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FOP Standardization Could Help Preempt State Suits And Ease Liability

An FDA-developed front-of-package food labeling scheme could alleviate some federal preemption issues by limiting litigation in state courts, although in the meantime some lawsuits are proceeding in individual states where certain claims are not preempted by FDA regulations and related statutes, sources said. An industry attorney said an FOP scheme developed by manufacturers or FDA could help stem liability in state courts, while a nutrition advocacy attorney said states should retain authority because FDA has not consistently enforced misleading label claims.

The issue of FOP preemption arose in a court decision decided last month in a false advertising case brought against the Quaker Oats Company for claims on its Chewy Bars packaging. In the case, *Robert Chacanaca, et al. v. Quaker Oats Company*, the U.S. District Court for the Northern District of California held that states can determine the validity of health claims like “wholesome” or “smart choices made easy,” while it ruled in favor of preemption for trans fat, whole grains and other nutrient claims that appear on the front of packages.

The plaintiffs, acting on behalf of California Consumers, raised claims for false advertising for including “0 grams trans fat” and “wholesome” statements as well as images of oats, nuts and children playing soccer on packaging for Chewy Bars.

“Without question, the FDA has extensively regulated food labeling in the context of a labyrinthine regulatory scheme,” according to the decision, which was signed by U.S. District Judge Richard Seeborg. “Nonetheless, plaintiffs advance a relatively straightforward claim: they assert that defendant has violated FDA regulations and marketed a product that could mislead a reasonable consumer. As courts faced with state-law challenges in the food labeling arena have reasoned, this is a question ‘courts are well-equipped to handle.’”

The court decision comes as FDA and industry research and develop plans for a front-of-package labeling schemes. The food and beverage industry announced last week that it would debut its own system early next year and launch a \$50 million public education initiative to accompany the effort (*FDA Week*, Oct. 29).

“I think that unless the FDA passes regulation or Congress passes a law, companies are not going to be able to use preemption as a firewall,” said Ken Odza, a partner at Stoel Rives LLP in Seattle.

The court ruled in favor of preemption with respect to the zero trans fat and other nutrient claims because the state’s laws match FDA regulations under the Nutrition Labeling Education Act, which explicitly says that the federal government’s nutrition standards preempt state law. Under the statute, trans fat content that is below 0.5 grams can be rounded down to zero on the nutrition facts panel. While the agency has no explicit requirements regarding corresponding package claims, it has urged companies to stay consistent with the facts panel on their labeling as a whole, according to court documents.

While the nutrient claims were preempted, a state jury could be left to decide whether the package’s images and other health claims such as “wholesome” are valid, an example of how multi-state enforcement could become problematic and how state courts are not equipped to make the determinations, Odza said.

“We have a lot of experts looking at this,” he said, referring to the pending government and industry studies. “This is a very complicated subject.”

The absence of a government FOP labeling system leaves the claims that are not subject to NLEA or other regulation open to interpretation as to whether they are preempted. But, research that supports implementing the upcoming FOP systems industry-wide could make it more difficult to bring cases against companies because of the standardization, Odza said. The system itself could also help contain litigation, he said.

“I think the more research and science that is put in behind the industry and government standards, the harder it will be to make these claims,” he said.

The Center for Science in the Public Interest has been outspoken against the industry’s current and past FOP initiatives, including the Smart Choices program. CSPI Litigation Director Steve Gardner said the agency’s absence of decision making in respect to package claims should not be interpreted legally as regulation. He said states should be able

to step in where federal regulation has failed. He also noted that there is a long history of state preemption.

“Zero, to consumers, means actually zero,” he said, adding that by industry and FDA standards, it means, “not so much.” Gardner, who also supported state enforcement of trans fat and other nutrient claims, said that juries are equipped to make determinations on claims like “wholesome.”

Companies, meanwhile, are using the facts panel as guidance for other claims. “They’re using what they can get away with in the panel,” he said. “No one can challenge what’s in the panel.” NLEA, which regulates the panel, should not be a “get out of jail free card” for other claims that appear on packaging, Gardner said.

An industry-wide FOP system might preclude the need for lawsuits, but would not necessarily clarify existing regulations, especially a system developed solely by industry, Gardner said citing the Smart Choices program as an example. The program ended after FDA sent a several of warning letters for false label claims.

While the agency uses warning letters as enforcement, larger cases are less frequent, he said. “The problem is that FDA has all but abandoned labeling fraud,” Gardner said. — *Alaina Busch*