

In Practice

Food Regulation And Litigation Is Expanding How Companies Can Cope

By Reni Gertner

The food industry is under siege. Whether blaming fast food restaurants and junk food manufacturers for the nation's obesity epidemic, or voicing a growing concern about the vulnerability of the food supply to bioterrorist attack, a small but powerful band of plaintiffs' lawyers has gotten the food industry in their crosshairs. And it's clear that the

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food industry is not taking the challenge lightly.

According to Madeleine McDonough, an attorney with Shook, Hardy and Bacon in Kansas City, Mo., litigation over food issues has evolved beyond traditional suits over E-coli and foreign materials in soup cans.

"Historically, food litigation has focused on processing or manufacturing errors — a metal bolt from an assembly line ending up in a sealed can of vegetables, or food poisoning in a restaurant," said McDonough, who specializes in product liability litigation, including suits over food, agriculture and pharmaceuticals. "But plaintiffs' counsel has publicly announced that they are looking beyond such issues."

McDonough believes that the apparent increase in scrutiny comes from the fact that food is on the nation's radar screen.

"Obesity has received more attention as a health issue, the government has revised the food pyramid, and the 24/7 news cycle reports food-related incidents instantly and widely," McDonough said.

Here's a look at some of the aspects of food litigation that have moved into the spotlight:

• Obesity lawsuits.

In January, the 2nd Circuit held that the families of two overweight New York teenagers could sue McDonald's for deceptive practices under state consumer law. (*Pelmar v. McDonald's Corp.*, 396 F.3d 508; See "Ruling Puts Fast-Food Litigation On Front Burner," *Lawyers Weekly USA*, Feb. 14, 2005; Search words for LWUSA Archives: burner and rekindling.)

A U.S. District Court judge had dismissed the case for the second time in September 2003. But the 2nd Circuit held that the court had erred because New York's consumer law — which makes it illegal to commit deceptive acts or practices — "does not require proof of actual reliance" on the plaintiffs' part.

The two plaintiffs — who ate at McDonald's three to five times a week from 1987 through 2002 — suffer from obesity, diabetes, heart disease, high blood pressure and high cholesterol.

Their families are accusing McDonald's of engaging in misleading advertising about the nutritional value of its products and of failing to disclose that the use of additives and its food processing methods makes its products less healthy than the company indicates.

The plaintiffs allege that as a result of McDonald's deceptive practices, the teens were "led to believe that [McDonald's] foods were healthy and wholesome, not as detrimental to their health as medical and scientific studies have shown."

Some experts have predicted that the court's ruling will lead to a "flurry" of obesity lawsuits.

But McDonough, who represents food companies, believes that isn't necessarily so, partly because the threshold for bringing a claim under New York state law isn't especially high.

To bring this claim in New York, "a plain-



Lawsuits against fast-food restaurants and junk food manufacturers are some examples of the growing number of claims against the food industry.

tiff must only state that the food claim was objectively misleading or deceptive, and that [he or she] was injured as a result," she noted.

When this case moves forward, she said the plaintiffs may have difficulty "establishing causation, among many other obstacles." Further, McDonough claimed, even some plaintiffs' attorneys have conceded there are problems with obesity-related suits. "I have heard of long-time food industry critics [predicting] a wave of lawsuits. However, there has yet to be a surge in obesity-related filings."

tion radar, McDonough said. These items, also known as "functional foods" are a cross between foods, pharmaceuticals and herbal or dietary supplements, which makes it complicated to regulate them.

Some examples include margarine with substances added to help reduce cholesterol and fruit juices with herbs added, such as echinacea, added to boost immunity.

One big issue in this area of food law is regulators' concern that they don't have sufficient knowledge and understanding of the products to regulate them appropriately and guarantee their safety.



"Listening to regulators, critics, consumers and independent experts may contribute to changes that are not only good for the consumers and for the business, but [also] help to forestall and eliminate any need for litigation," said Madeleine McDonough.

However, McDonough believes that one likely result of the ruling will be more suits against businesses — including businesses in the food industry — under state unfair and deceptive business practices laws.

• Functional foods.

Nutraceuticals — foods marketed as having specific medical or physiological benefits — are also likely to surface on the litiga-

Some of these products are covered by the Dietary Supplement Health Education Act, which was passed in 1994. However, as more food items are billed as health-focused, there is increased blurriness as to when a food become a drug or a supplement — and these are the types of issues that have come up in litigation. For example, one company marketed a rice-fermented product with a dried red mold as a "dietary sup-

plement," and claimed on the label that it lowered cholesterol by a certain percentage — something that is barred by federal law.

The FDA asked U.S. Customs to issue an injunction, blocking the product from being imported to the U.S. The company, Pharmamex, went to U.S. District Court in Utah and convinced a judge to remove the injunction because the product brought in 80 percent of their business. The FDA appealed the ruling, and the 10th Circuit held that the active ingredient in the product was on the market as a prescription drug called Mevacor before 1994, when the federal supplement law was passed, and remanded the case to the district court. The U.S. District Court then forced Pharmamex to remove the cholesterol benefit claims from its product, holding that "red yeast rice" must be regulated as a drug, according to Dr. Ted Labuza, a professor of food science at the University of Minnesota in St. Paul.

McDonough said that cases like this illustrate that "if nutraceuticals are intended to have health benefits, there is a gray area about what [companies] can say about certain products," and whether they might actually be considered a drug.

It is also unclear what rules govern items that seem to transcend the various sets of regulations, and how the government should standardize the way different versions of similar products are manufactured.

"This is a transitional area," McDonough said.

• Bioterrorism.

Ever since the Sept. 11 terrorist attacks, the potential for bioterrorism in the food supply has also been an area of concern.

As a result, in December 2004, the FDA promulgated recordkeeping regulations under the Public Health Security and Bioterrorism Response Act of 2002, which requires "persons who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain records" that identify "the immediate previous source of all food received, as well as, the immediate subsequent recipient of all food released." Depending on the size of the business, companies must have their records in compliance with the law in place either later this year or in late 2006, McDonough said.

In her view, "this act imposes heavy burdens on businesses and creates the potential for new legal claims arising from failures to comply with [its] onerous provisions."

The act also requires companies to give "prior notice" of the arrival of food imports to the U.S. The notice rules differ based on whether the food is arriving by water, rail or road, McDonough said. Any food that arrives "without prior adequate notice" will be refused entry and held. The interim final rule went into effect in November 2004, and McDonough said a final rule is expected in June.

Advice For Food Companies

McDonough suggested that companies can try to protect themselves from litigation and regulatory penalties by:

- Paying careful attention to regulatory deadlines and legislative developments;
- Responding to requests for comment and indicating if any compliance deadlines might be difficult to meet and why; and
- Providing suggestions as to how regulations can be constructed to make it easier for companies to comply.

Companies can help the governmental agencies "appreciate the practicalities of

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their businesses," McDonough said. She suggested that it is also helpful for companies to pay attention to lawsuits filed over food issues relevant to their business, noting that her firm puts out a newsletter to assist its clients in doing that.

McDonough stressed the importance of

companies listening in an open way to what consumers, attorneys and regulators say about the safety of their products.

"Listening to regulators, critics, consumers and independent experts may contribute to changes that are not only good for the consumers and for the business, but [also] help to forestall and eliminate any

need for litigation," she suggested.

For example, companies she advises have had success with making food label changes in response to customers' concerns.

"A lot of times they have to make labeling clearer," she said. A customer might say, "I interpreted your label to mean something different than what you intended,"

and a company can then make the "packaging more accurate and helpful."

The FDA is currently asking for comment on food labeling regulations, she noted.

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