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Immunity is a bad medicine for Americans' well-being

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On Feb. 20, the U.S. Supreme Court granted legal immunity to manufacturers of medical devices that secure "pre-market approval" from the Food and Drug Administration for their products. The 8-1 decision in *Riegel v. Medtronic* guarantees medical-device manufacturers will have no financial accountability for their mistakes when their products are simply made according to FDA minimum specifications. Those standards are, in the words of noted Harvard pharmaco-epidemiologist Jerry Avorn, so minimal they "would be unacceptable anywhere else in research."

What could conceivably be the justification for such a drastic decision? The Supreme Court used the doctrine of *preemption*, a constitutional doctrine that in recent years has been advocated as a sword to abolish a patient or consumer's right to sue. The court's justification is that the FDA has the congressionally mandated job of approving and monitoring the risks of medical devices.

It is a well-known scandal, however, that the FDA is nearly unable to perform its most basic tasks. Just last week, we learned that a Chinese facility that manufacturers the blood-thinner Heparin was never inspected by the FDA because the agency had the name confused with another facility.

A recent poll conducted by the Union of Concerned Scientists reported that 42 percent of the FDA's own scientists were "not at all confident" or only "somewhat confident" that the final decisions of the FDA's Center for Drug Evaluation adequately assess a drug's safety. There have been numerous reports that FDA management has pressured scientists to bury analyses that show hazards.

The Institute of Medicine, the Government Accountability Office, and the FDA's own science board have all recently issued reports concluding the FDA is largely incapable of protecting the public against unsafe medical devices, drugs and even food. The FDA's former chief counsel, Peter Barton Hutt, recently told a congressional panel that the FDA was "barely hanging on by its fingertips." David Kessler, a physician and former FDA commissioner, has written that despite a recent increase in funding by Congress, the FDA still does not have the authority or the money to fulfill its mission.

There is a lesser-known scandal: The FDA is at the mercy of Big Pharma. The FDA is funded by, outmaneuvered by, and downright manipulated by industry at every turn. In 2004, more than half of the FDA's budget for the review of human drug applications was obtained through user fees from the pharmaceutical industry, not from our impartial tax dollars.

The FDA not only does not do its own testing, but it is also almost totally dependent upon the pharmaceutical industry to provide it with data on the safety and effectiveness of new drugs and devices. One extreme example of the mischief this has caused was revealed in the Vioxx litigation, where we proved that key analyses showing an increase in heart attacks, and key studies showing an increase in hypertension compared with other drugs on the market, were all withheld from the FDA during a critical decision-making time regarding a revision to the Vioxx label. A New Jersey jury heard this testimony, and, for good reason, awarded punitive damages.

The government is putting medical device and drug makers above the public's health.

Is the Medtronic decision the tip of the iceberg? This week, the court fell one vote short of granting immunity to a drug company that withheld information from the FDA. On deck is yet another case seeking prescription-drug immunity. If the court does so, it will need to sharply diverge from its past decisions in which Justices Breyer, Thomas and Scalia, have outright rejected preemption arguments.

In the almost 30 years I have been involved in medical device and drug litigation, from the Dalkon Shield to Vioxx, I have been privy to internal documents and sworn testimony that has exposed conduct by pharmaceutical and device-makers that has led to injury and death among tens of thousands of Americans.

Approximately a quarter-century ago, I presented testimony to a federal jury from a manager of the former AH Robbins company who told his superiors in the 1970s, while their infamous Dalkon Shield was still on the market, that their product was unsafe. The manager testified he told company executives his conscience could not allow him to remain silent. He was reminded his "conscience didn't pay his salary."

Within the past few years, many juries have seen an e-mail where the most senior scientist at Merck mocked FDA scientists as "grade D high schoolers." None of this figured into the Medtronic decision, but figures into the safety equation for every person who uses a pharmaceutical device or medicine.

Americans have always looked to our courts to vindicate our rights. Congress should move quickly to pass corrective legislation to restore and assure the fundamental right to seek both protection and compensation for defective devices and drugs, and assure that there is no further erosion in service and drug product safety. We should never be at the mercy of anyone who places profit over public safety. We should not be left undefended, without recourse, against the newly privileged class — device manufacturers.

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