In 2011, in *PLIVA, Inc. v. Mensing* the Supreme Court held that the Federal Food, Drug and Cosmetic Act preempts failure to warn claims regarding a generic medication. The Court reiterated that similar claims would not have been preempted if they had been asserted against a name-brand manufacturer, but based its ruling on differences in the statutory schemes. The critical distinction is that, for name-brand drugs, the manufacturer has the unilateral right to strengthen a medication’s warning label. Advance approval by the FDA is not required, although the FDA can rescind the manufacturer’s change. By contrast, the statute requires a generic drug to have the same label as the name-brand medication. The manufacturer of a generic drug has no ability to change the label, but can only ask the FDA to work with the name-brand manufacturer to change the name-brand label.

The Court concluded that these federal restrictions made it impossible for the generic medication manufacturer to comply with the state law tort duty to change its label, and therefore the state law was preempted. The Court did not, however, address whether 2007 amendments to the Federal Food, Drug, and Cosmetic Act would change its analysis. In 2013, the FDA proposed a rule that would effectively overrule *Mensing* by granting both brand and generic manufacturers the ability to improve labeling unilaterally and then seek approval from the FDA. However, in 2018 it withdrew the proposed rule.

In 2013, in *Mutual Pharmaceutical Co. v. Bartlett* the Court held that design defect claims against manufacturers of generic drugs are also preempted, on the theory that the only way the manufacturer could avoid liability would be to strengthen the warning label, which federal law prohibited. The Court rejected the argument that the manufacturer could have chosen to stop manufacturing the product and thus there was no conflict with federal law. However, the Court left open the possibility that a statute that imposed absolute liability without regard to breach of any duties might not be preempted. It also left open the possibility that a generic drug manufacturer might be liable for failing to pull a drug from the market when new information showed that it was dangerous even when used in accord with the label. Like *Mensing*, the case arose before the 2007 statutory amendments.

Lower courts have still found that some claims against manufacturers of generic drugs are not preempted. For example, a claim that a generic manufacturer should have sent letters to doctors reiterating the information on the label may not be preempted. A claim is not preempted if the generic manufacturer failed to conform its label to that approved for the name-brand version. Nor does federal law preempt a failure to update claim—that is, a claim that a generic drug manufacturer did not promptly change its labels to reflect new warnings added by the non-generic manufacturer. Claims based on marketing materials other than the label may also survive. However, the Sixth Circuit has held that express warranty claims are preempted and that an implied warranty claim is at core a design defect claim that is also preempted.

Because the brand-name manufacturer controls the labeling for the generic drug, the question arises whether it can be held responsible for injuries that consumers suffer because of the generic drug’s label. The highest court in Massachusetts held that a consumer who took the generic version of a drug could assert a common law claim of recklessness against a brand-name manufacturer that intentionally failed to update the label, knowing or having reason to know of an unreasonable risk of death or grave bodily injury associated with its use, but could not assert a negligence or UDAP claim.

### Footnotes

255 [238] *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 131 S. Ct. 2567, 180 L. Ed. 2d 580 (2011). *Accord* *Strayhorn v. Wyeth Pharmaceuticals, Inc.*, 737 F.3d 378, 397–398 (6th Cir. 2013) (finding most of plaintiffs’ claims against generic drug manufacturers to be, at core, failure to warn claims and therefore preempted). *See also* *Schrack v. Wyeth, Inc.*, 727 F.3d 1273 (10th Cir. 2013) (applying *Mensing* to hold that warranty claims based on the label are also preempted).


264 [246] Brasley-Thrash v. Teva Pharmaceuticals USA, Inc., 2011 WL 4025734 (S.D. Ala. Sept. 12, 2011). But see In re Darvocet, Darvon, & Propoxyphene Products Liab. Litig., 756 F.3d 917, 932–933 (6th Cir. 2014) (claim that generic manufacturer should have sent letters to doctors is preempted); Strayhorn v. Wyeth Pharmaceuticals, Inc., 737 F.3d 378, 397–398 (6th Cir. 2013) (claim that manufacturer should have sent letters to doctors with additional warnings is preempted).


269 [251] Id. at 935.

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