures.
7. Upon evaluating the intended use included use levels and estimated daily intakes of guarana extract, milk thistle extract and ginseng extract, the Expert Panel unanimously concluded that the use of these extracts in Rockstar energy drink products is safe, and GRAS based on scientific procedures.
8. In evaluating these ingredients, the Expert Panel considered the potential for synergistic effects of the ingredients as well as any known adverse health effects.
9. Claims that the American Academy of Pediatrics recommends no more than 100 mg caffeine per day for adolescents are inaccurate. Neither Rockstar nor the U.S. FDA (FDA letter dated November 21, 2012) has been able to verify this purported recommendation.
10. Adverse event reports do not establish a cause and effect relationship, and the number of such reports for Rockstar is very low in comparison to retail sales of approximately 3 billion cans of Rockstar energy drink products in the USA since Rockstar brand inception in 2001.

The above points are addressed more fully in the following sections of this report.

"Energy drinks" are popular drinks available for purchase at most supermarkets, box stores, grocery stores, convenience stores and gas stations, with current annual unit sales in USA for all brands estimated to be 4.4 billion units (Rockstar personal

communication). There are numerous brands of energy drinks currently on the market containing caffeine. Caffeine is the constituent of teas, coffees and colas that is responsible for the increased alertness following consumption. Since inception in 2001, Rockstar has produced over 3 billion cans of Rockstar energy drink products for the U.S. market. Rockstar energy drink products in the 2013 portfolio contain either 160 mg or 240 mg of total caffeine from all sources per 16 oz. ounce can (with one 16 oz. can containing two 8 oz. servings), depending on product.

The FDA posted a summary of adverse effect reports (AER) obtained via the Center for Food Safety and Applied Nutrition Adverse Event Reporting System (CAERS) through October 2012, that related to products marketed as energy drinks or energy shots, which included the brands Red Bull, 5 Hour Energy, Monster, and also Rockstar (U.S. FDA, 2012a). The reports were received under this post-surveillance system between January 1, 2004 and October 23, 2012. It is important to note that these reports cannot determine cause and effect, as stated by the FDA in the summary: "*the adverse effect report itself about a particular product only reflects information AS REPORTED [FDA's emphasis] and does not represent any conclusion by FDA regarding a causal relationship or association with the product or ingredient.*"

The summary of CAERS reports (through October 2012) released by the FDA included only 13 reports for Rockstar—including zero deaths—over the 7 year time frame of 2006 to 2012. The lethal dose of caffeine in an average person weighing 150 pounds (68 kg) is approximately 10,000 mg of caffeine, which is equivalent to the consumption of 41 cans of 16 oz. Rockstar or 656 ounces of liquid—putting it in perspective this amount of liquid weighs 41 pounds. This volume is 10 times greater than the total amount of fluid that is typically consumed in a day and it is therefore physically impossible to consume this many drinks.

Compared to the over 2 billion cans of Rockstar products sold in the U.S. since 2006 (with over 3 billion sold since brand inception in 2001), the 13 CAERS reports attributed to Rockstar energy drink products between 2006 and October 2012 (and it should be noted that these are only recorded in the AER system, and represent no defined relationship or proof of association with the product or ingredient) represent a very small fraction (0.00000065 percent) of the overall number of units produced since 2006. It is also important to note that of the 13 CAERS reports received regarding Rockstar energy drink products over the 7 year time frame, 6 of those 13 CAERS reports received allegedly claimed either product spoilage or object in can.

The SAMHSA Drug Abuse Warning Network issued a report (SAMHSA, 2011) on hospital visits involving energy drinks (along with alcohol and/or illegal or legal drug abuse or intake) but the report did not specify how many of the visits cited involved Rockstar products. Greater than 50 percent of patients in the SAMHSA report aged 18 to 25 admitted to combining drug or alcohol use along with the energy drinks. The SAMHSA study did not present any estimate as to the quantity of energy drinks or amount of caffeine consumed, and it cannot be determined if the other half of subjects, particularly younger subjects, willingly disclosed all other drug or alcohol use. Thus, drug and alcohol use in addition to the energy drinks is likely to have been much higher than the admitted 50 percent identified in the report.

Numerous multi-ingredient foods and beverages contain caffeine including coffee, tea, chocolate, soft-drinks and ice cream, which have a long history of safe consumption in the U.S. and global diet, and are targeted towards all age groups. Regulating food products on the basis of caffeine content would therefore impact many different product categories. Following a comprehensive evaluation of the literature for caffeine, a panel of independent scientists, qualified by scientific training and relevant national and international experience to evaluate the safety of food ingredients, was convened to evaluate the conditions of use of caffeine in Rockstar energy drink products. The Expert Panel unanimously concluded that the intended use of caffeine, produced in accordance with current good manufacturing practice and meeting applicable *Food Chemical Codex specification,* in Rockstar energy drink products at levels up to 120 mg per 8 oz. serving (a centration of 15 mgs of caffeine per ounce) is safe. One 16 oz. can of Rockstar energy drink contains 2 servings, with total caffeine from all sources at 160 mg or 240 mg depending on the specific Rockstar product. The Expert Panel unanimously found further that use intended use of caffeine in Rockstar energy drink beverages is GRAS based on scientific procedures. The Expert Panel also noted that, in their unanimous opinion, other qualified experts would concur with these conclusions.

The caffeine level in energy drinks currently manufactured by Rockstar, at 80 mg or 120 mg per 8 oz. serving, is considerably less than in that of an 8 oz. serving of Starbucks or Einstein Bros. coffees, which would provide more caffeine at 160 mg and 150 mg respectively, while the 20 oz. Starbucks Pike Place® Roast coffee con-

tains 415 mg of caffeine. Ben and Jerry's Coffee Heath Bar Crunch also contains 84 mg of caffeine per 8 oz. serving.

Some media reports and health group websites have stated that the American Academy of Pediatrics (AAP) recommends that adolescents (persons ages 12 to 19) should not consume more than 100 mg of caffeine per day. However, following a thorough search of the literature a detailed reference for this statement could not be found in these reports.

In the FDA letter dated November 21, 2012 (U.S. FDA, 2012c), it is stated that the FDA contacted the AAP and reviewed their website but was not able to get verification that the AAP has a policy statement supporting an upper limit of 100 mg caffeine per day for adolescents. We also did an independent search of the AAP website and did not identify any such policy statement. Thus, it is incorrect to state that that the maximum safe amount of caffeine for adolescents is 100 mg per day.

In a letter dated August 10, 2012 concerning caffeine, the FDA stated that while the Agency is reviewing recently published safety studies on caffeine, "the available studies do not indicate any new, previously unknown risks associated with caffeine consumption" (U.S. FDA, 2012b). Furthermore, in another letter dated November 21, 2012 (U.S. FDA, 2012c) the FDA stated that it has "searched the literature but did not find any information that calls into question the safety" of taurine, an amino acid, or guarana, an herb, as currently used in beverages.

Given the above, there is no expectation that consumption of Rockstar energy drink products containing 80 mg or 120 mg of caffeine per 8 oz. serving (160 mg or 240 mg caffeine per 16 ounce can), in adherence with the product label, should be associated with adverse health effects. Also, the Expert Panel convened to evaluate the safety of caffeine also assessed ginseng extract, guarana extract, L-carnitine, milk thistle extract, inositol and taurine, and concluded unanimously that the use of these ingredients in Rockstar energy drink products are safe. The Expert Panel also found such uses to be GRAS based on scientific procedures. Estimates of dietary intakes of these non-caffeine ingredients from consumption of Rockstar energy drink products were determined to be well below estimates of consumption from other food sources and/or orders of magnitude below no-adverse-effect levels determined from safety studies. As all ingredients are present in amounts that are GRAS and/or are found in various foods in comparable amounts, there is no expected safety concern associated with these ingredients alone, or in combination, from consumption of Rockstar energy drink products.

SUMMARY OF DATA SUPPORTING THE SAFETY OF ROCKSTAR ENERGY DRINKS

1.0 Introduction

"Energy Drinks" are popular drinks with current USA annual sales for all brands estimated to be 4.4 billion units (Rockstar, personal communication). There are numerous brands of energy drinks currently on the market, with the predominant ingredient being caffeine. Caffeine is the constituent of teas, coffees and colas that is responsible for the increased alertness following consumption. The amounts of caffeine in the individual brands of energy drinks are highly variable as are the serving sizes. Since inception in 2001, Rockstar, Inc. (Rockstar) has produced over 3 billion cans of Rockstar energy drink products for the North American market (Rockstar personal communication).

The U.S. Food and Drug and Drug Administration (FDA) posted a summary of adverse effect reports (AER) obtained via the Center for Food Safety and Applied Nutrition Adverse Event Reporting System, (CAERS) through October 2012 that related to products marketed as energy drinks and energy shots, which included the brands Red Bull, 5 Hour Energy, Monster, and also Rockstar (U.S. FDA, 2012a). The reports were received under this post-surveillance system between January 1, 2004 and October 23, 2012. It is important to note that these reports cannot determine cause and effect as stated by the FDA in the summary: "*the adverse effect report itself about a particular product only reflects information AS REPORTED [FDA's emphasis] and does not represent any conclusion by FDA regarding a causal relationship or association with the product or ingredient.*"

The purpose of this report is to review the CAERS received through October 2012, and to summarize the data supporting the safety of Rockstar energy drinks.

In considering the safety of Rockstar energy drinks, it is important to clarify that these products are not intended for certain populations known to be sensitive to caffeine. Therefore the label includes a statement that Rockstar products are "not recommended for children, pregnant or nursing women, or those sensitive to caffeine." Rockstar considers "children" to encompass individuals under age 12.

2.0 Comparison of Caffeine Content of Different Foods

The amount of caffeine in Rockstar energy drink products is comparable to or less than that of standard coffee, which is widely consumed and purchased in specialty coffee shops.

Numerous foods and beverages contain caffeine including coffee, tea, chocolate, soft-drinks and ice cream that have a long history of safe consumption in the U.S. and global diet and are targeted towards all age groups. Regulating food products on the basis of caffeine content would therefore impact many different products. Energy drinks manufactured by Rockstar contain 80 mg or 120 mg of caffeine per 8 oz. serving. On a per can basis, caffeine levels of 160 mg to 240 mg are present in a 16 oz. can of Rockstar energy drink products. These amounts of caffeine are comparable to brand name coffees that are readily available in the U.S. Concentrations of caffeine present in 16 oz. servings of coffee obtained from common U.S. retailers were found to vary from 206 mg (Dunkin Donuts), 300 mg (Einstein Bros.), to 320 mg (Starbucks). Thus, 8 oz. servings of Starbucks or Einstein Bros. coffees would provide more caffeine (160 mg and 150 mg, respectively) than would be provided in an 8 oz. serving of Rockstar (80 mg or 120 mg, depending on product).

The amounts of caffeine in various energy drinks sold in the U.S. marketplace in serving sizes of 8 oz. or greater are summarized in Table 1. The amount of caffeine in Rockstar energy drink products is comparable to most other energy drink brands but is less than one sixth the caffeine concentration of 5-Hour Energy (a concentrated energy shot).

Table 1.—Caffeine Content of Select Energy Drinks Available in the U.S. Marketplace

Energy Drinks	Package Size (oz.)	Caffeine (mg)	Concentration (mg/oz.)
NOS	16.0	260	16.3
Rockstar Energy Drink	16.0	160	10.0
Rockstar Sugar Free	16.0	160	10.0
Rockstar Zero Carb	16.0	240	15.0
Monster Energy	16.0	160 (est.)	10.0 (est.)
Monster Lo-Carb	16.0	160 (est.)	10.0 (est.)
Full Throttle	16.0	200	12.5
RedBull	16.0	154	9.6
RedBull Sugar Free	16.0	154	9.6

The amount of caffeine in energy shots, which are a different type of product than energy drinks, is indicated in Table 2.

Table 2.—Caffeine Content of Select Energy Shots Available in the U.S. Marketplace

Energy Shot	Package Size (oz.)	Caffeine (mg)	Concentration (mg/oz.)
5-Hour ENERY	2.0	200 (est.)	100.0 (est.)

Table 3 lists the caffeine content of other foods and beverages. The amount of caffeine in Rockstar energy drink products on a mg per oz. basis, while about 3 times greater than soft drinks, is less than many coffees and some teas. Ben and Jerry's Coffee Heath Bar Crunch contains as much caffeine as many energy drinks at 84 mg of caffeine per 8 oz. serving.

Table 3.—Caffeine Content of Select Food and Beverage Products Available in the U.S. Marketplace

Product	Package Size (oz.)	Caffeine (mg)	Concentration (mg/oz.)
Starbucks Brewed Coffee (Grande) [Pike Place Roast] (Venti)	16.0 20.0	330 415	20.6
Einstein Bros. Regular Coffee (Medium)[a]	16.0	300	18.8
Dunkin' Donuts Regular Coffee (Medium)	16.0	206	12.9

Table 3.—Caffeine Content of Select Food and Beverage Products Available in the U.S. Marketplace—Continued

Product	Package Size (oz.)	Caffeine (mg)	Concentration (mg/oz.)
Starbucks Espresso (solo)	1.0	75	75.0
Jolt Cola	12.0	72	6.0
Coca-Cola	20.0	56	2.8
Mt. Dew	20.0	90	4.5
Ben & Jerry's Coffee Heath Bar Crunch	8.0	84	10.5
Ben & Jerry's Coffee Flavored Ice Cream	8.0	68	8.5
Jolt Caffeinated Gum	1 stick	33	33.0 (per stick)
Hershey's Special Dark Chocolate Bar	1.45	31	20.7

Source: CSPI (2007); source [a] = Turcotte (2010)

3.0 Caffeine Safety Assessment

Caffeine is present naturally in coffees, teas and herbs and has a long history of safe use in colas and other foods as an added ingredient.

Caffeine is considered safe for use in stimulant drug products for over-the-counter human use to restore mental alertness or wakefulness during fatigue or drowsiness (21 CFR 340) (U.S. FDA, 2012d). Use of caffeine in over-the-counter stimulant products to restore mental alertness or wakefulness during fatigue or drowsiness is acceptable for adults and for children 12 years of age and older (*i.e.,* adolescents) and if used at the maximum allowable levels would be over 1000 mg in a day. This amount of caffeine would equal about 4 Rockstar 16 oz. energy drinks.

Thus, it is incorrect to state that that the maximum safe amount of caffeine for adolescents is 100 mg per day.

The conditions of use of caffeine in Rockstar energy drinks has been evaluated by an Expert Panel in accordance with sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (U.S. FDA, 2010a,b) and FDA's implementing regulations in 21 CFR 170.3 and 21 CFR 170.30 (U.S. FDA, 2012d). Those regulations state that the use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food. The Expert Panel consisted of the following individuals: John Doull Ph.D., M.D., Stanley M. Tarka, Ph.D. and John A. Thomas, Ph.D.

Under 21 CFR 170.30(b) (U.S. FDA, 2012d), general recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive and ordinarily is based upon published studies, which may be corroborated by unpublished studies and other data and information.

Under 21 CFR 170.30(c) and 170.3(f) (U.S. FDA, 2012d), general recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers.

The Expert Panel unanimously concluded that the intended use of caffeine, produced in accordance with current good manufacturing practice and meeting applicable *Food Chemical Codex* specification, in Rockstar energy drink products at levels up to 120 mg per 8 oz. serving is generally recognized as safe (GRAS) based on scientific procedures. Rockstar energy drink products in the 2013 portfolio contain either 160 mg or 240 mg of caffeine per 16 oz. can depending on product.

The primary data noted by the Expert Panel in their evaluation of the safety of caffeine were as follows:

- The estimated lethal dose for caffeine in adult humans is 10,000 mg (Nawrot *et al.,* 2003). For an adolescent this dose would be expected to be closer to the adult estimate than for a child, given their greater body weight and height by age 12, which is more comparable to adults. Intake of 10,000 mg of caffeine, from the proposed food uses of caffeine in Rockstar energy drink products, would require the consumption of *forty-one* 16 oz. cans, corresponding to 20 liters of fluid *or approximately 41 pounds of Rockstar energy drink, consumed all at one time.* This volume is far in excess of the amount that would be consumed by anyone drinking any beverage, including energy drink consumers.
- Recent comprehensive reviews, conducted by qualified experts, on the reproductive and developmental effects of caffeine in humans have concluded that no ad-

verse consequences on reproduction or pregnancy have consistently been linked to caffeine (SCF, 1999; IOM, 2001; Peck *et al.,* 2010; Brent *et al.,* 2011). However, the European Commission's Scientific Committee on Food, the IOM, and Health Canada, recommend a reduction in caffeine consumption during pregnancy (SCF, 1999; Nawrot *et al.,* 2003).

- The Expert Panel noted that although infants and children are not intended consumers of energy drinks; consumption by children and potential effects on the developing nervous system of growing individuals should be considered. Caffeine has a long-history of safe use by clinicians for the treatment of apnea in infants. Caffeine and the structurally similar methylxanthine, theophyline, also have been widely used for the treatment of attention deficit disorder (ADHD) and asthma in young and adolescent children (<12 years of age). Under placebo controlled settings, the administration of caffeine (5 mg to 10 mg per kg body weight) to infants within the first 10 days of life for a median duration of 37 days, for treatment of apnea of prematurity, did not affect motor function, cognition, behavior, general health or other developmental measures (*e.g.,* deafness, blindness) during a 5-year follow-up period (Schmidt *et al.,* 2006, 2007, 2012). Meta-analyses of controlled studies evaluating the effects of caffeine on development and behavior in children and adolescents administered caffeine, or the structurally similar methylxanthine theophyline, for treatment of asthma or attention-deficit hyperactivity disorder do not support an association between methylxanthine use and adverse effects on cognition or behavior in these individuals (Lindgren *et al.,* 1992; Stein *et al.,* 1996). The Expert Panel concluded that available evidence do not suggest that dietary caffeine would represent a neurodevelopmental risk to humans of any age group.
- Researchers from the National Institute of Mental Health (Castellanos and Rapoport, 2002) conducted a literature review looking at potential effects of caffeine on developmental and behavior in infancy and childhood. A number of studies conducted from the 1970s to the 1990s were identified including studies in both hyperactive children and normal children. In the hyperactive children, the studies were generally small and adverse effects were noted to be minimal. Expected effects such as dose-dependent insomnia and minor increases in blood pressure and heart rate at doses of 320 mg were observed. In studies in normal children, low doses (~3 mg per kg) were not associated with any effects, while higher doses (~10 mg per kg) were reported to be associated with improvements in vigilance but also "fidgetiness" and "jumpiness". As such effects are typical for caffeine, it was concluded that effects of caffeine at moderate caffeine intakes were "modest" and "innocuous" (Castellanos and Rapoport, 2002). In an earlier review (Leviton, 1992), typical caffeine consumption among children obtained from sources such as coffee, tea, colas and chocolate was not found to be associated with adverse effects. It was noted from a study comparing responses to caffeine in boys and adult men that children were less likely than men to report caffeine related subjective effects such as faint, flushing or nervous/jittery.
- Coffee has been shown to have hypercholesterolemic properties (Jee *et al.,* 2001) and both coffee and caffeine have been shown to have hypertensive properties (Nurminen *et al.,* 1999; Nawrot *et al.,* 2003; Noordzij *et al.,* 2005); however, there is no definitive evidence to suggest that these effects would result in any long-term adverse effects since available epidemiological data have not demonstrated a clear and consistent association between coffee consumption and risk of coronary heart disease and hypertension. The IOM and Health Canada both state that 'moderate' caffeine intake does not adversely affect cardiovascular health (IOM, 2001; Nawrot *et al.,* 2003) with Health Canada further specifying 'moderate' as ≤400 mg caffeine per day (up to 4 cups of coffee) Nawrot *et al.,* 2003).
- Controlled metabolic studies in healthy adult subjects show that oral doses of caffeine can negatively affect calcium balance (Heaney and Recker, 1982; Massey and Wise, 1984; Bergman *et al.,* 1990). The magnitude of this effect is small. Urinary calcium losses of 5.1 mg and 7 mg have been reported in healthy male subjects administered oral caffeine doses of 3 or 6 mg per kg body weight respectively (Massey and Hollingbery, 1988). These urinary losses of calcium are equivalent to the quantity of calcium in 2 tablespoons of milk (Heaney, 2002), and among individuals consuming adequate calcium in the diet the effects of caffeine on calcium balance are nutritionally irrelevant. Comprehensive reviews of intervention and observational studies evaluating the association between caffeine and/or coffee intake and measures of bone health have been conducted by authoritative scientific bodies including the IOM and Health Canada

(IOM, 2001; Nawrot *et al.,* 2003). The IOM concluded that an association between caffeine consumption and bone health cannot be established (IOM, 2001). Health Canada more specifically concluded that caffeine intakes ≤400 mg per day (up to 4 cups of coffee per day) do not have adverse effects on bone status or calcium balance in individuals meeting their recommended calcium intakes (Nawrot *et al.,* 2003). The Expert Panel similarly concluded that the effect of dietary caffeine from the proposed food uses of caffeine in energy drinks would be negligible among individuals consuming adequate quantities of calcium in the diet.

- Caffeine at doses of 250 mg or more may have a mild, transient diuretic effect, especially among infrequent users. However, regular caffeine users become habituated to the effects of caffeine, diminishing its actions (Armstrong, 2002; Maughan and Griffin, 2003). Overall, beyond a mild transient diuretic effect, there is no substantive evidence to indicate that moderate caffeine consumption in beverage form results in biologically significant changes in hydration status in subjects, either at rest or under exercise conditions, who consume an otherwise normal diet (Grandjean *et al.,* 2000; Armstrong, 2002; Roti *et al.,* 2006; Goldstein *et al.,* 2010; Campbell *et al.,* 2013). Caffeine doses of 600 mg to 900 mg (approximately 6 to 9 cups of coffee) may increase fluid and electrolyte losses in urine; however, a normal diet will replace these losses (IOM, 2001). Total body water loss depends on the amount of caffeine consumed, the individual's history of caffeine use, the total solute load of food/beverage intake, and environmental/physical stresses (*e.g.,* temperature, level of exercise) (IOM, 2001).
- Caffeine has been shown to have stimulatory effects, increasing performance, vigilance, alertness, memory, and mood (Nehlig *et al.,* 1992; Riedel *et al.,* 1995; Fredholm *et al.,* 1999; ANZFA, 2000; Lieberman *et al.,* 2002; Smith, 2002). Higher doses (reported differentially in the literature as >300, >400 or >500 mg caffeine per day) have demonstrated negative effects, such as feelings of anxiety, *nausea,* jitteriness, and nervousness (Greden, 1974; Lader and Bruce, 1986; Lieberman, 1992; Green and Suls, 1996; Garrett and Griffiths, 1997; Childs and de Wit, 2006). Individuals with panic and/or anxiety disorders may be particularly sensitive to the anxiogenic effects of caffeine (Lara, 2010). However, the negative effects of caffeine on anxiety and sleep appear to be self-limiting—*i.e.,* individuals aware of their sensitivities limit their caffeine intakes.
- Caffeine users can become physically dependent on caffeine, demonstrating minor withdrawal symptoms, notably headache, with cessation of intake (Ozsungur *et al.,* 2009; Sigmon *et al.,* 2009).
- Studies suggest that caffeine has similar anxiogenic and withdrawal effects in younger individuals as seen in adults (Meltzer *et al.,* 2008). Health Canada regards children as an 'at risk' subgroup that may require specific advice on moderating their caffeine intake and suggests a caffeine consumption of ≤2.5 mg per kg body weight/day in children under 12 years of age (Nawrot *et al.,* 2003; Health Canada, 2011).
- Concurrent consumption of caffeine and certain medications can result in significant changes in the pharmacokinetics of both caffeine and/or the interacting drug (Durrant, 2002; Broderick *et al.,* 2005). It should be noted that the Rockstar energy drink product labels contain the admonition that persons sensitive to caffeine should avoid the product.

The Expert Panel was aware of increasing concerns expressed in the literature by various scientific and medical experts, including regulators, regarding the safety of caffeinated energy drink use by teenagers (*e.g.,* Schneider and Benjamin, 2011; Seifert *et al.,* 2011; Wolk *et al.,* 2012). The dietary intake analyses indicated that, among teenagers, the use of energy drinks was a greater contributor of caffeine intake than the background diet. However, at the 90th percentile, based on NHANES data, the caffeine intakes contributed by the background diet (*i.e.,* food and dietary supplements) and consumption of energy drinks were below the 400 mg per day level commonly cited by regulatory and authoritative bodies as not associated with adverse effects. The FDA recognizes that "*for healthy adults, caffeine intake up to 400 mg per day 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"* (U.S. FDA, 2012b). The Expert Panel also noted that Rockstar products containing caffeine as an ingredient bear the following label statement: "Not recommended for children, pregnant or nursing women, or those sensitive to caffeine." Following the Expert Panel's comprehensive review of all available scientific evidence related to the safety

of caffeine, it was unanimously concluded that the intended use of caffeine, produced in accordance with current good manufacturing practice and meeting applicable Food Chemicals Codex specifications, in Rockstar energy drink beverages at levels up to 120 mg per 8 oz. serving, is generally recognized as safe based on scientific procedures. The Expert Panel also noted that, in their unanimous opinion, other qualified experts would concur with these conclusions.

4.0 Summary of CAERS Reports

Adverse events reports are not considered reliable indicators that energy drinks pose safety concerns.

The FDA Center for Food Safety and Applied Nutrition (CFSAN) Adverse Event Reporting System (CAERS) is a post marketing surveillance system. CAERS includes mandatory reports of serious (*e.g.,* death and injury) adverse events related to dietary supplements, and voluntary reports of serious and non-serious adverse events related to beverages or conventional foods. Non-serious adverse events (*e.g.,* reversible non-life threatening effects) linked to dietary supplements also may be voluntarily reported. Voluntary reports may be filed by the public or medical professionals.

A filing of a CAERS report is not sufficient to prove cause and effect. Thus, the CAERS reports do not prove that energy drinks caused any adverse health effects reported. As stated by the FDA *"The existence of an adverse event report does not necessarily mean that the product identified in the report actually caused the adverse event."* The FDA carefully investigates and evaluates other possible causes before deciding whether the product actually caused the reported adverse event.

Deficiencies of CAERS which can preclude identification of a cause and effect relationship, as noted by the FDA itself (*http://www.fda.gov/Food/NewsEvents/ucm328536.htm*) (U.S. FDA, 2012a), include:

- *"reports with incorrect, incomplete or no contact information, which make following up with the complainant difficult or impossible;*
- *variability among the completeness of the reports. Some reports may consist only of a single sentence with little detail;*
- *reports that list the brand, but do not identify the specific product;*
- *absence of or lack of FDA access to other information related to the report, such as medical records and medical histories (In fact, some state medical privacy laws prevent FDA from obtaining medical records related to the adverse event report.);*
- *use of other supplements or medications at the same time;*
- *pre-existing or undiagnosed medical conditions;*
- *improper use of the product"*

The summary of CAERS reports through October 2012 released by the FDA included only 13 reports for Rockstar and zero deaths (over the time-frame of 7 years—2006 to October 2012). Among the other energy drink brands there were 21 CAERS reports and zero deaths for Red Bull (from 2004 to October 2012), 40 reports including 5 deaths, for Monster (from 2004 to October 2012), and 92 reports including 13 deaths for 5-Hour Energy (from 2005 to October 2012). More than half of the reports of death for these other brands gave no information on symptoms leading up to death. Other reports provided some description in addition to "death" that was confounding including the following:

- fall and head injury (Report #121679, 5-Hour Energy); this same case seems to have been reported twice (Report #s 121679 & 121680, 5-Hour Energy) as case was for the same date and numbers are sequential)
- pneumonia and acute respiratory failure (Report #129061, 5-Hour Energy)
- suicide (Report #155230, 5-Hour Energy).

Other reports for 5-Hour Energy (Report #s 137118, 144858, 157207) noted that death followed myocardial infarctions (heart attacks) however no information was given on the pre-existing health of the patient. As there are approximately 1.5 million cases of myocardial infarction per year in the U.S., with 30 percent resulting in death, it is not possible to conclude from the CAERS report alone that the few cases noted were in fact caused by energy drinks.

Furthermore, based on literature reports, the amount of caffeine that would be fatal to humans if consumed all at once is approximately 10,000 mg in adults. To put this into perspective, that is the amount of caffeine in 41 cans of 16 ounce Rockstar can (containing 240 mg caffeine per can), or 656 total ounces—*approximately 41 pounds of Rockstar.* Rockstar energy drink products include a statement

on the label that the products should not be consumed by children (<12 years of age). Total fluid (all drinks and water) intake per day is usually 67 oz. (2 liters) for adults. Therefore, individuals would need to consume about 10 times more energy drinks than the typical full day fluid amounts, and in a short timeframe, to reach fatal levels of caffeine.

Certain media reports have contended that the number of incidents of emergency department visits and adverse events attributable to energy drinks is much higher than that suggested by CAERS. As the basis for this contention, the media has cited a report by the Substance Abuse and Mental Health Services Administration (SAMHSA), dated November 22, 2011, entitled: "The DAWN Report: Emergency Department Visits Involving Energy Drinks" where DAWN stands for Drug Abuse Warning Network. SAMHSA determined that there were 16,053 and 13,114 energy drink-related emergency department visits in 2008 and 2009, respectively, noting that the amount of caffeine in a can or bottle of energy drink can vary from about 80 mg of caffeine to more than 500 mg (SAMHSA, 2011); however precise estimates of caffeine intake associated with each visit are not provided. DAWN is noted to be a public health surveillance system that "monitors" drug related emergency visits where the visit is classified as a DAWN case if it involves drugs. A drug is defined as "alcohol; illegal drugs, such as cocaine, heroin, and marijuana; pharmaceuticals (*e.g.,* over-the-counter medicines and prescription medications); and nutraceuticals, such as nutritional supplements, vitamins, and caffeine products."

The report indicates that for more than half of the visits in which energy drinks were reportedly used (brands not specified) in the 18 to 25 year age range, the subjects also reported using alcohol and other drugs. Since this was likely to have been a self-reporting system it is probable that the use of alcohol and illicit drugs would have been under reported especially in those subjects below the legal drinking age of 21. For the DAWN report, the information is collected from the chart documents. The patient outcomes were not provided. However it was noted that 57 percent of visits involving energy drinks in combination with drugs were classified as "misuse or abuse" while 30 percent were classified as "adverse reactions." No other information, such as the specific energy drinks consumed, or the amounts of energy drinks and drugs consumed were provided in the DAWN report. Likewise, no precise estimate of caffeine intake associated with each visit was provided.

In an update to this report, SAMHSA (2013) reported an increase in emergency department visits to 20,783 in 2011 supposedly attributed to energy drink consumption. In comparison, the number of visits in 2007, 2008, 2009 and 2010 were 10,068, 16,053 13,114 and 15,219 respectively and so over the time-frame from 2007 to 2011, there were both increases and decreases in the number of incidents that occurred annually. In addition, the number of visits involving adverse reactions involving the misuse or abuse of drugs, also approximately doubled with almost half of the total reported incidences being associated with pharmaceuticals, illicit drugs and alcohol. With such confounding factors it cannot be determined from the information provided what role, if any, the energy drink contributed to the visit and/or the symptoms. Furthermore, given that it was a self-reporting system it cannot be determined if those subjects visiting the emergency department, particularly younger patients disclosed all other concomitant drug or alcohol use. Again, information on the amounts of caffeine intake or the type of energy drink/shot consumed was not determined.

4.1 Incidence of Adverse Reports Versus Volumes Sold

The total number of CAERS reports (through October 2012) over the past 9 years for energy drinks (166) is very low compared to the number of units of energy drinks that have been consumed. It is estimated that the current annual energy drink consumption in the USA is on the order of 4.4 billion units.

Rockstar since inception in 2001 has produced over 3 billion cans of Rockstar energy drink products for the U.S. market, and approximately 2 billion since 2006. The 13 CAERS reports received between 2006 and October 2012 represent a very small fraction (0.00000065 percent) of the overall number of units produced since 2006, with none proven to be causative to drinking Rockstar energy drinks. It is also important to note that of the 13 CAERS reports received regarding Rockstar energy drink products over the 7 year time frame, 6 of those 13 CAERS reports received allegedly claimed either product spoilage or object in can.

The numbers of visits in the DAWN report estimated for the U.S. are actually based on a "probability sample" of hospitals rather than real numbers. For the visits involving drugs and alcohol, it cannot be determined from the information provided what, if any, role the energy drink would have contributed to the symptoms. For hospital visits attributed to energy drinks alone, it cannot be determined if patients, particularly younger patients, disclosed all other drug use or alcohol. Nevertheless,

in the unlikely event that all 20,783 visits in 2011 (the highest number of visits noted) were related to energy drinks, the incidence of visits compared to the annual energy drink consumption estimate, in 2011, of 3.5 billion would be approximately 0.0006 percent or 1 visit for every 168,400 units sold. Excluding the alcohol and drug combination use (about 50 percent), the incidence would be approximately 0.0003 percent or 1 visit for every 336,800 units sold. Further, it should be noted that according to the Centers for Disease Control and Prevention, the number of emergency department visits from all causes in 2011 was 136,100,000 in total.

