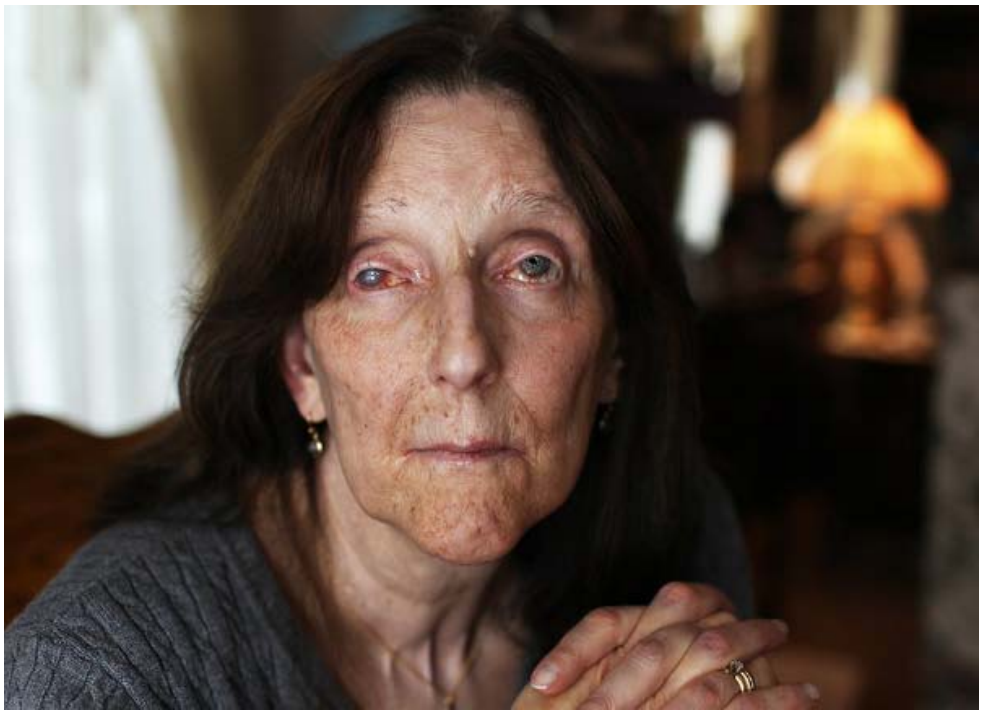
Justices to Take Up Case on Generic Drug Makers' Liability



Cheryl Senter for The New York Times

A reaction to the anti-inflammatory drug sulindac rendered Karen Bartlett legally blind.

By KATIE THOMAS
Published: March 4, 2013

The injuries that Karen Bartlett suffered after taking a mild pain pill are enough to make anyone squeamish.

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Cheryl Senter for The New York Times

Ms. Bartlett contends the maker of the drug she took should be liable for her injuries. The drug maker says it was not responsible for the design of the medication.

Ms. Bartlett, who lives in Plaistow, N.H., developed a rare but severe reaction to the anti-inflammatory drug sulindac after a doctor prescribed it to treat shoulder pain in 2004. Within weeks of taking the drug, her skin began to slough off until nearly two-thirds of it was gone.

She spent almost two months in a burn unit, and months more in a medically induced coma. The reaction permanently damaged her lungs and esophagus and rendered her legally blind.

Ms. Bartlett sued Mutual Pharmaceutical Company, which made the drug she took, a generic pill, arguing that the drug's design was dangerous and defective. During her trial in 2010 in Federal District Court in Concord, N.H., her burn surgeon described her experience as "hell on earth," and a jury awarded her $21 million. An appeals court upheld the verdict.

"I wouldn't want anybody to go through what I went through," Ms. Bartlett said in a recent interview. "It was horrible. And this medication that I took, sulindac, I don't think it should be prescribed."

Now, in a case that is being closely watched by pharmaceutical companies, federal regulators and others, the Supreme Court will hear arguments this month on whether Mutual can be held responsible for Ms. Bartlett's injuries. The outcome is likely to further clarify the legal recourse for patients who take generic drugs, which now account for 80 percent of all prescriptions in the United States.

Two years ago, the Supreme Court severely limited the conditions under which consumers of generic drugs could sue the manufacturers, ruling in Pliva v. Mensing that such companies did not have control over what warning labels said and therefore could not be sued for not alerting patients to the risks of taking their drugs.

