Caffeinated Beverages

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Agenda

Background
- Caffeine and Energy Drink Misperceptions
- Caffeine 101
- Latest Caffeine Reviews

ABA Caffeine Research
- U.S. FDA Areas for Further Inquiry
- Highlights
- Pipeline (Details)
- Key Takeaways

ABA Additional Efforts
- ABA Energy Drink Guidelines
- ABA Energy Drink Microsite

Summary and Next Steps

Background

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Since the introduction of energy drinks into both the North American and European markets over two decades ago, comprehensive and robust datasets on caffeinated beverage consumption patterns and trends, caffeine effects and caffeine clearance have been developed.

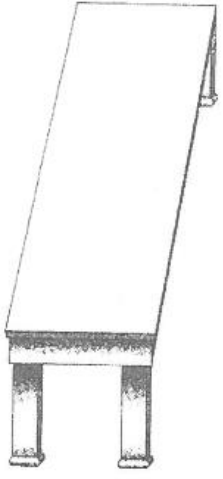
Large body of evidence available to inform sound science-based policies.

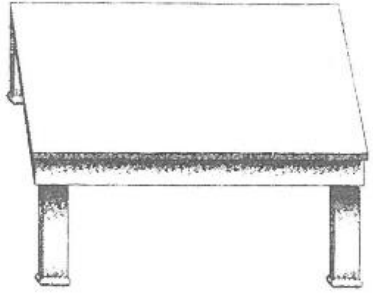
Existing FSSAI requirements

- **≤ 145 mg caffeine/L:** CONTAINS CAFFEINE
- **145 mg/L < x ≤ 300 mg/L:** CONTAINS CAFFEINE

High Caffeine Content. Xx mg/serving size. Not recommended for children, pregnant or lactating women, or people sensitive to caffeine.

Are these tables' dimensions different?





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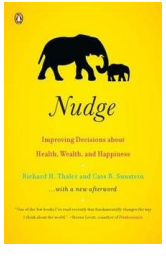

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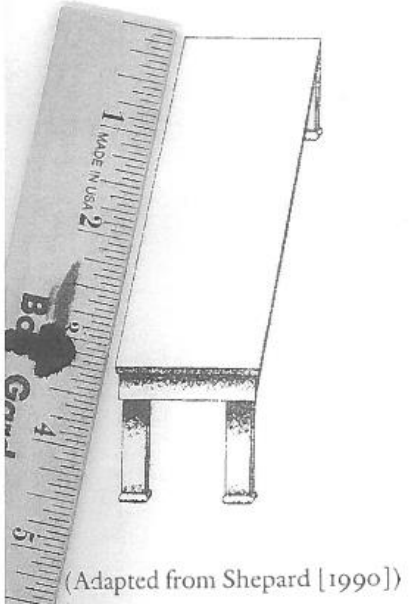
Perception versus reality - Scientific Objectivity



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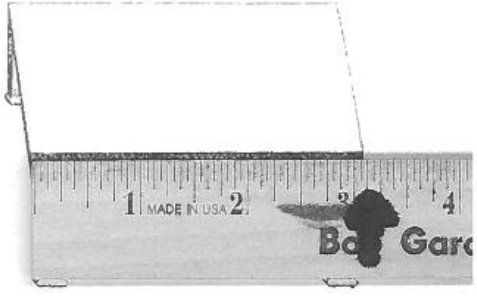

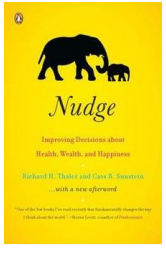

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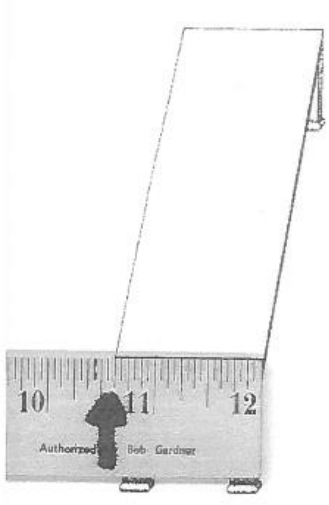

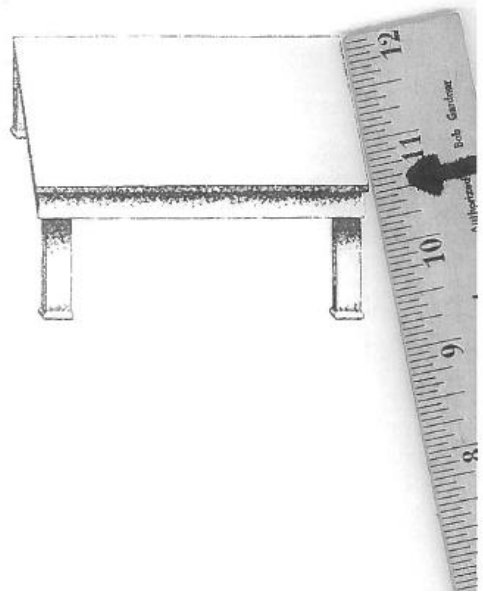

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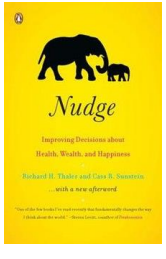

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Caffeine Misperceptions

Misperception: Energy drinks contain excessive amounts of caffeine.

