

**Alliance for Justice \* Center for Justice and Democracy  
Government Accountability Project \* OMB Watch  
National Association of Consumer Advocates  
USAction \* US Public Interest Research Group**

May 12, 2008

The Honorable Frank Pallone, Jr.  
Chairman  
Health Subcommittee  
House Energy and Commerce Committee

The Honorable Henry A. Waxman  
Member  
House Energy and Commerce Committee

Dear Representatives Pallone and Waxman:

We, the undersigned national consumer advocacy organizations, are writing to express our support for the “Medical Device Safety Act of 2008.” This much needed legislation addresses the Supreme Court’s recent decision in *Riegel v. Medtronic*, by restoring Congressional intent and the ability of injured consumers to hold negligent medical device manufacturers accountable for product related deaths and injuries. Immunity should not be given to device manufacturers who fail to adequately warn about device risks – especially when a risk, known to manufacturers, later causes permanent and debilitating injuries.

Under *Riegel*, manufacturers of FDA approved medical devices are given complete immunity from liability for product related deaths and injuries. This immunity protection even extends to manufacturers who fail to warn about device problems that arise after FDA approval. By eradicating manufacturer accountability, thousands of consumers injured by defective devices would be unable to receive any remedies for their injuries. In the last decade alone, consumers were harmed by defective devices like the Trident prosthetic hip and the Prodisc spinal implant. An upcoming Supreme Court case dealing with prescription drugs could further limit the rights of consumers to hold drug manufacturers accountable.

The Medical Device Safety Act of 2008 addresses these gaps and capitalizes on 30 years of experience under the 1976 Medical Device Amendments by utilizing both FDA regulation and state tort law to ensure the safety of medical devices. This legislation explicitly states that actions for damages under state law are preserved and makes this retroactive to the date when Congress enacted the Medical Devices Amendment of 1976.

For these reasons, we strongly support the Medical Device Safety Act of 2008. Manufacturer accountability for defective devices cannot be so easily eliminated after 30 years of proven effectiveness. Reiterating Congress’ intent and restoring manufacturer accountability is a much needed first step towards ensuring reasonably safe medical devices. We look forward to working with you and your staff to pass the very important legislation.

Sincerely,

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