

Supreme Court Decision to enhance Drug Companies exemption from Lawsuits

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By Laima Jonusiene, MD

Product liability is the area of law in which manufacturers, distributors, suppliers, retailers, and others who make products available to the public are held responsible for the injuries those products cause. In the United States, the claims most commonly associated with product liability are [negligence](#), [strict liability](#), [breach of warranty](#), and various [consumer protection](#) claims. Under strict liability, the manufacturer is liable if the product is defective, even if the manufacturer was not negligent in making that product defective. The man who makes your car, your stairs, or your elevator is liable for damages if you are hurt from any of them. But because the drug companies do not have the money or the technology to make safe products they historically do not have the same kind of liability.



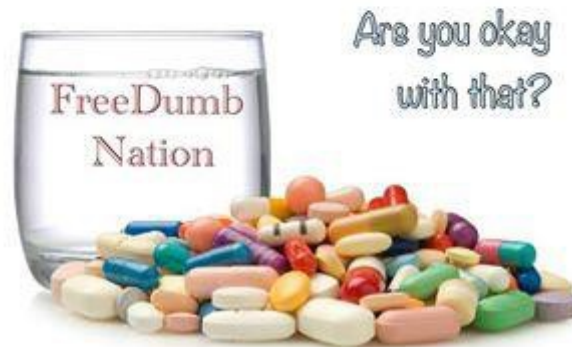
To get damages from the drug companies you must prove premeditated plans to hurt. You must prove they knew it was unsafe and still sold it. Now even that is challenged and now it becomes difficult to make any lawsuit against the drug companies.

The US Supreme Court July 2013 made a ruling on lawsuits against drug companies for fraud, mislabeling, side effects and accidental death. Now, 80 percent of all drugs are exempt from legal liability.



Drug companies did not warn patients that toxic epidermal necrolysis was a side effect.

But the Supreme Court ruled the Drug Company is still not liable for damages.



In a 5-4 vote, the US Supreme Court struck down a lower court's ruling and award for the victim of a pharmaceutical drug's adverse reaction. According to the victim and the state courts, the drug caused a flesh-eating side effect that left the patient permanently disfigured over most of her body. The adverse reaction was concealed by the drug maker and later required to be included on all warning labels. But the highest court in the land, the Supreme Court ruled that victims have no legal basis to sue the corporation because its SYNthetic drugs are exempt from lawsuits.

Karen Bartlett vs. Mutual Synthetic Pharmaceutical Company

In 2004, Karen Bartlett was prescribed the generic anti-inflammatory drug Sulindac, manufactured by Mutual Pharmaceutical, for her sore shoulder. Three weeks after taking the drug, Bartlett began suffering from a disease called, 'toxic epidermal necrolysis'. The disorder is enormously painful and causes the victim's skin to peel off, revealing raw flesh in the same manner as a third degree burn victim.

Karen Bartlett sued Mutual Pharma in New Hampshire state court, arguing that the drug company built-in no warning about the possible side effect. A NH court agreed and awarded her \$21 million. The FDA went on to force both Mutual, as well as the original drug manufacturer Merck & Co., to include the side effect on the two drugs' warning labels for the future.

Nine years later the tragedy began, the US Supreme Court overturned the state court's verdict and award. **Justices cited the fact that all generic drugs and their manufacturers, some 80% of all drugs consumed in the United States, are exempt from liability for side effects, mislabeling or virtually any other negative reactions caused by their drugs. In short, the Court ruled that the FDA**

has ultimate authority over pharmaceuticals in the US. And if the FDA says a drug is safe, that takes precedent over actual facts, real victims and any and all adverse reactions.

The Court ruling

The Court's ruling on behalf of generic drug makers is actually a continuation of a ruling made by the same Court in 2011. At that time, the Justices ruled that the original inventors and manufacturers of pharmaceutical drugs, also known as 'name brand' drugs, are the only ones that can be sued for mislabeling, fraud or adverse drug reactions and side effects. If the generic versions of the drugs are made from the exact same formula and labeled with the exact same warnings as their brand name counterparts, the generics and their manufacturers were not liable.

