Los Angeles Times

From the Los Angeles Times

PHARMACEUTICALS

Patients' ability to sue at risk

Justices could shield FDA-backed drugs from suits, as they did for devices. Critics say the agency is fallible.

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March 3, 2008

Years of high-profile court battles over drugs such as Vioxx and Celebrex, along with billion-dollar settlements and jury verdicts, could soon be a thing of the past.

The U.S. Supreme Court, in an 8-1 decision, ruled last month that patients injured by most medical devices can't sue their manufacturers. And this fall, a similar case could extend the same legal protection to the much larger pharmaceutical industry -- a frequent target of lawsuits.

In last month's case, the high court backed a legal theory, supported by the Bush administration, that maintains that the Food and Drug Administration adequately regulates the drug and device industries and should not be second-guessed by courts.

Critics say such an argument would make more practical sense if the FDA were doing a better job.

The high-profile cases come as the federal agency faces growing challenges and some of its most withering criticism in years, some from within its own walls.

In recent weeks, the agency has acknowledged that it never inspected a Chinese factory that produced batches of the blood thinner heparin, which has been linked to as many as 21 deaths. Congress is investigating the agency's handling of cholesterol drug Vytorin in the wake of a study that raised questions about whether the widely advertised blockbuster works any better than a cheaper generic.

The FDA "doesn't have the ability at this time to oversee in a comprehensive fashion everything it regulates," said David A. Kessler, a former FDA chief and a professor at UC San Francisco.

A trio of recent reports, including one by the FDA's own advisory committee, has raised serious questions about the agency's recent performance.

Last fall a yearlong study by the FDA's advisory committee found "the agency is so underfunded and understaffed that it's putting U.S. consumers at risk in terms of food and drug safety."

In an unusual public departure from the view of the Bush administration, the current FDA commissioner, Andrew C. von Eschenbach, said in an interview last week that the agency needed a systemic overhaul that could take years.

In last month's Supreme Court case, the widow of a New York man who died after a balloon catheter burst in his chest during surgery sued the manufacturer, Medtronic Inc., saying the catheter was defective.

Because federal law makes few provisions for suits against drug and device makers, injured patients have turned to state law and won substantial awards.

In 2004, the Bush administration reversed a long-standing federal policy, contending that if the FDA approves a medical product, that should protect manufacturers from damages under state law.

Supporters of that stance say it is overdue. Drug and medical-device manufacturers have contended for years that the legal environment around their products has grown too restrictive and is stymieing innovation.

"You have to balance the costs that so many lawsuits place on" the system, said Glenn Lammi, chief counsel for the Washington Legal Foundation. The foundation, a group that seeks restrictions on lawsuits, submitted an amicus brief on behalf of the device manufacturer in last month's case.

Dane Titsworth of Bakersfield sees things differently. After nearly a decade of worsening back pain, the former building manager had disks in his lower back replaced two years ago with new-generation artificial disks.

But after the surgery, he said, his pain was worse than before, immobilizing him to the point that he could no longer garden or play catch with his children. He has since left his job.

Titsworth and several dozen patients with similar stories have sued the disk's maker, DePuy Spine Inc., a Raynham, Mass.-based subsidiary of Johnson & Johnson.

"This sounds to me like just another way big business can line their pockets," Titsworth said. "I was a guinea pig for this company. I should be compensated for that." He expects his case to be heard later this year.

In October, the court will hear arguments in another case, Levine vs. Wyeth, in which it might decide whether FDA approval bars personal-injury lawsuits involving drug companies.

The mere prospect that the high court could bar injury claims for FDA-approved pharmaceuticals helped precipitate the recent $4.85-billion settlement of Vioxx claims, according to lawyers involved in the negotiations.

Some legal experts and attorneys are concerned that without such lawsuits, regulators and the public may never hear of evidence that manufacturers knowingly marketed products they knew were unsafe.

In recent years, documents and e-mails uncovered in court cases have shown that some companies kept safety issues involving their products from the FDA.

"Without the tort system, what reasonable assurance do we have we will learn about the bad actors?" asked David Vladek, a law professor at Georgetown University.

"A lot is lost without these lawsuits."

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