## Supreme caveat

*by the St. Louis Post-Dispatch*

FDA approval is a ticket to market medical devices and drugs. It could soon also become a kind of "get-out-of-jail free" card for their makers, freeing them from liability for producing defective or unsafe products.

The U.S. Supreme Court ruled last week that consumers cannot sue the makers of faulty medical devices if those products have been approved by the Food and Drug Administration. In another case argued last week, the court seems poised to extend similar protections to the makers of unsafe drugs.

FDA approval protects consumers from faulty products, Justice Antonin Scalia wrote in the majority opinion, because the review that precedes it "is focused on safety."

In theory, maybe. In reality: - The FDA is inadequately funded and poorly equipped. Since 1994, it has lost 1,311 employees. Adjusted for inflation, its budget is down by nearly $300 million during that time.

- Separate reviews by the Institute of Medicine (part of the National Academies of Science), the Government Accountability Office and a scientific advisory panel established by the FDA have concluded that the agency is in urgent need of reorganization and a substantial budget increase. The advisory panel called for an increase of 150 percent over five years.

- FDA head Dr. Andrew von Eisenbach said his agency needs more funding than the almost 3 percent increase recommended in President George W. Bush's budget. "I think what we do requires substantially more dollars than what has been invested in the FDA so far," he told The Wall Street Journal.



- The agency is in the middle of yet another major drug recall - this time involving the anti-clotting drug heparin. Congress is investigating the failure of FDA regulators to inspect overseas plants that make key ingredients and finished medicines sold in this country.

- A separate congressional panel is studying potential financial conflicts of interest among doctors whose research led the FDA to approve a new artificial spinal disk. That investigation has raised questions about payments from drug and device makers to doctors who recommend their products.

- Last summer, the FDA was faulted for allowing poisonous pet food into the country. In recent years, some of the agency's own drug reviewers have raised questions about drugs it allowed on the market. Among them is Vioxx, the arthritis medicine withdrawn in 2004 after studies showed it increased the risk of heart attack and stroke.

- In 2005, it was revealed that FDA officials waited four months to warn patients about potentially life-threatening problems with a medical device called an implantable defibrillator. The devices at issue in that case were made by Medtronic, the same company at the center of last week's Supreme Court ruling. So-called pre-marketing approval is based on tests involving relatively small numbers of patients; unforeseen risks often emerge when drugs and medical devices are in widespread use. In other cases, as with the faulty defibrillators, design shortcomings only become apparent later.

Before President George W. Bush took office, the FDA supported allowing patients to sue. In a 1997 filing, an agency lawyer wrote that "even the most thorough regulation of a product such as a critical medical device may fail to identify problems."

Blocking lawsuits will prevent problems from coming to light, but it won't prevent them from occurring. Even though problems are supposed to be reported to the FDA, that doesn't always happen.

Congress can, and must, clarify the right of patients to seek damages when injured by faulty products. It also must increase significantly the FDA's budget so it can do the job we all expect of it. Until that happens, consumers should take FDA approval with a large grain of salt.

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