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The United States Supreme Court ruled in favor of generic drug manufacturers in PLIVA, Inc. v. Mensing, holding that federal drug regulations applicable to generic drug manufacturers bar the plaintiffs' state-law failure to warn claims. The Supreme Court, in a 5-4 decision, held that manufacturers of generic drugs cannot be sued for failure to provide adequate warnings to consumers, so long as they copy the warnings provided by the brand name manufacturer. The ruling means that consumers harmed by prescription drugs sold by generic manufacturers will be left with no remedy whatsoever – they will simply not be permitted to pursue legal claims based on failure to provide adequate warning of a drug's harmful side effects under any circumstances. In a marked departure from prior law, such consumers will have no opportunity to even have the merits of their claims decided by a jury; instead, the courthouse doors will essentially be closed to such victims.

The case involved the drug Metoclopramide, the generic form of the brand name drug Reglan. The drug is used to treat digestive problems, such as gastroesophageal reflux disorder. Medical studies demonstrated that patients taking Reglan/Metoclopramide on a long-term basis were at risk of developing tardive dyskinesia, a severe, often permanent, neurological disorder. That condition resulted in approximately 1 in 4 patients taking the drug on a long-term basis. Despite knowledge of that risk and of the fact that physicians were routinely prescribing Reglan/Metoclopramide for long-term therapy, the warning label, for many years, simply stated that "therapy longer than 12 weeks has not been evaluated and cannot be recommended." The warning was eventually strengthened. In 2004, the label was changed to add that "therapy should not exceed 12 weeks in duration." In 2009, the FDA ordered a "black box" warning stating: "Treatment with Metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. Treatment with Metoclopramide for longer than 12 weeks should be avoided in all but rare cases."

The plaintiffs were two women who separately sued the manufacturers of Metoclopramide after developing tardive dyskinesia following long-term use of the drug. The plaintiffs asserted that the manufacturers knew or should have known of the high risk of tardive dyskinesia associated with long-term use of the drug and that the manufacturers violated state law in failing to provide adequate warning of that side effect. Two Circuit Courts of Appeal, the Fifth Circuit and the Eighth Circuit, held that the plaintiffs' lawsuits could continue. However, the U.S. Supreme Court,

reversed the Circuit Courts and held that the plaintiffs' state-law failure to warn claims were preempted - barred - by federal law.

The Supreme Court held that there was no way a generic drug manufacturer could comply with FDA regulations requiring that labeling for a generic drug be the same as its brand name counterpart on the one hand and also with state-law requirements that a manufacturer provide adequate warning regarding dangerous side effects with a drug. Since the Supreme Court perceived a conflict in meeting those duties, the Court held that the federal interest trumps the state requirement. The end result is that consumers taking generic drugs, as happens about 75 percent of the time when a prescription is filled at a pharmacy, will be unable to pursue any claim based upon inadequate warnings. A patient who suffered the same injury but who was given the brand name version of the drug instead could still sue. In that respect, the opinion makes little sense – a consumer's ability to pursue a claim is subject to mere happenstance, depending upon whether the pharmacist decided to dispense the generic or brand name form of a medication. Justice Sotomayor wrote a powerful dissent, in which Justices Ginsburg, Breyer, and Kagan joined. The dissent noted the absurdity of the Court's ruling and would have required more of a generic manufacturer claiming that it could not comply with both FDA regulations and obligations under state law to provide adequate warning of drug side effects to customers. The ruling confers blanket immunity on manufacturers of generic prescription drugs and eliminates any economic incentive they would otherwise have to ensure that their drug labeling is clear or accurate.
