



# Four Loko a.k.a. Blackout in a Can: The Federal Regulation of Caffeinated Alcoholic Beverages

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Four Loko a.k.a. Blackout in a Can: The Federal Regulation  
of Caffeinated Alcoholic Beverages

Caroline L. Mayberger  
Class of 2012  
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This paper is submitted in satisfaction of the Food and Drug Law (January  
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## Abstract

Caffeinated alcoholic beverages (“CABs”) such as “Four Loko” exploded onto the drinking scene in recent years, creating a youth culture fad and sparking concern and even outrage among politicians, the media, law enforcement officials, and health professionals. Part I of this article provides an overview of the effects of CAB consumption, and federal agencies’ steps toward CAB regulation. Part II explains the jurisdictional overlap of the Food and Drug Administration (“FDA”), the Federal Trade Commission (“FTC”), and the Alcohol and Tobacco Tax and Trade Bureau (“TTB”) with respect to alcoholic beverage regulation, arguing that the government’s reaction to the apparent health risks of CABs demonstrated notable interagency coordination and cooperation. Part III canvasses the extent to which CAB manufacturers may be exposed to civil liability in light of deaths and hospitalizations associated with CAB consumption, hypothesizing that CAB manufacturers may still face liability even after the removal of caffeine from their products. Part IV addresses the marketing issues related to CAB advertising, and Parts V and VI examine the arguments that FDA regulation of CABs is arbitrary and paternalistic, respectively. The article concludes in Part VII by presenting alternative solutions to an outright ban of CABs.



([http://www.myfoxboston.com/dpps/news/calif-teens-dead-beside-empty-can-of-four-loko-dpgonc-20110124-gc\\_11570684](http://www.myfoxboston.com/dpps/news/calif-teens-dead-beside-empty-can-of-four-loko-dpgonc-20110124-gc_11570684))

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## I. Background

Sales of CABs have recently skyrocketed; the two leading brands of CABs sold 22,905,000 gallons in 2008, as compared with only 337,500 gallons in 2002, the first year of significant CAB production.<sup>1</sup> CABs are regularly consumed by 31% of 12- to 17-year-olds, and 34% of 18- to 24-year olds.<sup>2</sup>

When Four Loko, otherwise known as “Blackout in a Can,” hit the market in 2005, it contained the caffeine equivalent of three cups of coffee and the alcoholic equivalent of five to six cans of beer. It also contained the stimulants guarana (a seed extract which itself contains caffeine), taurine (an amino acid), and wormwood (the active ingredient in absinthe).<sup>3</sup> Four Loko no longer contains caffeine or other stimulants, as will be explained. The beverages are 12% alcohol by volume in 23.5-ounce,<sup>4</sup> brightly colored cans, and are sold for about three dollars apiece in flavors like watermelon, grape, blue raspberry, and fruit punch.<sup>5</sup> The manufacturer of Four Loko, Phusion Products (“Phusion”), developed Four Loko after perceiving that students were mixing alcoholic beverages and energy drinks. Four Loko quickly

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<sup>1</sup> *Caffeinated Alcoholic Beverages*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/alcohol/fact-sheets/cab.htm> [hereinafter CDC FACT SHEET].

<sup>2</sup> Id.

<sup>3</sup> Michael Varvara, *Loco For “Four Loko,”* HEALTH PSYCH NEWS (Sep. 29, 2010), <http://healthpsychnews.wordpress.com/2010/09/29/loco-for-four-loko/>.

<sup>4</sup> A 23.5 ounce can is roughly twice the size of a standard 12-ounce soda or beer can.

<sup>5</sup> See Rebecca Black, *Four Loko and Other Alcohol-Caffeine Drinks Being Banned in U.S.*, USA LIVE HEADLINES (Nov. 16, 2010), <http://www.usaliveheadlines.com/2386/four-loko-and-other-alcohol-caffeine-drinks-being-banned-in-us.htm>.

became a youth culture fad.<sup>6</sup>

### **A. The Effects of Four Loko**

Studies have shown that the consumption of caffeine, a central nervous system stimulant, and alcohol, a depressant, limits the consumer's ability to perceive their true level of intoxication. In a state of "wide-awake drunk," individuals are more likely to suffer alcohol-related harm such as alcohol poisoning, physical injury, drunk driving incidents, and sexual victimization.<sup>7</sup>

Public health expert Ken Briggs explained the effect as follows:

You have a wide awake drunk who may not feel the warning signs of dangerous drinking such as the important subjective effects of tiredness and loss of coordination, which are good signals that it's time to shut it down and stop drinking.<sup>8</sup>

One *Time Magazine* reporter put it simply: "Alcoholic energy drinks are a crime against taste – but worse, they trick your brain into believing you're not as drunk as you are."<sup>9</sup> Health professionals have indicated that consuming alcohol and caffeine in combination will lead to increased

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<sup>6</sup> For example, the music group Delightful recently released an ode to Four Loko called "Four Lokos Only." In the music video, posted on Youtube, the members of the group ride in a limo while drinking Four Loko out of champagne flutes. See *Hottub Video Features Dolores Park, Four Loko, Girls Rapping*, SFIST (Aug. 10, 2011), [http://sfist.com/2011/08/10/hottub\\_video\\_features\\_dolores\\_park.php](http://sfist.com/2011/08/10/hottub_video_features_dolores_park.php).

<sup>7</sup> See *Marin Institute Commends New FDA Probe of Caffeinated Alcohol Producers*, FDA WEEK (Dec. 3, 2009) (citing ALCOHOL, ENERGY DRINKS, AND YOUTH: A DANGEROUS MIX, <http://www.marininstitute.org/site/campaigns/alcoholic-energy-drinks.html>); Meredith Melnick, "Blackout in a Can": *Alcoholic Energy Drinks Keep Wreaking Havoc*, TIME (Oct. 26, 2010), <http://healthland.time.com/2010/10/26/blackout-in-a-can-alcoholic-energy-drinks-keep-wreaking-havoc.htm>.

<sup>8</sup> Id.

<sup>9</sup> Id.

dehydration, because both are diuretics.<sup>10</sup> Health professionals have indicated that consuming alcohol and caffeine in combination will lead to increased dehydration, because both are diuretics.<sup>11</sup> Additionally, a 2010 study at the School of Public Health at the University of Maryland, tracking nearly 1,100 seniors, reported that those who consumed energy drinks mixed with alcohol showed signs of alcohol dependency.<sup>12</sup>

Furthermore, Four Loko has been linked to a variety of injuries, illnesses, and incidents of extremely bizarre behavior. For example, in October 2010 alone, several people went to the hospital after drinking Four Loko in Lancaster, Pennsylvania<sup>13</sup>; nine female Central Washington University students were hospitalized after drinking Four Loko<sup>14</sup>; and a man drunk on Four Loko was arrested after breaking and entering into the home of a seventy-year-old woman and defecating on her floor in Tampa, Florida.<sup>15</sup> In August of 2011, the *Annals of Emergency Medicine* published data collected by a team of emergency room doctors in New York, describing 11

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<sup>10</sup> Jenny L. Grus, *Giving You Wings: Should the Food and Drug Administration Investigate the Safety of Red Bull and So-Called Energy Drinks?* 47 (2003), in Peter Barton Hutt, ed., *Food and Drug Law: An Electronic Book of Student Papers*.

<sup>11</sup> *Id.* at 47.

<sup>12</sup> Daniel B. Wood, *Four Loko: Does FDA's Caffeinated Alcohol Beverage Ban Go Too Far?*, CHRISTIAN SCIENCE MONITOR (Nov. 19, 2010), <http://www.csmonitor.com/USA/Society/2010/1119/Four-Loko-Does-FDA-s-caffeinated-alcoholic-beverage-ban-go-too-far/%28page%29/2>.

<sup>13</sup> Erin Poserina, *Going Loko on Four Lokos*, BU NOW BLOOMSBURG (Nov. 7, 2010), <http://bunow.bloomu.edu/10039-going-loko-on-four-lokos>.

<sup>14</sup> *Student Illnesses at Party Blamed on Four Loko*, MSNBC (Oct. 25, 2010), [http://www.msnbc.msn.com/id/39835017/ns/us\\_news-life/t/student-illnesses-party-blamed-four-loko/](http://www.msnbc.msn.com/id/39835017/ns/us_news-life/t/student-illnesses-party-blamed-four-loko/). Based on their behavior before hospitalization, witnesses speculated that the women had been given a date rape drug. Melnick, *supra* note 7.

