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Extreme Refreshment Crackdown

The FDA's Misguided Campaign Against Alcohol Energy Drinks

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Over the past decade, caffeinated energy drinks like Red Bull and Monster have become increasingly popular, both as stand-alone beverages and as mixers for consumption in combination with alcohol. The appeal of these drinks as cocktail mixers has led drink makers to also market caffeinated pre-mixed beverages containing alcohol. Popular brands include Joose, Four Loko, Hard Wired, and many others. The rise of this alcohol energy drink (AED) market segment, however, has drawn unwanted scrutiny from federal and state regulators because of allegations that the products are designed and marketed to appeal to underage drinkers. A movement is now afoot to ban these pre-mixed drinks altogether, on the grounds that combining alcohol and caffeine may be unsafe. Consequently, if the Food and Drug Administration (FDA) and some self-styled public-health advocates have their way, alcohol energy drinks may soon see their final days.

Although the alcohol energy drink market is fairly small, the FDA's crackdown on it could have much broader ramifications. The same legal rationale being used to attack AEDs—the argument that the addition of caffeine to certain foods and beverages has not been proven to be safe—applies equally to dozens of other popular products that have been on the market for years with no ill effects, such as many caffeinated soft drinks, coffee flavored liquors, and various foods with added caffeine. Consequently, the FDA's war on pre-mixed alcohol energy drinks could cause substantial collateral damage in the nation's food and beverage market.

The FDA came to demonize pre-mixed drinks containing alcohol and caffeine—and sometimes other natural substances like ginseng and guarana—by latching onto a few tangentially relevant scientific studies in a misguided effort to shut down a small, politically incorrect segment of the alcohol beverage market. Worse, the FDA has ignored both history and its own regulations in a politicized effort to crack down on caffeine and alcohol.

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History of the AED Controversy. Critics cite several factors to justify their anti-AED crusade. They allege that drink makers market their products to the same underage drinkers who make up a primary target market of traditional energy drink manufacturers. Opponents also claim that the levels of caffeine and alcohol in AEDs are too high and that AEDs are unsafe because they simultaneously cause drunkenness and mask its effects. They argue that drinkers will consume more alcohol than they would otherwise, because caffeine allegedly reduces the perception of intoxication. Critics contend that these factors cause both a spike in underage drinking levels and exacerbate the harms associated with both adult and underage drinking.¹

In November 2009, responding to a complaint from several state attorneys general, the FDA took the unusual step of demanding that makers of AEDs prove the safety of their products. In FDA parlance, what the agency seeks from the beverage makers is scientific proof that the combination of alcohol and caffeine in a pre-mixed consumer product is “generally recognized as safe” (GRAS).² Congress created the GRAS status more than 50 years ago as a guide for the FDA to follow in distinguishing between genuinely novel “food additives”—some of which have to be approved by the FDA in much the same manner as new pharmaceuticals—and more common ingredients like salt, flour, and sugar, which history has shown to have safe uses in foods.

By demanding that AED makers prove their products are GRAS, the FDA is essentially threatening the existence of many of these products, because compliance involves a time-consuming process that can be prohibitively expensive for all but the largest companies. But this was not the first run-in between AED makers on one hand and government regulators and nanny state activists on the other. Drink makers have seen these storm clouds gathering on the horizon for some time.

The first pre-mixed AEDs were introduced in the U.S. in 2000 by two small manufacturers, apparently with the hope of appealing to adults who were already using energy drinks as cocktail mixers. The product class remained small, however, until Miller (now MillerCoors) and Anheuser-Busch, the two largest U.S. brewers, entered the market in 2006. This move quickly drew the attention of anti-alcohol campaigners and crusading politicians, who argued, among other things, that AED packaging was too easily confused with non-alcoholic energy drinks and that much of it appeared to be designed to attract underage drinkers.³

