

Do Federal Drug Labeling Requirements Preempt State-Law Failure-to-Warn Claims Against the Manufacturer of a Generic Drug Whose Warnings Were the Same as Those the FDA Approved for the Generic's Brand-Name Equivalent?

CASE AT A GLANCE

Gladys Mensing and Julie Demahy were both injured after consuming a generic drug, as prescribed, beyond the safe period of use. They filed state court claims against the manufacturers for failure to warn of the dangers associated with long-term use of the drug. The manufacturers argue that they complied with federal labeling requirements under the Food, Drug, and Cosmetic Act (FDCA), and that the FDCA preempts such state court claims.

PLIVA, Inc., et al. v. Mensing
Actavis Elizabeth v. Mensing
Actavis, Inc. v. Demahy

Docket Nos. 09-993, 09-1039, and 09-1501

Argument Date: March 30, 2011
From: The Fifth and Eighth Circuits

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INTRODUCTION

The Supreme Court ruled in 2009 that warning requirements in the Federal Food, Drug, and Cosmetic Act (FDCA) did not preempt state-law failure-to-warn claims against *brand-name* prescription drug manufacturers. But this ruling does not obviously also apply to failure-to-warn claims against *generic* manufacturers. After all, under the FDCA, generics have less control over the content of their labels and therefore less ability to comply with more robust state labeling standards, set through state tort claims. With this difference in mind, this case tests whether the 2009 ruling extends to *generic* drug manufacturers and thus whether federal labeling requirements do not preempt state failure-to-warn claims against generic manufacturers.

ISSUE

Do federal drug labeling requirements, which require generic drugs to issue the same warning as their brand-name equivalents, preempt state failure-to-warn claims against the manufacturer of a generic drug whose warnings meet this federal requirement?

FACTS

In March 2001, Gladys Mensing's doctor prescribed Reglan to treat her diabetic gastroparesis. Ms. Mensing's pharmacist filled her prescription with the generic equivalent, metoclopramide. Ms. Mensing took metoclopramide, as prescribed, for four years and, as a result of her long-term use, developed tardive dyskinesia, a severe and irreversible neurological disorder.

In 2002, Julie Demahy's doctor prescribed Reglan to treat her gastroesophageal reflux disorder. Like Ms. Mensing's pharmacist, Ms. Demahy's pharmacist filled her prescription with metoclopramide. Ms. Demahy took the drug for four years and, like Ms. Mensing, also developed tardive dyskinesia.

Ms. Mensing and Ms. Demahy both sued the manufacturers of the metoclopramide they took, asserting state-law products liability claims for failure to warn. They alleged that the manufacturers provided inadequate warnings about the risks of long-term use of metoclopramide—that mounting evidence suggested that long-term use carried a risk of tardive dyskinesia far greater than indicated on the label and that no metoclopramide manufacturer moved to change the label. They also alleged that the manufacturers knew that doctors prescribed Reglan for long-term use and that despite the mounting evidence, the manufacturers even promoted metoclopramide for long-term use. Ms. Mensing and Ms. Demahy claimed that the inadequate labels thus caused their injuries.

In fact, the labels reflected only minimal risk of tardive dyskinesia (about 1 in 500) and did not change between 1985 and 2009. But in 2009, the Food and Drug Administration (FDA), acting on its own, ordered manufacturers of Reglan and metoclopramide to add a "Boxed Warning" to their labels reflecting the increased risk of tardive dyskinesia from long-term metoclopramide use.

The manufacturers moved to dismiss the cases, arguing that federal law—in particularly, the Hatch-Waxman Amendments to the FDCA—preempted the state failure-to-warn claims. The district courts granted the manufacturers’ motions to dismiss, at least in part. But the Fifth Circuit (in Demahy’s case) and the Eighth Circuit (in Mensing’s case) both reversed, ruling that federal law did not preempt Demahy’s and Mensing’s state failure-to-warn claims. The Supreme Court consolidated the cases (three in all—two involving Mensing, and one involving Demahy) and agreed to hear them.