<sup>15</sup> Barbara Hijek, *Deputies: Naked Man Trashed Two Homes*, SUNSENTINEL.COM (Oct. 15, 2010), [http://weblogs.sun-sentinel.com/news/specials/weirdflorida/blog/2010/10/deputies\\_naked\\_man\\_trashed\\_two.html](http://weblogs.sun-sentinel.com/news/specials/weirdflorida/blog/2010/10/deputies_naked_man_trashed_two.html).



cases of young people who were taken to Bellevue Hospital Center in 2010 after consuming Four Loko.<sup>16</sup> The study's lead author, Dr. Deborah Levine, commented on why these instances of hospitalization due to intoxication stood out: "one kid was found on the subway tracks, another was unconscious at school . . . These were exceptions to the typical Friday night teenage intoxication. These were more extreme and hazardous circumstances."<sup>17</sup>

### **B. Steps Toward Regulation**

Concerned about CABs' ability to mask the effects of intoxication and induce a state of wide-awake drunk,<sup>18</sup> in 2008 various state attorneys general began investigating CAB manufacturers.<sup>19</sup> In October of 2008, a group of scientists and physicians also petitioned the FDA to more tightly regulate CABs, indicating that the widely differing levels of caffeine and alcohol in different kinds of CABs, which are not clearly noted on the beverage labels, increase the risk of "caffeine intoxication" and unsafe use of alcohol.<sup>20</sup> That same year, several CAB companies, such as Anheuser-Bush, ceased producing CABs, creating a space in the market for smaller companies like

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<sup>16</sup> Eliza Barclay, *Four Loko, 11 Young People and a Busy Emergency Room*, SHOTS: NPR'S HEALTH BLOG (Aug. 2, 2011), [http://www.npr.org/blogs/health/2011/08/04/138932012/four-loko-11-young-people-and-a-busy-emergency-room?ps=sh\\_sthdl](http://www.npr.org/blogs/health/2011/08/04/138932012/four-loko-11-young-people-and-a-busy-emergency-room?ps=sh_sthdl).

<sup>17</sup> Id.

<sup>18</sup> *Wide-Awake Drunk: Loko Consumers are Underage, Unwise & Unwell*, EMS WORLD (Aug. 2, 2011), [http://www.emsworld.com/web/online/Top-EMS-News/Wide-Awake-Drunk--Loko-Consumers-are-Underage--Unwise-and-Unwell/1\\$17829](http://www.emsworld.com/web/online/Top-EMS-News/Wide-Awake-Drunk--Loko-Consumers-are-Underage--Unwise-and-Unwell/1$17829).

<sup>19</sup> See, e.g., *Conn. AG Calls on FDA to Ban Alcoholic Energy Drinks*, PREPARED FOODS NETWORK (Nov. 17, 2010), <http://www.preparedfoods.com/articles/conn-ag-calls-on-fda-to-ban-alcoholic-energy-drinks>.

<sup>20</sup> *Four Loko Wrongful Death Lawsuit Filed by Family of 15 Year Old Boy*, ABOUTLAWSUITS.COM (May 20, 2011), <http://www.aboutlawsuits.com/four-loko-wrongful-death-lawsuit-18343>.

Phusion.<sup>21</sup> On September 25, 2009, several state attorneys general asked the FDA to look into whether caffeine as a food additive in alcoholic beverages is “generally recognized as safe” (“GRAS”) according to FDA standards.<sup>22</sup> A food additive is any substance with an intended use that may reasonably be expected to result in its becoming a component or otherwise affecting the characteristics of any food, and is presumed to be unsafe unless its intended use has been specifically approved by federal regulation, or qualified experts generally recognize its use to be safe.<sup>23</sup> Although the FDA has approved caffeine as GRAS in non-alcoholic beverages (in a maximum concentration of 200 parts per million),<sup>24</sup> the FDA has never formally approved caffeine as a food additive in alcoholic beverages.<sup>25</sup> Thus, for the addition of caffeine to alcoholic beverages to be legal, it must be shown to be GRAS.

In response to this pressure to regulate, on November 13, 2009, the FDA warned Phusion and about 30 other CAB manufacturers that it was

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<sup>21</sup> See *Anheuser to Stop Selling Alcoholic Energy Drinks*, REUTERS (June 26, 2008), <http://uk.reuters.com/article/2008/06/26/us-anheuser-settlement-idUKN2633937920080626>.

<sup>22</sup> CAB Letter to FDA from Attorneys General (Sept. 25, 2009), <http://www.fda.gov/downloads/Food/FoodIngredientsPackaging/UCM190371.pdf>. Companies currently conduct their own GRAS studies, and voluntarily submit them to FDA for review. While some industry attorneys argue that the FDA should *require* companies to provide the FDA with GRAS information, others, including FDA insiders, support the current self-regulation model. See Alaina Busch, *FDA Deems Caffeinated Alcohol Unsafe, Delauro Calls for GRAS Oversight*, FDA WEEK (Nov. 19, 2010).

<sup>23</sup> Grus, *supra* note 10, at 18 (citing Lars Noah & Richard Merrill, *Starting from Scratch? Reinventing the Food Additive Process*, 78 B.U.L. REV. 329, 330 (1998)).

<sup>24</sup> Gwendolyn Prothro, *The Caffeine Conundrum: Caffeine Regulation in the United States*, 27 CUMB. L. REV. 65, (1996-97).

<sup>25</sup> Abby Goodnough, *F.D.A. Issues Warning Over Alcoholic Energy Drinks*, N.Y. TIMES (Nov. 17, 2010), available at <http://www.nytimes.com/2010/11/18/us/18drinks.html?sq=F.D.A.%20Issues%20Warning%20Over%20Alcoholic%20Energy%20Drinks&st=cse&adxnnl=1&scp=1&adxnnlx=1317306513-YGg2MEHPrwR0jVR8g+MZ2A>.

looking into the safety of CABs.<sup>26</sup> Noting that it was “unaware of the basis upon which manufacturers may have concluded that the use of caffeine in alcoholic beverages is GRAS or prior sanctioned,” the FDA requested that the companies produce evidence of their rationale, with supporting data and information, within 30 days.<sup>27</sup> On June 25, 2010 (seven and a half months later), Phusion submitted its GRAS Notice to the FDA, in which it argued that the use of caffeine in alcoholic beverages has been determined GRAS by scientific procedures, and that the studies challenging Four Loko’s safety are flawed.<sup>28</sup> However, despite its claim that mixing caffeine and alcohol is safe, after complaining in a later press release that “[w]idespread media attention around [CABs] has caused many to seek retroactive bans on these legal, regulated products,” on November 16, 2010, Phusion announced it would voluntarily remove caffeine (and guarana, taruine, and wormwood) from the Four Loko formula.<sup>29</sup>

At this time, CABs such as Four Loko were receiving a high level of media attention. The consumption of Four Loko had been linked to numerous harmful incidents, including the deaths of two Florida college students, the

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<sup>26</sup> FDA To Look Into Safety of Caffeinated Alcoholic Beverages (Nov. 13, 2009), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm190427.htm>.

<sup>27</sup> Id.

<sup>28</sup> Notice of GRAS Exemption Claim for Use of Caffeine in Alcoholic Beverages from Phusion Products to the FDA (June 25, 2010), [http://www.accessdata.fda.gov/scripts/fcn/gras\\_notices/GRN000347.pdf](http://www.accessdata.fda.gov/scripts/fcn/gras_notices/GRN000347.pdf).

<sup>29</sup> Phusion Projects Releases Open Letter to Regulators (Nov. 10, 2010), <http://chicagopressrelease.com/press-releases/phusion-projects-releases-open-letter-to-regulators>; Phusion Projects to Remove Caffeine, Guarana and Taurine from Products (Nov. 16, 2010), <http://www.prnewswire.com/news-releases/phusion-projects-to-remove-caffeine-guarana-and-aurine-from-products-108540319.html>.

abduction and torture of gang members in NYC, and the death of a 15-year-old-boy in Illinois who drank two cans at a concert, was taken home, and then unexpectedly ran out into a busy road where he was struck and killed by a car.

Upon review, the FDA determined that the addition of caffeine to alcoholic beverage products constitutes an unsafe health additive under the Food, Drug, and Cosmetic Act (“F, D & C Act”), and on November 17, 2010, the FDA issued warning letters to four CAB companies.<sup>30</sup> Those companies were Phusion, Charge Beverages Corp. (which sold “Core High Gravity HG,” “Core High Gravity HG Orange,” and “Lemon Lime Core Spiked”), New Century Brewing Co., LLC (which sold “Moonshot”), and United Brands Company Inc. (which sold “Joose” and “Max”). In the warning letters, the FDA claimed that the addition of caffeine to alcoholic beverages masks certain “sensory cues” that typically alert drinkers as to how intoxicated they are, making “risky behaviors that may lead to hazardous and life-threatening situations” more likely.<sup>31</sup> Furthermore, the warning letter to Phusion noted that in its GRAS Notice, Phusion “did not cite any scientific literature of which the agency was not already aware,” and criticized Phusion’s reliance on “safety studies of caffeine alone (i.e., not in the presence of alcohol) to support

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<sup>30</sup> FDA Warning Letters Issued to Four Makers of Caffeinated Alcoholic Beverages, FDA NEWS RELEASE (Nov. 17, 2010), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm234109.htm> [hereinafter FDA CAB Warning Letters Press Release]. Although only four companies received warning letters, FDA Principal Deputy Commission Joshua Sharfstein said that the FDA “expect[ed] these warning letters to be read across the industry.” Busch, *supra* note 21.