The Court ruled, "Because it is impossible for Mutual and other similarly situated manufacturers to comply with both state and federal law, New Hampshire's warning-based design-defect cause of action is pre-empted with respect to FDA-approved drugs sold in interstate commerce."

And that ruling flies in the face of both common sense and justice. And as Karen Bartlett can now attest, it leaves 240 million Americans unprotected from the deadly and torturous side effects of pharmaceutical drugs. As a reminder, the number one cause of preventable or accidental death in the US is pharmaceutical drugs.

Public Reaction

Immediately upon the Supreme Court's ruling, both drug manufacturers and Wall Street investors were celebrating. As one financial analyst pointed out, drug company profits should skyrocket going forward. Not only do the pharmaceutical companies no longer have to worry about safety or side effects, they are exempt from the multi-million dollar court-imposed settlements awarded to victims of their drugs.

One industry critic was quoted by [Reuters](#) after the verdict. "Today's court decision provides a disincentive for generic makers of drugs to monitor safety of their products and to make sure that they have a surveillance system in place to detect adverse events that pose a threat to patients," Michael Carome, director of Public Citizen's Health Research Group told the news outlet.

Senate Judiciary Committee Chairman Patrick Leahy (D-VT) was quick to react to the ruling by writing a stern letter to FDA Commissioner Margaret Hamburg, "A consumer should not have her rights foreclosed simply because she takes the generic version of a prescription drug."

But an attorney for the drug companies, Jay P. Lefkowitz, took the opposing position saying, "It makes much more sense to rely on the judgments of the scientific and medical experts at the FDA, 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."

In other words, if the FDA says something is safe, it doesn't matter if that decision is wrong or the result of lies, fraud or deception on the part of the world's pharmaceutical companies. And there's no way to sue the FDA for being wrong and costing millions of unsuspecting Americans their lives. That result leaves 240 million Americans unprotected from an industry responsible for more preventable deaths in the US than any other cause.

Every drug that has been recalled by the FDA...



was first proven to be "safe and effective" by the FDA



And Yet over 20,000 drugs have been removed from the market for hurting and killing people

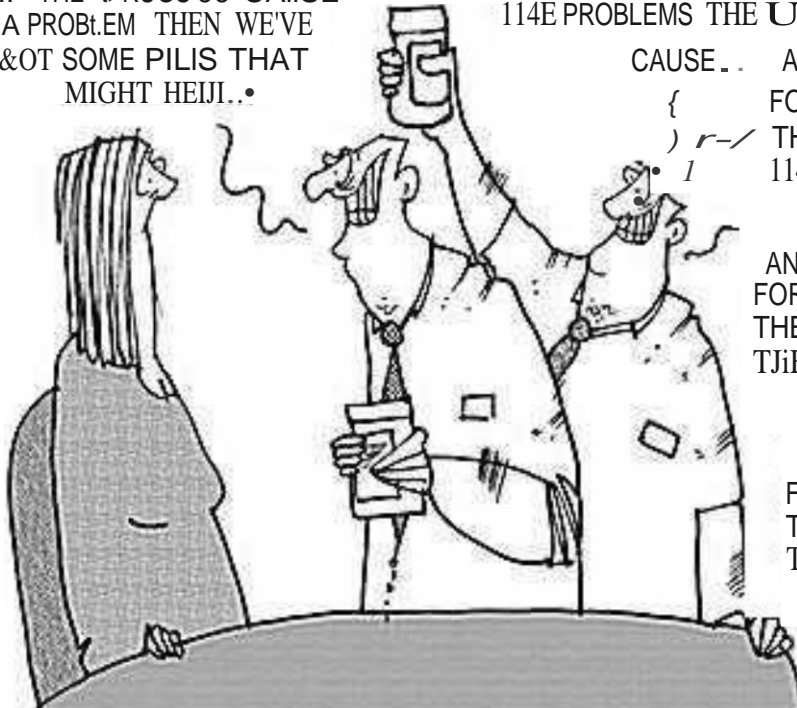


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