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Plaintiffs Look Beyond Labels And Toward Product Testing

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Food and nutraceutical companies are increasingly facing a new type of purported class action, one where plaintiffs arrive armed with results from alleged product testing. These plaintiffs claim their testing shows deviations from labeled amounts of ingredients, and thus allege fraud or violation of consumer protection laws. Defendants confronted with this type of false labeling allegation might hesitate. After all, this plaintiff has data! Analysis of plaintiffs' "tests," however, often reveals significant (and sometimes fatal) flaws. Knowing how to respond to a product testing claim is vital, particularly now because of the advent of product testing websites and crowdfunded research. The increased scrutiny of the dietary supplement industry means that companies can only expect more of these lawsuits.

As a first response, when a plaintiff's testing does not comply with U.S. Food and Drug Administration standards for evaluating nutrition labeling, the claims should be preempted by federal law. The Federal Food, Drug, and Cosmetic Act/Nutrition Labeling and Education Act expressly prohibit state-labeling requirements that are not identical to federal requirements, including requirements for the nutritional information on a label. In turn, the FDA regulates not only which numbers must appear on a food label, but also the methods by which it tests those numbers.

The FDA requires a sample from a "lot," which means a "collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, or in the absence of any common container code or marking, a day's production."[1] Once a lot is identified, the FDA requires a random sample of at least 12 consumer units (e.g., bottles). Then, the composite from this sample must be tested "by appropriate methods as given in the 'Official Methods of Analysis of the AOAC International,' 15th Ed. (1990) ... or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures."[2]

By requiring appropriate testing procedures and random sampling, the FDA protocol not only provides a standardized measure and lexicon, it also minimizes the likelihood that a different protocol will simply find (and report) a statistical outlier. This is intuitive: if a single consumer unit is tested, it is hard to tell whether the result differs from the labeled amount because of an actual problem, or because that unit was simply an outlier in an otherwise compliant lot. Indeed, in the opposite of random sampling, if

plaintiffs consecutively test single unit after single unit, chances statistically increase that they will eventually find a noncompliant unit, however well-controlled a manufacturer's production process. This is particularly problematic because plaintiffs frequently bring product testing claims as class actions — imposing classwide liability based on a single outlier test result has the potential to amplify the consequences of that outlying result a thousand times over. In contrast, as compared to a single unit test, or seriatim tests of single units, test results from a random sample of 12 from the same lot are much less likely to differ significantly from the true nutrient content of the product by selection or by chance. FDA testing requirements are designed to minimize statistical aberrations (and also have the added benefit of exposing plaintiff cherry-picking of outlier test results).

From this perspective, it's clear why many product testing claims should fail on preemption grounds. If a plaintiff tests her purchase of a single consumer unit and files a lawsuit, she seeks to impose liability based on a sample size smaller than the FDA requires. This would impose stricter requirements on a manufacturer's production process than those the FDA has chosen, and thus should be preempted by federal law. Similarly, if a plaintiff seeks to impose liability based on a test that does not comply with AOAC standards, her claim should be preempted because she asks companies to comply with testing procedures in addition to those specified by the FDA. An individual lawsuit based on product testing is thus little different than any other labeling claim — when the FDA has regulated in an area covered by the FDCA/NLEA's express preemption provisions, a state cannot impose nonidentical requirements.

In one of the leading cases on the subject, Salazar v. Honest Tea Inc. (E.D. Cal. June 10, 2014), a plaintiff alleged Honest Tea's Honey Green Tea contained less flavonoids than as labeled, based on an independent "test," and sought to recover damages on behalf of a putative class. The court found this claim preempted:

[B]ecause defendant's label statements are nutrient content claims, their accuracy must be challenged under the 12–sample test method established by 21 C.F.R. § 101.9(g). Yet, the Complaint does not allege plaintiff tested Honey Green Tea using this method. Consequently, the Complaint does not show that defendant's statements on the product labels violate the FDCA's labeling requirements. Because plaintiff's allegations do not show a violation of the FDCA, plaintiff's state law claims are preempted; if allowed to proceed, the state law claims would impose liability inconsistent with the FDCA.[3]

Even if a plaintiff does comply with FDA requirements for product testing, her test results might not be sufficiently different from a label claim to impose liability. The FDA does not require that test results be exactly equal to the labeled amount. After testing performed on an appropriate sample, with the appropriate methods, the FDA has two standards to determine label compliance. For nutrients from naturally occurring ingredients, the nutrient content need only be 80 percent of the amount declared on the label. For added nutrients in a fortified food, the nutrient content need only be at least equal to the label's claim.[4] If plaintiff attempts to impose liability because her fortified product tested with slightly higher nutrient content than as labeled, or if her naturally occurring product tested with slightly lower nutrient content than as labeled, she is again imposing standards not identical to those promulgated by the FDA, and so her claims should be preempted by federal law.

Based on these principles, food and nutraceutical companies can take measures today that will protect them from liability tomorrow. They can ensure that their production processes (or those of any contract manufacturers used) produce FDA-compliant test results and conduct regular tests of their products to assure compliance with nutrition labeling per FDA-testing procedures. And, if they do face a product testing lawsuit based on a sample that fails to follow FDA requirements, they might do well to

remember the old adage: there is safety in numbers.

—By James P. Muehlberger and Jeff Lingwall, Shook Hardy & Bacon LLP

DISCLOSURE: Honest Tea Inc. was represented by Shook Hardy & Bacon LLP.

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[1] 21 C.F.R. § 101.9(g)(1).

[2] 21 C.F.R. § 101.9(g)(2).

[3] Salazar v. Honest Tea Inc., No. 2:13–cv–02318–KJM–EFB (E.D. Cal. June 10, 2014).

[4] 21 C.F.R. § 101.9(g)(4).
