WRITTEN TESTIMONY OF
RODNEY SACKS
CHAIRMAN AND CHIEF EXECUTIVE OFFICER
MONSTER BEVERAGE CORPORATION

BEFORE THE
COMMITTEE ON COMMERCE, SCIENCE, & TRANSPORTATION

U.S. SENATE

JULY 31, 2013

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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% 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% 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%) 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

[1] The original label was amended a few years ago to include the reference to women who are nursing.

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, 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.

16oz

160mg of Caffeine

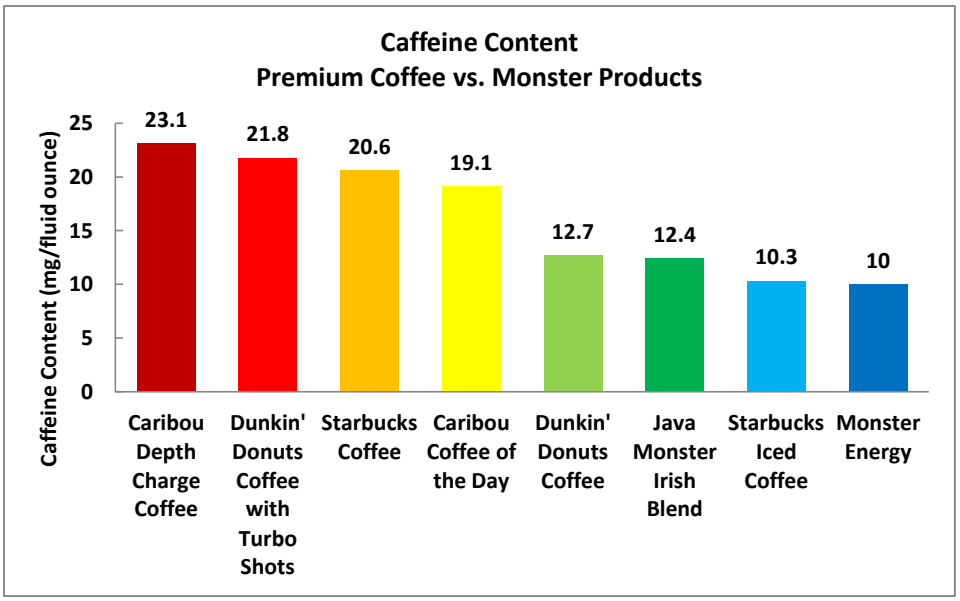
Monster Energy

16oz

330mg of Caffeine

Starbucks

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.

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July 29, 2013

Margaret A. Hamburg, MD
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

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,

[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).

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 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.

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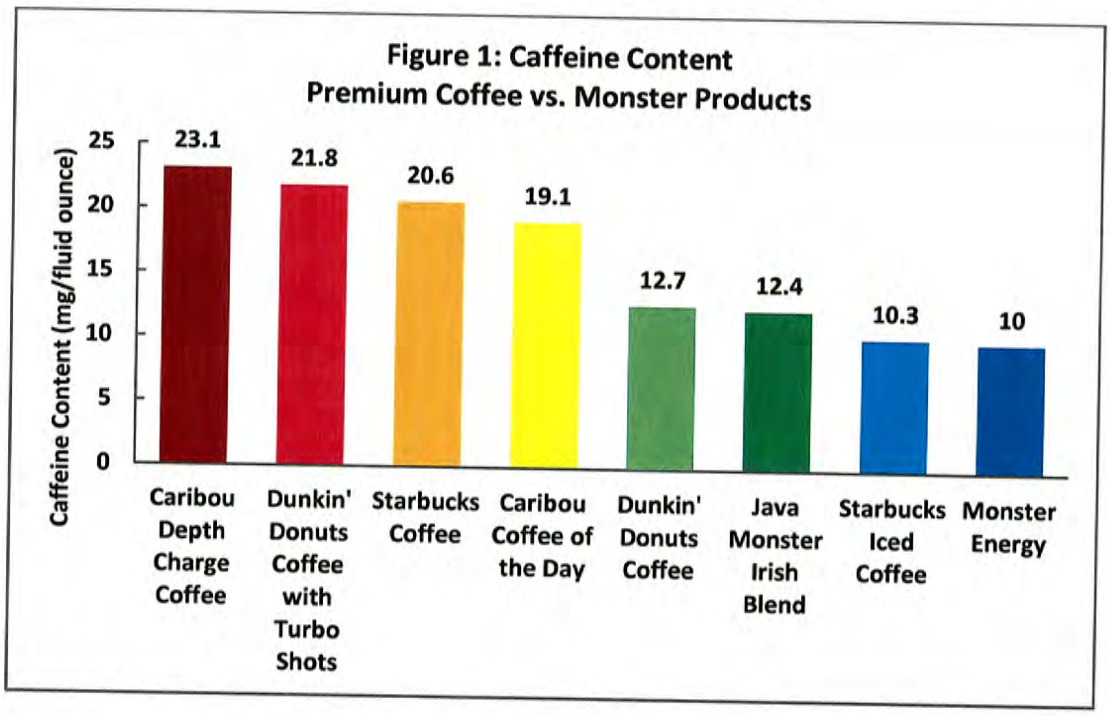
[2] *Id.*

[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.

