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Citation

Jennifer Yince Kan, Loco for Four Loko: Regulating Caffeinated Alcoholic Beverages (May 2011).

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**Loco for Four Loko:
Regulating Caffeinated Alcoholic Beverages**

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Class of 2011

May 2011

Food and Drug Law
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Winter 2011

This paper is submitted in satisfaction of
the Food and Drug Law course requirement.

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Professor Peter Barton Hutt for his guidance and support.

ABSTRACT

Young people across the nation have been going loco for Four Loko, a caffeinated alcoholic beverage (CAB) that some college students have dubbed "blackout in a can." Just a few months ago, the Food and Drug Administration (FDA) issued warning letters to four CAB manufacturers—including Phusion Projects, the maker of Four Loko—notifying them that the caffeine added to their alcoholic beverages was an "unsafe food additive." However, for various reasons FDA's approach to the situation appears questionable.

This paper begins by providing background information on the relevant products and ingredients involved—namely alcoholic beverages, caffeine, energy drinks, and CABs. It also explores the government regulation of these products and ingredients, including the recent events pertaining to CABs in particular. In sum, this paper presents a critique of FDA's response to the CAB phenomenon and ultimately recommends that FDA set a specified caffeine level limit after obtaining sufficient scientific research.

There is still much more scientific research to be done on the safety of CABs, particularly with respect to what caffeine-alcohol ratio in CABs would be safe for consumers. Until FDA obtains sufficient scientific research and sets a specific caffeine level limit, its inconsistent treatment of products combining caffeine and alcohol will illustrate its evasion of the underlying public health objective. Instead of banning CABs altogether, FDA and TTB should consider adding warnings on CAB labels or simply keep consumers informed about CAB safety through publicly available resources.

I. INTRODUCTION

Young people across the nation have been going loco for Four Loko, a caffeinated alcoholic beverage (CAB) that some college students have dubbed "blackout in a can."¹ Just a few months ago, the Food and Drug Administration (FDA) issued warning letters to four CAB manufacturers—including Phusion Projects, the maker of Four Loko—notifying them that the caffeine added to their alcoholic beverages was an "unsafe food additive."² However, for various reasons FDA's approach to the situation appears questionable.

This paper presents a critique of FDA's response to the CAB phenomenon and ultimately recommends that FDA set a specified caffeine level limit after obtaining sufficient scientific research. Section II of this paper provides background information on the relevant products and ingredients involved—

¹ Martin Finucane, *Goodbye, 'blackout in a can' -- state bans alcohol-caffeine mixes*, BOSTON GLOBE, Nov. 18, 2010, available at

http://www.boston.com/news/local/breaking_news/2010/11/state_bans_beve.html.

² Food and Drug Administration, *FDA News Release: FDA Warning Letters issued to four makers of caffeinated alcoholic beverages; these beverages present a public health concern*, Nov. 17, 2010,

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm234109.htm>

(hereinafter "FDA Warning Letters").

namely alcoholic beverages, caffeine, energy drinks, and CABs. Section III explores the government regulation of these products and ingredients, including the recent events pertaining to CABs in particular. Section IV analyzes and critiques the facets of those events and then suggests some recommendations for the future. Section V offers concluding remarks.

II. THE PRODUCTS AND INGREDIENTS

A. Alcoholic Beverages

Alcoholic beverages are so strongly associated with human society that they are said to have developed in parallel with civilization.³ The Arabs developed distillation in about 800 C.E., and the word *alcohol* is derived from the Arabic word for "something subtle."⁴ Alchemists in the Middle Ages thought that the invisible "spirit" distilled from wine was a remedy for practically all diseases.⁵

Alcoholic beverages contain the two-carbon alcohol *ethanol* (CH₃CH₂OH), which is primarily a central nervous system

³ GOODMAN & GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 591 (Laurence L. Brunton et al. eds., 11th ed. 2006).

⁴ *Id.*

⁵ *Id.*

depressant.⁶ The relevant pharmacological properties of ethanol include effects on the gastrointestinal, cardiovascular, and central nervous systems, effects on disease processes, and effects on prenatal development.⁷ Ethanol disturbs the fine balance between excitatory and inhibitory influences in the brain, producing disinhibition, ataxia, and sedation.⁸

The alcohol content of alcoholic beverages typically ranges from 4% to 6% (volume/volume) for beer, 10% to 15% for wine, and 40% and higher for distilled spirits (the "proof" of an alcoholic beverage is twice its percentage of alcohol; e.g., 40% alcohol is 80 proof).⁹ A glass of beer or wine, a mixed drink, or a shot of spirits contains about 14 g alcohol, or about 0.3 mol ethanol.¹⁰ Consumption of 1 to 2 mol over a few hours is not uncommon.¹¹