FACT: Energy drinks have about half the caffeine of a similarly-sized brewed coffeehouse coffee

Caffeine Misperceptions

Misperception: The growth of the energy drink category has led to higher levels of caffeine consumption across the population.

FACT: For all age groups, overall caffeine intake has not increased since energy drinks entered the market. This is due to apparent substitution of caffeinated beverage sources.

Caffeine Misperceptions

Misperception: Teens and young adults are uniquely vulnerable to the effects of caffeine.

FACT: Children and adolescents are not at a unique risk for health effects from caffeine consumption, including from energy drinks.

- After infancy, caffeine-dose response is a function of body weight, not age.
- 'Caffeine clearance in children and adolescents is at least that of adults…' (EFSA, 2015)

Caffeine Misperceptions

Misperception: Other energy drink ingredients may enhance caffeine effects.

FACT: Mixture of a handful of ingredients in energy drinks is ‘unlikely’ to ‘adversely’ modulate effects from caffeine. (EFSA, 2009, 2015) While coffee contains over 1,000 compounds. (coffeechemistry.com)

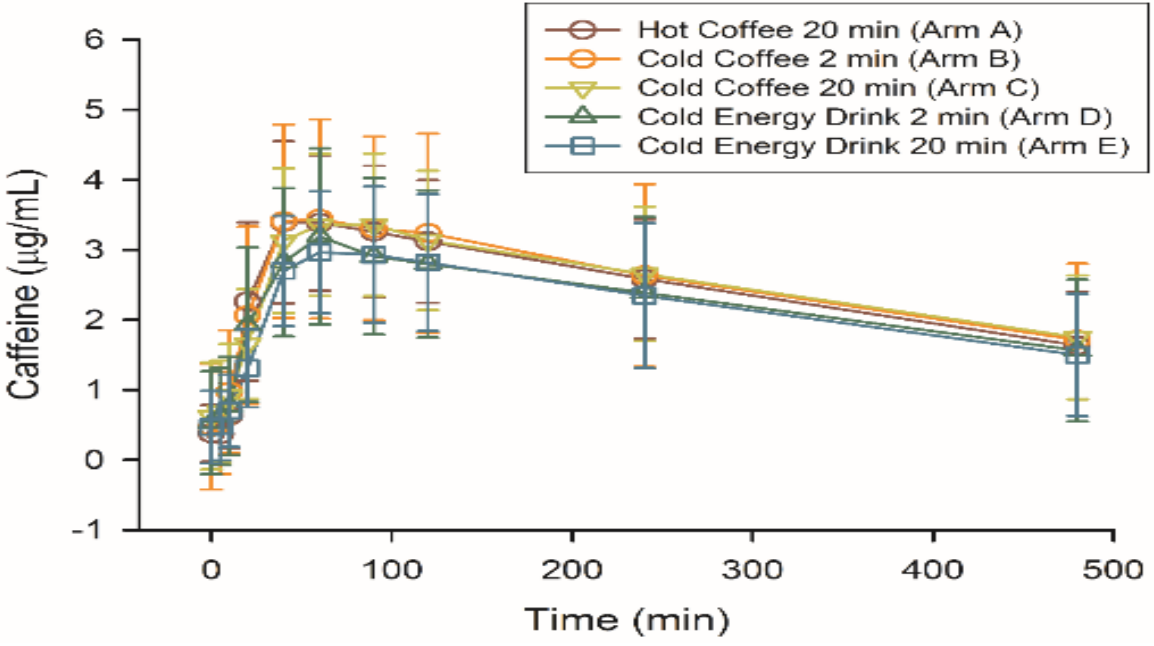
Caffeine 101

FACT 1: Caffeine has been safely consumed for hundreds of years, in hundreds of countries, by billions of people (everyday).

FACT 2: Caffeine is one of the most studied ingredient in the food supply!

FACT 3: Caffeine is caffeine, no matter the source. Whether naturally occurring or synthetic, or hot or cold, it is chemically identical and has the same effect on the human body.

No difference in caffeine clearance between natural/synthetic or hot/cold



- No meaningful difference in caffeine PK (160 mg)
- Independent of rate of consumption, beverage temp or vehicle

*** Analyses by Washington State University (ABA funded)**

Latest Caffeine Reviews

2017 ILSI NA 2017 (systematic review 2001-2015)
Reasserts confidence that 400 mg/day of caffeine is not associated with adverse health effects

2015 EFSA
Caffeine safety reaffirmed among children, adolescents and adults

EFSA Caffeine Reviews – Safety Reaffirmed

EFSA 2015 Scientific Opinion on the Safety of Caffeine

- '…***[C]onservative*** approach'
- No safety concerns from caffeine consumption for…
    - Single dose up to 200 mg (adults), and up to 3 mg/kg bw (children and adolescents, 3-18 years)
    - Daily up to 400 mg (adults), and up to 3 mg/kg bw (children and adolescents, 3-18 years)
- Above quantities ***not upper limits*** for safe caffeine consumption, nor amounts over these levels unsafe.
- '[C]ommon constituents… not expected to adversely interact with caffeine on its effects…'

EFSA 2009 Scientific Opinion on the use of taurine and D-glucurono-γ-lactone as constituents of the so-called "energy" drinks

- '…[U]nlikely that D-glucurono-γ-lactone would have any interaction with caffeine…'
- '…[E]xposure to taurine… at levels currently used in "energy" drinks … is not a safety concern.'

