Caffeinated Beverages

Maia Jack, Ph.D.
ABA Vice President, Science and Regulatory Affairs
mjack@ameribev.org
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
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

- $\leq 145$ mg caffeine/L: CONTAINS CAFFEINE
- $145$ mg/L < $x \leq 300$ 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?

(Adapted from Shepard [1990])
Perception versus reality - Scientific Objectivity

(Adapted from Shepard [1990])
Perception versus reality - Scientific Objectivity

(Adapted from Shepard [1990])
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)
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. (coffechemistry.com)
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...
  o Single dose up to 200 mg (adults), and up to 3 mg/kg bw (children and adolescents, 3-18 years)
  o 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
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
Caffeine consumption patterns and trends across NHANES cycles 2003-2012
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.
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
ABA Caffeine Research – Highlights

• Caffeine intake among adolescents and young adults half that of older adults.
• Apparent substitution of caffeinated sources. American’s 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.
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.

* Analysis by Intertek/Kantar (KWP conducted a 7-day beverage survey)
Caffeine consumption patterns and trends
Across NHANES cycle 2013-2014
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.
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)
Individual caffeine consumption patterns: Energy Drink 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)
Caffeine adverse events incident reporting in Texas
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.
Virtually no adverse events over 5 year span – Texas case study

0.00000000633
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

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

* Analysis by TexasTech

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


ABA Caffeine Research - Key Takeaways
<table>
<thead>
<tr>
<th>U.S. FDA Areas for Further Inquiry</th>
<th>Summary of Evidence</th>
</tr>
</thead>
</table>
| 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
2014 ABA Guidance for the Responsible Labeling and Marketing of Energy Drinks

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
Energy drinks are a popular non-alcoholic caffeinated beverage that are consumed globally. Learn the facts, get the latest, and what’s in them.
Summary and Next Steps
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.