<sup>31</sup> FDA CAB Warning Letters Press Release, *supra* note 29.

[its] view that caffeine is safe under the relevant conditions of use.”<sup>32</sup> The letter also noted that the studies Phusion relied on in its GRAS Notice actually reported adverse behavioral effects related to CAB consumption.<sup>33</sup> The FDA warned that if the companies failed to comply with its warning and remove caffeine from the products or its product from the market, it “may pursue an enforcement action that could include seizure of the products or an injunction to prevent the firm from continuing to produce the product until the violation has been corrected.”<sup>34</sup>

The TTB of the Department of Treasury, which enforces the Federal Alcohol Administration Act (“FAA Act”)<sup>35</sup> and thus regulates the labeling of alcoholic beverages,<sup>36</sup> also sent letters to the four companies. In a press release, the TTB stated that if a CAB producer should receive a notification from the FDA that its product is “adulterated” due to the unsafe additive of caffeine under the F, D & C Act, the TTB will consider that product illegally mislabeled under the FAA Act, meaning it cannot be sold or shipped in interstate commerce.<sup>37</sup>

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<sup>32</sup> FDA Warning Letter to Phusion Products (Nov. 17, 2010), <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/ucm234023.htm> [hereinafter FDA Notice to Phusion].

<sup>33</sup> Id.

<sup>34</sup> FDA CAB Warning Letters Press Release, *supra* note 29.

<sup>35</sup> 27 U.S.C. § 201.

<sup>36</sup> PETER BARTON HUTT ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS 136 (2007) [hereinafter HUTT, FOOD AND DRUG LAW].

<sup>37</sup> TTB Issues Warning on the Sale or Shipment of Caffeinated Alcohol Beverages Determinated by FDA to be Adulterated (Nov. 17, 2010). <http://www.ttb.gov/press/fy10/press-release-caffeinated-alcohol-beverages1102.pdf>. This is very similar to BATF’s approach to the regulation of sulfites in wine. See Judson O. Berkey, The History of Alcoholic Beverage Labeling Regulation and its Implications for a Health Claim on Wine Labels 14 (1998), in Peter Barton Hutt, ed., Food and Drug Law: An

The FTC, which regulates advertising of alcoholic beverages, also issued letters to the four companies, warning that marketing of CABs could constitute an unfair or deceptive practice in violation of the Federal Trade Commission Act (“FTC Act”).<sup>38</sup> The FTC wrote in its letter to Phusion Products that it was “aware of a number of recent incidents suggesting that alcohol containing added caffeine may present unusual risks to health and safety . . . suggest[ing] that consumers, particularly young adults, may not fully appreciate the potential effects of consuming caffeinated alcohol beverages such as Four Loko and Four Maxed.”<sup>39</sup>

All four companies took heed of the warning letters and indicated they would remove caffeine from their malt beverage products. Since removing caffeine from its CAB “Joose,” the CEO of United Brands. Co. Inc. stated: “Has doing that hurt our business? . . . Yes, it has. A lot.”<sup>40</sup> Following the media blow-up and the agencies’ issuance of warning letters, several states (Michigan, Utah, Washington, Massachusetts, Kansas, Oklahoma, and California) have banned the sale of products mixing alcohol and

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Electronic Book of Student Papers. (“While the FDA was conducting its study of sulfites, the ATF proposed a rule to require reductions of permitted levels of sulfites in wine to 275 parts per million. . . . [T]he ATF stated that if at some future date the [FDA] were to determine that the sulfating of foods and beverages presents a risk to public health and requires labeling disclosure, ATF [will] promptly propose disclosure in labeling of sulfur dioxide and sulfiting agents. Thus, the ATF was clearly willing to defer to the scientific determinations of the FDA as long as it retained control over the final form of the labeling restrictions.”).

<sup>38</sup> FTC Sends Warning Letters to Marketers of Caffeinated Alcohol Drinks, FTC Press Release (Nov. 17, 2011), <http://www.ftc.gov/opa/2010/11/alcohol.shtm>.

<sup>39</sup> FTC Notice of Potentially Illegal Marketing of Caffeinated Alcohol Product to Phusion Products, Inc. (Nov. 17, 2010), <http://www.ftc.gov/os/closings/warnings/phusionletter.pdf> [hereinafter FTC Notice to Phusion].

<sup>40</sup> James Nash, *California Joins Six U.S. States Banning Beer Drinks Laced with Caffeine*, BLOOMBERG, <http://www.bloomberg.com/news/2011-08-02/california-s-new-law-takes-the-caffeine-kick-out-of-alcoholic-beverages.html>.

caffeine.<sup>41</sup> Many college campuses have also banned CABs.<sup>42</sup>

## II. FTC, FDA, and TTB Jurisdictional Overlap

Alcohol is the only product mentioned in the Constitution; there are two amendments discussing its production and distribution.<sup>43</sup> The U.S. Government has always been concerned with the regulation of alcohol. The F, D & C Act empowers the FDA to regulate alcoholic beverages as food. First, under § 402(a) of the F, D & C Act, the FDA regulates the safety of food additives in alcoholic beverages.<sup>44</sup> Second, § 403 of the Act broadly prohibits the misbranding of any food in interstate commerce, deeming food misbranded if its labeling is false or misleading in any particular.<sup>45</sup> Alcohol has been determined a good under the meaning of the F, D & C Act.<sup>46</sup> However, the FDA currently does not regulate alcoholic beverage labeling, as will be explained.

### A. The FDA and the FTC

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<sup>41</sup> *Id.*; Black, *supra* note 5.

<sup>42</sup> Black, *supra* note 5. New York State Senator Jeff Klein has been lobbying for a statewide ban of CABs in New York, arguing that the continued presence of the old, caffeinated version of Four Loko on store shelves in New York demonstrates that “a simple gentleman’s agreement is not enough to keep this dangerous product off store shelves and out of New York State.” The New York Senate passed Klein’s bill in June of 2011, but the bill never made it to the Assembly floor for a vote. Ian Thomas, *Senator Revives Call to Ban “Blackout in a Can”*, CRAIN’S NEW YORK BUSINESS.COM (July 29, 2011), <http://www/crainsnewyork.com/article/20110729/FREE/110729868>.

<sup>43</sup> Mary Hancock, *Federal Jurisdictional Disputes in the Labeling and Advertising of Malt Beverages*, FOOD DRUG COSMETIC L. J. 271, 271 (1979).

<sup>44</sup> HUTT, FOOD AND DRUG LAW, *supra* note 35, at 37.

<sup>45</sup> Matthew J. Elliott, Happy Inconsistency: Health Claims Standards at the FTC and FDA 2 (1997), in Peter Barton Hutt, ed., Food and Drug Law: An Electronic Book of Student Papers. “A food is also deemed to be misbranded if its label contains health-related information that fails to adhere to detailed agency regulations designed to contextualize it.” *Id.*

<sup>46</sup> Jenna Myers, Fomentation About Fermentation: A Study on Ingredient Labeling on Alcoholic Beverages, 9-10 (2002), in Peter Barton Hutt, ed., Food and Drug Law: An Electronic Book of Student Papers.

The FTC regulates the advertising of alcoholic beverages. The FTC Act gives the FTC the express authority to prohibit unfair or deceptive acts or practices in or affecting commerce, 15 U.S.C. § 45, and the false advertising of food, drugs, devices, services, or cosmetics, 15 U.S.C. § 52. Alcoholic beverages have been deemed “food” within the meaning of the section.<sup>47</sup>

The FTC evaluates food advertising claims based on the questions of (1) whether the advertising claim is adequately substantiated, and (2) whether the claim is deceptive.<sup>48</sup> The advertiser’s intent to deceive is not relevant.<sup>49</sup> The omission of material information (even if the other representations are accurate) may be considered deceptive and therefore violate the FTC Act.<sup>50</sup>

The FTC and the FDA have different statutory mandates. The FTC prevents only unfair advertising practices, while the FDA aims to ensure that foods are safe, products are accurately and informatively represented, and the public is educated about health issues.<sup>51</sup> In 1954, the FDA and FTC agreed that the FTC would focus on food advertising, and the FDA would regulate food labeling.<sup>52</sup> However, there is still a high level of agency interaction between the FDA and the FTC. For example, the FTC will

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<sup>47</sup> Hancock, *supra* note 42, at 282.

