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Preemption and Jurisdiction Defenses in Caffeine Litigation

From popular "energy drinks" to increasingly popular "energy foods," caffeinated products have recently come under scrutiny from Congress and the Food and Drug Administration, with litigation ongoing and likely to increase in the near term.

Caffeine is a naturally occurring stimulant, commonly extracted from several different species of plants. Ninety percent of Americans consume some amount of caffeine on a daily basis, and the FDA considers caffeine to be a "Generally Recognized as Safe" (GRAS) ingredient for beverages in amounts not exceeding .02 percent of the product. GRAS status for caffeine rests on the fact that a toxic dose in adults consists of 10 grams or more of caffeine, while a typical cup of coffee contains 80-135 milligrams and a 12-ounce soft drink around 40 milligrams. The FDA does not require manufacturers to include the caffeine content of their products on packaging.

Increased attention from federal regulators has accompanied the rising popularity of caffeine in new types of products and at levels far higher than those found in coffee or colas. Energy drinks can contain 200 milligrams or more in a single can, with some brands containing caffeine levels as high as 700 milligrams.[1] One brand of "energy" chewing gum contains 400 milligrams of caffeine in a pack. Federal regulators have recently expressed a number of concerns regarding the safety of caffeinated foods and beverages, including the risks accompanying higher caffeine levels, different consumption patterns than traditional caffeinated beverages and the marketing of these products to children. In May 2013, the FDA announced that it would investigate the safety of caffeinated food and beverages.

As often happens when the FDA expresses concerns over the safety of a class of products, litigation concerning caffeinated foods and beverages has also increased during the last year. Thus far, energy drink manufacturers have been a particular focus of lawsuits, but given the current spotlight on this issue, any manufacturer of caffeinated products could end up being affected. In defending lawsuits involving caffeinated products, manufacturers should consider the jurisdictional defenses of preemption and primary jurisdiction, and familiarize themselves with both the utility and limitations of these defenses.

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Primary Jurisdiction

Primary jurisdiction is a judicially created doctrine addressing the proper relationship between courts and administrative agencies. This defense is typically successful when a court concludes that the relevant issues require the technical expertise of an administrative body, and thus declines to substitute its judgment for that of the administrative agency. When it comes to FDA-regulated products, this includes not only cases requiring technical expertise, but also cases where FDA guidance is in progress or unintentionally absent, or where the issues being litigated implicate a need for national uniformity.

If a court applies the primary jurisdiction doctrine, the underlying case may either be dismissed or stayed until the issue governed by the regulatory body is resolved. While the advantage of a dismissal is clear, a stay can also be useful to the defendant, especially if the regulatory action renders the litigation claims moot. At a minimum, a stay offers a defendant time to develop a defense strategy or to potentially engage the plaintiff in negotiations to resolve the claims extrajudicially.

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In 2010, courts in New Jersey and California invoked primary jurisdiction to stay consumer class actions alleging that the term "natural" was misleading when used on labels of foods containing high-fructose corn syrup. Those stays were eventually lifted after the FDA announced that it would not be taking additional steps to define the disputed term.[2] That same year, the U.S. District Court for the Southern District of California invoked primary jurisdiction to dismiss state law claims that the maker of Redline energy drink wrongly promoted the safety and health effects of its product. Finding that plaintiff's claims "are based upon the contention that Redline is not safe" the court stated that in order to evaluate the claims it would "likely need to evaluate conflicting studies and determine whether Redline and/or its ingredients should be approved as safe." The court concluded that "these issues are best suited for the FDA.[3]

To support a primary jurisdiction defense, the manufacturer of a caffeinated product should argue that caffeine is largely unregulated by the FDA, with the only existing caffeine regulations dating back to the 1950s. Given the recent focus on the use of caffeine in foods and beverages, updated regulations appear be on the horizon. Moreover, attention has also recently centered on the ability of energy drink manufacturers to choose which mandatory labeling requirements will apply to their caffeinated products by deciding whether to market them as dietary supplements or as beverages. Under the 1990 Nutritional Labeling and Education Act (NLEA),[4] products classified as beverages are required to make certain mandatory disclosures on their packaging. Beverage manufacturers are also required to obtain FDA approval for all additives that are not GRAS. Because caffeine is GRAS only up to .02 percent of the beverage, this effectively caps the caffeine content of beverages unless the manufacturer obtains FDA approval.

