Leahy To Introduce Bill To Protect Consumers Who Take Generic Drugs

Bill To Address Supreme Court Decision In Pliva v. Mensing

WASHINGTON (Monday, March 26, 2012) – Senator Patrick Leahy (D-Vt.) will introduce legislation as early as this week to reverse a recent Supreme Court decision that threatens the safety of consumers taking generic drugs.

In a narrow, 5-4 decision in 2011, the Supreme Court held that state law tort claims against generic manufacturers are preempted by federal law, which requires generic drug manufacturers to use the same label as a brand name drug, even when the generic pharmaceutical company knows that the warning on the label is inadequate. Just three years ago, the Supreme Court held that a patient can sue a brand-name drug manufacturer for failing to warn because the brand name is permitted by law to update its warning. The plaintiff in that case was Vermont musician Diana Levine, who sustained life-altering injuries due to a drug manufactured by the pharmaceutical company Wyeth.

"The *Mensing* decision creates a troubling inconsistency in the law with respect to prescription drugs," said Leahy. "If a consumer takes the brand-name version of drug, she can sue the manufacturer for inadequate warnings. If the pharmacy happens to give her the generic version, she will not be compensated for her injuries. The result is a two-track system that penalizes consumers of generic drugs—even though many consumers have no control over which drug they take, because state law and their health insurance plan require them to take generics if they are available. I will introduce legislation to address this contradiction so that consumers are fully protected from harm and receive adequate warnings."

Leahy has been working to craft legislation that permits generic manufacturers to improve the warning information for their products in the same way as brand manufacturers, providing adequate warnings to consumers. Over 75 percent of all prescriptions are filled by generic drugs.

A number of public interest groups opposed the Court's decision in *Mensing*, and have urged Congress and the Food and Drug Administration to address the issue. This weekend, a *New York Times* editorial (http://www.nytimes.com/2012/03/24/opinion/a-bizarre-outcome-on-generic-drugs.html?_r=1&partner=rssnyt&emc=rss) called on Congress to enact legislation to address the outcome in *Mensing*.

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