<sup>48</sup> Nicole Gerhart, The FDA & the FTC: An Alphabet Soup Regulating the Misbranding of Food 29 (2001), in Peter Barton Hutt, ed., Food and Drug Law: An Electronic Book of Student Papers.

<sup>49</sup> Id. at 31.

<sup>50</sup> Id.

<sup>51</sup> Elliott, *supra* note 44, at 3-4.

<sup>52</sup> Id. at 3.



occasionally adopt the factual findings of the FDA in order to determine whether a marketing practice is false or deceptive.<sup>53</sup>

### **B. The FDA and the TTB (BATF)**

The FAA Act provides independent authority for the regulation of alcoholic beverages.<sup>54</sup> While the Bureau of Alcohol, Tobacco and Firearms (“BATF”) in the Department of the Treasury previously enforced the FAA Act, the Homeland Security Act of 2002 shifted the responsibility of regulating beer products and wine products containing 7% alcohol or more to the Alcohol and Tobacco Tax and Trade Bureau, a new unit of the Treasury Department.<sup>55</sup> As such, the TTB now regulates the labeling of alcoholic beverages.

The F, D & C Act and the FAA Act overlap in some ways. The apparent overlap

occurs with the misbranding section of the 1938 [F, D & C] Act and the labeling section of the FAA Act. Specifically, the 1938 Act requires ingredient listing on foods for which standards of identity have not been promulgated. The FAA Act, however, has no such ingredient requirement, although it has many other requirements concerning the labeling of the contents of alcohol, which are not found in the food misbranding provisions of the 1938 Act.”<sup>56</sup>

While in 1940 the FDA agreed to relinquish its jurisdiction over labeling alcoholic beverages to BATF (despite its concurrent jurisdiction over alcohol

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<sup>53</sup> Gerhart, *supra* note 48, at 35.

<sup>54</sup> HUTT, FOOD AND DRUG LAW, *supra* note 35, at 136. The FAA Act requires adequate information as to identity, quality, alcoholic content, net contents, and manufacturer, bottler or importer. See Frederic P. Lee, *Adulteration and Misbranding of Alcoholic Beverages*, FOOD DRUG COSMETIC LAW QUARTERLY 82, 84 (March 1948).

<sup>55</sup> HUTT, FOOD AND DRUG LAW, *supra* note 35, at 36.

<sup>56</sup> Elaine T. Byszewski, *What's in the Wine? A History of FDA's Role*, 57 FOOD & DRUG L. J. 545, 561 (2002).

labeling), in the early 1970's, the FDA responded to a request by the Center for Science in the Public Interest to look into promulgating ingredient labeling requirements for alcoholic beverages.<sup>57</sup> The FDA decided to defer to BATF in developing the proposed regulations, and on October 8, 1974, the FDA and BATF entered a Memorandum of Understanding ("MOU") designating BATF as "the primary agency responsible for the promulgation and enforcement of labeling regulations of distilled spirits, wine and malt beverages."<sup>58</sup> BATF agreed that the regulations it promulgated under the FAA Act would be consistent with the F, D & C Act's food labeling requirements and corresponding regulations.<sup>59</sup>

However in 1975, BATF yielded to pressure from the alcohol industry and decided not to require alcoholic beverage ingredient labeling, citing factors such as costs to the industry, international trade implications, the extensiveness of existing regulations, and the uniqueness of the alcoholic beverage manufacturing process.<sup>60</sup> As one commentator wrote, "FDA's primary constituency was the consuming public, while BATF's main constituency was the liquor industry, so it is not surprising that FDA wanted to require ingredient labeling on alcoholic beverages, while BATF did not."<sup>61</sup> Soon after, the FDA revoked the initial MOU and announced it would enforce

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<sup>57</sup> Iver P. Cooper, *The FDA, the BATF, and Liquor Labeling: A Case Study of Interagency Jurisdictional Conflict*, FOOD DRUG COSMETIC L. J. 370, 375 (1979). See also Berkey, *supra* note 36, at 5-7.

<sup>58</sup> Cooper, *supra* note 57.

<sup>59</sup> Id.

<sup>60</sup> Byszewski, *supra* note 56, at 562-63.

<sup>61</sup> Id. at 563.

liquor industry compliance with § 403.<sup>62</sup> After discussions, the FDA and BATF entered into another MOU, which assigned regulation of alcoholic labeling *except for ingredient labeling* to BATF, while reserving jurisdiction over alcohol ingredient labeling to the FDA.<sup>63</sup> However, “[t]his attempt at reconciliation did not succeed . . . and the next stage of the relationship between the two agencies occurred in the courts.”<sup>64</sup> In *Brown-Forman Distillers Corp. v. Mathews, Secretary of Health Education, and Welfare*,<sup>65</sup> vintners and distillers opposed to FDA regulation of alcohol labeling sought a declaratory judgment in a Kentucky district court that the FDA did not have jurisdiction over the labeling of alcoholic beverages.<sup>66</sup> The *Brown-Forman* court held that BATF has *exclusive* jurisdiction over alcohol labeling, and the Office of Management and Budget later instructed the Department of Justice not to appeal the decision.<sup>67</sup>

After *Brown-Forman*, BATF promulgated a final rule containing alcoholic beverage ingredient labeling regulations, which required the disclosure of ingredients either through a list on the beverage label, or by providing a mailing address on the label to which one could write to obtain ingredient information.<sup>68</sup> The rule also mandated the disclosure on the label

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<sup>62</sup> Cooper, *supra* note 57, at 376.

<sup>63</sup> Id.

<sup>64</sup> Berkey, *supra* note 36, at 8.

<sup>65</sup> 435 F. Supp. 5 (W.D. Ky. 1976).

<sup>66</sup> Byszewski, *supra* note 56, at 564; Cooper, *supra* note 57, at 377.

<sup>67</sup> Cooper, *supra* note 57, at 377.

<sup>68</sup> Berkey, *supra* note 36, at 10.

of the presence of F D & C Yellow No. 5.<sup>69</sup> However, pursuant to encouragement by President Reagan to conduct cost-benefit analyses of regulations, BATF rescinded its ingredient labeling rule not long after.<sup>70</sup> A litany of litigation ensued, culminating in the D.C. Circuit's holding that BATF's rescission was based on a justifiable and reasoned analysis, and did not violate either the FAA Act or the Administrative Procedure Act.<sup>71</sup> With that, the controversy concluded: BATF had won exclusive jurisdiction over the regulation of alcoholic beverage labeling, and had decided not to require it.

In 1987, BATF and the FDA entered into another MOU in order to clarify the enforcement responsibilities of each agency with respect to alcoholic beverage regulation.<sup>72</sup> The new MOU established that if the FDA determined that the presence of an ingredient in an alcoholic beverage posed a risk to public health, BATF would promulgate labeling regulations with respect to that ingredient.<sup>73</sup> The agreement also established that BATF and the FDA would consult regularly about the regulation of labeling of other ingredients in alcoholic beverages, and that the FDA would provide BATF with a health hazard evaluation of any substance contained in alcoholic beverages upon BATF's request.<sup>74</sup> Since the promulgation of this MOU,

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<sup>69</sup> Myers, *supra* note 46, at 25.

<sup>70</sup> Berkey, *supra* note 36, at 10.

<sup>71</sup> Center for Science in the Public Interest v. Department of the Treasury, 797 F.2d 995 (D.C. Cir. 1986).

<sup>72</sup> 52 Fed. Reg. 45502 (Nov. 30, 1987).

<sup>73</sup> Berkey, *supra* note 36, at 16.

<sup>74</sup> Id.

BATF has issued some regulations requiring the disclosure of certain alcoholic beverage ingredients on labels, such as F D & C Yellow No. 5.<sup>75</sup>

### **C. Interagency Coordination for CAB Regulation**

As the history of conflict and cooperation between the FDA and BATF, and the FDA and the FTC demonstrates, when jurisdictional overlap occurs, agencies have several options: one agency can defer to another, the agencies can work together and share jurisdiction, or the agencies can compete by promulgating contradictory regulations to provoke judicial intervention.<sup>76</sup> The FTC, FDA, and TTB have responded to public concern about CABs in a relatively integrated, effective manner, deferring to while also reinforcing each other's power. Demonstrating inter-agency cooperation between the FTC and the FDA, the FTC's warning letters to Phusion stated:

We have further been advised that the Food and Drug Administration ("FDA") has warned you that caffeine, as used in your product, Four Loko, is an "unsafe food additive" under the Federal Food, Drug, and Cosmetic Act. As a result, this product is deemed adulterated.

The FDA's warning that caffeine is an "unsafe food additive," as used in Four Loko, is a relevant consideration in the FTC's analysis of whether the marketing of caffeinated alcohol products such as Four Loko and Four Maxed is deceptive or unfair under the Federal Trade Commission Act. In the past, the FTC has accorded significant weight to FDA findings regarding product safety and efficacy.<sup>77</sup>

This cooperation is notable; a lawyer and former associate chief counsel at the F.D.A. stated in a *New York Times* article on CABs that it was unusual for the FDA and the FTC to take joint action, and that "the liability risk goes

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<sup>75</sup> Myers, *supra* note 46, at 40.

