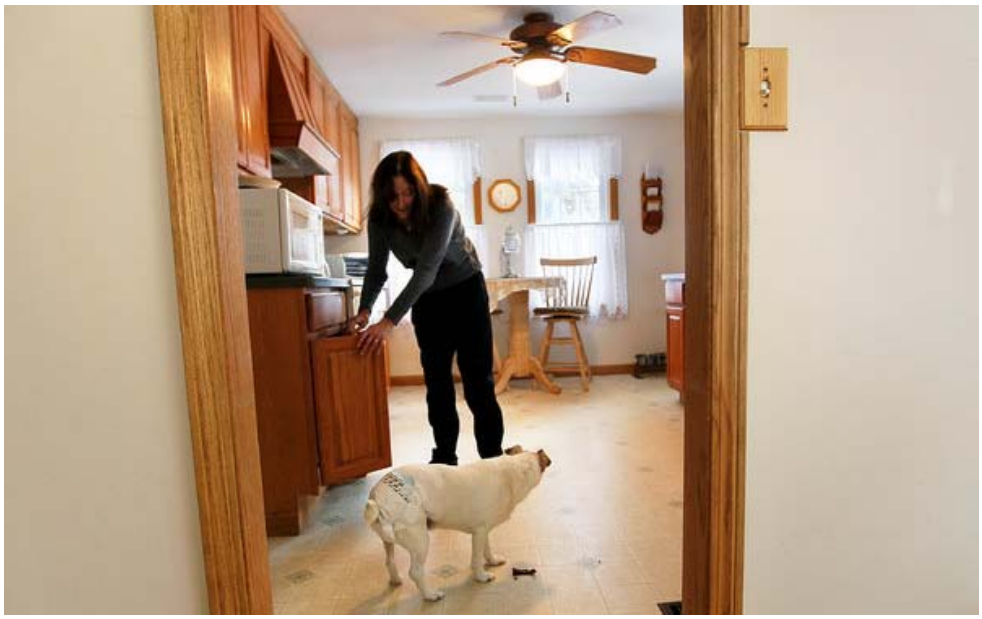
In 5-4 Ruling, Justices Say Generic Makers Are Not Liable for Design of Drugs



Cheryl Senter for The New York Times

Karen Bartlett with her dog, Molly, in Plaistow, N.H. Ms. Bartlett developed a debilitating skin disease after taking a generic version of the pain medication sulindac.

By KATIE THOMAS
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The Supreme Court ruled on Monday that generic drug manufacturers could not be sued by patients who claim that drugs they took were defectively designed. The decision is a significant victory for the generic drug industry, but further narrows the recourse for people who are injured by such drugs.

The 5-to-4 decision overturned the verdict of a New Hampshire jury, which in 2010 awarded $21 million to a woman who developed a debilitating skin disease after taking a generic version of the pain medication sulindac.

The court found that because the drug's manufacturer, the Mutual Pharmaceutical Company, was required by federal law to make a copy of the brand-name drug, Clinoril, it could not be held responsible for claims that the drug was

unsafe.

Writing for the majority, Justice Samuel A. Alito Jr. acknowledged the horrific injuries sustained by Karen Bartlett, who lost nearly two-thirds of her skin, was placed in a medically induced coma and is legally blind after suffering a reaction to the medication she took for a sore shoulder.

"But sympathy for respondent does not relieve us of the responsibility of following the law," Justice Alito wrote.

The ruling is similar to a decision by the court in 2011, in Pliva v. Mensing, which found that generic drug makers could not be held liable for failing to warn about a drug's dangers because they must use the same safety label as the brand-name version. Monday's decision further limits the legal avenues for people who take generic drugs, which now account for more than 80 percent of all prescriptions.

"Now, presumably, a patient harmed by those drugs has no remedy, either through a defective warning or a defective design argument," said Bill Curtis, a Houston lawyer who specializes in pharmaceutical cases.

Generic drug manufacturers hailed the decision, arguing that the decisions of state courts should not supplant the authority of the Food and Drug Administration, which approves the brand-name drugs and the generic copies.

"It makes much more sense to rely on the judgments of the scientific and medical experts at the F.D.A, who look at drug issues for the nation at large, than those of a single state court jury that only has in front of it the terribly unfortunate circumstances of an adverse drug reaction," said Jay P. Lefkowitz, who represented Mutual before the Supreme Court and also argued on behalf of generic companies in the Pliva v. Mensing case.

Mutual is a subsidiary of Sun Pharmaceutical Industries of India.

In a dissenting opinion, Justice Sonia Sotomayor said a decision by the F.D.A. to approve a drug should not absolve a company of its responsibility to sell a safe product.

"Manufacturers regularly take drugs off the market when evidence emerges about a drug's risks, particularly when safer drugs that provide the same therapeutic benefits are available," she wrote in her dissent, which was joined by Justice Ruth Bader Ginsburg. Justice Stephen G. Breyer wrote a separate dissent, which was joined by Justice Elena Kagan.

Some have called on Congress and the F.D.A. to make generic drug companies more accountable by permitting them to change their warning labels when they become aware of a safety risk. Brand-name companies can already do so. Such a change would, presumably, allow the generic manufacturers to be sued again.

Generic drug makers now have a responsibility to mirror the safety label of the brand-name company and to alert the F.D.A. whenever they learn of an adverse event related to their products. It is then up to the agency to decide whether to change the label.

Critics have said the current system works too slowly, and does not

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account for situations when problems arise with a drug after the brand-name manufacturer has left the market.

The consumer advocacy group Public Citizen released a report Monday that found 11 instances over the last five years in which serious safety warnings were added to the labels of drugs for which there were no longer any brand-name versions on the market.

This situation "poses a threat to the safety of prescription drugs, creating unnecessary risks to patients," Dr. Michael Carome, director of the Health Research Group at Public Citizen, said in a statement Monday.

Sandy Walsh, a spokeswoman for the F.D.A., said the agency was considering permitting generic companies to change warning labels on their drugs, but said it would be premature to discuss specifics.

Generic drug companies have argued that such a change could create a chaotic situation, with the potential for the same drug to bear different warning labels depending on the manufacturer. "That would be terribly confusing, and, I think, harmful for public health," Mr. Lefkowitz said.

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