



215 Pennsylvania Avenue, SE • Washington, D.C. 20003 • 202/546-4996 • [www.citizen.org](http://www.citizen.org)

## **The Significance of the Medical Device Safety Act in Light of *Wyeth v. Levine***

The Medical Device Safety Act will restore injured patients' ability to bring claims for injuries caused by defective medical devices. The bill will also reconcile the legal regime used for device manufacturers with the one used for drug manufacturers, in light of the Supreme Court's 2009 decision in *Wyeth v. Levine*. That decision confirmed that Food and Drug Administration (FDA) marketing approval of prescription drugs does not bar patients' state-law claims seeking damages for harm caused by those products. The Court's reasoning in *Wyeth* touches on the core purposes of the Medical Device Safety Act.

The Medical Device Safety Act responds to *Riegel v. Medtronic*, the Supreme Court's 2008 decision that held that premarket approval of a medical device by FDA immunizes the device manufacturer from almost all state tort liability through a legal doctrine called preemption. The decision removed a vital and long-standing consumer protection.

In the more recent *Wyeth* case, the Court rejected the premise that a manufacturer is shielded from state liability simply because the product received FDA's approval. While the Court specifically addressed drugs, many of its observations, stated below, apply equally to medical devices.

**FDA Compliance as Evidence.** The trial court judge in *Wyeth* allowed the jury to consider evidence that the company complied with FDA requirements to support the assertion that it acted reasonably. But the judge also held - and the Supreme Court agreed - that compliance with federal regulations is not a complete shield from liability. Similarly, although medical devices manufacturers must comply with FDA regulations, compliance should not constitute a get-out-of-jail-free card for the manufacturer when evidence also exists that the product is defective or the company failed to provide adequate warnings.

**FDA's Longstanding Position.** First, the *Wyeth* Court noted FDA's own longstanding position that state law offers an important layer of consumer protection, and is complementary to federal law. The Court noted that before 2006, FDA had never suggested that state tort law, in particular stood as an obstacle to its statutory mission. For example, while making its rules, FDA has issued statements recognizing the role of tort liability, such as in 1979, when it stated "It is not the intent of FDA to influence the civil tort liability of the manufacturer." In 1988, the agency said that it "does not believe that the evolution of state tort law will cause the development of standards that would be at odds with the agency's regulations."

**FDA's Limitations and Manufacturers' Superior Knowledge.** The Court noted the agency's limited resources to accomplish its gargantuan task of monitoring the 11,000 drugs on the market. It also observed that "manufacturers have superior access to information about their

products, especially in the post-marketing phase as new risks emerge.” These statements apply equally in the context of medical devices.

**Benefits of State Tort Suits.** According to the Court, state tort suits will:

- uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly
- serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the [Food, Drug, and Cosmetic Act] premise that manufacturers, not FDA, bear primary responsibility for their drug labeling at all times, and
- encourage injured patients to share their experiences.

State tort suits provide similar safety incentives for medical device manufacturers.

**Congressional Intent.** The Court concluded that Congress did not intend the Food, Drug, and Cosmetic Act to preempt state law damages claims against drug manufacturers, and confirmed that Congress’ intent is the “ultimate touchstone” for evaluating preemption. With the MDSA, Congress has the opportunity to correct the Court’s understanding of congressional intent with regard to medical devices, as determined in the *Riegel* decision, and to state clearly its meaning that federal medical device law is not intended to preempt state common law

**No Federal Remedy.** Finally, the Supreme Court noted that Congress did not provide a federal remedy for consumers harmed by prescription drugs, apparently because state-law rights of action provided sufficient avenues for recovery. The federal statute regulating medical devices also does not provide any measures for patients to be compensated for their injuries, leaving state law as their only avenue for redress. Passage of the Medical Device Safety Act will restore this state law remedy for patients seeking to hold medical device manufacturers accountable for negligence and intentional wrongdoing.