Elsevier Business Intelligence

PUBLISHED WEEKLY

"The Tan Sheet"

NONPRESCRIPTION PHARMACEUTICALS AND NUTRITIONALS

MAY 27, 2013

Monster Lawsuits Test State Preemption Of FDA

Lisa Gillespie l.gillespie@elsevier.com

The outcomes of dueling lawsuits between **Monster Energy Corp.** and the city of San Francisco could swing on whether judges say federal Food, Drug & Cosmetic Act regulations are preempted by state laws when FDA does not act on a city's or state's concerns.

Monster filed a lawsuit in federal court April 30 to halt an investigation of the firm's sales and advertising that San Francisco City Attorney Dennis Herrera launched in December 2012.

Herrera filed a lawsuit against Monster May 6 in San Francisco Superior Court, alleging the firm violated California laws with "marketing of highly caffeinated energy drinks to children as young as 6 years old, despite scientific findings that such products may cause 'significant morbidity in adolescents' from elevated blood pressure, brain seizures, and severe cardiac events."

The city's lawsuit also alleges Monster engaged in unfair and deceptive business acts under California's Business and Professions Code, including misbranding its products as supplements, not adequately warning of the dangers of drinking the products, marketing to minors and making unsubstantiated claims about the benefits of the products' ingredients.

Herrera said he contacted FDA about his investigation on March 19, 2013, stating there is neither sufficient evidence nor a consensus of scientific opinion to conclude that high levels of added caffeine in energy drinks are safe under generally recognized as safe standards for food additives.

The city attorney urged FDA – without success – to "protect children and adolescents from the danger of highly caffeinated energy drinks" by applying the existing GRAS standard for soda to energy drinks and other beverages that contain caffeine as an additive and requiring manufacturers to include caffeine content on product labels.

Without FDA Action, City Acts

The litigation follows meetings between Herrera's office and Corona, Calif.-based Monster to discuss the largest U.S. energy drink manufacturer's claims substantiation, and the city attorney's request for FDA intervention.

According to the firm's lawsuit, Monster's representatives stated that FDA has jurisdiction in enforcing federal FD&C Act regulations, which govern the firm's products and manufacturing; showed evidence of compliance with the agency's regulations and guidelines; and provided information on the safety of Monster products and citations to scientific studies.

Herrera on March 29 responded to Monster's defense of its products and marketing, asserting that the firm's drinks are not GRAS under FDA regulations. He instructed the firm to take immediate steps to reformulate its products to safe caffeine levels, provide adequate warning labels and cease promoting over-consumption, according to official documents.

"Monster Energy is unique among energy drink makers for the extent to which it targets children and youth in its marketing, despite the known risks its products pose to young people's health and safety," Herrera said when he filed the complaint.

Monster Asserts Federal Preemption

Monster's complaint asks the U.S. District Court of the Central District of California, Eastern Division, to "declare illegal" Herrera's demands to reformulate Monster energy drinks, reduce their caffeine content, limit the size of the drinks and change advertising messaging. The firm seeks a preliminary and permanent injunction against Herrera's demands.

Herrera says that because Monster conducts business in San Francisco, the city attorney has authority to prosecute the case, but Monster says the federal FD&C Act preempts California's Food, Drug and Cosmetic Law.

Attorney Ashish Talati, of Chicago-based Amin Talati LLC, explained that where the FD&C Act specifically addresses a particular regulated product or activity and provides guidelines such as requiring labeling content on foods, a state regulation in direct conflict with the requirements is preempted by federal regulations. And where FDA has not made specific guidelines,

state laws still are subject to implied preemption, he said.

On issues where FDA remains silent and a state has specific regulations, a state's rules are not preempted and have authority.

Talati pointed out that California's FD&C Law adopts a large portion of the federal FD&C Act verbatim, making it possible that in the absence of FDA action, San Francisco could enforce against the firm for the purposes of Herrera's demands.

