

ALERTS

Food Drug & Device Law Alert - Third Circuit Finds Certain Food Labeling Claims Expressly Preempted By Food, Drug & Cosmetic Act

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The U.S. Court of Appeals for the Third Circuit recently issued a non-precedential opinion affirming a finding that alleged food labeling claims asserted against Johnson & Johnson were expressly preempted by the Food, Drug & Cosmetic Act, as amended by the Nutrition Labeling & Education Act (NLEA). Thomas Young sought to pursue a class action against J&J based on claims that the labels for its Benecol® butter/margarine substitute spreads included various false claims to the effect that the products included “No Trans Fat” and were “Proven to Reduce Cholesterol.”

The Court began its analysis by noting that the NLEA expressly preempts any state-law imposed requirement for nutrition labeling of food that is not identical to the requirement set forth in the NLEA itself. With respect to the “No Trans Fat” claims, Young alleged that the Benecol® spreads include some trans fat. Although Young admitted that FDA regulations allowed Benecol® to claim it contained “0g of Trans Fat Per Serving,” he argued that his claims were not inconsistent with the regulations because he sought to prohibit false claims made on a per product basis.

The Court rejected Young’s argument, noting that 21 C.F.R. § 101.62(b)(1) and (c)(1) allow claims such as “no fat” and “no saturated fat” as long as a product contains less than 0.5 grams per serving. The Court then discussed other FDA regulations that “authorize nutrient content claims based on per serving amounts, even if those claims are not entirely accurate on a per product basis.” The Court cited three other decisions which reached the same conclusion.

Young argued that the “Proven to Reduce Cholesterol”-type claims were not preempted because FDA’s regulations allow claims about plant sterol/stanol esters, not about products as a whole. Again, the Court disagreed. The Court stated that the cholesterol claims were governed by 21 C.F.R. §§ 101.14 and 101.83. Section 101.14 governs health claims that characterize the relationship of a substance to a disease or health-related condition. Section 101.83 allows a food product to make a health claim based on plant stanol esters if the product includes at least 1.7g of such esters per reference amount customarily consumed, even if there is no evidence that the product as formulated reduces cholesterol. According to the Court, it was irrelevant that Benecol® includes some trans fat because the regulation allows the claim based on plant stanol ester content without regard to other nutrients. Accordingly, the Court affirmed the dismissal of Young’s claims.

A copy of the Third Circuit’s decision can be [found here](#). The Court’s conclusion is consistent with the 2011 decision of the Seventh Circuit in

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Turek v. General Mills, a summary of which can be [found here](#). Food labeling claims have recently become one of the more popular types of consumer litigation. A company facing such claims should always evaluate a potential preemption defense, among others.

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