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Editorial:

## Medical-Device Immunity

FDA to the rescue?

The Supreme Court stripped away a key consumer health protection for Americans last week by granting legal immunity to makers of federally approved medical devices, such as joint prosthetics, breast implants and defibrillators.

- > As a result, injured patients who want to sue for damages in state court are basically out of luck.
- > The impact from the high court's decision was immediate. Hours after the ruling, a state court judge in Florida asked attorneys with cases involving Johnson & Johnson's drug-coated Cypher heart stent whether the lawsuits should continue.
- > This is part of a pattern by the pro-business Roberts court that is undermining individuals' rights to seek justice through the courts.
- > On Monday, the nine justices heard arguments in the first of two cases that could extend similar protection to drug makers. If the Supreme Court sides with the pharmaceutical industry, patients with personal injury claims for a drug such as Vioxx won't be able to sue in state courts.
- > Since 2004, the court has issued rulings against plaintiffs in five securities cases, including one that limits suits against third parties involved in corporate fraud.
- > In *Stoneridge v. Scientific-Atlanta*, the court ruled that third parties complicit in corporate wrongdoing aren't liable unless they have directly misled investors. In his dissent, Justice John Paul Stevens said the court has continued a "campaign" to render the private cause of action "toothless."
- > The 8-1 medical-device decision essentially bars damage lawsuits in state courts when consumers are injured by such equipment. In dismissing a lawsuit brought by the widow of a New York heart patient whose balloon catheter burst inside a coronary artery, the justices ruled that the device maker was shielded because the Food and Drug Administration approved the catheter device.
- > The high court ruling in effect makes the FDA the only line of defense against defective medical devices. Now, if the FDA approves the device, companies bear no liability if patients are injured by products made to agency specs.
- > Here's the problem: The FDA doesn't have a stellar reputation in keeping dangerous devices off the market

- > Even a recent in-house study said the agency was outgunned in terms of meeting its mission of safeguarding the nation's food supply and drugs. The report said the agency was short-staffed, weak on critical research, and hampered by archaic computer systems.
- > FDA Commissioner Andrew von Eschenbach, a Philadelphia native, says the agency is making key improvements in the way it operates. He says consumers should be reassured that the FDA is up to the big and complex job of protecting them - but he doesn't sound too convincing given the agency's own conclusions as to its mission-worthiness.
- > The threat of legal action over defective products is a key consumer protection in helping to hold companies accountable. In a climate where the government's watchdog role is hampered by tight-fisted budgets, damage lawsuits help keep manufacturers vigilant about product safety, despite some frivolous suits.
- > The medical-device ruling didn't break down along the usual conservative-liberal ideological divide on the court, so the decision may well indicate that there's a flaw in federal law that Congress needs to fix.
- > It's clear from key players in Congress that, in regulating medical devices during the 1970s, they never intended to provide such legal immunity.