March 2, 2009

The Honorable Frank Pallone, Jr.
Chairman
House Energy and Commerce Health Subcommittee
U.S. House of Representatives
Washington, D.C. 20015

The Honorable Henry Waxman
Chairman
House Energy and Commerce Committee
U.S. House of Representatives
Washington, D.C. 20015

Dear Representatives Pallone and Waxman:

On behalf of AARP's almost 40 million members, we are pleased to endorse the Medical Device Safety Act of 2009. Your legislation would make clear that the Medical Device Amendments of 1976 (MDA) do not preempt state laws that permit individuals harmed by devices the opportunity for legal recourse.

The MDA was enacted by Congress in the wake of medical devices that severely injured or resulted in the death of individuals. Last year, in Riegel v. Medtronic the Supreme Court determined that the MDA preempted state tort law, leaving consumers the inability to obtain recourse when injured by unsafe medical devices. Your legislation would permit those who are harmed to pursue legal relief through the courts. The legislation will maintain FDA's oversight and regulatory approval process, and provide individuals a much needed supplement to this authority.

Consumers need to be assured that the medical devices – like heart valves, cerebral stimulators, and pacemakers – implanted into them are safe and effective. If these products cause harm, consumers should be able to pursue compensation through the legal system.

We thank you for your leadership and look forward to working with you to ensure that this much needed legislation is enacted. If you have any questions, please contact me or have your staff contact Anna Schwamlein Howard of our government relations staff at 202-434-3770.

Sincerely,

David P. Sloane
Senior Vice President
Government Relations & Advocacy

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

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

The NEW ENGLAND JOURNAL of MEDICINE

EDITORIAL OFFICE

February 27, 2009

Congressman Henry Waxman
2204 Rayburn House Office Building
Washington, D.C. 20515

Congressman Frank Pallone, Jr.
2125 Rayburn House Office Building
Washington, DC 20515

Dear Congressmen Waxman and Pallone:

The editors of the *New England Journal of Medicine* have read the "Medical Device Safety Act of 2009," which is designed to strengthen product safety in the medical device industry, and we endorse it. We think this is critical legislation that will protect patients and help ensure the safety of medical devices in the United States.

Sincerely yours,

Jeffrey M. Drazen, M.D., Editor-in-Chief

Gregory D. Curfman, M.D., Executive Editor

Stephen Morrissey, Ph.D., Managing Editor

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Representative Frank J. Pallone, Jr.
237 Cannon Building
Washington, D.C. 20515

Representative Henry Waxman
2204 Rayburn House Office Building
Washington, DC 20515

February 27, 2009

Dear Representatives Waxman and Pallone:

On behalf of the National Conference of State Legislatures (NCSL) I write in support of the "Medical Device Safety Act of 2009." This legislation is a very important first step in combating the tide of federal regulatory preemptions of state laws that have done more harm than good to the citizens of this country. NCSL has watched with great dismay as one by one, federal agencies have undermined important state policy decisions designed to protect the health and safety of our citizens. The FDA has been the most aggressive agency in this area. NCSL is encouraged by legislation like the Medical Device Safety Act of 2009 which would help reverse this troubling trend.

This legislation is supportive of state product safety laws and reinstates the primacy of state laws for product safety. The bill recognizes that some decisions, such as how to protect people from defective products, are best made by the state legislatures, not by the federal government. NCSL applauds your leadership and willingness to support the states in achieving a more harmonious federalism system.

NCSL looks forward to working with you and your staff on this bill as it makes its way through the House of Representatives. NCSL's staff contact on this issue is Susan Parnas Frederick (202) 624-3566, or susan.frederick@ncsl.org. Thank you.

Sincerely,

Representative Joe Hackney
Speaker of the House, North Carolina
President, NCSL

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March 2, 2009

The Honorable Frank Pallone
Chairman of the Energy and Commerce Subcommittee on Health
United States House of Representatives
Washington, DC 20515

Dear Chairman Pallone:

The National Research Center (NRC) for Women & Families strongly supports the Medical Device Safety Act of 2009. This Act will restore the rights of injured patients and consumers to sue the manufacturers of defective medical devices in state courts.

Last year, the U.S. Supreme Court ruled in *Riegel v. Medtronic, Inc.* that medical devices makers are shielded from personal injury lawsuits, if their defective or unsafe product was approved by the Food and Drug Administration's (FDA) pre-market approval (PMA) process.

The Supreme Court and the medical device manufacturing industry stated that the FDA's "rigorous pre-market approval process" will protect patients and consumers from dangerous devices, so patients do not need state protections. However, numerous recent product recalls make it clear that many medical devices that are sold in the United States are not safe.

The Institute of Medicine and the U.S. Government Accountability Office have issued reports concluding that poor management, scientific inadequacies, and lack of resources, inspections, and post-market surveillance systems have undermined the agency's ability to protect Americans from unsafe drugs and medical devices.

NRC for Women & Families is gravely concerned that the Supreme Court ruling will shield from lawsuits manufacturers who received FDA approval through inadequate or false data or by withholding important safety and effectiveness data. In the past, lawsuits have helped to elicit information about false or misleading data. Without the discovery process from lawsuits, risk information that was covered-up by a company might never be made public.

It is clear that patients and consumers cannot have full confidence in the ability of the FDA to protect them from dangerous and deadly medical devices. The Supreme Court ruling has already had a negative impact on patients. Recently, a Minnesota district court relied on *Riegel* to dismiss the state law claims of more than 1,000 patients who were injured or died from Medtronic's faulty Sprint Fidelis implantable defibrillator. According to news reports, "More than 235,000 people received the Sprint Fidelis leads before they were recalled, and many of those patients still have them in place."[1]

The Medical Device Safety Act of 2009 would allow injured patients to seek redress in state courts, and the threat of litigation would provide a financial incentive to manufacturing companies to ensure that their products are as safe as possible. For the above reasons, NRC for Women & Families strongly supports this legislation.

Sincerely,

Diana Zuckerman, PhD
President

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[1] Meier, B. 2009, February 24. "Study Finds More Failure of Heart Device," *The New York Times*