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Energy Drinks: Considering the Legal Risks

Sales of "Energy Drinks" have increased every year for the past 10 years. With rising popularity, however, has come increased scrutiny from Congress and federal regulators.

In November 2012, three Senators requested that the Federal Trade Commission open an investigation into the marketing of energy drinks, and in January 2013 the same group of Senators sent questionnaires to 14 energy drink makers inquiring about their marketing practices.

Congress has also shown concern regarding potential health risks associated with energy drinks. In an October 2012 letter to the Food and Drug Administration, Senators Durbin and Blumenthal wrote: "There has been alarming evidence that energy drinks pose a potential threat to the public's health." This followed a report by the U.S. Health and Human Services Department that referred to energy drinks as a "rising public health problem," and gave figures suggesting that emergency room visits linked to energy drinks doubled between 2007 and 2012.

It is not surprising that this increased public attention on energy drinks has been accompanied by litigation. Four energy drink makers were served with personal injury or wrongful death lawsuits in the second half of 2012, and there are now numerous websites that solicit plaintiffs who claim to have suffered energy drink related injuries.

Below are several key questions that an energy drink maker should consider, in consultation with legal counsel, to assess their potential vulnerability to litigation. These questions will also be useful going forward, in helping to design marketing campaigns and packaging that is less likely to serve as the basis for consumer litigation.

What does advertising claim regarding the effects of the product?

Energy drinks typically differentiate themselves from other soft drinks by claiming to increase a consumer's energy level. The legal implications of these claims are considerable.

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This article was originally published in two parts on *Food Manufacturing* in March 2013.

Under FDA guidelines, health claims for foods and dietary supplements are limited to claims about reducing the risk of a disease or health-related condition.[1] Claims about treating, mitigating, or curing medical conditions are reserved for drugs. Nonetheless, advertising for various energy drinks claims that they will "fix the feeling of tired," provide "hours and hours of energy," and make the consumer "sharper and more alert." One popular energy drink claims that it "increases concentration and improves reaction speed."

Producers of energy drinks should carefully evaluate whether health effect claims in their marketing are permissible under FDA regulations, and make corrections if needed. Manufacturers may decide that they can avoid the FDA requirements by not referring to their products as a "dietary supplement" or as an "energy" product per se, but the key factor determining how the FDA will treat the product will likely be the nature and tone of the labeling and marketing.

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Most energy drinks are marketed as either dietary supplements or as conventional beverages.[2] For the manufacturer, a major advantage to marketing as a supplement is that supplements are allowed to contain higher caffeine levels than beverages. However, a 2006 law (the Dietary Supplement and Nonprescription Drug Consumer Protection Act) requires producers of dietary supplements to file adverse event reports with the FDA, without imposing a similar requirement on beverage producers. While this law does not require that the FDA make adverse event reports public, and the FDA typically has not done so, in October 2012 it reversed course and began releasing the reports.

Compliance with adverse event reporting would be a key component in any potential defense to an injury claim. A drink maker who markets a supplement and complies with reporting requirements, can argue that the FDA was fully informed as to the potential effects of the product. By contrast, one who fails to provide accurate reports loses the opportunity to make this defense, and opens themselves to accusations that they knowingly misled the FDA. Even producers who market their product as beverages should consider whether there is an advantage in submitting adverse event data to the FDA, as disclosure allows the argument that the producer went beyond what was required in order to keep regulators fully informed.

One focus of congressional inquiry has been on advertising directed primarily to children and teenagers, and the FDA includes "young people" among the "vulnerable groups" in which it is assessing the health effects of energy drink consumption. Accordingly, any advertising aimed primarily at young people should be vetted with special care by drink makers and legal counsel.

Does packaging contain sufficient language regarding potential health hazards?

The FDA has acknowledged: "There is a long history of safe use of...caffeine-containing products in the United States." For this reason, it appears more likely that product liability suits against energy drink makers will be based on an alleged failure to warn of potential health hazards than on claims of direct toxic effects of caffeine per se.

The prominence and content of warning statements included on packaging for energy drinks varies widely between different brands. One popular drink displays a 14-line boxed warning that lists numerous potential side effects and cautions against use with certain concomitant drugs and medical conditions. Another simply recommends against use by pregnant women and those under age 12.

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Unfortunately, this inconsistency in information is fertile ground for potential plaintiffs, who may choose to focus on cases involving drinks with relatively brief warning statements. Product liability plaintiffs could argue that they were not adequately warned, and point to similar products with more comprehensive warnings in their packaging as evidence that the challenged label is inadequate.

The challenge for a drink maker is to craft a warning for its packaging that offers the best defense against a failure to warn claim. In doing so, it will be crucial to consult with legal counsel, as the warning should do its best to afford protection under the potentially conflicting laws of multiple states. Generally, in drafting a warning, drink makers should consider statements regarding: 1) Dangers to individuals with certain pre-existing health conditions; 2) Dangers to those taking certain medications; 3) Advice on the duration of use; 4) Advice on recommended serving size and maximum amount to consume in a 24-hour period; 5) Specific populations for whom consumption is not recommended; 6) Identified potential negative health effects; and 7) Warnings against foreseeable misuses of the product (see below).

What are consumers told about how to use the product?

Although misuse of a product is often a defense to a product liability claim, many states will permit a plaintiff to recover from a manufacturer for injuries due to a misuse of their product that was foreseeable. For energy drink makers, several misuses are imaginable, including excessive consumption of the drink or use in an attempt at weight loss.

To guard against liability for a foreseeable misuse, drink makers should be careful that no aspect of the marketing or packaging promotes consumption of their product in dangerous quantities. As noted above, a warning about the health hazards of excess consumption -- while seemingly obvious -- may be a valuable tool in guarding against foreseeable misuse liability.

Drink makers should also consider what quantities to make available to consumers in individual bottles or cans. Many popular energy drinks are already sold only in single servings, the familiar "energy shots" found on many store shelves. However, one popular energy drink is sold in an 8 ounce bottle even though the suggested serving size is 2 ounces and a warning on the packaging cautions consumers never to drink more than 4 ounces at one time. Energy drink makers who produce multiple serving bottles and cans should assess whether these larger sizes make misuse more likely, or invite accusations that consumers could be confused and accidentally consume dangerous quantities.

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Considering these questions is an important initial step for an energy drink maker who wishes to assess the potential issues that they may face in litigation. Depending on the answers, the manufacturer may need to make disclosures to the FDA, modify their advertising campaign, or draft more comprehensive warning language for their packaging. By taking the necessary steps, a drink maker can reduce the potential that the use of their product will result in injury, while also enhance their ability to defend against future lawsuits. In an industry that is increasingly a target for plaintiffs' attorneys, these precautions are a worthwhile effort.

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[1] See *Whitaker v. Thompson*, 353 F.3d 947 (D.C. Cir.), cert. denied, 125 S. Ct. 310 (2004))

[2] For guidance on distinguishing between supplements and conventional beverages see *FDA Guidance for Industry*: "Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods." (December 2009) FDA has promised to release additional guidance in 2013.