Attorney Katie Weitzman, of Mineola, N.Y.-based Collins, McDonald and Gann P.C., said in cases where it is unclear whether federal or state law applies, a court would look to the intent of Congress to determine whether a federal regulation would apply. A state would need permission from FDA to impose labeling regulations if those rules differed from the agency's requirements or no existing regulations are in effect, said Weitzman.

"Preemption issues are not always black and white," she said.

Commerce Clause Argued

Monster's attorney, Dan Marmalefsky, of Morrison & Forrester LLP in San Francisco, argues that Herrera's demand, among other errors, violates the Commerce Clause under the Constitution, which reserves for Congress the authority to regulate interstate commerce.

A state law cannot directly regulate interstate commerce by affecting transactions across state lines or entirely outside of the state's borders, or if the law imposes a burden that is excessive in relation to its local benefits.

Monster says that because it markets and sells its drinks nationwide, creating labels and marketing exclusive to California would unduly "burden interstate commerce ... there is little putative local benefit to targeting only one energy drink manufacturer."

Attorney Michael Cohen said if the case goes to trial, Monster could argue that it would have to change labeling and marketing that already meets federal requirements.

However, as much as "it may be an economic burden on the company," a court might not consider Herrera's labeling demand an undue burden on interstate commerce, said Cohen, of Michael H. Cohen Law Group in Beverly Hills, Calif.

Talati said Herrera could argue that the public benefit of the regulations he seeks to impose are incidental and outweighs the burden on Monster.

"This would be up to the court to weigh whether Monster is sufficiently impeded" in violation of the Commerce Clause, Talati said.

Weitzman said laws rather than government authorities' demands traditionally have been found to violate the clause. "The court would apply a balancing test to make a determination," she said.

First Amendment Broached

Herrera asks the court to declare Monster engaged in unfair and unlawful business acts in violation of the state's Unfair Competition Law. He also asks that Monster change its advertising and pay civil penalties.

The lawsuit says Monster "aggressively" markets its products to children and teenagers by sponsoring youth sports tournaments and featuring profiles of youth ranging from 6 to 17 on its "Monster Army" website. The lawsuit says Monster failed to warn consumers of the dangers of consuming its drinks.

The firm says Herrera's demand that Monster products include warnings violates the First and 14th Amendments because the advertising Herrera targets is protected as compelled, commercial and content-based speech.

Monster says Herrera seeks to stop the firm from distributing advertising and messaging that references extreme sports, music or gaming, or sponsoring events that feature athletes under the age of 18. The restriction, the firm says, would limit Monster's expression based on subject matter and content.

Monster also argues there is no conclusive evidence to support Herrera's allegation that the firm's marketing and labeling are deceptive because the drinks contain unsafe levels of caffeine. Without such evidence, Herrera cannot show his demands would advance a substantial interest, the firm says.

The Monster lawsuit also says the demands are vague. Herrera asks for "adequate warnings" on drinks and that Monster reformulate drinks to not exceed "safe" levels of caffeine, but the city attorney did not identify a safe level.

"That defendant's demands are arbitrary, overbroad, discriminatory and incapable of advancing the interests defendant has offered is clear from the fact that he has not targeted for enforcement any other energy drink manufacturer," attorney Marmalefsky says in Monster's complaint.

Arguing a constitutional amendment violation turns on multiple variables, says Cohen. "Constitutional arguments need a lot of weight to gain traction. It's all too easy to invoke the First Amendment, when there are competing interests, such as the municipality's right to regulate locally," he said.

Supplements Or Food Regulation?

Herrera also alleges Monster mislabeled its drinks as supplements rather than conventional food beverages, a violation of California's Business and Professions Code and FD&C and Health and Unfair Competition laws.

