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St. Jude Hit by Suits

Cases Challenge Liability Protection Enjoyed by Device Makers

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A raft of lawsuits filed Thursday against St. Jude Medical Inc. over an implanted heart device could challenge the broad liability protection that medical-device makers have enjoyed since a key Supreme Court ruling in 2008.

The lawsuits, filed both in Los Angeles Superior Court and federal court in the Central District of California, claim that problems with the manufacturing and oversight of Riata defibrillator "leads" injured or killed more than 30 patients. Faulty leads, which connect the heart to defibrillators that zap irregular heart rhythms back to normal, caused the devices to fail or needlessly deliver blasts of electricity, the suits allege.

One plaintiff, Rebecca Clawson, said in an interview that she was shocked several times over 25 minutes while in bed at her Orange County, Calif., home last November. Her lead was surgically removed and doctors said it displayed faulty wiring, said Ms. Clawson, who is 55 years old.

"As a matter of policy, we generally don't comment on pending litigation," a St. Jude spokeswoman said.

If the new cases succeed, they could help reopen a closed-off corner of the law that has left people who believe they were injured by medical devices with little recourse—and tempered the business of both plaintiff and defense lawyers who once earned hefty fees from device cases.

In recent years, the legal landscape has shifted against would-be plaintiffs injured by devices that go through the Food and Drug Administration's premarket approval process, lawyers specializing in device cases say.

The 2008 Supreme Court ruling, Riegel v. Medtronic, shielded makers of such devices from most product-liability claims, which are governed by state law, so long as the companies had complied with the federal standards of the FDA, including those for manufacturing, labeling and device monitoring. That meant that even if such devices were later found to be defective, companies are protected from many suits.

A 1976 law governing medical devices generally prohibits states from attempting to regulate devices, which are subject to federal rules, but Riegel broadly interpreted those provisions in a way that plaintiffs' attorneys say made it much harder to pursue claims.

To push cases through, lawyers generally must find state laws that specifically address violations of the FDA's requirements.

"Riegel was basically a graveyard for" device cases, said George Conk, a professor at Fordham Law School in New York and former product-liability attorney. In 2010, an appeals court upheld the dismissal of more than 8,000 cases alleging that a Medtronic Inc. defibrillator lead had injured patients, after the firm argued Riegel protected it. The company, though, had agreed to pay $268 million to settle the cases days earlier.

Medtronic said that without such protections from state law, "there would be no central standard for device safety, effectiveness, testing, labeling and marketing, which would ultimately be detrimental to patients."

Lawyers in the new Riata cases are alleging that St. Jude violated both the FDA's requirements for the company to report device flaws to the agency, along with state product-liability laws, an emerging approach to clearing Riegel's hurdles that has been buttressed by several recent appeals-court rulings.

They will also attempt to show St. Jude erred in manufacturing the devices in accordance with FDA rules, the approach favored in most device cases since Riegel.

The industry defends Riegel and its broad protections. "There is no absolutely safe medical device," said Ralph Hall, a Minnesota lawyer who has worked with device makers. "Making risk-benefit determinations in any design is FDA's job," he said.

St. Jude's Riata problems led to a recall of the leads in late 2011, and researchers have attributed at least 20 deaths to problems with the leads. Wires inside the Riata leads can break through their insulation, becoming exposed and potentially leading to electrical problems.

Some patients with the leads have seen their cases turned down by lawyers. Greg Jessee, 51, the general manager of a hydraulics-repair firm in Portsmouth, Va., was shocked three times before his heart briefly stopped during his son's football game in late 2011. He consulted an attorney last year to consider suing St. Jude, but the lawyer declined the case. "He studied it and came back to me to say he has found no way around" the protections, Mr. Jessee said.

The lawyer, Duncan Garnett, of Newport News, Va., didn't immediately respond to a request for comment.

Since the ruling "we've had numerous clients—including clients who have had Medtronic devices implanted in them—who have been reluctant to bring a case," said Brian J. McCormick Jr., a partner with Sheller PC, a Philadelphia law firm that specializes in cases involving defective products, drugs and medical devices.

Attorneys at large law firms that once made a lucrative business of defending the industry also say the Riegel ruling affected their businesses. "It has narrowed the playing field by 75%," said one defense lawyer specializing in devices who declined to be named because he still represents the industry in some matters.

Appeals courts are now split on the breadth of claims that Riegel blocks. A January ruling, for instance, in the Ninth U.S. Circuit Court of Appeals, which includes California, found Medtronic wasn't protected from liability related to a Medtronic pain-medicine pump malfunction, in part because the plaintiff, a patient named Richard Stengel, alleged the company failed to warn the

FDA about known risks.

Medtronic said it disagreed with the January ruling.

The lawyers in the newly filed cases are hoping such rulings could propel their cases.

"What the judges are recognizing now is that there's no recourse for consumers, and that's changing," said Reza Torkzadeh, a Los Angeles attorney representing the plaintiffs in the new cases.

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