Supreme Court Rules in Favor of Generic Drug Preemption

On June 23, 2011, the United States Supreme Court held in *Pliva, Inc.* v. *Mensing*[1] that federal drug labeling laws directly conflict with, and therefore impliedly preempt, state law failure-to-warn claims against generic drug manufacturers. *Mensing* is the latest in a series of federal preemption cases involving the pharmaceutical and medical device industry. In 2008, in *Riegel* v. *Medtronic, Inc.*,[2] the Court held that the preemption clause of the Medical Device Amendments of 1976 bars state law claims challenging the safety or efficacy of medical devices approved by the US Food and Drug Administration (FDA). Then in 2009, in *Wyeth* v. *Levine*,[3] the Court held that federal drug labeling laws do not categorically preempt state law failure-to-warn claims. Earlier this year, in *Bruesewitz* v. *Wyeth*,[4] the Court held that state law design-defect claims against vaccine manufacturers are expressly preempted by the National Childhood Vaccine Injury Act.

In *Mensing*, the Court consolidated two state law failure-to-warn cases originating in the Fifth[5] and Eighth[6] Circuits against generic manufacturers of metoclopramide (Reglan®), a drug used to treat stomach and intestinal problems. Both respondents claimed to have developed tardive dyskinesia, a neurological movement disorder, from the drug. The Fifth and Eighth Circuits held that federal drug labeling laws did not preempt state law failure-to-warn claims against generic drug manufacturers.

The Supreme Court reversed the Fifth and Eighth Circuit decisions in a 5–4 opinion by Justice Clarence Thomas, joined in full by Chief Justice John Roberts and Justices Antonin Scalia and Samuel Alito, and in part by Justice Anthony Kennedy.[7] The Court held that it was *impossible* for manufacturers to comply with state law duties to strengthen generic

1 *PLIVA, Inc.* v. *Mensing*, No. 09-993 (U.S. June 23, 2011).
2 552 U.S. 312 (2008).
3 129 S. Ct. 1187 (2009).
4 131 S. Ct. 1068 (2011).
5 *Demahy* v. *Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010).
6 *Mensing* v. *Wyeth*, 588 F. 3d 603 (8th Cir. 2009).
7 Justice Kennedy did not join Part II(b)(2) of the majority's opinion, which interprets the Supremacy Clause's language as "effectively repealing contrary state law." *Mensing*, at *15.

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drug labels without violating federal drug labeling laws, which require generic drugs' labels to be identical to those of their brand-name counterparts.[8] FDA, while not supporting all of Respondents' arguments, submitted an *amicus* brief opposing preemption.

The Court rejected respondents' arguments that generic manufacturers could warn about new risks unilaterally by either utilizing the "changes being effected" (CBE) process, which allows manufacturers to unilaterally strengthen approved drug labeling without prior FDA approval, or sending "Dear Healthcare Practitioner" letters. Paying deference to FDA's interpretation of its own regulations, the Court held that both methods would violate FDA regulations requiring approved generic drugs to have the same labels as brand-name drugs.[9]

The Court rejected respondents' and FDA's argument that generic manufacturers learning about new risks could approach FDA and suggest labeling changes.[10] The court found that the success of such actions was too speculative, being contingent upon resulting action by a federal agency or Congress.

A key question is whether the reasoning in *Mensing* suggests a departure from the Court's approach to preemption in pharmaceutical cases as recently articulated in *Levine*. Justice Sonia Sotomayor, in a dissent joined by Justices Ruth Bader Ginsburg, Stephen Breyer, and Elena Kagan, found the two opinions inconsistent. The dissent found that the "impossibility" defense accepted by the Supreme Court constituted only a possibility of impossibility. If generic manufacturers had approached FDA, they in fact may have been able to strengthen the warnings.[11] True impossibility would have applied, in the dissent's view, only if FDA had rejected a request for a labeling change or respondents' injuries had arisen before FDA responded to a labeling-change request.[12] Justice Sotomayor also expressed concerns about *Mensing's* impact on drug safety, given the predominance of generics in the prescription drug market. At least two justices — Thomas and Kennedy — supported the result in both cases so apparently believed the decisions could be squared.

Generic drugs now account for about seven out of ten prescriptions nationwide.[13] Proponents of generic liability have argued that *Mensing* strips consumers of remedies for injuries from generic drugs. As the Fifth Circuit noted, finding preemption could result in consumers demanding and paying more for brand-name drugs to preserve their rights to bring state law injury claims.[14] The majority in *Mensing* in fact acknowledges that had the respondents "taken Reglan, the brand-name drug prescribed by their doctors, *Levine* would have controlled and their lawsuits would not be pre-empted."[15]

However, courts may respond by increasingly holding brand-name manufacturers liable for injuries caused by their generic equivalents. Prior to *Mensing*, the majority of courts considering this issue had followed *Foster* v. *American Home Products Corp.*, which rejected such theories.[16] In *Foster*, the Fourth Circuit—applying Maryland law—appropriately held that imposing a duty on brand-name drug manufacturers for harm caused by generic equivalents stretched the foreseeability doctrine too far. The 2009 decision of the California Court of Appeal in *Conte* v. *Wyeth, Inc.*,[17] however, reached the opposite conclusion. It is certainly possible that *Mensing* will give more traction to the reasoning in *Conte*, though one case does not a trend make.

8 21 U.S.C. § 355(j).

9 *Mensing*, at *8.

10 The respondents conceded that their state law claims are not based on the generic manufacturers' failure to approach FDA to change the labeling, as the Supreme Court has previously held such state law claims preempted. Id. at *16; *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U. S. 341 (2001).

11 *Mensing*, at *10 (Sotomayor, J. dissenting).

12 *Id.* at *13 (Sotomayor, J. dissenting).

13 *Demahy* v. *Actavis, Inc.*, 593 F.3d at 432 (citing Susan Okie, *Multinat'l Medicines-Ensuring Drug Quality in an Era of Global Mfg.*, 361 New Eng. J. Med. 737, 738 (2009)).

14 *Demahy*, 593 F.3d at 449.

15 *Mensing*, at *18.

16 29 F.3d 165 (4th Cir. 1994).

17 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008).

Such a result-oriented solution would not answer additional questions about what happens when the brand-name drug manufacturers have left the market. Are injured consumers really left without a remedy under such circumstances, as the dissent suggests?[18] Although not addressing this question directly, the majority seems to suggest that this may be the "unfortunate result" of federal drug regulation. Some have argued that this situation is likely rare in that such drugs would have a long track record and well-established labeling.[19] There have been, however, numerous cases in which the adequacy, specificity and prominence of warnings have been the subject of suits initiated many years post-approval. Any legislative or regulatory attempt to "remedy" perceived inequities created by *Mensing* would need to consider these variables.

18 *Mensing*, at *20 (Sotomayor, J. dissenting).

19 *Id.* at *19 n.9.

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