JOURNAL OF CAFFEINE RESEARCH
Volume 3, Number 3, 2013

DOI: 10.1089/jcr.2013.0017

Commentary

Caffeine Content Labeling: A Missed Opportunity for Promoting Personal and Public Health

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Current regulation of caffeine-containing products is incoherent, fails to protect consumers' interests, and should be modified in multiple ways. We make the case for one of the regulatory reforms that are needed: all consumable products containing added caffeine should be required by the Food and Drug Administration (FDA) to include caffeine quantity on their labels. Currently, no foods or beverages that contain caffeine are required to include caffeine content on their labels. Strengthening these lax labeling requirements could prevent direct caffeine-induced harm, protect those most vulnerable to caffeine-related side effects, and enhance consumer autonomy and effective caffeine use. Consumers have an interest in regulating their intake of caffeine and thus, ought to know how much caffeine their foods and beverages contain.

Introduction

Caffeine, a central nervous system stimulant, is the world's most commonly used psychoactive substance, and more than 87% of U.S. adults report regular caffeine use with an average daily intake of 193 mg.[1] Though moderate caffeine consumption is generally considered safe for adults, increased consumption of highly caffeinated energy drinks, particularly among youth, has raised concern about the health effects of excessive caffeine consumption.[2]

Though energy drinks pose the most acute concerns, the health effects of caffeine consumption and the appropriate regulation of caffeinated products are broader issues raised not only by energy drinks but also other caffeinated beverages and the increasing number of foods with added caffeine. Current regulation of caffeine-containing products is incoherent and fails to protect consumers' interests, as we explain below in Food and Drug Administration (FDA) Regulation of Caffeine-Containing Products section. Though this regulation should be modified in multiple ways, including stricter regulation of energy drinks, the regulatory reform that we argue for in this article is stricter labeling requirements for caffeinated foods and beverages. We argue, in The Case for Caffeine Content Labeling section, that any consumable product containing added caffeine should include its caffeine quantity on its label.

Energy drinks and caffeine-related harm

Energy drinks typically contain a combination of caffeine, herbal supplements, vitamins and sweeteners, but their high caffeine content is believed primarily responsible for their stimulant effect.[3–5] Their high caffeine content also appears to be making people sick. From 2005 to 2011, the number of emergency room visits due to adverse events from energy drinks increased 10-fold to more than 14,000, with patients typically suffering from caffeine-related symptoms.[6,7] There have also been reports that caffeine in energy drinks can trigger seizures[8,9] liver and kidney injury,[10] heart arrhythmias and psychotic symptoms.[11] There is active litigation against Monster Beverage Corporation after the death of five people who consumed their energy drinks.[12] Consumption of energy drinks in combination with alcohol is particularly dangerous, as caffeine appears to diminish subjective awareness of alcohol intoxication, which may lead to overconsumption of alcohol.[13]

Numerous policymakers at the federal, state and local levels, as well as physicians, lawyers, and public health experts, have called for stricter regulation of energy drinks.[2,5,14–16] Most recently, in March 2013, a group of eighteen physicians and public health officials urged the FDA to limit the caffeine content of energy drinks and require caffeine content on their labels.[15] Others have called for limitations on the marketing or sale of energy drinks to minors.[14]

We support stricter regulation of energy drinks, and we hope that concern with energy drinks will focus attention on the broader issue of how other caffeinated beverages, and the increasing number of foods with added caffeine, are regulated. Current regulation of caffeine-containing products is incoherent and fails to protect consumers' interests.

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FDA Regulation of Caffeine-Containing Products

Categories of caffeine-containing products

FDA regulation of caffeine-containing products is byzantine.[14] We have identified five distinct categories of consumable products that contain caffeine, each of which is regulated differently by the FDA (see Table 1). The FDA recognizes a distinction between over-the-counter drugs, dietary supplements (which are considered foods, not drugs) and conventional foods (which includes all foods besides dietary supplements).[17] The 1994 Dietary Supplement Health and Education Act (DSHE Act) defined *dietary supplements* as a distinct category of foods, which are regulated differently than all other foods, classified as *conventional foods*. Many energy drinks are classified as liquid dietary supplements.

Within the category of conventional foods, there are three subcategories of caffeine-containing products useful to keep distinct because they are regulated differently: foods and beverages with naturally occurring caffeine, such as coffee and tea; carbonated sodas with added caffeine; and other foods containing added caffeine, such as caffeinated chewing gum, potato chips, and other snack food. Of all these product types, only over-the-counter drugs and carbonated sodas have limits on added caffeine. Only over-the-counter drugs are required to list caffeine quantity on the product label.