Caffeine Reviews - Conclusions

- The overwhelming majority of consumers do not exceed EFSA's caffeine consumption levels not associated with adverse health effects.
- Overall caffeine intake has not increased since energy drinks entered the market, due to apparent substitution of caffeine sources by caffeine consumers.
- More than 90% of population's caffeine intake comes from coffee (mostly), tea, and soft drinks.
- Energy drinks contribute only very small portion of caffeine consumers' total daily caffeine consumption, even among teens. In both U.S. and Europe, energy drinks constitute about 10% or less of daily caffeine intake for all age groups of caffeinated-beverage consumers.
- After infancy, caffeine dose-response is largely a function of body weight (mg/kg), not age and effects are transient.

ABA Caffeine Research

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U.S. FDA Areas for Further Inquiry

- Caffeine consumption patterns and trends
- Acute effects of energy drink consumption (poison control center)
- Chronic effects of caffeine consumption

ABA Caffeine Research – Highlights

- Caffeine intake among adolescents and young adults half that of older adults.
- Apparent substitution of caffeinated sources. American's overall caffeine intake has not increased over time. Increased prevalence among coffee consumers, slight increase in prevalence of energy drink consumers and decreased prevalence among soda consumers.
- Major source of caffeine among Americans is coffee.
- As Americans get older, their higher caffeine intake results from increased coffee consumption.
- Most caffeine consumed primarily mornings, driven by coffee.
- No evidence of major adverse events from energy drink consumption alone.
- Effects from caffeine not adverse, even among teen and young adults.

ABA Caffeine Research - Pipeline

- Exponent caffeine intake – trends/patterns (published)
- Intertek/Kantar caffeine intake patterns (published)
- NHANES 2013-2014 pattern clustering (*manuscript in preparation*)

- Contextualize poison control center incident reporting data (published)

- Support for ILSI NA comprehensive review (published)
- CNS effects – what is considered adverse? (published)
- CVD effects – (published)

- Pharmacokinetics of caffeine consumption (hot and cold beverage comparison) (published)

Caffeine consumption patterns and trends

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Food and Chemical Toxicology

Trends and patterns of caffeine consumption among US teenagers and young adults, NHANES 2003–2012

Caffeine consumption patterns and trends Across NHANES cycles 2003-2012

Exponent
Engineering and Scientific Consulting

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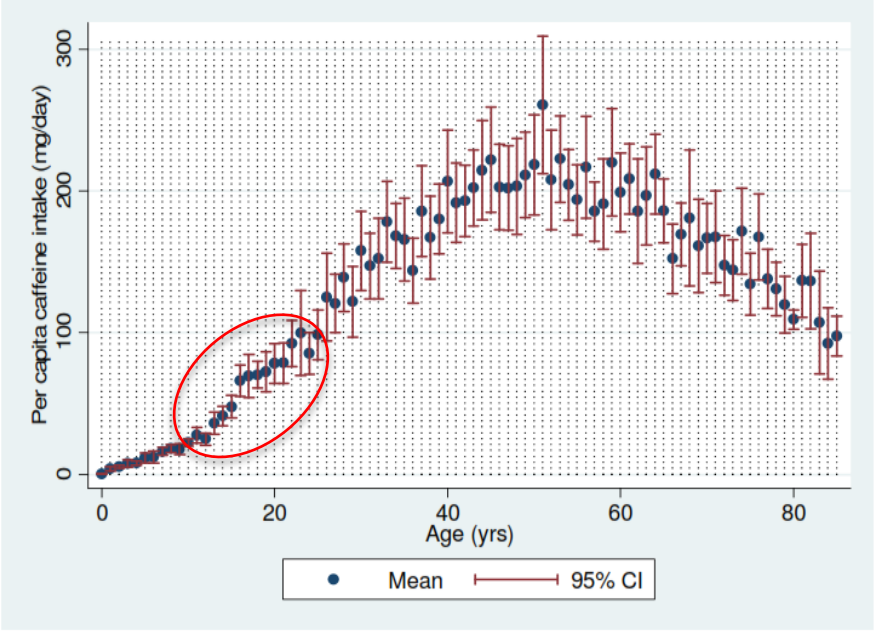
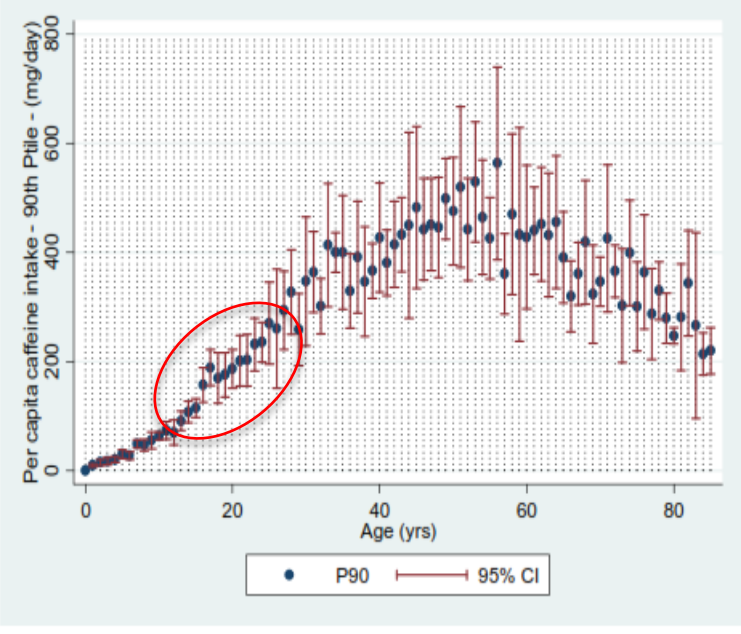
Caffeine consumption rises with increasing age (2-day average)*