<sup>76</sup> Cooper, *supra* note 57, at 378-79.

<sup>77</sup> FTC Notice to Phusion, *supra* note 38.

up considerably once you have not one, but two federal agencies either stating or suggesting there are violations of federal law at work.”<sup>78</sup>

Similarly, in TTB’s letter to Phusion, TTB stated:

The Alcohol and Tobacco Tax and Trade Bureau (TTB) enforces the labeling provisions of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. § 205(e). While TTB regulates the labeling of alcohol beverages, it is FDA’s responsibility to evaluate the safety of ingredients added to alcohol beverages, pursuant to FDA’s authority under the FFDCFA. TTB is hereby putting you on notice that FDA’s determination that a product is adulterated under the FFDCFA would have consequences under the FAA Act. It is TTB’s position that adulterated malt beverages are mislabeled within the meaning of the FAA Act.<sup>79</sup>

However, demonstrating interagency tension and the potential duplication of efforts to ensure alcoholic beverage safety, in the FDA’s letter to Phusion, the FDA pointed out:

The agency is aware that your company received a Certification/Exemption of Label/Bottle Approval (COLA) from the Alcohol and Tobacco Tax and Trade Bureau (TTB) and that, as part of your application for the COLA, you informed TTB that your product would contain caffeine. A COLA does not constitute a food additive petition approval, a statement regarding GRAS status, or a prior sanction, and you are obligated to abide by the provisions of the Federal Food, Drug, and Cosmetic Act.<sup>80</sup>

Here, the FDA makes clear that meeting one agency’s requirements does not equal meeting another’s.<sup>81</sup> The TTB’s letter also acknowledges this tension.<sup>82</sup>

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<sup>78</sup> Goodnough, *supra* note 24.

<sup>79</sup> TTB Warning Letter to Phusion Products (Nov. 18, 2010), [http://www.ttb.gov/pdf/phusion\\_letter\\_final.pdf](http://www.ttb.gov/pdf/phusion_letter_final.pdf) [hereinafter TTB Notice to Phusion].

<sup>80</sup> FDA Notice to Phusion, *supra* note 31.

<sup>81</sup> *See* Gerhart, *supra* note 48, at 35 (“Not only are there consumed resources on the agency-side is this dual system [the jurisdictional overlap between the FDA and the FTC], but the manufacturers must evaluate their claims and try to anticipate both the FDA’s and FTC’s reaction to any proposed claims. By regulating advertising and labeling, the government changes businesses’ costs of providing market information.”).

### III. Civil Liability

Apart from facing enforcement action by the FDA, FTC, or TTB, CAB manufacturers risk civil liability from individuals allegedly harmed from consuming Four Loko. Since Four Loko hit the college drinking scene, the public and the media have been in an uproar over reports of young people being hospitalized after drinking Four Loko. One blogger defined the term “Four Loko Effect” as “a dramatic increase in visits to the ER by wasted 20-somethings.”<sup>83</sup> At least one law firm is already advertising its services to potential plaintiffs harmed from drinking CABs.<sup>84</sup>

#### A. Lawsuits Against Phusion

Jason Kieran was a twenty-year-old Florida State University student when he fatally shot himself with a .22-caliber pistol after drinking Four Loko in September of 2010.<sup>85</sup> His family sued Phusion, five convenience stores that sold Four Loko, and Busch-Transou, L.C., a Four Loko distributor,

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<sup>82</sup> TTB Notice to Phusion, *supra* note 79 (“[I]f FDA determines that your alcohol beverage product is adulterated under the FFDCFA, its sale or shipment in interstate or foreign commerce by an industry member subject to the provisions of 27 U.S.C. § 205(e) constitutes a violation of the FAA Act even if the product is covered by a COLA or an approved formula. It is each producer’s responsibility to ensure that its alcohol beverages are in compliance with the requirements of the FFDCFA.”).

<sup>83</sup> Brit Trogen, *The Four Loko Effect*, SCIENCE IN SECONDS BLOG (May 25, 2011), <http://www.scienceinseconds.com/blog/The-Four-Loko-Effect>.

<sup>84</sup> *Caffeinated Alcoholic Beverages Dangerous*, CHILDER’S, SCHLUETER & SMITH, LLC, [http://www.cssfirm.com/2011/06/08/caffeinated-alcoholic-beverages-dangerous/#\\_ftn2](http://www.cssfirm.com/2011/06/08/caffeinated-alcoholic-beverages-dangerous/#_ftn2) (“Alcoholic beverages containing stimulants like caffeine are examples of defective design in products . . . One product in particular, Four Loko, is so dangerous that the manufacturer’s insurance company, Selective Insurance Company of South Carolina, refuses to cover the product for liability. Phusion Projects owns the brand and faces several lawsuits over the caffeinated alcoholic drink.”).

<sup>85</sup> Kim Janssen, *Four Loko’s Manufacturer Sued by Dead Teen’s Mom*, SUN TIMES (May 19, 2011), <http://www.suntimes.com/news/metro/5469230-417/four-lokos-manufacturer-sued-by-dead-teens-mom.htm>.

in Orange County Circuit Court in Florida. According to the complaint, at the time of his death, Jason “had been awake for over 30 hours, and was in a disoriented and agitated state.”<sup>86</sup> The complaint alleged a negligence/products liability claim and a strict liability/products liability claim against all defendants, and a dram shop liability claim against the five convenience stores.

Later that same month, fifteen-year-old Bo Rupp died in Washington D.C. after drinking two cans of Four Loko, wandering onto a highway, and getting hit by a car.<sup>87</sup> His mother sued Phusion earlier this year in Illinois state court, arguing that Four Loko’s negligent targeting of underage caused her son’s death.<sup>88</sup> Phusion, insisting it does not market to underage drinkers, expects to fight the lawsuit in court.<sup>89</sup> One news source reported: “Bo, an honor roll student and lacrosse fanatic, drank no other alcoholic drinks and took no drugs, but had a blood alcohol level of 0.19 when he died, the attorneys claim.”<sup>90</sup> After drinking Four Loko at a concert and being sent home with his mother, Bo apparently acted “paranoid and disoriented” on the ride home.<sup>91</sup> Upon returning home, Bo took off running onto a busy highway

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<sup>86</sup> Plaintiff’s First Amended Complaint for Declaratory Judgment 13 (Nov. 24, 2010), [http://newsandinsight.thomsonreuters.com/uploadedFiles/National\\_Litigation/Legal\\_Materials/Court\\_Filings/2010/11\\_-\\_November/fourloko.pdf](http://newsandinsight.thomsonreuters.com/uploadedFiles/National_Litigation/Legal_Materials/Court_Filings/2010/11_-_November/fourloko.pdf).

<sup>87</sup> Janssen, *supra* note 85.

<sup>88</sup> *Four Loko Sued: Family Blames Chicago Company for Teen’s Death*, HUFFPOST CHICAGO (May 25, 2011), [http://www.huffingtonpost.com/2011/05/19/four-loko-sued-family-bla\\_n\\_864198.html](http://www.huffingtonpost.com/2011/05/19/four-loko-sued-family-bla_n_864198.html).

<sup>89</sup> Janssen, *supra* note 85.

<sup>90</sup> *Id.*

<sup>91</sup> *Four Loko Sued*, *supra* note 88.



and was fatally struck by a car.<sup>92</sup> In the complaint, Bo's mother claims that Phusion "was careless and negligent in formulating a caffeinated alcoholic beverage that desensitizes users to the symptoms of intoxication, and increases the potential for alcohol-related harm."<sup>93</sup> In response to the complaint, Phusion pointed out that Four Loko no longer contains caffeine.<sup>94</sup> The Rupp family responded that the high level of alcohol and the sweet flavoring of Four Loko still make it too dangerous to be available in stores.<sup>95</sup>

In 2011, a Texas man filed a products liability suit against Four Loko, claiming that the caffeinated version of Four Loko caused him to have a stroke.<sup>96</sup> The plaintiff claims Phusion failed to warn consumers about the possible side effects of consuming Four Loko, and seeks \$75,000 in damages for pain and suffering, emotional stress and mental anguish, and lost income.<sup>97</sup> Additionally, the plaintiff seeks punitive damages against Phusion.<sup>98</sup>

Interestingly, a news source noted that deaths related to Four Loko have increased the drink's appeal as a "taboo" product.<sup>99</sup> Whether the "taboo"

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<sup>92</sup> Id.

<sup>93</sup> Janssen, *supra* note 85.

