

**DRUG & DEVICE
BULLETIN**



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**FAILURE-TO-WARN CLAIMS AGAINST GENERIC
DRUG MAKERS PREEMPTED**

Yesterday, the U.S. Supreme Court shut the door on failure-to-warn claims filed against generic drug manufacturers. *PLIVA, Inc. v. Mensing*, 564 U.S. ____ (2011). In a 5-4 opinion authored by Justice Clarence Thomas, the Court held that “federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus pre-empt ... state-law claims” for failure to provide adequate warnings.

Plaintiffs Mensing and Demahy alleged in separate cases that their use of a generic version of Reglan® caused tardive dyskinesia (a neurological movement disorder). The courts of appeals for the Fifth and Eighth Circuits rejected the generic drug manufacturers’ argument that Mensing and Demahy’s claims were preempted. Their cases were consolidated on appeal to the U.S. Supreme Court.

According to the Court, Minnesota and Louisiana law (the state laws applicable to the *Mensing* and *Demahy* claims) require a drug manufacturer that is or should be aware of its product’s danger to label that product in a way which renders it reasonably safe. Mensing and Demahy alleged that the manufacturers knew or should have known about the high risk of tardive dyskinesia associated with the product’s use. The parties did not dispute that, if those allegations were true, state law required the manufacturers to use a different, safer label. That requirement, the Court determined, conflicted with the manufacturers’ duties under federal labeling requirements.

The Court found, at the outset, that that brand-name and generic drug manufacturers have different duties under federal labeling laws. In holding that federal law preempts failure to warn claims in generic drug cases, the Court relied heavily on the Food and Drug Administration’s (FDA’s) *amicus* brief, focusing on what it called the “federal duty of ‘sameness’”—“the warning labels of a brand-name drug and its generic copy must always be the same.”

To get around the “sameness” requirement, Mensing and Demahy argued that FDA’s changes-being-effected (CBE) process allowed generic drug manufacturers to unilaterally change their labels. FDA interpreted the CBE regulation to allow changes to generic drug labels only to match an updated brand-name label or follow FDA



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instructions. Thus, unilateral CBE changes by a generic drug manufacturer would violate the regulations requiring “sameness.” Because it was not plainly erroneous or inconsistent with the regulations, the Court found that FDA’s interpretation of its regulations controlled.

Mensing and Demahy next argued that generic drug manufacturers could issue “Dear Doctor” letters to warn health-care professionals. FDA, however, interpreted “Dear Doctor” letters as “labeling” subject to the “sameness” requirement. The Court agreed, ruling that a “Dear Doctor” letter that contained substantial new warning information would not be consistent with the drug’s approved labeling” and “would inaccurately imply a therapeutic difference between the brand and generic drugs ...”

FDA did not interpret its regulations to completely eliminate a generic manufacturer’s duty to ensure that its labeling is accurate. According to FDA, generic drug manufacturers are required to propose stronger warning labels if the manufacturers believe such warnings are necessary. Because the Court found preemption even assuming such a duty, it did not attempt to resolve this issue.

The Court determined that state and federal law conflicted here because generic drug manufacturers could not comply with both state and federal requirements. The manufacturers could not satisfy their state-law duty by unilaterally changing their label or issuing “Dear Doctor” letters without violating federal law. Although the manufacturers could have complied with federal law by requesting FDA assistance to change the label, such a request would not have satisfied their state-law duty to provide adequate warnings. “State law demanded a safer label; it did not instruct the Manufacturers to communicate with the FDA about the possibility of a safer label.”

The Court rejected Mensing and Demahy’s contention that generic drug manufacturers must actually seek FDA’s assistance to change the label to satisfy their federal affirmative defense of preemption, stating that “[t]he question for ‘impossibility’ is whether the private party could independently do under federal law what state law requires of it.” According to the Court, accepting Mensing and Demahy’s argument would render conflict preemption meaningless. That argument hinged on generic drug manufacturers seeking FDA’s assistance and the possibility that FDA would work with the brand-name manufacturer to change the label. The Court held that “when a party cannot satisfy its state duties without the Federal Government’s special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for preemption purposes.” Because state law imposed a duty on the manufacturers to take an action that federal law banned—altering their label—Mensing and Demahy’s claims were preempted.

The Court distinguished *Wyeth v Levine* on the basis that a brand-name manufacturer can take unilateral action to change its label under the CBE provision, while a

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generic drug manufacturer cannot. Thus, the direct conflict between federal and state law for generic drug labeling found in *Mensing* does not exist for brand-name manufacturers under *Wyeth*.

Though the Court's holding is not expressly limited to any time frame, a footnote states that the relevant events in the *Mensing* and *Demahy* cases predate the FDA Administration Amendments Act of 2007 (FDAAA), 121 Stat. 823. The Court declined to express an opinion on the FDAAA's effect, relying exclusively on pre-FDAAA statutes. We will follow up with an analysis regarding the potential impact of *Mensing* on post-FDAAA cases. ■