Legally allowed blood alcohol levels (BALs) typically are set at or below 80 mg% (80 mg ethanol per 100 ml blood; 0.08% w/v).¹² A 12-oz bottle of beer, a 5-oz glass of wine, and a 1.5-

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.* at 591-92.

oz shot of 40% liquor each contains approximately 14 g ethanol, and the consumption of one of these beverages by a 70-kg person would produce a BAL of approximately 30 mg%.¹³

An increased reaction time, diminished fine motor control, impulsivity, and impaired judgment become evident when the concentration of ethanol in the blood is 20 to 30 mg/dl.¹⁴ In the United States, most states set the ethanol level defined as intoxication at 80 mg/dl.¹⁵ More than 50% of persons are grossly intoxicated by a concentration of 150 mg/dl, and the average concentration in fatal cases is about 400 mg/dl.¹⁶

B. Caffeine

Caffeine ($C_8H_{10}N_4O_2$), belonging to the family of chemicals known as methylxanthines, is an alkaloid that is ingested widely.¹⁷ The basis for the popularity of caffeine-containing beverages is the ancient belief that they have stimulant and antisoporific actions that elevate mood, decrease fatigue, and

¹³ *Id.* at 592.

¹⁴ *Id.* at 599.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.* at 727.

increase capacity for work.¹⁸ Classical pharmacological studies of caffeine later confirmed this belief.¹⁹

Caffeine is a mild stimulant that is thought to be “the most widely used psychoactive drug in the world.”²⁰ It mildly increases norepinephrine and dopamine release and enhances neural activity in numerous brain areas.²¹ Caffeine is absorbed from the digestive tract and is distributed rapidly throughout all tissues.²² Many of caffeine’s effects are believed to occur by means of competitive antagonism at adenosine receptors.²³ Adenosine, a neuromodulator, influences a number of functions in the central nervous system, and the mild sedating effects that occur when adenosine activates particular adenosine-receptor subtypes can be antagonized by caffeine.²⁴

Caffeine is present in soft drinks, coffee, tea, cocoa, chocolate, and numerous prescription and over-the-counter drugs.²⁵ At least half the world population consumes tea, which

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.* at 622.

²¹ *Id.*

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.* at 622.

naturally contains caffeine; cocoa and chocolate contain some caffeine as well.²⁶ Coffee is the most popular source of caffeine in the American diet, and cola drinks usually contain considerable amounts of natural and added caffeine.²⁷

Caffeine quantities vary significantly in foods. For instance, 1 oz of chocolate contains 8-25 mg of caffeine; 7 oz of tea contains 30-70 mg; 7 oz of coffee contains 65-175 mg; and 12 oz of cola contains 30-72 mg (with a Coca-Cola specifically containing about 46 mg).²⁸ An espresso contains approximately 100 mg of caffeine, nearly twice the caffeine content as an instant coffee.²⁹ It has been reported that a majority of adult Americans drink an average of three and a half cups of coffee a day, in addition to tea, cola, chocolate, and over-the-counter caffeine-containing drugs.³⁰

²⁶ *Id.* at 727.

²⁷ *Id.*

²⁸ Gwendolyn Prothro, *The Caffeine Conundrum: Caffeine Regulation in the United States*, 27 CUMB. L. REV. 65, 83 (1996-1997) (internal citations omitted).

²⁹ *Id.*

³⁰ Prothro, *supra* note 28, at 68 (citing Ed Blonz, *The Buzz About Caffeine*, BETTER HOMES AND GARDENS, May 1995, at 50).

C. Energy Drinks

High-caffeine soft drinks have existed in the United States since at least the 1980s beginning with Jolt Cola.³¹ Energy drinks—beverages with caffeine as their primary “energy” component—began being marketed as a separate beverage category in the United States in 1997 with the introduction of the Austrian import Red Bull.³² Energy drink sales and consumption have exploded since then, with a 516-percent inflation-adjusted increase from 2001 to 2006.³³

The United States energy-drink market is dominated by five producers: Red Bull (by far the market leader), Hansen Natural Corporation (Monster brands), PepsiCo (SoBe and Amp brands), Rockstar International, and Coca-Cola (Full Throttle and Tab brands).³⁴ The multibillion-dollar industry has been said to target teens and young adults through aggressive and innovative

³¹ Michele Simon & James Mosher, *Alcohol, Energy Drinks, and Youth: A Dangerous Mix*, Marin Institute 1, 3 (2007), available at www.marininstitute.org/alcopops/resources/EnergyDrinkReport.pdf.

³² Kerry A. Dolan, *The Soda With Buzz*, FORBES.COM, Mar. 28, 2005, available at http://www.forbes.com/global/2005/0328/028_print.html.

³³ Mintel International Group Ltd., *Energy Drinks*, Mintel 1, 5 (2007) (hereinafter “Mintel Report”).