CASE ANALYSIS

Under the Supremacy Clause in Article VI of the U.S. Constitution, federal law can preempt state law in one of three ways. First, federal law can expressly preempt state law through the plain language of the federal act. Second, federal law can “occupy the field” in a particular area, thus leaving no room for state regulation. Finally, federal law will preempt state law when a state law conflicts with the federal law—when compliance with both state and federal law is impossible, or when state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363 (2000).

Against this backdrop, the Supreme Court ruled in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), that the FDCA did not preempt state failure-to-warn claims against *brand-name* prescription drug manufacturers. The Court ruled that state-law suits posed no obstacle to federal objectives under the FDCA and that Congress did not enact an express preemption provision at any point during the FDCA’s 70-year history, despite its awareness of the prevalence of state tort litigation.

This case tests whether *Levine* extends to generic prescription drug manufacturers such that the FDCA does not preempt state failure-to-warn claims against generic prescription drug manufacturers. The parties’ arguments center around the differences and similarities between generic and brand-name drugs within the FDCA regulatory scheme.

The petitioners, the generic prescription drug manufacturers, claim that in a situation such as this, they stand in a position that is substantially different from brand-name prescription drug manufacturers, and as such *Levine* should not extend to them. The petitioners proffer two principal arguments to distinguish themselves from brand-name manufacturers.

First, the petitioners argue that generic manufacturers, unlike brand-name manufacturers, cannot unilaterally add safety information to their labels. They contend that the Hatch-Waxman Amendments, which establish an abbreviated new drug application procedure (ANDA) for generics, requires that generic drugs display the same label as their brand-name equivalents, and FDA regulations prohibit generic manufacturers from adding a warning to their labels if that warning would make a label different than the counterpart name-brand label.

Second, the petitioners argue that generic manufacturers, unlike brand-name manufacturers, cannot issue letters to health-care professions who prescribe their drugs with supplemental information and warnings about their products. The petitioners contend that such a “Dear Health-Care Professional” letter would run afoul of the FDCA

and FDA regulations that treat such letters as changes to the labels—actions that generics, as described above, cannot take.

In short, the petitioners argue that because generics are beholden to their brand-name counterparts to set and alter their federal labeling standards, generics are fundamentally different from brand-names for purposes of federal labeling requirements and state failure-to-warn claims: brand-names can move to alter federal labeling requirements, while generics cannot. Thus holding brand-names to a higher standard through state failure-to-warn claims, as in *Levine*, is fully consistent with the FDA; but holding generics to a higher state standard forces them to do something beyond their power—change their labels. Because generics are different from brand-names, they argue, *Levine* is distinguishable, and the FDCA should preempt.

Amici Morton Grove Pharmaceuticals, Inc., and Impax Laboratories, Inc., refine these arguments and add an important new one: even the more modest claim that the generic manufacturers should have merely taken steps to alert the FDA of the need for a label change (even if they had no power to change their labels on their own) is preempted. Amici argue that this “taking steps” claim violates the Court’s holding in *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001) (holding that a similar abbreviated review process for medical devices preempted state claims based upon the manufacturer’s alleged fraudulent misrepresentations to the FDA), and the federal plenary authority to enforce the FDA and decide when labels should be changed. Moreover, amici argue that state failure-to-warn claims would burden the very generic manufacturers that Congress sought to exempt from certain safety and efficacy mandates applicable to brand-names, thus thwarting the federal scheme. Finally, amici argue that state failure-to-warn claims would impose substantial costs on, and create new problems for, the FDA.

Respondents Mensing and Demahy respond with four principal arguments. First, the respondents argue that Congress did not intend to preempt state-law tort claims against generic manufacturers. They note that Congress was silent on the issue over the 70-year history of the FDA, and that Congress did not include an express preemption provision with the Hatch-Waxman Amendments. Moreover, they contend that preemption of state-law tort claims, coupled with the absence of any federal remedy, would leave injured parties like Mensing and Demahy without a judicial remedy. They claim that this is particularly arbitrary when parties injured by a brand-name drug have state-law tort remedies available under *Levine*.

