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HEALTH LEADERS IN CONGRESS INTRODUCE LEGISLATION REVERSING SUPREME COURT'S MEDICAL DEVICE DECISION

Legislation will Protect Patients from Dangerous & Defective Devices

Washington, D.C. --- U.S. Reps. Frank Pallone, Jr. (D-NJ), Chairman of the House Energy and Commerce Subcommittee on Health, and Henry A. Waxman (D-CA), Chairman of the House Oversight and Government Reform Committee, today introduced legislation in the House that will reverse a U.S. Supreme Court decision earlier this year involving medical devices. A companion bill will soon be introduced in the Senate by U.S. Sens. Edward Kennedy (D-MA), Chairman of the Senate Health, Education, Labor, and Pensions Committee, and Patrick Leahy (D-VT), Chairman of the Senate Judiciary Committee.

In February, the U.S. Supreme Court, for the first time, immunized medical device companies from state lawsuits brought by patients who are injured by certain medical devices. In *Riegel v. Medtronic, Inc.* the Court found that those claims are barred by a preemption clause included in the Medical Device Amendments of 1976 (MDA). This decision ignores both congressional intent and 30 years of experience in which FDA regulation and tort liability played complementary roles in protecting consumers from device risks.

The Court's decision has left consumers without any ability to seek compensation for their injuries, medical expenses and lost wages resulting from injuries caused by defective premarket approval (PMA) devices or inadequate safety warnings. It also removes one of the industry's most important incentives to maintain product safety after approval and disclose newly-discovered risks to patients and physicians.

The *Medical Device Safety Act of 2008* protects patients from dangerous and defective devices by correcting the Court's flawed interpretation of the MDA. The legislation explicitly clarifies that state product liability lawsuits are preserved.

"This bill reverses an unfortunate Supreme Court decision that denied victims any legal recourse and gave medical device makers blanket immunity for the life of a product," Rep. Pallone said. "Congress should pass this legislation so that we can protect patients from dangerous and defective medical devices."

"The Riegel decision protects the financial interests of medical device companies at the expense of patients harmed by FDA approved devices," said Rep. Waxman. "If manufacturers face no liability, all the financial incentives will point them in the wrong direction: away from ensuring the safety of their medical devices. We must act quickly to address this dangerous situation."

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"This bill will be about protecting patients from dangerous medical products," Sen. Kennedy said. "It's wrong for companies to enjoy blanket immunity and this bill ensures that they are held accountable when their medical products injure people."

"The extraordinary power to preempt state law and regulation lies with Congress alone," said Sen. Leahy. "It should not be left to the discretion of bureaucrats or the political appointees in the executive branch. I look forward to the Senate's consideration of legislation to protect consumers and patients in the future, and I thank Senator Kennedy for his leadership on this issue. I also look forward to working with Representative Pallone and Representative Waxman on this important issue."

The Court premised its decision on the theory that approval by the U.S. Food and Drug Administration (FDA) adequately protects patients from unsafe medical devices, but the four lawmakers said that theory has proven false time and again. They point to numerous recent stories of patients who have suffered serious injuries from defective FDA-approved devices or devices without adequate safety warnings, like implantable cardiac defibrillators and pacemakers.

Until the Bush administration, FDA had always viewed state product liability cases as an important supplement to the Agency's regulation of medical devices and as an added layer of protection for consumers.

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