5.0 Consideration of Caffeine Consumption by Adolescents

Caffeine has been used clinically in the treatment of apnea in infants at doses of 5 to 10 mg per kg body weight (*i.e.,* ~100 mg total), as well as in the treatment of attention deficit disorder (ADHD) and asthma in young and adolescent children (<12 years of age). There is no expectation that adolescents (individuals 12 to 18 years of age) should be unduly sensitive to caffeine in comparison to infants and children. Consequently, it is incorrect to state that 100 mg of caffeine per day is the maximum safe amount for adolescents (12 years of age and older). Literature searches were conducted to identify additional studies specific to adolescents given the recent media concerns about the consumption of energy drinks in this age group.

Some media reports and health group websites have stated that the American Academy of Pediatrics (AAP) recommends that adolescents should not consume more than 100 mg of caffeine per day. However, following a thorough search of the literature a detailed reference for this statement could not be found in these reports.

In the FDA letter dated November 21, 2012 (U.S. FDA, 2012c), it is stated that the FDA contacted the AAP and reviewed their website but was not able to get verification that the AAP has a policy statement supporting an upper limit of 100 mg caffeine per day for adolescents.

We also did an independent search of the AAP website and did not identify any such policy statement. While no policy statement by the AAP was identified, an independent publication in the AAP journal Pediatrics by authors from the Department of Pediatrics and the Pediatric Integrative Medicine Program, University of Miami, Leonard M. Miller School of Medicine, Miami, Florida, Seifert *et al.* (2011), did state that "Adolescent and child caffeine consumption should not exceed 100 mg per day and 2.5 mg per kg BW per day, respectively", with three references provided as support for this intake limit. However, upon close review of the references, none laid out or were proven to recommend this intake limit. The references are summarized below:

(1) Babu KM, Church RJ, Lewander W. Energy drinks: the new eye-opener for adolescents. Clin Pediatr Emerg Med. 2008;9(1):35–42. Babu *et al.* (2008) cites to Canadian recommendations that children aged 10 to 12 consume no more than 85 mg per day. No recommendations are given for adolescents aged 12 to 18.

(2) BfR Federal Institute for Risk Assessment. Health risks of excessive energy shot intake. December 2, 2009. Available at: *www.bfr.bund.de/cm/245/health_risks_of_excessive_energy_shot_intake.pdf.* Accessed January 17, 2011. The BfR Federal Institute for Risk Assessment refers to "children" and uses a 10-year-old as an example but makes no reference to "teens" or "adolescents" or a 100 mg per day recommended limit. This reference focuses on energy shots and not energy drinks such as Rockstar. With respect to children, this article states the following: "With portions of 150 mg, children (10 years old, 30 kg BW) reach intake levels of 5 mg caffeine per kg BW. These have been connected with the temporary appearance of arousal, irritability, nervousness and anxiety in several children (SCF, 1999). These products should therefore be labelled as unsuitable for children."

Interestingly, the SCF (1999) report which is cited by the BfR includes this statement: "Studies on the effects of direct caffeine consumption by pre-school and school children have given variable results. In experimental studies in which single doses up to 10 mg per kg bw have been given to children, either no effect or small, inconsistent effects have been noted on mood, behavioural, cognitive and motor functions, some of which could be interpreted as beneficial."

(3) Heatherley SV, Hancock KM, Rogers PJ. Psychostimulant and other effects of caffeine in 9- to 11-year-old children. J Child Psychol Psychiatry. 2006; 47(2):135–142. Heatherley *et al.* (2006) did not evaluate children older than 12 years of age.

Overall, the published literature collected that specifically looked at adolescent populations did not indicate that 100 mg per day of caffeine was likely to be

associated with health concerns. In caffeine sensitive individuals, the effects of caffeine may be associated with transient behavioural changes, such as increased arousal, irritability, nervousness or anxiety (SCF, 1999). These are the same effects noted in sensitive adults and would be expected to be self limiting.

A recent letter prepared by the FDA (2012c) noted the following key points with respect to intakes of caffeine among consumers, including adolescents.

- Based on the results of a commissioned consumption study, the mean caffeine consumption by the U.S. population has remained stable, despite the entry of energy drinks on the market, at approximately 300 mg per person per day.
- Among consumers aged 14 to 21 years of age, the mean amount of caffeine consumed was 1/3 of that of adults or ~100 mg per day, with the caffeine contributed predominantly from coffee, soft drinks and teas.
- Caffeine intakes from energy drinks represented only a small portion of daily intakes, even for teens.

In related information, a recent media report ("Moderation key to energy drinks" Hinton Parklander, Mon Dec 3 2012, Byline: ED MOORE EDSON LEADER) cited the Alberta Health Services medical officer of health, Kathryn Koliaska, that older children (>12 years of age) should limit their intake of caffeine to 400 mg per day.

The U.S. National Center for Health Statistics' (NCHS) National Health and Nutrition Examination Surveys (NHANES) most recent data also suggest very low energy drink consumption among adolescents (CDC 2011). The NHANES data are collected and released in 2-year cycles with the most recent cycle containing data collected in 2009–2010. NHANES 2009–2010 survey data were collected from individuals and households via 24-hour dietary recalls administered on 2 non-consecutive days (Day 1 and Day 2). Additionally, NHANES respondents provided 24-hour recall data concerning the use of dietary supplements on 2 non-consecutive days.

The results as presented in Table 4 indicate that only 1.1 percent of adolescent girls and 4.5 percent of adolescent boys are consumers of energy drinks.

Table 4.—Summary of Most Relevant Dietary Intake Assessments Conducted Using 2009–2010 NHANES Data

Population Group	Age Group (years)	Caffeine intakes from background diet[a], *Caffeine Users*[b] *Only (mg/day)*			Caffeine intakes from intended uses in energy drinks (120mg/8oz), Energy Drink Users Only (mg/day)			Caffeine intakes from background diet and intended uses in energy drinks (120mg/8oz), Energy Drink Users Only (mg/day)		
		% Users	n	Mean	% Users	n	Mean	% Users	n	Mean
Infants	0 to 2	42.2	648	8	0	0	na	0	0	na
Children	3 to 11	86.1	2,308	18	0.4	8	109*	0.4	8	121*
Female Teenagers	12 to 19	89.2	851	53	1.1	15	143*	1.1	15	172*
Male Teenagers	12 to 19	86.8	908	67	4.5	36	145	4.5	36	164
Female Adults	20 and up	94.1	4,757	155	1.8	65	105	1.8	65	156
Male Adults	20 and up	94.1	4,340	205	3.3	145	140	3.3	145	207
Total Population	All Ages	90.2	13,812	143	2.2	269	129	2.2	269	145

na=not applicable

[a] Background diet includes food and dietary supplements.

[b] A caffeine user is defined as a consumer of a caffeine-containing food and/or dietary supplement. * low numbers of users diminishes reliability of results

Similarly in Canada, very low consumption estimates have been determined from surveys of adolescents (12 to 17 year olds) in the province of Quebec. The Réseau du sport étudiant du Quebec (RSEQ, 2011) surveyed the energy drink consumption habits of over 10,000 Quebec teens (12 to 17 years of age) and found that 93 percent of teens rarely or never consumed energy drinks while only 1 percent consumed them daily. Research by the Institut de la Statistique du Québec (Institut de la Statistique du Québec, 2012) in a survey of more than 60,000 teens (13 to 17 years of age) found that 82.8 percent of teens rarely or never consumed energy drinks,

and only 1.5 percent consumed them daily. Based on information from Statistics Canada (2009), similar beverage consumption patterns occur all across Canada.

6.0 Other Ingredients

There are no safety concerns related to the other ingredients in Rockstar energy drink products, all of which are common in the diet.

As noted in the DAWN Report (SAMHSA, 2011), other ingredients in energy drinks may include vitamins, amino acids, herbs, sugars, and sugar alternatives. The specific ingredients in Rockstar are similar in nature and all are either GRAS ingredients or approved food additives.

The Expert Panel convened to undertake a safety evaluation of caffeine also assessed other ingredients in the Rockstar drinks including L-carnitine, and taurine, and the flavors ginseng extract, guarana extract, and milk thistle extract. The Expert Panel concluded that under the conditions of intended use in Rockstar energy drink products, these ingredients are safe and GRAS based on scientific procedures.

L-Carnitine is a naturally occurring compound found in all mammalian species. It is required for conversion of fatty acyl coenzyme A (CoA) esters for energy. L-Carnitine is produced endogenously by humans, and occurs naturally in the diet as a component of meat and dairy products, and found in negligible amounts in fruits and vegetables. The safety of L-carnitine also is corroborated by the findings of numerous human studies conducted on L-carnitine that included endpoints relevant to safety. In these studies, no adverse effects attributable to the consumption of L-carnitine were reported following daily oral ingestion at doses ranging from 2 to 3 g L-carnitine per day for up to 3 months and at a dose of 2 g per day for up to 6 months. L-Carnitine is also acceptable for use in baby foods and infant formula (EFSA, 2003).

Panax Ginseng Extract: The safety of *P. ginseng* extract is corroborated by the findings of numerous human studies in which *P. ginseng, P. ginseng* rootlets, body, and extracts (aqueous or ethanolic), *P. quinquefolius* root, *P. notoginseng* root, panaxtriol saponin from *Radix/Rhizoma notoginseng* extract, *P. japonicas* root, and *P. vietnemensis* root were consumed by generally healthy subjects or those with various underlying diseases or conditions. Although the various species may differ quantitatively in ginsenoside content, qualitatively, many of the ginsenosides are common to all of the species. Thus, the human studies conducted with various ginseng species also are directly relevant to the safety of the *P. ginseng* extract intended for use in Rockstar energy drink products. The overall absence of treatment-related differences in any of the safety-related parameters assessed following the consumption of up to 9 g per day *P. ginseng* or up to 2 g per day *P. ginseng* extracts for periods of up to 24 weeks further supports the safety of the intended use of *P. ginseng* extract in energy drinks.

Guarana Extract: Guarana extract is an approved food additive permitted for use as a natural flavoring substance and natural substance used in conjunction with flavors (21 CFR 172.510). Guarana also is considered to be Generally Recognized as Safe (GRAS) for use as a flavoring agent by the Flavor and Extract Manufacturers' Association of the United States. Of the ingredients in Rockstar energy drink products, only the guarana seed extract contains some minor amounts of caffeine. The maximum guarana seed extract present in each 8 oz. serving of Rockstar energy drink products would contribute less than 1 mg of caffeine, which is insignificant in comparison to the 80 mg or 120 mg of caffeine added directly to the drink.

Milk thistle extract: As a food, several parts of the milk thistle plant are consumed, including the flowers (seeds), leaves, heads, and roots. In Canada, the NHP monograph for milk thistle extract considers intakes of 140 mg to 600 mg per day silymarin (calculated as silybin/silibinin), not to exceed 200 mg per dose, safe for consumption (Health Canada, 2009). In the monograph published by the German Commission E, 200 mg to 400 mg per day silymarin (calculated as silibinin) are considered safe (Blumenthal *et al.,* 1998). The lowest of these intakes (*i.e.,* 140 mg per day silymarin), is 41-fold greater than the estimated 90th percentile intake of silymarin in energy drink users from all sources (*i.e.,* from the intended use of milk thistle extract in energy drinks plus the intake of milk thistle from dietary supplements).

Taurine occurs naturally in the diet as a component of meat and poultry, seafood, and dairy products. It also is present in breast milk and infant formula (4 mg to 7 mg per 100 mL) (Laidlaw *et al.,* 1990; Hayes and Trautwein, 1994). The presence of taurine in cow's milk-based infant formula is attributed to its natural occurrence in the milk, whereas taurine is added to infant formula formulated from soy protein (Laidlaw *et al.,* 1990). Infants cannot produce taurine and require it from breast milk or formula, therefore taurine is a conditionally essential amino acid. Safety is corroborated by the findings of numerous human studies conducted on taurine that

included endpoints relevant to safety. In these studies, no adverse effects attributable to the consumption of taurine were reported. The European Food Safety Authority (EFSA) reviewed the available human data and concluded that daily oral ingestion of taurine at doses ranging from 3 g to 6 g per day for up to 1 year did not produce adverse health effects (EFSA, 2009). More recently, EFSA's Panel on Additives and Products or Substances used in Animal Feed estimated the observed safe level of taurine in humans to be 6 g per person per day (EFSA, 2012).

It should also be noted that taurine does not have any stimulatory activity. Thus, there is no potential enhanced activity of caffeine due to the presence of taurine. L-Carnitine which is a derivative of the amino acid lysine is not a stimulant and therefore does not compound caffeine activity.

Estimates of exposure to these non-caffeine ingredients from consumption of energy drinks were determined to be well below estimates of consumption from other food sources and/or orders of magnitude below no-adverse-effect levels determined from safety studies. As confirmed by the independent Panel of food safety experts, the above described ingredients, there is no expected safety concern associated with these ingredients alone, or in combination, from consumption of Rockstar energy drink products.

7.0 Conclusions

There is insufficient information presented in the CAERS summaries (through October 2012) or the DAWN report to demonstrate that energy drinks were the cause of the adverse events noted therein. Furthermore, there are no data to indicate that Rockstar energy drinks containing 80 mg or 120 mg of caffeine per 8 oz. serving (160 mg or 240 mg of caffeine per 16 oz. can), caused any adverse events. Some of the other brand energy drinks on the market have more than twice this amount of caffeine per ounce. The amount of caffeine in various coffees is higher than the same volume of Rockstar energy drink products. Concentrations of caffeine present in 16 oz. servings of Einstein Bros. and Starbucks coffee were 300 mg and 320 mg, respectively. The 20 oz. serving of Starbucks Pike Place Roast contains 415 mg of caffeine. Thus, 8 oz. servings of Starbucks or Einstein Bros. coffees would provide more caffeine (160 and 150 mg, respectively) than would be provided in an 8 oz. serving of Rockstar products (80mg or 120 mg). Ben and Jerry's Coffee Heath Bar Crunch also contains 84 mg of caffeine per 8 oz. serving.

Rockstar, Inc. has produced over 3 billion cans of Rockstar energy drink products in the USA since brand inception in 2001 and approximately 2 billion cans since 2006. The incidence of alleged adverse events reports in CAERS (through October 2012) citing Rockstar products is incredibly low at 13 total, or 0.00000065 percent, compared to 2 billion cans sold during the time-frame (through October 2012) that the CAERS reports were received. There has never been an incidence of a reported death from consumption of a Rockstar energy drink product. Current annual energy drink consumption in the USA, total category, is estimated at 4.4 billion units. The number of hospital visits listing energy drinks with and without alcohol and drug substances as reported by SAMHSA in 2011 was 20,783. These events are taken from hospital charts at emergency rooms and they do not appear to be substantiated for legitimacy (*i.e.,* reports are anecdotal and appear not to have been medically vetted). The incidence of visits in 2011 compared to the annual energy drink consumption at that time total category, estimated at 3.5 billion units, would be approximately 0.0006 percent or 1 visit for every 168,400 units sold. Excluding the visits where there was admission of alcohol and drug combination use (about 50 percent), the incidence would about 0.0003 percent or 1 visit for 336,800 units sold.

Any substance if administered at high enough doses may be fatal. The amount of caffeine that is reported in the literature to be fatal to adults is approximately 10,000 mg. Therefore, an adult would need to consume 41 cans of 16 oz. (at 120 mg caffeine) Rockstar energy drink products to reach fatal caffeine levels. The total volume of fluid required to be consumed to reach these levels is 656 oz. (41 pounds of fluid) or about 20 L, which is 10 times the typical amount of total fluid consumed in a full day by an adult.

It is acknowledged that there are certain populations that are potentially sensitive to caffeine. However, all Rockstar energy drink product labels recommend against consumption of energy drinks by children, pregnant or nursing women, or those sensitive to caffeine.

The safety of the amount of caffeine used in Rockstar energy drink products (up to 120 mg per 8 oz. serving) is supported by the findings of an Expert Panel convened to evaluate the conditions of use of caffeine in Rockstar products. The Expert Panel unanimously concluded that the intended use of caffeine, produced in accordance with current good manufacturing practice and meeting applicable *Food Chemical Codex* specification, in Rockstar energy drink products at levels up to 120 mg

per 8 oz. serving is both safe and generally recognized as safe (GRAS) based on scientific procedures (Rockstar energy drink products contain either 160 mg or 240 mg of caffeine per 16 oz. can, depending on product).

The FDA (2012b) has stated in a letter dated August 10, 2012, that, while the Agency is reviewing recently published safety studies on caffeine, the available studies do not indicate any new, previously unknown risks associated with caffeine consumption.

Given the above, there is no expectation that consumption of Rockstar energy drink products containing 80 mg or 120 mg caffeine per 8 oz. serving, in adherence with the product label, should be associated with adverse health effects.

Also, the Expert Panel convened to assessment caffeine also assessed *Panax* ginseng extract, guarana extract, L-carnitine, inositol, milk thistle extract, and taurine, and concluded that under the conditions of intended use, including use levels and estimated dietary intakes, in Rockstar energy drink products, these ingredients are both safe, and GRAS, based on scientific procedures. The guarana extract ingredient does not significantly increase caffeine amounts. The caffeine content of the guarana seed extract is 0.75 to 1.25 percent; provides an additional 0.0875 mg which is insignificant compared to the 80 mg or 120 mg of caffeine added directly to an 8 oz. serving). Estimates of exposure to these non-caffeine ingredients from consumption of Rockstar energy drink products were determined to be well below estimates of consumption from other food sources and/or orders of magnitude below no-adverse-effect levels determined from safety studies. Thus, there is no expected safety concern associated with these ingredients alone, or in combination, from consumption of Rockstar energy drink products.

Furthermore, scientific research that has compared caffeine consumer to non-consumers, has found that the consumption of caffeine enhances mental and physical performance (Smith, 2002; Ruxton, 2008).

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Part	Section §	Section Title
170-Food additives	170.3	Definitions
	170.30	Eligibility for classification as generally recognized as safe (GRAS)
172—Food additives permitted for direct addition to food for human consumption	172.510	Natural flavoring substances and natural substances used in conjunction with flavors
340—Stimulant drug products for over-the-counter human use	All sections	All sections

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ATTACHMENT 2

July 25, 2013

EMERGENCY DEPARTMENT VISITS INVOLVING ENERGY DRINKS AND LIMITATIONS OF THE DRUG ABUSE WARNING NETWORK (DAWN)

Prepared for the American Beverage Association by PinneyAssociates

Table of Contents

1 Executive Summary

The Substance Abuse and Mental Health Services Administration (SAMHSA) released a report in January 2013, based on data from the Drug Abuse Warning Network (DAWN), suggesting an increase in the number of emergency department (ED) visits involving energy drinks and concluding that the consumption of energy drinks is a "rising public health problem". At the request of the American Beverage Association, Pinney Associates (PA) was asked to conduct a review of the DAWN report and its findings.

Overall, reports of energy drink-related ED visits need to be viewed in a broader context, as an analysis of DAWN public use data indicates that drug-related ED visits have also increased (both by a similar proportion and absolute magnitude as compared to energy drinks) for a number of other products, including infant formula, vitamins, and laxatives. Furthermore, the vast majority of energy drink-related ED visits appear to have been occasioned by non-serious medical conditions: 84.4 percent of visits related to caffeine/multivitamins resulted in discharge home, rather than admission to a treatment facility. In comparison, only 75.5 percent of alternative medicine-related ED visits resulted in home discharge. Given that there are a number of other products demonstrating comparable increases in ED visits, and that these products appear to be associated with a less benign profile than that associated with energy drinks, it is unclear why energy drinks have been singled out by SAMHSA as a public health concern. The DAWN public use data do not support the public health concern flagged by SAMSHA.

2 Drug Abuse Warning Network (DAWN)

DAWN is a public health surveillance system that monitors "drug-related" visits to hospital EDs. Each year DAWN produces estimates of such visits for the Nation as a whole and for selected metropolitan areas. To be a DAWN case, the ED visit must involve a drug, either as the direct cause of the visit or as a contributing factor. Such a visit is referred to as a "drug related visit." The reason a patient used a drug is not part of the criteria for considering a visit to be drug-related. Drugs

include: alcohol;[1] illegal drugs, such as cocaine, heroin, and marijuana; pharmaceuticals (*e.g.,* over-the-counter medicines and prescription medications); and nutraceuticals, such as nutritional supplements, vitamins, and caffeine-containing products. DAWN cases are identified by the systematic review of ED medical records in participating hospitals. DAWN cases broadly encompass all types of drug-related events, including accidental ingestion and adverse reactions, as well as explicit drug abuse. SAMHSA noted in its report on energy drinks that although energy drinks are not treated as drugs by the FDA, ED visits involving energy drinks were classified as adverse reactions if the chart documented them as such.[2]

The exact DAWN survey methodology has been adjusted over time in order to, according to SAMHSA, "improve the quality, reliability, and generalizability of the information produced by DAWN" (Source: DAWN 2010 Codebook). The current approach, which was developed based on recommendations from a 1997 panel of experts and a 2-year SAMHSA evaluation of design alternatives, was introduced in 2003, but not fully implemented until the 2004 data collection year.

3 Data Analysis Approach

In order to put the SAMHSA findings on energy drinks into perspective, PA conducted a number of additional analyses using the DAWN public-use dataset. However, there is an important caveat to these analyses that must be acknowledged; namely, information on the use of energy drinks per se is not currently available in the public-use data file. Rather, the public-use data file only contains information on the larger category of "caffeine/multivitamins," of which the "energy drinks" category is a subset. As this larger category appears to be mostly comprised of energy drink-related visits (about 80 percent overall, from 2005–2011) information pertaining to caffeine/multivitamin-related ED visits are used as a proxy for energy drink-related visits in all reported analyses. Outreach to SAMHSA revealed that the agency has received several requests for the specific energy drink data, but thus far has declined to make these data public.

4 Increasing Number of Energy Drink-Related ED Visits: Real Phenomenon or Artifact?

According to the SAMHSA report, the number of ED visits involving energy drinks doubled from 10,068 visits in 2007 to 20,783 visits in 2011.[3] Notably, however, an analysis of DAWN public-use data indicates that the total number of overall drug-related ED visits (regardless of the specific drug/s involved) also increased between 2007 and 2011, rising from 3.9 million visits to 5.1 million visits. Therefore, the increase in energy drink-related visits should be understood in the context of an increase in overall drug-related ED visits. It is not known whether this reflects a real increase in the utilization of EDs, or an artifact perhaps resulting from change in the data collection or case identification methodology. In 2007, energy drink-related visits comprised 0.25 percent of all drug-related ED visits. In 2011, energy drink-related visits comprised 0.41 percent of all drug-related ED visits.

Furthermore, as shown in Table 1 below, estimated drug-related ED visits appear to have increased not only for energy drinks, but for a number of other drugs/products, including infant formula, alternative medications, and other miscellaneous products such as dermatological agents (*e.g.,* Vick's, hand lotion), gastrointestinal agents (*e.g.,* laxatives), isopropyl (rubbing) alcohol, and ophthalmic preparations (*e.g.,* eye drops, contact solution). Not only have drug-related ED visits increased for these other products by similar proportions as for energy drinks, for many, their absolute magnitude is similar, too (see Figure 1 below). In addition, energy drink-related ED visits appear to be more likely to be associated with non-serious complaints that do not require further medical follow-up, compared to ED visits related to other product/medications. Yet, increasing ED visits associated with these other products have not been identified as a public health concern.

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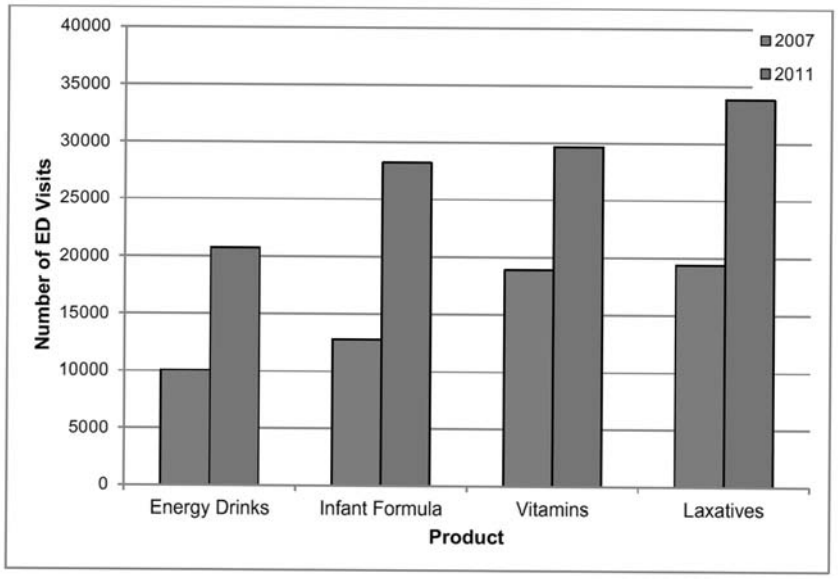
[1] Alcohol is considered a reportable drug when consumed by patients aged 20 or younger. For patients aged 21 and older, alcohol is reported only when it is used in conjunction with other drugs.

[2] Within DAWN, an ED visit is categorized as an adverse reaction when the chart documents that a prescription or over-the-counter pharmaceutical, taken as prescribed or directed, produced an adverse drug reaction, side effect, drug-drug interaction, or drug-alcohol interaction.

[3] It is important to note that these are not raw numbers of visits, but estimates projected to a national sample. The limitations of the weighting system used to derive these projected estimated are discussed in Section 4.1.1 below.

Figure 1 Number of ED Visits Related to Specific Products



It is unclear whether these data reflect an increase in the levels of accidental and/or intentional exposure to substances and drugs in general, including energy drinks, or if there are methodological and statistical processes that may give the appearance of notable increases in drug-related ED visits. It is possible, for example, that the observed increases in some categories could be due to increased awareness by health professionals of certain substances, or increased perception of certain categories as problematic. This could lead to either increased detection of such substances (*e.g.,* if the medical interviewer asks about them more than previously) or increased attribution of ED visits to the substance (*e.g.,* if the medical interviewer is more likely to record the substance or to name it as a factor in the ED visit).

Table 1.—Number of ED Visits Related to Specific Products

Drug	2007	2008	2009	2010	2011	% Change, 2007–2011
Total drug-related ED visits	**3,998,228**	**4,383,494**	**4,595,263**	**4,916,328**	**5,067,374**	26.74%
Total drug reports	**6,248,023**	**6,957,634**	**7,270,914**	**7,808,492**	**8,046,258**	28.78%
Caffeine/multivitamin	12,750	18,970	14,415	18,734	29,379	130.42%
Energy drinks	*10,068*	*16,059*	*13,119*	*15,219*	*20,783*	*106.43%*
Nutritional products	59,389	74,437	80,724	93,749	95,089	60.11%
Iron products	7,800	8,885	11,020	12,982	12,711	62.96%
Minerals and electrolytes	11,140	16,364	15,088	16,094	14,946	34.17%
Electrolyte replacement solutions, oral [a]	673	689	855	1,282	1,824	171.03%
Oral nutritional supplements	15,388	15,919	20,835	26,014	33,855	120.01%
Infant formula	12,764	12,019	16,582	22,242	28,212	121.03%
Vitamin and mineral combinations	9,499	13,566	13,847	16,369	14,834	56.16%
Vitamins	18,915	26,905	28,857	29,381	29,672	56.87%
Alternative medicines	13,320	15,892	15,951	20,806	24,222	81.85%
Herbal products	8,603	6,661	8,864	11,915	12,508	45.39%
Nutraceutical products	4,385	8,975	7,356	8,600	10,087	130.03%
Probiotics	330	485	128	752	1,760	433.33%
Gastrointestinal agents	78,826	94,468	104,390	101,940	103,358	31.12%
Antidiarrheals	6,947	8,462	8,526	12,113	10,859	56.31%
Laxatives	19,424	28,053	27,621	29,668	33,861	74.33%
Dermatological agents	30,072	30,438	36,016	44,262	50,632	68.37%
Topical emollients	2,832	2,937	2,972	5,622	4,836	70.76%
Hydrocortisone, topical	2,019	2,817	4,206	4,284	3,997	97.97%
Camphor [b]	460	1,402	238	1,032	2,204	379.13%
Hydrogen peroxide, topical	593	471	957	2,361	1,503	153.46%
Miscellaneous						
CNS Stimulants	48,732	53,169	53,652	66,888	93,457	91.78%
Caffeine [c]	6,434	5,930	7,293	8,633	8,936	38.89%
Isopropyl alcohol, topical	2,252	4,504	2,473	2,779	3,219	42.94%
Ophthalmic preparations [d]	9,137	9,125	11,828	13,653	14,506	58.76%

[a] Electrolyte replacement solutions include products such as Gatorade, Powerade, Pedialyte, etc.
[b] Camphor includes products such as Vick's, Biofreeze, etc.
[c] Caffeine includes coffee, as well as other caffeine-containing products, including caffeine pills and diet pills.
[d] Ophthalmic preparations include contact solution, eye drops, etc.

An important consideration in the assessment of drug-related ED visits is the health outcomes or consequences associated with such visits. While DAWN does not capture information on the nature of the complaint or symptom severity that prompted the ED visit, there is information available on the disposition or discharge status of ED visits that can serve as a proxy for measuring clinical severity and acuity. Table 2 below shows the results of an analysis of the 2011 DAWN public-use data that was conducted to determine the percentage of visits resulting in discharge home for all drug-related ED visits, caffeine/multivitamin-related visits, and for three groups of selected comparator products (nutritional products, which includes iron products, minerals and electrolytes, oral nutritional supplements, vitamins; alternative medicines, which includes herbal products, nutraceutical products, probiotics; and CNS stimulants) (see Appendix Table 5 for additional information on the visit and demographic characteristics associated with caffeine/multivitamin-related ED visits, as well as the three selected comparator products).

Of the overall caffeine/multivitamin-related ED visits in 2011, 84.4 percent resulted in discharge home. Considering ED visits related to caffeine/multivitamin use only (*i.e.,* no other drug involvement), the percentage of visits resulting in discharge without any further follow-up was even higher (88.3 percent), demonstrating that the vast majority of energy drink-related ED visits are for non-serious complaints that do not require further medical care. Notably, home discharge rates for caffeine/multivitamin-related ED visits are substantially higher than those for drug-related ED visits overall (63.8 percent). These findings are consistent with information from the American Association of Poison Control Centers' (AAPCC) National Poison Data System which indicates that in cases involving energy drink exposure where medical outcome was assessed, the vast majority of cases were considered to be not serious

(83 percent of cases with medical outcomes classified as "none" or "minor").[4] This suggests that ED visits associated with consumption of energy drinks are not as serious as those associated with other drugs.

Table 2.—Home discharge rates for selected ED visit types

Visit Type	% of Visits Resulting in Discharge Home
All drug-related ED visits	63.8%
CNS stimulants-related visits	74.2%
Alternative medicines-related visits	75.5%
Nutritional products-related visits	80.3%
Caffeine/multivitamin-related visits	84.4%

4.1 Limitations of DAWN

Though not directly addressing the reported rise in energy drink-related ED visits, there are a number of limitations of DAWN that are worth noting.

4.1.1 Representativeness of the Sample and Validity of Projected Rates for the U.S.

DAWN uses a sample of hospital EDs to estimate national ED visit rates, including 13 major metropolitan areas and a supplementary sample to cover the remainder of the U.S. In 2002, prior to the most recent DAWN re-design, there were 21 metropolitan areas included in the sample. The DAWN redesign methodology report called for an expansion to 48 metropolitan areas in order to provide better national coverage and to increase the reliability and stability of their estimates. However, in 2004 (the first complete year of the redesigned DAWN) only 15 metropolitan areas had sufficient participation to warrant separate, stand-alone estimates. As of 2011 (the latest year for which public use data are available), the number of metropolitan areas with sufficient participation was further reduced to 13. Thus, although the expert panel that evaluated DAWN recommended *more* participating hospitals to increase reliability, in fact there are now *fewer* participating hospitals.