Mean



90th Percentile

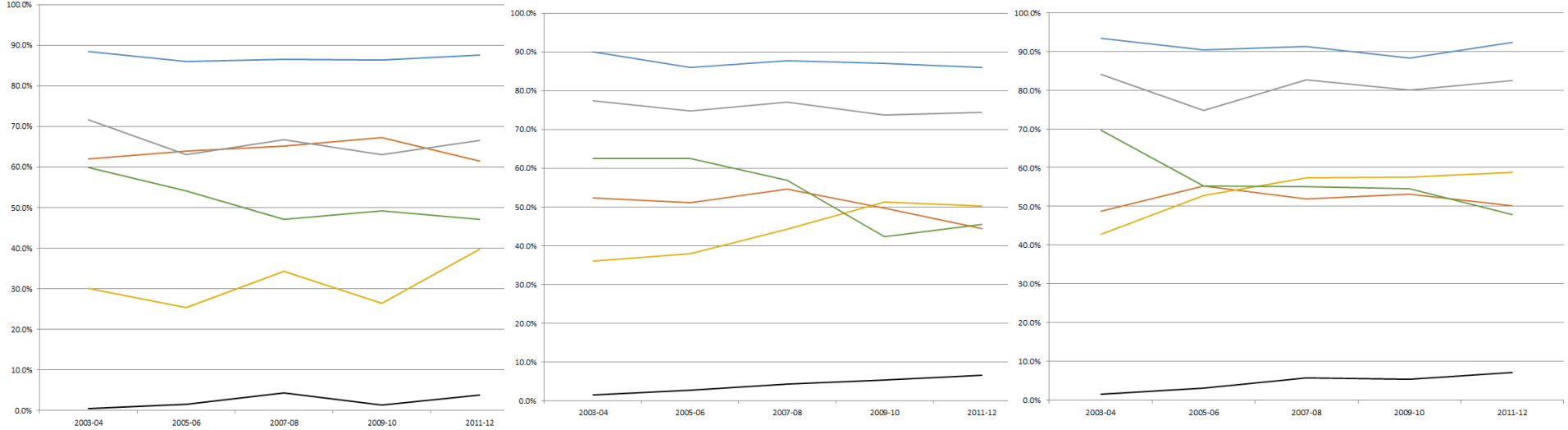


NHANES 2003-2012

*** Analysis by Exponent (NHANES 2-day survey)**

Prevalence of energy drink consumers overshadowed by all other caffeinated beverage consumers

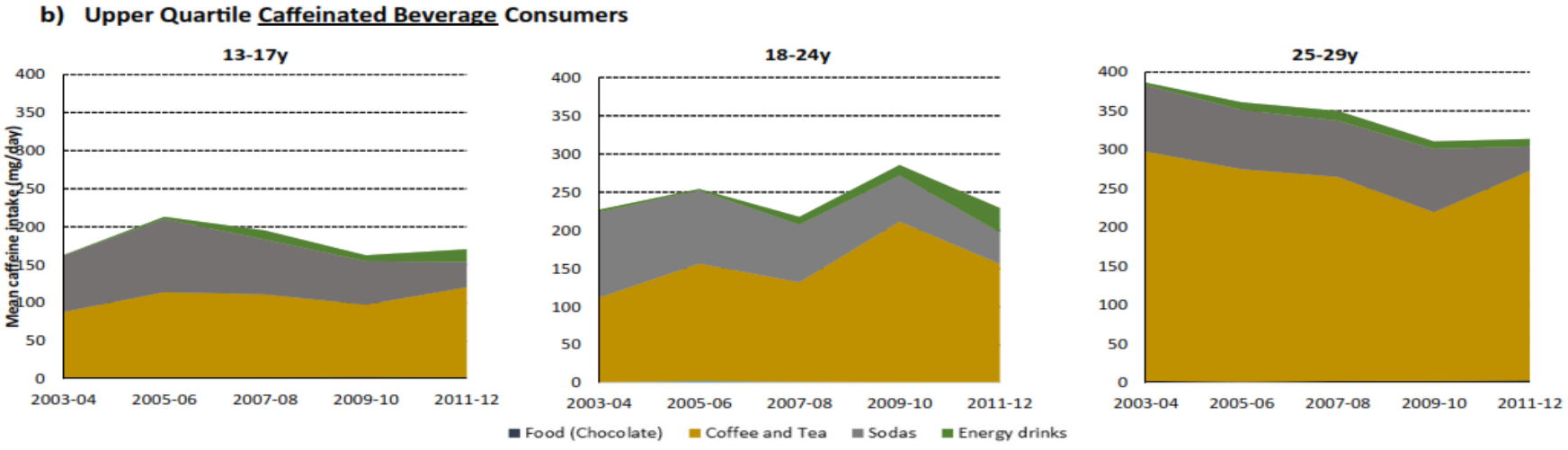
13-17 yrs **18-24 yrs** **25-29 yrs**



All caffeine **Beverages** **Food** **Coffee+Teas** **Sodas** **Energy Drinks**

*** Analysis by Exponent (NHANES 2-day survey)**

Substitution of caffeinated beverage sources
Major caffeine contributor is coffee, increasing with age