In February 2007, a group of 29 state attorneys general, acting under the auspices of the National Association of Attorneys General Youth Access to Alcohol Committee (YAAC), called on Anheuser-Busch and Miller to change their AED products’ “youth-friendly” packaging and marketing.⁴ Joseph Califano, president of the National Center on Addiction and Substance Abuse, called the introduction of AEDs “a predatory move to attract underage drinking.”⁵ And in August 2007, the attorneys general (now with 30 members joining in) wrote to the Treasury Department’s Alcohol and Tobacco Tax and Trade Bureau (TTB), which oversees alcohol-beverage labeling, urging TTB to clamp down on the makers of AEDs because of “the potentially severe, adverse consequences of mixing caffeine or other stimulants and alcohol.”⁶

The attorneys general asked TTB to consider using its authority to reclassify AEDs as distilled spirits, rather than under their current designation as malt beverages, claiming that distilled

spirits are not as “readily available to young people” as are malt beverages like beer. They also asked TTB to prevent AED labels and advertising from making “misleading health-related statements,” such as suggesting that they may “increase a person’s stamina or energy level.”⁷ Despite the seemingly moderate nature of these requests, however, the YAAC’s goal is “to have AEDs removed from the marketplace.”⁸ TTB decided to take no action at that time, however, opting instead to defer to the FDA.⁹

The advocacy group Center for Science in the Public Interest (CSPI) also mounted a campaign against pre-mixed caffeinated alcoholic beverages, labeling such drinks “alcospeed.” In September 2008, the organization filed a lawsuit against MillerCoors, brewer of the AED Sparks, alleging that the product was “adulterated” because the addition of caffeine to an alcoholic beverage had not been approved by the FDA as GRAS. The lawsuit further alleged that MillerCoors had engaged in unfair and deceptive marketing practices by promoting the stimulant effect of taurine and ginseng without adequate substantiation that either acts as a stimulant.¹⁰ CSPI also threatened to sue Anheuser-Busch, maker of the AEDs Tilt and Bud Extra, on similar grounds.¹¹ By the end of 2008, both brewers had given in to the public pressure and threat of costly litigation. They separately reached settlement agreements, with terms negotiated by the YAAC, and they promised to discontinue making and selling caffeinated alcoholic drinks.¹²

Tangentially Relevant Studies behind the Attack on AEDs. Conspicuously absent from the attorneys general letter and CSPI lawsuit was any credible scientific evidence supporting the claims that AEDs are unsafe. In September 2009, though, a group of five university researchers, including Wake Forest University Associate Professor of Emergency Medicine Mary Claire O’Brien, wrote to the YAAC co-chairs arguing that published scientific studies support the view that AEDs are responsible for higher rates of intoxication, injury, and sexual assault among college-age students. According to the researchers, these studies show that “frequent consumers of caffeinated energy drinks drink greater quantities of alcohol than individuals who do not drink caffeinated energy drinks,” that “a person’s subjective perception of alcohol intoxication (i.e., ‘feeling drunk’) may be reduced by the ingestion of caffeine,” and that “consumption of caffeinated alcoholic beverages by college students is associated with significantly increased heavy episodic drinking and episodes of weekly drunkenness.”¹³

Notably, the researchers also argued that, “there is no evidence to support the claim that caffeine is ‘generally recognized as safe’ (‘GRAS’) for use in alcoholic beverages,” providing support to the legal basis of the YAAC’s effort to outlaw AEDs.¹⁴ Only four days after receiving the researchers’ letter, the YAAC co-chairs wrote to FDA Commissioner Margaret Hamburg urging the FDA to seek “the immediate removal of AEDs from the marketplace” on the grounds that the addition of caffeine to alcoholic beverages is not generally recognized as safe.¹⁵

With this material in hand, the FDA likely considers the matter of AEDs to be an open-and-shut case. But what does the science really show?

The most widely cited study in the war on AEDs, an Internet-based survey of college students conducted by researchers at Wake Forest University,¹⁶ has nothing to do with pre-mixed AEDs targeted by the FDA’s current action. Instead, the study examined the consumption of *any* “alcohol mixed with energy drinks.” The study methodology does not mention pre-mixed AEDs

in any way, making it impossible to distinguish between pre-mixed drinks and the consumption of cocktails—such as vodka and Red Bull or “Jaeger Bombs,” which contain Jägermeister and Red Bull—mixed by the study participants themselves, by their friends, or by bartenders.