³⁴ *Id.* at 83.

marketing strategies.³⁵ In one comprehensive study, 31 percent of young teens and 34 to 51 percent of young adults aged 18 to 24 reported regular consumption of energy drinks.³⁶

Depending on the brand, energy drinks can contain several stimulants, including caffeine, guarana, taurine, and sugar derivatives.³⁷ Caffeine, the primary stimulant, is found at levels ranging from 50 to 505 mg per can or bottle.³⁸ Energy drinks typically contain 80 to 141 mg caffeine per 8 oz, which is approximately equivalent to a 5-oz cup of coffee or two cans of soft drinks.³⁹

D. Caffeinated Alcoholic Beverages

Caffeinated alcoholic beverages (CABs), also sometimes called alcoholic energy drinks, are premixed beverages containing alcohol and caffeine (and often other stimulants as well).⁴⁰ They may be malt- or distilled-spirits-based and

³⁵ Simon & Mosher, *supra* note 31, at 4.

³⁶ Mintel Report, *supra* note 33, at 56-59.

³⁷ M. Boyle & V. Castillo, *Monster on the Loose*, 154 FORTUNE 116-22 (2006).

³⁸ Jonathan Howland et al., *Caffeinated Alcoholic Beverages: An Emerging Public Health Problem*, 40 AM. J. PREV. MED. 268, 268 (2011) (internal citations omitted).

³⁹ *Id.* (internal citations omitted).

usually have higher alcohol content than beer (5 to 12 percent on average for CABs, and 4 to 5 percent for beer).⁴¹ The caffeine content in CABs is usually not reported.⁴²

Before the production of premixed CABs, it was a common practice for bartenders to mix Red Bull with vodka and other spirits, first in Europe and then the United States.⁴³ Both alcohol and energy drink companies appear to encourage this practice through their marketing and promotional activities, although some—including Red Bull—deny this allegation.⁴⁴ Advertising energy boosts for prolonged partying, such marketing promotes the perception that energy drinks counteract the sedating effects of alcohol and related impairment.⁴⁵

While energy drinks continue to be used as mixers at bars and clubs, for some time consumers could also find premixed CABs at a nearby convenience store or grocery store.⁴⁶ Alcoholic

⁴⁰ Centers for Disease Control and Prevention (CDC), *Fact Sheets: Caffeinated Alcoholic Beverages*, July 20, 2010, <http://www.cdc.gov/alcohol/fact-sheets/cab.htm> (hereinafter "CDC CAB Fact Sheet").

⁴¹ *Id.*

⁴² *Id.* (internal citations omitted).

⁴³ Simon & Mosher, *supra* note 31, at 5.

⁴⁴ *Id.*

⁴⁵ Howland, *supra* note 38, at 268.

⁴⁶ Mintel Report, *supra* note 33, at 81.

beverage (especially beer) manufacturers began to launch such products that would appeal to young adults.⁴⁷ The trend of alcoholic beverage makers capitalizing on the increased popularity of energy drinks began in 2000 with the introduction of Agwa (distilled from cocoa leaves), which was billed as the “world’s first alcoholic energy drink.”⁴⁸ Hanson Natural introduced its product Hard E also in 2000, though it was discontinued in 2004.⁴⁹ Miller and Anheuser-Busch, the two largest brewers in the United States, soon followed suit with Sparks and Tilt, respectively.⁵⁰

Since being introduced into the marketplace, CABs have experienced rapid growth in popularity. For instance, two leading brands of CABs together experienced a 67-fold increase in sales, from 337,500 gallons in 2002 (the first year of significant CAB production) to over 22.9 million gallons in 2008.⁵¹ In August 2008, a young Chicago company called Phusion Projects introduced Four Loko—a fruit-flavored malt beverage, packaged in a 23.5-oz can, with an alcohol content of 12 percent

⁴⁷ *Id.*

⁴⁸ Simon & Mosher, *supra* note 31, at 6.

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ CDC CAB Fact Sheet, *supra* note 40 (internal citations omitted).

or 6 percent (two varieties) and 135 mg of caffeine (about as much caffeine as a cup of coffee).⁵²

Although mixing alcohol and caffeine is not a novel concept, multiple cases involving students and others landing in hospitals after drinking CABs have raised alarm bells across the country.⁵³ Though CAB producers such as Phusion Projects deny it, critics claim that CAB producers specifically target underage drinkers.⁵⁴ In particular, commentators contend that CAB producers target young people in at least two significant ways: (1) CABs are inexpensive and can serve as a cheap alternative to mixed drinks, and (2) CAB containers' similarities to those of non-alcoholic energy drinks can create brand confusion.⁵⁵ It was only a matter of time before the mounting concerns about the potential dangers of CABs—especially to young consumers—would inevitably lead to a drastic change.⁵⁶

⁵² Abby Goodnough, *Caffeine and Alcohol Is Potent Mix for Young*, N.Y. TIMES, Oct. 26, 2010, available at http://www.nytimes.com/2010/10/27/us/27drink.html?_r=1.

