New Jersey Law Journal

VOL. 206 - NO 11 MONDAY, DECEMBER 12, 2011 ESTABLISHED 1878

Product Liability & Toxic Torts

Irreconcilable Differences in Prescription Drug Liability Cases

Levine, *Mensing* and pre-emption of failure-to-warn claims brought under state law

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Traditionally, the United States Supreme Court has followed a presumption against pre-emption. In June, however, in the case of *Pliva v. Mensing,* 131 S.Ct. 2567 (2011), the Court ruled in favor of federal pre-emption of failure-to-warn claims brought against generic manufacturers of prescription drugs under state law.

Mensing is seemingly inconsistent with the Court's ruling two years ago in *Wyeth v. Levine*, 129 S.Ct 1187 (2009). In the *Levine* decision, often touted as the "mother" of all pre-emption rulings, the high Court found that failure-to-warn claims asserted against name-brand prescription drug manufacturers are *not* pre-empted by federal law. Accordingly, because *Mensing* represents such a significant development in the law of federal pre-emption, it is certain to have considerable impact on product liability law, generally, and prescription drug liability specifically.

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The Historical Underpinnings of Implied Pre-emption

The doctrine of pre-emption is derived from the Supremacy Clause, found in Article VI of the United States Constitution. The Supreme Court has interpreted the Supremacy Clause to strike down state laws in limited circumstances where state laws "interfere with, or are contrary to" federal law. *Gibbons v. Ogden*, 22 U.S. 1, 211 (1824). The pre-emption doctrine arises when (a) "compliance with both federal and state regulations is a physical impossibility," or (b) when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Sprietsma v. Mercury Marine*, 123 S.Ct. 518, 528 (2002). In determining whether pre-emption exists, there is a presumption against pre-emption.

Pre-emption of Failure-to-Warn Claims Against Drug Manufacturers

In the simplest terms, both *Levine* and *Mensing* involved failure-to-warn claims against prescription drug manufacturers under various state tort law theories of liability. In both cases, the drug manufacturers argued that the state law failure-to-warn claims were pre-empted due to the manufacturers' inability to modify the warnings accompanying a prescription drug without Food and Drug Administration (FDA) approval. The drug manufacturers argued that if they unilaterally revised their warnings to comply with state tort law duties, they would violate the Federal Food, Drug & Cosmetic Act (FDCA) and related federal regulations. Accordingly, the manufacturers argued that it was impossible to comply with both state product liability law and with applicable federal statutes and regulations.

Levine — The Recap

In *Levine*, the plaintiff allegedly was injured from use of the antinausea drug Phenergan. As a result, the plaintiff sued

Wyeth, the brand-name manufacturer of the drug, alleging a failure to warn. The issue before the Supreme Court was whether the plaintiff's failure-to-warn claim was pre-empted by the FDCA and applicable FDA regulations. Wyeth and the FDA, acting as amicus curiae, argued it would have been impossible for Wyeth to comply with both state tort law and with federal law.

The *Levine* Court held that federal law did *not* pre-empt failure-to-warn claims brought against brand-name manufacturers under state law. The Court found that brand-name manufacturers have a mechanism available to them, under FDA regulations, to revise the labels on their brand-name pharmaceuticals without FDA approval. Therefore, a brand-name manufacturer can comply with a state tort duty that imposes an obligation to warn beyond the contents of an FDA-approved label, within the confines of the FDA regulations. *Levine* left open, and arguably invited, consideration of the viability of state law failure-to-warn claims against generic drug manufacturers under federal pre-emption doctrine.

And Then Came *Mensing*

During the past term, the United States Supreme Court did consider the viability of state law failure-to-warn claims against generic drug manufacturers under the federal pre-emption doctrine. As such, in June of this year, the much anticipated *Mensing* decision was issued, and with a surprising outcome: a finding of pre-emption.

The Court held that failure-to-warn claims against generic drug makers are pre-empted under a theory of implied pre-emption. To understand the issues in *Mensing*, one must start with an examination of the 1984 Hatch-Waxman Amendments to the FDCA. 21 U.S.C. § 355(j). The primary goal of the Hatch-Waxman Amendments was to allow greater access to inexpensive generic medications. Under the amendments, manufacturers of generic medications are permitted to submit a streamlined application to the FDA. For example, generic drug manufacturers are not required to conduct their own clinical trials as part of the FDA approval process. Instead, the generic manufacturer's application relies on the information that the brand-name manufacturer submitted to the FDA as part of the brand-name approval process. The short form application must demonstrate that the generic is the "bioequivalent" of the brand-name drug (also referred to as the "listed drug") and that "the labeling proposed for the [generic] drug is the same as the labeling for the listed drug." This regulatory structure, and specifically the requirement that the labeling on the generic mirror the brand-name identically, is at the heart of the Supreme Court's decision in *Mensing*. The Court ruled that it is impossible for generic manufacturers to comply with both federal and state law: federal law prohibited them from changing their label and state tort law required them to change their label. The fact that federal law allows generic manufacturers to petition the FDA for a label change did not avoid impossibility pre-emption, since compliance with state-imposed tort duties would have *required* such a label change.

The Court noted the contrary result in *Levine*, which of course rejected brand-name pre-emption: "We recognize that from the perspective of *Mensing* and *Demahy*, finding pre-emption here but not in *Wyeth* makes little sense. Had [they] taken Reglan, the brand-name drug prescribed by their doctors, *Wyeth* [*v. Levine*] would control and their lawsuits would not be pre-empted." The Court went on to say that it is not the Court's role to reconcile a statutory scheme that may be "unusual or even bizarre." Instead, "Congress and the FDA retain the authority to change the law and regulations if they so desire." Accordingly, under *Mensing*, failure-to-warn claims against generic drug makers are pre-empted as a matter of law.

The *Mensing* decision, particularly within the context of *Levine*, certainly will have an impact on pre-emption going forward, including the presumption against pre-emption. Clearly, *Mensing* may pave the way to a more liberal application of federal pre-emption doctrine. As such, *Mensing* may prove to strengthen defenses available to drug manufacturers based on implied conflict pre-emption principles.

The inability to reconcile the holdings and findings of *Mensing* with its predecessor, *Levine*, may, however, either limit the breadth of the *Mensing* decision or lead the Supreme Court to revisit its federal pre-emption jurisprudence in the near future. Writing for the plurality in finding pre-emption, Justice Thomas freely admitted the irreconcilable differences between the holdings in *Levine* and *Mensing* and noted that the conflict between the two decisions "makes little sense." Thus, in light of this inconsistency in the Court's decisions resolving the pre-emptive effect of federal law concerning prescription medications, the broader, lasting impact of *Mensing* remains unknown. ■