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Wyeth V. Levine In Light Of Merck's Vioxx Litigation

Law360, New York (November 04, 2008) -- Preemption, or the displacing effect that federal law has on a conflicting or inconsistent state law, has been a divisive issue and the subject of much confusion since the founding of this country.

The Supremacy Clause of the United States Constitution provides that "The Laws of the United States ... shall be the supreme Law of the land," and, therefore, attorneys understand and can expect that when a state law conflicts with a federal law, the federal law trumps, or "preempts," the state law.

Notwithstanding the Supremacy Clause, however, courts have recognized a presumption in favor of the validity of a state law and, as such, will attempt to reconcile seemingly inconsistent state and federal laws where possible.

Today, state and federal courts are fiercely divided over the issue of whether Food and Drug Administration ("FDA") rules and regulations preempt state law product liability claims.

Earlier this year, the Appellate Division of the New Jersey Court of Appeals joined the longstanding debates concerning federal preemption when they partially overturned a consolidated appeal from two adverse jury verdicts against Merck & Co. Inc. that awarded a plaintiff \$9 million in punitive damages and \$4.5 million in compensatory damages. *McDarby v. Merck & Co. Inc.*, 949 A.2d 223 (N.J. Super. App. Div. 2008).

The court decided that "failure-to-warn" claims under the state's product liability law that challenge the adequacy of prescription drug labeling are not preempted whereas state law punitive damage provisions are preempted by federal law.

This recent decision by no means resolves whether federal approval of prescription drug labeling preempts state-law product liability claims. An upcoming decision on this important issue will be made by the United States Supreme Court during its present term during which the Court is scheduled to hear *Wyeth v. Levine*, 944 A.2d 179 (Vt. 2006), cert. granted, 128 S. Ct. 1118 (Jan 18, 2008) (No. 06-1249).

Similar to the facts and legal questions presented in *McDarby*, *Wyeth* is appealing a Vermont Supreme Court decision that upheld a \$7 million jury award to Diana Levine after her use of the pharmaceutical manufacturer's anti-nausea drug Phenergan® resulted in serious blood complications.

In her lawsuit, Levine alleges that Phenergan had inadequate warnings, whereas the pharmaceutical manufacturer posits that the FDA's authority to approve drug labeling preempts state laws governing the adequacy of drug warning labels.

The Supreme Court clearly recognizes the confusion that exists in this muddled area of the law and seems ready to give courts clarity on the issue. Understanding the reasoning in the New Jersey decision may offer some insights as to how the Supreme Court may decide the issue.

A Supreme Court ruling broadly in favor of federal preemption would appreciably undermine product liability claims of injured plaintiffs against pharmaceutical manufacturers and would limit a plaintiff's ability to sue a pharmaceutical manufacturer through state law when a drug has already been approved by the FDA.

Background Of The Merck Vioxx Litigation

During the 1990s, Merck synthesized and marketed the substance rofecoxib, later trademarked under the name Vioxx®, as having potent pain-relieving and anti-inflammatory properties, without causing the associated gastrointestinal tract problems found in the pain-relievers ibuprofen, naproxen, and aspirin.

Before Vioxx could be marketed, it had to obtain an assortment of FDA approvals designed to ensure safety and effectiveness in humans for the uses proposed by the pharmaceutical manufacturer.

During the clinical trials, researchers hypothesized that Vioxx could increase the risk for thromboembolic cardiovascular experiences with long-term treatment, including an increased chance of blood-clotting, heart attacks, and strokes.

Nevertheless, the FDA determined that the data available was inconclusive on serious adverse events observed in some patients. Ultimately, the FDA approved Vioxx and its labeling in May 1999, without requiring Merck to disclose any warnings of possible cardiovascular risks.

Prior to the approval of Vioxx by the FDA, Merck had commenced a large-scale study, given the acronym VIGOR, to test the effectiveness of Vioxx on patients with rheumatoid arthritis.

By March 2000, the VIGOR study confirmed that although Vioxx was effective against rheumatoid arthritis, the drug demonstrated an alarming four-fold increase in the incidence of heart attacks in patients taking Vioxx.

Merck purported to report the results of the study to the FDA in March 2000 and simultaneously issued a news release on VIGOR stressing the gastrointestinal safety of Vioxx, but not admitting to the possibility that Vioxx was increasing cardiovascular risks.