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% 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).



[4] *See, e.g.*, Letter at 1.

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
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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
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[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.

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% 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 appeared 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.

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[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.

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% 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

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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.

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.

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

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[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).

and young adults has remained stable or *decreased* between 2001 - 2010, despite the availability of energy drinks (Table 3 and Figure 2).

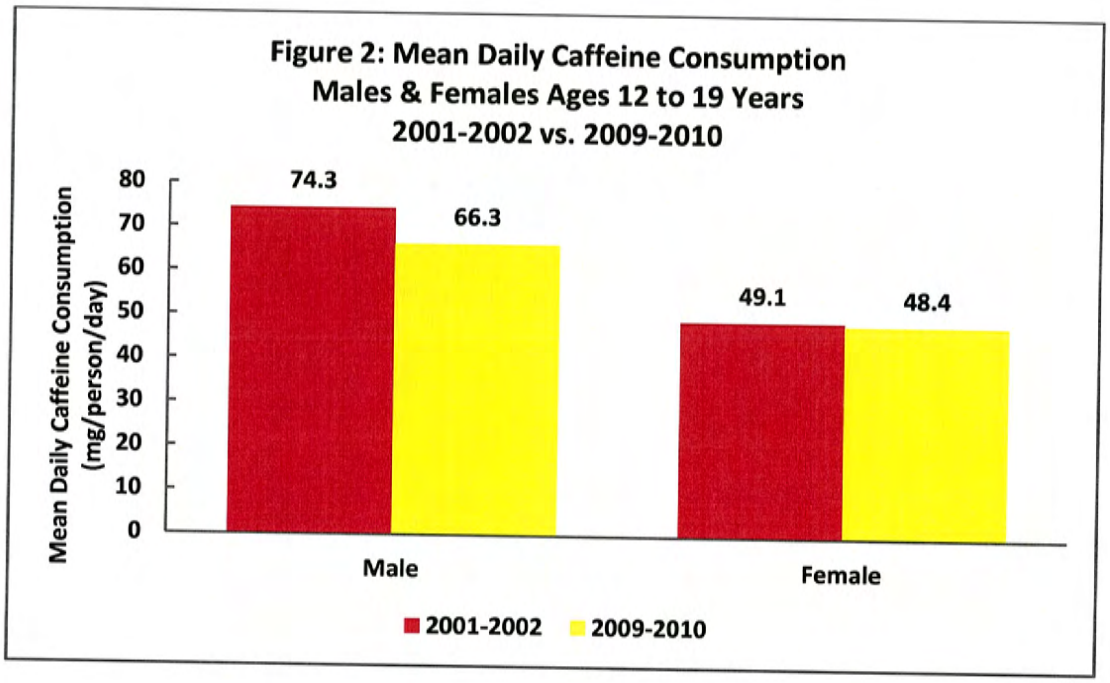

Table 3. Caffeine Intakes From Beverages and Foods (NHANES 2001-2010)*				
Age (years)	Caffeine (mg)/person			
	2001-2002[1]	2005-2006[2]	2007-2008[3]	2009-2010[4]
Males				
2-5	15.2	8.4 ± 0.72	7.8 ± 0.80	6.0 ± 0.70
6-11	26.1	19.7 ± 2.74	29.9 ± 3.59	18.2 ± 1.78
12-19	74.3	69.5 ± 6.70	73.6 ± 10.18	66.3 ± 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

[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").

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% of 14-21 year old individuals are "regular energy drinkers."[19] Somogyi assumed that 2% 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% 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

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[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.

[19] Somogyi, *supra* note 14, at 61; Somogyi assumed that 2% 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.

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%) 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% 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% of teens aged 13 to 17 rarely or never consumed energy drinks, with only 1.5% 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% reported that they rarely or never consumed energy drinks as compared to only 1% of participants who consumed them daily.[27]

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[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).