*** Analysis by Exponent (NHANES 2-day survey)**

Caffeine consumption patterns and trends across weekdays and time of day

intertek
Total Quality. Assured.
KANTAR WORLDPANEL

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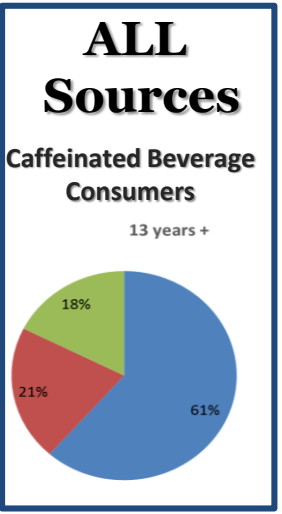
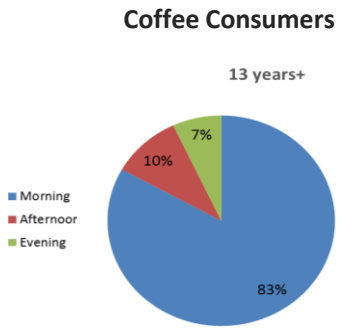
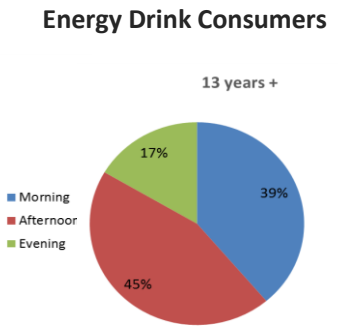
Coffee drives morning caffeine consumption

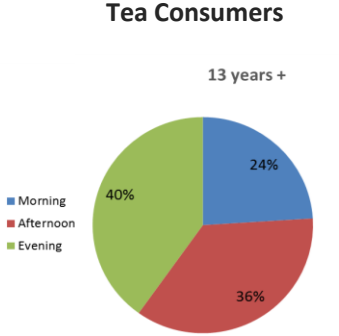
- Most caffeine primarily mornings – driven by coffee.
- Caffeine from coffee, primarily mornings.
- Caffeine from energy drinks, primarily mornings and afternoons.
- Caffeine from teas and sodas, primarily afternoon and evening.

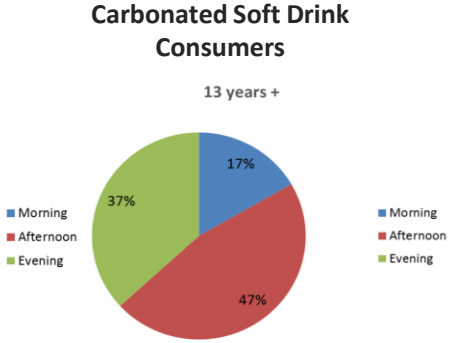
ALL Sources











*** Analysis by Intertek/Kantar (KWP conducted a 7-day beverage survey)**

Caffeine consumption patterns and trends Across NHANES cycle 2013-2014

Cardno ChemRisk
Shaping the Future

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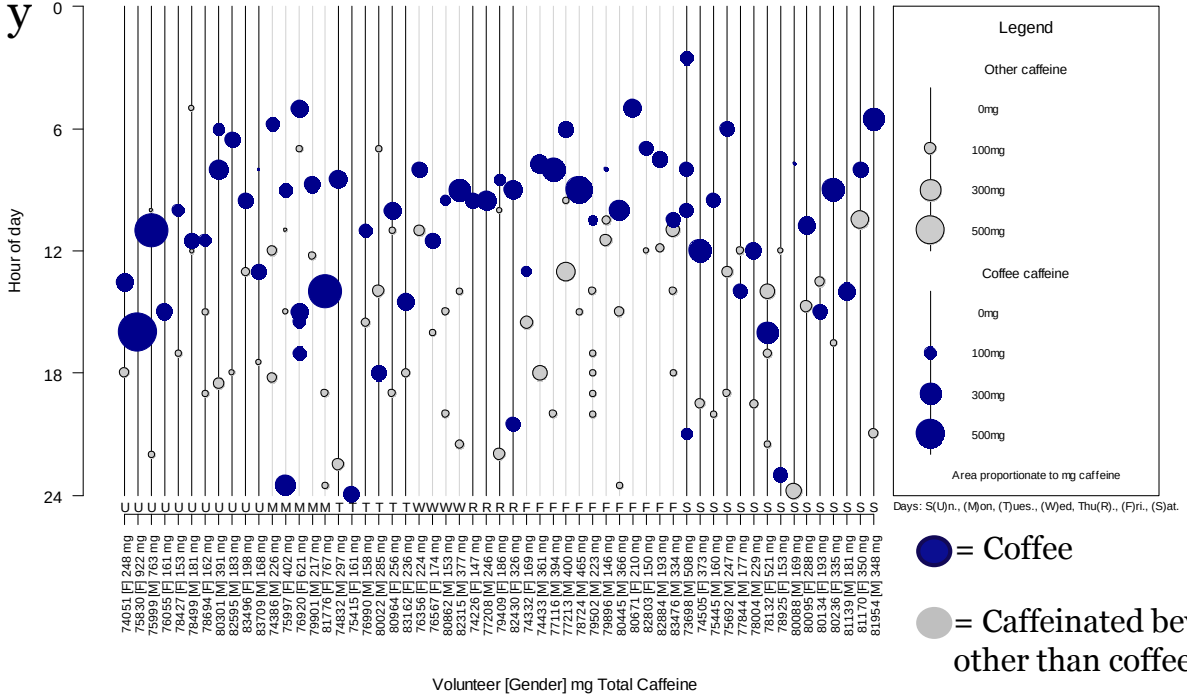
Individual caffeine consumption patterns: Coffee consumers 18-24 y* (upper quartile)

