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Early Defense Lessons From Surge Of Protein Label Cases

By **Olivia Dworkin and Cortlin Lannin** (June 9, 2022, 5:59 PM EDT)

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In the past few years, there has been a surge of litigation challenging the protein-related representations that food and beverage manufacturers routinely include on their product labels.

These consumer class actions, centered in the U.S. District Court for the Northern District of California, have generally included two theories of liability — one based on so-called protein content claims made outside the nutrition fact label, and one based on the protein percent daily value representation that sometimes appears inside the label.

Defendants' efforts to defeat these claims have yielded varied results, but those decisions are instructive for companies that could face similar challenges in the future.

Challenges to Protein Content Claims

One theory of liability has targeted the quantitative protein content claims that manufacturers sometimes place on the front of pack or elsewhere on their product labels. These could include, for example, representations that a product includes a certain number of grams of protein.

The plaintiffs typically assert that manufacturers prominently label the challenged products as providing specific amounts of protein in order to capitalize on consumers' allegedly heightened interest in healthy or protein-rich foods.

U.S. Food and Drug Administration regulations direct manufacturers to use the nitrogen method — which generally calculates protein content by multiplying the nitrogen content of the food by 6.25 — when calculating the amount of protein reported inside the nutrition fact label.

Companies have generally used the same method for protein claims made elsewhere on the label. In a 2020 lawsuit in the Northern District of California challenging certain Kodiak Cakes products, Minor v. Baker Mills Inc., the plaintiffs asserted that such protein claims must be based on the Protein digestibility corrected amino acid score, or PDCAAS, which is a way of adjusting the amount of reported protein to reflect its purported digestibility.

According to these plaintiffs, using the nitrogen method for quantitative protein claims outside the nutrition fact label can be deceptive and/or misleading under state law to the extent it overstates the digestible amount of protein in the product. Food manufacturers have generally taken the stance, however, that FDA regulations do not require use of the PDCAAS method to calculate protein content claims.

Indeed, doing so would create consumer confusion to the extent the amount of protein reported inside the nutrition fact label — based on the nitrogen method — would differ from the amount claimed elsewhere on the pack — calculated using the PDCAAS method if the plaintiffs' theory was accepted.

The court in the Kodiak Cakes case sided with the plaintiffs on this issue. It acknowledged that "the regulations do not address the issue with complete clarity or specificity," but nonetheless concluded the "apparent intent manifest in the structure of the regulations" indicated that manufacturers could not use the nitrogen method when making protein content claims.

This order appears to have fueled the wave of similar complaints that followed against other companies making protein content claims, including Kind LLC and Kashi Co.

Recent decisions, however, suggest the tide is turning in manufacturers' favor on this issue. In a February 2022 decision in Nacarino v. Kashi Co., a different court in the Northern District of California squarely answered whether state law could be used to challenge protein content claims based on the nitrogen method: "The answer is no."

In that decision, which dismissed a complaint against Kashi on preemption grounds, the court reasoned that "[g]iven the FDA's express approval of the nitrogen-content method and failure to require manufacturers to adjust for protein quality when stating the amount of protein in the nutrition label, it does not make sense to read the regulations as barring manufacturers from making identical statements elsewhere on their packaging."

In reaching this conclusion, the court found persuasive a Q&A the FDA had issued the month before stating that manufacturers can use either the nitrogen or PDCAAS method for calculating protein content claims outside the label. As the court observed, the FDA had now "clearly stated that its regulations do not require protein content statements to adjust for digestibility, demonstrating that 'uncorrected' claims are not inherently misleading within the meaning of the regulation."

The court acknowledged earlier decisions had come out the other way, including Minor, but noted it "sees the issue differently" and that those earlier decisions "came down before the FDA issued its most recent guidance on the topic."

The Nacarino decision proved prescient. Just days later, the court that had originally issued the Minor decision against Kodiak Cakes in 2020 changed course, dismissing with prejudice in Chong v. Kind LLC a virtually identical case against Kind and acknowledging Minor was "incorrectly decided."