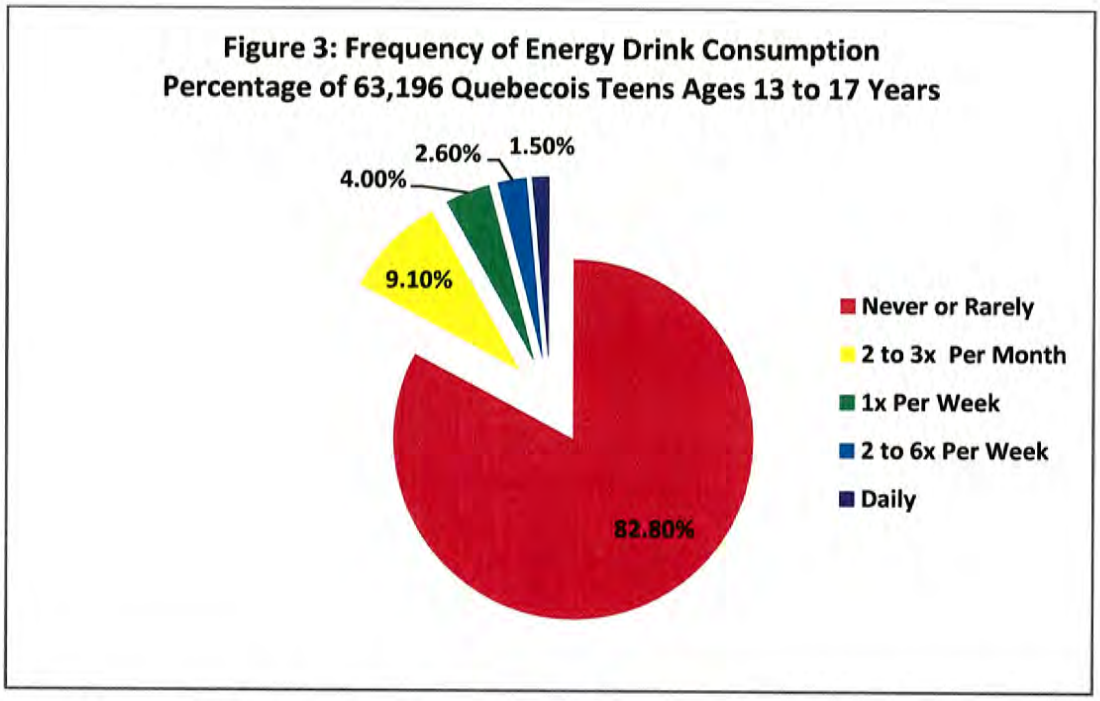
[23] *Id* (emphasis added).

[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% 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%, 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% 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.

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[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).

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% of energy drink consumers are 13-to 35-year-olds" and that "[M]ore recent reports show that 30 to 50% of adolescents and young adults consume energy drinks."[29] Such statistics provide no information 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% of eighth graders and 29% 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% 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.

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[29] Letter at 1-2. The Authors cite one of their own articles to suggest that 30% to 50% 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% to 34% 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% of adolescents had "tasted" energy drinks, 24% drank <1 8 oz. can per week, and 3% 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 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).

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:

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[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).

- 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 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% 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]

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[35] J. Shen, *Dietary Factors and Incident Atrial Fibrillation: the Framingham Heart Study*, 93 AM. J. CLIN. NUTRITION 261, 261 (2011) ("Framingham Study").

[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,
(continued...)

- 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

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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.

evidence (see, for instance, the discussion immediately below) supports the paper's basic conclusions.

- 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% 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

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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.

incident atrial fibrillation (multivariable-adjusted relative risk: 0.78, 95% 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% 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% 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 intake: 51 mg/day), there was no significant difference in the relative risk of coronary heart disease.[62]

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[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.

[62] *Id.* at 461, Figure 1.

- 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

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[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).

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 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

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[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.

[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.

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% confidence interval: 0.41-1.47; epilepsy relative risk: 0.97, 95% 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% confidence interval: 0.80-1.11, p = 0.5; epilepsy relative risk: 0.97, 95% 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.

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[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).

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 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.

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[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.

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

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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).

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 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]

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[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.

[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

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]

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[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.

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.

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

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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).

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) 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

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[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.

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% 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

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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).

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 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

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[106] *Id.* at 134.

[107] PEDIATRICS 2011, *supra* note 103, at 1185.

[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).

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

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[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).

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 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

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[116] Letter at 5.

[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).

"[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

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[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).

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 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.

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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).

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,

Miriam J. Guggenheim
Counsel to Monster Beverage Corporation

cc: Michael Taylor
Michael Landa