March 5, 2009

The Honorable Henry A. Waxman
Chair
Committee on Energy and Commerce

The Honorable Frank Pallone, Jr.,
Chair
Subcommittee on Health
Committee on Energy and Commerce

Dear Chairman Waxman and Rep. Pallone:

Our groups, advocates for consumer health and safety, write to express our strong support for the Medical Device Safety Act. This bill will restore injured patients' ability to bring claims for injuries caused by defective medical devices.

The legislation was drafted in response to *Riegel v. Medtronic,* a 2008 Supreme Court decision which held that pre-market approval of a medical device by the Food and Drug Administration (FDA) under the Medical Device Amendments of 1976 immunizes the device manufacturer from tort liability. The decision removes a vital and long-standing component of the consumer safety net for medical devices and deprives injured patients of their only avenue for seeking compensation for their injuries.

Injured patients already have begun to feel the effects of *Riegel*. Recently, a Minnesota district court relied on *Riegel* to dismiss the state law claims of thousands of patients who were injured or died from Medtronic's faulty Sprint Fidelis implantable defibrillator, leaving them with no means for obtaining compensation for their injuries. Medtronic recalled the devices in October 2007 but reportedly knew about the defects since at least January 2007. Despite this knowledge, the company launched a direct-to-consumer advertising campaign urging consumers to ask their doctors whether a defibrillator would benefit them.[1] Thus, Medtronic manufactured a defective device that hurt its users, continued marketing the product even after it knew that the product was injuring people, and yet escapes accountability because the FDA had approved the product before it went on the market, and well before the defect was known.

Preemption of state tort suits over medical devices is especially harmful because it places all responsibility for device regulation in the hands of the FDA, which cannot protect consumers on its own. Numerous reports list the numerous challenges that the agency faces. For example, an FDA subcommittee concluded in 2007 that the agency "suffers from serious scientific deficiencies" and "is not positioned to meet emerging regulatory responsibilities,"[2] while a 2008 report by the House Committee on Oversight and Government Reform shed light on the political motivations behind the agency's efforts to immunize drug manufacturers from liability.[3] The FDA also has conceded that its post-approval monitoring of medical devices is "not working well."[4] Although the agency has the authority to withdraw device approval, it rarely uses this tool, choosing instead to rely upon the tort system, market forces, and the

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[1] Medtronic Press Release, Jan. 15, 2007.
http://www.medtronic.com/Newsroom/NewsReleaseDetails.do?itemId=1168456009954&lang=en_US.
[2] SUBCOMM. ON SCI. AND TECH., U.S. FOOD AND DRUG ADMIN., FDA SCIENCE AND MISSION AT RISK 2 (2007).
[3] U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM MAJORITY STAFF REPORT. FDA CAREER STAFF OBJECTED TO AGENCY PREEMPTION POLICIES. (2008).
[4] Petitioner's Brief at 5, *Riegel*, 552 U.S. ___, 128 S. Ct. 999 (No. 06-179).

threat of agency action to induce manufacturer recalls. Even when a defective device is identified and removed, the agency lacks authority to secure compensation for injured patients.

Further, the premarket approval process for medical devices does not provide the public with foolproof protection – and was never intended to do so. It is only one part of a broader consumer protection regime, in which private tort litigation plays a critical role. Even comprehensive pre-market testing cannot uncover all defects or risks posed by a new product. Tort litigation facilitates the discovery of flaws in devices on the market and brings them to the FDA's and the public's attention. Damages actions also deter risky device designs, encourage continued research and testing of devices on the market, and compensate victims for deaths and injuries caused by device defects. As an October 2008 editorial in the Journal of the American Medical Association succinctly stated: "tort law serves in effect as a way to close regulatory gaps in the FDA premarketing approval process and to provide a mechanism for post marketing surveillance."[5]

Under *Riegel*, the Medical Device Amendments immunize manufacturers from liability for injuries caused by design defects, inadequate instructions, and failure to warn of risks associated with using premarket approved devices. With passage of the Medical Device Safety Act, Congress will restore a patient's ability to seek to hold medical device manufacturers accountable for any wrongdoing. We strongly urge you and all members of Congress to support this legislation.

Sincerely,

Center for Justice & Democracy

Consumer Federation of America

Consumers Union

Homeowners Against Deficient Dwellings

National Association of Consumer Advocates

National Consumers League

OWL - The Voice of Midlife and Older Women

Progressive States Network

Public Citizen

U.S. Public Interest Research Group

cc: Members of the House Energy and Commerce Committee

[5] Catherine D. DeAngelis; Phil B. Fontanarosa. Prescription Drugs, Products Liability, and Preemption of Tort Litigation. JAMA (2008.)