It is important to understand that DAWN's reporting is not based on a straightforward enumeration of cases. DAWN projects to a national estimate of cases based on combining results from two sources: approximately 183 hospitals in 13 major metropolitan areas, and approximately 50 supplementary hospitals in 2011. Although the metropolitan hospitals actually report more cases, the supplementary hospitals actually exert greater influence on the projected national estimate. On average, one case in the supplementary sample represents 135 weighted cases, whereas one case in any of the 13 main metropolitan areas represents, on average, fewer than 5 weighted cases (see Appendix Table 4). Therefore, a single case from a supplementary hospital can count 27 times more than a case from one of the metropolitan hospitals that report data to DAWN. This can distort the estimate. For example, a small 'outbreak' at a community hospital could potentially skew the national statistics; a single case of energy drink use presenting to a hospital in the supplementary sample could be counted as though it were 863 cases (the maximum weight for a single case in 2011), possibly seriously skewing the national statistics and resulting in misleading trend data.

In 2011, the vast majority (85.6 percent) of weighted caffeine/multivitamin-related ED visits were derived from the supplementary sample. This does not appear to be unique to caffeine/multivitamins, however, as an analysis of selected comparator products (*i.e.,* nutritional products, alternative medicines, and CNS stimulants) revealed that for these three other drug classes/product categories the bulk of the weighted reporting is also coming from the supplementary sample: 83.7 percent for nutritional products, 83.4 percent for alternative medicines, and 87.3 percent for CNS stimulants.

Using the publicly available DAWN data, we examined trends in caffeine/multivitamin-related ED visits by individual metropolitan area and observed a variable pattern. Among the 11 metropolitan areas with available data between 2007–2011, two areas experienced a decrease in caffeine/multivitamin-related ED visits during this time period (Denver, Phoenix); four areas experienced an increase between 50–100 percent (Boston, Chicago, Houston, Minneapolis-St. Paul); and five areas (Dade County (Miami), Detroit, New York City, San Francisco, and Seattle) experienced an increase greater than 100 percent. This may imply that there are regional vari-

[4] Bronstein AC, *et al.,* 2011 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 29th Annual Report. Clinical Toxicology 2012;50:911–1164. Note: Energy drinks were added as a generic code to NPDS in 2010. Because only partial year data is available for 2010, it is not yet possible to assess trends related to energy drinks with these data.

ations in trends in ED visits related to energy drinks or that there are regional variations in the characterization of ED visits, possibly from a greater local awareness in the higher reporting areas. An analysis of selected comparator products also revealed regional variation in ED visits. For the category of CNS stimulants, for example, one metropolitan area experienced a decrease in ED-related visits between 2007 and 2011; one area experienced an increase of less than 50 percent; five areas experienced an increase between 50–100 percent and two areas experienced an increase greater than 100 percent.

4.1.2 Reliability of Self-Reported Data

The reliability of DAWN data is dependent on information listed by the provider on the ED medical chart, which is typically based on patient self-report taken by the triage nurse. Therefore, the drugs actually involved in ED visits might not all be identified and documented. As noted in the SAMHSA report, of the 20,783 ED visits involving energy drinks in 2011, more than half (58 percent) were reported to involve energy drinks only. However, it is possible that while some patients presenting to the ED may have readily reported use of an energy drink (a legal product, and thus more likely to be considered socially acceptable), they may have been reluctant to report any other drug use that may have occurred in conjunction with their use of an energy drink (*e.g.,* use of illegal drugs, drugs for which there was no valid prescription or use of alcohol by those under legal age). Further, as described above, the salience of certain drugs/substances and the perception of the drug/substance as a problem could also affect reporting by the provider.

4.1.3 Inability to Determine Causation

Many drug-related ED visits involve multiple drugs. As noted in the SAMHSA report, of the 20,783 ED visits involving energy drinks in 2011, 42 percent reportedly involved other drugs. Use of pharmaceuticals was most commonly reported in conjunction with energy drink use (27 percent), with 9 percent of visits involving energy drinks and central nervous stimulants. About 13 percent of visits involved energy drinks and alcohol and 10 percent of visits involved energy drinks and illicit drugs, with 5 percent involving energy drinks and marijuana. In these instances, it may be difficult or impossible to determine whether a single drug or product is responsible for the visit or if the visit was the result of the interaction between the drugs. Furthermore, important information that could aid in assessing causation is not captured (*e.g.,* nature of the complaint/symptoms that brought the patient to the ED, overall health of the patient, amount used/exposure information). Importantly, there is no specific information on consumption of other caffeine-containing products (*e.g.,* coffee—which is included in the larger caffeine category by DAWN, but not listed as a specific product). This is particularly important given the wide variability in caffeine content of popular brands of coffee. According to an analysis prepared for the Food and Drug Administration (FDA) on caffeine consumption in the U.S.[5], the mean amount of caffeine consumed by the U.S. population has remained relatively stable between 2003 and 2008 at approximately 300 milligrams per person per day despite the entry of energy drinks into the marketplace. Furthermore, according to the same analysis, energy drinks contribute a small portion of the caffeine consumed, with major sources of caffeine being coffee, soft drinks and tea.

5 Potential Issues

The estimates provided in the SAMHSA report are based solely on number of ED visits, and do not account for the availability of the product (*i.e.,* sales). As shown in Table 3 (which includes data for the years 2007–2011, since as noted by SAMHSA, statistical tests were not used until 2007 when the number of ED visits involving energy drinks exceeded 10,000) and Figure 2 (which displays data for the years 2005–2011, consistent with the figure presented in the SAMHSA report), the increase in energy drink-related ED visits was accompanied by an increase in the number of cases of energy drinks sold. However, ED visits still appear to be increasing at a higher rate than sales.

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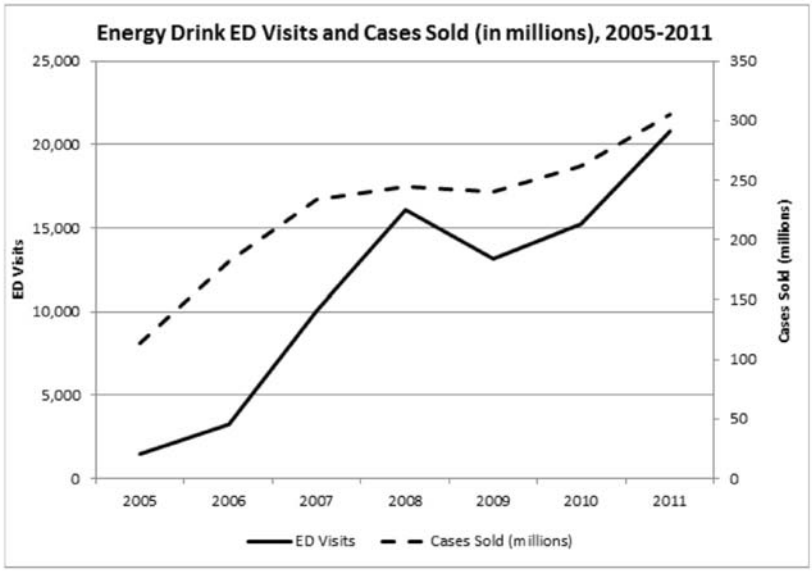
[5] Caffeine Intake by the U.S. Population. Prepared by Laszlo P. Somogyi, Ph.D. for the Food and Drug Administration, Oakridge National Laboratory. Subcontract Number 70000073494. Completed September 2009 and revised August 2010. Available at: *http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/UCM333191.pdf*

Table 3.—Energy drink-related ED visits and number of cases of energy drinks sold (2007–2011)

	2007	2008	2009	2010	2011	% Change 2007–2011
Number of energy drink-related visits	10,068	16,059	13,119	15,219	20,783	106.4%
Cases sold (millions)±	234.1	244.5	240.1	261.5	305.0	30.3%
Number of energy-drink related visits per 1 million cases sold	43.0	65.7	54.6	58.2	68.1	58.4%

±BB Source: Beverage Digest Fact Book

Figure 2 Energy drink-related ED visits and cases of energy drinks sold (in millions), 2005–2011



6 Conclusion

Although the DAWN report has attracted a lot of attention, careful analysis of the report and the public data underlying it, do not appear to be consistent with a signal of substantial medical harm. The vast majority of caffeine/multivitamin-related ED visits appear to be associated with non-serious complaints that do not require further medical follow-up, as 84.4 percent of visits related to these products resulted in discharge home, a higher rate than observed for other products. The reported rate of ED visits related to caffeine/multivitamins remains quite small, representing a tiny fraction of the overall visits to EDs each year. Finally, the limitations of the DAWN system suggest caution in basing public health policy on the results relative to energy drinks.

8 Appendix

Table 4.—DAWN weighting by metro area (2011)

	Number of Cases, Unweighted	% of Unweighted Cases	Average Weight	Minimum Weight	Maximum Weight
BOSTON-CAMBRIDGE-QUINCY, MA-NHMSA:(1)	24,889	10.86%	3.86	1.60	8.54
NEW YORK CITY—5 BUROUGHS (PART OF NEW YORK-NEWARK-EDISON, NY-NJ-PA MSA):(2)	39,776	17.35%	3.13	0.94	22.84
CHICAGO-NAPERVILLE-JOLIET, IL-IN-WI MSA:(3)	21,918	9.56%	6.68	1.42	28.77
DETROIT-WARREN-LIVONIA, MI MSA:(4)	22,502	9.82%	4.20	1.23	11.62
MINNEAPOLIS-ST. PAUL-BLOOMINGTON, MN-WI MSA:(5)	12,049	5.26%	4.50	1.33	8.04
FORT LAUDERALE DIVISION OF MIAMI-FORT LAUDERDALE, FL MSA:(6)	5,352	2.33%	6.15	2.59	14.30
DADE COUNTY DIVISION OF MIAMI-FORT LAUDERDALE, FL MSA:(7)	7,101	3.10%	4.46	2.57	8.57
HOUSTON-BAYTOWN-SUGAR LAND, TX MSA:(8)	9,115	3.98%	10.31	3.32	27.90
DENVER-AURORA, CO MSA:(9)	12,112	5.28%	3.01	1.10	7.34
PHOENIX-MESA-SCOTTSDALE, AZ MSA:(10)	13,166	5.74%	4.76	1.05	15.87
OAKLAND DIVISION OF SAN FRANCISCO-OAKLAND-FREMONT, CA MSA:(11)	2,462	1.07%	13.29	9.22	18.18
SAN FRANCISCO DIVISION OF SAN FRANCISCO-OAKLAND-FREMONT, CA MSA:(12)	8,936	3.90%	4.09	1.14	10.06
SEATTLE-TACOMA–BELLEVUE, WA MSA:(13)	18,973	8.28%	2.86	1.03	7.74
ALL OTHER LOCATIONS:(14) (a.k.a. *"supplementary sample"*)	30,860	13.46%	135.13	2.01	862.82

Table 5.—Visit characteristics and demographics for caffeine/multivitamin-related ED visits, nutritional products-related ED visits, alternative medicine-related ED visits and CNS stimulant-related ED visits (2011)

	Caffeine/Multivitamin Products	Nutritional Products	Alternative Medicines	CNS Stimulants
Total ED Visits	29,379	95,089	24,222	93,457
Combinations				
Product Only	14,393 (48.99%)	63,780 (67.07%)	11,374 (46.96%)	45,951 (49.17%)
Product, Any Pharmaceutical Combination	11,952 (40.68%)	11,090 (11.66%)	4,497 (18.57%)	40,648 (43.49%)
Product, Any Alcohol Combination	8,615 (29.32%)	1,644 (1.73%)	1,523 (6.29%)	17,118 (18.32%)
Product, Any Illicit Drug Combination	3,701 (12.60%)	201 (0.21%)	1,653 (6.82%)	12,914 (13.82%)
Product, 2+ Substances, Not Misuse/Abuse	3,503 (11.92%)	23,735 (24.96%)	8,870 (36.62%)	14,974 (16.02%)
Visit Characteristics				

Table 5.—Visit characteristics and demographics for caffeine/multivitamin-related ED visits, nutritional products-related ED visits, alternative medicine-related ED visits and CNS stimulant-related ED visits (2011)—Continued

	Caffeine/Multivitamin Products	Nutritional Products	Alternative Medicines	CNS Stimulants
Quarter				
First Quarter	5,580 (18.99%)	25,279 (26.59%)	9,059 (37.40%)	20,909 (22.37%)
Second Quarter	7,764 (26.43%)	26,784 (28.17%)	5,738 (23.69%)	25,739 (27.54%)
Third Quarter	8,503 (28.94%)	22,483 (23.64%)	5,485 (22.64%)	26,334 (28.18%)
Fourth Quarter	7,532 (25.64%)	20,542 (21.60%)	3,939 (16.26%)	20,475 (21.91%)
Part of the Day				
Early morning (12:00–5:59 AM)	6,367 (21.67%)	14,965 (15.74%)	3,605 (14.88%)	16,914 (18.10%)
Morning (6:00–11:59 AM)	5,044 (17.17%)	18,738 (19.71%)	4,274 (17.64%)	18,896 (20.22%)
Afternoon (12:00–5:59 PM)	8,236 (28.03%)	29,750 (31.29%)	9,610 (39.68%)	27,655 (29.59%)
Evening/Night (6:00–11:59 PM)	9,733 (33.13%)	31,637 (33.27%)	6,734 (27.80%)	29,993 (32.09%)
Number of Substances				
One	14,393 (48.99%)	63,780 (67.07%)	11,374 (46.96%)	45,951 (49.17%)
Two or more	14,986 (51.01%)	31,308 (32.93%)	12,848 (53.04%)	47,506 (50.83%)
Case Type				
Suicide Attempt	917 (3.12%)	1,473 (1.55%)	1,363 (5.63%)	4,715 (5.05%)
Seeking Detox	364 (1.24%)	5 (0.01%)	14 (0.06%)	2,272 (2.43%)
Alcohol Only (Age<21)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Adverse Reaction	15,914 (54.17%)	79,638 (83.75%)	16,656 (68.76%)	41,311 (44.20%)
Product Only	13,061 (44.46%)	57,447 (60.41%)	8,528 (35.21%)	28,970 (31.00%)
Product, Any Pharmaceutical Combination	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Product, Any Alcohol Combination	0 (0.00%)	820 (0.86%)	659 (2.72%)	1,594 (1.71%)
Product, Any Illicit Drug Combination	5 (0.02%)	5 (0.00%)	0 (0.00%)	5 (0.00%)
Product, 2+ Substances, Not Misuse/Abuse	2,849 (9.70%)	21,366 (22.47%)	7,469 (30.84%)	10,743 (11.49%)
Overmedication	1,247 (4.25%)	9,240 (9.72%)	1,769 (7.30%)	10,959 (11.73%)
Malicious Poisoning	30 (0.10%)	293 (0.31%)	0 (0.00%)	94 (0.10%)
Accidental Ingestion	232 (0.79%)	2,883 (3.03%)	1,693 (6.99%)	4,510 (4.83%)
Other	10,675 (36.34%)	1,557 (1.64%)	2,729 (11.27%)	29,596 (31.67%)

Table 5.—Visit characteristics and demographics for caffeine/multivitamin-related ED visits, nutritional products-related ED visits, alternative medicine-related ED visits and CNS stimulant-related ED visits (2011)—Continued

	Caffeine/Multivitamin Products	Nutritional Products	Alternative Medicines	CNS Stimulants
Disposition				
Discharged Home	24,798 (84.41%)	76,326 (80.27%)	18,295 (75.53%)	69,379 (74.24%)
Product Only	12,714 (43.28%)	58,968 (62.01%)	9,470 (39.09%)	39,000 (41.73%)
Product, Any Pharmaceutical Combination	9,722 (33.09%)	6,949 (7.31%)	2,613 (10.79%)	27,820 (29.77%)
Product, Any Alcohol Combination	6,416 (21.84%)	461 (0.48%)	1,060 (4.37%)	11,016 (11.79%)
Product, Any Illicit Drug Combination	3,103 (10.56%)	101 (0.11%)	767 (3.17%)	7,032 (7.52%)
Product, 2+ Substances, Not Misuse/Abuse	3,431 (11.68%)	14,007 (14.73%)	6,545 (27.02%)	10,506 (11.24%)
Released to Police/Jail	15 (0.05%)	100 (0.11%)	8 (0.03%)	260 (0.28%)
Referred to Detox/ Treatment	363 (1.24%)	430 (0.45%)	32 (0.13%)	2,134 (2.28%)
ICU/Critical Care	367 (1.25%)	1,133 (1.19%)	288 (1.19%)	2,074 (2.22%)
Surgery	5 (0.02%)	387 (0.41%)	0 (0.00%)	5 (0.01%)
Chemical Dependency/ Detox, Psychiatric Unit	50 (0.17%)	189 (0.20%)	1,056 (4.36%)	2,973 (3.18%)
Other Inpatient	1,804 (6.14%)	13,263 (13.95%)	3,653 (15.08%)	5,608 (6.00%)
Transferred	972 (3.31%)	2,244 (2.36%)	697 (2.88%)	9,401 (10.06%)
Left Against Medical Advice	326 (1.11%)	90 (0.09%)	60 (0.25%)	718 (0.77%)
Died	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Other	672 (2.29%)	222 (0.23%)	108 (0.45%)	823 (0.88%)
Not Documented	7 (0.02%)	703 (0.74%)	25 (0.10%)	81 (0.09%)
Demographics				
Sex				
Male	20,502 (69.78%)	40,796 (42.90%)	10,684 (44.11%)	54,926 (58.77%)
Female	8,877 (30.22%)	54,293 (57.10%)	13,538 (55.89%)	38,531 (41.23%)
Age Category				
0–11	668 (2.27%)	32,032 (33.69%)	2,762 (11.40%)	10,926 (11.69%)
12–17	3,082 (10.49%)	2,345 (2.47%)	1,145 (4.73%)	13,859 (14.83%)
18–24	9,260 (31.52%)	2,627 (2.76%)	3,494 (14.43%)	23,543 (25.19%)
25–34	7,038 (23.96%)	6,510 (6.85%)	4,148 (17.13%)	21,486 (22.99%)

Table 5.—Visit characteristics and demographics for caffeine/multivitamin-related ED visits, nutritional products-related ED visits, alternative medicine-related ED visits and CNS stimulant-related ED visits (2011)—Continued

	Caffeine/Multivitamin Products	Nutritional Products	Alternative Medicines	CNS Stimulants
35+	9,332 (31.76%)	51,575 (54.24%)	12,673 (52.32%)	23,643 (25.30%)
Race/Ethnicity				
White Only	18,293 (62.26%)	60,953 (64.10%)	17,926 (74.01%)	68,763 (73.58%)
African American Only	3,475 (11.83%)	14,800 (15.56%)	2,284 (9.43%)	9,108 (9.75%)
Hispanic or Latino	7,055 (24.02%)	16,528 (17.38%)	3,140 (12.96%)	14,404 (15.41%)
All Other Races	556 (1.89%)	2,807 (2.95%)	873 (3.60%)	1,181 (1.26%)

ATTACHMENT 3

AMERICAN BEVERAGE ASSOCIATION
Washington, DC, July 26, 2013

MARGARET A. HAMBURG, M.D.,
Commissioner of Food and Drugs,
Food and Drug Administration,
Silver Spring, MD.

Dear Dr. Hamburg:

We are writing in response to a March 19, 2013, letter ("the Arria Letter") to you from 18 healthcare professionals ("the Authors") concerning the safety of caffeine as an ingredient in energy drinks. The Authors of that letter assert that "there is neither sufficient evidence of safety nor a consensus of scientific opinion to conclude that the high levels of added caffeine in energy drinks are safe."[1] The Authors further assert that the use of caffeine in energy drinks under the intended conditions of use is not generally recognized as safe ("GRAS"). Finally, the authors conclude that "the best available scientific evidence demonstrates a robust correlation between caffeine levels in energy drinks and adverse health and safety consequences, particularly among children, adolescents, and young adults."[2]

The Authors paint a distorted and highly inaccurate picture of caffeine use and safety, ignoring the vast number of robust and reliable scientific publications that have, for decades, established the safety of caffeine at the levels presented in energy drinks, including for younger consumers. Caffeine is a well-studied, widely used, and safely consumed food ingredient. The vast majority of U.S. consumers consume a caffeine-containing beverage daily without any evidence of risk or harm. The amount of caffeine in mainstream energy drinks is typically less than the caffeine in a 12–16 fluid ounce ("medium") coffee-shop brewed coffee.[3] Recent surveys of consumption of caffeine-containing beverages, including a survey sponsored by FDA, consistently demonstrate that coffee drinkers consume the most caffeine. For example, in a recent consumption survey sponsored by the International Life Sciences Institute ("ILSI"), the authors noted that "caffeine intakes were highest for adult coffee drinkers over 35 years of age."[4] Surveys demonstrate that while more than fifty percent of people consuming caffeine-containing beverages drink coffee, only about four percent drink energy beverages.[5]

The Authors' focus on caffeine intake from energy beverages ignores increased caffeine intake from coffee. Coffee consumption increased by 700 percent from 1995 to

[1] Letter from Amelia M. Arria, Ph.D. *et al.,* to the Honorable Margaret A. Hamburg, M.D., Commissioner, Food and Drug Administration, at 1 (March 19, 2013) (hereinafter "Arria Letter").

[2] *Id.*

[3] A 16 fluid ounce StarbucksTM Grande coffee contains about 330 mg (about 20 mg/fluid ounce). Mainstream energy drinks contain 10 to 15 mg/fluid ounce or about 80 to 120 mg/8 fluid ounce serving. A 16 fluid ounce energy drink container would typically contain 160 to 240 mg of caffeine, less than a 16 fluid ounce cup of brewed Starbucks™ coffee.

[4] Mitchell, D.C. *et al., Beverage Caffeine Intakes in the U.S.,* Poster session presented at the American Society for Nutrition Annual Meeting at EB 2013, Boston, MA (Apr. 20–24, 2013).

[5] *Id.*

2000.[6] Furthermore, the National Coffee Association's National Coffee Drinking Trends study for 2012 showed that increases in coffee consumption were most significant among those between 18 and 39 years old: "Among those 18 to 24 years old, daily consumption jumped from 40 to 50 percent and for those 25 to 39 years old, from 54 to 63 percent."[7] The Authors' persistence in attacking energy drinks cannot be reconciled with the data.

About twenty-five years ago, two distinguished academicians, Dr. P.B. Dews and Dr. Jack Bergman, introduced a chapter in a book on Nutritional Toxicology entitled "Dietary Caffeine and Its Toxicity" with the following:

> Caffeine is part of the diet of most people. It is generally accepted that caffeine helps people work and enjoy their days a little better, but that has not been established by rigorous, objective, and quantitative studies. There is much more substantial evidence that dietary consumption is harmless in normal people. There has continued to be a perhaps never-ending series of suggestions of adverse effects which, so far, on further investigation have been shown to be ill-founded. Use of the term toxicity for the effects reported or suggested for caffeine as a component of the diet, the main concern of this review, may therefore be misleading. What is toxic and what is not, what is sought after and what is an unwanted side effect, depends on the circumstances.[8]

In spite of the Authors' attempt to paint caffeine as unsafe, the weight of the scientific evidence clearly establishes that caffeine is a safe food ingredient under the intended conditions of use in energy drinks, and is properly designated as a GRAS food ingredient for use in beverages generally and energy drinks in particular. Energy drinks have been marketed worldwide for about three decades and are safely consumed throughout the world. It is estimated that nearly 5 billion cans of energy drinks are consumed in the United States annually and many more billion cans are consumed each year worldwide. Regulatory bodies in Europe and Canada (and elsewhere) have evaluated these beverages previously and concluded that they are safe, as detailed below.

Contrary to the assertion by the Authors that "the best available scientific evidence demonstrates a robust correlation between the caffeine levels in energy drinks and adverse health consequences, particularly among children, adolescents, and young adults,"[9] the scientific evidence demonstrates that: (1) caffeine is safely consumed by virtually all consumers; (2) the effects of "excess" caffeine consumption are self-limiting and reversible; (3) serious adverse events associated with caffeine are extremely rare and typically involve inherent, individual health-related factors beyond caffeine; and (4) for most consumers the benefits of caffeine—increased attention, vigilance, improved productivity, and concentration—are obtained without any adverse effect whatsoever.

We address the principal allegations set forth by the Authors in turn below.

I. Energy Drinks Are Not Typically High in Caffeine in Comparison to Competing Beverages

One of the Authors' principal premises is that energy drinks contain "high levels of added caffeine."[10] The Authors do not define what they mean by "high" levels of caffeine. For purposes of this discussion, we will assume that "high" means substantially in excess of the level of caffeine otherwise widely available in comparable or competing beverages such as coffee. Even with that generous interpretation of the Authors' meaning, their assertion is unsupported by facts.

Most energy drinks are sold in containers ranging from about 8 fluid ounces to 16 fluid ounces with approximately 10–15 mg/fluid ounce of caffeine. A typical container of an energy drink will therefore contain between 80 and 240 mg caffeine.[11]11 In contrast, prepared coffees often exceed the levels of caffeine in a typical energy drink. For example, a medium Starbucks Coffee (a Grande, in Starbucks parlance), which is a 16 fluid ounce beverage, contains 330 mg caffeine (Table 1). Also, shelf-stable coffees and iced coffees are sold in retail outlets on shelves and in refrigerators, often adjacent to energy drinks. Indeed, some coffee flavored ice creams and

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[6] Lumin Interactive (Designer), How Coffee Changed America (Web Graphic), available at *http://newswatch.nationalgeographic.com/2012/01/19/coffee-changed-america-infographic/* (last accessed May 30, 2013).

[7] National Coffee Association, *2012 National Coffee Drinking Trends Study* (2012).

[8] Bergman, J. and Dews, P.B., *Dietary Caffeine and Its Toxicity,* 2 NUTRITIONAL TOXICOLOGY 199, 199–200 (John N. Hathcock ed., 1987).

[9] Arria Letter, at 1.

[10] *See, e. g.,* Arria Letter, at 1.

[11] *See* Center for Science in the Public Interest ("CSPI"), *Caffeine Content Of Food & Drugs* (Dec. 2012), available at *http://www.cspinet.org/new/cafchart.htm* (last accessed May 30, 2013).

frozen yogurts contain about as much caffeine in a serving as would typically be found in an 8 fluid ounce energy drink (Table 1). Therefore, the focus on the caffeine content of energy drinks seems misplaced.

Table 1.—Caffeine Content of Select Foods Available in the U.S.

Product	Amount [12]	mg of Caffeine [13]	Mg caffeine/oz.
Dunkin' Donuts with Turbo Shots	*20 fl. oz.*	*436*	*21.8*
Caribou Depth Charge	*16 fl. oz.*	*370* [14]	*23.1*
Starbucks Coffee (Grande/ Medium)	*16 fl. oz.*	*330*	*20.6*
Caribou Coffee of the Day	*16 fl. oz.*	*305* [15]	*19.1*
Panera Frozen Mocha	*16.5 oz.*	*267*	*16.2*
Baskin Robbins Cappuccino Blast	*24 fl. oz.*	*234*	*9.75*
Dunkin' Donuts Coffee (Medium)	*14 fl. oz.*	*178*	*12.7*
Starbucks Iced Coffee	*16 fl. oz.*	*165*	*10.3*
Monster	*16 fl. oz.*	*160*	*10*
Rockstar	*16 fl. oz.*	*160*	*10*
McDonalds Premium Roast Iced Coffee	*22 fl .oz.*	*145*	*6.59*
Ben & Jerry's Coffee Heath Bar Crunch Ice Cream	*4 oz.*	*42*	*10.5*
Red Bull	*8.4 fl. oz.*	*80*	*9.5*
Ben & Jerry's Coffee Flavored Ice Cream	*4 oz.*	*34*	*8.5*
Mio (by Kraft)	*1 squirt (1/2 tsp.)*	*60 per serving; 1080 per 1.62 fl. oz. bottle*	
Coca-Cola, Coke Zero, or Diet Pepsi	*12 fl. oz.*	*35*	*2.9*
Hershey's Special Dark Chocolate Bar	*1.45 oz.*	*31*	*21.4*
Brewed tea	*8 fl. oz.*	*30–80*	*3.75–10*

Table 1 shows, numerous foods and beverages contain caffeine at levels comparable to or greater than those in energy drinks. These foods have a long history of safe consumption in the U.S. and globally by persons of all age groups. It is therefore clear that energy drinks do not introduce new or alarming levels of caffeine into the food supply, as has been suggested by the Authors of the Arria Letter. Further, while the Arria Letter states that "many energy drinks and related products containing added caffeine exceed the caffeine concentration of even the most highly caffeinated coffee," [16] the data in Table 1 regarding caffeine content of coffee make clear that this statement is not correct.

The Authors of the Arria Letter suggest a distinction between "naturally occurring" caffeine and "added" caffeine, implying somehow that "added" caffeine is more problematic.[17] There is no scientific basis for this assertion. The body identifies and processes added caffeine, from any source, in the same way that it processes caffeine that may be naturally occurring in foods and beverages.[18] We also note that many energy drinks incorporate "naturally occurring" caffeine, including from green tea and coffee. Significantly, manufacturers who add caffeine to their products can control the amount to a far greater extent than producers or marketers of food in which caffeine is naturally occurring such as tea or coffee. An energy drink manufacturer can ensure with a high degree of precision and accuracy that its products contain the amount of caffeine declared on their labels. By contrast, the caffeine content of

[12] The amounts used in Table 1 correspond to typical serving or container sizes. Where multiple size containers are offered for sale (coffee products, for example), the mid-sized container was used.

[13] *See* CSPI, *Caffeine Content of Food and Drugs, supra* note 11 and public industry information. Table 1 includes values from the current version of the CSPI chart, as well as previous versions of the CSPI page.

[14] CARIBOU COFFEE CO., *Depth Charge,* available at *http://www.cariboucoffee.com/page/1/beverage-food-detail.jsp?id=1439&type=drink* (last accessed May 30, 2013).

[15] CARIBOU COFFEE CO., *Coffee of the Day,* available at *http://www.cariboucoffee.com/page/1/beverage-food-detail.jsp?id=1436&type=drink* (last accessed May 30, 2013).

[16] Arria Letter, at 2.

[17] *Id.*

[18] One of the Authors, Dr. Roland Griffiths, recently stated that "caffeine is caffeine," (quoted in Hill, M., *Energy Drinks Go Natural as Market Buzzes Along,* USA TODAY, July 6, 2013, available at *http://www.usatoday.com/story/money/business/2013/07/06/energy-drinks-go-natural/2479993/* (last accessed July 10, 2013)).

coffee products varies widely due to many factors, such as brewing method, origin of the bean, degree of roasting, and other attributes. Indeed, one well-cited study found that the caffeine content of one specific coffee (Starbucks Breakfast Blend) at a single coffee shop varied by hundreds of milligrams (from 259 to 564 mg in a 16 fl. oz cup) over the course of six consecutive days.[19]

The Authors also distinguish energy drinks from coffee by saying that "coffee is typically served hot, tastes bitter, and is consumed slowly by sipping. By contrast, energy drinks are typically carbonated, sweetened drinks that are served cold and consumed more rapidly."[20] No data are offered to support these statements, which are selective characterizations that fail to account for the fact that many, if not most, consumers sweeten their coffee and add milk and drink it quickly enough to avoid it becoming cold. Perhaps even more relevant in the context of the Authors' focus on children and adolescents, these statements do not account for cold or iced coffee beverages, which are typically sweetened and are quite popular among younger consumers. Moreover, the Authors fail to account for the difference in caffeine content between coffee and energy drinks. As noted, a medium 16 fluid ounce premium coffee contains twice the amount of caffeine found in a 16 fluid ounce serving of energy drinks, negating any discrepancy that might arise from differences in the rate of consumption. In any case, the human body absorbs, distributes, metabolizes, and excretes caffeine in the same exact manner regardless of whether it is delivered to the stomach cold or hot.

Even if the purported differences asserted by the Authors are correct, there is no scientific evidence provided or available that establishes that sipping coffee or drinking an energy drink changes caffeine absorption from the gut in a meaningful manner, or that different manners of ingesting caffeine-containing beverages alter the metabolism of caffeine in the body. Given the pharmacokinetic parameters of caffeine, oral administration of equal doses over a short window (five minutes, for example) as opposed to an extended window (30 minutes, for example) would have a negligible effect on serum levels.[21]

Using available data and simple clinical pharmacokinetic models, it is possible to evaluate the absorption of caffeine with different input times. When an evaluation of concentrations achieved (instantaneous intravenous administration versus 5 minute ingestion time versus 30 minute ingestion time) after a 240 mg dose of caffeine is given, using the following accepted pharmacokinetic assumptions and models, only nominal differences in concentration are revealed. In each of these three cases peak concentrations of approximately 4–4.3 mg/L would be achieved and concentrations of 1.6–1.8 mg/L would be expected eight hours after the dose.

- Subject wt= 80 kg
- S= salt fraction= 1
- F= bioavailability= 1 or 100 percent
- D= 240 mg
- V_d= 0.7 L/kg= 56L
- Absorption time= 0.75 hr
- Cl= 0.078L/kg/hr= 6.24L/hr
- K_e= Cl/Vd= 0.11 hr^{-1}
- A non-steady state short infusion model.[22]

When taken together, these three scenarios (intravenous administration, 5 minute, and 30 minute, oral administration) demonstrate that, given the absorption

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[19] McCusker, R.R. *et al., Caffeine Content of Specialty Coffees,* 27 J. ANALYTICAL TOXICOLOGY 520 (2003).