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ Simon & Mosher, *supra* note 31, at 6-8.

⁵⁶ See *infra* Section III(D), on the government regulation of caffeinated alcoholic beverages.

III. GOVERNMENT REGULATION

A. Alcoholic Beverages

The Alcohol and Tobacco Tax and Trade Bureau (TTB) of the Department of the Treasury has jurisdiction over alcoholic beverages under the Federal Alcohol Administration Act.⁵⁷ TTB was formerly the Bureau of Alcohol, Tobacco, and Firearms (BATF), but the Homeland Security Act of 2002 divided BATF into two new agencies: The Bureau of Alcohol, Tobacco, Firearms, and Explosives (now called ATF) which became part of the Department of Justice, and the Alcohol and Tobacco Tax and Trade Bureau (now called TTB) which was left in the Department of Treasury.⁵⁸ The current TTB is responsible for administration of the Federal Alcohol Administration Act and related statutes.⁵⁹

TTB regulates all beer products regardless of their alcohol content.⁶⁰ While TTB regulates only those wine products that contain 7 percent alcohol or more, the Food and Drug Administration (FDA) regulates all wine products containing less

⁵⁷ 49 Stat. 977 (1935), codified in 27 U.S.C. §§ 201 *et seq.*

⁵⁸ PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, *FOOD AND DRUG LAW: CASES AND MATERIALS* 138 (3d ed. 2007).

⁵⁹ *Id.*

⁶⁰ 51 Fed. Reg. 39666 (Oct. 30, 1986).

than 7 percent of alcohol.⁶¹ Alcoholic beverages have been regulated as food under both the Federal Food and Drugs Act of 1906 and the Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act).⁶² Apart from the labeling of alcoholic beverages, which is subject to TTB jurisdiction, in other respects alcoholic beverages are regulated as food by FDA, though TTB and FDA have a memorandum of understanding that confirms TTB's primarily responsibility for overseeing voluntary recalls of adulterated products.⁶³

B. Caffeine

The FD&C Act defines the term "food" as "(1) articles used for food and drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."⁶⁴ When caffeine is added to food, such as a soft drink, FDA does not regulate the product as a drug, even if the manufacturer promotes the food's high level of caffeine and its "energizing" qualities.⁶⁵ In FDA's view, such products fall within the food

⁶¹ FDA Compliance Policy Guide No. 7101.05 (Oct. 1, 1980).

⁶² HUTT, *supra* note 58, at 136.

⁶³ *Id.* at 36-37.

⁶⁴ 21 U.S.C. § 321(f) (2006).

⁶⁵ HUTT, *supra* note 58, at 34.

exception to the structure/function drug definition in Section 201(g) (1) (C) of the FD&C Act.⁶⁶

In sharp contrast to its strict regulation of caffeine as a drug, FDA is fairly lenient in its regulation of caffeine as food.⁶⁷ However, food regulation of caffeine varies, depending on whether the caffeine is naturally occurring or an added food substance.⁶⁸ In coffee, tea, and chocolate, for example, caffeine occurs naturally and is non-added; yet in soft drinks, most of the caffeine is added.⁶⁹

When Congress enacted the Food Additives Amendment of 1958, there arose a subcategory of foods called "food additives," which are subject to premarket safety approval by FDA.⁷⁰ Section 201(s) of the FD&C Act sets forth the definition:

"The term 'food additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety . . . to be safe under the conditions of its intended use."⁷¹

⁶⁶ *Id.*

⁶⁷ Prothro, *supra* note 28, at 80.

⁶⁸ *Id.* at 80 n.106.

⁶⁹ *Id.* (internal citations omitted).

⁷⁰ HUTT, *supra* note 58, at 35.

⁷¹ 21 U.S.C. § 321(s) (2006).

Section 201(s) also lists a number of specific exceptions to the definition of "food additive," expressly excluding a substantial portion—probably the majority—of such substances.⁷² Among the excluded substances are those that are generally recognized as safe ("GRAS"); the exemption for GRAS foods frees most conventional food ingredients from the requirement of FDA premarket safety approval.⁷³ FDA placed caffeine for use in cola-type beverages on the original GRAS list⁷⁴ and it remains listed as GRAS for use in soft drinks today.⁷⁵

C. Energy Drinks

Energy drinks are generally regulated as food under the FD&C Act.⁷⁶ Energy drinks usually contain added caffeine as their primary component, and caffeine is recognized as GRAS in such beverages as they are considered soft drinks, so long as the caffeine is found in concentrations of no greater than 200 parts per million.⁷⁷ Although there has been controversy over

⁷² *Id.*

⁷³ HUTT, *supra* note 58, at 35.