Caffeine content

Foods and beverages with naturally occurring caffeine, such as coffee and tea, have no limits on caffeine content. Carbonated sodas do have limits on added caffeine. In 1980, citing caffeine's psychoactive properties and related health concerns, the FDA proposed eliminating caffeine from soft drinks.[5] Facing significant industry resistance, the FDA instead placed a limit on caffeine added to carbonated beverages of 0.02% concentration, or 71 mg for a 12 ounce beverage.[5]

In contrast to caffeinated sodas, there are no limits on the caffeine that may be added to other foods and beverages. An increasing number of food products with added caffeine are being introduced, including gum, jelly beans, potato chips, beef jerky, and waffles.[18] The FDA has stated that its established soda caffeine limit "does not automatically preclude other uses of caffeine from being considered GRAS [Generally Recognized as Safe] nor does it automatically give GRAS status to other uses. A manufacturer that has made a determination that a food ingredient is GRAS for its intended use(s) may market that ingredient without informing FDA." This means that, as things stand, food manufacturers may declare that the level of added caffeine in a food product is GRAS, and offer it for sale; but the FDA may subsequently dispute that. However, this regulatory situation might soon change. In April 2013, soon after Wrigley released its new Alert Energy Caffeine Gum,[19] the FDA announced that it would investigate the safety of caffeine in foods, particularly with regard to children and adolescents. "Existing rules never anticipated the current proliferation of caffeinated products," the FDA announcement read.[20]

Energy drinks pose somewhat different regulatory issues than foods with added caffeine. Because they contain herbs and other natural ingredients, manufacturers of many energy drinks are permitted by the DSHE Act to classify their beverages as liquid dietary supplements, rather than conventional foods, though the FDA may subsequently dispute that classification. There is no limit on caffeine that can be added to dietary supplements, and more than 130 energy drinks exceed the caffeine limit imposed on caffeinated sodas.[5] Those concerned about the caffeine content of energy drinks have queried whether it make sense for energy drinks to be classified as dietary supplements (with no caffeine limits) rather than classified as conventional foods (and thus, face the caffeine limits imposed on caffeinated sodas).[14] What exactly would justify this distinction, if energy drinks are sold side-by-side with carbonated sodas? The FDA

Table 1. Categories of Caffeine-Containing Products and Regulatory Requirements

Category	*Examples*	*Label must indicate product contains caffeine*	*Label must indicate caffeine quantity*	*Limits on caffeine quantity*
Carbonated soda with added caffeine (classified as conventional foods)	Coca-Cola	Yes	No	Yes
Beverages and foods with naturally occurring caffeine (classified as conventional foods)	Coffee Tea Coffee ice cream Chocolate Cracker Jack'd (Cracker Jacks with added coffee)	No	No	No
Foods with added caffeine (classified as conventional foods)	Jelly Belly "Extreme Sport Beans" Perky Jerky beef jerky Wrigley's Alert Energy Caffeine Gum	Yes	No	No
Energy drinks classified as liquid dietary supplements	5-Hour Energy	Yes (but caffeine can be listed as one of many ingredients comprising a blend)[40]	No	No
Over-the-counter drug	NoDoz	Yes	Yes	Yes

has agreed to release guidance clarifying the distinction between liquid dietary supplements and beverages classified as conventional foods.[21] The FDA is also investigating the safety of caffeinated energy drinks, particularly for young people and those with pre-existing medical conditions.[22]

Caffeine labeling

No foods or beverages containing caffeine are required to list caffeine content on their labels. Only over-the-counter drugs must list caffeine content. Carbonated sodas and other conventional foods and beverages containing added caffeine must list caffeine as an ingredient, but need not indicate the quantity of caffeine. Foods and beverages containing naturally occurring caffeine need not indicate that the food contains caffeine. For example, a candy bar containing chocolate must list chocolate as an ingredient, but need not indicate that the chocolate contains caffeine. Similarly, coffee ice cream must list coffee as an ingredient but need not indicate that this coffee contains caffeine. Dietary supplements containing added caffeine must list caffeine as an ingredient on the label, but need not indicate the quantity of caffeine. If caffeine is listed as part of a "proprietary blend," then the amount of the blend must be listed, but not the amount of caffeine in the blend.