[20] Arria Letter, at 2.

[21] Arnaud, M., *Pharmacokinetics And Metabolism Of Natural Methylxanthines In Animal And Man,* METHYLXANTHINES, HANDBOOK OF EXPERIMENTAL PHARMACOLOGY 200, at 33–91 (B. Fredholm ed., 2011)). *See also* Liguori A. *et al., Absorption and Subjective Effects of Caffeine from Coffee, Cola and Capsules,* 58 PHARMACOLOGY BIOCHEMISTRY AND BEHAVIOR 721 (1997) (finding that peak caffeine absorption, time to peak absorption, and subjective effects do not appear to be influenced by a cold cola vehicle versus hot coffee or capsule vehicles).

[22] *See* Carillo J.A., and Benitez, J., *Clinically Significant Pharmacokinetic Interactions Between Dietary Caffeine and Medications.* 39 CLIN. PHARMACOKINET. 127–153 (Aug. 2000); Heckman, M.A. *et al., Caffeine (1, 3, 7-trimethylxanthine) in Foods: A Comprehensive Review on Consumption, Functionality, Safety, and Regulatory Matters,* 75 JOURNAL OF FOOD SCIENCE R77–R87 (Apr. 2010); Juliano, L.M. *et al., The Pharmacology of Caffeine, in* PRINCIPLES OF ADDICTION MEDICINE (4th ed. 2009); Winter, M.E., BASIC CLINICAL PHARMACOKINETICS (5th ed. 2010); IOM, *Caffeine for the Sustainment of Mental Task, Performance: Formulations for Military Operations* (2001) (hereinafter "*IOM Report on Caffeine*"); Arnaud, *supra* note 21.

pattern of caffeine, the duration of administration is not clinically significant. The model used above does have limitations but generally demonstrates that rate of input is not a major factor in determining peak serum concentrations. This is because caffeine is well absorbed within about 45 minutes, and has a half-life of about 5 hours.[23] This means that not very much of the compound is eliminated during the absorption time.

The major factor governing an overdose/toxicity of caffeine is the total dose. A fatal acute dose of caffeine in adult humans is estimated to be between 10 and 20 g.[24] Subjects consuming caffeine-containing beverages tend to self-regulate the amount they consume, often based on previous experience.[25] Fatal caffeine overdose via beverages is very difficult if not impossible to achieve because the volume of fluid required to provide a toxic dose of caffeine is dose limiting (for example, 100 cups (8 fluid oz.) of coffee, 62 servings (16 fluid oz.) of a typical energy drink). Conversely, toxic doses are more readily achieved with consumption of caffeine tablets.

In sum, the foregoing data and information document that mainstream energy drinks are not "high" in caffeine relative to other common caffeine-containing beverages and foods, and there is no genuine difference in how the human body absorbs caffeine from coffee or other foods or from energy drinks.

II. Consumption Data Confirm that Children and Adolescents Are Not Frequent Consumers of Energy Drinks and that Overall Consumption of Caffeine Has Not Markedly Increased

The Arria Letter includes several very general statements on energy drink consumption in adolescents (persons aged 12–17). For example, it states "65 percent of energy drink consumers are 13- to 35-year-olds,"[26] yet the Arria Letter does not further identify which age groups within that very broad age range are the frequent and infrequent consumers of energy drinks. Nor does it identify how many energy drinks were consumed by a specific age group during any particular time period. The Arria Letter includes several additional statements related to adolescent consumption of energy drinks: (1) "More recent reports show that 30 to 50 percent of adolescents and young adults consume energy drinks"; (2) "35 percent of eighth graders and 29 percent of both tenth and twelfth graders consumed an energy drink during the past year"; and (3) "18 percent of eighth graders reported using one or more energy drinks every day."[27]

These statements do not support the allegations of the Authors that adolescents are regular consumers of high amounts of energy drinks. On the contrary, the fact that 30 to 50 percent of adolescents "consume" energy drinks is vague and could mean a consumption of only one energy drink during the period of time in question. Similarly, the second statement shows only that over the course of one year 35 percent of eighth graders and 29 percent of tenth and twelfth graders consumed at least one energy drink. (Indeed, it does not specify whether "consume" means drink an entire can, or merely taste or sample.) The third stands at odds with most other consumer research on energy drink consumption, including that conducted or commissioned by government bodies. In any case, government data show that consumption of energy drinks by younger consumers has not increased those consumers' overall caffeine intake. Therefore, the amount of energy drinks consumed by younger people is not a cause for alarm.

U.S. caffeine consumption data obtained from the United States Department of Agriculture ("USDA") National Health and Nutrition Examination ("NHANES") surveys show that caffeine consumption in the U.S. has remained essentially stable over the past decade. The NHANES survey results from 2001–2010 show caffeine intake has remained steady, despite the introduction of energy drinks and caffeinated waters during that time. Moreover, in direct contrast to the Authors' conclusions, the survey data indicate that the level of caffeine consumption for children decreased between 2001—2010, despite the availability of energy drinks (Table 2).

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[23] Blanchard, J. and Sawers, S.J.A., *Comparative Pharmacokinetics of Caffeine in Young and Elderly Men,* 11 J. PHARMACOKIN. BIOPHARM. 109–126 (1983).

[24] *IOM Report on Caffeine, supra* note 22 at 56.

[25] Kaplan, G.B.et al., *Dose-dependent pharmacokinetics and psychomotor effects of caffeine in humans,* 37 J CLIN. PHARMCOL. 693–703 (1997).

[26] Arria Letter, at 1.

[27] *Id.* at 1–2.

Table 2. Caffeine Intakes From Beverages and Foods (NHANES 2001 - 2010)*				
Age (years)	Caffeine (mg)/person			
	2001-2002[1]	2005-2006[2]	2007-2008[3]	2009-2010[4]
Males				
2-5	15.2	8.4 ± 0.72	7.8 ± 0.80	6.0 ± 0.70
6-11	26.1	19.72.74	29.9± 3.59	18.21.78
12-19	74.3	69.5 ± 6.70	73.6± 10.18	66.3 ± 11.12
20-29	151.9	133.4 ±14.46	139.6± 14.39	124.0 ±13.82
30-39	215.0	211± 12.21	187.8 ±18.29	187.9 ± 18.79
40-49	240.1	263.6 ±14.78	259.6 ±20.99	253.3 ± 22.34
50-59	243.0	295.6± 26.51	273.4 ±22.40	282.0 ± 19.41
60-69	203.8	228.0± 16.17	228.3 ±17.81	220.5 ± 15.75
70 and over	160.1	156.9 ±12.81	162.7 ± 8.23	174.8 ± 15.93
20 and over	207.7	216.1 ± 8.23	211.0 ±10.78	208.6 ± 10.70
Females				
2-5	12.3	6.9 ± 0.90	8.9 ± 1.63	5.7 ± 0.56
6-11	23.0	170 ± 1.26	19.0± 3.29	16.1 ± 0.99
12-19	49.1	46 6 ± 4.18	60.4 ± 4.40	48.4 ± 4.28
20-29	91.4	82.2 ± 8.14	105.8 ±13.35	107.6 ± 7.62
30-39	168.9	165.2 ± 19.3	153.5 ±15.04	155.8 ± 12.22
40-49	190.0	219.8 ±10.24	194.4 ±11.96	168.8 ± 12.22
50-59	190.6	225.3 ±15.33	207.2 ±32.17	186.1 ± 15.95
60-69	153.0	163.7 ±19.05	180.7 ±17.96	166.8 ± 14.61
70 and over	118.5	120.8 ± 7.61	139.1 ±10.39	121.9 ± 11.93
20 and over	153.4	165.3 ± 4.91	163.8 ± 8.51	152.2 ± 7.79
Males and females				
2 and over	142.1	149.8 ± 5.27	148.8 ± 7.44	142.2 ± 6.33

* Data are reported as mean error *per* individual (*per capita*) by gender and age in United States people 2 years and over (excluding breast-fed children) unless indicated otherwise.

[1] No standard errors were reported. Does not include separate food codes for energy drinks.

[2] Includes separate food codes for one brand of energy drinks and a general food code for "Energy Drink."

[3] Includes separate food codes for ten different brands of energy drinks and a general food code for "Energy Drink."

[4] Includes separate food codes for ten different brands of energy drinks and a general food code for "Energy Drink."

In addition, the results of a study commissioned by FDA ("the Somogyi study") confirm the NHANES consumption data, showing that caffeine consumption in the U.S. has remained "relatively stable at approximately 300 milligrams per person per day (mg/p/d), despite the entry of 'energy drinks' into the market place."[28] The study results also confirm that U.S. consumers have not significantly modified their caffeine consumption patterns since the appearance of energy drinks on the market: "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

[28] Letter from Michele Mital, Acting Associate Commissioner for Legislation, FDA, to the Honorable Richard J. Durbin, United States Senate at 4 (Nov. 21, 2012) (hereinafter "FDA November 2012 letter"), *citing* Somogyi, L., *Caffeine Intake* By The *U.S. Population* (September 2009, rev'd Aug. 2010) available at *http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/UCM333191.pdf* (last accessed July 9, 2013).

consumption of energy drinks is considered, most of the caffeine consumed comes from what is naturally present in coffee and tea."[29]

Based on data from U.S. government sources, it is clear that adolescents do not consume high amounts of caffeine. The Somogyi study reported that "teens and young adults (14–21 years of age) consume, at the mean, approximately one-third (or about 100 mg/p/d) the amount of caffeine as adults, and that their caffeine consumption is mainly from coffee, soft drinks, and tea."[30] Adolescent caffeine consumption also has remained relatively stable since 2001.[31] FDA has therefore concluded that "'energy drinks contribute a small portion of the caffeine consumed, even for teens."[32]

Moreover, only a small percentage of adolescents regularly consume energy drinks. The Somogyi study cited a recent, nationwide survey of 2,000 nationally representative households, which concluded that 0.9 percent of 14–21 year old individuals are "regular energy drinkers."[33] Because the survey might have under-reported energy drinking for young persons, Somogyi assumed that 2 percent of the entire population older than 10 are "regular consumers" of energy drinks, though "regular consumers" was not defined. Somogyi noted that "[r]eliable consumption data for habitual energy drinkers are unavailable" for any age group.[34] The study assumed that the 2 percent of the general population estimated to consume energy drinks consume about 1.55—16 fluid oz. servings per day.[35] This amount would yield caffeine exposures that are well within those accepted as safe in the published scientific literature and statements of governmental and other authoritative bodies, as discussed herein.

The Somogyi and NHANES findings were echoed in a large survey (over 37,000 participants) of the caffeine intake from beverages throughout the U.S. conducted between 2010 and 2011 by researchers at Penn State University on behalf of ILSI. These researchers again found that Americans consume the bulk of their caffeine from coffee and soft drinks, and not from energy drinks. Specifically with respect to energy drinks, the researchers determined that "[t]he percentage of energy drink users was low (*<10 percent*) and these beverages were minor contributors to overall caffeine intakes in *all* age groups."[36] The researchers found that only 4 percent of caffeine consumers reported consuming energy drinks, and that even teenagers (ages 13 to 17) in the 90th percentile of caffeine consumption ingest their caffeine from coffee at a far greater level than they do from energy drinks—132.9 milligrams/day from energy drinks v. 223.7 milligrams/day from coffee.[37]

Finally, these data are consistent with a survey conducted in Québec, Canada, in 2011, which evaluated 10,000 teens between the ages of 12 to 17 years, and found that 93 percent of teens rarely or never consumed energy drinks while only 1 per-

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[29] Letter from Jeanne Ireland, Assistant Commissioner for Legislation, FDA, to the Honorable Richard J. Durbin, United States Senate (Aug. 10, 2012) (hereinafter "FDA August 2012 letter").

[30] FDA November 2012 letter, *supra* note 28, at 4, *citing* Somogyi.

[31] Somogyi, *supra* note 28, at 48, Table 26.

[32] FDA November 2012 letter, *supra* note 28, at 4.

[33] Somogyi, *supra* note 28, at 61.

[34] *Id.* at 2. In contrast, the Authors cite one of their own articles to suggest that 30 percent to 50 percent of adolescents and young adults consume energy drinks. Seifert, S. *et al., Health Effects of Energy Drinks on Children, Adolescents, and Young Adults,* 127 PEDIATRICS 511 (2011). The levels of consumption cited in that 2011 Seifert report do not provide any insight, however, into regular energy drink consumption. One 2007 source cited by the 2011 Seifert report found that 28 percent to 34 percent of teens and young adults reported "regularly consuming" energy drinks but did not define "regular consumption." Another source cited by the 2011 Seifert report, a German study published in 1996, referred to consumption "regularly but at a rate of < 1 can per week." The German study also found that 53 percent of adolescents had "tasted" energy drinks, 24 percent drank <1 8 oz. can per week, and 3 percent drank 1 to 7 such cans per week. In fact, the German study concluded that all young people in Germany knew about energy drinks but that they actually consume them moderately, and that they prefer cola drinks. Viell, B. *et al., New Caffeinated Beverages: A Pilot Survey Of Familiarity And Consumption By Adolescents In North-Rhine Westphalia And Berlin And Considerations Of Consumer Protection* [in German], 35 Z. ERNÄHRUNGSWISS 378–386 (1996). While Seifert asserts that "[m]ost children in the study consumed energy drinks in moderation but a small group consumed extreme amounts," that "small group" appears to have been comprised of just three out of 1265 survey participants who said they consumed 32 oz. of energy drinks a day, for a total of 320 mg of caffeine, which is not "extreme amounts." In sum, data referenced in the 2011 Seifert report provide little insight into current patterns of energy drink consumption in the U.S., and are far less relevant than the recent U.S. consumption figures recorded in the study commissioned by the FDA.

[35] Somogyi, *supra* note 28, at 61.

[36] Mitchell, *et al., supra* note 4.

[37] *Id.*

cent consumed them daily.[38] The table below (Table 3) summarizes the results from this survey.

Table 3.—Frequency of Energy Drink Consumption by Quebec Teens

Frequency	Percent
Daily	1%
3 to 4 times/week	1%
1–2 times/week	5%
Rarely	28%
Never	65%

Similarly, a survey of more than 60,000 teens, 13 to 17 years of age in Québec found that 82.8 percent of teens rarely or never consumed energy drinks, and only 1.5 percent consumed them daily.[39]

III. Children and Adolescents Are Not at Unique Risk for Health Effects from Energy Drinks or Caffeine Consumption

The bulk of the Arria Letter discusses the alleged "health complications associated with the consumption of energy drinks"[40] by children and adolescents, including the alleged relationship between energy drinks/caffeine and fatalities and injuries, emergency room ("ER") visits, cardiovascular complications, seizures, behaviors, and childhood obesity.

As detailed below, the bulk of the scientific literature does not provide a "robust correlation" between caffeine levels in energy drinks and adverse health effects, nor does it show that children are uniquely susceptible to caffeine effects. To the contrary, as detailed below, the weight of the published, peer-reviewed scientific and medical literature supports the conclusion that consumption of mainstream energy drinks is not associated with such health risks.

It should be noted that 19 of the 66 articles cited in the Arria Letter were written by the Letter's Authors, and that these articles form the basis for the Authors' conclusions regarding the adverse effects of energy drink consumption. Two of these studies have not been published or peer-reviewed.[41] Nevertheless, in the Letter, the Authors self-proclaim their studies as part of the "best available scientific evidence."[42] The Authors fail to discuss in the Letter any of the limitations of their studies, and, as explained in more detail below, most of the conclusions in their studies are refuted by, or in conflict with, the majority of the published peer-reviewed scientific medical literature.

In support of their conclusion that energy drinks should not be consumed by adolescents, the Authors reference statements in a review article by the American Academy of Pediatrics' ("AAP") Committee on Nutrition and the Council of Sports Medicine and Fitness, which states that "caffeine and other stimulant substances contained in energy drinks have no place in the diet of children and adolescents" and "are not appropriate for children and adolescents and should never be consumed."[43] The statement in the AAP Committee article that "caffeine and other stimulant substances contained in energy drinks have no place in the diet of children and adolescents," cites to a 2007 IOM report on nutrition standards for foods

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[38] *Enquête Québécoise sur le Marketing de la Malbouffe: 10,000 Jeunes se Prononcent! Ste-Thérèse,* Québec: Réseau du sport étudiant du Québec (RSEQ) (2011). available at *http://ll.rseq.ca/download/attachments/15958040/Rapport+d'enquete-FRA-1-page.pdf?version=1&modificationDate=132812270990* (last accessed July 9, 2013).

[39] Institut de la Statustique du Québec, *Tableau A3.2: Fréquence de consommation habituelle de certaines boissons sucrées, élèves du secondaire, Québec, 2010–2011,* in L'ENQUÊTE QUÉBÉCOISE SUR LA SANTÉ DES JEUNES DU SECONDAIRE 2010–2011: TOME 1: LE VISAGE DES JEUNES D'AUJOURD'HUI: LEUR SANTÉ PHYSIQUE ET LEURS HABITUDES DE VIE. (2012) available at *http://www.stat.gouv.qc.ca/publications/sante/eqsjs.htm* (last accessed July 9, 2013)

[40] Arria Letter, at 3.

[41] *See* Seifert, S. *et al., Energy Drink Exposures In The American Association Of Poison Control Centers (AAPCC) National Poison Data System (NPDS) Database,* Paper presented at Annual Meeting of the North American Congress of Clinical Toxicology, Las Vegas, Nev. (2012); Higgins, J. and Babu, K., *Caffeine Reduces Myocardial Blood Flow During Exercise,* AM. J. MED. (in press).

[42] Arria Letter, at 1.

[43] AAP Committee on Nutrition and the Council on Sports Medicine and Fitness, *Sports Drinks and Energy Drinks for Children and Adolescents: Are They Appropriate*? 127 PEDIATRICS 1182, 1185 (2011) (hereinafter "PEDIATRICS 2011").

in schools in support.[44] That 2007 IOM report concluded that "[a]lthough there may be some benefits associated with caffeine consumption among adults," the IOM Committee on Nutrition Standards for Foods in Schools did not support offering caffeinated beverages in schools because of the potential for effects such as physical dependency and withdrawal.[45] This recommendation related to *all* caffeinated beverages except those with trace amounts of naturally occurring caffeine substances. That is, this recommendation applied to coffee, tea, and caffeinated sodas, as well as energy drinks. Further, the potential effects described, such as physical dependence and withdrawal, were not unique effects on children and adolescents but were the same as those experienced by adults. Thus, this citation does not establish any unique health effects of caffeine on youth.

The second statement is not associated with a particular citation, but is reflective of an overall cautious tone, which perhaps is not inappropriate for the AAP Committee but which does not reflect evidence of a different effect of caffeine on children and adolescents. Notably, the authors of that article acknowledge that caffeine has been shown to enhance physical performance in adults by increasing aerobic endurance and strength, improving reaction time, and delaying fatigue, though they state that these effects have not been studied in children and adolescents.[46] They note a number of effects of caffeine that have been addressed herein, such as increases in blood pressure, increases in attentiveness, withdrawal effects and sleep disturbances, but these effects are neither unique to children nor documented to pose genuine health risks. The AAP Committee article states that caffeine is "known also to play a role in triggering arrhythmias," but cites for this proposition only an experimental study in dogs with a review of the literature,[47] which stands at odds with the comprehensive analyses discussed above refuting the alleged association of caffeine and arrhythmias.

The AAP Committee discourages dietary intake of caffeine by children—from *all* sources, not just energy drinks –"[b]ecause of the potentially harmful adverse effects and developmental effects of caffeine."[48] Such potential developmental effects are the only effects alleged to be particular to children, but the apparent source cited in support for these effects is equally cautious and speculative. That source, Nawrot, *et al.,* noted behavioral effects of caffeine in children and adolescents comparable to those discussed below, as well as reports of beneficial effects such as improvements in attention.[49] Nawrot concludes, "Owing to these findings [of behavioral effects], as well as the fact that the nervous system in children is continually developing and the lack of available information on the longer-term effects of caffeine in this population, a cautious approach is warranted."[50] Thus, the reference to potential developmental effects is a cautionary one and not grounded in evidence of such an effect or evidence of an impact of caffeine on children that is qualitatively different from that on adults.

Finally, the authors of the AAP Committee article express concern about "large and varied amounts of caffeine" in energy drinks stating that the "total amount of caffeine contained in some cans or bottles of energy drinks can exceed 500 mg (equivalent to 14 cans of common caffeinated soft drinks)."[51] As noted in Table 2, above, reflecting approximately 95 percent of the energy drink category, virtually all energy drinks have less than half this amount. Thus, it appears the view of these authors may have been skewed by a misperception of the caffeine content of typical energy drinks.

Similarly, the Authors selectively quote from or interpret the study by Kaplan, Greenblatt, Ehrenberg et al.[52] The Authors cite the Kaplan study for the proposition that metabolism of caffeine at high doses (500 mg) was non-linear as compared to a 250 mg dose. While the understanding that caffeine does not follow linear kinetics as concentration changes has been documented since at least 1990,[53] this very prop-

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[44] IOM, *Nutrition Standards For Foods In Schools: Leading The Way Toward Healthier Youth* (2007).

[45] *Id.* at 134.

[46] PEDIATRICS 2011, *supra* note 43, at 1185.

[47] *Id.,* citing Mehta, A. *et al., Caffeine and cardiac arrhythmias: an experimental study in dogs with review of the literature,* 52 ACTA CARDIOL. 273–283 (1997).

[48] PEDIATRICS 2011, *supra* note 43, at 1185.

[49] Nawrot P. *et al., Effects of caffeine on human health,* 20 FOOD ADDIT. AND CONTAM. 1–30 (2003).

[50] *Id.* at 23.

[51] PEDIATRICS 2011, *supra* note 43, at 1185.

[52] *See* Arria Letter, at 3 (citing Kaplan, *et al., supra* note 25)).

[53] *See* Denaro, C.P. *et al., Dose-dependency of Caffeine Metabolism with Repeated Dosing,* 48 CLINICAL PHARMACOLOGY AND THERAPEUTICS 277 (1990); Cheng, W. *et al., Dose Dependent*

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erty of non-linearity kinetics may have some impact on the self-regulating nature of caffeine (notably, this property does not directly have an impact on the known human fatal dose of caffeine of 10,000 mg to 20,000 mg). The Authors fail to note that the referenced paper cites cognitive and performance improvement at the 250 mg dose with some unpleasant effects at the higher dose. Importantly, the authors of the cited study conclude that "the unfavorable and somatic effects, as well as performance disruption, from high doses of caffeine may intrinsically limit the doses of caffeine used in the general population."[54] In reality, the Kaplan study tells us what we already know. Caffeine in low to intermediate doses produces favorable effects while higher doses tend to be perceived unfavorably and are not associated with consistent enhancement of performance which, in turn, results in self-regulation of intake. None of these latter conclusions are acknowledged by the Authors.

The Arria Letter also asserts that the accumulation of caffeine metabolites could compound the "negative effects of caffeine at high blood levels."[55] This would only be the case in situations of overt caffeine overdose (for example, purposeful caffeine tablet overdose). Caffeine is known not to accumulate in any body tissues.[56] Additionally, under normal metabolic conditions, accumulation of metabolites is not something that has been demonstrated as the three primary metabolites paraxanthine, theobromine, and theophylline are themselves metabolized and excreted via multiple pathways.[57] The Arria Letter also describes the metabolites as stimulants themselves.[58] With normal caffeine ingestion, the metabolites are present at small levels, do not accumulate, and while they may have stimulant properties similar to caffeine they are not the source of the primary stimulant effect of caffeine-containing beverages.

While selectively quoting from a limited set of articles, the Authors fail to reference any of the authoritative publications confirming the safety of energy drinks and of caffeine at levels delivered by energy drinks for adolescent as well as adult consumers. For example, energy drinks have been reviewed by European food safety authorities on three occasions spanning a decade, and have been found to be safe, including for young consumers. In a 1999 opinion, the European Commission Scientific Committee on Food ("SCF") expressed no safety concerns with consumption of energy drinks formulated with a caffeine content comparable to that in mainstream energy drinks.[59] SCF also addressed consumption of energy drinks by children and reported no safety concerns from the exposure of young people to the caffeine in these products. SCF revisited energy drinks again in 2003 and estimated mean chronic, high chronic, and acute consumption of energy drinks by regular consumers of such drinks to be 125, 350, and 750 ml/day, respectively, concluding that its 1999 opinion on the safety of caffeine and energy drinks remained unchanged.[60] In 2009, the European Food Safety Authority ("EFSA"), SCF's successor entity, evaluated new data on taurine and glucuronolactone in caffeinated energy drinks and did not identify any safety concerns.[61]

Contrary to the Authors' assertions, the vast body of scientific and medical literature has conclusively established the safety of caffeine. Regulatory authorities in the U.S., Canada, Australia/New Zealand and Europe have reviewed this literature and have concluded that the level of caffeine in mainstream energy drinks is safe. Caffeine is one of the most widely studied ingredients in the food supply and has been the subject of clinical and other research for decades. Consequently, there are hundreds of peer-reviewed, published studies confirming the safety, function, and pharmacology of caffeine. Included below are examples of the body of evidence on the safety of caffeine as determined by scientists and governmental or other authoritative bodies.

Pharmacokinetics of Caffeine in Humans: Relevance as a Test of Quantitative Liver Function, 47 CLINICAL PHARMACOLOGY AND THERAPEUTICS 516 (1990).

[54] Kaplan, *et al., supra* note 25.

[55] Arria Letter, at 3.

[56] Carillo, *supra* note 22.

[57] Juliano *et al., supra* note 22.

[58] Arria Letter, at 3.

[59] SCF, *Opinion On Caffeine, Taurine, And D-Glucurono-γ-Lactone As Constituents Of So-Called "Energy" Drinks* (1999), available at *http://ec.europa.eu/food/fs/sc/scf/out22 en.html* (last accessed May 30, 2013).

[60] SCF, *Opinion of the Scientific Committee on Food on Additional Information on "Energy" Drinks,* at 2–3, 12 (2003), available at *http://ec.europa.eu/food/fs/sc/scf/out169__en.pdf* (last accessed July 9, 2013).

[61] EFSA, *The Use Of Taurine And D-Glucurono-γ-lactone As Constituents Of The So-Called "Energy" Drinks,* 935 THE EFSA JOURNAL 1, 23 (2009).

A. Caffeine Effects are a Function of Body Weight, Not Age

The substantial body of scientific and medical literature demonstrates that: (1) children and adolescents experience no particular or unique safety effects from caffeine; (2) dose response is always a function of body weight (mg/kg), not age; and (3) any behavioral or other effects adolescents may experience from caffeine are the same as those experienced by adults.[62] For these reasons, many of the analyses in the scientific literature refer to safe levels of caffeine in terms of mg/kg body weight per day, either in addition to, or instead of, an absolute amount.

Perhaps most notably, FDA has approved caffeine as safe for use in over-the-counter ("OTC") drug products at levels up to 200 mg caffeine every 3 to 4 hours for consumers aged 12 and older.[63] The agency made no distinction between adolescents and adults and concluded that these acute and repeated caffeine consumption levels were safe for both age groups. These levels of caffeine are comparable to, or higher than, those found in mainstream energy drinks. FDA's conclusions in this monograph (which went through a 1975 proposed rule, 1978 tentative final order, and 1988 final rule, all published in the *Federal Register* allowing for public comment) establish that caffeine at the levels present in mainstream energy drinks are safe for adolescents as well as adults.

The following examples from the published, peer-reviewed scientific and medical literature also demonstrate that caffeine metabolism and caffeine effects are dependent on body weight, not age.

As long as two decades ago, Dr. Alan Leviton, of Harvard Medical School and Children's Hospital in Boston, Massachusetts, presented a paper at the Annual Meeting of the American Academy of Pediatrics ("AAP") which documented that after infancy, neither caffeine's absorption, its excretion, nor its half-life are age-dependent and that "[c]affeine, at levels consumed by most children, does not appear to produce adverse effects."[64]

Articles reviewing the relative caffeine amounts in particular bodily fluids or tissues reflected no appreciable differences in children's and adults' caffeine pharmacokinetics.[65] For example, "[a] mean distribution volume of 0.7 L/kg (0.5–0.8 L/kg) was found in newborn infants, adult subjects, or aged subjects. The pharmacokinetics of caffeine in healthy young men aged 20.5 ± 2.0 years and in healthy elderly men aged 71.2 ± 3.9 years showed that Tmax, Cmax, and caffeine bioavailability were essentially identical."[66] Therefore, as in adults, the amounts of caffeine that distribute to a child's or adolescent's tissues appear to be a result of the individual's caffeine intake in relation to his or her weight, rather than of any differences in the rate and extent of children's and adults' caffeine metabolism.

The foregoing discussion confirms there are no scientific grounds for safety concerns about consumption of caffeine or energy drinks simply based upon the consumer's chronological age, as caffeine effects are a function of body weight. For example, the term "teenagers" captures 13- to 19-year-olds, yet a 13-year-old typically weighs considerably less than a 19-year-old. Recent data (2007–2010) reported by the Centers for Disease Control and Prevention (CDC) reveal that for adolescent males, mean weight ranges from 59.2 kg for 13-year-olds to 79.5 kg for 19-year-olds.[67] For adolescent females, mean weight ranges from 56.8 kg for 13-year-olds to 68.0 kg for 19-year-olds.[68] These data reveal that even the youngest teenagers are, on average, not particularly small.

The Authors also make the argument that the safety of caffeine should take into consideration "individuals having varying sensitivities to caffeine" rather than on "healthy" individuals.[69] Mainstream energy drinks are prominently labeled as not recommended for people sensitive to caffeine. This is consistent with the FDA regulatory approach to food ingredients for sensitive subpopulations, which requires disclosure of ingredients rather than limitations on their use simply because a small

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[62] Leviton, A., *Behavioral Correlates Of Caffeine Consumption By Children,* 31 CLIN. PEDIATR. 742, 743, (1992). *See also* Arnaud, *supra* note 21, at 35–36.

[63] *See* 21 C.F.R. § 340.50. FDA's approved OTC monograph for stimulant drug products includes the following directions for use: "Adults and children 12 years of age and over: Oral dosage is 100 to 200 milligrams not more often than every 3 to 4 hours." *Id.* at § 350.50(d). FDA noted that caffeine from other sources should be taken into account. *Id.* at § 350.50(c)(1).

[64] Leviton, *supra* note 62 at 743, 748;*see also* Arnaud *supra* note 21 at 35–36.

[65] Arnaud, *supra* note21, at 36–37.

[66] *Id.* at 45.

[67] Centers for Disease Control and Prevention, *Anthropometric Reference Data For Children And Adults: United States,* 2007–2010, 11 VITAL HEALTH STAT. 1, 7–9 (2012).

[68] *Id.*

[69] *See* Arria Letter, at 3 (stating that caffeine safety standards should not be based on "healthy" individuals because doing so "does not take into consideration that individuals have varying sensitivities to caffeine.").

portion of the population may have a special sensitivity. For example, peanuts and eggs are not deemed harmful even though allergic consumers may have serious or even life-threatening reactions to these ingredients in a food. Rather, FDA requires that the presence of these ingredients be declared on the product label, even if they are only used in a flavoring or otherwise at very low levels.[70] The agency takes the same approach to added sulfiting agents, which also may cause serious harm to those with sulfite sensitivities. These ingredients are not deemed unsafe but rather must be declared where present over 10 ppm, even if used only as incidental additives.[71] Thus, the safety of caffeine is not undermined by the fact that some consumers may be differentially affected by the ingredient. Rather, such sensitivities are managed through labeling, which enables caffeine-sensitive individuals to manage their caffeine consumption. American Beverage Association member companies voluntarily declare the caffeine content from all sources on the label of their energy drinks.