On the other hand, there are no such limitations on the amount of caffeine that can be added to dietary supplements. The FDA is aware of congressional concerns over this apparent contradiction, and a more comprehensive set of new caffeine regulations may emerge from the agency's ongoing review. Accordingly, a compelling argument can be made that it is preferable for a court to stay litigation until the new regulatory scheme is put in place, or until the FDA declines to alter the status quo.

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Preemption

Manufacturers of caffeinated foods and beverages potentially face two distinct types of lawsuits. The first are personal injury lawsuits by individual plaintiffs who claim that they suffered physical harm from consuming the product. The second are class actions brought under various state consumer protection laws. Both personal injury suits and consumer class actions tend to focus on the information provided to consumers through the product's packaging and marketing. Because caffeine is not toxic at doses below 10 grams, it will be more difficult for a personal injury plaintiff to argue the direct toxicity of the product than to argue that the product failed to provide adequate warnings of its risk, especially the risk of cumulative caffeine exposure resulting from the consumption of multiple caffeinated foods and beverages over a short time period. For plaintiffs in a consumer class action, proving that the packaging failed to provide adequate information ties directly to the claim that they were improperly influenced to purchase the product.

Preemption is a constitutionally created defense to certain types of state law claims, based on the contention that if a state law conflicts with a federal law, the state law is unenforceable. [5]As noted above, labeling of food and beverages is controlled by the NLEA, which expressly preempts states from directly or indirectly establishing food and beverage labeling requirements that are "not identical" to the FDA requirements for labeling of ingredients, nutrition and health-related claims.[6] These provisions have been used successfully in the past to dismiss state law claims that would have required packaging to include statements about ingredients that were different from the statements mandated under the NLEA.[7] In a lawsuit related to a caffeinated food or beverage, preemption is likely available against any plaintiff who claims that the manufacturer should have disclosed the caffeine content of the product.

One complication in mounting a conflict preemption defense applies particularly to manufacturers of energy drinks. Conflict preemption depends on the existence of a controlling federal statute. Without a federal statute covering the relevant issues, there is no direct conflict between federal and state laws. For an energy drink that is marketed as a beverage, preemption is available based on potential conflict between state laws and the NLEA.

For an energy drink that is marketed as a dietary supplement, however, the price of less restrictive regulation may be the inability to mount a preemption defense against accusations of false or misleading labeling. In the past, courts have been unreceptive to preemption arguments in food and beverage cases where the statements at issue were of a type not addressed by federal laws.[8] [8]As dietary supplements are not subject to the same labeling requirements that apply to beverages under the NLEA, a state law claim that seeks to impose labeling requirements on a dietary supplement is far less likely to be deemed preempted under the NLEA or other FDA regulations.

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The suitability of preemption as a defense to a personal injury lawsuit is less clear. NLEA §6(c)(2) exempts from preemption "any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food." While the language of §6(c)(2) is clear, the history of this provision is somewhat tortured. The NLEA's other preemption provisions were codified at 21 USC §343. The §6(c)(2) "carve out," however, was not included in the same section of the code, but instead, appears as a note. Subsequently, when proposing new rules and discussing their preemptive impact, the FDA referred to only the codified preemption provisions of 21 USC §343, without referencing the note or §6(c)(2) of the statute.[9]

In 2011, the FDA clarified that its prior discussion of preemption should have included §6(c)(2), supporting the conclusion that §6(c)(2) is equal in force to the NLEA's codified preemption provisions.[10] To date, no court has dismissed a preemption argument under §6(c)(2). However this may only indicate that defendants are reluctant to mount a preemption defense given the clear language of this section.