⁷⁴ 26 Fed. Reg. 938 (Jan. 31, 1961).

⁷⁵ 21 C.F.R. § 182.1180 (2010).

⁷⁶ 21 U.S.C. § 321(f) (2006).

some of the other added ingredients often found in energy drinks—such as taurine, guarana, and ephedrine—and the impact of the Dietary Supplement Health and Education Act of 1994 (DSHEA),⁷⁸ this paper will focus solely on the regulation of added caffeine in beverages.⁷⁹

D. Caffeinated Alcoholic Beverages

As CABs rose exponentially in popularity, concerns over the potential public health threat posed by CABs grew just as rapidly, especially after numerous cases involving the hospitalization of CAB drinkers began to appear in the media.⁸⁰ Four Loko came under particular scrutiny after students who drank it at Ramapo College in New Jersey and Central Washington

⁷⁷ Food and Drug Administration, *FDA News Release: FDA To Look Into Safety of Caffeinated Alcoholic Beverages, Agency Sends Letters to Nearly 30 Manufacturers*, Nov. 13, 2009, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm190427.htm> (hereinafter “FDA To Look Into CAB Safety”).

⁷⁸ See generally Tod L. Stewart, *Getting High with a Little Help from the Feds: Federal Regulation of Herbal Stimulants*, 6 J. PHARMACY & L. 101 (1997).

⁷⁹ See *supra* Section III(B).

⁸⁰ See, e.g., Goodnough, *supra* note 52.

University in Washington ended up in emergency rooms, some with high levels of alcohol poisoning.⁸¹

In 2008, thirteen State Attorneys General and the San Francisco City Attorney initiated an investigation of CABs, which resulted in negotiated settlements with two CAB producers who agreed to remove all stimulants from their alcoholic products.⁸² The nonprofit Center for Science in the Public Interest (CSPI) also negotiated an agreement in June 2008 with Anheuser-Busch to remove caffeine from its CAB products, Tilt and Bud Extra,⁸³ but in September 2008 CSPI filed suit against MillerCoors over its CAB product, Sparks.⁸⁴ Moreover, since CABs may have higher alcohol content than beer, some states (such as Montana) classified CABs as liquor, thereby limiting the locations where they could be sold.⁸⁵ Lawmakers in several states even sought to ban CABs in their own states.⁸⁶

⁸¹ *Id.*

⁸² CDC CAB Fact Sheet, *supra* note 40 (internal citations omitted).

⁸³ Center for Science in the Public Interest, *Anheuser-Busch to Stop Caffeinating Alcoholic Beverages*, June 26, 2008, <http://www.cspinet.org/new/200806261.html>.

⁸⁴ Center for Science in the Public Interest, *CSPI Sues to Stop MillerCoors' "Sparks" Alcoholic Energy Drink*, Sept. 8, 2008, <http://www.cspinet.org/new/200809082.html>.

At the urging of eighteen Attorneys General expressing concerns about CABs, FDA took the products under review.⁸⁷ On November 13, 2009, FDA notified nearly thirty CAB manufacturers that it intended to look into the safety and legality of their products and that it was considering whether caffeine could lawfully be added to alcoholic beverages.⁸⁸ By that point in time, FDA had only approved caffeine as a GRAS additive for use in non-alcoholic soft drinks in concentrations of no greater than 200 parts per million; it had not approved caffeine for use at any level in alcoholic beverages.⁸⁹ FDA's letter informed the CAB companies that if FDA determined that the use of caffeine in CABs is not GRAS or prior sanctioned, FDA would take appropriate action to ensure the removal of the products from the marketplace.⁹⁰

On November 17, 2010, FDA warned four companies that the caffeine added to their malt alcoholic beverages was an "unsafe food additive" and thus the products were adulterated under

⁸⁵ CDC CAB Fact Sheet, *supra* note 40 (internal citations omitted).

⁸⁶ Goodnough, *supra* note 52.

⁸⁷ *Id.*

⁸⁸ FDA To Look Into CAB Safety, *supra* note 77. See 45 Fed. Reg. 69815 (Oct. 21, 1980); 52 Fed. Reg. 18922 (May 20, 1987).

⁸⁹ FDA To Look Into CAB Safety, *supra* note 77.