B. Alleged Fatalities and Injuries

The Authors assert, as a preface to a discussion of alleged fatalities and injuries associated with energy drinks, that the absence of a systematic system to ascertain the prevalence of possible adverse events related to energy drinks properly leads to the conclusion that the available data understate the actual occurrence of adverse events. It is just as plausible that the existing data overstate the occurrence of adverse events reasonably attributed to energy drinks. When one considers the fact that nearly 90 percent of North Americans consume caffeine with regularity,[72] the notion that a small number of deaths in people consuming caffeine-containing beverages must have been caused by those beverages is non-defensible on its face. The overwhelming body of knowledge regarding caffeine clearly demonstrates that its use is at best a healthy activity, and at worst neutral. Additionally, specific to energy drinks, there are no data nor is there a plausible suggested mechanism by which any of the commonly utilized additives and additional ingredients would cause any form of toxicity.[73]

The relatively small number of adverse events reported to FDA in connection with energy drinks marketed as supplements do not establish any causal relationship (as FDA acknowledges). Notably, with regard to reports submitted to the FDA through its voluntary Adverse Event Reporting System ("CAERS"), the data from these reports cannot be used to calculate the actual incidence of an adverse event or any causal relationships between the reports and the products due to stated limitations. FDA acknowledges that individual adverse event reports about a particular product and the total number of adverse event reports for that product in CAERS only reflect information as reported, and do not represent any conclusion by FDA about whether the product actually caused the adverse events. CAERS records what the person/entity submitting the report believes to be the cause of the adverse event. Reports to FDA do not necessarily include all relevant data, such as whether an individual also suffered from other medical conditions (such as cardiac disease) or took other supplements or medication at the same time. Reports often do not contain enough detail to properly evaluate an event and may not include accurate or complete contact information for FDA to seek further information about the event, or complainants may choose not to participate in the follow-up investigation. Additionally, duplicate reports may exist in CAERS for the same adverse event because multiple people (such as an injured consumer and a health care provider) may have submitted reports.

In support of their conclusion that energy drinks are the cause of fatalities and injuries, especially in children, the Authors reference several adverse event reports ("AERs") submitted to FDA that cite energy drinks.[74] FDA has repeatedly emphasized that AERs associated with a consumer product are not reports by FDA and do not establish any cause or link between a product and the reported event.[75] In

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[70] *See* 21 U.S.C. § 343(w).

[71] *See* 21 C.F.R. § 101.100(a)(4).

[72] Mitchell, *supra* note 4.

[73] The most current reviews of taurine and glucoronlactone have concluded that they are safe in the amounts commonly encountered in energy drinks.

[74] Arria Letter, at 3–4.

[75] FDA, *Energy "Drinks" And Supplements: Investigations Of Adverse Event Reports* (Nov. 16, 2012), available at *http://www.fda.gov/Food/NewsEvents/ucm328536.htm* (last accessed May 30, 2013). In a statement that accompanied FDA's November 16, 2012 release of AERs pertaining to energy drinks, FDA explained, "[t]he existence of an adverse event report does not necessarily mean that the product identified in the report actually caused the adverse event. FDA assesses the relationship, if any, between a product or ingredient and the reported adverse event."

a recent interview, you stressed that AERs related to energy drinks do not suggest a causal effect: "Frankly, many of the reports, when examined with a real look at the science and the potential for a causal relationship, are not very compelling."[76] FDA has long been aware of the AERs for energy drinks and has stated that the available evidence reveals no new previously unknown risks associated with caffeine consumption.[77] In addition, the Authors concede that FDA did not disclose the ages of the consumers identified in the AERs allegedly associated with energy drinks, so these AERs provide no support for the Authors' argument that energy drinks are particularly harmful to young consumers.

The Authors identify the case of 14-year-old Anais Fournier who died of a cardiac arrhythmia to try and establish a link between energy drinks and the fatality.[78] According to published news reports, Ms. Fournier's medical records establish she had a known, pre-existing heart condition, for which she was taking medication. It is alleged that Ms. Fournier consumed two 24-ounce cans of Monster Energy drink 24 hours apart. She drank the first can without incident. According to the body of scientific and medical literature on normal caffeine metabolism, the caffeine from the first beverage would have completely dissipated by the time she drank the second beverage 24 hours later. While the death of Ms. Fournier is a tragedy, there is simply no scientific or medical basis upon which to conclude that the levels of caffeine in mainstream energy drinks are unsafe when consumed in accordance with the labels of those products.

The Authors also reference an unpublished paper, co-authored by one of the Authors, in support of the conclusion that there has been a greater incidence of accidental ingestion of caffeine from energy drinks than other forms of caffeine in children under 6 years of age.[79] All mainstream energy drinks bear a label statement "not intended/recommended for children." The accidental ingestion of substances to which children should not be exposed provides no basis for concluding that the substances themselves are unsafe for their intended use.

C. Emergency Room Visits

The Authors cite to the oft-mischaracterized report on so-called energy drink-related ER visits (the Drug Abuse Warning Network ("DAWN") report)[80] in an attempt to establish an increase in energy drink-related ER visits. The DAWN report, however, has many limitations, and therefore does not establish a causal relationship between energy drink consumption and ER visits.

For example, the report did not track the energy drink brands consumed or provide estimates of amounts of caffeine consumption. The report is based on ER visits involving use of drugs, where drugs are defined as alcohol, cocaine, heroin, marijuana, pharmaceuticals, nutritional supplements, vitamins, and caffeine products, though DAWN does not track ER visits related to caffeine consumption from coffee. In more than half of the visits in which energy drinks were reportedly consumed by 18-to 25-year olds, the subjects also reported using alcohol and other drugs (and this figure is likely an underestimate given that alcohol and drug use was self-reported and thus likely underreported). The DAWN report did not provide patient outcomes. Where energy drink consumption was reported, the report did not include the amount of energy drink consumed or the amount of other sources of caffeine consumed. The DAWN report, therefore, does not contain sufficient information to determine the nature of patients' complaints, the amount of caffeine consumed from all sources (including coffee, sodas, etc.), or whether there was any causal connection between the complaints and the consumption of energy drinks. Moreover, the report concludes that while ER visits doubled, "visits among adolescents aged 12–17 remained stable."[81]

Moreover, the doubling of energy drink-related emergency room visits reported in the DAWN report must be viewed in context. The 20,000 reported ER visits is a tiny percentage of the total number of ER visits in the time period covered by the DAWN Report (an estimated 136 million). Most of the ER visits did not require further treatment because they were not serious. Finally, during the period covered by the DAWN Report, there were greater increases in ER visits for adverse events re-

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[76] Choi, C. and Jalonick, M., *Monster Hits Back at Lawsuit Over Teenager's Death,* YAHOO! NEWS (Mar. 4, 2013), available at *http://news.yahoo.com/monster-hits-back-lawsuit-over-160836281.html* (last accessed May 30, 2013).

[77] FDA August 2012 letter, *supra* note 29, at 2–3.

[78] Arria Letter, at 3–4.

[79] *Id.* at 4.

[80] *See* Substance and Abuse Mental Health. Servs. Admin., Ctr. for Behavioral Health. Statistics and Quality, *The DAWN Report Update on Emergency Department Visits Involving Energy Drinks* (Jan 10, 2013).

[81] *Id.* at 3.

lated to topical hydrogen peroxide and oral nutritional supplements than for energy drinks.[82]

In contrast to the implications of the DAWN report, the International Society of Sports Nutrition's ("ISSN's") 2013 position statement on energy drinks, which is based on a thorough review of the scientific literature and 224 medical and clinical studies, states, "the rate of adverse events [associated with energy drinks] appears low in the population of consumers" and the current evidence "suggests that consumption of energy drinks and energy shots are safe in healthy populations and similar to ingesting other foods and beverages containing caffeine."[83]

D. Cardiovascular Effects

The Authors discuss several adverse cardiac effects in children associated with "consumption of highly caffeinated energy drinks," such as elevated blood pressure, altered heart rates, and severe cardiac events, yet none of the studies they cite to that reportedly demonstrate adverse cardiac effects of energy drinks were conducted in children. Rather, the bulk of the articles they cite studied caffeine consumption in adults (including young adults) or adolescents. In addition, the Authors concede that adverse cardiac effects related to caffeine are more significant for "those with underlying cardiovascular diseases." Significantly, the Authors do not define the amount of caffeine that makes a "highly caffeinated" energy drink, so it is unclear what level of caffeine would result in the cardiac effects identified by the Authors. Because mainstream energy drinks are not "highly caffeinated" as explained above, the conclusions of the Authors regarding high levels of caffeine and cardiac effects do not apply to them.

It should be noted that in support of their conclusions of caffeine-related adverse cardiac effects, the Authors cite only eight studies, five of which were authored by the Authors, including one paper that is not a published peer-reviewed article. This latter unpublished paper is used by the Authors in support of their conclusion that consumption of energy drinks before or during exercise "might be linked" to an increased risk for myocardial ischemia. The Authors do not provide details of the study, including the type of study or the type of energy drink consumed. Given the absence of study information and the paper's lack of publication, lack of peer review, and its feeble conclusion that caffeine consumption "might be linked" to cardiac effects, the paper is not sufficiently rigorous to support an association between energy drinks and adverse cardiac effects.

In contrast, several substantial reviews of the scientific literature on caffeine and cardiac effects conducted by highly reputable governmental and other authoritative organizations find no scientifically valid relationship between consumption of up to 500 to 600 mg caffeine per day and heart disease or cardiac arrhythmias, nor does the evidence document significant or long-term effects on blood pressure. Literature reviews conducted by scientific experts reach the same conclusion. The following are a sample of published peer-reviewed scientific studies that refute the few studies cited by the Authors, and establish that the bulk of the published scientific literature confirms that caffeine consumption at levels similar to those in mainstream energy drinks does not result in adverse cardiac effects.

In perhaps the best clinical study of its kind, the Framingham Study (a landmark longitudinal study initiated in 1948 to identify cardiovascular risk factors) examined whether there was any relationship between various dietary factors, including caffeine, and the incidence of atrial fibrillation, the most commonly encountered cardiac arrhythmia in clinical practice.[84] The Framingham Study included 4526 individuals who had undergone 9640 clinical examinations and were prospectively followed for four years. A multivariate analysis was performed to account for nine important confounding factors including age, gender, and body-mass index. Individuals were divided into four quartiles based on daily caffeine intake. Compared to individuals with the lowest daily caffeine intake (median 23 mg/day, range 0 to 82 mg/day), the individuals with the highest daily caffeine intake (median 452 mg/day, range 366 to 1203 mg/day) were at no higher risk for atrial fibrillation (hazard ratio: 0.98, 95 percent confidence interval: 0.70—1.39).[85] The authors concluded that consumption of caffeine "was not significantly associated with [atrial fibrillation] risk.[86]

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[82] Pinney Associates Report Prepared for the American Beverage Association, *Emergency Department Visits Involving Energy Drinks and Limitations of the Drug Abuse Warning Network (DAWN),* at 5 (Jul. 25, 2013) (attached).

[83] Campbell, B. *et al., International Society of Sports Nutrition Position Stand: Energy Drinks,* 10 J. INT. SOC. SPORTS NUTR. 1, 10 (2013).

[84] Shen, J. *et al., Dietary Factors and Incident Atrial Fibrillation: the Framingham Heart Study,* 93 AM. J. CLIN. NUTRITION 261, 261 (2011).

[85] *Id.* at 264.

[86] *Id.* at 261, 265.

- The 2001 IOM study of caffeine for the military concluded: "The preponderance of evidence indicates that the use of caffeine by the military would not place personnel at increased risk of cardiovascular disease." [87] That report stated further that, "[d]espite numerous studies attempting to show a relationship between caffeine and serum lipoproteins, blood pressure, cardiac arrhythmias, and risk of coronary heart disease, results have failed to show a consistent adverse effect of ingestion of moderate amounts of caffeine." [88]
- The Organisation for Economic Co-operation and Development ("OECD") reported in 2002: "Though consumption of caffeine (eight cups of regular coffee corresponding to 500 mg caffeine per day) may exhibit acute increases in blood pressure, the long-term effects appear to be minimal. After one to four days of regular consumption a tolerance develops, with blood pressure returning to previous levels." [89]
- The 2002 OECD report also concludes that although studies before the mid-1970s suggested an association between consumption of more than six cups of coffee and coronary heart disease, retrospective and prospective studies conducted since then have consistently failed to demonstrate an association between caffeine and heart disease.[90] It also cites repeated dose toxicity rodent studies of caffeine that showed the average No Observable Adverse Effect Levels ("NOAELs") were 160 mg for each kilogram of body weight of the rat per day, and 170 mg/kg bw/day (highest dose tested) in mice.[91]
- A thorough review of the scientific literature on caffeine consumption examining the supposed causal connection between caffeine and heart disease concludes that the body of relevant scientific literature fails to show that the consumption of caffeine in moderate quantities results in an increased risk of coronary heart disease or arrhythmias. In particular, the review notes that more recent and better-conducted research undermines earlier erroneous assumptions that caffeine consumption has a significant, long-term impact on cardiovascular health.[92]
- A 2011 review concludes that human studies examining the effect of caffeine on cardiovascular endpoints are consistent in finding minimal to no effect of caffeine on coronary artery disease or stroke, and that large human studies generally reveal no association between caffeine and arrhythmias.[93]
- A 2010 article on a prospective study of caffeine consumption by women concluded that increased consumption was not associated with an increased risk of atrial fibrillation.[94] In follow-up observations, participants in the study comprising the highest quintile of caffeine consumption were found to have a similar risk of developing atrial fibrillation as their counterparts in the lowest quintile of caffeine consumption.[95] The researchers discovered that women in the third quintile of caffeine consumption were found to have a lower risk of incident atrial fibrillation, suggesting that the consumption of small to moderate amounts of caffeine may even be beneficial, as it may have a "small but significant protective effect on the occurrence of [atrial fibrillation]." [96]
- A 2011 review of eleven prospective studies was performed to examine the effect of caffeine on arrhythmia. The Danish Diet, Cancer and Health study (47,949 subjects followed for an average of 5.7 years), the Women's Health Study (33,638 women followed for an average of 14.4 years), and some smaller-scale studies in healthy men or men with heart disease or known arrhythmias showed no effect of up to 450 mg/day caffeine on heart rhythm. The review con-

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[87] *IOM Report on Caffeine, supra* note 22, at 59.
[88] *Id.* at 51.
[89] United Nations Environment Programme, Organisation for Economic Co-Operation and Development, *Screening Information Dataset: Cafeine,* available at *http://www.chem.unep.ch/irptc/sids/OECDSIDS/CAFEINE.pdf* last accessed July 11, 2013).
[90] *Id.* at 15.
[91] *Id.* at 24.
[92] Chou, T. and Benowitz, N., *Caffeine And Coffee: Effects On Health And Cardiovascular Disease,* 109 COMP. BIOCHEM. PHYSIOL. 173, 185–186 (1994).
[93] Pelchovitz, D. and Goldberger, J., *Caffeine And Cardiac Arrhythmias: A Review Of The Evidence,* 124 AM. J. MED. 284, 285 (2011).
[94] Conen, D. *et al., Caffeine Consumption And Incident Atrial Fibrillation In Women,* 92 AM. J. CLIN. NUTR. 509, 512 (2010).
[95] *Id.* at 512–13.
[96] *Id.* at 513.

cludes that in most patients (even those with known or suspected arrhythmia), moderate doses of caffeine are well tolerated.[97]

- A meta-analysis of eleven prospective, longitudinal cohort studies shows no increased risk of coronary heart disease associated with consumption of < 6 cups of coffee per day.[98] Based on an average of 133 mg caffeine per cup of coffee, six cups of coffee would result in a dose of 798 mg/day caffeine (approximately 11.4 mg/kg bw/day).
- A prospective study involving 85,747 women over a time course of ten years indicates no association between consumption of 4–5 or > 6 cups of coffee per day (approximately 532–665 mg or 798 mg/day caffeine, respectively) and risk of coronary heart disease in women.[99]
- Recent review articles show that although some case control (retrospective) studies have shown increased risk of myocardial infarction in individuals consuming > 4 cups of coffee/day, the more reliable prospective studies with a follow-up period of 3–44 years have shown that consumption of > 4 cups of coffee/day (approximately 532 mg caffeine) is not associated with increased risk of acute myocardial events and cardiovascular mortality.[100]

E. Seizures

In support of their conclusion that seizures have been "attributed to energy drink consumption," the Authors cite a handful of individual case reports.[101] The Authors do not cite any human clinical studies or animal studies. The case reports cited by the Authors have significant limitations and do not establish any causal link between seizures and consumption of energy drinks. For example, most of the patients had a past history of seizures, had consumed other high caffeine sources such as diet pills, had a past history of stroke, or had neurological or other disorders.[102]

In contrast to the anecdotal reports cited by the Authors, the largest and best study on this subject found that moderate-to-high intake of caffeine was not associated with risk of seizures or epilepsy.[103] For its analysis of caffeine, the Nurses' Health Study followed 105,941 study participants for a total of 1,440,850 person-years of follow up. A multivariate analysis was performed to take into account important potential confounding factors. Compared to individuals with a long-term average caffeine intake of < 200 mg/day, individuals with a long-term average caffeine intake of ≥ 400 mg/day did not have a greater risk of seizures or epilepsy (seizure relative risk: 0.77, 95 percent confidence interval: 0.41–1.47; epilepsy relative risk: 0.97, 95 percent confidence interval: 0.57–1.67). In addition, there was no linear relationship between increasing caffeine intake and seizure or epilepsy risk (seizure relative risk: 0.95, 95 percent confidence interval: 0.80–1.11, p = 0.5; epilepsy relative risk: 0.97, 95 percent confidence interval: 0.85–1.11, p = 0.6).[104]

F. Childhood Obesity

The Authors state that energy drinks "have been shown to contribute to youth obesity due to their high calorie and sugar content[,]" and they cite to an AAP report to conclude that "the consumption of excessive carbohydrate calories from energy drinks increases risk for pediatric overweight."[105] It is common knowledge that "excessive" consumption of calories from any food or beverage without concomitant energy expenditure increases the risk of obesity for any person and that "excessive" consumption of sugary foods should be avoided. Some energy drinks have no sugar or are low in sugar. There are no published data that specifically associate energy drink consumption and obesity.

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[97] Pelchovitz *et al., supra* note 93.

[98] Myers, M. and Basinski, A., *Coffee And Coronary Heart Disease,* 152 ARCH INTERN. MED. 1767 (1992).

[99] Willett, W. *et al., Coffee Consumption And Coronary Heart Disease in Women: A Ten-Year Follow-Up,* 275 JAMA 458 (1996).

[100] Riksen, N., *et al., The Cardiovascular Effects of Methylxanthines,* 200 HANDB. EXP. PHARMACOL. 413 (2011); Sofi, F. *et al., Coffee Consumption And Risk Of Coronary Heart Disease: A Meta-Analysis,* 17 NUTR. METAB. CARDIOVAS. 209 (2007).

[101] *See* Arria Letter, at 5.

[102] *See, e.g.,* Iyadurai, S. and Chung, S., *New-Onset Seizures In Adults: Possible Association With Consumption Of Popular Energy Drinks,* 10 EPILEPSY BEHAV. 504–508 (2007); Trabulo, D.et al., *Caffeinated Energy Drink Intoxication,* 28 BMJ CASE REP. 712–714 (2011).

[103] Dworetzky, B. *et al., A Prospective Study of Smoking, Caffeine, and Alcohol as Risk Factors for Seizures or Epilepsy in Young Adult Women: Data from the Nurses' Health Study II,* 51 EPILEPSIA 198 (2009).

[104] *Id.*

[105] Arria Letter, at 5.

G. Behavioral Effects

The Authors conclude that caffeine consumption is associated with several negative behavioral effects in "youth."[106] The science, however, establishes that caffeine effects on behavior are dependent upon the amount of caffeine a person normally consumes, and are not unique for young consumers. This body of evidence includes the work of Judith L. Rapoport, M.D., Chief, Child Psychiatry Branch, and colleagues at the National Institute of Mental Health, National Institutes of Health. As early as 1984, their review of the literature led to the conclusion that "[t]here is no clear behavioral toxicity from caffeine in normal children. Those self-selecting high caffeine diets generally do not seem to get negative effects."[107] An earlier study by Rapoport even found no negative outcomes when 19 children were given 3 mg/kg or 10 mg/kg caffeine (500 mg for a 110-pound child).[108] Rapoport and another NIH colleague reviewed the literature again in 2002, and described the results of seven studies performed with hyperactive children and eight with normal children.[109] The authors concluded that "[t]he effects of caffeine in children seem to be modest and generally innocuous."[110] Notably, the authors reported that the administration to children habituated to caffeine of 10 mg/kg bw/day produced no significant behavioral effects.[111] The review concludes that in children (as with adults), the amount of caffeine a person normally consumes is very important in determining their behavioral response to caffeine. The behavioral effects that were observed in children not habituated to caffeine were the same as those observed in adults, thereby indicating no unique effects on children. Similar conclusions have been reached by medical researchers studying the effects of caffeine on a wide range of children.[112]

H. Combining Energy Drinks with Alcohol

The authors state that "energy drinks also pose unique dangers when combined with alcohol."[113] FDA has previously acted to remove from the market alcoholic beverages that contained caffeine on the grounds that the use of caffeine in an alcoholic beverage has not been shown to be generally recognized as safe.[114] The fact that some users of a product such as an energy drink may choose to combine it with alcohol is not pertinent to consideration of the legal status of the product or the GRAS status of caffeine. Alcohol is routinely combined by consumers with many liquid refreshments without their regulatory status being questioned. Energy drinks should be treated similarly.[115]

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[106] Arria Letter, at 5.

[107] Rapoport, J. and Kruesi, *M., Behavior And Nutrition: A Mini Review,* 51 J. DENT. CHILD. 451 (1984); *see also* Rapoport, J. *et al., Behavioral Effects Of Caffeine In Children,* 41 ARCH. GEN. PSYCHIATRY 1073 (1984); Zahn, T. and Rapoport, J., *Acute Autonomic Nervous System Effects Of Caffeine In Prepubertal Boys,* 91 PSYCHOPHARMACOLOGY (BERL.) 40 (1987).

[108] Rapoport, J. *et al., Behavioral And Autonomic Effects Of Caffeine In Normal Boys,* 3 DEV. PHARMACOL. THER. 74 (1981).

[109] Castellanos, F. and Rapoport, J., *Effects Of Caffeine On Development And Behavior In Infancy And Childhood: A Review Of The Published Literature,* 40 FOOD CHEM. TOXICOL. 1235 (2002).

[110] *Id.* at 1242.

[111] *Id.* at 1241.

[112] *See, e.g.,* Bernstein, G. *et al., Caffeine Effects On Learning, Performance, And Anxiety In Normal School-Age Children,* 33 J. AM. ACAD. CHILD ADOLESC. PSYCHIATRY 407 (1994); Barr, H. and Streissguth, A., *Caffeine Use During Pregnancy And Child Outcome: A 7-Year Prospective Study,* 13 NEUROTOXICOL. TERATOL. 441 (1991); Baer, R., *Effects Of Caffeine On Classroom Behavior, Sustained Attention, And A Memory Task In Preschool Children,* 20 J. APPL. BEHAV. ANAL. 225 (1987); Elkins, R., *et al., Acute Effects Of Caffeine In Normal Prepubertal Boys,* 138 AM. J. PSYCHIATRY 178 (1981).

[113] Arria Letter, at 5.

[114] FDA Warning Letter to Phusion Projects, Inc. (November 17, 2010), *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/ucm234023.htm (last accessed July 12, 2013).

[115] The Authors assert without qualification that caffeine and alcoholic beverages are harmful. The most comprehensive assessment of this issue was undertaken by the United Kingdom Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment, which was asked by the UK Food Standards Agency "to comment on concerns that caffeine in energy drinks may interact with alcohol in causing adverse behavioural or toxic effects." The Committee concluded that "the current balance of evidence does not support a harmful toxicological or behavioural interaction between caffeine and alcohol." The Committee did acknowledge that its conclusion should be reviewed if "important new evidence emerges." UK Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment, *COT Statement on the Interaction of Caffeine and Alcohol and their Combined Effects on Health and Behaviour* (December 2012), available at *http://cot.food.gov.uk/pdfs/cotstatementcaffalco201204.pdf* (last accessed July 12, 2013).

IV. Conclusion

The totality of the scientific data and information on caffeine in beverages, including the long history of safe use worldwide, demonstrates fully that caffeine at the levels found in mainstream energy drinks is safe under the intended conditions of use. Those extensive data amply support the conclusion that caffeine is generally recognized as safe when used in mainstream energy drinks.

The scientific and medical literature clearly refutes the Authors' ultimate conclusion that there is no general consensus among qualified experts that the addition of caffeine in the amounts used in energy drinks is safe under its conditions of intended use. As plainly and thoroughly set forth above, scientists, medical professionals, and regulators generally agree that caffeine effects are a function of body weight, not age, and that caffeine levels such as those delivered by most energy drinks present no safety issues for children or adults alike. The Arria Letter is founded on speculation that is simply not borne out by the data.

FDA has made clear, and courts have confirmed, that the consensus of expert opinion needed to establish GRAS status does not require unanimity among qualified experts,[116] and that "mere conflict among experts is not enough to preclude a finding of general recognition." [117] The conclusions of the Authors and selective citations in their Letter—including frequent citations to their own, sometimes unpublished, work—do not undermine the GRAS status of caffeine for use in mainstream energy drinks. Rather, the weight of the scientific and medical literature, including that by governmental and other authoritative bodies, establishes the safety and GRAS status of caffeine as used in mainstream energy drinks.

Sincerely yours,

RICHARD H. ADAMSON, PH.D.
For the American Beverage Association.

cc: Michael R. Taylor
Michael M. Landa

Senator BLUMENTHAL. Thank you, Ms. Weiner.

Mr. Coughlin?

STATEMENT OF JAMES R. COUGHLIN, PH.D., PRESIDENT, COUGHLIN & ASSOCIATES

Dr. COUGHLIN. Mr. Chairman, Ranking Member Thune, and members of the Committee, my name is Dr. James R. Coughlin, and I want to——

Senator BLUMENTHAL. Is your microphone on?

Dr. COUGHLIN. I pressed it a couple of times, yes.

Senator BLUMENTHAL. There you go. Thank you.

Dr. COUGHLIN. And I want to thank the Committee for the opportunity to provide testimony today on the safety of energy drinks and caffeine. I am an independent consultant in food toxicology with over 35 years experience in food, nutrition, and chemical safety.

I have over 30 years of experience on health and safety issues surrounding caffeine and caffeine-containing products, and I am currently serving as an invited Planning Committee member for the Workshop on Caffeine Safety being convened next Monday and Tuesday by the Institute of Medicine, at the request of FDA Commissioner Hamburg.

There are three things I would like to address to you today. First, caffeine is naturally present in many plants, such as coffee,

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[116] FDA Proposed Rule, *Substances Generally Recognized as Safe,* 62 Fed. Reg. 18938, 18939 (April 17, 1997) ("Unanimity among experts regarding safety of a substance is not required.") (citing *United States* v. *Articles of Drug * * * 5,906 boxes,* 745 F.2d 105, 119 n. 22 (1st Cir. 1984); *United States* v. *An Article of Drug * * * 4,680 Pails,* 725 F.2d 976, 990 (5th Cir. 1984); *United States* v. *Articles of Food and Drug * * * Coli-Trol 80,* 518 F.2d 743, 745 (5th Cir. 1975); *Promise Toothpaste,* 624 F.Supp. 776, 782 (N.D. Ill. 1985)).

[117] 62 Fed. Reg. at 18939 (citing *Coli-Trol 80, supra* note 116, at 745 (5th Cir. 1975)).

tea, cacao, guarana, and yerba mate, and it is also added to such products as soft drinks, energy drinks, and medications. The common ingredient in energy drinks is caffeine, and the majority of mainstream energy drinks contain comparable amounts of caffeine as the same size cup of coffee and only about half the caffeine content compared to coffeehouse coffees.

Second, health outcomes of caffeine have been extensively researched for decades, and the weight of the clinical and scientific evidence demonstrates that moderate caffeine intake is well tolerated and does not adversely affect general health outcomes. In human clinical studies, caffeine has shown no adverse effects on electrocardiographic parameters, and no consistent evidence shows that caffeine causes or triggers cardiac arrhythmias, even in consumers who have preexisting arrhythmias.

However, caffeine does produce a very small elevation in systolic blood pressure, which lasts only a few hours. But this effect is limited to those people who do not regularly consume caffeine. What is important to understand here is that this effect on blood pressure is minimal or nonexistent after repeated caffeine ingestion.

And many long-term studies of caffeine consumption from various products, including coffee, which is the largest source of caffeine, have shown there is no increased risk for hypertension, arrhythmias, heart attacks, cardiovascular disease, or even all-cause mortality, as been shown in a series of recent studies.

Last, the primary sources of caffeine in the U.S. consumers of all ages are coffee, tea, and soft drinks, not energy drinks. And despite the entry of energy drinks into the marketplace, the mean caffeine intake of the adult population over the age of 22 remains steady with past estimates of about 300 milligrams per day. This was determined in that study you have heard others talk about, the Somogyi FDA study that was published in 2010.

This study, sponsored by FDA, also showed that teens and young adults aged 14 to 21 years of age have an average daily consumption of only about 100 milligrams of caffeine, which is approximately one third the amount of caffeine intake compared to adults in that study. And again, this caffeine intake is primarily from coffee, tea, and soft drinks, not from energy drinks.

In April of this year at the American Society for Nutrition conference, researchers presented a dietary intake survey, which investigated caffeine consumption patterns in the U.S. population collected during 2010 and 2011 among over 37,000 consumers of caffeinated beverages. Results showed that mean daily intake of caffeine from all beverages was about 165 milligrams for all age groups combined.

Caffeine intake was highest in 50- to 64-year-olds, and that level was about 225 milligrams per day. And intakes were lowest in consumers less than 6 years of age, at about 36 milligrams per day. For energy drinks, the study showed that percentage of adolescent users was quite low, less than 10 percent, and that energy drinks were only minor contributors to overall caffeine intake in all age groups.

In summary, I believe that restrictions on the sale or promotion of energy drinks cannot be supported from a clinical or scientific point of view for three main reasons. First, caffeine from main-

stream energy drinks represents only one of many sources of caffeine, and coffee, tea, and soft drinks collectively contribute the majority of caffeine in the U.S. diet.

Second, the caffeine content in mainstream energy drinks is comparable to and often less than what is found in various coffee products. And finally, caffeine intake has been established by decades of careful clinical and scientific research to be safe at levels found in commonly consumed beverages like coffee, tea, soft drinks, and energy drinks.

Thank you for your time, Senator.

[The prepared statement of Dr. Coughlin follows:]

PREPARED STATEMENT OF JAMES R. COUGHLIN, PH.D., PRESIDENT, COUGHLIN & ASSOCIATES

Mr. Chairman and Members of the Committee,

My name is Dr. James R. Coughlin. I am an independent consultant in food toxicology with over 35 years of experience in food, nutrition and chemical safety, toxicology and regulatory affairs. I received my M.S. in Food Science and Technology, Ph.D. in Agricultural and Environmental Chemistry and postdoctoral training in Environmental Toxicology at the University of California, Davis. I have been elected a Fellow of the Institute of Food Technologists and serve as a Food Science Communicator for this organization. In the early 1990s, I served as President of the Paris-based professional society for coffee scientists, the Association for Science and Information on Coffee, and I continue to serve on its Board. I have over 30 years' experience on health and safety issues surrounding coffee, caffeine and other caffeine-containing beverages. I am currently serving as a member of the Planning Committee for the Workshop entitled "Caffeine in Food and Dietary Supplements: Examining Safety," to be held on August 5 and 6, 2013, under the auspices of the Institute of Medicine.

Caffeine is a safe food ingredient widely consumed in a variety of foods, beverages and dietary supplements daily throughout the world. I would like to address today three conclusions concerning caffeine consumption and safety:

(1) Health outcomes of caffeine have been thoroughly studied for many decades, and the best available clinical and scientific evidence does not support the idea that caffeine consumption (and certainly not a singular source of caffeine) is unsafe.

(2) The caffeine content in mainstream energy drinks is equivalent to that contained in an equal amount of coffee, and less than that of coffeehouse coffees.

(3) Coffee, tea and soft drinks are the primary sources of caffeine in U.S. diets, including the diets of children and teens. The most current exposure assessments conducted by the Food and Drug Administration (and others) indicate that caffeine consumption by children and youth is not of safety concern.

Health Outcomes of Caffeine Consumption

Caffeine has been consumed for millennia and is one of the most widely consumed substances in the world. The best available clinical and scientific evidence does not support the view that consumption of energy drinks by minors causes adverse health effects. For most of the symptoms mentioned as justification for limitations on the sale of energy drinks, there is little or no evidence demonstrating causal effects. Several of the reported symptoms are based on anecdotal or confounded reports that have not stood up to more rigorous clinical investigation.

For example, while caffeine does produce a small elevation in systolic blood pressure, this effect is limited clinically to individuals who do not generally consume caffeine, and the slight increase in blood pressure only lasts a few hours; on repeated caffeine ingestion, blood pressure changes are minimal or nonexistent. This phenomenon was clearly demonstrated in the early 1980s. And many long-term studies of caffeine consumption from various products, including coffee, the largest source of caffeine, have demonstrated that there is no increased risk for hypertension in men or women.