A supplemental drug application was submitted to the FDA in June 2000 to add the VIGOR results to the Vioxx label. Primarily, Merck sought to disclose that the results of the VIGOR study had provided conclusive evidence of gastrointestinal tract safety, but Merck continued to deemphasize the safety concerns of cardiovascular risks in the revised label.

In April 2002, Merck successfully obtained the FDA's consent to use a revised Vioxx warning label. The new label contained no mention of cardiovascular risks in the "Warnings" section but contained a "Precaution" that limited use of Vioxx only among patients "with a history of

ischemic heart disease” or patients whose already-diagnosed coronary artery disease was symptomatic.

Following the approval of the new label, Vioxx continued to be marketed until September 2004, when another study found evidence of adverse cardiovascular risks, which led to the voluntary withdrawal of the drug from the market.

In the New Jersey case, plaintiff John McDarby had been prescribed Vioxx for osteoarthritic pain prior to the FDA’s approval of Merck’s revised label but after the initial VIGOR results were known, and he took the drug daily until his heart attack in April 2004.

Plaintiff filed state law product liability and consumer fraud claims against Merck, alleging that the pharmaceutical manufacturer inadequately warned users of cardiovascular risks. A jury awarded McDarby \$15.7 million for compensatory and punitive damages as well as attorney fees and costs.

Merck appealed the jury’s verdict in favor of McDarby on his product liability claim, arguing first that the trial judge failed to give proper effect to the state law’s presumption of adequacy for prescription drug warnings approved by the FDA, and, second, that the Federal Food Drug and Cosmetics Act preempts McDarby’s claims challenging the adequacy of the FDA-approved Vioxx warning labels.

Federal Preemption Of State Product Liability Law

Affirming the award of compensatory damages awarded to McDarby, a unanimous New Jersey appellate panel held that state-law product liability claims based on violation of federal regulations do not conflict and are not federally preempted, because FDA regulation requires a pharmaceutical manufacturer to add risk information to an FDA-approved drug warning “as soon as there is reasonable evidence of an association of a serious hazard with a drug,” without first securing the FDA’s prior approval.

The court reasoned that Merck had a post-market responsibility to provide additional warnings about cardiovascular risks, and therefore, was not compelled to choose between complying with FDA rules and regulations and being exposed to jury verdicts in pharmaceutical mass tort actions or strengthen their warning labels and violate federal law.

Therefore, Merck could have complied with New Jersey product liability law without being in violation of FDA regulations.

The New Jersey appellate court did, however, agree with Merck’s argument that the \$9 million punitive damage award was implicitly preempted by federal law.

New Jersey’s product liability law precludes plaintiffs from recovering an award of punitive damages unless the pharmaceutical manufacturer “knowingly withheld or misrepresented information required to be submitted under [FDA] regulations, which information was material and relevant to the harm in question.” N.J.S.A. 2A:58C-5c.

McDarby alleged that Merck withheld from the FDA the complete meta-analysis results of the Vioxx clinical trials suggestive of increased cardiovascular risks.

The court ruled that such so-called “fraud-on-the-FDA” exceptions found in many state product liability statutes are preempted by the United States Supreme Court’s decision in *Buckman v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001).

Because "fraud-on-the-FDA" exceptions are "designed to effectuate the State's interest in punishing unlawful conduct," they are, in effect, state efforts to regulate a pharmaceutical manufacturer's dealings with the FDA. Such provisions impinge upon federal regulation and are therefore preempted by federal law.

The ruling in *McDarby* is at best a partial victory for Merck and the pharmaceutical industry.

While the New Jersey appellate court decision prevents plaintiffs from recovering punitive damages under New Jersey's product liability law unless the pharmaceutical manufacturer misrepresented or withheld material safety information, the court affirmed the \$4.5 million compensatory damages award for the plaintiff because the pharmaceutical manufacturer's "economically-driven manipulation of the post-market regulatory process" overcame the statutory presumption that an FDA-approved warning label is adequate.

Significantly, this decision extends potential liability to a pharmaceutical manufacturer whose drug warning label received pre-market approval by the FDA, even absent a showing of deliberate concealment of a drug's health risks.

The court makes clear that a pharmaceutical manufacturer seeking to be immunized from potential liability under a state's product liability law has a continuous post-market obligation to provide additional and strengthened warnings to any newly-discovered health risks.

A central issue in *Wyeth v. Levine*, as in *McDarby*, is whether a pharmaceutical manufacturer that complies with the warning requirements required by the FDA for the particular drug in question can be held liable under state tort law for not supplying adequate warnings. All eyes will be on the United States Supreme Court when it considers *Levine* later this year.

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