In contrast to foods, beverages and dietary supplements that contain caffeine, over-the-counter drugs that contain caffeine must include their caffeine content on their labels along with warning labels, such as: "The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat" and "Do not give to children under 12 years of age." As Ressig *et al.* point out: "It is a striking inconsistency that, in the United States an over the counter (OTC) stimulant medication containing 100 mg of caffeine per tablet (e.g., NoDoz) must include all the above warnings, whereas a 500 mg energy drink can be marketed with no such warnings and no information on caffeine dose amount in the product."[5]

Need for reform

This regulatory scheme is incoherent and fails to protect consumers' interests: products are regulated differently even if consumers view them and use them as interchangeable.[14] If concern for consumers' safety demands limits on caffeine added to soda, it also demands limits on caffeine added to energy drinks sold side-by-side with soda, and limits on caffeine added to the snack foods consumed alongside soda. If concern for consumers' safety demands that over-the-counter drugs, such as NoDoz list caffeine content, it also demands that energy "shots" used as stimulants, such as 5-Hour Energy, list caffeine content.

At the very least, consumers should know the caffeine content of their beverages and foods. Caffeine content ranges widely and can be opaque to consumers (see Table 2). A 20 ounce bottle of Coca-Cola has 58 mg caffeine, a 20 ounce bottle of Pepsi MAX has 115 mg, and a 1.9 ounce bottle of 5-Hour Energy has 207 mg.[23] Caffeine labeling on energy drinks is remarkably uninformative: a recent report revealed 40% of the most popular energy drink products give no quantitative caffeine information, and 30% of those products that do offer this information understated caffeine content by more than 20%.[24] The caffeine content of food also varies and is opaque to consumers: a 1 ounce package of Perky Jerky beef jerky contains 150 mg caffeine, a 2 ounce package of Arma potato chips contains 70 mg, and 1 piece of Jolt Gum contains 45 mg.[18]

Table 2. Caffeine Content of Coffee, Soda and Energy Drink Beverages

Beverage	*Serving size*	*Caffeine content (mg)*
Coffee		
McDonald's coffee	16 ounces (large)	160
Starbucks coffee (drip coffee)	16 ounces (grande)	330
Starbucks Cappuccino	16 ounces (grande)	150
Soda		
Coca-Cola	12 ounce can	35
Pepsi MAX	12 ounce can	69
Energy drinks		
5-Hour Energy	1.9 ounces	208
Monster Energy	16 ounces	160
Jolt Energy Drink	23.5 ounces	280
Red Bull	8.4 ounces	80

Caffeine Content of Food and Drugs.[18]

We recommend that any consumable product containing added caffeine should list its caffeine quantity on its label, including beverages classified as liquid dietary supplements, beverages classified as conventional foods with added caffeine, solid foods containing added caffeine, as well as over-the-counter drugs.[25] Physicians, public health researchers, and public health advocates have repeatedly called for caffeine content labeling.[5] In 1997, the Center for Science in the Public Interest petitioned the FDA to require caffeine content labeling on all foods and beverages containing caffeine.[26] In 2008, a group of dozens of public health experts asked the FDA to require caffeine content labeling and warnings on products containing more than a specified level of caffeine.[27] In March 2013, a group of eighteen physicians and public health officials urged the FDA to limit the caffeine content of energy drinks and require caffeine content on their labels.[15] Now is the time for the FDA, as part of its ongoing investigation of the safety of caffeinated beverages and foods, to improve the labeling of caffeinated products. Caffeine content labeling could help prevent caffeine-induced harm, protect children and adolescents, and enhance consumer autonomy and effective caffeine use. Caffeine content labeling is a necessary part of broader reform of caffeine regulation.

Under public pressure and subject to FDA scrutiny, Monster Beverage Corporation recently volunteered to change the status of its energy drink from a dietary supplement to a conventional food, and to provide quantitative caffeine labeling on each can.[28] While it is encouraging that Monster took this unilateral action, industry self-regulation should not be relied as an effective substitute for regulatory reform.

The Case for Caffeine Content Labeling

Prevent harm

As discussed above, energy drink consumption has been linked to harm. Excessive caffeine use poses particular risks

to people with certain medical illnesses. Patients with kidney disease must be careful to avoid electrolyte shifts, and high consumption of caffeinated beverages is known to cause potassium shift.[29] Caffeine interferes with insulin sensitivity and worsens hyperglycemia,[30] a problematic interaction that may affect some of the 25.8 million Americans with diabetes. To protect themselves from harm, these patients need to know how much caffeine they're consuming.