Furthermore, caffeine has no adverse effect on electrocardiographic parameters, even in doses up to 400 mg. There is no consistent human epidemiologic evidence that caffeine causes or triggers cardiac arrhythmias, even in patients with pre-existing arrhythmias. This phenomenon was also clearly established in studies conducted

in the late 1980s. Overall, moderate caffeine intake (less than 400 mg per day for healthy adults) has not been demonstrated to adversely affect cardiovascular health, even in consumers prone to hypertension or arrhythmias.

Caffeine-Containing Products

Caffeine can be found in various products that may be classified as foods, dietary supplements or drugs. Caffeine can be present naturally (such as in coffee, tea, cacao, green coffee extract, tea extracts, guarana and yerba mate) or added (such as in some soft drinks, energy drinks or medications). In some products, there may be more than one ingredient that contributes caffeine, such as a coffee beverage that also contains cocoa or an energy drink that contains added caffeine as well as guarana. While caffeine can be present in solid foods (like chocolate), more than 97 percent of the caffeine intake of teenagers and adults and about 95 percent of the intake of the children 2 to 13 come from beverage sources including coffee, tea, sodas, chocolate beverages and energy drinks [FDA, Somogyi, 2010].

In a recent evaluation commissioned by the U.S. FDA [Somogyi, 2010], daily caffeine contributions from all sources (including foods, dietary supplements and drugs) were evaluated. From this report, an eight fluid ounce cup of coffee contains between 55–180 mg caffeine, while the three market leading energy drinks contain between 77 and 120 mg of caffeine per eight fluid ounces. These caffeine concentrations are roughly the same amount, if not less than, what is found in a similar size cup of coffee. The bottom line is that the majority of mainstream energy drinks contain the same or lessor amounts of caffeine than the same size cup of coffee.

Dietary Sources of Caffeine

Caffeine from energy drinks represents a very small contribution to the overall daily exposure of caffeine from all sources, while coffee, tea and soda collectively remain the primary contributors in all age groups, as reported in the Somogyi (2010) study commissioned by FDA to evaluate caffeine exposure from all sources in the U.S. population. What is interesting about this report is that despite the market entry of energy drinks, the mean daily caffeine intake of the adult population older than 22 remained steady with past estimates at 300 mg.

With regard to the younger age groups, this report demonstrated that teens and young adults (14–21 years of age) have an average daily consumption of about 100 mg caffeine, which is approximately one-third the amount of caffeine compared to adults. And importantly for this younger age group, the primary caffeine contributions are from soft drinks, tea and coffee. The author concluded that any significant change in the caffeine intake of the U.S. population would depend on modification of coffee drinking practices, given that all other caffeine sources make only a minor contribution to overall caffeine consumption.

In April of this year, a survey was presented at the American Society for Nutrition annual conference in Boston, which investigated caffeine consumption patterns in the U.S. population. In this survey, conducted in the U.S. by the International Life Sciences Institute, a nationally representative sample of 37,815 consumers of caffeinated beverages (≥ 1 year of age) completed 7-day diaries including type, amount and preparation of each beverage. The data from this study were collected from 2010–2011, and a database was developed to contain brand-specific caffeine values developed from information obtained from several resources, including company websites, commonly used nutrient databases and published literature.

Results showed that 84 percent of the U.S. population consumes at least one caffeinated beverage per day, and that mean daily caffeine intake from all beverages was 165±1 mg for all ages combined. Caffeine intake was highest in the 50–64 year age group (226±2 mg/day), and intakes were lowest in consumers less than 6 years of age (36±3 mg/day). The 90th percentile caffeine intake was 379 mg/day for all ages combined.

Coffee, as was also shown in the FDA-commissioned study, was the primary contributor to caffeine intakes in all age groups, but was a larger contributor in adults (>18 years of age). Carbonated soft drinks and tea were also important caffeine sources, particularly in the younger age groups. Importantly, the percentage of energy drink users across all age groups was low (≤10 percent), and the contribution of energy drinks to total caffeine intake was 2 percent in the total population and 7 percent or less in all age groups.

Conclusions

In summary, restrictions on the sale or promotion of energy drinks cannot be supported from a clinical or scientific point of view for three main reasons. First, caffeine from energy drinks represents only one of many sources of caffeine, and coffee, tea and soda collectively contribute the majority of dietary caffeine in the U.S. diet. Second, the caffeine content in mainstream energy drinks is comparable to and

sometimes less than that found in various coffee products. And finally, caffeine has been established by decades of careful clinical and scientific research to be safe at the levels found in commonly consumed beverages like coffee, tea and energy drinks. The best available clinical and scientific evidence supports the conclusion that the levels of caffeine currently consumed in the U.S. are safe.

Senator BLUMENTHAL. Thank you, Mr. Coughlin.

I want to begin my questions, and then if Ranking Member Thune returns, we will go to him and then Senator Markey.

And thank you all for being here. Again, I appreciate your taking the time, and we have contrasting points of view here. I want to reiterate my thanks to Senator Rockefeller for giving us this opportunity to have a hearing and really the beginning, I think, not the end, of what has to be an open and honest discussion.

And you know, I must say that I find the denials of marketing to children to be difficult to accept. And I know that, Mr. Sacks, you have said that the company, and I am quoting, "does not market Monster to children and has never done so." And that claim has been made by the industry repeatedly, but the facts and common sense show that the marketing and promotions and pitches to kids have been open and blatant and relentless.

And I just want to cite here and ask you about the "Monster Army." And on your own website, you say, "The Monster Army is Monster Energy's athlete development program that supports athletes ages 13 to 21 in moto, bike, skate, surf, snow, and wake. Athletes from all over the world are evaluated and invited into the program to represent the Monster Energy brand."

And then on the Monster Army Web page, the program is explained with the following statement. "Most companies spend their money on ad agencies, TV commercials, radio spots, and billboards to try and tell you how good their products are. At Monster, we choose to support the scene and our athletes. Every athlete in the Monster Army is an important piece of the Monster Energy brand."

Recently, Monster revised its age requirements for sponsorships to be athletes 13 to 21. But in the past, you have sponsored athletes as young as 6 years old, and I have displayed an example here of a 6-year-old reserve and an 11-year-old major in the Monster Army. I have a hard time accepting your contention that Monster has never marketed to children. That just defies what I have seen and heard and what most people in America have seen and heard.

Mr. SACKS. Mr. Chairman, I think the Monster Army program is exactly that. It is an athlete development program. The children that you have shown on the boards, I don't have personal knowledge of. But they were there with the permissions of their parents.

This we regard as an opportunity to allow athletes to develop so that, ultimately, as a feeder system—there is no organized feeder system for action sports. And in this way, we do work with athletes until they can develop and ultimately turn professional.

We have over 90 athletes that have gone through the Monster athlete system and have turned professional on our riding. Our current world champion in Motocross, Ryan Villopoto, started in the Monster Army. So we are encouraging the development of athletes. We are developing our own team of athletes.

Ultimately, when they really get exposure is when they go professional, when they turn older, when they get older. We don't—the amount that we spend on this program, Senator, is very—very little in relation to our overall marketing budget. So we do still say that we don't market to children. This is a development program.

Does it reach young children? Yes, it does, with their parents' permission. As you indicated, we did change the age limit to limit this to 13 and above, and we received a lot of irate parents who value the program as being an opportunity for their kids to participate in sports and develop.

Senator BLUMENTHAL. You are saying that these 6- and 7- and 10- and 11-year-olds are part of an athlete development program. But the marketing is to 6- and 10- and 11-year-olds. And I ask you whether, in fact, this marketing is not intended to reach those young people?

Mr. SACKS. I don't believe it is intended to reach them in that sense. If you look at the website, over the whole history of our website, less than 0.5 percent were under the age of 13. It is a handful compared to our marketing, our consumer base. It is simply not our focus.

But ultimately, it is an important development program that we use.

Senator BLUMENTHAL. Let me ask you, if a tobacco company—and the analogy has been drawn to tobacco because tobacco, in the same way, had a feeder program. They didn't use those words, but they marketed to 6- and 7- and 11-year-olds because they want to develop smokers.

If tobacco companies put a cigarette in the mouth or hand of one of those children, their denials of marketing to children would be laughed out of this building. I am hard put to accept that whatever the percentage in terms of your investment in that marketing, that it was unintended to reach young people that age.

Mr. SACKS. I can only repeat that our demographic is young adults. We regard this as a part of the way we develop the brand platform, which is a sporting platform, and to develop young athletes as they go through and eventually progress to the levels where they do become professionals and they do start competing in the major events.

Senator BLUMENTHAL. Well, let me shift to a different area. You are aware that the American Beverage Association of Monster, Rockstar, and Red Bull, and you are all members, includes in its guidelines, and I am quoting here. "Energy drink products should not promote energy drinks for mixing with alcohol, nor should they market energy drinks to counter the effects of alcohol consumption." Should not promote energy drinks for mixing with alcohol and not market it to counter the effects of alcohol consumption.

Now Monster Energy produces a product that is called "Cuba Lima," which is compared on its website to a very popular alcoholic beverage, "Cuba Libre." And we are going to put up here these ads and promotions.

On the website, there appears the following, and you probably can't read it here. But it is there in the smaller print, "As legend has it, a buzzed-up Cuban hears his country has been liberated, holds up his drink, yells "Cuba libre!" And the famous cocktail is

born. As big fans of the drink, we decided to make our own, substituting our tried and true energy blend for the alcohol and adding a squeeze of sweet lime. We know it sounds crazy, but don't knock it until you try it. You are going to love it because it is a new kind of buzz."

Doesn't that marketing violate the American Beverage Association standards?

Mr. SACKS. No, quite the opposite. It is actually intended to be a nonalcoholic version of the drink. It is to appeal to our consumer graphic, which is adults, and it is simply a nonalcoholic version.

The story lines we generally use at Monster are intended to be light-hearted, really puffery, a way of communicating with our consumers. But this is intended to be not to encourage consumption or mixing. On the contrary, it is intended to substitute for it, and that is how we see that.

Senator BLUMENTHAL. So your contention is that this marketing tactic is a way of telling young people don't drink?

Mr. SACKS. Absolutely. We do not encourage the marketing, particularly of that particular drink, you know, for mixing at all.

Senator BLUMENTHAL. So the glorification of Cuba Libre is a message that young people should stay away from alcohol?

Mr. SACKS. Not a message to young people. It is a message to our consumers, including adults, that this is how it was born. We are trying to just tell people how we came up with the drink, how to do something that is fun and different. It is very light-hearted. That is the intention.

Senator BLUMENTHAL. Let me call your attention to the Nitrous line. Monster Nitrous line was renamed the Anti-Gravity line, is displayed here, and I am quoting, "We supercharged our Monster Energy base, then injected it with nitrous oxide for a unique texture and buzz that is bigger than ever. This is no "whip-it,"—in quotes, whip-it—but it will whip you good."

Now you know the phrase "whip-it" is a slang term for a practice popular among teenagers of using a pressurized canister, such as a whipped cream canister, to get high by inhaling the nitrous oxide pressurizing the can. Like a lot of drugs, whip-its are not really good for you, and they can cause hearing loss, liver and kidney damage, limb spasms, central nervous system harm, other kinds of physical and emotional damage.

Is that in any way related to the use of nitrous oxide or other drugs?

Mr. SACKS. No, again, it is just a light-hearted way of just communicating. That's our marketing team, they are probably more familiar with the term than I am.

But it was just intended to be light-hearted. I just don't believe that is encouraging anything. It is just saying this is no whip-it, it'll whip—it will give you a good energy boost. That is all we are trying to say now in talking the language of our consumers.

Again, it is light-hearted. It is not intended to mean anything other than that.

Senator BLUMENTHAL. My time has expired on this round of questioning. We will have at least one more round, and I want to yield to Ranking Member Thune.

Senator THUNE. Thank you, Mr. Chairman.

Mr. Coughlin, critics of the energy drink industry frequently cite a report by the Substance and Mental Health Services Administration, or SAMHSA, stating that the number of American emergency hospital visits involving energy drinks doubled between 2007 and 2011 to more than 20,000. And I am wondering how you interpret those findings?

Dr. COUGHLIN. Senator, I am familiar with that report. It has been mentioned several times today. I don't believe that report, because it is only a snapshot of emergency room visits, really gets at any causal relationships between energy drinks or the ingredients in energy drinks and the reason that the individual showed up at the emergency room. There are many limitations in the report.

When someone comes to the ER, there is no indication of how much of any specific product they drank, including other products that may contain caffeine. The report points out that over half of the young adults who reported to—for whatever reason they needed to report to the ER actually admitted to the use of alcohol and drugs of abuse, and I actually think they probably underreported that when they arrived at the emergency room.

And so, this snapshot, this 20,000 during this period from 2007 to 2011, there were actually 136 million visits to the ERs by individuals. And so, a 20,000—N is equal to 20,000, we call it in the clinical world, is not a large number, and I think there are limitations in this data that just never seem to come out.

Senator THUNE. Let me direct this to the folks on the panel representing the various energy drinks. The drink ingredients often include things other than caffeine, which has been pointed out, such as guarana, taurine, and vitamins. How do you test your products and the formulation of the ingredients in your products to ensure that they are safe and that there are no negative health effects from this combination of ingredients?

Ms. WEINER. I will take that question. Am I on? OK.

Yes, thank you, Senator Thune.

Rockstar has an independent expert panel that reviews our key ingredients and use levels in Rockstar energy drink products, all the beverages, and they conclude unanimously that the intended use of the ingredients after investigating—and these are using peer-reviewed scientific papers as a basis of their opinion. And they investigate them and they say that the use of these key ingredients alone or in combination in Rockstar's beverages is generally recognized as safe, based on scientific procedures established by the United States Food and Drug Administration.

So we rely upon our scientists to vet our products and make sure that they are safe. As we said, safety is our number-one concern, consumer safety.

Senator THUNE. Any of the others care to comment? Ms. Taylor?

Ms. TAYLOR. Yes, Senator. I think it bears—it is worth mentioning that there is no source of any other stimulant or no source of caffeine in Red Bull other than the caffeine itself. So I think that bears mentioning.

And then Red Bull, with a long history, of course, I would cite the European Food Safety Authority, which is the rough equivalent of the United States FDA, completed a 10-year review of the ingre-

dients of Red Bull and concluded that there was no synergistic effect amongst the ingredients in Red Bull.

Senator THUNE. When you develop and implement your marketing campaigns, there has been a lot of discussion about who you are targeting with that advertising. How do you ensure that energy drinks aren't marketed to children?

Again, any of the drink reps.

Mr. SACKS. I will take the question. I think that we look at the demographics and the top sport to try and portray the personality and image that we are trying to establish for the brand. We do so, and our principal platform where we spend probably well over half of our funds are on motor sports.

But like any sport, whether it be basketball, baseball, football, the audience is a very wide audience, and the audience is going to comprise children. The audience is going to comprise teenagers, and the audience is going to comprise older people than our demographic. But we look at the demographic and we generally try and focus on the sports that are most appropriate for our target demographic. So you can't exclude other demographics.

And if you look at some of the sports that we do sponsor, we get some of the statistics, one of the sports that people sometimes cite as saying it is an action sport. Does that in any way skew younger?

The average age of the viewers of the X Games, which is the premier platform for action sports, is in the 30s. So, yes, you will have younger teenagers at that event or watching the event. But that is how you generally try and do it. You simply can't have a magical wand and cutoff anywhere, whether it is on—whether it is actually viewing or what is on TV.

And so, we just try and get to sports that really represent our brand lifestyle. As I indicated in my remarks, I think it would be very difficult for us and we would alienate adults and older teens, young adults, if we were to try and target our marketing and focus it on events that were primarily attractive to young teens or children. It just wouldn't work.

But there is just no way you can exclude them. Nor do any of the beer companies or alcohol companies exclude them when they advertise at normal sporting events.

Senator THUNE. One of the issues that surfaced with regard to energy drinks has been their classification either as nutritional supplements or traditional beverages. It is my understanding that while Red Bull has always been classified as a traditional beverage, Monster and Rockstar have recently switched from marketing their products as nutritional supplements to traditional beverages.

Ms. WEINER. That is correct.

Senator THUNE. And I am wondering why that change was made, and what are the impacts of the change, both with regard to the companies and to the consumers?

Ms. WEINER. I can answer that for Rockstar, of course. In the fall of 2012—oh, thank you.

In the fall of 2012, Rockstar, the company, for competitive reasons, decided it was preferable to include nutrition fact panels, consistent with FDA views and product reformulation. Rockstar energy drink has always, since 2005, displayed the caffeine content

per serving and per container on all of its beverages and will continue to do so.

Rockstar will continue to comply with the adverse events reporting, even though not required to do so. Rockstar is volunteering to do that with the nutrition panel going forward. Rockstar is very proud of its record in food safety.

Thank you.

Senator THUNE. Mr. Sacks, do you want to comment on that distinction?

Mr. SACKS. Yes, thank you, Senator Thune.

When we originally launched Monster in 2002, we got advice from our legal, regulatory attorneys. And they told us that our products qualified to be labeled both as a supplement because they contained supplements that supplement the diet and also as a conventional food because the ingredients we believed were GRAS, generally accepted as safe.

Based on their advice, we elected to label the products as dietary supplements. We included a warning label right from the outset, as I indicated. And we continue to do so. At that time, most of the other energy drinks were also labeled as supplements.

Over the years and in the more recent years, many of the energy drinks' labels have changed from the major beverage companies as well. And earlier, toward the end of last year, early this year, there started to be a lot being written in the press about the fact or the suggestion that Monster was being marketed as a supplement in order to somehow avoid the regulations as a food.

We felt that that was unfounded. There was just no basis for it because we felt our product was equally qualified as a food. And as the industry tended to and other competitors tended to move to be a food, we felt there was just no purpose in staying a supplement, and we then notified the FDA, and we made the change. The change didn't result in any change in our formulations.

We do—we had a different type of warning label about consumption on our supplements. We then elected to fall in line again with the industry. We provide the caffeine content of our product per serving and per can and also continue to have the warning label that our product should be consumed responsibly and is not recommended for children.

So it really has been a non-event for us from that point of view.

Senator THUNE. Mr. Chairman, my time has expired. Thank you.

Senator BLUMENTHAL. Thank you.

Senator Markey?

Senator MARKEY. Thank you, Senator.

Ms. Weiner, your company has indicated in testimony and previous letters to Senator Blumenthal and Senator Durbin and to me that all of your marketing practices are intended to target individuals aged 18 to 35 and that you follow American Beverage Association guidelines to not promote them to children. So my question to you is does this individual, who is shown in one of your Facebook albums, appear to be in your target marketing demographic?

Ms. WEINER. Are we looking at the child that is——

Senator MARKEY. Yes, the child.

Ms. WEINER.—holding a skateboard and an energy drink?

Senator MARKEY. That is correct. That is not in your demographic that you are talking——

Ms. WEINER. No, he is clearly under 12 years old. That is correct.

Senator MARKEY. So this child is wearing and holding Rockstar-branded paraphernalia and a can of Rockstar energy drink at what appears to be a company-promoted event. And your company has posted this on its Facebook page with the tag line "A Rockstar fan for life."

So I see no reason why we should not conclude that your company is intentionally promoting its products to children like this in order to make them consumers for life, just like this Facebook promotion says. You know, hook them early. Keep them for life. Be a Rockstar for life. Huh? Makes a lot of sense to me as a marketing promotion.

Why would we not think that this is not part of the corporate promotion plan that you have?

Ms. WEINER. Well, Senator, first of all, this is a single instance amongst a huge amount of marketing campaigns. But I will address this single photograph in the following manner.

One, it is highly likely that that child is accompanied by his parents. In today's society, it is hard to imagine anyone permitting a child to—with the degree of danger associated with children being alone, it is difficult to imagine that any child under the age of 12 is wandering around alone at an event.

Senator MARKEY. Well, we——

Ms. WEINER. So presumably——

Senator MARKEY. I will tell you what we will do for you. This is just one of many examples which we found, and we will give all of the examples to you.

Ms. WEINER. I would like to look at—thank you.

Senator MARKEY. So that you can see this not as an isolated instance, but as a pattern of conduct in terms of using children as a way of making these kids think of themselves as "rockstars for life."

Now, and Mr. Sacks, in your testimony and in your past correspondence with myself and Senator Blumenthal and Senator Durbin, your company as well says that it does not market to children and stated that Monster Energy complies with voluntary American Beverage Association guidelines that instruct that energy drink companies should not market to children.

So I was listening to your conversation with Senator Blumenthal and making reference back to smoking and how the smoking—the tobacco industry actually has a product problem, and it is this. That as a couple of thousand people die each day from having smoked, the tobacco industry has to find new customers.

And it turns out that replacing those customers is not easy since, statistically, if someone reaches the age of 19 and has not started to smoke yet that they are highly unlikely to ever smoke. So that is a real marketing problem for an industry, huh?

Your old customers are dying, and your new ones can't really be influenced after age 19 or 20 to start up. And so, obviously, getting younger kids to start has always traditionally been part of the marketing strategy.

So my question is, obviously, based upon what appears to be kind of a pattern where we are listening to arguments made about how hard it is to segment out these younger kids, that they are kind of part of a larger population. But yet we know that that is where a big part of all these problems are.

So I guess my first question to you is that many of your products are distributed by third parties. Are your distributors contractually bound to prohibit promoting or sampling of your products to children?

Mr. SACKS. Senator, they are not—I do not believe that they are contractually bound to do so. They are independent companies, and they follow their own rules. But they do, I believe, take into account our guidelines, and we have been——

Senator MARKEY. You think that they take into account your guidelines? Do they—do you use your power as the source for this product which they sell to ensure that they follow the guidelines?

Mr. SACKS. I think that we do. We recently took steps to write to them and to communicate to them through our sales team——

Senator MARKEY. Well, what is it that you tell them that you don't want them to do with your product?

Mr. SACKS. We have asked them to, first, not market to events or at local events that are——

Senator MARKEY. What is the penalty that they pay if they do market to kids?

Mr. SACKS. Ultimately, there is a penalty that——

Senator MARKEY. Would your company withdraw distribution of your product by these companies if they did market to children?

Mr. SACKS. Well, we would have to look at it at the time and look at what our contractual rights would be. We have commitments. We have contracts.

Senator MARKEY. Well, you can create your own contractual rights. So would you, if these third parties did distribute to children, withdraw the product from them? You could put that right in your contract. Would you be willing to do that?

Mr. SACKS. I don't think we could just put it in a contract. These are contracts that exist and are long-term contracts. We can't unilaterally change a contract.

Senator MARKEY. How about any new contracts? Would you agree for any new contracts that they would not be allowed to be marketed to children?

Mr. SACKS. I think that in new contracts, we will look at discussing and putting in a clause going forward that we would have the right to do so.

Senator MARKEY. Do you actually know if these third parties market to children or not? Do you have that as information inside of your company?

Mr. SACKS. There were one or two instances that we found that they had done so, and we took steps to terminate the marketing and advised them that they should not follow that marketing practice. And so——

Senator MARKEY. So you are saying you do know what is going on with these third-party distributors, and you are monitoring their activity to make sure they do not market your product to juveniles?

Mr. SACKS. We are far more aware of it now, and I think that wasn't done as strictly in the past. We are now looking at monitoring it and trying to monitor and work with our distributors.

Senator MARKEY. Yes. And what is—again, the key here is what is the penalty which a distributor would have because, obviously, they have a lower level of concern about your corporate reputation. They are a step removed.

So what would be the penalty? What would be the price they would have to pay? Do you have any thoughts about that? Or is it just going to be a verbal warning to all of the distributors?

Mr. SACKS. I think it is a written warning, and I think that it would be—the way we could deal with it would be to look at not working with them to provide them with funds for marketing and contributions for marketing, which is something you do all the time. So I think it would fall short of contractual issues.

Senator MARKEY. Would you agree to require them not to market to children contractually as part of receiving access to your product for those companies to distribute?

Mr. SACKS. I would be favorably inclined to see what we could do legally. I don't know what we can do legally because we have existing contracts with hundreds of distributors.

Senator MARKEY. No, I am talking about new contracts, not old ones. New contracts.

Mr. SACKS. Yes. Yes, sir.

Senator MARKEY. Would you be willing to include in those contracts requirements that there not be distribution?

Mr. SACKS. Yes, I would.

Senator MARKEY. Would you, Ms. Taylor? Yes?

Ms. TAYLOR. Our distributors do limited marketing on our behalf in accordance with our standards. We do the majority of our marketing and sampling directly through our field source.

Senator MARKEY. OK. Ms. Weiner?

Ms. WEINER. In all future contracts going forward, yes, that would seem to be an agreeable clause.

Senator MARKEY. Thank you.

Thank you, Mr. Chairman.

Senator BLUMENTHAL. Thank you, Senator Markey.

Let me ask Mr. Sacks and Ms. Weiner, would you be willing to make the same commitments that Red Bull has made, most especially the commitment not to encourage or condone excessive or rapid consumption of energy drinks? That is among the commitments that Red Bull has made. Would you be willing to make the same commitment?

Ms. WEINER. If you would permit us to study the commitments? We have just heard them for the first time today.

Senator BLUMENTHAL. Well, let me ask that one in particular. The commitment not to encourage or condone excessive or rapid consumption of energy drinks.

Ms. WEINER. I don't believe we do that currently. So I would be——

Senator BLUMENTHAL. So you would be willing to make that commitment?

Ms. WEINER. I believe it sounds like something that—we don't encourage rapid consumption as it is. So it is nothing—it would not

represent a change for us. So, consequently, I don't see that it would be an issue.

Senator BLUMENTHAL. Not an issue. So you do commit to it?

Ms. WEINER. It does seem that it would be something that we could do.

Senator BLUMENTHAL. Mr. Sacks?

Mr. SACKS. Yes, Senator. We had, again, phrases which we looked at as being light-hearted and puffery. But we have taken them off our—and removed them from our cans, and we would be prepared to make that commitment.

Senator BLUMENTHAL. And would you each be willing to make the commitment that you will not say that larger sizes, more caffeine, or higher concentrations of caffeine are better or have a better, stronger effect? I am quoting again from the letter.

Ms. Weiner?

Ms. WEINER. That would seem, on the face of it, to be a reasonable commitment, yes.

Senator BLUMENTHAL. Mr. Sacks?

Mr. SACKS. I believe it would be reasonable, but I would need to actually look at it in context and look at our marketing because it doesn't necessarily follow that a higher concentration is necessarily not better. It all depends on the ultimate level of caffeine that is consumed.

But I would be prepared to review it, to look at it and see what we could come to on that request.

Senator BLUMENTHAL. Would you all commit that you will not use 6- or 11-year olds or, in other words, anyone under 18 in any of your marketing or promotions? Mr. Sacks?

Mr. SACKS. I believe we will commit to use—not use anybody who is a child. I don't believe we would commit to not use anybody under 18. We believe our product is safe for teenagers, and there is no reason why teenagers should not be part of being able to consume the brand or to be athletes that perform.

Senator BLUMENTHAL. What about 6-year-olds and 11-year-olds?

Mr. SACKS. I said, Senator, that I would—we would be prepared to commit to children. We regard children as 12 and under.

Senator BLUMENTHAL. Ms. Weiner?

Ms. WEINER. Rockstar always has been committed to "not recommended for children." And by that, we mean under 12. According to our independent expert panel that has reviewed the key ingredient use levels——

Senator BLUMENTHAL. Well, let me—let me just ask you, isn't an ad——

Ms. WEINER.—they have determined——

Senator BLUMENTHAL.—doesn't an ad that uses a 13-year-old appeal to a 6- and 7-year-old?

Ms. WEINER. I don't agree with that. But number one, I——

Senator BLUMENTHAL. You don't?

Ms. WEINER. No, I don't.

Senator BLUMENTHAL. Mr. Sacks?

Mr. SACKS. No, I don't. Most of our teenage——

Senator BLUMENTHAL. Let me ask you, Ms. Taylor.

Ms. TAYLOR. I don't think I could say outright what does or doesn't appeal to a child. But I will say very firmly that Red Bull has not and will not ever market to children.

We do believe that the consumption of energy drinks by teens is safe. But again, as a matter of strategy and differentiation, we have chosen 18 to 34 as our target demographic and that to which we are committed. And I think that is evident in our business plans, particularly over the last 2 years.

Senator BLUMENTHAL. Well, I want to say that I welcome the steps that you have taken, and I don't have time to go through each of them, asking Mr. Sacks and Ms. Weiner whether they would be willing to make that—you have to some, not to others. I would ask you, as part of your written response to some of the questions I am going to be putting in the record, that you indicate whether you are willing to commit to the same conditions and restrictions that Red Bull has adopted in its communication to this committee.

And I recognize that you haven't had time to study them. Yes, Ms. Weiner?

Ms. WEINER. May I make a statement? Red Bull has commented that they manufacture and produce their product in 8-ounce and 12-ounce cans. Rockstar and others market their drinks in 16-ounce cans predominantly. We have two servings per can, two 8-ounce servings per can.

The caffeine in Rockstar is between 160 and 240 milligrams per container. I want to make that very clear that a coffeehouse coffee contains 330 milligrams of caffeine in a 16-ounce container. And at that same coffeehouse, you can go up to the counter and buy an espresso shot that contains 75 milligrams an ounce of caffeine and throw it into that coffee, and you could wind up in that 16-ounce cup with over 1,000 milligrams of coffee.

And teenagers frequent these coffeehouses every day of the week. They are some of the biggest consumers of these coffees at these coffeehouses. And it is very important for this committee to understand that the largest—according to the Somogyi report, the largest intake of caffeine by teenagers is not coming from energy drinks, and we feel a bit—you know, we have been unfairly accused of being—you know, we are being demonized in a sense here.

We feel that if you are going to look at caffeine, you must, in all fairness to all of us, look at caffeine that is coming to these teenagers from coffee. And then, further to the point, our expert panel has reviewed the consumption patterns from the Somogyi report and other data that the FDA has commissioned, and they have—according to peer-reviewed articles, they have researched the literature. In their expert opinion, they have no problem with persons 13 to 17 consuming the caffeine that is contained in our products.

Senator BLUMENTHAL. Well, you know this is an area where you know the old saying, "A picture is worth a thousand words?" I think we have seen pictures here which we would never see a coffee manufacturer, a coffee retailer, coffee meaning the standard—and I don't want to single out brands here. But we don't see coffee drinkers on skateboards or in the types of ads that we have seen today.

So there is somewhat—we have heard this argument ad nauseam, if I may? And I mean no disrespect.

Ms. WEINER. I understand. May I say one more thing?

Senator BLUMENTHAL. But we have heard that argument repeatedly. I am simply asking that you go through the Red Bull letter, and you respond in writing. I don't want to press you here, which I think would be unfair if you haven't had a chance to read the letter.

But going to Ms. Taylor, would Red Bull be willing to make a commitment that it would place a label on its product stating "not recommended for consumers under 18 years old"?

Ms. TAYLOR. Senator, we would not feel that would be an appropriate move. We do have a label that reads that it is not appropriate for children, and we stand by that. The reason——

Senator BLUMENTHAL. Which is why I am asking about 18-year-olds.

Ms. TAYLOR. Yes. The reason that we wouldn't label our product as not appropriate for those under 18 is the following. First, Red Bull is safe for teens and for teen consumption. So we believe it would send the wrong message, and we think that is important.

The other reason is that we believe that we have the advantage of good timing here in the sense that the FDA is getting ready to undertake a study of the safety of caffeine. And if, differently from in the past, the FDA were to conclude that there was an issue for the consumption of caffeine by teens and if the industry of caffeine-producing beverages would, therefore, agree to limit the sale of their products to those under 18, then we would be a part of that larger solution.

So I suppose that would be a conditional response.

Senator BLUMENTHAL. Thank you.

I want to give Dr. Schneider and Dr. Harris an opportunity to respond to what you have heard so far. Dr. Schneider? Sorry.

Dr. SCHNEIDER. Our message in looking—in looking at these drinks, the big issue is that it is not just the caffeine that we are looking at. It is caffeine and other substances in these drinks. It is the portion size. We know that it impacts on basically every system within a child's body.

And as an adolescent medicine physician, I would be hard pressed to be OK with 12 versus a 13 versus a 14. My favorite picture is always those eighth grade boys. They are 14 years old. Some of them are—look like they are 6, and some of them look like grown men with beards. They are not all the same.

Adolescents are growing. Their bodies are changing. Their minds are changing. And the effect of caffeine on this group is not—it is not addressed in a lot of the adult studies. There are many studies on adults. The studies that really look at children, the studies that look at adolescents are far fewer, and there are many more concerns because their bodies have other tasks to perform.

And as part of the AAP looking at the health and welfare of children, which includes adolescents as part of that, I think that it is really important to understand that these drinks contain caffeine. They contain other substances that really potentiate the caffeine. So even if the caffeine is labeled as X amount of milligrams of caffeine, what do the other components ultimately do to that number?

And it is why, I think, we look at it in a little bit of a different way.

The other part of it is that all caffeinated substances are addictive, and I do not really believe that any of us—I mean, we can all deal with this to a certain degree as adults. But I don't think that any of us really want to do anything addictive in terms of children.

