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LIFE SCIENCES PRACTICE

ALERT

BECAUSE THE "BEST STUFF ON EARTH" SOMETIMES MAKE THE BEST LAWSUITS ON EARTH

In the recent *Holk v. Snapple Beverage Corporation* decision, the United States Court of Appeals for the Third Circuit was one of the first appellate courts to apply *Wyeth v. Levine*, a landmark U.S. Supreme Court decision, upholding a $7 million verdict against a drug manufacturer in a failure-to-warn drug labeling case. The Third Circuit held that federal law did not preempt state consumer fraud claims over Snapple's use of the term "All Natural" on its drink labels. This decision not only breathed new life into a previously dismissed class action suit filed by Snapple consumers in New Jersey, but also has ramifications for companies that work in industries that may be subject to the purview of federal agencies. As previously predicted, it is apparent that these rulings will not only affect the labeling requirements of beverage and food companies but will also impact pharmaceutical, biotechnology and medical devices companies.

Stacy Holk, the lead plaintiff in *Holk* and a New Jersey resident, filed suit in New Jersey State Court against Snapple, claiming that its use of the term "All Natural" on its labels was misleading because the drinks contained high fructose corn syrup, which is derived from processed cornstarch. Snapple removed the lawsuit to the United States District Court for the District of New Jersey and argued to dismiss the case based on the fact that the state law claims were preempted by the Food, Drug and Cosmetic Act (FDCA). The District Court agreed and dismissed the case because the court stated that the Food and Drug Administration (FDA) had used its authority under the FDCA to regulate the labeling and naming of juice drinks. The District Court therefore concluded that the nature of these regulations and the FDCA impliedly preempted state law claims and thus, Holk's suit was dismissed. Holk appealed the decision of the District Court to the Third Circuit.

The preemption doctrine is rooted in the Supremacy Clause of the United States Constitution, which allows federal law to preempt state laws when federal law expressly states preemption, already occupies a certain field or area of law reserved for federal law or impliedly conflicts with state law. The Third Circuit, in reaching its conclusion that federal law did not preempt state law, began its analysis in accordance with the *Wyeth* decision and noted that all preemption arguments must overcome a presumption against preemption and further, food labeling had been an area historically governed by state law.

In 1991, the FDA announced that it was considering defining the term "natural" for the purposes of rule-making. The proposed definition of the term "natural" was "nothing artificial or synthetic… is included in, or has been added to, the product that would not normally be expected to be there. For example, the addition of beet juice to lemonade to make it pink would preclude the product being called 'natural.'" Additionally, the FDA also issued letters instructing food or beverage manufacturers to remove the term "natural" from one of its labels for violating the FDA policy on the use of the term "natural." However, because the FDA declined to officially adopt a formal definition, the Third Circuit found that the consideration of a

definition did not have a preemptive effect. It also rejected the letters as not having the weight of federal law. As such, the Third Circuit concluded that no federal preemption existed, and the plaintiff in *Holk* is now able to continue the original suit under state law.

This case will have ramifications for companies not only in the food and beverage industries but in other industries, such as the pharmaceutical or medical manufacturing industry, where companies may be subject to federal regulations. *Wyeth* appears to have set the stage for the rejection of the preemption argument. Now *Holk*, as a continuation of *Wyeth*, further erodes arguments by companies that federal law preempts certain state law tort claims. Pharmaceutical, biotechnology and medical device companies that may have previously been protected from state law tort claims because of federal preemption may not be able to rely on this argument anymore. Although each case is different, companies must carefully navigate state and federal laws in the labeling of their products. Failure to consider such issues may have adverse consequences. This is particularly true in *Holk* where the plaintiffs may be seeking disgorgement of profits for Snapple's alleged mislabeling.

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