⁹⁰ *Id.*

Section 402(a)(2)(C) of the FD&C Act.⁹¹ The four companies that received warning letters were Phusion Projects (Four Loko), United Brands Company (Joose and Max), Charge Beverages Corporation (Core High Gravity HG), and New Century Brewing Company (Moonshot).⁹²

In its letters, FDA said it had examined the published peer-reviewed literature on the co-consumption of caffeine and alcohol, consulted with experts in the fields of toxicology, neuropharmacology, emergency medicine, and epidemiology, reviewed information provided by product manufacturers, and performed its own independent laboratory analysis of these products.⁹³ FDA stated that, after conducting this scientific review, it did not find support for the claim that the addition of caffeine to these alcoholic beverages is GRAS, and to the contrary that there was "evidence that the combinations of caffeine and alcohol in these products pose a public health concern."⁹⁴ The agency said that the products named in the warning letters were being marketed in violation of the FD&C

⁹¹ FDA Warning Letters, *supra* note 2; Food and Drug Administration, *Warning Letters: Phusion Projects Inc. 11/17/10*, Nov. 17, 2010, <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm234023.htm>.

⁹² FDA Warning Letters, *supra* note 2.

⁹³ *Id.*

⁹⁴ *Id.*

Act, and that the recipients were to inform FDA in writing within fifteen days of specific steps to remedy the violation.⁹⁵

On November 18 2010, TTB supported FDA's actions by notifying the four companies that a determination by FDA that their products were adulterated under the FD&C Act would render their products mislabeled under the Federal Alcohol Administration Act (which is enforced by TTB) and make it illegal to sell or ship them in interstate or foreign commerce.⁹⁶

By November 24, 2010, FDA had discussions with all four companies.⁹⁷ Phusion Projects advised FDA that it had ceased producing CABs, was no longer shipping such products, and expected to have all of its CABs off retail store shelves by December 13, 2010.⁹⁸ United Brands Company informed FDA that it had ceased shipping Joose and similarly expected to have it off

⁹⁵ *Id.*

⁹⁶ Alcohol and Tobacco Tax and Trade Bureau, Department of the Treasury, *TTB Press Release: TTB Issues Warning on the Sale or Shipment of Caffeinated Alcoholic Beverages Determined by FDA To Be Adulterated*, Nov. 18, 2010, <http://www.ttb.gov/press/fy10/press-release-caffeinated-alcohol-beverages1102.pdf>.

⁹⁷ Food and Drug Administration, *Update on Caffeinated Alcoholic Beverages: FDA Announces Progress on Removal of Certain Caffeinated Alcoholic Beverages from the Market*, Nov. 24, 2010, <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm234900.htm>.

⁹⁸ *Id.*

retail store shelves by December 13; it also informed FDA that it no longer markets Max.⁹⁹ Charge Beverages Corporation notified FDA that it ceased producing its CABs in September and has not shipped any CABs since early November.¹⁰⁰ New Century Brewing Company advised FDA that it had ceased manufacturing Moonshot.¹⁰¹

IV. DISCUSSION

A. Analysis and Critique of FDA's Response

For several reasons, FDA's response to the CAB situation seems rather questionable. This subsection explains how FDA's actions—such as its ban of CABs without sufficient scientific research, its failure to set a caffeine level limit and address the issue of proportions, its use of an illusory natural-versus-added distinction, and its silence as to other significant policy questions—were less than ideal.

1. Ban without Sufficient Scientific Research

By the time it sent the warning letters in November 2010, FDA had been examining the scientific research on CAB safety for

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

only about one year.¹⁰² However, FDA's decision to send the warning letters appears to have been prompted by the growing public concern about the safety of CABs rather than the completion of its scientific investigation. Headlines about the potential dangers of CABs were blaring all over the media,¹⁰³ and state governments were starting to take action on their own by negotiating with CAB manufacturers or limiting CABs in their respective states.¹⁰⁴ As the cries from the media and state governments grew louder, it seems only natural that FDA would feel pressured into taking swift action.

Nevertheless, FDA's course of action seemed to be a premature, shotgun approach to the situation. Though FDA did conduct a scientific review, the current scientific understanding of combining alcohol and caffeine still remains incomplete. CABs are novel products that, according to public health experts, "have been subject to very little systematic research."¹⁰⁵ It is imperative that FDA's actions be substantiated by adequate scientific research, for a scientific basis is critical for the legitimacy of FDA's efforts; when there is a dearth of scientific research with regard to a

¹⁰² See *supra* Section III(D).

¹⁰³ See, e.g., Goodnough, *supra* note 52.

¹⁰⁴ See *supra* Section III(D).

¹⁰⁵ Howland, *supra* note 38, at 268.

particular policy question, FDA should wait until it has obtained sufficient scientific research before taking action. Here, FDA should have waited until it could make robust conclusions before issuing warning letters that effectively forced the four companies to discontinue their CAB products.

2. Failure to Set a Caffeine Level Limit

Further scientific research was particularly critical with respect to the question of a caffeine level limit—more specifically, what ratio of caffeine to alcohol in CABs would be deemed safe for consumers. The *levels* of caffeine in CABs, and not simply the mere *presence* of added caffeine, is what is in fact at the core of the safety concerns. If its mission is to protect the public health, FDA ought to ban only CAB products that are in fact unsafe—due to caffeine levels that are scientifically proven to be too high for safe consumption.

