ALERTS AND UPDATES

Acting Solicitor General Gives Government's Position on Generic-Pharma Preemption to U.S. Supreme Court

November 4, 2010

In a brief filed in the U.S. Supreme Court on November 2, 2010, Acting U.S. Solicitor General Neal Katyal provided the federal government's position on federal preemption of state laws regarding the labeling of generic drugs. The amicus brief addressed the question of whether "federal law preempts a tort claim under state law that a generic drug approved by the Food and Drug Administration was inadequately labeled." The brief was submitted in response to the Supreme Court's invitation for the U.S. government's views on this significant issue in the context of petitions for certiorari in cases on appeal from the Eighth Circuit, *Mensing v. Wyeth, Inc.* and *Mensing v. Actavis Elizabeth, LLC*.[1] The Acting Solicitor General urged the Supreme Court to deny the petitions, and, in so doing, provided the U.S. government's position on whether the *Mensing* plaintiffs' state-law based failure-to-warn claims brought against generic drug manufacturers are preempted by the Hatch-Waxman Amendments and other federal drug laws and regulations.

The U.S. government's views have been much anticipated since the U.S. Supreme Court's landmark March 2009 opinion in *Wyeth v. Levine*.[2] Since *Levine*, state and federal courts have struggled with how to apply the decision to products liability claims against generic pharmaceutical manufacturers. Because *Levine* involved a brand and not a generic drug, and because generic drug manufacturers' preemption arguments differ from those of brand drug companies, courts in the wake of *Levine* have been unable to reach a consensus on whether and the extent to which *Levine* applies to generic drugs.

While the U.S. government's brief recommends that the Supreme Court deny the petitions for certiorari, it does provide a cogent summary of the U.S. government's current position on generic preemption. The lack of a discovery record at the trial court level was the primary ground for the U.S. government's recommendation against granting certiorari. The Acting Solicitor General emphasized that on an empty record the plaintiff had not articulated what stronger warnings the generic drug manufacturer should have proposed to the Food and Drug Administration (FDA), or how the FDA would have responded had the generic drug manufacturers proposed the plaintiffs' suggested warnings. The dearth of evidence at the trial level also led the U.S. government to conclude that the Eighth Circuit had "correctly rejected petitioners' contention that respondents' failure-to-warn claims are categorically preempted by the FDCA . . . ."

The U.S. government emphasized that the FDA has primary authority under federal law for disseminating strengthened warnings for post-approval ANDA holders, but that generic drug manufacturers themselves—as their brand drug counterparts—have (a) the primary responsibility for properly labeling their products, and (b) an independent duty to inform the FDA of any new information on risks that may require a change in labeling. While conceding, as generic drug manufacturers have argued, that generics are not able to unilaterally change a drug's approved labeling using the changes being effected ("CBE") supplement process, the U.S. government said that they were nevertheless obligated to provide the FDA with information about labeling concerns. Moreover, the Acting Solicitor General emphasized that generic drug manufacturers have an independent and continuing duty to inform the FDA of adverse events from the use of their prescription pharmaceuticals. Acknowledging the inability of generic drug companies under existing regulations to forward "Dear Doctor" letters unilaterally and without the FDA's prior approval, the U.S. government stressed the importance that the FDA be alerted to newly recognized drug risks that may form the basis for disseminating a "Dear Doctor" letter, so that the FDA could properly assess the need for further communications to the medical community. The U.S. government also

concluded in its brief that failure-to-warn claims against generic drug companies do not necessarily frustrate the purposes of the Hatch-Waxman Act.

The U.S. government's position on the federal preemption of products liability claims against generic drug companies will undoubtedly influence appeals currently pending in the Supreme Court, as well the Sixth and Ninth Circuits. These issues, however, remain "in play" for the immediate future, awaiting a case with a more fully developed trial court record to provide guidance to generic drug manufacturers and plaintiffs on this significant issue.

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.

Notes

1. *Mensing v. Wyeth, Inc*., 588 F.3d 603 (8th Cir. Minn. 2009); *Actavis Elizabeth, LLC v. Mensing*, 130 S. Ct. 3349 (U.S. 2010).
2. *Wyeth v. Levine*, 129 S. Ct. 1187 (U.S. 2009).