
# Justice Kagan and the Future of Generic Drug Preemption

December 17, 2010 by Kelly Savage

US Supreme Court Will Decide Fate of Preemption Defense for Generic Companies this Term

Since the decision of the Supreme Court in *Wyeth v. Levine*, 129 S.Ct. 1187 (2009), the Eighth Circuit (in *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009)) and the Fifth Circuit (in *DeMahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010)) have both concluded that failure-to-warn claims against generic drug manufacturers are not automatically preempted by the federal Food, Drug and Cosmetic Act's (FDCA) requirement that generic labeling conform to the approved labeling for the innovator drug. Last Friday, the United States Supreme Court agreed to decide whether a plaintiff's state-law failure-to-warn claim against a generic drug manufacturer for failing to modify its labeling to include warnings that differ from the name-brand equivalent is preempted by the FDCA's requirement that the label for a generic drug be the same as the label for the brand-name counterpart. Against the advice of acting solicitor general, Neil Katyal, the Court agreed to address the issue in three cases *Pliva v. Mensing*, 09-993; *Actavis v. Mensing*, 09-1039; and *Actavis v. DeMahy*, 09-1501 and consolidated them for review.

Since a majority of all drug prescriptions (approximately 75 percent) are now filled with generic drugs, the impact of this decision will be widespread. The stakes are enormous for consumers and the generic pharmaceutical industry alike.

**But It Remains Unclear Whether Justice Kagan Will Take Part in that Decision**

Though several commentators have discussed the potential ramifications of the Court's ultimate holding, there is another more pressing issue: Whether Justice Elena Kagan will recuse herself from the case, and how her recusal could affect the Court's decision. Before her appointment to the Supreme Court, Justice Kagan served as solicitor general, the Government's chief advocate in the Supreme Court and the nation's lower courts of appeal, for 14 months. Kagan has already recused herself in an unusually large number of cases; about half of the 55 cases the Court has agreed to hear this year. She could potentially recuse herself here because she was SG when her office was invited to submit a brief in these cases.

Under federal law, judges who have worked in the government must not participate in any case where they were involved "as counsel, adviser or material witness concerning the proceeding or expressed an opinion concerning the merits of the particular case in controversy." During her confirmation hearings, Kagan said she would recuse herself from any case she worked on as a lawyer. The term "worked on" includes any cases for which she edited or signed briefs, as well as those cases where she participated in discussions about the position the government should take in a given case.


It is unclear whether Kagan played a role or expressed her opinion about the preemptive effect of the FDA's labeling requirements or whether the White House conferred with her before the President issued his May 2009 Presidential Memorandum on Preemption. The SG is the third ranking official at the Justice Department, and its senior expert on constitutional issues. Thus, Kagan may have been asked at least in passing about a constitutional challenge in these types of cases. *Levine* had been decided just two months before her nomination and its preemptive effect in the generic drug arena was being debated amongst the lower courts, so the issue may well have been discussed at Attorney General Eric Holder's senior staff meetings, which the SG typically attends. Her office also withdrew its previous amicus brief in support of generic drug manufacturers in *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008) *cert. petition granted by* 129 S.Ct. 1578 (2009) during the same month she was nominated.

**Kagan's Potential Recusal Has Significant Implications**

An eight-member court normally creates an advantage for respondents (here, plaintiffs); they need only convince four justices in order to win in the Supreme Court, because an evenly divided court keeps the lower court ruling in place without creating national precedent. This case, however, may be one where recusal could work to the ultimate advantage of petitioners (here, defendants).
It is unclear whether Kagan would agree on preemption issues with the justice she replaced, Justice John Paul Stevens, but her potential recusal could actually benefit defendants. Kagan's anti-preemption position, set forth in her amicus brief to the Court in *Williamson v. Mazda*, suggests that she would likely cast a vote against preemption here. Thus, if the decision results in a four-to-four tie, it would result in a win for these plaintiffs with no precedential value in future cases. This would save the issue for another case down the road with a potentially different bench.