Protect children and adolescents

Informing children and adolescents' consumption of caffeinated beverages is an important motivation for caffeine labeling. Children have a higher sensitivity to caffeine than adults and the American Academy of Pediatrics recommends no more than 100 mg caffeine a day for adolescents and children.[31] One energy drink may have double this amount. A recent 2011 review in *Pediatrics*, outlining the risks of excessive caffeine, put it simply: "energy drinks have no therapeutic benefit and… these drinks may put some children at risk for serious adverse health effect."[11] Children with attention deficit hyperactivity disorder (ADHD), eating disorders, cardiac conditions and juvenile diabetes are at particular risk of harm. With marketing of highly caffeinated beverages heavily directed at youth[5,32] it seems especially important that they and their parents know how much caffeine is in their beverages.

Enhance consumer autonomy and effective caffeine use

Caffeine content labeling would allow consumers to better control their caffeine intake, allowing optimal use of caffeine while minimizing negative effects.

Moderate caffeine use has a variety of potential benefits. Use of caffeine at moderate doses (around 200 mg) creates positive effects, including enhanced feelings of well-being, improved concentration, and increased arousal and energy.[33] Moderate caffeine use improves exercise stamina, muscle performance, and postworkout recovery.[34,35] Long-term regular moderate caffeine intake is associated with less cognitive decline with age[36] and appears to protect against Alzheimer's Disease.[37] However, caffeine is a stimulant, and significant fluctuations in use can cause symptoms typical of addiction: tolerance (escalation of use for same effect), withdrawal symptoms (such as headache/fatigue), and dependence (regular use for regular functioning).[38]

To capitalize on the benefits of moderate caffeine use, and avoid the drawbacks of fluctuations in use, consumers need to know the caffeine content of the foods and beverages they consume.

What form should caffeine labeling take?

Caffeine content labeling could take several forms: a declaration of caffeine content, such as "contains [number] mg caffeine per serving," below the Nutrition Facts or Supplement Facts panel; a warning, such as "contains high amounts of caffeine," on products containing more than a threshold level, such as 200 mg; or a label that visually represents that a product contains low, medium or high amounts of caffeine. As part of its ongoing effort to revamp nutrition labeling,[39] the FDA should investigate how to effectively communicate caffeine content to consumers. Nutrition labeling should be made simpler, more consumer friendly, and more understandable, and this should include modifying labels so that they effectively communicate products' caffeine content to consumers.

Should caffeine content be required on products with naturally occurring caffeine?

We recommend that consumable products containing *added* caffeine should include caffeine quantity on their labels. This labeling recommendation does not apply to foods with naturally occurring caffeine, such as tea, coffee, foods with added coffee (e.g., coffee ice cream), and chocolate. The primary argument for this exemption is the difficulty of accurately determining the caffeine content of foods with naturally occurring caffeine, given that caffeine content varies plant to plant and is affected by processes, such as roasting coffee.

There are two arguments against exempting foods with naturally occurring caffeine from labeling requirements. The first is that consumers might not know that certain food ingredients, for instance guarana, have high levels of naturally occurring caffeine. Thus, an energy drink or other food product with added guarana could potentially have a high level of naturally occurring caffeine—unbeknownst to many consumers and without the product labeling making any indication thereof.

A second argument against exempting naturally occurring caffeine from labeling requirements is that the caffeine content of coffee drinks is increasingly variable, as the number of coffee brands and the variety of coffee drinks increases. Even though consumers might be expected to know that coffee contains caffeine, they might not know the caffeine content of their coffee beverages, leaving them unable to regulate their caffeine consumption. "As much caffeine as a cup of coffee" is the metric used to communicate the caffeine content of over-the-counter drugs, and an 8 ounce cup of coffee has approximately 100 mg caffeine.[5] However, instant coffee can have less than 50 mg/8 ounce, a 16 ounce McDonald's coffee has 133 mg, a 16 ounce Starbucks drip coffee has 330 mg, and a 16 ounce Starbucks Cappuccino has 150 mg.[18] Thus, a single coffee beverage can have less than half "as much caffeine as a cup of coffee" or several times "as much caffeine as a cup of coffee." Given this wide variability, consumers would benefit from caffeine content labeling on coffee, were this feasible.

Conclusions

All consumable products with added caffeine should have quantitative labeling of their caffeine content to help prevent serious harms, protect children and adolescents, and enhance effective consumer use. Excessive caffeine consumption by youth poses the most urgent need for caffeine content labeling, but even consumers in no danger of exceeding safe consumption levels would benefit from knowing how much caffeine they are consuming. Caffeine is a psychoactive substance and has noticeable effects well below safe levels of consumption. All consumers have an interest in knowing how much caffeine their foods and beverages contain.

Author Disclosure Statement

No competing financial interests exist.

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