Comparison between 18-24 y coffee & energy drink consumers:

1. More coffee consumers among upper quartile.
2. On individual basis, caffeine from coffee far exceeds that from energy drinks.
3. Caffeinated beverages are not additive. Mostly substitution observed.



*** Analysis by Cardno ChemRisk (NHANES 2013-2014, 1-Day Recall)**

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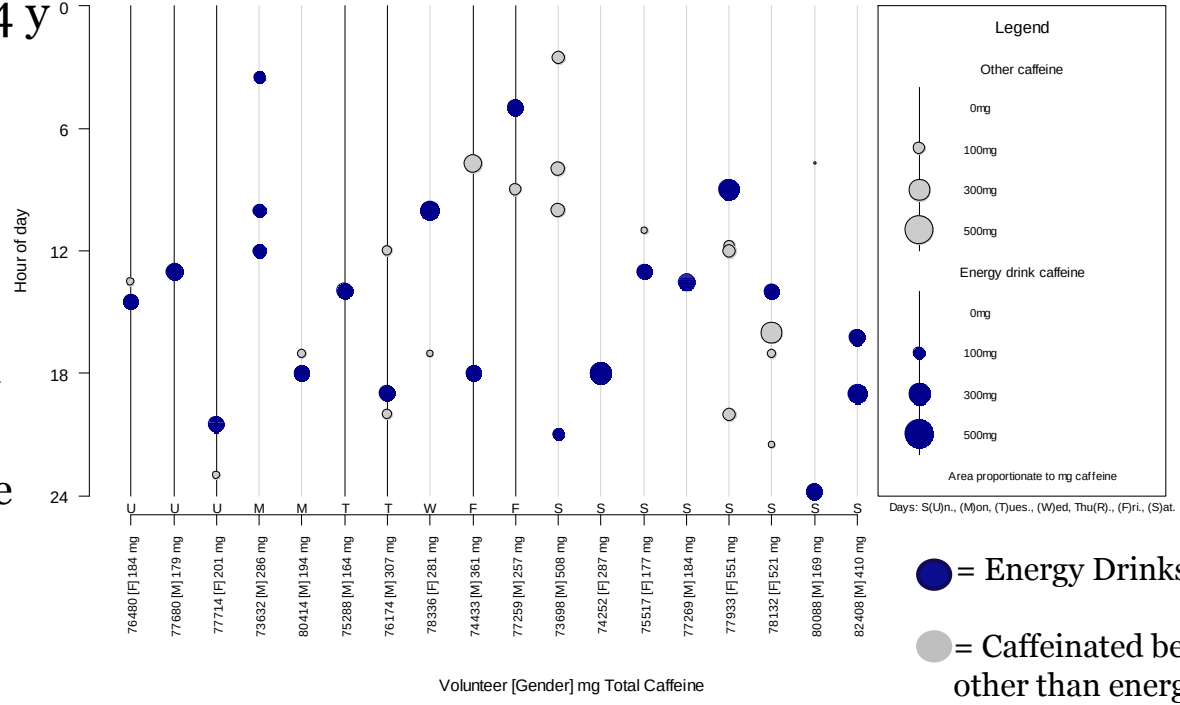

= Energy Drinks

= Caffeinated beverages other than energy drinks

*** Analysis by Cardno ChemRisk (NHANES 2013-2014, 1-Day Recall)**

Caffeine adverse events incident reporting in Texas

TEXAS TECH UNIVERSITY

TEXAS Health and Human Services

Texas Department of State Health Services

SafetyCall INTERNATIONAL

BEVERAGE MARKETING CORPORATION

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Virtually no adverse events over 5 year span – Texas case study

0.000000000633

Incident reports (major or moderate outcomes) per energy drink unit

*** Analysis by TexasTech**

Virtually no adverse events per 100,000,000 energy drink beverages sold* – Texas case study

Year	Energy Beverages Sold in Texas***	Year-over-year growth of energy beverages sold	Texas population estimates	Annual Energy Beverages Sold Per Capita	Moderate / Major Outcomes for Energy Beverages	Moderate / Major Outcomes per Hundred Million Energy Beverage Units Sold	Moderate / Major Outcomes per Hundred Thousand Population
2010	327,373,703	ND	25,244,310	13.0	0/0	0/0	0/0
2011	343,707,798	5.0%	25,646,389	13.4	3/1	0.87/0.29	0.01/0.004
2012	371,057,399	8.0%	26,071,655	14.2	2/0	0.54/0	0.008/0
2013	395,061,356	6.5%	26,473,525	14.9	1/0	0.25/0	0.004/0
2014	443,572,051	12.3%	26,944,751	16.5	5/0	1.13/0	0.019/0
Total	1,880,772,308	35.5%			11/1	0.58/0.053	
Mean ± SD	376,154,462 ± 45,719,062		26,076,126 ± 668,776	14.4 ± 1.4			0.008 ± 0.007/0.0008 ± 0.002

Pharmacovigilance trigger when more than 1 adverse event report (for a given type) per 10,000 products sold.

