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Court Bars Second-Guessing Of FDA Food Labeling Rules Lawsuit

(Young v. Johnson & Johnson)

U.S. Court of Appeals for the Third Circuit

The U.S. Court of Appeals for the Third Circuit today affirmed a trial court decision that barred plaintiffs' lawyers from bringing state-law tort suits against food purveyors for making nutrition claims on their product packaging.

The decision in *Young v. Johnson & Johnson* was a victory for the Washington Legal Foundation (WLF), which filed a brief urging affirmance. The court agreed with WLF that any common law tort suit that seeks to regulate nutrition claims is barred by federal law when, as here, the claims comply with labeling rules established by the Food and Drug Administration (FDA). WLF argued that Congress sought to prevent such suits in order to ensure creation of uniform, nationwide food labeling laws.

"Plaintiffs' lawyers have been filing an increasing number of tort suits against food manufacturers, claiming that their labeling violates consumer protection laws," said WLF Chief Counsel Richard Samp following the court's decision. "If these suits are allowed to go forward, we soon will have 50 unique food labeling regimes across the country. Business cannot effectively operate nationwide under that sort of regulatory scheme," Samp said.

The case involved Benecol Spread, a low-fat butter/margarine substitute manufactured by Johnson & Johnson. Benecol contains an insignificant amount of trans fat. FDA permits such small quantities of trans fat to be listed as "zero" in the official "Nutrition Box" that federal law requires to be included on every food label. On the basis of that FDA ruling, Johnson & Johnson also added the phrase "no trans fat" to the front of its product label. The plaintiff in this case alleged that the "no trans fat" claim was false and misleading because Benecol did, in fact, contain an insignificant quantity of trans fat.

The front of the Benecol label also states, "Proven to Reduce Cholesterol." That claim is based on one of Benecol's ingredients, plant stanol esters, which FDA has determined is effective in reducing overall blood and LDL ("bad") cholesterol. The plaintiff alleged that the cholesterol claim was false or misleading because the label should have said that it is the plant stanol esters – not Benecol itself – that reduce cholesterol.

The issue at this stage of the case was whether the state law claims are preempted by an express preemption provision of the Nutrition Labeling and Education Act of 1990 (NLEA). The preemption provision bars any state labeling requirements that are not "identical" to the federal

labeling requirements established by the NLEA and FDA's implementing regulations. Federal courts have reached sharply conflicting results regarding the scope of the provision. The plaintiff in this case argued that preemption is unwarranted because his claims did not directly conflict with any federal labeling rules. He noted that while FDA has issued some rules regarding trans fat and cholesterol claims, it has never explicitly either approved or disapproved the wording on Benecol labeling.

The Third Circuit's decision interpreted the NLEA preemption provision broadly and dismissed the plaintiff's claims on the basis of that provision. As WLF had pointed out, the NLEA requires preemption not simply of state rules that conflict with federal law but also of any state rules that are not "identical" to the rules established by FDA. Under that standard, WLF argued, state tort claims alleging misleading food labeling should be dismissed unless the plaintiff can provide strong evidence that FDA agrees that the labeling in question is false or misleading. The court agreed with WLF that the plaintiff could not possibly make that showing here, given FDA's rulings that: (1) insignificant amounts of trans fat should be listed as "zero" in a food label's Nutrition Box; and (2) FDA has approved claims touting the cholesterol-lowering effects of plant stanol esters.

WLF is a public interest law and policy center with supporters in all 50 states. WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. In particular, WLF has appeared in numerous federal and state courts in cases raising issues regarding federal preemption of state tort law.

For further information, contact WLF Chief Counsel Richard Samp, (202) 588-0302. A copy of WLF's brief is posted on its web site, www.wlf.org.