

WHAT IS THE MEDICAL DEVICE SAFETY ACT?

In February of 2008, the U.S. Supreme Court, for the first time, immunized medical device companies from 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 federal regulation, by the U.S. Food and Drug Administration (FDA), 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 defective premarket approval devices or inadequate safety warnings. It also removed one of the industry's most important incentives to maintain product safety after approval and disclose newly-discovered risks to patients and physicians. "State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly." *Wyeth v. Levine*.¹ The Court premised its decision in *Riegel* on the theory that approval by the FDA adequately protects patients from unsafe medical devices, but that theory has proven false time and again. In the past year alone, patients have suffered serious injuries from defective FDA-approved devices or devices without adequate safety warnings, like implantable cardiac defibrillators and pacemakers.²

Avery DeGroh of McHenry, Illinois was just three years old when the Medtronic lead to her implanted heart defibrillator fractured, sending nine shocks to her heart, similar to the sensation of being electrocuted nine times. When the episode occurred, Avery thought monsters were attacking her as her mother felt the shocks going through the little girl's body.

The FDA regulates both medical devices and prescription drugs, but the law treats them differently. The FDA approves both medical devices and prescription drugs, but as the law now stands, failure-to-warn and design-defect lawsuits are preempted for medical devices but not for drugs. This perplexing state of affairs defies all logic. To address this inconsistency and to improve the safety of medical products, Congressmen Henry Waxman (D-CA), chair of the House Committee on Energy and Commerce, and Frank Pallone (D-NJ), chair of the Health Subcommittee, recently introduced the Medical Device Safety Act. This bill, along with a companion bill introduced by Senators Edward Kennedy (D-MA) and Patrick Leahy (D-VT), would nullify the Court's ruling in *Riegel* by adding language to the Medical Device Amendments of 1976 to make clear that the law does not prohibit suits against device companies, and would thereby place medical devices and drugs on a level playing field with respect to patient lawsuits.

"[T]he documents received by the Committee call into question whether FDA has acted in the best interests of public health. The agency's actions have undoubtedly helped shield drug manufacturers from liability. According to the agency's own experts, however, they have done so at the cost of delaying the dissemination of important safety information to the public."

~ October 2008 report by the US House of Representatives Committee on Oversight and Government Reform

THE FDA'S ROLE

The FDA's mission – to protect the public health – depends on vigorous oversight and enforcement. When the FDA fails to enforce certain regulations, the consequences can be lethal. A 2007 report from experts in industry, academia and government concluded that the FDA is now understaffed and overworked.³ Some critics of the FDA suggest that manufacturers' requests for evaluation of drugs and devices are processed by the FDA too hastily and with a bias towards approval. They see the FDA as frequently bowing to the wishes of the industry it regulates, and as susceptible to pressure by politicians who were influenced by industry lobbyists.⁴

¹ *Wyeth v. Levine*, 555 U.S. ____ (slip op., at 23).

² Committee on Energy and Commerce. Health leaders introduce legislation reversing Supreme Court's medical device decision. (Accessed March 24, 2009, at http://energycommerce.house.gov/index.php?option=com_content&task=view&id=1518.)

³ Food and Drug Administration Science Board, *FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology*, November 2007

⁴ Project on Government Oversight, *The FDA's Deadly gamble with the Safety of Medical Devices*, February 18, 2009

HOW YOU CAN HELP

- Sign our petition at www.afj.org or on Facebook.com
 - Talk to your friends and colleagues about the Medical Device Safety Act
 - View our films, *Access Denied* and *Hit and Run* at www.afj.org, and share them with others
 - Write a letter to the editor of your local paper
 - Contact your elected officials and urge them to work to pass the Medical Device Safety Act
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Supporters of the Medical Device Safety Act Include Doctor and Patient Organizations, Consumer Groups, Women's Groups, and Civil Justice Organizations

Alliance for Justice	National Council of Women's Organizations
American Association for Justice	National Multiple Sclerosis Society
American Association for Retired Persons (AARP)	National Organization for Women (NOW)
American Bar Association	National Research Center for Women & Families
American Medical Women's Association (AMWA)	National Senior Citizens Law Center
Center for Justice and Democracy	National Women's Health Network
Center for Medical Consumers	National Research Center (NRC) for Women & Families
Clearinghouse on Women's Issues	New England Journal of Medicine
Community Catalyst	Northwest Women's Law Center
Consumer Federation of America	OMB Watch
Consumers Union	OWL - The Voice of Midlife and Older Women
Dalkon Shield Information Network	Ovarian Cancer National Alliance
DES Action	Prescription Access Litigation
Disability Rights Education and Defense Fund	Progressive States Network
Easter Seals	Public Citizen
Families USA	Pulmonary Hypertension Association
Friends of Residents in Long Term Care	Toxic Discovery
Government Accountability Project	State Public Policy Group Inc.
InjuryBoard.com	United Spinal Association
National Asian Pacific American Women's Forum	US Action
National Association of Consumer Advocates	US Public Interest Research Group
National Capital Area Union Retirees	Women's International Public Health Network
National Conference of State Legislatures	Women's Research and Education Network
National Consumers League	

“Since the Supreme Court ruling in *Riegel*, thousands of lawsuits against medical-device manufacturers have been tossed out of court by judges following the Court’s lead in deeming such lawsuits to be preempted. We contend that preemption will result in medical devices that are less safe for the American people.”

The New England Journal of Medicine, March 18, 2009

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