With the application of the preemption provisions of the NLEA to caffeinated products, a state law claim is not likely to be preempted if it seeks to add language to the packaging that links the product to particular negative health effects. By contrast, a claim that consumers should have been informed as to how many milligrams of caffeine are contained in the product would be preempted. In a personal injury lawsuit, the plaintiff is likely to allege that packaging should have included additional safety information conveying the risk of the particular injury that he or she claims to have suffered. For this reason, preemption is not likely available as a defense to a personal injury lawsuit for a caffeine-related product.

The courts have not yet confirmed what exactly qualifies as a statement of "warning concerning the safety of the food" such that it is not preempted by the NLEA. Plaintiffs in consumer class actions may attempt to evade preemption by arguing that adding language to a product's label regarding caffeine content is effectively adding a warning about the safety of the product. The purpose for providing this or

any additional information regarding caffeine, plaintiffs may argue, is to make the consumer more aware of the safety risks that come with consumption.

The appeal of such an argument to a plaintiff is that clear warning language such as "caffeine causes X side effect" may be strongly challenged on its scientific accuracy, while arguing that a product label should contain an accurate statement that "this product contains 400mg of caffeine" cannot be refuted. In response, a defendant will want to draw a clear distinction that any attempt to impose a state-level requirement that would lead to "non-identical" labeling as to ingredients, nutrition, or health information as opposed to a statement or warning of a specific health risk is preempted by the NLEA.

Conclusion

Any manufacturer of a caffeinated food or beverage should consider the defenses of primary jurisdiction and preemption when faced with a lawsuit targeting one of their products. The success of these defenses will depend, in part, on the nature of the suit. However, it is worth noting that the majority of NLEA preemption and primary jurisdiction decisions are relatively recent—all within the last seven years.

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At the same time, the regulatory framework of FDA regulation on caffeine is likely to shift, as the FDA determines the best course for updating regulations and regulating new types of products, including whether there is a meaningful distinction between dietary supplements and foods and beverages when it comes to ingredient labeling. As a result, the applicability of preemption and primary jurisdiction is likely to remain fluid for some time, and for this reason it is important for counsel working in this field to stay informed on the latest developments.

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[1] Energy drinks may be marketed as either beverages or dietary supplements, with the manufacturer making the initial determination as to the category. The significance of this distinction is discussed below.

[2] See *Ries v. Hornell Brewing*, Case No. 10-1139-JF, 2010 U.S. Dist. LEXIS 86384 (N.D. Cal. July 23, 2010); *Holk v. Snapple Beverage*, Civil Action No. 07-3018, 2010 U.S. Dist. LEXIS 81596 (D.N.J. Aug. 10, 2010).

[3] *Aaronson v. Vital Pharmaceuticals*, Case No. 09-CV-1333W, 2010 WL 625337 (S.D. Cal. Feb. 17, 2010) at *2.

[4] 21 U.S.C. §343-1.

[5] This article does not discuss the suitability of a defense based on "field preemption," wherein courts infer an intention to preempt state law if the federal regulatory scheme is so pervasive as to "occupy the field" in that area

of the law. The viability of such a defense may be affected by how far the FDA chooses to involve itself in the regulation of caffeine content in foods, beverages and dietary supplements.

[6] See 21 U.S.C. §343-1(a)(1)-(5).

[7] See e.g. *Pom Wonderful v. Coca-Cola*, 679 F.3d 1170 (9th Cir. 2013); *Young v. Johnson & Johnson*, No. 12-2475, 2013 WL 1911177 (3rd. Cir. 2013);*Turek v. General Mills*, 662 F.3d 423 (7th Cir. 2011).

[8] See e.g. *Chacanaca v. Quaker Oats*, 752 F.2d 1111 (N.D. Cal. 2010) (no preemption because NLEA does not address "front of the box" symbols).

[9] See e.g. 21 CFR Part 131 at 2458 (2009).

[10] 21 CFR Ch. 1 at 61565 (2011).