Per 100,000,000 energy beverages sold, more than 10,000 adverse event reports (of a given adverse event type) would be required.

** **Energy beverages = Energy drinks that are considered conventional beverages**

* **Analysis by TexasTech**

ToxStrategies

ENVIRON

ENVIRON

ILSI NA caffeine review
ABA-funded CNS and CVD caffeine review

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Effects from caffeine not adverse, even among teen and young adults

- 2017 ILSI NA/ToxStrategies* review reasserts confidence in 400 mg/d
  - (Health outcomes of interest – cardiovascular (CVD), behavioral, repro/ developmental, acute, bone status)

- 2016-2017 Environ reviews** on central nervous system (CNS) and CVD effects suggest arbitrary default could be elevated to 600 mg/d generally
  - Potential CNS/behavioral effects of interest – sleep disturbances, anxiety, aggression/risk-taking
  - Broad spectrum of potential CVD effects

*** ILSI review partially funded by ABA**
**** Environ reviews funded by ABA**

ABA Caffeine Research - References

1. Tran, N.L., L.M. Barraj, X. Bi and Jack, M.M. 2016. Trends and Patterns of Caffeine Consumption among US Teenagers and Young Adults, NHANES 2003 – 2012. *Food and Chemical Toxicology*. 94: 227-242 http://dx.doi.org/10.1016/j.fct.2016.06.007
2. Martyn, D., A. Lau, P. Richardson and A. Roberts. 2018. Temporal patterns of caffeine intake in the United States. Food and Chemical Toxicology. 111: 71-83 https://doi.org/10.1016/j.fct.2017.10.059
3. Benson, S.M., K.M. Unice, M.E. Glynn. Hourly and Daily Caffeine Consumption Patterns among U.S. Teenagers and Young Adults, NHANES 2011-2014. *Manuscript in preparation*.
4. Turnbull, D., J.V. Rodricks and G.F. Mariano. 2016. Neurobehavioral Hazard Identification and Characterization for Caffeine. *Regulatory Toxicology and Pharmacology* 74: 81-92; http://dx.doi.org/10.1016/j.yrtph.2015.12.002
5. Turnbull, D., J.V. Rodricks, G.F. Mariano and F. Chowdhury. 2017. Caffeine and Cardiovascular Health. *Regulatory Toxicology and Pharmacology* 89: 165-185 http://dx.doi.org/10.1016/j.yrtph.2017.07.025
6. Borron, S.W., S.H. Watts, J. Herrera, J. Larson, S. Baeza, R.L. Kingston. Energy drink exposures reported to Texas Poison Centers: Analysis of adverse incidents in relation to total sales, 2010-2014. *Regulatory Toxicology and Pharmacology*. https://doi.org/10.1016/j.yrtph.2018.05.008
7. White, J.R. Jr., J.M. Padowski, Y. Zhong, G. Chen, S. Luo, P. Lazarus, M.E. Layton, S. McPherson. 2016. Pharmacokinetic Analysis and Comparison of Caffeine Administered Rapidly or Slowly in Coffee Chilled or Hot vs. Chilled Energy Drink in Healthy Young Adults. *Clinical Toxicology*. 54:4, 308-312; http://dx.doi.org/10.3109/15563650.2016.1146740
8. Wikoff D, Welsh BT, Henderson R, *et al*. Systematic review of the potential adverse effects of caffeine consumption in healthy adults, pregnant women, adolescents and children. *Food Chem Toxicol*. 2017. http://dx.doi.org/10.1016/j.fct.2017.04.002 - ILSI NA study, ABA partially funded
9. Adamson, R.H. 2016. The acute lethal dose 50 (LD_{50}) of caffeine in albino rats. *Regulatory Toxicology and Pharmacology* 80: 274-276. http://dx.doi.org/10.1016/j.yrtph.2016.07.011

ABA Caffeine Research – Key Takeaways

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U.S. FDA Areas for Further Inquiry	Summary of Evidence
Caffeine consumption pattern and trends	Exponent 2-day NHANES 2003-12 caffeine trends/patterns (published) Intertek/Kantar 7-day caffeine patterns (published) Cardno 1-day NHANES 2013/14 caffeine pattern clustering (*manuscript in preparation*)
Acute effects of energy drink consumption (PCC)	Texas poison control center incident reporting data (published)
Chronic effects of caffeine consumption	Support ILSI NA comprehensive review (published) Environ CNS effects (published) Environ CVD effects (published) Pharmacokinetics of caffeine consumption (hot/cold) (published) 2015 EFSA Caffeine Opinion 2009 EFSA Energy Drink Ingredients Opinion

Key Takeaways

- American's overall caffeine consumption trends over time are relatively stable.
- Apparent substitution (not addition) of caffeinated sources among caffeinated beverage consumer types.
- Major source of caffeine among Americans is coffee. Most caffeine consumed primarily mornings, driven by coffee.
- Caffeine intake among adolescents and young adults are half that of older adults.
- Effects from caffeine not adverse, even among teen and young adults. After infancy, caffeine effects are a function of body weight. Caffeine clearance among children is at a minimum equivalent to adults.
- No evidence of major adverse events from energy drink consumption alone, and none among adolescents. Reported energy drink beverage adverse events are misrepresented. True adverse event reports are very rare and likely due to confounders.
- No central nervous system or cardiovascular-related safety concerns up to 600 mg caffeine/d (limited data at levels > 600 mg/d).