However, Monster recently joined the American Beverage Association and will follow the trade group's recommendations to label energy drinks as conventional foods and to list caffeine amounts on labels. The firm in mid-February began relabeling Monster Energy drinks as conventional foods (*"Energy Drinks Swayed By Liquid Supplement Draft Guidance After All" – "The Tan Sheet," Mar. 25, 2013*).

According to a Monster spokeswoman, the label change should be 90% complete by the end of May and products with supplement labeling that already shipped are being sold.

The firm made the change for several reasons, including eliminating Monster's competitive disadvantage in states where energy drinks labeled as conventional foods are exempt from sales tax and are eligible for food stamps, the spokeswoman said.

Additionally, changing was good for Monster's image, she said. "The company saw no reason to continue being subjected to the erroneous and misguided criticism that its drinks are being marketed as dietary supplements to avoid FDA regulation."

Changing the labeling, however, might not make Herrera's argument moot, says Weitzman. "You can't un-ring a bell. If it's determined that it was misbranding to market the products as supplements, correcting the violation later on doesn't erase the previous legal misconduct," she said.

She said because FDA allows energy drinks to be labeled as conventional beverages or supplements, a court would "have a high evidentiary burden to meet to prove the claim."

Weitzman explained that the state's Business and Professions Code also covers past actions and would allow a court to order restitution going back four years, but this argument could come down to the preemption issue. Since FDA allows energy drinks to currently market as either supplements or beverages, if a court finds the FD&C Act preempts the state law, Herrera would not be able to pursue damages under California law.

A 2009 FDA draft guidance appeared to narrow the definition of what types of products qualify as supplements – which some in industry said focused on energy drinks labeled with long lists of novel ingredients. The Center for Food Safety and Applied Nutrition guidance said liquid supplements with packaging and labeling representative of conventional beverages do not fit the definition of a dietary supplement under the FD&C Act (*"FDA Supplement Beverage Guidance May Open Can Of Regulatory Worms" – "The Tan Sheet," Dec. 14, 2009*).

At SupplySide MarketPlace May 1 in New York, the director of CFSAN's Division of Dietary Supplement Programs, Daniel Fabricant, said the agency "pretty soon" will finalize the guidance on distinguishing between foods and supplements, focusing on products straddling the fence between supplement and beverage.

"The agency is very interested in the effects of caffeine, there has been a lot of news with new products coming to market, both in the supplement space and food space, and where exactly the line will be drawn on caffeine – I don't have a good answer on that. I think the agency probably is going to focus on populations that are perceived at risk, especially with children," Fabricant said.

On May 8, FDA announced the agency will investigate the safety of caffeine in food products, particularly the ingredient's effects on children and adolescents. FDA has met with companies to hear the rationale for adding caffeine to products, a far more common practice than the agency anticipated.

"Existing rules never anticipated the current proliferation of caffeinated products," said Michael Taylor, deputy commissioner for foods and veterinary medicine.

"We need to better understand caffeine consumption and use patterns and determine what is a safe level for total consumption of caffeine," Taylor added in a release.

He said manufacturers currently can add caffeine to products if the ingredient meets the relevant safety standards and if they include it on a product's ingredient list. While various uses could meet federal food safety standards, the only time FDA explicitly approved adding caffeine was for colas in the 1950s.

Enforcing age restrictions would present a practical challenge, but Taylor said FDA will determine whether foods attractive and accessible to children should contain caffeine and whether the agency should limit the amount of caffeine in certain products.

Members of Congress also are interested in the effects of caffeine. Rep. Edward Markey, D-Mass., and Sens. Dick Durbin, D-Ill., and Richard Blumenthal, D-Conn., in April published a report based on information received from 13 energy drink makers on marketing and products. The energy drink market is worth more than $12.5 billion annually, but is marred by inconsistent labeling, unsubstantiated claims and allegedly illegal marketing to children, according to the report (*"Congressional Energy Drink Report Pushes Voluntary Industry Actions" – "The Tan Sheet," Apr. 15, 2013*).