Dinsmore&Shohl LLP
ATTORNEYS

Federal Pre-Emption in Medical Device and Pharmaceutical Litigation

A Manufacturer's Discretion Under FDA Regs May Be the Difference

November 11, 2009

C. James Zeszutek , John J. Richardson , Melanie M. Jones , Randal M. Whitlatch

***As seen on Product Liability Law360.**

Over the past two years, the United States Supreme Court has had two opportunities to address and add to the jurisprudence in the area of federal pre-emption of state law claims regarding allegedly defective medical devices and prescription drugs, which are both regulated by the US Food and Drug Administration (FDA). In Riegel v. Medtronic, Inc., 128 S.Ct. 999 (U.S. 2008), the United States Supreme Court held that the Medical Device Act's pre-emption clause expressly pre-empts state law claims challenging the safety and effectiveness of a medical device marketed in a form that received premarket approval from the FDA. The Court made it explicitly clear, however, that such claims are only pre-empted insofar as they seek to impose state requirements that are "different from, or in addition to" the requirements imposed by federal law. Id. at 1011.

On March 4, 2009, the United States Supreme Court issued its decision in Wyeth v. Levine, 129 S.Ct. 1187 (U.S. 2009), which provided a ruling on federal pre-emption of state law claims over allegedly defective prescription drugs. In Levine, the Court held that federal law does not pre-empt a claim that the label for Wyeth's drug, Phenergan, did not contain an adequate warning regarding proper administration of the drug. Specifically, the Court concluded that it was not impossible for Wyeth to comply with both state and federal law obligations and that the common law claims did not stand as an obstacle to the achievement of Congress' intended purposes in enacting the Federal Food, Drug, and Cosmetics Act. Id. at 1204. That is, the Court held that there was no conflict pre-emption in the case.

At first blush, these two opinions may appear to send conflicting messages about the extent to which federal law pre-empts state common law tort claims in the areas of medical devices and prescription drugs; however, one might argue that the different outcomes stem, at least in part, from the differences in the separate regulatory approval processes that govern devices and drugs. The FDA left Medtronic, Inc. with little discretion, i.e., "the FDA requires a device that has received pre-market approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." Riegel, 128 S.Ct. at 1007. On the other hand, there is "an FDA regulation that permits a manufacturer to make certain changes to its label before receiving the agency's approval." Levine, 129 S.Ct. at 1196. The changes permitted by the FDA likely would have permitted Wyeth to make changes like those at issue in the state court tort suit. See Id. Additionally, the Levine Court gave the FDA's stance in favor of pre-emption no weight because it was procedurally deficient. Thus, the Riegel and Levine opinions seemingly turned, in part, on the amount of latitude and responsibility for safety given to the manufacturer under the FDA's regulatory scheme.

In short, while the U.S. Supreme Court has added significantly to pre-emption jurisprudence over the last year or so, the Court has left several questions open. For example, the Levine Court explicitly left open the

possibility that certain state-law claims over prescription drugs might well frustrate the achievement of congressional objectives. Indeed, the Court was not faced with a situation where the FDA did not ultimately approve a manufacturer's temporary drug label, nor was it faced with a situation where the FDA made it clear that temporary labeling would almost certainly not be approved. Likewise, Riegel did not involve a case where the state court tort suit over a medical device was premised on violations of FDA regulations. Either situation could arguably change the outcome of a pre-emption argument.

Riegel and Levine have been interpreted, and distinguished, many times since the U.S. Supreme Court issued these decisions. Courts, in deciding on pre-emption issues in light of the Riegel and Levine cases, have looked to, among other things, the nuances and differences in applicable federal regulations. See, e.g., Stacel v. Teva Pharmaceuticals USA, 620 F.Supp.2d 899 (N.D. Ill. 2009) (holding state law claims over prescription drugs to not be pre-empted and noting that the U.S. Supreme Court's analysis in Levine was not directly controlling law since Levine dealt with a new drug manufacturer, whereas Teva is a generic drug manufacturer). The reach of Riegel and Levine will almost certainly be litigated for years to come; however, it likely remains a best practice to plead pre-emption as an affirmative defense in medical device and pharmaceutical litigation with the caveat that federal statutory and regulatory law, the discretion given to manufacturers under these laws, and the unique facts of each case may help or hurt the ultimate success of the pre-emption defense in this arena.