A more recent study that examines real world consumption patterns also makes no distinction between pre-mixed AEDs and self-mixed cocktails.¹⁷ Researchers at the University of Florida surveyed patrons exiting seven bars near the university campus in Gainesville. Among other things, the survey subjects were asked about their alcohol consumption that night and were given an alcohol intoxication breath test. Again, while the published results make no mention of pre-mixed AEDs, the study methodology almost guarantees that most, if not all, of the “alcohol mixed with energy drink” consumption that was tested was most likely of the bartender-mixed variety.

Some laboratory research suggests that consumption of caffeine generally, or energy drinks specifically, reduces a drinker’s subjective perception of alcohol intoxication, but does not inhibit alcohol’s negative effects on motor coordination skills.¹⁸ But, here again, these studies mainly examine the consumption cocktails of alcohol and energy drinks mixed by the researchers conducting the tests, not pre-mixed AEDs. For example, one commonly cited study conducted by researchers in Brazil examined the effects of consuming vodka and Red Bull.¹⁹ Consequently, little if any of the laboratory and real-world consumption research in the published literature reveals anything particularly enlightening about the pre-mixed AEDs, which the attorneys general want banned.

Moreover, the gap in difficulty in determining the contents of AEDs and that of self-mixed energy drink cocktails could not be wider. The proportions of caffeine and alcohol in the former are consistent and published right on the label, as with the alcohol content in a can of beer. Such is not the case with self-mixed energy drink cocktails. The amount of alcohol and caffeine, and the ratio of one to the other, in a given drink will vary substantially depending upon the specific energy drink and alcoholic beverage being mixed and upon the portions of each in the cocktail. And each of these factors is likely to vary from bartender to bartender. So, while the amount of caffeine and alcohol in a pre-mixed AED will be printed on each can, the amount of these constituents is likely to be a mystery to the person consuming a self-mixed energy drink cocktail.²⁰ The availability of a consistent, labeled product is likely to aid consumers in their efforts to self-manage alcohol consumption.

Still, the distinction between the known (AEDs) and the unknown (self-mixed energy drink cocktails) seems not to matter to Mary Claire O’Brien, primary author of the Wake Forest study, and one of the signers of the September 2009 letter to the YAAC. She told the anti-alcohol Marin Institute in 2008 that she would “like the federal government to immediately ban all alcoholic energy drinks *and the adding of caffeine to all alcoholic beverages.*”²¹ Such a ban would not only eliminate the AED market, it would also threaten a host of venerable traditional cocktails that contain caffeine, including Irish coffee and rum and Coke. The approach advocated by O’Brien also belies the activists’ claims that they are most concerned about preventing underage drinking. Many, if not all, AED opponents seem just as interested in eliminating the availability of these products for adults as for underage drinkers.

Perhaps just as importantly, advocates of an AED ban seem to assume, without sufficient evidence, that mixing caffeine and alcohol *causes* bad behavior. For example, the Wake Forest study concludes that consuming alcohol and caffeine together was associated with increases in heavy drinking, twice as many episodes of weekly drunkenness, and an increase in risky behavior and injuries. The University of Florida study concludes that bar patrons who consumed alcohol mixed with energy drinks were more likely to leave the bar highly intoxicated and to drive upon leaving the bar district. But neither study establishes whether there is a causal connection—that is, they do not reveal whether consumers who are disinclined to drink heavily consume more alcohol than they normally might when combining alcohol and caffeine or whether those already inclined to drink heavily choose to drink caffeine and alcohol in combination. Of course, in neither case would an AED ban impede consumers’ ability to mix alcohol and energy drinks on their own.

FDA’s Regulatory Authority. The irrelevance of the surveys on caffeine and alcohol consumption to the safety of pre-mixed AEDs may not matter, however, given the FDA’s authority to regulate the ingredients added to food products sold in interstate commerce. In November 2009, the FDA ordered 30 AED makers to “produce evidence of their rationale, with supporting data and information, for concluding that the use of caffeine in their product is GRAS or prior sanctioned.”²²

“GRAS” and “prior sanctioned” are terms of art in food and beverage law. They refer to FDA rules for determining whether a certain ingredient may be added to a given food or beverage sold in interstate commerce. An ingredient is prior sanctioned if, and only if, the FDA approved that ingredient in writing prior to 1958.²³ An ingredient may be GRAS if:

1. The FDA affirmatively granted it such status after 1958;
2. A company has notified the FDA that the substance is GRAS and the agency did not challenge that determination; or
3. The substance was commonly used in food prior to 1958.

