U.S. Supreme Court Holds State Law Failure-to-Warn Claims Impliedly Preempted

Pliva v. Mensing

The United States Supreme Court in *Pliva, Inc. v. Mensing*, 564 U.S. __ (2011), by a 5-4 majority, held that state law failure-to-warn claims brought against manufacturers of generic pharmaceutical products are impliedly preempted by federal drug regulations, reversing decisions from the Eighth and Fifth Circuit Courts of Appeals. The Supreme Court found that because federal regulations prevent generic manufacturers from unilaterally changing their products' labeling, federal law conflicts with and preempts contrary state-law duties requiring those manufacturers to update their warnings to account for new risk information.

The plaintiffs in *Mensing* claimed that they suffered neurological injuries as a result of taking the prescription drug metoclopramide, which also is sold under the brand name Reglan. Plaintiffs sued the manufacturers of generic metoclopramide, alleging that the drug's warnings were inadequate to advise their physicians about the potential risk of harm. The generic manufacturers asserted that federal law preempted those claims. They argued that federal statutes and FDA regulations required them to use the same safety and efficacy labeling as the brand-name equivalent drug, and that it thus was impossible for them to comply both with federal law and with any state tort-law duty to use a different label.

The Supreme Court agreed that the federal regulatory scheme barred the plaintiffs' tort claims. It explained that the 1984 Drug Price Competition and Patent Term Restoration Act – commonly called the Hatch-Waxman Amendments – permits manufacturers to gain FDA approval for generic drugs by showing equivalence to an already-approved reference listed drug without the need for duplicating clinical trials already performed on the brand-name product. That law further provides that generic drug labeling must be "the same" as that for the brand-name drug. The Court concluded that there was no regulatory mechanism available that would have permitted the generic manufacturers to unilaterally alter their labeling because such action would render the generic warnings out of step with the brand-equivalent product's warnings.

The Supreme Court rejected three arguments raised by the plaintiffs that the federal scheme was broad enough to allow generic manufacturers to revise their products' warnings. First, the Court deferred to the FDA's interpretation of its regulations that manufacturers of generic drugs cannot take advantage of the FDA's "changes being effected" (CBE) process, which otherwise allows a brand-name drug manufacturer to add or strengthen a warning without prior approval for the change from the FDA. Second, the Court agreed with the FDA that generic manufacturers are prohibited from issuing "Dear Doctor" letters advising prescribing physicians of warning information different from that contained in the approved labeling, because such a letter would improperly imply a therapeutic difference between the brand and generic drugs. Finally, the Court rejected the notion that a generic manufacturer could have complied with both its federal and state obligations by proposing stronger warnings to the FDA, which the agency then could have made to both drug labels. It was this final point that proved most controversial and consumed the bulk of discussion in both the majority and dissenting opinions.

The *Mensing* majority found that although generic manufacturers could have requested the FDA's help in strengthening the brand-name label, such action would not have satisfied their state-law duty to actually provide a different label to their customers. More significantly, the Court held that the generic manufacturers' failure to take these steps did not vitiate their preemption defense on impossibility grounds. Plaintiffs' argument that such steps could have made a difference depended upon a series of assumptions – that is, *if* the manufacturer had asked for the FDA's help in changing the label, and if the FDA had found there was sufficient supporting information for a label change, and *if* the FDA undertook negotiations with the brand manufacturer, and if

adequate label changes were implemented, then the generic manufacturer's request might eventually have led to a better label. The Court declined to make federal preemption dependent upon what it characterized as a "Mouse Trap game" requiring a series of decisions by different actors.

The Court instead found that the relevant question for preemption purposes "is whether the private party could independently do under federal law what state law requires of it." The generic manufacturers could not facilitate a label change without the assistance and acquiescence both of the FDA and the brand manufacturer. The Court found that this was the key distinction from its 2009 decision in *Wyeth v. Levine*, 555 U.S. 555 (2009), where it held that the brand manufacturer *unilaterally* could make changes to its drug labeling without the FDA's assistance or permission. In contrast, the *Mensing* majority wrote that "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for preemption purposes." Because the generic manufacturer could not have changed the label on its own, plaintiffs' failure-to-warn claims were preempted.

Among the questions raised by *Mensing* is the impact it will have on general conflict preemption principles, including the presumption against preemption. For example, a plurality of the *Mensing* Court suggests that "[w]hen the 'ordinary meaning' of federal law blocks a private party from independently accomplishing what state law requires, that party has established pre-emption[,]" regardless of whether the party could have taken action that might eventually have satisfied its state-law duty to warn. The plurality explained that the Supremacy Clause suggests "that courts should not strain to find ways to reconcile federal law with seemingly conflicting state law." These sentiments arguably strengthen implied conflict preemption as a defense.

The *Mensing* decision is notable not just for its obvious impact on the viability of tort claims against generic drug manufacturers, but also for its interpretation of implied preemption principles generally. These and other issues are likely to affect pharmaceutical and product liability litigation as a whole, and thus are worthy of close examination by the drug industry.

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