<sup>94</sup> *Four Loko Wrongful Death Lawsuit Filed by Family of 15 Year Old Boy*, ABOUTLAWSUITS.COM (May 20, 2011), <http://www.aboutlawsuits.com/four-loko-wrongful-death-lawsuit-18343>.

<sup>95</sup> Id.

<sup>96</sup> *Four Loko Stroke Lawsuit Filed by Texas Man*, ABOUTLAWSUITS.COM (July 26, 2011), <http://www.aboutlawsuits.com/four-loko-stroke-lawsuit-19706>.

<sup>97</sup> Id.

<sup>98</sup> Id.

<sup>99</sup> Janssen, *supra* note 85.

appeal of Four Loko will lead to more harmful incidents associated with the beverage remains to be seen.

### **B. Evidence of Remedial Measures**

All four CAB manufacturers that received warning letters voluntarily removed caffeine from their products. However, Phusion, for example, continues to maintain that drinking alcohol and caffeine together is safe.<sup>100</sup> In federal court, Rule 407 of the Federal Rules of Evidence prohibits the introduction of evidence of measures taken after the allegedly injurious event that “if taken previously, would have made the injury or harm less likely to occur,” with a few exceptions.<sup>101</sup> Depending on the rules of the court in which a suit is brought, evidence of a CAB manufacturer’s subsequent removal of caffeine could help a plaintiff alleging negligence show that the manufacturer was aware of the high probability that injury would result from caffeinated products remaining on the market.

### **C. A Causation Problem?**

A significant problem plaintiffs bringing suit against Four Loko and other CAB manufacturers face is that the reason CABs are associated with drinking-related hospitalizations and injuries may be that those who are attracted to beverages like Four Loko are naturally more likely to binge drink and take risks, like drinking and driving. In other words, consumption of Four Loko and intoxicated misbehavior may be symptoms of the same root

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<sup>100</sup> See Barclay, *supra* note 15.

<sup>101</sup> Fed. R. Evid. 407.

problem: today's dangerous youth drinking culture.

In its fact sheet on CABs, the Centers for Disease Control and Prevention ("CDC") reports:

Drinkers who consume alcohol mixed with energy drinks are 3 times more likely to binge drink . . . than drinkers who do not report mixing alcohol with energy drinks.

Drinkers who consume alcohol with energy drinks are about twice as likely as drinkers who do not report mixing alcohol with energy drinks to report being taken advantage of sexually, to prepare taking advantage of someone else sexually, and to report riding with a driver who was under the influence of alcohol.<sup>102</sup>

One has to question whether the real issue is that the kind of person who chooses to consume CABs, perhaps a risk-taker or heavy drinker, may already be substantially more likely to engage in risky behavior.

Furthermore, as one commentator noted, "environments where partiers are seeking to dance all night such as raves are often locations where other drugs are consumed."<sup>103</sup>

After the incident at Central Washington University in October, 2010, in which nine female students were hospitalized after attending a party where Four Loko was present, Phusion responded by questioning the evidence indicating that Four Loko was to blame. A statement released by Phusion pointed out:

In fact, while our product is mentioned only twice in the 44-page police report, hard liquor, vodka, rum or other alcohol is mentioned at least 19 times; beer is mentioned at least 3 times; and illegal drugs or roofies are mentioned at least 14 times – including twice in connection

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<sup>102</sup> CDC Fact Sheet, *supra* note 1.

<sup>103</sup> Grus, *supra* note 10, at 47.

with an individual attending the party with the intention of bringing drugs with him and once in connection with smoking marijuana.”<sup>104</sup>

Although one could argue that Four Loko consumption is a “but-for cause” in a strict sense of a drinking-related incident like this,<sup>105</sup> a drinker’s over-consumption or misuse of Four Loko, consumption of other alcohol and drugs, or subsequent irresponsible behavior may constitute intervening causes or contributory negligence.<sup>106</sup>

#### **D. Liability After the Removal of Caffeine**

Phusion and other CAB manufacturers removed caffeine and other stimulants from their malt beverages, likely in order to decrease the risk of future liability for drinking-related incidents. Four Loko in its current form is considered an “alco-pop,” a very strong malt beverage available in a variety of fruity flavors in colorful cans.<sup>107</sup> As such, do CAB manufacturers still face the same threat of liability?

##### **1. Size and Alcohol Volume**

In 2011, Alcohol Justice (formerly Marin Justice) released a study called “From Alcoholic Energy Drinks to Supersized Alcopops: A Rare Victory

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<sup>104</sup> Melnick, *supra* note 7.

<sup>105</sup> See Restatement (Third) of Torts § 26 (“Tortious conduct must be a factual cause of physical harm for liability to be imposed. Conduct is a factual cause of harm when the harm would not have occurred absent the conduct . . .”).

<sup>106</sup> However, Four Loko’s very large serving size complicates the over-consumption as intervening cause argument.

<sup>107</sup> Other alco-pop predecessors of Four Loko include Joose, Sparks, and Steel Reserve 311. Melnick, *supra* note 7. One blogger reported that a “thriving black market” of caffeine-containing Four Loko has risen up to fill the CAB void. Trogen, *supra* note 83.

in Protecting Youth from Big Alcohol.”<sup>108</sup> The report suggested that “supersized alcopops” with four to five standard drink sizes in a can may pose just as lethal a threat to underage youth as CABs.<sup>109</sup> A different study noted that Four Loko’s high alcohol content, not its caffeine, may be responsible for its substantial intoxicating effects, pointing out that drinking a can of Four Loko is about the equivalent of drinking a bottle of wine.<sup>110</sup> As Michael Jacobson, the executive director of the Center for Science in the Public Interest, stated, “Four Loko and Joose might no longer have caffeine, but they still contain three to four beers’ worth of alcohol in 23-ounce, single-serving cans . . . That these drinks are made with kid-friendly flavors like watermelon, blue raspberry, and lemonade says all one needs to know about their target audience.”<sup>111</sup>

## 2. Fruitiness

A new study published in *Perspectives on Psychological Science* suggests that the most dangerous aspect of Four Loko is not caffeine, but its *fruitiness*, because the fruitiness leads to a “situation specificity of tolerance.”<sup>112</sup> According to this theory, where alcohol is paired with unfamiliar or unusual situations and flavors, the effects of alcohol are

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<sup>108</sup> *Regulators Play Whack-A-Mole with Flavored Malt Beverages*, PR NEWSWIRE (Sep. 7, 2011), <http://www.marketwatch.com/story/regulators-play-whack-a-mole-with-flavored-malt-beverages-2011-09-07>.

<sup>109</sup> Id.

<sup>110</sup> Catherine Pearson, *Report: Four Loko Still Has “Extraordinary Intoxicating Effects,”* HUFFINGTON POST (May 25, 2011), [http://www.huffingtonpost.com/2011/05/25/four-loko-effect\\_n\\_866817.html?view=print](http://www.huffingtonpost.com/2011/05/25/four-loko-effect_n_866817.html?view=print).

<sup>111</sup> Busch, *supra* note 21.

<sup>112</sup> Trogen, *supra* note 83.

heightened.<sup>113</sup> In an interview, the author of the study, Dr. Shepard Siegel of McMaster University in Canada, explained that

[y]ou can have a similar experience where you might typically have a cocktail in the evening, but if you decide instead to drink the same amount in the afternoon, you could feel more intoxicated . . . When you consume a drug in circumstances not previously associated with the drug, it can have a more profound effect.<sup>114</sup>

It is unclear whether those injured from drinking non-caffeinated Four Loko will bring suit against Phusion in the future, but if they do, they could ostensibly rely on the theory that malt beverage fruitiness is dangerous due to the “situation specificity of tolerance.”

### 3. Leftover Caffeinated Four Lokos

Phusion could also face increased liability if the reports on a recent *New York Times* blog are true that the old, caffeinated version of Four Loko still appears on convenience store shelves in New York, despite that Phusion halted production of the old version and ordered retailers and distributors to stop selling it.<sup>115</sup> Phusion has offered no explanation for how the drinks are still reaching shelves.<sup>116</sup>

## IV. Marketing

### A. Marketing of Four Loko

The warning letters the FTC issued to the four CAB manufacturers do

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<sup>113</sup> Id.

<sup>114</sup> Pearson, *supra* note 110.

<sup>115</sup> Chelsia Rose Marcius, *Banned Version of Four Loko Still Sold*, N.Y. TIMES: THE LOCAL EAST VILLAGE BLOG (July 22, 2011),

<http://eastvillage.thelocal.nytimes.com/2011/07/22/banned-version-of-four-loko-still-sold/?scp=1&sq=old%20version%20caffeine%20four%20loko%20new%20york&st=cse>.