However, FDA failed to address the issue of a caffeine level limit at all, most likely because it did not yet have the scientific research supporting what such a figure would be. Instead of using the all-or-nothing standard of whether caffeine was GRAS in alcoholic beverages, FDA should have determined a specific caffeine level limit, as it has done previously for

non-alcoholic soft drinks.¹⁰⁶ FDA is empowered by Section 409(c) (1) (A) of the FD&C Act to prescribe conditions necessary to assure that an additive's use will be safe,¹⁰⁷ and such conditions typically include limitations on the levels of use.¹⁰⁸ Without any guidance from FDA as to what caffeine level limits might be appropriate, the CAB companies were forced to discontinue their CAB products altogether rather than reformulate them in order to attain a safe caffeine-alcohol ratio.

3. Illusory Natural-versus-Added Distinction

FDA's failure to address the issue of caffeine levels becomes especially apparent when it made an illusory distinction between natural and added caffeine in alcoholic beverages. Though the food regulation of caffeine does vary depending on whether it is naturally occurring or an added substance,¹⁰⁹ FDA runs into problems of inconsistency by hiding behind this distinction. While it finds the CABs produced by the four

¹⁰⁶ FDA has approved caffeine as a GRAS additive for use in non-alcoholic soft drinks in concentrations of no greater than 200 parts per million. FDA To Look Into CAB Safety, *supra* note 77.

¹⁰⁷ 21 U.S.C. § 349(c) (1) (A) (2006).

¹⁰⁸ HUTT, *supra* note 58, at 401.

¹⁰⁹ See *supra* Section III(B).

specified companies to be unlawful, FDA still permits other premixed caffeine-alcohol products such as coffee liqueurs, reasoning that these products “only contain caffeine as a natural component of one or more of their ingredients, such as coffee flavoring,” as opposed to containing caffeine that has been “directly added . . . as a separate ingredient.”¹¹⁰

One would imagine that coffee liqueurs were not banned along with CABs because the caffeine level in coffee liqueurs is very low, but instead FDA relied on the natural-versus-added distinction to ban CABs and not coffee liqueurs. As nonsensical as this distinction may seem in light of the underlying public health concern, it actually serves FDA quite well. Not only can FDA evade the issue of caffeine levels, but it can also attack the already targeted CAB products while leaving other popular caffeine-alcohol products such as coffee liqueurs unaffected. Nevertheless, it is apparent that this distinction disregards the real issue of determining what caffeine level would be safe in premixed caffeine-alcohol products, whether or not the caffeine is naturally occurring or an added substance.

¹¹⁰ Food and Drug Administration, *Questions and Answers: Caffeinated Alcoholic Beverages*, Nov. 17, 2010, <http://www.fda.gov/Food/FoodIngredientsPackaging/ucm233726.htm>.

4. Premixed-versus-Postmixed Distinction

By focusing only on premixed CABs, FDA also in a way draws a distinction between premixed CABs and postmixed caffeine-alcohol drinks (such as those created by a bartender mixing Red Bull and vodka). This distinction highlights yet another inconsistency in FDA's actions, as the purported danger posed by the chemical composition of a caffeine-alcohol beverage is essentially the same regardless of mixture timing.

Though FDA effectively banned premixed CABs, surely bartenders nationwide will continue to mix similar drinks containing both caffeine and alcohol. Unless state and local governments make the improbable move of changing their bartending regulations to ban such mixing, the inconsistency created by the premixed-versus-postmixed distinction will be allowed to perpetuate.

5. Which One is the Additive?

Even the difference in terminology—"caffeinated alcoholic beverages" versus "alcoholic energy drinks"—highlights the two ways in which these products could be viewed. Caffeine can be an additive to an alcoholic beverage, but can alcohol be an additive to a caffeine beverage? FDA attacked premixed CABs on the ground that the caffeine added to the alcoholic beverages

was an “unsafe food additive,”¹¹¹ but technically speaking that leaves open a loophole for alcoholic products with natural caffeine, such as premixed alcoholic coffee beverages (including coffee liqueurs).

By relying on such reasoning, FDA has not fully tackled the issue of combining alcohol and caffeine. To close the loophole and address the safety concern in a consistent manner, FDA would also have to deem alcohol an unsafe food additive to caffeine beverages. However, since FDA was specifically targeting CABs and probably did not want to disrupt the production of other products such as coffee liqueurs, it seems very unlikely that FDA would ever take such a stance. Instead, FDA’s focus on caffeine as an additive enabled FDA to avoid addressing substance proportions in mixed-ingredient products and determining a safe caffeine-alcohol ratio, while still managing to accomplish its goal of getting CABs off the market.