Ms. Bartlett's case is slightly different because she did not argue that the drug's warning label was inadequate. She claimed that the drug itself was defective. But Mutual has contended that the rationale is the same since, like the label, it has no control over the drug's design.

Under federal law, generic companies are not allowed to deviate from the brand-name drug they are copying. Sulindac is the scientific name for Clinoril, a drug similar to ibuprofen that was approved by the Food and Drug Administration in 1978 and is sold by Merck. Like ibuprofen, sulindac is in a class of drugs known as nonsteroidal anti-inflammatory drugs or Nsaids, which are in widespread use.

Mutual is appealing a decision by the United States Court of Appeals for the First Circuit, in Boston, that upheld the jury verdict and argued that even if Mutual could not have changed the drug's design, it had no obligation to continue selling a defective product and could have taken the drug off the market. Mutual is a subsidiary of Sun Pharmaceutical of India.

Interest groups on both sides say any decision could have serious consequences.

If the court agrees with Mutual and rules that generic companies cannot be sued for defective products, trial lawyers warn that patients will be left with very few options if they are injured by a generic drug.

"The question becomes, can you sue a generic manufacturer for anything?" said Bill Curtis, a Dallas lawyer who specializes in pharmaceutical cases.

But manufacturers of generic drugs and other business groups have said that if the court sides with Ms. Bartlett, the decisions of individual juries

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could trump the authority of federal agencies like the Food and Drug Administration and potentially lead drug makers to remove valuable medicines from the market. The federal government has sided with the generic drug makers in this case even though it opposed the industry in the Mensing case.

"Tort judgments second-guessing F.D.A.'s expert drug safety determination would undermine the federal regime to the extent that they forbade or significantly restricted the marketing of an F.D.A.-approved drug," the government wrote in its brief to the court.

Keith M. Jensen, Ms. Bartlett's lawyer, disputed this argument, saying, "that presumes the F.D.A. always has all the information and that drug companies never have incentive to hide it from them." He said lawsuits like Ms. Bartlett's could uncover new information about the safety of a drug.

In the case of sulindac, he presented evidence at trial that patients taking the drug were more at risk of developing the condition that Ms. Bartlett contracted, known as toxic epidermal necrolysis, a severe form of a related condition called Stevens-Johnson Syndrome, than those taking other, similar pain drugs. The conditions can be set off by a negative reaction to many drugs, but only rarely.

It is difficult to estimate how common the reactions are because some contend they are underreported, but one recent review of medical literature found that fewer than a handful of people out of a million users of Nsaids would be affected.

Like all Nsaids, sulindac carried a notice on its label that patients could develop Stevens-Johnson Syndrome. But in 2005, after Ms. Bartlett's reaction, the F.D.A. recommended that all manufacturers of Nsaids strengthen their labels by specifically listing the risk of developing the skin reactions in the "Warnings" section of the label. That same year, Pfizer removed the pain drug Bextra from the market after the F.D.A. warned that patients were at a heightened risk for developing Stevens-Johnson Syndrome and other skin reactions.

In its brief, the federal government disputed the conclusion that sulindac was unsafe, saying the F.D.A. had reviewed the drug and determined that it could remain on the market.

Ms. Bartlett said that before her injury she was independent, active and loved her job as a secretary at an insurance company. In 2004, she visited her doctor because her shoulder hurt, and he prescribed Clinoril. The pharmacist dispensed a generic version of the drug.

Today, Ms. Bartlett is 53 and legally blind despite 13 eye operations. She said she struggled to reach the mailbox each day and could no longer drive or work. Her lungs are severely damaged, and she has trouble eating.

To her, it makes no difference who made the drug she took. "I think the generic companies as well as brand-name companies, they should be held accountable for the medicines that they put out there," she said.

This article has been revised to reflect the following correction:

Correction: March 7, 2013

An article on Tuesday about a Supreme Court case that weighs the liability of generic drug makers described incorrectly the Food and Drug Administration's efforts in 2005 to strengthen warning labels on nonsteroidal anti-inflammatory drugs (Nsaids). It recommended that manufacturers specifically list the risk of skin reactions; it did not require manufacturers to list that risk, as it had no authority to do so.

A version of this article appeared in print on March 5, 2013, on page B1 of the New York edition with the headline: A Liability Challenge.

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