<sup>116</sup> Thomas, *supra* note 41.

not specifically reveal what marketing practices it found potentially deceptive or unfair under the FTC Act, stating only:

The FDA's warning that caffeine is an "unsafe food additive," as used in Four Loko, is a relevant consideration in the FTC's analysis of whether the marketing of caffeinated alcohol products such as Four Loko and Four Maxed is deceptive or unfair under the Federal Trade Commission Act. In the past, the FTC has accorded significant weight to FDA findings regarding product safety and efficacy.<sup>117</sup>

So what did the FTC take issue with? Some commentators argue that Four Loko's bright colors and design make it look like non-alcoholic energy drinks and iced teas, such that a sales clerk might not realize it contains alcohol.<sup>118</sup> If this is true, it would be easier for an underage drinker to purchase CABs like Four Loko. The family of Jason Kieran's complaint against Phusion notes Four Loko's colorful cans and fruity flavors, and also points out that Four Loko "is sold mainly in convenience stores, where clerks are less likely to verify a customer's age, or may even fail to recognize Four Loko as containing alcohol."

The drink's fruity flavors and bright colors may also initially attract underage drinkers. When back in July of 2010 U.S. Senator Charles Schumer requested that the FTC review the marketing of CAB manufacturers, warning that their marketing practices could violate federal law, he expressed "grave concern over the marketing of certain alcoholic beverages which seem explicitly designed to attract underage drinkers," citing the drinks' colorful packaging and flavors like watermelon, blue raspberry and

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<sup>117</sup> FTC Notice to Phusion, *supra* note 38.

<sup>118</sup> See, e.g., Barclay, *supra* note 15.

lemon-lime.<sup>119</sup>

So, could the companies have retained the caffeine in their beverages and simply altered the cans' appearances in order to quell the FTC's concerns? Would warning labels pacify the FTC?<sup>120</sup> Without more specifics in the FTC's warning letter, the question remains unanswered.

### **B. Marketing of "Lazy Cakes," the Faux Pot Brownie**

Similar marketing issues were recently raised when the FDA issued warning letters to the makers of "Lazy Cakes" brownies, a melatonin-laced "relaxation food." The FTC claimed that added levels of melatonin render the brownies "adulterated" because melatonin has not been deemed a safe food additive.<sup>121</sup> Melatonin is a naturally occurring hormone that induces sleep, and is often advertised as a stress-reliever.<sup>122</sup> The brownies' packages feature Larry the Brownie with droopy eyes and a happy expression (which one blogger described as the "brownie stand-in for SpongeBob SquarePants"<sup>123</sup>),

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<sup>119</sup> Goodnough, *supra* note 24.

<sup>120</sup> See infra Part VII.

<sup>121</sup> FDA Letter to HBB, LLC dba Baked World (July 28, 2011), <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm266129.htm>.

<sup>122</sup> Ben Yakas, *Last Call for "Lazy Cakes," The Poor Man's Faux Pot Brownie*, GOTHAMIST (Aug. 4, 2011), [http://gothamist.com/2011/08/04/last\\_call\\_for\\_lazy\\_cakes\\_the\\_poor\\_m.php](http://gothamist.com/2011/08/04/last_call_for_lazy_cakes_the_poor_m.php).

<sup>123</sup> Landon Hall, *Your Kids Will Have to Explain Lazy Cakes to Me*, THE ORANGE COUNTY REGISTER (Aug. 3, 2011), <http://healthyliving.ocregister.com/2011/08/04/you-kids-will-have-to-explain-lazy-cakes-to-me/36523/>.





([http://blogs.browardpalmbeach.com/cleanplatecharlie/2011/03/lazy\\_cakes\\_relaxation\\_brownie.php](http://blogs.browardpalmbeach.com/cleanplatecharlie/2011/03/lazy_cakes_relaxation_brownie.php))

and advertisements invoke the idea of marijuana with the words “Relaxation Baked In.”<sup>124</sup> The company’s website claims that the brownies will “put a smile on your face,”<sup>125</sup> and states: “Warning: this product may cause extreme relaxation and excessive use of the word ‘dude.’”<sup>126</sup> The company denies any link between its product and pot brownies, and last month changed the name of the product to “Lazy Larry” to appease critics. While in its warning letter the FDA cited only potential health risks from eating foods with high melatonin levels (medical experts worry pairing melatonin with food could lead to impaired driving, respiratory problems, or excessive consumption<sup>127</sup>), Lazy Cakes’ marketing strategy of evoking pot brownies and the ensuing media attention may have factored into the FDA’s decision to step in, despite that it is the FTC’s job to regulate unfair or deceptive marketing practices.

<sup>124</sup> Yakas, *supra* note 122.

<sup>125</sup> *Melatonin-Laced Pastries Pack a Disputable Punch*, ST. PETERSBURG TIMES (May 21, 2011), available at <http://www.tampabay.com/opinion/editorials/article1170800.ece>.

<sup>126</sup> Scott Hensley, *FDA: Wake Up, People, Those Lazy Brownies Are Unsafe*, SHOTS: NPR’S HEALTH BLOG (Aug. 2, 2011), <http://www.npr.org/blogs/health/2011/08/06/138918647/fda-wake-up-people-those-lazy-brownies-are-unsafe>.

<sup>127</sup> *Melatonin-Laced Pastries*, *supra* note 125.

### C. CAB Online Marketing

CAB manufacturers' internet advertising of CABs also raises marketing issues. The CDC pointed out that "CABs are heavily marketed in youth-friendly media (e.g., on web sites with downloadable images) and with youth-oriented graphics and messaging (e.g., connected with extreme sports or other risk-taking behaviors)."<sup>128</sup> Four Loko's website, [www.drinkfour.com](http://www.drinkfour.com), features a colorful background and a scrollable array of different Four Loko flavors. When one clicks on one of the scrolling cans of Four Loko, the website provides a description of that flavor; for example, clicking on the purple and blue Four Loko can brings up the following description: "A wild Brazilian berry, Uva is part of the grape family and has been revered for centuries for its mystical healing powers. With 12% alcohol by volume, blended with the flavor of the ancient Uva berry, LOKO Uva is truly a mind blowing experience!"<sup>129</sup> The site also features a poll allowing visitors to vote on the "neXXXt Limited Edition Four Loko": Coconut, Kiwi Strawberry, Pomegranate Blueberry, or Margarita.<sup>130</sup>

Phusion takes precautions on its website as well. When a visitors first goes to the site's address, they must type in their birthday to verify that they are over 21 years of age. The homepage of the site includes a large icon entitled "Responsibility," which leads to a page explaining Phusion's

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<sup>128</sup> CDC Fact Sheet, *supra* note 1.

<sup>129</sup> Id.

<sup>130</sup> Id.

“commitment to responsible consumption of [their] products.”<sup>131</sup> The site also offers a downloadable “Responsible Marketing Guidelines Poster,” which reminds vendors to require purchasers to show ID, place Four Loko in the alcohol section (not the soda or energy drink section), and become familiar with the labels on Four Loko and other flavored alcoholic beverages.<sup>132</sup> However, despite these precautions and its removal of caffeine from Four Loko, Phusion may still face FTC action if it continues to produce the beverage in brightly colored cans and fruity flavors, and fails to effectively convey accurate information about the drink’s alcoholic content to consumers.

## V. Arbitrariness

Many commentators argue that the government’s decision to crack down on Four Loko is arbitrary and thus unjustifiable. If we can drink Red Bull and Vodkas and Rum and Cokes in bars, or have a cup of coffee after drinking wine at dinner, they argue, why can’t we buy a pre-mixed CAB in a store? Alcohol, cigarettes, and factories that pour smoke into the atmosphere are all injurious to health – why not ban them?

Even though the consumption of energy drinks and alcohol in combination has been linked to deaths in other countries,<sup>133</sup> mixed drinks like Red Bull and Vodka are extremely popular in bars and clubs in the United States. “In some drinking establishments, the Red Bull manufacturer provides a logoed mini refrigerator to stock with cans of its elixir in the clear

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<sup>131</sup> <http://www.phusionprojects.com/responsibility.html> (last visited Sep. 29, 2011).

<sup>132</sup> [http://www.phusionprojects.com/pdf/Four\\_Responsibilities\\_Poster.pdf](http://www.phusionprojects.com/pdf/Four_Responsibilities_Poster.pdf).

<sup>133</sup> Grus, *supra* note 10, at 44.

view of customers.”<sup>134</sup> Mixed drinks containing energy drinks like Red Bull are potentially more dangerous than other more traditional drinks combining caffeine and alcohol, such as Irish Coffee and Rum and Coke. Coffee cannot be chugged down in the same way that an energy drink can, and coffee is not a popular drink at clubs and bars.<sup>135</sup> Additionally, sodas like Coca-Cola are regulated by the FDA as food rather than as dietary supplements like energy drinks, and thus are more likely to be safe.<sup>136</sup>

So why don't regulators crack down on the sale of alcohol mixed with energy drinks in bars? Even if drinking CABs is not actually more dangerous than similar consumption behaviors (like having a Red Bull and Vodka), agency action against CABs may have stemmed more from a desire to quell public anger incited by Four Loko's association with recent binge-drinking-related tragedies than a rational comparative analysis.