The Chong decision confirms that "[b]ecause plaintiffs are attempting to use state law to impose labeling requirements that go beyond what the FDA regulations require, their claims are preempted."

Subsequent to these decisions, other courts in the Northern District of California have uniformly rejected the proposition that protein content claims must account for protein digestibility. For example, in a March 2022 decision in Brown v. Nature's Path Foods Inc., the court concluded that FDA regulations

"do not require protein content claims to adjust for digestibility or to be calculated using amino acid content testing."

Another court followed suit in an April 2022 decision in Brown v. Kellogg Co., dismissing the plaintiff's complaint and endorsing the reasoning from Kashi. In May 2022, the court in Brown v. Van's International Foods Inc. concluded that "FDA regulations permit protein content claims to be calculated via the nitrogen method."

That same month, the court in Swartz v. Dave's Killer Bread Inc. held that "FDA's explicitly statement that nutrient content claims may be based on total protein, calculated using the nitrogen-content method, is dispositive."

In total, five different judges in the Northern District of California have now squarely rejected the plaintiffs' theory. While the plaintiffs have appealed several of these decisions to the U.S. Court of Appeals for the Ninth Circuit, the uniformity of the orders and the consistent reasoning therein would seem to auger well for defendants on appeal.

Challenges to Lack of Percent Daily Value

These cases often assert another theory of liability: that manufacturers are required by FDA regulations to include a percent daily value, or %DV, figure for protein in the label if they make a protein content claim elsewhere on the package, and that failing to include that %DV can be false or misleading under state law.

Unlike the protein content claim theory discussed above, the courts have not yet adopted a uniform approach to claims challenging the omission of %DV from the label.

In Chong, the court held that such claims were subject to implied preemption under the U.S. Supreme Court's 2001 decision in Buckman v. Plaintiffs' Legal Committee, reasoning the claims were "ultimately ... dependent on the existence of violations of federal law."

The plaintiffs there had argued that their claims were based on preexisting state common law duties that merely paralleled federal requirements, but were not dependent on the existence of violations of federal law.

Chong rejected this argument, reasoning that the plaintiffs were not "pursuing pre-existing, traditional, state tort law claims," but instead were relying on a state law that "post-dates and is entirely dependent upon the [Federal Food, Drug, and Cosmetic Act], in that it expressly adopts the FDCA and regulations as state law." Accordingly, the court held this claim was preempted.

This particular holding has not been universally accepted. In Van's, the court noted its disagreement with Chong on this point, explaining that it "did not read Buckman or its progeny as sweeping so broadly."

The court concluded that the plaintiff's claims "fit within the 'narrow gap' that avoids preemption" because she was "suing for conduct that violates the FDCA, but not because the conduct violates the FDCA."

The court also rejected the proposition that state statutory claims must predate the FDCA to avoid

preemption, observing that courts in the Northern District had routinely rejected exactly that argument.

Even though the Van's court found Buckman preemption did not apply to this theory of liability, the court nevertheless dismissed the claim in light of the plaintiff's failure to "plausibly allege that she was deceived by the omission of digestibility-adjusted protein figure from the Nutrition Facts panel."

The courts in Nature's Path and Swartz likewise dismissed this %DV theory based on the plaintiffs' failure to plead exposure to and/or reliance on the %DV representation, and thus did not reach the Buckman question.

These decisions are instructive for defendants who may face similar "%DV" claims in the future. While the vitality of a Buckman argument is unsettled, the courts do appear sympathetic to more traditional arguments that these claims must be dismissed where the plaintiffs fail to plausibly allege (or allege at all) that they relied on and/or were deceived by the omission of the %DV in the label.

Looking Ahead

Taken as a whole, these six recent cases suggest that claims challenging a manufacturer's use of the nitrogen method for protein content claims are unlikely to gain much traction, at least in the Northern District of California.

A consensus approach has not yet emerged for claims challenging a manufacturer's failure to include a %DV in the label — although the recent decisions certainly point to vulnerabilities in this theory that a savvy defendant should seek to raise at the motion to dismiss phase or, if necessary, develop in discovery.

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