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COMMENTARY

McGarity: The danger in defective medical devices

Thomas O. McGarity, UNIVERSITY OF TEXAS [Click-2-Listen](#)

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Today, the Supreme Court is hearing an obscure case with huge implications for the safety and economic well-being of the millions of Americans who depend on prescription drugs and medical devices. If the court agrees with the "buyer beware" approach of the Bush administration and the manufacturer of a balloon catheter that exploded inside Charles Riegel's coronary artery during a routine angioplasty procedure, patients hurt by defectively designed and marketed medical devices will lose their right to sue manufacturers.

The case dates back to a 1976 law enacted in response to the public health disaster caused by the Dalkon Shield intra-uterine birth control device. At the time, the federal government did not regulate medical devices. After lawyers for injured victims uncovered evidence that the manufacturer knew the devices were dangerous but marketed them anyway, Congress empowered the Food and Drug Administration to regulate medical devices in much the same way it regulates prescription drugs.

Because several states already regulated devices, Congress included a provision prohibiting states from imposing "requirements" inconsistent with those of the FDA. Known as an express preemption clause, it did not limit lawsuits brought by victims of defective devices. Because it apparently never occurred to anyone that a state law claim for compensation could impose a "requirement," for several years, state courts routinely awarded compensation to victims of defectively designed or marketed medical devices.

Then, in a 1992 case involving cigarette warning labels, the Supreme Court held that the word "requirement" in an express preemption clause could include litigation-induced changes to products. Armed with this defense of "federal preemption," medical device manufacturers argued that common law courts must dismiss cases before information from their files about their negligence or fraud saw the light of day. The Supreme Court rejected this argument more than a decade ago, but it left open the question of whether common law claims involving approved devices were preempted.

That critical issue is now before the court.

The problem is that the FDA has not always done a great job of keeping defective devices off the market. As congressional hearings and reports from the Government Accountability Office have revealed, the FDA's staff has been stretched by limited resources and a flood of sophisticated medical devices. Presented with incomplete or questionable studies from manufacturers seeking full approval, FDA screeners must choose between requiring further testing — thereby keeping a potentially life-saving device off the market — or approving a potentially defective device that could cause devastating damage. It's a tough job, and the FDA sometimes makes the wrong choice.

Doctors and manufacturers who discover potential defects in approved devices are legally obligated to report them to the FDA. But it often takes years before the agency takes action to require manufacturers to fix them or to stop marketing defective devices. Even then, doctors struggle with the serious question of what to do about defective devices installed in patients — such as defibrillators — that cannot be removed without creating even greater risks.

That is where common law comes in. If patients receiving defective devices could sue for damages, manufacturers have an incentive to keep potentially defective products off the market and to warn doctors who prescribe them. But if such lawsuits are preempted, the incentive disappears, and companies are free to leave defective devices on the market until the FDA forces them to do otherwise.

When defective devices cause catastrophic harm, common law provides the prospect of compensation to damaged patients. If such lawsuits are preempted, victims must rely upon their own resources or seek aid from state agencies or local charities. And the law will no longer hold manufacturers of defective products accountable for their fraud or negligence.

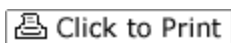
The court's opinion also will have important implications for the pharmaceutical industry, which, with the backing of the Bush administration, claims that similar suits against FDA-approved prescription drug manufacturers are likewise preempted.

Emergency bypass surgery saved Riegel's life after the balloon catheter exploded in his chest. He and the millions of us who rely on modern medical technologies need a strong federal regulatory agency to protect us from such defective devices. But when an imperfect government fails in that task, we also need to know we can still seek recourse against companies that market defective products.

McGarity, a UT law professor, is president of the Center for Progressive Reform (www.progressivereform.org).

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