

Bills were recently introduced in the Senate and the House of Representatives that would allow generic drug companies to update warning information about the drugs they manufacture and sell. The bills would also clear the way for consumers harmed by generic drugs to bring failure to warn claims against generic manufacturers. The bills are in response to a U.S. Supreme Court decision from last year, Pliva v. Mensing, which barred patients from suing generic drug companies because the generic manufacturers purportedly did not have control over the content of their drug labels which the generic manufacturers simply copy from the brand name manufacturers.

Since the Supreme Court's decision, numerous cases have been tossed out of court even though the claims were asserted by patients who suffered the same injuries as those who took the brand-name versions of the drugs. Often, a patient has no control over whether his or her prescription will be filled with the brand name drug or with the generic version. Under the Supreme Court's Pliva decision, the whim of a pharmacist in filling a prescription with either a brand name drug or the generic counterpart can dictate whether an injured person may pursue legal claims. Many have criticized the Supreme Court's decision as unfair to consumers.

The consumer advocacy group Public Citizen asked the Food and Drug Administration to take action similar to that sought with the legislation, but the FDA reported it needed more time to study the issue. The changes proposed with the recent bills and through FDA action seek to impose an obligation on generic drug manufacturers, as well as brand name manufacturers, to ensure that drug labels are complete and accurately warn of known side effects.

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