The FDA’s demand that AED makers produce evidence that the addition of caffeine as an ingredient in an alcoholic beverage is either GRAS or prior sanctioned is absurd on its face, as the agency should already know the answer to that question. Despite the FDA’s suggestion that makers of AEDs could offer a “rationale” for prior sanctioning, it seems almost certain that no pre-1958 approval letter exists. (If it does exist, someone has yet to produce it.)

Furthermore, the agency is surely aware that it has not affirmatively granted caffeine GRAS status for use in anything but “cola-type beverages.”²⁴ And, in undertaking this investigation into the status of drinks containing alcohol and caffeine, the FDA almost certainly presumes that AEDs use a combination of alcohol and caffeine in a different manner than existed prior to 1958. FDA must believe that makers of AEDs have concluded, on their own, that caffeine is GRAS for use in alcoholic beverages. Unless the manufacturers can demonstrate that this is true, the agency believes it has the authority to force pre-mixed AEDs off the market.

Collecting the scientific data necessary to file a GRAS petition is a particularly burdensome and expensive process. According to the FDA, a petitioner must include:

“[A] comprehensive discussion of, and citations to, generally available and accepted scientific data, information, methods, or principles that the notifier relies on to establish safety, including a consideration of the probable consumption of the substance and the probable consumption of any substance formed in or on food because of its use and the cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substances in such diet... [a] comprehensive discussion of any reports of investigations or other information that may appear to be inconsistent with the GRAS determination; and... [t]he basis for concluding, in light of the data and information described [in the Food, Drug and Cosmetics Act], that there is consensus among experts qualified by scientific training and experience to evaluate the safety of substances added to food that there is reasonable certainty that the substance is not harmful under the intended conditions of use.”²⁵

And yet the FDA only gave AED makers 30 days to compile this information and present their findings to the agency.²⁶

Caffeine and Alcohol Cocktails: Your Grandparents’ Drink of Choice. Claims by the FDA and some in the scientific community that AEDs are some new species of beverage are historically incorrect. The implications of this fact have significant legal and policy implications because, in the FDA’s view, a substance is generally recognized as safe if it was used in food in the same manner prior to 1958. Determining common use in food prior to 1958 requires a simple inquiry along the same lines as determining whether a substance was prior sanctioned: If the manufacturer can demonstrate that the substance was used, it was; if it cannot, it was not (at least for regulatory purposes). The Food, Drug and Cosmetics Act and FDA’s regulations make clear that this type of GRAS determination “shall be based solely on food use of the substance prior to January 1, 1958, and shall ordinarily be based upon generally available data and information.”²⁷

Historical data and information showing caffeine and alcohol consumed in tandem in one beverage could hardly be more ubiquitous, leading to the obvious conclusion that these products must surely be GRAS.

Caffeine and alcohol have been consumed together in the United States since at least the early part of the 20th century, and likely much earlier. Rum and Coca-Cola—which contained not only caffeine and alcohol but, early on, the stimulating cocaine alkaloids from the coca leaf as well—is rumored to have first been mixed by American troops in a bar in Havana, Cuba in 1900. Moxie, a caffeinated beverage that was America’s most popular fountain drink until Coca-Cola came to dominate in the early 1920s, also was known to pair “splendidly with a jigger of Jamaican or Demerara rum.”²⁸ And “Rum and Coca-Cola,” a calypso hit song by The Andrews Sisters trio, a testament to the drink’s popularity among American troops during World War II, spent several weeks at number one on the Billboard charts in 1945.²⁹ Furthermore, there were pre-mixed caffeinated alcoholic beverages on the market prior to 1958, as caffeine has long been present in coffee-flavored liqueurs, such as Kahlúa.