However, drinking establishments may want to err on the safe side and cease serving alcohol and energy drinks. A recent *New York Times* article quoted Ricardo Carvajal, a D.C. lawyer and a former FDA associate chief counsel, as follows: “The crackdown does not apply to caffeinated alcoholic drinks that do not come premixed, like a cocktail of Red Bull and vodka, but Mr. Carvajal said bars that served them could face heightened liability, too.”<sup>137</sup> Judging from the fact that the Kiernan complaint brings a

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<sup>134</sup> Id.

<sup>135</sup> Id.

<sup>136</sup> Id.

<sup>137</sup> Goodnough, *supra* note 24.

dram shop liability claim against the convenience stores that sold Four Loko, in light of the recent flood of information about the dangers of CABs, it is possible that bars and clubs could face heightened liability from continuing to serve drinks like Red Bull and Vodka.

## VI. Paternalism

Bloggers and commentators take further issue with what they see as consistent governmental encroachment on the private consumption habits of individuals. As discussed earlier, the FDA recently issued a warning letter to the makers of the melatonin-containing “Lazy Cakes” (now “Lazy Larry”) brownies, citing the “potential reproductive, cardiovascular, ocular and neurological side effects,” and sparking spirited debates in the blogosphere.<sup>138</sup> One blogger criticized the steps the FDA recently took toward regulating medical applications for smart phones, such as calorie-counting applications and X-ray viewers that allowing doctors to view a patient’s X-rays on their mobile device.<sup>139</sup> He wrote:

Calorie-counting isn’t exactly a matter of life and death. If someone is morbidly obese, they need more help than a calorie-counting app. And if one calorie-counting app is inaccurate, so what? Another developer will come up with a better one. That’s how markets work. FDA regulation could only create additional costs and drive some developers out of the market, reducing consumers’ choices.<sup>140</sup>

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<sup>138</sup> Anna Merlan, *Do Melatonin Brownies Actually Do Anything? An Unfair Park Special Report*, DALLAS OBSERVER BLOGS (Aug. 9, 2011), [http://blogs.dallasobserver.com/unfairpark/2011/08/do\\_melatonin\\_brownies\\_actually.php](http://blogs.dallasobserver.com/unfairpark/2011/08/do_melatonin_brownies_actually.php).

<sup>139</sup> Enrique, *Great – FDA to Help Us by Meddling with Health-Related Smartphone Apps*, 411MANIA.COM (July 27, 2011), <http://www.411mania.com/politics/columns/195675>.

<sup>140</sup> Id.

The same blogger also complained about the FDA's regulation of electronic cigarettes, in light of the fact that smoking regular cigarettes is legal.<sup>141</sup>

Another blogger commented on FDA regulation of Four Loko by pointing out that “[t]here are millions of people who choose to eat at McDonald’s every day. Should the FDA ban McDonald’s since some of the people who eat fast food irresponsibly have heart attacks, get high cholesterol or develop diabetes?”<sup>142</sup>

The main goal of the FDA is consumer protection, and the idiosyncrasies of the food industry may account for the need for increased paternalism in the regulation of food by the FDA. A major distinguishing factor of the food industry is that “Americans have to buy food in some form or another; unlike many consumer products, food is not generally a luxury item and the public deserves to be protected when attempting to address its basic needs.”<sup>143</sup> However, although the FDA must be paternalistic to some degree in order to carry out its statutory mandate, commentators have a right to be concerned with where the FDA will go next.

## VII. Conclusion

A source in an *FDA Week* article speculated: “Whether it’s some combination of state attorneys general, the FDA or the FTC, I would be

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<sup>141</sup> Id. See also *FDA Acts Against 5 Electronic Cigarette Distributors*, FDA PRESS RELEASE (Sept. 9, 2010),

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm225224.htm>.

<sup>142</sup> Robby Milo, *Blackout in a Can: Are Four Lokos really to Blame?*, ARBITER ONLINE (Jan. 20, 2011), <http://arbiteronline.com/2011/01/20/blame-the-drinker-not-the-drink/>.

<sup>143</sup> Eric C. Wall, A Comprehensive Look at the Fair Packaging and Labeling Act of 1966 and the FDA Regulation of Deceptive Labeling and Packaging Practices: 1906 to Today 19 (2002), in Peter Barton Hutt, ed., Food and Drug Law: An Electronic Book of Student Papers.

surprised if this [CAB] niche exists 18 months from now.”<sup>144</sup> The same source predicted CAB regulation would spark an increase in the regulation of all caffeinated products. The FDA posted on its website in 2009 that “products containing added caffeine may be subject to agency review if the available scientific data and information indicate that added caffeine may pose a safety concern, or is being unlawfully used, under the condition of its use in other products.”<sup>145</sup>

Are there other solutions to the CAB problem that could circumvent the slippery slope of over-regulating or banning products? Instead of banning CABs outright, states could impose a high tax, like the “tanning bed tax,”<sup>146</sup> on CABs in order to discourage their production and consumption. The CDC outlines several other potential measures, pointing to a community that “has enacted an ordinance requiring retailers to post signs warning of the risks of CABs.”<sup>147</sup> The TTB could also promulgate regulations mandating the

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<sup>144</sup> Seth Freedland, *Senators Hike Pressure on FDA to Control Caffeinated Alcoholic Drinks*, FDA WEEK (Aug. 6, 2010).

<sup>145</sup> *Id.* Caffeine, known as the most widely used psychoactive substance in the world, is constantly the subject of study: high caffeine consumption has been linked to high blood pressure, heart disease, pregnancy problems, osteoporosis, insomnia, and other health issues. Grus, *supra* note 10, at 34-35. It is also noted for its positive effects; just recently, reports indicated that caffeine consumption can prevent the risk of Parkinson’s disease, Dr. Shelley Narula, *Positive and Negative Health Effects of Caffeine*, STUDYHEALTH (Jan. 14, 2009), [http://www.steadyhealth.com/articles/Gallstones\\_a801.html](http://www.steadyhealth.com/articles/Gallstones_a801.html), and even reduce the risk of clinical depression for women, Amanda Gardner, *Coffee May Reduce Depression Risk for Women*, USA TODAY (Sept. 29, 2011), <http://yourlife.usatoday.com/health/medical/mentalhealth/story/2011-09-27/Coffee-may-reduce-depression-risk-for-women/50567316/1>.

<sup>146</sup> Blake Ellis, *Tanning Salons Burned by Health Care Bill*, CNN MONEY (Mar. 24, 2010), [http://money.cnn.com/2010/03/24/news/economy/tanning\\_tax/](http://money.cnn.com/2010/03/24/news/economy/tanning_tax/).

<sup>147</sup> CDC Fact Sheet, *supra* note 1. Other countries mandated warnings on certain energy drinks following deaths associated with the consumption of energy drinks in combination with exercise or alcohol. *See* Grus, *supra* note 10. However, requiring warning labels and thus advertising the danger of a CAB could encourage consumption of the beverage by young

disclosure of more information on malt beverage labels. For example, the TTB could require the indication of alcohol content on malt beverages in more understandable terms, such as “one can of Four Loko contains the alcohol equivalent of about five beers,” or “one can of Four Loko contains the caffeine equivalent of two cups of coffee.”<sup>148</sup>

The CDC also recommends “limiting alcohol outlet density . . . maintaining existing restrictions on days of sale,”<sup>149</sup> and reducing youth exposure to alcohol marketing by “lowering the voluntary industry standard governing the placement of alcohol advertising from the current 30% threshold to 15%, based on the proportion of the audience that is age 12-20 years.”<sup>150</sup> The FDA could also monitor negative reports related to CABs or alco-pops, and issue public warnings as necessary.<sup>151</sup>

It remains to be seen whether the FDA, FTC, and TTB will continue to scrutinize Phusion and other malt beverage manufacturers after the removal of caffeine from their products, and whether courts will impose liability for what many see as simply irresponsible misuse of alcoholic products by under-age drinkers.

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drinkers. *See id.* Furthermore, “[e]ducation is important but over-warning is insulting to the intelligence of individuals: this goes to cultural notions in the United States regarding individual autonomy.” *Id.* at 58.

<sup>148</sup> 55 Fed. Reg. 5414 (February 14, 1990), issued by BATF, requires a warning on the risks of consuming alcohol while pregnant to appear on the labels of all containers of alcoholic beverages in the United States. Myers, *supra* note 46, at 37.

<sup>149</sup> Other countries limit the locations that can sell energy drinks like Red Bull. Grus, *supra* note 10.

<sup>150</sup> CDC Fact Sheet, *supra* note 1.

<sup>151</sup> Grus, *supra* note 10, at 26.