Second, the respondents argue that the generic manufacturers have not shown that they cannot simultaneously comply with both federal law and state law (as set by the state-law tort cases). They point out that the manufacturers could have asked the FDA to change their labels or to issue a “Dear Health-Care Provider” letter. They also identify several regulatory actions that the manufacturers might have taken to seek approval for a revised label or to notify health-care providers of the risks. (The respondents note that the parties, the courts, and the government disagree about which of these procedures the manufacturers could have used, but they maintain that four distinct procedures were available: (1) the PAS process, in which a generic drug company submits an application to the FDA for a change to an approved new drug application (NDA) or ANDA; (2) the CBE process, in which a generic drug company may petition for increased label warnings; (3) the citizen petition process, in which any “person” may

petition the FDA to take any “form of administrative action” under FDA regulations; and (4) the “Dear Health-Care Provider” letter, which, according to respondents, a generic drug manufacturer could send, notwithstanding the petitioners’ arguments to the contrary.) Finally, they argue that the generic manufacturers failed to show that the FDA would have rejected stronger warnings—a burden on the defendants (and not the plaintiffs) in a conflict preemption case.

Third, Mensing and Demahy argue that state liability for failure to warn would not obstruct federal objectives. Drawing on *Levine*, they contend that state liability in fact complements federal objectives by providing a judicial remedy for injured parties. And they argue that preemption would actually frustrate federal objectives in promoting drug safety, reducing health-care costs, and promoting confidence in generics: preemption would eliminate any incentive for generics to ensure that labels are accurate; it would shift costs of injuries to individuals and their providers and insurers (and away from generic manufacturers); and it would encourage doctors, pharmacists, and patients to prefer name-brands (because only name-brands could be liable in state court) and thus undermine confidence in generics.

Finally, Mensing and Demahy argue that their claims are not preempted as “take steps” claims, as the generic manufacturers argue. Mensing and Demahy contend that what the amici call “take steps” claims are in reality traditional products liability claims under applicable state law. They argue that amici overread and stretch the Court’s precedent to support their position. In particular, they argue that amici overread *Arkansas Louisiana Gas Co. v. Hall*, 453 U.S. 571 (1981) and *Buckman*. As to the former, Mensing and Demahy argue that amici misuse it to support their claim that speculation about how the FDA might have responded to suggestions for increased warnings preempts state-law claims. (In fact, they argue, that case has a very narrow holding related to the filed rate doctrine, and the Court has never cited it outside of that context.) As to the latter, respondents argue that amici misuses it to support their argument that a “take steps” claim is preempted. (In reality, Mensing and Demahy argue, *Buckman* involved a fraud-on-the-agency claim, not a traditional state law cause of action, as here). The respondents conclude with an argument that allowing state-law claims will not deluge the FDA with petitions for new warnings. They claim that defendants made that same argument in *Levine*, and the Court implicitly rejected it there.

SIGNIFICANCE

This case has an obvious and immediate significance to Mensing, Demahy, and others who have won state-law tort judgments against generic manufacturers for failure to warn, and to PLIVA, Actavis, and other generic manufacturers now subject to state suits. It has a more mediate significance for potential generic drug consumers and other generic manufacturers not now subject to state suits.

In particular, a ruling against preemption would give injured plaintiffs a judicial remedy through the state courts and subject generic manufacturers to potentially greater liability. Such a ruling would also likely encourage generic manufacturers to more aggressively seek label changes (one way or another) in order to help avoid or mitigate state-law judgments. On the other hand, a ruling in favor of preemption would leave injured plaintiffs without a judicial remedy (unless Congress acted to create or to authorize one) and allow generic

manufacturers to avoid liability. As Mensing and Demahy argue, this would likely undermine some of the core purposes of the FDA and of the Hatch-Waxman Amendments. It would also mean that plaintiffs injured by brand-names would have a judicial remedy, while plaintiffs injured by generics would not. Even if this different treatment would make sense under the FDA and the Hatch-Waxman Amendments, it probably would seem for most prescription drug consumers a rather arbitrary result.

There is perhaps one interesting twist in the case. When the generic manufacturers sought review at the Supreme Court, the Court asked for the views of the U.S. government. The government recommended that the Court decline to hear the case: it argued that the Fifth and Eighth Circuits correctly ruled against preemption and that there was no circuit split on the issue. The Court’s rejection of the government’s recommendation alone says nothing about the likely ruling on the merits. But it does suggest that this is a case that the Court really wants to hear.

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PREVIEW of United States Supreme Court Cases, pages 272–275.
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