No state lawsuits on generic drugs: US Supreme Court

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The US Supreme Court narrowly ruled on Thursday that people may not sue generic drug makers under state laws if they believe a generic drug label failed to adequately warn of side effects.

The 5-4 ruling handed a victory to drug makers Teva Pharmaceutical Industries Ltd of Israel, the US company Mylan Inc and Actavis Inc of Iceland by blocking three consolidated lawsuits against them.

Plaintiffs had argued that they suffered a neurological disorder called tardive dyskinesia after taking the generic anti-heartburn drug metoclopramide (Reglan, Metozolv), which they said did not contain adequate warning labels.

The plaintiffs were prescribed the generic drug for Reglan in 2001 and 2002.

As early as 1985, evidence began to surface that long-term use of the drug could have serious side effects, but strong warnings were not added to the brand name drug labels by federal regulators until 2004 and 2009.

In 2009, the Food and Drug Administration ordered its strongest black box label warning that "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."

Even though the plaintiffs were prescribed the generic drugs before the stronger labels were federally ordered, they argued that the state should have done more to protect them by changing the generic drug labels because there was evidence to suggest long-term use could be harmful.

They sued the generic manufacturers under state tort laws that said the companies should have taken steps to protect consumers.

However the US high court said that federal laws require generic drugs to have the same labels as the brand names they copy, so courts could not demand they meet a different state standard at the same time.

"State tort law places a duty directly on all drug manufacturers to adequately and safely label their products," said the decision read by Justice Clarence Thomas.

"If the manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law.

"Thus, it was impossible for the manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same."

The four liberal justices -- Sonia Sotomayor, Ruth Bader Ginsburg, Elena Kagan and Stephen Breyer -- dissented.

"As a result of today's decision, whether a consumer harmed by inadequate warnings can obtain relief turns solely on the happenstance of whether her pharmacist filled her prescription with a brand-name or generic drug," said Sotomayor.

The decision affects 75 percent of all prescription drugs dispensed in the United States, the court said. When a generic is available to substitute

for a brand name drug, the generic version is given out 90 percent of the time.

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