The one thing I would like to put in is that there are kids who have a whole host or variety of medical issues. There is a substantial proportion of the population at this point that has been growing that has things like attention deficit disorder, where they may already be on stimulants so that they focus in school.

These kids are actually at a substantially higher risk of now taking one stimulant that they have been medically prescribed in a dosage that we know what they are getting. It is very clear. They can—there is a prescription, and it is written with a certain number of milligrams in it. But we also know that those kids can then use other substances, other stimulants on top of it, and there is really concern about the health effects for that particular group, which is actually also a growing group.

So I think, again, the take-home messages from my perspective are that these drinks have more than caffeine in them in general that are really part of the real concern. We don't want kids using anything that is addictive, that could possibly cause them to die.

We know that parents, I think, really, really mean well. But the parents need education. I have had more than one opportunity where parents are giving their kids energy drinks. I have been on ABC because parents of 2- to 4-year-olds before they went out on stage were giving their kids energy drinks.

I don't think these parents were doing anything that they thought was wrong. I really believe that these parents thought that they were just giving their kids more energy.

Caffeine and caffeine toxicity gets looked at in a milligram per kilogram. If you are little, you weigh less. You can be 14 years old, and at 14, you can weigh 200 pounds. You can be 14, and you can weigh 50 pounds. So, to me, distinguishing between 12, 13, 14 is not so clear.

And I think that education of not just—I mean, it is not just labeling. It is education. It is having a label that actually for parents would say, you know, something—something is important here that I need to take a look at this label and understand that, gee, my teenager, my child, maybe they shouldn't be drinking it. So I think, number one, making labels clearer in terms of what the content is.

Number two, I think really just making sure that the marketing, that there is a little bit of a different strategy. And then my hope is that if people get more and more educated, and again, we need more research to look at further impact, which I think that we are all 100 percent in agreement on this panel that that is something that we want to see.

But again, looking to say that these drinks, from the view of the American Academy of Pediatrics, should never be consumed by children, and not just children, but by children and adolescents, which is what the AAP represents.

Senator BLUMENTHAL. Thank you.

Dr. Harris?

Dr. HARRIS. I would just like to make a few comments on some of the discussion about marketing. One is that if you take Marketing 101, you will learn that marketing is aspirational. So if you are showing an 18-year-old in an ad, you are appealing to a 15 -or 16-year-old who wants to be grown up.

And so, I think that that is one thing to recognize that if they are including 16-year-olds in their ads, they really are appealing to younger kids.

Another thing is that we have heard a lot about, well, they can't control who sees their marketing. Well, that simply isn't true. For example, Monster's website, it over indexes for teens. What that means is that teens are more likely to visit that website than the population in general. So it is appealing to teens, and we can see that with the data that I am sure they also have available.

I would also like to say that there are other ways to not market to teens. For example, Facebook, you could block anyone under 18 being able to access your Facebook pages. That is what alcohol companies do. That is even what Cap'n Crunch does, and it says it doesn't market to adults. So it is definitely possible.

And the last thing I would like to say is we haven't talked at all about mobile marketing, but that is where marketing is going in the future. So not only will kids be able to access this marketing on the Internet, they will be able to access it on their phone.

They will be able—the company will be able to know that the child is going into a convenience store, and they can send them a message about an energy drink. And that just should not be allowed, and the companies can stop it if they would want to.

Senator BLUMENTHAL. Thank you very much.

I apologize that I have to leave to preside over the Senate. I am going to turn the questioning to Senator Markey for his final round and once again thank all the members of the panel for your cooperation and your information and testimony. I am sure we will be continuing this conversation and discussion, and I look forward to continuing our work together.

Thank you so much.

At the end of the hearing, when Senator Markey is finished, he will adjourn, and the record will remain open for 1 week for additional questions and responses.

Thank you.

Senator MARKEY [presiding]. I thank the gentleman.

We have pulled some more kids from Rockstar. We are going to find some more for you as we are going along so that you can see that it is not just an isolated aberrational thing.

Ms. WEINER. May I respond to that?

Senator MARKEY. Sure.

Ms. WEINER. I would like to say a couple of things about what we mean by a "rockstar." You know, the word "rockstar"—I want to tell you how we mean it. This means someone that is very successful and is a winner in life. We, in our company, our accounting firm, when we have an accountant that comes in that does a great job, we say, "You are a rockstar," meaning you have done a great job.

Senator MARKEY. My only point is that these are up on your website.

Ms. WEINER. I am aware of that, sir. What I am trying to differentiate for you is the concept of the term "rockstar" and how we mean it.

Senator MARKEY. Again——

Ms. WEINER. We are not encouraging the drinking of the product by having that——

Senator MARKEY. I appreciate that. It is just—it is just——

Ms. WEINER. And in terms of the comment about——

Senator MARKEY. You don't have to be Dick Tracy to figure out what the point of this is——

Ms. WEINER. No, but I wanted to go to another point.

Senator MARKEY.—in terms of creating a culture, an atmospheric—you know, much of life is just "monkey see, monkey do." And if you are creating a culture where—where—you can't preach temperance from a barstool, in other words, you know?

Ms. WEINER. May I——

Senator MARKEY. The father can't be saying drinking is bad for you with a beer in his hand and smoking is bad for you with a cigarette in your hand. But putting these kids up on your website, as younger kids are surfing, you know, just kind of creates——

Ms. WEINER. We are promoting—we are promoting a——

Senator MARKEY.—a culture that makes it more likely that it is just part of what you should be thinking about doing. And so, let me just say that, first of all, it was not——

Ms. WEINER. If I may?

Senator MARKEY.—isolated. We are going to find other examples——

Ms. WEINER. If I may, could I say one more thing?

Senator MARKEY.—and give them to you as well. So let us just keep——

Ms. WEINER. We are also promoting a healthy lifestyle. What we are doing is we are indicating that we think that young people should stay away from dangerous things, and they should be physical, eat well, exercise, be engaged in physical sports. As a mother, I can tell you, as a soccer coach of kids——

Senator MARKEY. And again, it is not just about peddling caffeine to kids——

Ms. WEINER. Yes.

Senator MARKEY.—it is about the creation of a marketing culture that promotes consumption of a combination of stimulants that can have significant damaging consequences for the health of children and adolescents. And that is all we are really talking about here today. And having kids like this up on the website, it is helping to create that kind of a culture.

So let me now turn, if I could, to you, Dr. Schneider. Red Bull's testimony states that the company is "committed to promoting active and healthy lifestyle choices." But on Instagram, Red Bull suggests that people take a sleeping pill, wash down with Red Bull, and let the battle begin.

So, to you, Dr. Schneider, do you believe that taking sleeping pills and washing them down with energy drinks is a healthy lifestyle choice?

Dr. SCHNEIDER. No. No, but from my perspective, I think that we, as adults, get so many different messages that are not great,

and hopefully, you would look at that and say that is really not what I am going to do. You are responsible. You are educated. You are responsible, and you are going to look at it, and it is not going to be what you are going to do.

The concern is an adolescent looking at that, it is very impressionable. It is a very impressionable group of kids that have a lot of buying power. So that would be my primary concern.

Senator MARKEY. Yes. So would you agree, Ms. Taylor, with Dr. Schneider that it is not consistent with a healthy lifestyle to be talking about mixing Red Bull and sleeping pills?

Ms. TAYLOR. I will take it one step further. This is also not consistent with our strategy or positioning. It absolutely shouldn't have been messaged. So that will be addressed.

Senator MARKEY. OK. Well, and again, it is all part of a culture, and we are in this hearing dealing with that. And we are trying to be, obviously, clear about the message from the Committee that we just want it all to end. It just has to end, and we don't want any more semantical games to be played with regard to this mixed messaging that is going on out there.

And we want to make sure that it is done in a way that does, in fact, protect young people. And by young people, I think we are all agreeing here that we are talking about 13- and 14- and 15-year-olds. We are not pretending that if they can't buy a beer or if they can't drive a car or they can't do most things in society that we are not going to be—we might be treating them as adolescents, but the society treats them as children, and we understand why.

Because they are still highly impressionable, and creating this artificial line of 12 years of age basically defies what Dr. Schneider was talking about, which, amongst other things, is the great variation that can exist in 12- and 11-year-olds in terms of their maturity and their level of growth.

Do you want to add something, Dr. Schneider?

Dr. SCHNEIDER. Yes. One of the other issues that comes up in the research on kids and stimulants is that it becomes, number one, the beginning of an addictive pattern. So, for me looking at this, I see two things that are addictive on the same page, and I think that is one thing that really appeals to kids.

And certainly, we wouldn't want to be, I mean, promoting stimulants, seeking behavior promoting other potentially addictive behaviors would not be a good message.

Senator MARKEY. Dr. Spencer, you want to get in on this?

Dr. SPENCER. Thank you. Thank you.

I think it is important to also realize that we have representatives here of the major players in the industry, but every day there are minor players that are popping up not playing by the same rules. So even if we could get the industry to come to some sort of consensus, we still need a level playing field that all players have to abide by.

One of the most striking things that I hear when I had hearings in my legislative chamber in Suffolk County was the idea that these items are safe. And I think that we have to be careful of the semantics in terms of that word "safe" and "natural."

When you look at caffeine, caffeine appears in nature on plants and in beans as a natural insecticide. The point of caffeine is to

prevent insects from eating the plant. And so, we are taking something that its function in nature was a stimulant, is to have a toxic impact, and we are using it in a human model.

And what I am concerned about is when we hear testimony that caffeine consumption has remained stable, but we see a massive increase in emergency room visits. Although we can challenge some of those visits, we still, when we see a number such as tenfold going from 2005 to 2008, we hear twice going from 2008 to 2011, there is something going on here.

So if the caffeine consumption has remained the same, then it means there has been a shift from soda and coffee to energy drinks, and I think that it defies logic to not believe that there is not some sort of cause and effect relationship when we see this alarming trend.

Thank you.

Senator MARKEY. Yes, and it is an alarming trend, Dr. Spencer. We thank you for that.

I mean, it is pretty clear that what we are talking about here are marketing practices by these companies and other companies that are clearly aimed at children and adolescents, and what we are saying is stop it. We are saying stop it, and we are trying to basically use these illustrations as a way of getting that message out that we want to see real safeguards that are put in place and that there is no ambiguity that we are hearing from the industry, including these outliers who will try to take advantage of any agreement that we reach to make sure that those kinds of safeguards are put in place.

So, Ms. Taylor, your testimony says that Red Bull believes in teaching moderation in consumption. This is an instruction on your Tumblr site, to "pound" the 20-ounce can of Red Bull. And the question is, is that teaching moderation when you are saying pound a 20-ounce can of an energy drink?

Ms. TAYLOR. Yes, I think when we talk about moderation, the emphasis is in the fact that, again, 85 percent of our sales are in the form of 8- and 12-ounce cans. But to your point, and I will answer your question, this is not the language that we see suited for our brand, and I would say partially for the reason that you are pointing out, but additionally because it is not really appropriate for our positioning the voice of our brand as the premium player.

And I think it is an excellent example of the nature of the commitments that we are making today in drawing a clearer line—not a gray one, but a black and white one—regarding language around excessive or rapid consumption.

I will admit that this conversation can be a subjective one, and casual language common in social media, it will take some scrutiny to determine exactly what we are talking about here. But the example you provide here as well as the example behind you are not on brand for Red Bull and also covered within the commitments that we make today going forward.

Senator MARKEY. OK. Ms. Weiner, would you agree that that is not a proper message to pound a 20-ounce can of Red Bull or any other product?

Ms. WEINER. I don't believe we have employed any such language in any of our marketing. I would agree with that.

Senator MARKEY. Do you agree as well, Mr. Sacks, it is not an appropriate message?

Mr. SACKS. Yes.

Senator MARKEY. That rapid consumption of energy drinks at that level, 20 ounces, is not a good thing to be advocating?

Mr. SACKS. Yes.

Senator MARKEY. So would each of you agree to remove any references that would be encouraging people to consume at a rapid rate your energy drinks?

Mr. SACKS. Senator, we have done so, and I agree with that.

Senator MARKEY. Ms. Weiner?

Ms. WEINER. Yes, I would agree with that, and I don't think we have any such language. But of course, yes.

Senator MARKEY. OK. So let me just keep moving forward then. Ms. Taylor, would your company commit to putting social media restrictions in place so that individuals under the age of 18 are not inundated with unhealthy promotion of your beverages while browsing social media sites?

Ms. TAYLOR. Senator, we wouldn't believe that would be an appropriate message for us to send for a couple of different reasons. Red Bull is safe for teen consumption.

Our target demographic, as you know, is 18 to 34, and we have been quite crisp about that, especially in the last 2 years since we made a strategic shift. But the other reason is that we believe that there is nothing harmful on our social media sites for that age bracket, and frankly, it is quite positive and inspiring.

And now that we have made the public commitments that we have made today, we believe the language that you have pointed out will be changed, and it will be crisp in our commitments today. So to restrict the visitation of our sites from a teen population would simply send the wrong message.

Senator MARKEY. OK. That is important for us to know because, again, we are looking at 13-, 14-, or 15-year-olds a little bit different than you are. A lot different than you are, to be honest with you. A lot different.

We think they are still a vulnerable target audience for any products, and we don't view them the same way we view 18- or 19-year-olds. I don't think most people do. These kids are still in grammar school for the most part, and it is just a completely different audience.

So, Ms. Weiner, would you commit to putting social media restrictions in place so that individuals under the age of 18 are not inundated with unhealthy promotion of your beverages while browsing social media sites?

Ms. WEINER. No, we wouldn't. Currently, we have a caveat where we restrict from 13-year-olds, 12 and under, that is, not to get involved with our social network.

Senator MARKEY. But not 13-, 14-, and 15-year-olds?

Ms. WEINER. No. And I would like to mention another point to that in that we hear that these things are aspirational. But I don't think people are looking at the other side of the coin, which is that 60 is the new 40, OK? This is a phrase you hear a lot amongst mature adults. My own dentist watches the X Games and can't get enough of getting stickers.

To speak to the point exactly, our independent panel has illustrated no issue to us for the consumption of our product safely. In combination, these key ingredients have been demonstrated as safe for the consumption of 13- to 17-year-old persons.

Senator MARKEY. May I just say this? And I know that 60 is the new 40, but having hit 60, I can just tell you that it is not accurate.

[Laughter.]

Ms. WEINER. Well, I don't know——

Senator MARKEY. And in the same way, 13 is not the new 18, OK? There is a big difference between a 13-year-old and an 18-year-old, and to say that there isn't is to say that a 40-year-old and a 60-year-old is the same. And whether you like it or not, certain things just start to wear down a little bit more than you would have liked to.

And I like the—actually, I really—I like the Ed Markey 1.0. I wish I could get that guy back. But I am the Ed Markey 2.0 now, and actually, Ed Markey 2.0 is in the majority in the Senate. So that is a good thing. OK?

Ms. WEINER. That is a good thing.

[Laughter.]

Senator MARKEY. That is a very good thing. But we are just honestly trying to be pretty—let us just be honest about this, OK?

Ms. WEINER. We are being——

Senator MARKEY. A 13-year-old and an 18-year-old are just two different species almost in terms of their level of maturity. And to just lump them all together and to pretend that the 13- and 14-year-olds don't belong with younger kids——

Ms. WEINER. I am speaking to the——

Senator MARKEY.—is just completely wrong. They are very impressionable.

Ms. WEINER. I am speaking to the safety——

Senator MARKEY. And I just—I continue to be a little bit dismayed by the willingness of the industry to lump those younger kids in with the older teenagers because that is really where I think the problem is in most people's minds, and the industry's kind of obliviousness to the concern, which the public has, knowing that they are being targeted in the same way we know that you really want to get a kid hooked on cigarettes at age 12, 13, and 14. That is the impressionable age, 15, when they are just trying to do what everyone else is doing.

So——

Ms. WEINER. Our target demographic is 18 to 35.

Senator MARKEY. I understand that, and we are trying to help you to help us to ensure that your marketing does not——

Ms. WEINER. But I want to reassure you——

Senator MARKEY.—reach an earlier age.

Ms. WEINER. My point here is to reassure you that we have taken the appropriate steps as a responsible company to investigate the ingredients with scientists that have assured us that they are 100 percent safe for the age bracket of 13 to 17. I want to reassure you. That is what I am trying to do.

Senator MARKEY. Well, let me just ask you then. Will you commit to going through the existing images on social media to erase any

images that promote unhealthy consumption of any of these energy drinks, Ms. Weiner?

Ms. WEINER. That is a big task. Do you want me to take on every energy drink company?

Senator MARKEY. No, just your company.

Ms. WEINER. Oh, OK. Good. OK. Yes, I would be pleased to do a review.

Senator MARKEY. That would be good. Ms. Taylor?

Ms. TAYLOR. Excuse me. The commitments we are making today we take very seriously. We want to be able to measure ourselves and have you agree. So I am sorry. Can you repeat the request?

Senator MARKEY. Yes, the question is that you would be going through existing images on your social media to erase any images that promote unhealthy consumption of your energy drink.

Ms. TAYLOR. I believe that would be consistent with our commitment about rapid and excessive consumption. So, absolutely, that is a commitment we are making today.

Senator MARKEY. OK. Mr. Sacks?

Mr. SACKS. We would be happy to do that.

Senator MARKEY. OK. Will you put in place social media restrictions so that those under 18 aren't bombarded with instructions to rapidly or excessively consume your products? Ms. Weiner?

Ms. WEINER. As I stated, we do not currently suggest that people rapidly consume our products.

Senator MARKEY. So the answer is yes?

Ms. WEINER. I would say to the entire population, our target demographic as well, I would say from 13 to 95, I would say don't rapidly——

Senator MARKEY. OK. Ms. Taylor?

Ms. TAYLOR. We will not include that messaging going forward.

Senator MARKEY. OK. Great. Mr. Sacks?

Mr. SACKS. Yes. We would endeavor to do so.

Senator MARKEY. All three of the companies here today have stated in your testimony and in previous communications to members of the Committee that the company does not intend to promote to children. This question is for each of the companies. Please respond yes or no.

Will you commit to placing a label on your product indicating that the product isn't intended for children under the age of 16? Yes or no?

Ms. WEINER. No.

Senator MARKEY. No. Ms. Taylor?

Ms. TAYLOR. We are not prepared to make that commitment.

Senator MARKEY. Mr. Sacks?

Mr. SACKS. No.

Senator MARKEY. No. OK.

Will you commit to including binding contractual language prohibiting distributors and any third-party entity from promoting, marketing, or sampling to children. Ms. Weiner?

Ms. WEINER. As Mr. Sacks discussed, we also—Rockstar has contracts in place that we would be unable to modify.

Senator MARKEY. I am talking about future contracts. Yes, future contracts.

Ms. WEINER. You spoke before about future contracts, and could you repeat the question? For future contracts?

Senator MARKEY. Would you commit to including binding contractual language in future contracts prohibiting distributors and any third-party entity from promoting, marketing, or sampling to children?

Ms. WEINER. We are speaking of children 12 and under?

Senator MARKEY. Again, I would like to make it under 16. I will say under 16.

Ms. WEINER. We couldn't agree to that. We could agree to children under 12.

Senator MARKEY. You could not agree to that. OK. I appreciate that.

Ms. Taylor?

Ms. TAYLOR. Our distributors are not permitted to market or sample on our behalf. If the request is that we put that in writing and make it legally binding, absolutely.

Senator MARKEY. OK, great. Mr. Sacks?

Mr. SACKS. Going forward, we would be prepared to put a commitment in our contracts that our distributors who are people who we are contracting with, not other third parties we don't know, that they should not market or sample to, again, children. But again, as defined, which is up to 13, 12 and under.

Senator MARKEY. Some of the testimony today indicates that consumers are often confused in the marketplace on the differences between sports drinks that contain electrolytes for rehydration and energy drinks that contain caffeine and other stimulants that are purported to improve athletic performance.

That National Collegiate Athletic Association and the National Federation of State High School Associations have both stated in letters to Senator Durbin and Senator Blumenthal and to me that they advise their student athletes to avoid energy drinks or other stimulants because they may be detrimental to the health of athletes and are not effective forms of fuel or hydration.

And I ask for unanimous consent to enter those letters into the record.

[The information referred to follows:]

NATIONAL COLLEGIATE ATHLETIC ASSOCIATION
Indianapolis, IN, March 13, 2013

Hon. EDWARD MARKEY,
U.S. House of Representatives,
Washington, DC.

Dear Representative Markey:

The Association shares your concern for the health and safety of NCAA student athletes and young people throughout the country. At the core of our mission is the importance of providing a safe and equitable playing environment for our student-athletes. With the health and safety at the forefront, the NCAA national office staff has been persistent in its educational efforts to underscore the dangers of certain products, and has adopted policies to limit student-athletes' access to supplement products that may compromise their health. Energy drinks and other supplements are of particular concern because they are legal and easily accessible to individuals of all ages. For that reason, we look forward to working with you on this important matter and hope that the following information provides you with an overview of the NCAA's policies as they relate to "energy products."

The NCAA established clear guidelines, policies and resources related to "energy products". While these products promise to deliver "quick energy," they typically do so through drugs such as caffeine and other stimulants in concentrations that are

not well defined, and with substances or resultant caffeine levels that are banned by both the World Anti-Doping Agency and the NCAA. Because of these uncertainties, and because stimulant use can have adverse health consequences if consumed before or during strenuous exercise, the Association believes that these products pose a health and safety risk for student-athletes; especially for those who are overweight, carry the sickle cell trait, or exercise in hot and humid conditions.

Under NCAA Bylaw 16.5.2.g, established in 2000, the NCAA restricts the provision of certain types of supplement products to student-athletes. This regulation defines what nutritional supplement products are permissible for NCAA schools to provide to student-athletes and appropriately assist them with calorie and fluid replacement. This regulation also precludes the use of supplement products with questionable value and potentially harmful effects, and defines such products as impermissible for schools to provide to student-athletes. Such supplements, including energy drinks, are marketed to student-athletes as performance enhancing products despite the lack of scientific evidence to support such claims. NCAA institutions may not distribute energy products that contain caffeine and other stimulants per this NCAA regulation.

There is also a concern about the lack of pre-market testing for purity and safety of dietary supplement products and how this may contribute to a positive drug test. The NCAA raises awareness through its Drug Testing Consent Form, which contains a list of the NCAA Banned Drugs and an advisory about the use of supplement products in general. Division I institutions are required to have a staff member identified to answer questions about supplement products. The national office also subscribes to the Resource Exchange Center, staffed by a third-party drug testing administrator, to answer student-athlete and institutional staff questions related to dietary supplement products. NCAA staff educates the membership through educational presentations at member institutions to student-athletes regarding dietary supplements. We will also be distributing a poster to student-athletes that focuses attention on caffeine consumption and possibly very high caffeine content in energy drinks. This is a point of emphasis moving forward to protect the student-athletes and make them aware that some energy drinks contain banned substances that could cause them to become ineligible for NCAA competition.

We also foster partnerships and create resources to address this issue. For example, we are working with the Academy ofNutrition and Dietetics' Sports, Cardiovascular and Wellness Nutrition (SCAN) Dietetic Practice Group to develop and distribute handouts and news articles that promote proper eating and hydration strategies for NCAA student-athletes. In addition, the national office publishes and disseminates annually to its membership the Sports Medicine Handbook with "Guideline 2h: Nutrition and Athletic Performance" and "Guideline 2g: Dietary Supplements," to provide guidance and recommendations to member institutions on proper nutrition and hydration strategies for student-athletes.

- Guideline 2h states that "fluids containing electrolytes and carbohydrates are a good source of fuel and re-hydration. Fluids (*e.g.,* energy drinks) containing questionable supplement ingredients and high levels of caffeine or other stimulants may be detrimental to the health of the competitive athlete and are not effective forms of fuel or hydration."
- Guideline 2g explains that "student-athletes should be aware that nutritional supplements are not limited to pills and powders; 'energy' drinks that contain stimulants are popular. Many of these contain large amounts of either caffeine or other stimulants, both of which can result in a positive drug test."

The NCAA conducts 89 championships annually; the culminating events celebrate the achievements of those student-athletes and athletic programs that have demonstrated excellence in individual and team performances. The NCAA is charged with governing these events, while maintaining Advertising and Sponsorship Standards that disallow advertising of"energy products" in NCAA championships broadcasts if the advertisement suggests that the use of that product will have an impact on athletic performance. In addition, NCAA Advertising and Sponsorship Standards prohibit the manufacturers of these products from sponsoring NCAA championships and certified postseason bowl games. Within this framework, NCAA Advertising and Sponsorship policies have greatly curtailed marketing of products that contain banned substances and products that are not permissible for member institutions to distribute to student athletes.

The NCAA has taken a multifaceted approach to address concerns with energy drinks and related supplements. We look forward to learning more about these products from your examination and will employ that information to evaluate the

effectiveness of current policies. Thank you for your interest and leadership on this important matter.

Sincerely,

MARK A. EMMERT,
President.

cc: Senator Richard Durbin
Senator Richard Blumenthal

NATIONAL FEDERATION OF STATE HIGH SCHOOL ASSOCIATIONS
Indianapolis, IN, March 7, 2013

Hon. RICHARD J. DURBIN,
United States Senate,
Washington, DC.

Hon. RICHARD BLUMENTHAL,
United States Senate,
Washington, DC.

Hon. EDWARD J. MARKEY,
United States House of Representatives,
Washington, DC.

Dear Senators Durbin and Blumenthal, and Congressman Markey:

Thank you for your February 21, 2013 letter about energy drinks. The National Federation of State High School Associations (NFHS) has long been a leader in raising concerns about such beverages with the Nation's high school community, and we welcome a broadened national discussion. Our focus is on student welfare, and we want young people to understand the consequences of energy drink consumption. We encourage Congressional interest.

For more than a decade, the NFHS has included in each edition of its Sports Medicine Handbook, a section warning of the effect energy drinks can have on proper hydration, and highlighting the risks of consumption before, during and after athletic activity. The NFHS distributes each edition of the Sports Medicine Handbook for free to the Nation's high schools.

Moreover, the NFHS has promulgated two position statements that included information relating to energy drink consumption by young athletes. In "NFHS Position Statement and Recommendations for Hydration to Minimize the Risk for Dehydration and Heat Illness," originally released in April 2008 and revised in 2011, the NFHS Sports Medicine Advisory Committee warns students about the risks of energy drink consumption, noting that they are not regulated by the FDA. In "NFHS Position Statement and Recommendations for the Use of Energy Drinks by Young Athletes," originally released in October 2007 and revised in 2011, students are advised of the potential negative effects of energy drinks, and provided with recommendations for proper hydration. Such recommendations include the avoidance of energy drinks prior to, during and after physical activity. The position statements are available on the NFHS website at *http://www.ntbs.org/SportsMed.aspx.*

Most recently, in the issue of *High School Today* dated March 2013, the NFHS published an article on the impact of energy drinks on young people. *High School Today* has a circulation of more than 75,000 high school superintendents, principals and athletic directors.

The NFHS believes the health and safety of participants in all 17 sports for which we write playing rules is of paramount importance. As such, we monitor new developments and seek to further the conversation in areas that may present risks to young people. We welcome your involvement in the discussion.

Sincerely,

ROBERT B. GARDNER,
Executive Director.

Enclosures:

February 2009 *High School Today* Article
NFHS Sports Medicine Handbook
NFHS Position Statement "Recommendations for the Use of Energy Drinks by Young Athletes" March 2013 *High School Today* Article

NATIONAL FEDERATION OF STATE HIGH SCHOOL ASSOCIATIONS

POSITION STATEMENT AND RECOMMENDATIONS FOR THE USE OF ENERGY DRINKS BY YOUNG ATHLETES

National Federation of State High School Associations (NFHS) Sports Medicine Advisory Committee (SMAC)

Background: Energy drinks have become increasingly popular among adolescents and young adults in recent years. In 2006, nearly 500 new brands were introduced to the market place, and over 7 million adolescents reported that they had consumed an energy drink. Estimated sales of energy drinks for 2011 are expected to exceed $9 billion. These beverages are particularly popular among young athletes who see the consumption of energy drinks as a quick and easy way to maximize athletic and academic performance.

The NFHS SMAC strongly recommends that:

1. Water and appropriate sports drinks should be used for rehydration as outlined in "*NFHS Position Statement and Recommendations for Hydration to Minimize the Risk for Dehydration and Heat Illness.*"
2. Energy drinks should not be used for hydration prior to, during, or after physical activity.
3. Information about the absence of benefit and the presence of potential risk associated with energy drinks should be widely shared among all individuals who interact with young athletes.
4. Athletes taking over the counter or prescription medications should not consume energy drinks without the approval of their primary care provider.

WARNING: The exact content and purity of energy drinks cannot be insured, as there are no regulatory controls over these products. Thus, there is the risk for adverse side-effects, potentially harmful interactions with prescription medications (particularly stimulant medications used to treat ADHD), or positive drug tests.

Frequently Asked Questions

What is an energy drink?

- An energy drink is a beverage marketed to both athletes and the general public as a quick and easy means of relieving fatigue and improving performance. In addition to water, nearly all energy drinks contain carbohydrates and caffeine as their main ingredients. The carbohydrates provide nutrient energy while the caffeine acts as a stimulant to the central nervous system.

What are the differences between an energy drink and a sports drink?

- Sports drinks are designed to provide re-hydration during or after athletic activity. While contents vary, most sports drinks contain a 6 to 8 percent carbohydrate solution and a mixture of electrolytes. The carbohydrate and electrolyte concentrations are formulated to allow maximal absorption of the fluid by the gastrointestinal tract.
- Energy drinks often contain a higher concentration of carbohydrate (usually 8 to 11 percent), and thus a larger number of calories than sports drinks. They also contain high amounts of caffeine and, in some cases, other nutritional supplements. Energy drinks are not appropriate for re-hydrating athletes during physical activity and should not be used in such circumstances.

What ingredients are found in energy drinks?

- *Carbohydrates*—Most energy drinks have from 18g to 25g of carbohydrate per 8 ounces. The high carbohydrate concentration can delay gastric emptying and impede absorption of fluid in the gastrointestinal tract.
- *Caffeine*—Nearly all energy drinks contain some quantity of "natural" or synthetic caffeine. The caffeine concentration may range from the equivalent to an 8 ounce cup of coffee (85mg) to more than three times that amount.
- *Herbs*—Many energy drinks include herbal forms of caffeine such as guarana seeds, kola nuts, and Yerba mate leaves, in addition to synthetic caffeine. The "performance enhancing" effects, safety, and health benefits of other herbs like Astragalus, Echinacea, Ginko biloba, ginseng, and countless others have not been well established by scientific studies.
- *Vitamins*—Athletes with even reasonably good diets should be assured that they are at low risk for vitamin deficiency and typically do not need supplementation. There is no evidence to suggest that vitamin supplementation improves athletic performance. Female athletes may benefit from iron and calcium sup-

plements; but, those are more easily and inexpensively obtained in pill form rather than from energy drinks.

- *Proteins and amino acids*—Only a small amount of protein is used as fuel for exercise. Carbohydrates are utilized as the primary fuel source. To date, there is no definitive evidence that amino acid supplementation enhances athletic performance.
- Other ingredients—With the hundreds of energy drink brands that are available, the potential ingredients which they may contain are virtually unlimited. Possible additions include pyruvate, creatine, carnitine, medium-chain triglycerides, taurine and even oxygen.

What are the possible negative effects of using energy drinks?

- *Central nervous system*—Caffeine often has the effect of making a person feel "energized." Studies have shown some performance-enhancing benefits from caffeine at doses of 6mg/kg of body weight. However, these and higher doses of caffeine may produce light headedness, tremors, impaired sleep, difficulty with fine motor control, and may exceed drug testing caffeine thresholds.
- *Gastrointestinal system*—The high concentrations of carbohydrates often found in energy drinks may delay gastric emptying, resulting in a feeling of being bloated. Abdominal cramping may also occur. Both carbohydrates and caffeine in the high concentrations found in most energy drinks may cause diarrhea.
- *Dehydration*—Energy drinks should not be used for pre-or re-hydration. The high carbohydrate concentration can delay gastric emptying and slow absorption from the gastrointestinal tract and may cause diarrhea. Caffeine can act as a diuretic and, therefore, may result in increased fluid loss.
- *Positive drug tests*—Like all nutritional supplements, there is little or no regulatory oversight of energy drinks. The purity of the products cannot be assured and it is possible that they may contain substances banned by some sports organizations.
- Consumption of energy drinks by adolescents and young adults has been linked to heart arrhythmia and liver problems.
- Sales of certain energy drinks have been banned in Denmark, Turkey, Uruguay, Germany, and Austria. Some states in the U.S. have introduced legislation to restrict sales of energy drinks to adolescents and children. In September 2010, the Virginia High School League banned the use of energy drinks.
- Recently, healthcare providers have voiced increasing concerns about the consumption of energy drinks in association with alcohol because of the interaction of the stimulant effects of energy drinks and the depressant effects of alcohol.