Critics might argue that rum and Coke are “mixed,” rather than “pre-mixed,” making that drink different from the products FDA is now investigating. But if the science used to attack AEDs

(such as the Wake Forest and University of Florida studies) has been based on data examining self-mixed or bartender-mixed cocktails, not AEDs, then certainly data *supporting* AEDs may also be drawn from the same subject matter. In any event, that same data could be used to support the assertion that AEDs are safer, because of the predictability of their alcohol content.

Conclusion. If a determination of generally recognized as safe status must “be based solely on food use of the substance prior to January 1, 1958” and should rely on “generally available data and information,” then the only conclusion one can draw is that caffeine is GRAS in AEDs because it has been used in alcoholic beverages since well before 1958.

Moreover, if the FDA were to follow its caffeine regulations to the letter, then it would have to ban *every* food that contains added caffeine but is not a “cola-type beverage.” No more Dr. Pepper—a soda but not a cola. No more Mountain Dew or caffeinated root beer. And no more Perky Jerky beef jerky, Morning Spark oatmeal, and at least a dozen other foods that contain caffeine as an added ingredient. This scenario is not as far-fetched as it may sound. Several other countries, including Canada, already forbid the addition of caffeine to all foods and most beverages—with cola-type soft drinks being the only exception.³⁰

If underage drinkers are consuming AEDs, then local governments can and should better enforce existing age restrictions. And, although the FDA may have a role to play in ensuring proper product labeling so consumers know the contents of various products, prohibiting a class of food or drink is, like any diminution of culinary choice, bad law based on bad policy. Banning pre-mixed drinks like AEDs based in large part on studies that focus only on *self-mixed drinks* is bad law based on bad science. It is unreasonable to believe that banning AEDs would have any measurable effect on drinking or drunkenness, especially given the ubiquity of self-mixed cocktails combining alcohol and energy drinks. A ban would do nothing more than remove from commerce—for no good reason—a beverage choice that many consumers enjoy.

The FDA regulates nearly 80 percent of all food products in America³¹ and constantly claims it is understaffed for that mission. For it to take the time and effort to ban Dr. Pepper or caffeinated root beer is ludicrous. The agency’s campaign against AEDs is wasteful and misguided. It is based on research unrelated to AEDs and targets products the FDA should classify as generally recognized as safe due to their pre-1958 use. With more than 100 years of historical evidence that consumers can safely consume caffeine and alcohol together, the FDA should not stand in the way of adults’ drink choices.

Notes

¹ See, for example, Communication from the Chief Legal Officers of Thirty States to The Honorable John J. Manfreda, Administrator, Alcohol and Tobacco Tax and Trade Bureau, August 20, 2007, http://www.marininstitute.org/alcopops/resources/TTB_Letter_Final_Sigs_08172007.pdf.

² <http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/default.htm>

³ Michele Simon and James Mosher, “Alcohol, Energy Drinks, and Youth: A Dangerous Mix,” San Rafael, Calif: Marin Institute, 2007, <http://www.marininstitute.org/alcopops/resources/EnergyDrinkReport.pdf>.

⁴ Ibid.

⁵ Jeremiah McWilliams, “A-B gets skewered on ‘Spykes’ drinks,” *St. Louis Post-Dispatch*, April 6, 2007, p. A1. Califano served as Secretary of Health, Education, and Welfare in the Carter administration.

⁶ Communication From the Chief Legal Officers of Thirty States to The Honorable John J. Manfreda, Administrator,

Alcohol and Tobacco Tax and Trade Bureau, August 20, 2007.

⁷ Ibid.

⁸ Office of Maryland Attorney General Douglas F. Gansler, “Attorney General Gansler Applauds FDA’s Decision to Have Alcoholic Energy Drink Manufacturers Prove That Their Products Safe,” Press Release, November 13, 2009, <http://www.oag.state.md.us/Press/2009/111309.htm>.

⁹ In February 2010, TTB announced it would “temporarily suspend consideration of such requests” while the FDA considers the matter. See, Alcohol and Tobacco Tax and Trade Bureau, “TTB Defers Review of Certain Alcohol Beverage Formulas,” February 24, 2010, http://www.ttb.gov/main_pages/defer-review-abf.shtml.

