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Testimony of

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On behalf of the

American Academy of Pediatrics

Before the

Senate Committee on Commerce, Science, and Transportation

“Hearing to examine energy drinks, focusing on exploring concerns about marketing to youth.”

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.ⁱ Caffeine is absorbed by all body tissues, and can have variable effects on the brain, heart, endocrine, gastrointestinal, musculoskeletal, renal and other body systems.ⁱⁱ 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.ⁱⁱⁱ

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.^{iv}

When consumed in higher doses, caffeine intoxication can occur.^v 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.^v 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% to 50% of adolescents and young adults.^v 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).^v

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.^{vi} 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^{vii}. 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 marijuana use, sexual risk-taking, fighting, smoking, drinking, and misuse of prescription drugs.^{viii,ix}

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.^x

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 and totaled \$12.5 billion.^{xi} 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.^{xii} 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.^{xiii} Frequently, companies sponsor young athletes and high school sporting events, and these advertisements promise things such as improved athletic performance and increased attention and alertness.^{xiv}

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.^{xv} 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.^{xvi} 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.^{xvii} 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.^{xviii}

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.^{xix} Notably, adolescents surveyed do not differentiate between “sports drinks” and energy drinks, highlighting the same benefits for both product categories.^{xx}

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.^{xxi} 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.^{xxii} These inconsistencies result in a dearth of information 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.^{xxiii} 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.^{xxiv}

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.^{xxv}

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.^{xxvi}

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*.^{xxvii} 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.^{xxviii} 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 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.^{xxix}
- **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.

ⁱ 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.

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

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

^{iv} 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.

^v 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.

^{vi} 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.

^{vii} American Association of Poison Control Centers, accessed online at <http://www.aapcc.org/alerts/energy-drinks/>

^{viii} Miller, K. E. (2008). Energy drinks, race, and problem behaviors among college students. *Journal of Adolescent Health*, 43(5), 490-497.

^{ix} 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.

^x FDA: Background Information Caffeinated Alcoholic Beverages:

<http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/UCM190372.pdf>

^{xi} 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.

^{xii} 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

^{xiii} *Pediatrics*. 2011 Jun; 127(6):1182-1189.

^{xiv} 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.

^{xv} 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

^{xvi} *Ibid*

^{xvii} 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.

^{xviii} American Academy of Pediatrics, Committee on Communications. Policy Statement: Children, Adolescents, and Advertising. *Pediatrics*. 2006 Jun; 118(6): 2563-2569.

^{xix} *Ibid*

^{xx} *Pediatrics*. 2011 Jun; 127(6):1182-1189.

^{xxi} *Ibid*

^{xxii} 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.

^{xxiii} *Ibid*.

^{xxiv} *Pediatrics*. 2011 Jun; 127(6):1182-1189.

^{xxv} FDA GRAS Notices, http://www.accessdata.fda.gov/scripts/fcn/gras_notices/grn000347.pdf

^{xxvi} FDA,

<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAct/SignificantAmendmentstotheFDCAct/ucm148003.htm>

^{xxvii} FDA, "Energy Drinks" and Supplements: Investigation into Adverse Event Reports, <http://www.fda.gov/Food/NewsEvents/ucm328536.htm>

^{xxviii} FDA: Guidance Document

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm196903.htm>

^{xxix} *Pediatrics*, Vol. 118 No.6 December 2006, pp 2563 - 2569