B. Recommendations for the Future

In light of FDA’s missteps, this subsection ultimately recommends that FDA set a specified caffeine level limit after obtaining sufficient scientific research. It also explores the

¹¹¹ FDA Warning Letters, *supra* note 2.

possibility of caffeine labeling and warnings about CABs if they are indeed potentially dangerous products.

**1. Setting a Caffeine Level Limit After Obtaining
Sufficient Scientific Research**

Much more research on the safety of CABs still needs to be done. For instance, public health experts emphasize that further research is required to examine the effects of CABs, relative to alcohol alone and to caffeine alone, on cognition and safety-related behaviors and outcomes.¹¹² They also stress that research is needed to examine the extent to which CABs, relative to alcohol alone, affect self-perception of intoxication and motivation to consume more alcohol.¹¹³ They additionally recommend that future studies examine other factors related to CAB consumption and health, since it is possible that CAB use and risk-taking may relate to one another because a third variable (e.g., personality traits) causes both.¹¹⁴

After obtaining sufficient scientific research, FDA would be in a better position to set a caffeine level limit for CABs. With the establishment of a caffeine level limit, FDA could deem

¹¹² Howland, *supra* note 38, at 270.

¹¹³ *Id.*

¹¹⁴ *Id.*

caffeine to be GRAS in alcoholic beverages but only at specified levels. In this way, FDA would be able to rid itself of an inconsistency and directly address the heart of the public health concern—what *level* of caffeine is safe in alcoholic beverages.

2. Caffeine Labeling and Warnings about Caffeinated Alcoholic Beverages

The caffeine content in CABs is usually not reported,¹¹⁵ and even beyond CABs, caffeine quantity information is generally absent from food labels.¹¹⁶ Commentators have proposed that FDA mandate the disclosure of caffeine quantities (expressed in milligrams) on food labels generally.¹¹⁷ Such caffeine labeling may be especially helpful and important for educating consumers about CAB products.

As for alcoholic beverages, TTB has declared that a statement of alcohol content (expressed in percent by volume) on the labeling of malt beverages is optional, unless it is required or prohibited by state law.¹¹⁸ In response to

¹¹⁵ *Id.* (internal citations omitted).

¹¹⁶ Prothro, *supra* note 28, at 83.

¹¹⁷ *See, e.g., id.* at 86-90.

petitions, TTB has considered the possibility of requiring alcoholic beverage labels to declare alcohol content and other factual information.¹¹⁹ Nonetheless, all alcoholic beverages are required to have warning labels. In the Alcoholic Beverage Labeling Act of 1988, Congress required the following statement on the container of every alcoholic beverage: "GOVERNMENT WARNING: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems."¹²⁰

Instead of banning CABs completely, FDA and TTB should consider the possibility of including an additional warning statement on CAB labels if CABs do pose a potential risk to the public health. For example, immediately below the two statements in the mandated government warning, CAB labels could include the following warning statement: "(3) The combination of alcohol and caffeine in caffeinated alcoholic beverages may increase impairment of your ability to drive a car or operate

¹¹⁸ Alcohol and Tobacco Tax and Trade Bureau, *The Beverage Alcohol Manual (BAM), A Practical Guide: Basic Mandatory Labeling Information for Malt Beverages*, available at <http://www.ttb.gov/beer/bam/chapter1.pdf>.

¹¹⁹ See, e.g., 70 Fed. Reg. 22274 (Apr. 29, 2005).

¹²⁰ 27 U.S.C. §§ 213 *et seq.* (2006).

machinery.” Such a warning statement would be comparable to the current warning statements required for alcoholic beverages and would be more consistent with the level of scientific research presently available on CAB safety.

Apart from labeling, the Centers for Disease Control (CDC) have already posted on its website a CAB fact sheet, which includes warnings on the dangers of mixing alcohol and energy drinks.¹²¹ Such warnings on the FDA and CDC websites about the potential dangers of mixing alcohol and caffeine appear to be adequate provisions of information, and increased awareness and public education about the safety of CABs can be appropriately accomplished through such channels and the media. With access to accurate data on CABs and their potential risks, consumers can make informed decisions about whether to drink CABs and can learn how to drink CABs responsibly.

V. CONCLUSION

As a result of FDA’s determination that the added caffeine in four companies’ CAB products was an unsafe food additive, the future of CABs remains uncertain. What is known for sure is that FDA could have taken a better approach to the situation. There is still much more scientific research to be done on the

¹²¹ CDC CAB Fact Sheet, *supra* note 40.

safety of CABs, particularly with respect to what caffeine-alcohol ratio in CABs would be safe for consumers. Until FDA obtains sufficient scientific research and sets a specific caffeine level limit, its inconsistent treatment of products combining caffeine and alcohol will illustrate its evasion of the underlying public health objective. Instead of banning CABs altogether, FDA and TTB should consider adding warnings on CAB labels or simply keep consumers informed about CAB safety through publicly available resources.