¹⁰ Letter to Tom Long, President and CEO, Miller Brewing Company, from CSPI Director of Litigation Stephen Gardner, February 28, 2008, <http://cspinet.org/new/pdf/cspimiller.pdf>

¹¹ Letter to August Busch IV, President and CEO, Anheuser-Busch Companies Inc., from CSPI Director of Litigation Stephen Gardner, February 28, 2008, <http://cspinet.org/new/pdf/cspiab.pdf>.

¹² Center for Science in the Public Interest, “State Attorneys General Negotiate End of Caffeinated ‘Sparks’ Beer,” Statement of CSPI Director of Litigation Stephen Gardner, December 18, 2008, <http://www.cspinet.org/new/200812182.html>.

¹³ Letter to Attorneys General Blumenthal, Shurtleff, and Limtiaco from Mary Claire O’Brien et al., September 21, 2009.

¹⁴ Ibid.

¹⁵ Letter from the Chief Legal Officers of Connecticut, Utah, & Guam to Dr. Margaret A. Hamburg, Commissioner, Food and Drug Administration, Sept. 25, 2009, http://www.oag.state.md.us/Press/Letter_to_FDA1113.pdf.

¹⁶ Mary Claire O’Brien et al., “Caffeinated Cocktails: Energy Drink Consumption, High-risk Drinking, and Alcohol-related Consequences among College Students,” *Academic Emergency Medicine* Vol. 15, 2008, pp. 1-8.

¹⁷ Dennis L. Thombs, Ryan J. O’Mara, Miranda Tsukamoto, Matthew E. Rossheim, Robert M. Weiler, Michele L. Merves, and Bruce A. Goldberger, “Event-level analysis of energy drink consumption and alcohol intoxication in bar patrons,” *Addictive Behaviors* Vol. 35, 2010, pp. 325-330.

¹⁸ See, for example, Sionaldo Eduardo Ferreira, Marco Túlio de Mello, Sabine Pompéia, and Maria Lucia Oliveira de Souza-Formigoni, “Effects of Energy Drink Ingestion on Alcohol Intoxication,” *Alcoholism: Clinical and Experimental Research* Vol. 30 No. 4, 2006, pp. 598-605.

¹⁹ Ibid.

²⁰ Even professional bartenders tend to over-pour alcohol consistently in certain instances. See Brian Wansink, *Mindless Eating*, New York: Bantam, 2006.

²¹ Emphasis added. Marin Institute, “Interview with Mary O’Brien,” December 3, 2008,

<http://www.marininstitute.org/site/resources/interviews/72-interview-with-mary-obrien-md.html>.

²² Food and Drug Administration, “FDA To Look Into Safety of Caffeinated Alcoholic Beverages: Agency Sends Letters to Nearly 30 Manufacturers,” FDA News Release, November 13, 2009,

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm190427.htm>.

²³ 21 C.F.R. § 170.30.

²⁴ 21 C.F.R. § 182.1180.

²⁵ Food and Drug Administration, “How to Submit a GRAS Notice,” FDA website, May 7, 2009,

<http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/ucm083062.htm>.

²⁶ In its letter to AED makers, “The FDA requested that, within 30 days, the companies produce evidence of their rationale, with supporting data and information, for concluding that the use of caffeine in their product is GRAS or prior sanctioned.” Food and Drug Administration, “FDA To Look Into Safety of Caffeinated Alcoholic Beverages.”

²⁷ 21 C.F.R. § 170.30.

²⁸ Wayne Curtis, *And a Bottle of Rum: A History of the New World in Ten Cocktails*, New York: Three Rivers Press, 2007, p. 198.

²⁹ “Number-one hits of 1945 (United States),” Wikipedia, [http://en.wikipedia.org/wiki/Number-one_hits_of_1945_\(United_States\)](http://en.wikipedia.org/wiki/Number-one_hits_of_1945_(United_States)).

³⁰ See, Government of Canada, Food and Drug Regulations, C.R.C., Chap. 870, Table VIII: Miscellaneous Food Additives, March 31, 2010, http://laws.justice.gc.ca/PDF/Regulation/C/C.R.C.,_c._870.pdf.

³¹ Food and Drug Administration, “How U.S. FDA’s GRAS Notification Program Works,” FDA website, December 2005/January 2006,

<http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/ucm083022.htm>.