

Erwin Chemerinsky: Beware before taking generic drugs

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2013-07-24 13:53:00



Without headlines or even much media attention, the Supreme Court has made it almost impossible to sue the makers of generic drugs, no matter how seriously a person has been injured.

According to the Food and Drug Administration, almost 80 percent of all prescriptions in the United States are filled with generic drugs; this rises to over 90 percent when there is a generic equivalent to the brand name drug. Congress needs to act immediately to protect all of us if we are injured from the side effects of a generic drug.

On June 24, 2013, in *Mutual Pharmaceuticals v. Bartlett*, the Court held that makers of generic drugs cannot be sued for defects in their design. Karen Bartlett took a generic form of the prescription pain reliever, Sulindac. She then experienced a horrific side effect, called toxic epidermal necrolysis. Sixty to sixty-five percent of the surface of her skin deteriorated, was burned off, or turned into an open wound. She spent months in a medically induced coma, underwent 12 eye surgeries and was tube-fed for a year. She is now severely disfigured with a number of physical disabilities, including being nearly blind.

She sued the maker of the generic drug, Mutual Pharmaceuticals, saying that there was a defect in the design of the drug. The jury ruled in her favor and awarded her \$21 million.

But the Supreme Court in a 5-4 decision reversed this award and held that federal law precludes such liability for makers of generic drugs. Justice Samuel Alito wrote the opinion for the Court, joined by his most conservative colleagues.

The Supreme Court said that under federal law a generic drug can be sold if it is chemically the same as the brand name version and if it has the warning label approved for the brand name drug. The Court said that this means that makers of generic drugs cannot change the chemical composition of the drug and therefore cannot be sued for defects in its design.

The Court said that the only alternative for the drug company would be to change the warning label to strengthen the warning to patients about possible side effects. But two years ago, again without headlines, the Supreme Court in *Pliva v. Mensing* held that makers of generic drugs cannot be sued on a claim that they inadequately warned consumers.

That case involved a prescription drug Reglan which is prescribed to help with digestive problems suffered by some with diabetes. A significant percentage of prolonged users of Reglan, about 30 percent, will suffer horrible, irreversible neurological side effects. Two women who took the generic form of the drug and suffered the side effects sued the manufacturer for failing to adequately warn patients.

The Supreme Court, again 5-4 with the conservative justices in the majority, said that makers of generic drugs cannot be sued for failing to adequately warn patients of side effects.

The irony is that two years earlier, the Supreme Court had ruled that makers of brand name drugs can be sued for failing to adequately warn consumers, even if their warning label had been approved by the FDA. The result is that for the identical drug, the same chemical compound, a person injured by a brand name drug can sue, but a person injured by the general equivalent cannot sue.

The dissenting justices in *Mutual Pharmaceuticals v. Bartlett* lamented the Supreme Court's closing the door on those seriously injured. They objected that the majority saw only two alternatives: change the drug or change the warning label. The dissent said that there are other options: cease selling the product or decide to pay the penalty for doing so.

All of us take generic drugs and any of us might be injured by them. If so, we are out of luck to get compensation for our injuries. Congress can remedy this by revising these statutes to make clear that makers of generic drugs can be sued, just as makers of brand name drugs, for claims based on failure to warn of design defects

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