ABA Additional Efforts

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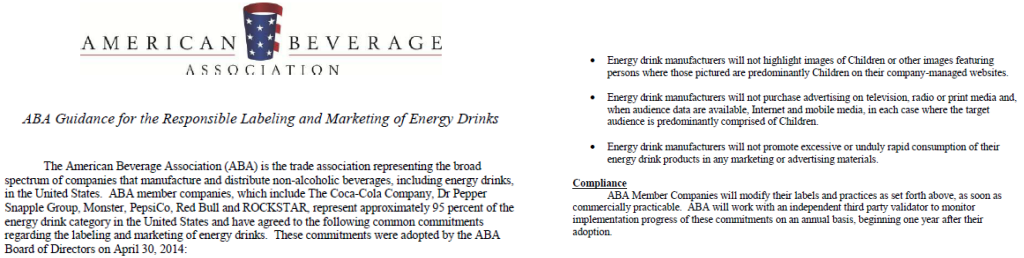
2014 ABA Guidance for the Responsible Labeling and Marketing of Energy Drinks



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ABA Guidance for the Responsible Labeling and Marketing of Energy Drinks

The American Beverage Association (ABA) is the trade association representing the broad spectrum of companies that manufacture and distribute non-alcoholic beverages, including energy drinks, in the United States. ABA member companies, which include The Coca-Cola Company, Dr Pepper Snapple Group, Monster, PepsiCo, Red Bull and ROCKSTAR, represent approximately 95 percent of the energy drink category in the United States and have agreed to the following common commitments regarding the labeling and marketing of energy drinks. These commitments were adopted by the ABA Board of Directors on April 30, 2014:

Labeling

- Energy drinks will be labelled as conventional foods/beverages, and not as dietary supplements.
- Energy drink labels will declare the total quantity of caffeine (from all sources) in the container, on a per can/bottle basis and, for multi-serving containers, on a per serving basis (e.g., "caffeine content: xx mg/8 fl oz; yy mg/per can."). This quantitative caffeine declaration will be separate and apart from the ingredient statement and the Nutrition Facts Panel.
- Energy drinks labels will include the following advisory statement, or its equivalent: "Not (intended/recommended) for children, pregnant or nursing women (and/or persons/those) sensitive to caffeine."
- Energy drink labels will not promote mixing with alcohol nor make any claims that the consumption of alcohol together with energy drinks counteracts the effects of alcohol.
- Energy drink labels will not promote excessive or unduly rapid consumption.

Marketing

- Energy drink manufacturers will not market their energy drink products to children under 12 years of age ("Children") as set forth in the International Council of Beverages Associations' (ICBA) Global Policy on Marketing to Children.
- Energy drink manufacturers will not sell or market their energy drink products in K-12 schools, in accordance with the industry's School Beverage Guidelines and in the ABA statement regarding the Sale of Energy Drinks in Schools. In addition, energy drink manufacturers will not market or sell their energy drink products at K-12 school events or activities on K-12 school premises, and will use commercially reasonable efforts to encourage third party distributors that deliver and sell their energy drink products to comply with these practices.
- Energy drink manufacturers will not provide energy drink product samples or product coupons to Children, nor will they provide energy drink product samples or product coupons in the immediate vicinity of K-12 schools. In addition, energy drink manufacturers will use commercially reasonable efforts to encourage their third-party distributors that deliver and sell their products to comply with these practices.
- Energy drink manufacturers will not highlight images of Children or other images featuring persons where those pictured are predominantly Children on their company-managed websites.
- Energy drink manufacturers will not purchase advertising on television, radio or print media and, when audience data are available, Internet and mobile media, in each case where the target audience is predominantly comprised of Children.
- Energy drink manufacturers will not promote excessive or unduly rapid consumption of their energy drink products in any marketing or advertising materials.

Compliance

ABA Member Companies will modify their labels and practices as set forth above, as soon as commercially practicable. ABA will work with an independent third party validator to monitor implementation progress of these commitments on an annual basis, beginning one year after their adoption.

Features

- Total caffeine declaration per container
- Statement: Not (intended/recommended) for children, pregnant or nursing women or persons sensitive to caffeine.
- No marketing/advertising to children< 12
- No energy drinks in K-12

ABA Energy Drink microsite

Summary and Next Steps

AMERICAN BEVERAGE ASSOCIATION

Summary

Additional data reconfirms prior safety findings.

Caffeine should be treated similarly, whether intrinsic or added. Exposure to total caffeine is what matters.

Caffeine in beverages, including energy drinks, remains safe.

ABA members voluntarily disclose caffeine content, place statement on-pack and do not market to children.