ALERTS AND UPDATES

Federal Government to Provide Its Position on Generic Preemption to the U.S. Supreme Court

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Following the U.S. Supreme Court's March 2009 landmark decision in *Wyeth v. Levine*, state and federal courts have struggled with how to apply *Levine* to failure-to-warn products liability claims against generic pharmaceutical manufacturers. Since *Levine* involved only a brand drug, and because generic drug manufacturers' federal preemption arguments differ from those of brand-drug companies, courts in the wake of *Levine* have been unable to reach a consensus on whether *Levine* equally applies in the context of generic drugs. The federal government, however, will soon supply its views on generic preemption to the U.S. Supreme Court, providing key guidance and clarification on whether the U.S. Food and Drug Administration (FDA) believes that failure-to-warn suits against generic drug manufacturers are preempted by the Hatch-Waxman Act and other federal laws and regulations.

U.S. Acting Solicitor General to Provide Views on Generic Preemption to the U.S. Supreme Court

On July 29, 2010, the U.S. Department of Justice sent a letter to the Sixth Circuit Court of Appeals, stating that the Acting Solicitor General intends to file an amicus brief with the U.S. Supreme Court outlining the federal government's views on generic preemption. The Justice Department was responding to a request made by judges considering a request to overturn three decisions by a district judge in the Western District of Kentucky who dismissed the plaintiffs' failure-to-warn claims against generic drug companies on the basis that these claims were preempted by federal law.

During oral argument in this appeal, the Sixth Circuit panel discussed the uncertain state of generic preemption following *Wyeth v. Levine* and expressed an interest in having the FDA provide its views to the Court. The judges then invited the FDA to file a brief outlining its position by July 29, 2010. In response to the invitation, the Department of Justice sent a letter to the Court, stating that the government was preparing an amicus brief in a generic preemption case, *Actavis v. Mensing*, in which a petition for certiorari is currently pending before the Supreme Court, and requested an extension of time to provide a similar response to the Sixth Circuit. In *Mensing*, the Eighth Circuit rejected a preemption claim, and the generic drug manufacturers have now asked the Supreme Court to review the case.

FDA Previously Filed a Brief in Support of Generic Preemption

Prior to the Supreme Court's decision in *Wyeth v. Levine*, the FDA filed an amicus brief in *Colacicco v. Apotex*, a case then pending in the U.S. District Court for the Eastern District of Pennsylvania. In its amicus brief, the federal government took the position that because generic drugs must have the same labeling as the corresponding brand drug, suits against generic drug manufacturers are preempted by federal law.

Following *Levine*, however, and after the Obama administration took office, the FDA wrote to the judge handling the *Colacicco* case and withdrew its pro-preemption brief on the basis that it needed to reevaluate its position on generic preemption. The *Colacicco* case subsequently settled, and until now, no court had asked the government or FDA for their position on generic preemption.

Although it cannot be foreseen whether the Acting Solicitor General's amicus brief in *Mensing* will support the preemption arguments advanced by generic drug manufacturers, the brief is likely to provide vital clarification of the FDA's and federal government's position on this issue.

Conclusion

As more drugs lose patent protection and generic versions are introduced, generic pharmaceuticals are becoming an increasingly significant aspect of American healthcare. Seven out of ten prescriptions filled today are for generic, not brand, drugs. The Supreme Court's interest in the *Mensing* case demonstrates that generic preemption remains a high-profile legal issue. The Acting Solicitor General's amicus brief in the *Mensing* appeal and its subsequent submission in the Sixth Circuit is likely to provide clarification on whether the federal government believes that failure-to-warn lawsuits against generic drug manufacturers are preempted by federal law.

For Further Information

If you have questions about this *Alert* or would like more information, please contact Alan Klein, Sharon L. Caffrey, Karen Shichman Crawford, any other member of the Products Liability and Toxic Torts Practice Group or the attorney in the firm with whom you are regularly in contact.