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High court may bar claims for FDA-approved drugs

Injured patients could be prevented from suing manufacturers. The cases may also affect lawsuits already filed.

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The U.S. Supreme Court will hear arguments today in the first of two cases this term that consumer advocates fear could shut courthouse doors to patients injured by FDA-approved drugs or medical devices.

Legal experts say the cases could also affect lawsuits already filed by tens of thousands of Americans challenging the safety of blockbuster drugs such as Celebrex and Prempro and a host of medical devices.

The case before the court today was brought by the family of a New York man who suffered severe medical complications when a balloon catheter burst during a procedure to clear his arteries. The second case, involving claims for injuries allegedly caused by Rezulin, a now-withdrawn drug used to treat diabetes, will be heard in February.

Pharmaceutical manufacturers have long complained that the expense of defending injury claims has slowed research into new medications and driven up costs for patients. Because Congress granted the Food and Drug Administration the authority to determine whether products are safe and effective, manufacturers argue that state judges and juries should not be allowed to second-guess the FDA once a product is approved for use.

State damage claims put pharmaceutical makers in a "Catch-22 between complying with FDA regulations on the one hand and still being subject to state liability on the other," said Rob Clark, a government affairs director for Medtronic Inc., which made the cardiac catheter.

But plaintiffs' lawyers and consumer groups say that the FDA has approved some drugs and devices based on sloppy or falsified test data, adding that lawsuits are the only way evidence of drug risks or drug maker fraud has come to light.

A report issued Friday by three members of the FDA's own Science Boardfound that the agency was so poorly organized and short of funds that it could not adequately protect the public from dangerous drugs.

A ruling for Medtronic would "take away the last possible safety net against unfettered corporate misbehavior and negligence," said Karen Barth Menzies, a Newport Beach lawyer who has

represented plaintiffs in cases against drug makers.

Menzies sees these "preemption" cases as a new battlefront in the tort-reform wars in the wake of limits imposed by Congress and state legislatures in recent years on class actions and medical malpractice claims.

Charles Riegel sued Medtronic, claiming his injuries were caused by the catheter's negligent design, manufacture and labeling, despite the fact the device had won FDA approval. Riegel died in 2004 of causes unrelated to the angioplasty, and his widow took over his claim. Her case was thrown out by a U.S. District Court judge and then by the U.S. Court of Appeals.

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

Lawyers representing plaintiffs who took the popular painkiller insisted on language that would allow the settlement to close and compensation be paid even if the high court sides with Medtronic. Vioxx maker Merck & Co. took the drug off the market in 2004 after a study showed it doubled the risk of heart attack and stroke in patients taking it for more than 18 months.

The question in the catheter case is whether Congress intended to bar state common law claims when it gave the FDA authority to regulate medical devices in 1976. Widespread injuries reported by women who used the Dalkon Shield intrauterine device and other products had earlier prompted California and a few other states to impose some labeling and design requirements in the absence of federal standards.

The 1976 federal statute specifically said that states couldn't maintain requirements that were different from federal standards. But Congress didn't specify that those federal standards preempted state common law claims, and device manufacturers didn't argue that they did until recently, said Allison Zieve, a lawyer with Washington-based Public Citizen Litigation Group who will be arguing for Donna Riegel before the court.

In rejecting the Riegel suit, the lower courts reasoned that if the plaintiffs reached trial and won, the damages would amount to a state "requirement" different from FDA requirements because the complaint depended on state law.

Glenn Lammi, chief counsel with the Washington Legal Foundation, said continuing to allow injury claims under state law could create "a patchwork of rules" governing product design and use that "creates confusion among consumers" and raises costs. The foundation, a group that advocates restrictions on lawsuits, submitted an amicus brief on behalf of the company.

Beyond the issue of whether patients have the right to sue under state law, Medtronic's Clark insisted the company was not responsible for Riegel's injuries because his doctor used the catheter improperly, inflating the balloon beyond the pressure specified on the FDA-approved instructions.

Zieve disagrees that the label was adequate, calling the instructions "confusing and misleading." However, she said the preemption argument was more central to the case, calling it "essentially a get out of jail free card."

If the court upholds Medtronic's position, Zieve said, it means that "no matter who messed up, you can't sue the company."