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Sports Medicine

PROPER NUTRITION, HYDRATION—NOT ENERGY DRINKS LEAD TO ATHLETIC SUCCESS

By Katherine Dec, M.D., and Steve Mcinerney, ATC

The use of energy drinks by high school athletes has become increasingly prevalent. Testimonials by notable athletes, easy access, peer pressure and a misunderstanding of athletes' nutritional needs are a few of the reasons behind this increased use.

While many athletes are looking for the "quick fix" that will lead to success on the courts and playing fields, the use of energy drinks is not limited to athletic endeavors. Students involved in music, theatre or forensic activities also seek that extra boost to be able to perform at their peak.

In many cases, it is the confusion between a "sports drink" and an "energy drink" that leads to the initial use by high school athletes. Each athlete has his or her own energy needs in order to be competitive in their chosen sport. However, proper nutrition, consisting of proper hydration and the optimal balance of proteins, carbohydrates and fats, provides the basic foundation for athletic success.

Within the realm of athletics, energy can be defined in two ways First, it is the strength and vitality required for sustained physical or mental activity Second, it may be viewed as a feeling of possessing such strength and vitality. The latter is most commonly associated with the concept of energy—the ability to stay awake and alert for tests, to feel a burst of strength or speed in order to complete a workout or to finish a game Promotional advertising for energy drinks appeals to this concept.

The primary energy source for the human body is glucose. The building blocks of proteins and fats are essential catalysts for the increased availability of glucose Through advertising, many high school athletes and coaches are led to believe that a magic combination of minerals, vitamins and other supplements provide the euphoric burst touted by these energy drinks. In many cases, this feeling of increased energy is provided by caffeine and other supplements with the same stimulating effects as caffeine.

The goal of sports drinks is to provide fluids and certain nutrients that are lost in sweating and exercise. Most commonly, sports drinks are used prior to, during and after athletic practices or competitions The caffeine content in sports drinks and soft drinks is regulated by the Federal Drug Administration (FDA), due to their classification as "food." However, energy drinks are viewed as a supplement, therefore, they are not regulated by the FDA. These drinks typically include various sup-

plements, amino acids or minerals to appear as a replenishment drink, but they may also have high levels of sugar and caffeine. Labeling of these drinks can be misleading. One container may actually contain two or more servings. Young athletes will drink the whole container, thereby ingesting two to three times the milligrams listed on the label.

Caffeine, as well as supplements that create caffeine-like effects such as Guarana, Green tea extract and Tuarine, create specific physiological reactions within the body. Caffeine attaches to specific receptor sites in the brain that are normally reserved for another molecule that prepares the body for sleep. Because this molecule cannot bind with its receptor, there is a continuing circulation of the other molecules that act as natural stimulants for the brain. The result may be increased alertness or wakefulness and the feeling of being more energetic.

Caffeine may have some positive effects on performance when consumed by particular athletes involved in specific sports. It may delay the feeling of muscle fatigue by helping to decrease the buildup of lactic acid and raising the lactate threshold In addition to increasing the feeling of energy, caffeine may quicken reaction time and enhance mental awareness in some athletes.

However, there can be negative effects from caffeine use as well. Common side effects may include rapid heart rate, shaking, restlessness, gastrointestinal upset, headache and possibly fainting. Caffeine can act as a diuretic, which may hasten the onset of dehydration and not only reduce athletic performance, but lead to catastrophic effects as well.

In addition, too much caffeine can mask fatigue and hinder performance, which may lead to injury Fatigue is an important signal in order to achieve proper rest and recovery intervals. Because of caffeine's effect on moods, dependence can be created involving the "need" to achieve the feeling of alertness that becomes associated with successful workouts. In order to maintain this feeling, greater amounts of caffeine must be ingested in order to continue the effect once the athlete develops a tolerance.

There is research to suggest that males less than 17 years of age who consume these energy drinks may be affecting the reward-addiction area of the brain that may, in turn, influence future food preferences. Due to caffeine's effect of delaying the body's natural sleep rhythms, there can be a negative effect for athletes who only have a short recovery interval or are traveling for competition. This lack of sleep will negatively affect the body's ability to repair, grow and recover.

As advertisers target high school students, it becomes increasingly important that high school coaches, teachers and administrators continue to stay abreast of the latest trends in sports nutrition. Employing proper nutrition will allow their bodies to function at peak capacity—not only on the playing field but in the classroom as well. A proper combination of nutrition and hydration enhances the body's ability to perform and will enable high school students to continue to lead productive lives.

Additional information may be obtained by reading the NFHS Position Statement and Recommendations for the Use of Energy Drinks by Young Adults.

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Steve Mcinerney, ATC, CAA, is division chair for physical education, health and drivers education at Carl Sandburg High School in Orland Park, Illinois. He is the National Athletic Trainers Association liaison to the National Interscholastic Athletic Administrators Association and serves on the NFHS Sports Medicine Advisory Committee.

THE USE OF ENERGY DRINKS BY YOUNG ATHLETES

By Michael C. Koester, MD, ATC. FAAP

The position statement is available in its entirety at *www.nfhs.orq.*

Dr. Michael C. Koester is a pediatric and adult sports medicine physician at the Siocum Center for Orthopedic and Sports Medicine in Eugene, Oregon. He is a member of the NFHS Sports Medicine Advisory Committee.

Energy drinks have become increasingly popular among high school students in recent years. Hundreds of brands have been introduced to the marketplace, and the drinks are consumed by millions of adolescents on a daily basis. These beverages are particularly popular among young athletes who see the consumption of energy drinks as a readily available and convenient way to maximize athletic performance. The drinks are also often used to provide an "academic" boost for a late night of studying or preparing a project.

Energy Drinks vs. Sports Drinks

Some confusion exists over where exactly the difference lies between an "energy drink" and a "sports drink." Simply put, an energy drink is a beverage marketed to both athletes and the genera public as a quick and easy means of relieving fatigue and improving performance "Sports drinks" are designed to provide rehydration during or after sustained physical activity, thus the contents of the two drinks differ in several important ways.

Nearly all energy drinks contain carbohydrates (sugar) and caffeine as their main ingredients. Prior to its being banned, many of these drinks also contained ephedra. The carbohydrates provide nutrient energy and the caffeine acts as a stimulant to the central nervous system. While contents may vary somewhat, most sports drinks contain a low percentage carbohydrate solution and a mixture of electrolytes such as sodium and potassium. The carbohydrate and electrolyte concentrations are specifically formulated to allow maximal absorption by the stomach, aiding in re-hydration.

Energy drinks should not be used for the purposes of hydration or re-hydration by athletes. The high carbohydrate concentration results in slow absorption from the gastrointestinal tract and may cause bloating and diarrhea. In addition, caffeine acts as a diuretic and, therefore, results in increased fluid loss during and after exercise secondary to increased urine output.

Energy Drink Contents

Since energy drinks contain a higher concentration of carbohydrates than sports drinks, they also contain more calories. The high caffeine level may come from large amounts of synthetic caffeine or "natural" forms of caffeine like guarana and kola nuts. Other nutritional supplements like Echinacea, Ginko biloba, and ginseng are often included. Some brands a so include vitamins, proteins, and amino acids.

Manufacturers make claims that these added ingredients have special benefits, typically related to maximizing the effects of the caffeine and carbohydrates in providing a boost of energy. However, none of the aforementioned herbs or nutrients has any beneficial effect that has been scientifically proven.

Potential Side Effects of Consuming Energy Drinks

As we all know, caffeine often has the effect of making a person feel "energized." Studies have shown some performance-enhancing benefits from caffeine, but only at very high concentrations. It would require the consumption of as many as five energy drinks in a short period of time to achieve these doses. Such high amounts of caffeine may produce light-headedness, tremors, impaired sleep and difficulty with fine motor control, and may exceed drug-testing thresholds for caffeine.

The high concentrations of carbohydrates found in energy drinks may also be a source of trouble. Delayed emptying of the stomach, due to the high sugar load, may result in a feeling of being bloated. Abdominal cramping may also occur. Both carbohydrates and caffeine in the high concentrations found in most energy drinks can cause diarrhea. Also, some athletes, and many non-athletes, may see an unwanted weight gain due to the high calorie content of many of these beverages.

An important point to remember is that like all nutritional supplements, there are currently no regulatory controls over energy drinks, thus their contents and purity cannot be assured. This may lead to a variety of adverse consequences. The most concerning is the potential for harmful interactions with prescription medications that the athlete may be already be taking There is particular danger for those taking stimulant medications for ADHD. For athletes who are subject to drug testing, there is also the possibility of positive drug screen if the manufacturer knowingly, or unknowingly, adds banned substances to the beverage.

Discouraging Use by Athletes

In addition to educating athletes about the tack of benefits and potential risks of energy drinks, teachers, coaches and administrators should consider their own habits. Discouraging the use of "energy drinks" while downing your second latte of the morning or sipping on your third caffeinated soda of the day will be perceived as hypocritical at best. Thus, adults in positions of responsibility should model behaviors that they would like to see in their students and athletes.

You must also be prepared to educate young athletes regarding the use of energy drinks. Such efforts should focus upon the potential harms and side effects of use as discussed above, in addition to the financial costs ($2–3 per bottle or cart). This message can be coupled with the explanation that there are no proven performance benefits to consuming these drinks prior to practices or games.

NFHS Sports Medicine Advisory Committee's Position on Energy Drinks

Following a review of the medical literature and in consideration of the issues discussed above, the NFHS Sports Medicine Advisory Committee has created and endorsed the following position statement regarding the use of energy drinks by young athletes:

1. Water and appropriate sports drinks should be used for re-hydration as outlined in the NFHS Document *"Recommendations for Hydration to Prevent Dehydration and Heat Illness."*
2. Energy drinks should not be used for hydration.
3. Information about the absence of benefit and the presence of potential risk associated with energy drinks should be widely shared among all individuals who interact with young athletes.
4. Energy drinks should not be consumed by athletes who are dehydrated.
5. Energy drinks should not be consumed without prior medical approval by athletes taking over-the-counter or prescription medications.

SPORTSMANSHIP COMES FROM WITHIN

Editor's Note: This article was distributed as a press release by the Iowa High School Athletic Association

You all may have heard the sportsmanship announcement that is read at the start of high school events. Often it is appreciated. And for the last quarter of a century, the Iowa High School Athletic Association has sharpened its focus on this one trait that makes educational athletics truly special in Iowa.

By all reports, sportsmanship has gotten better among the athletes and coaches. Spectators, perhaps, have lagged behind, but ever so often an event happens that tugs at your heart to be told and causes even the most blustery fan to cease yelling and to reflect that there is a higher purpose to interscholastic competition. Such events have a positive effect on spectator sportsmanship.

One occurred in the PCM, Monroe vs. Albia junior varsity game Monday, September 8 at Monroe.

Late in the game PCM was winning handily. Coaches from both schools had made sure all of their players had participated. With 90 seconds remaining, Wyatt Lagergren, a PCM ball carrier, sustained a broken ankle. An ambulance was called and it took several minutes to stabilize the young man and to transport him.

In the interim, the Albia coaches tasked with the PCM coaches and offered to terminate the game, but some PCM payers disagreed.

They told the coaches from both schools they wanted Albia player Kile Weiss, a sophomore student with special needs, to have a chance to score. PCM quarterback Brandon Kain visited with the Albia coaches and officials. Then with time running down, he fumbled in Kile's direction.

Players, coaches and fans on both sides cheered as Kile scooped up the ball and ran 60 yards for a touchdown. It was a special moment to treasure for Kile, all players, coaches and fans.

Albia has started a tradition this fall under new but veteran coach Jerry Staton to give the opposing team a sportsmanship cheer following the game. This time it was more special, and as they ended, the PCM players in unison shouted "Thanks!"

There is more to educational athletics than winning and this situation was initiated by some good young men who understand that. It reinforces the fact that when it comes to doing the right thing that "the kids get it," and moreover, by their deed, they can sell it.

From the coaches, administrators and officials who shared the story with us, they each added that there weren't many dry eyes after the game. The adults "got it" also.

Senator MARKEY. We will start with the scientists, but I would like the companies to answer as well. Would you agree with these student athlete associations that energy drinks should not be promoted as sports drinks that will improve athletic performance for youth?

Dr. SCHNEIDER. Yes. Sports drinks——

Senator MARKEY. Dr. Harris?

Dr. HARRIS. Yes. And I would also like to know what they mean by not promoting them as sports drinks because almost all of the marketing is related to sports in some way.

Senator MARKEY. Yes. And we are going to get to that.

Dr. Spencer?

Dr. SPENCER. Absolutely.

Senator MARKEY. Mr. Sacks?

Mr. SACKS. I think there is a distinction in some of the energy drinks. We have a line of energy drinks called Rehab that contain electrolytes at precisely the same levels as are contained in Gatorade and Powerade. The science—there is a substantial body of science that it confirms that caffeine at the levels that we have in our products do not have a diuretic effect and do not negate the effects of hydration that are included from the electrolytes.

So, again, you need to draw a distinction between that product that has the electrolytes in and an energy drink which doesn't and

which we don't—we don't market as a sports drink or having those benefits.

Senator MARKEY. So do you agree with the NCAA or the National Federation of State High School Associations, who have stated in letters to Senator Durbin and to myself and Senator Blumenthal, advising student athletes to avoid energy drinks or other stimulants because they may be detrimental to the health of athletes? Those that don't have large amounts of electrolytes in them.

Mr. SACKS. Again, I am not sure of what drinks they are referring to because we have a specific line that is different. But we also don't agree—everybody is entitled to their recommendation, which we respect.

However, we don't believe there are any concerns about our products being drunk by that demographic. Nine billion cans of our product have been safely consumed around—in more than 90 countries around the world, and we don't have any health issues that have been causally proven to be attributed to our product.

So, but everybody is entitled to consume our products as they choose.

Senator MARKEY. So you are saying the National Federation of State High School Associations are entitled to their opinion, but they are just wrong?

Mr. SACKS. We respect them. No, we respect their opinion, and they are entitled to it, Senator.

Senator MARKEY. OK. Ms. Taylor?

Ms. TAYLOR. With the information that I have in front of me, what you had just read to us, I would disagree. But I would say that if we were to give a statement on behalf of the company, we would need to review that in greater detail, understand the claims, and compare that against the science behind our product.

Senator MARKEY. Ms. Weiner?

Ms. WEINER. I would respectfully request time to evaluate that and bring that to our science committee for a review.

Senator MARKEY. OK. I thank you for that.

And I think it is important that we just divide this question between that which has obviously included in the product the electrolytes that high school athletic associations would support and those which are caffeine and——

Ms. WEINER. Senator, we make energy drinks——

Senator MARKEY.—give that shorter-term boost, but don't have that kind of ingredient that is preferred. So I think we have to divide the question, and I would ask—I will give each of you a chance in writing back to the Committee to tell us if you would divide that question between the two kinds of drinks that—or multiple kinds of drinks that you might be marketing.

And I will come back to you, Dr. Harris, so that you can make your comment on the issue of what it is that we should be concerned about in terms of these products.

Dr. HARRIS. Well, my issue is with the marketing that all of the associations with sports that we have seen today, and the marketing does imply that these products are good and enhance sports performance. So I am just trying to understand what the ABA com-

mitment is to not market these drinks as sports drinks, what that means.

Senator MARKEY. Well, why don't you just pose the question to them? Ask them what it is, what is your concern? Why don't you lay out what it is that you are concerned that they may not be pledging to do that you would like them to do?

Dr. HARRIS. All right. Well, the evidence is that energy drinks should not be consumed as part of sports and that they become more dangerous when that happens. And all of the sport sponsorships that these companies promote, in my mind, seem to be promoting these drinks as appropriate for sport. So I just want to understand that more.

Senator MARKEY. OK. Could you divide the question then in terms of——

Mr. SACKS. I think the——

Senator MARKEY. In terms of the types of energy drinks that you are promoting that you think are consistent with the goals that young athletes should have and those that are of concern to these high school associations? So, Mr. Sacks, Dr. Harris has a concern about this.

Mr. SACKS. I think there is simply no relationship between your marketing and supporting sports and promoting your drinks as being used for those sports. Every company promotes sports, whether it is beer companies, whether it is Coca-Cola, whether it is Pepsi. So I just don't get that.

On the other side, I think that what Ms. Harris is saying flies in the face of all the well-established literature and scientific research that these drinks shouldn't be drunk before sports or are in any way dangerous somehow in connection with sports. We have studies, Red Bull and everybody else has studies over many years that these drinks do improve performance, and there is no suggestion that these drinks are dangerous in those circumstances.

We have had no evidence at all. And again, there are over 50 billion energy drinks have been consumed in all of these circumstances for 25 years, and nobody has proved any——

Senator MARKEY. Mr. Sacks, do you—the American Beverage Association says that energy drinks should not be marketed as sports drinks. Do you disagree with the American Beverage Association?

Mr. SACKS. On that point, yes, we do. That was approved before we became a member, and what we say is, and our understanding of that is, that was before they had understood that we had drinks like the Rehab line, which contains electrolytes.

Second, we believe that that is in relation to not portraying sports, but it is—to compare energy drinks to sport drinks like Gatorade and Powerade, which have electrolytes, and that was the distinction they were trying to, I think, draw. But I can't speak for them, but that is not something we have endorsed.

Senator MARKEY. And Ms. Taylor and Ms. Weiner, do you agree with the American Beverage Association that energy drinks should not be marketed as sports drinks?

Ms. TAYLOR. Yes. Our position is we do agree. We are a member of the ABA. And sports drinks, by definition in the industry, companies like Nielsen, et cetera, are defined as electrolyte beverages, hydrating, and that is not appropriate for our positioning.

Senator MARKEY. OK. So, Ms. Weiner?

Ms. WEINER. As with Monster, Rockstar joined the ABA after these rules were in place, and there are only four companies that agree to these rules. And I would like to point out that there is no FDA or regulatory——

Senator MARKEY. Well, as you——

Ms. WEINER.—distinction between energy drinks and sports drinks. That is a business term. It is an industry term.

Senator MARKEY. Well——

Ms. WEINER. That is not an accepted Food and Drug Administration term. All Rockstar energy drink products are clearly labeled with the caffeine content, and there is no attempt to promote them as other than caffeine beverages, period.

Senator MARKEY. Well, see, from our perspective, OK, if you are members of the American Beverage Association, and these are voluntary guidelines. But Mr. Sacks doesn't feel bound by the voluntary guidelines, that is helpful for us to understand because, obviously, if guidelines are voluntary, but then individuals can make a decision not to abide by those guidelines, then it really does emphasize and underline the word "voluntary."

And so, then you begin to question what the regime is that ensures that there is, in fact, compliance with——

Ms. WEINER. Those are industry guidelines, and they are currently in flux. The American Beverage Association will confirm that those are not set in cement now.

Senator MARKEY. They will say what?

Ms. WEINER. They will confirm that those are in flux right now.

Senator MARKEY. Meaning the guidelines are——

Ms. WEINER. Those, that particular guideline between energy drinks and sports.

Senator MARKEY. Those guidelines should be changed. Is that what you are saying?

Ms. WEINER. Only that one, because of the fact that it is an industry standard. This has nothing to do with the Food and Drug Administration.

Senator MARKEY. I appreciate that.

Ms. WEINER. It is simply a technical thing where you put something on a shelf in a store. You put it in the sports drink section, or you put it, sorry, in the energy drink section.

Senator MARKEY. So, no, I appreciate that there could be an ongoing vigorous discussion going on at the American Beverage Association right now with regard to these standards——

Ms. WEINER. Yes. We have had them.

Senator MARKEY.—given the new members who have joined. But their old standards are clearly standards which they believed were accurate when they were put on the books. So I guess I am going to bring the hearing to a close. But just to tell you this, that we are going to be returning to this subject and would be asking you to very strongly reexamine your policies, especially when it comes to kids.

And I am not talking about the 18- and 19-year-olds. I am talking about the younger kids and what your policies are and what protections you are putting in place because we will be revisiting this. And we are going to be looking for real results to ensure that

lines are being drawn that will be protecting those who are most vulnerable in our population from being exploited.

So I would be encouraging each of our company witnesses when it comes to marketing to children and adolescents not to rely on semantics, but to focus on safety, to focus on those who are most impressionable, and to make sure that protections are being put in place. And so that when we return, you will have a strong body of evidence to prove to the Committee that your actions are, in fact, consistent with the protection of young people in our society that we want to see protected.

I have got to rush over to the Senate floor. I thank all of our witnesses for the testimony.

This hearing is adjourned.

[Whereupon, at 5:22 p.m., the hearing was adjourned.]

A P P E N D I X

FACT SHEET FROM THE COUNCIL FOR RESPONSIBLE NUTRITION TO THE U.S. SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

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FACT SHEET

The Facts about Caffeine in Dietary Supplements

Caffeine-containing products that are labeled as dietary supplements are regulated by FDA.

- As a category of food, all dietary supplements are subject to comprehensive, robust regulation. FDA imposes Good Manufacturing Practices (GMP) regulations on supplements that are more strict than those for other food. Dietary supplements are subject to post-market surveillance through mandatory serious adverse event reporting—a requirement that does not apply to conventional foods and beverages. FDA has the authority to review dietary supplement labeling and the ability to remove a dietary supplement from the market if it poses an "imminent hazard" or "significant or unreasonable risk of injury or illness."[1]

- FDA also has ample authority under the Food, Drug, and Cosmetic Act (FDCA) to demand recalls, to seize products, to detain imports or to impose civil and criminal penalties for products that are adulterated, misbranded, or that pose a safety risk to consumers.

- It is incorrect to say that energy drinks labeled as dietary supplements are beyond FDA's reach for evaluation of their safety, or that caffeine-containing products labeled as dietary supplements are less regulated than conventional beverages. This notion is false.

Manufacturers of liquid caffeinated products may choose to label these products as beverages or dietary supplements, but there are requirements for both, and that decision has regulatory consequences for the manufacturer.

- By law, manufacturers are permitted to label and market liquids as conventional food (if the product is intended to be a beverage that is part of the diet, e.g., juice or soda), or as a dietary supplement (if it is intended to supplement the diet). This distinction also applies to energy drinks, although FDA does not recognize these as a unique category. These products typically contain caffeine and sometimes other added ingredients. If the manufacturer markets the product as a beverage, it will have a "Nutrition Facts" box on the label; a dietary supplement will have a "Supplement Facts" box.

- In 2009, FDA issued a draft guidance to provide criteria to help industry distinguish liquid dietary supplements from beverages and other conventional foods.[2] Factors such as packaging, labeling, the serving size intended to be consumed, and statements about the product in labeling or advertising can all help to determine if the product is regulated as a liquid dietary supplement or beverage. In addition, FDA's draft guidance suggests that products packaged in cans or bottles greater than 8 oz., especially those without resealable closures, may be intended for use as a conventional food, and thus, should be labeled as a beverage. Although FDA is still finalizing this guidance, the agency's interpretations outlined in the draft indicate that products marketed as beverages are conventional foods under the FDCA, even if the label characterizes them as dietary supplements.

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[1] Sections 402(f)(1)(A) and (C) of the Federal Food, Drug, and Cosmetic Act.
[2] Draft Guidance for Industry Distinguishing Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods (2009), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm196903.htm.

CRN FACT SHEET

The Facts about Caffeine in Dietary Supplements

- FDA evaluates products on a case-by-case basis by examining product labeling, advertising, packaging, etc., and may challenge the marketer regarding a product's representation as a conventional food or dietary supplement. FDA has issued several warning letters to firms that it believes are inappropriately marketing their products in violation of the FDCA.[3]

Neither conventional food nor dietary supplement regulations specifically limit the amount of caffeine in these products—but in both cases, manufacturers must ensure safe levels of all product ingredients.

- The Code of Federal Regulations provides that caffeine in cola-type beverages may be added at levels not to exceed .02% by volume (about 70 mg caffeine per 12 oz. can). This is the amount of caffeine considered by FDA to be "generally recognized as safe" (GRAS), and the level at which a manufacturer may use the ingredient without conducting any safety tests of its own.[4] It essentially sets a "safe harbor" for use, and levels of that ingredient at or below that amount are presumed to be safe; it **does not** limit how much caffeine can be included.

- This GRAS level for caffeine has been inaccurately portrayed as a limit on added caffeine in products labeled as beverages. Manufacturers of conventional food products, including beverages, may use higher levels of caffeine as long as they self-affirm the safety of those levels—meaning that they have conducted their own safety studies and assembled a panel of experts who agree with those findings. The manufacturer is not required to provide FDA with this evidence in order to use higher levels of the ingredient.

- For dietary supplements, FDA does not impose similar "safe harbor" requirements for caffeine. Under supplement regulations, ingredients like caffeine that were on the market prior to 1994 are presumed to be safe unless FDA has evidence they are not. Supplement manufacturers must be able to demonstrate that the levels of all ingredients in their products are safe, based on the label instructions (including serving amounts), or if no instructions are provided, under normal conditions of use.

FDA regulations do not currently require any category of food products to declare the total amount of caffeine. CRN has developed recommended guidelines for the dietary supplement industry to provide consumers with this information.

- While federal regulations require both food and supplement labels to disclose the presence of added caffeine and the quantity of all listed ingredients, the law does not require disclosure of the total amount of caffeine. Nor does it require disclosure of caffeine from naturally occurring sources. For example, the caffeine content of coffee or tea, two naturally occurring sources of caffeine, is not typically disclosed on labeling. Dietary supplements that contain a propriety blend of herbs that may contain caffeine are similarly not required to disclose the amount, only the identity of the herbs.

- CRN has adopted recommended guidelines for its member companies to disclose the total amount of caffeine from all sources on dietary supplement labeling. CRN's guidelines also

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[3] See, e.g., FDA Warning Letter to Innovative Beverage Groups Holdings, Inc., 1/13/10, http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm201435.htm; FDA Warning letter to HBB LLC dba Baked World, 7/28/11, http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm266129.htm; FDA Warning Letter to RockStar, Inc. DBA Livingston Chocolate Company, 5/23/12, http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm309080.htm.

[4] 21 Code of Federal Regulations (CFR) § 182.1180.

recommend several advisories on labeling and encourage manufacturers to develop serving size and daily intake recommendations that are consistent with safety information about caffeine established by competent and reliable scientific evidence.

Caffeine is one of the most studied food ingredients and has a long history of safety at a wide range of serving levels.

- Caffeine is a safe ingredient when consumed at moderate levels, whether in a beverage or a dietary supplement. A recent FDA assessment of caffeine consumption found that most of the caffeine consumed in the U.S. comes from coffee and tea—even when energy drinks are considered. Further, FDA has also determined that for healthy adults, caffeine intake of up to 400 mg per day is not associated with negative health impacts.[5]

- Some recent reports have sensationalized data about adverse events associated with caffeine, but as FDA has stated time and time again, adverse event reports provided to FDA are not necessarily caused by the product. Similarly, emergency room data does not filter out likely causes of the ER visit. Further, as caffeine products are increasingly more present in the market, it follows that more people will be exposed to them, potentially leading to higher numbers of reports. However, regardless of the number of reports, the fact remains that both adverse events and ER visits should not be considered causal simply because they are reported.

FDA has ample authority to regulate dietary supplements.

- FDA has already taken action and issued warning letters in cases where a beverage was inappropriately labeled as a dietary supplement. FDA also has clear authority under the law to limit the levels of caffeine in any products regulated by the agency if a safety issue arises.

- FDA is currently conducting a review of the data for caffeine safety, both for adults and younger populations and those with pre-existing cardiac or other conditions.

- New laws are not needed; FDA should continue to use the array of regulatory tools available to the agency under the law to protect consumers.

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[5] Nawrot, P., et al., 2003, Effects of caffeine on human health. *Food Additives and Contaminants*, 20(1), 1-30.

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RECOMMENDED GUIDELINES:

Caffeine-Containing Dietary Supplements

PURPOSE:

Whether added as a pure ingredient or incorporated from a naturally-occurring source[1], caffeine is a safe dietary ingredient found in many dietary supplements. CRN supports consumer access to dietary supplements and consumers' ability to make informed decisions about caffeine in the dietary supplements they purchase. Therefore, CRN recommends that its members follow these voluntary guidelines for their products that contain caffeine, and encourages all dietary supplement producers and marketers to follow these recommendations. These guidelines address disclosure of caffeine content and set forth consumer advisories to promote the safe, responsible use of dietary supplements.

VOLUNTARY GUIDELINES:

In addition to compliance with applicable labeling laws and regulations, CRN recommends that its members adhere to the following guidelines for the labeling of caffeine-containing dietary supplements:

A. Disclosure of Total Caffeine Content

The purpose of this guideline is to provide consumers with information on the total caffeine content per serving in dietary supplements, whether from added or naturally occurring caffeine.

1. Caffeine content from both added caffeine and naturally occurring caffeine combined should be declared in milligrams per serving either in the Supplement Facts Box or in a separate statement elsewhere on the label.
2. This section does not apply to dietary supplements that contain no added caffeine and less than 25 mg per serving of naturally occurring caffeine.

B. Label Advisories for Conditions of Use

The purpose of this guideline is to provide consumers with additional information about the use of dietary supplements containing caffeine. As with all dietary supplements, consumers taking medication should consult a healthcare professional about the supplements they are taking.

1. Any supplement with total caffeine content of more than 100 mg per serving should provide the following statements or equivalent language on the product label:

[1] For purposes of this document, "added caffeine" refers to pure anhydrous caffeine. "Naturally occurring caffeine" refers to caffeine that occurs naturally in other dietary ingredients, including, but not limited to green tea, guarana, cocoa, kola nut, and yerba mate.

a. This product is not intended/recommended for children and those sensitive to caffeine.
b. Pregnant or nursing women, those with a medical condition, and those taking medication should consult a healthcare professional before use.

C. Serving Size and Daily Intake Recommendations

The purpose of this guideline is to encourage dietary supplement manufacturers and marketers to establish caffeine levels per serving and total servings per day that are consistent with current science and in compliance with applicable laws.

1. Labeling should provide serving size and daily intake recommendations that are consistent with safety information about caffeine established by competent and reliable scientific evidence.
2. Serving size and daily intake recommendations should comply with Section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act, which requires product ingredients to be safe under the conditions of use recommended in labeling, or if no conditions of use are recommended in the labeling, under ordinary conditions of use.

D. Restraints Against Marketing In Combination with Alcohol

The purpose of this guideline is to discourage marketing of caffeine-containing dietary supplements in a manner that encourages combination with alcohol.

1. CRN members should not advertise, market, or otherwise promote the use of caffeine-containing dietary supplements in combination with alcohol, or to counter the acute or immediate effects of alcohol.

E. Implementation

1. Within twelve months of the effective date, CRN recommends that dietary supplement companies comply with these guidelines for new product labels put into the market.

Effective Date: April 1, 2013

RED BULL NORTH AMERICA'S STATEMENT SUPPLEMENTING THE RECORD OF THE U.S. SENATE COMMITTEE ON COMMERCE, SCIENCE & TRANSPORTATION'S JULY 31, 2013 HEARING ON ENERGY DRINKS: EXPLORING CONCERNS ABOUT MARKETING TO YOUTH

Red Bull North America's Statement Supplementing the Record of the U. S. Senate Committee on Commerce, Science & Transportation's July 31, 2013 Hearing on Energy Drinks: Exploring Concerns About Marketing to Youth

Red Bull of North America would like to clarify the record regarding two of the exhibits presented at the hearing on Wednesday, July 31, 2013.

Senator Durbin referred to an image that he described as being the July 2012 cover of Red Bull's magazine Red Bulletin. The image that he presented was *not* the July 2012 cover of the Red Bulletin magazine. That image has never been used on the cover of any Red Bulletin nor on the cover of any other Red Bull publication. Attached is a copy of the actual cover of the July 2012 Red Bulletin, which features the 29-year-old Olympic Decathlete Trey Hardee.

The image to which Senator Durbin referred is the blow-up of a photograph taken of a Brazilian Red Bull development athlete in a photo booth against a background that makes the person who is in the photo booth *appear* as if he or she is on the cover of Red Bulletin. Photo booths such as these are used at some Red Bull events, and they allow individuals to email their photographs to themselves and/or to post their photographs directly to the individual's Facebook page.

In sum, the exhibit does not portray the actual cover of a Red Bulletin, and Red Bull did not use this photograph to target children.

Senator Markey referred to the blow-up of an Instagram that communicated a message that is inconsistent with Red Bull's support for a healthy life style. But Red Bull did not create this image, and Red Bull did not author this message. Red Bull did, however, re-post the image and the message. A celebrity comedian increased its circulation by posting the graphic on Twitter. In the future, Red Bull will not share such messaging with Red Bull audiences, no matter the age.

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