ISSUE UPDATE: MEDICAL DEVICE LIABILITY

New Bill Could Revitalize Protections for Consumers of Medical Devices Lost in the *Riegel v. Medtronic* Case

By Levin & Perconti

The House and Senate are currently seeking to override the Supreme Court's recent decision in *Riegel v. Medtronic, Inc.* Their efforts to pass the Medical Device Safety Act of 2008 could help protect many consumers from faulty medical devices.

Prior to *Riegel*, state law and Food and Drug Administration (FDA) requirements applied to all medical devices. State law allowed anyone hurt by a faulty or dangerous medical device to seek damages from the companies that make them. However, *Riegel* now blocks state law tort recovery for faulty medical devices.

In *Riegel*, the Supreme Court held that the 1976 law giving the FDA the authority to regulate medical devices limits the ability for injured patients to sue device manufacturers using state tort claims. Effectively, *Riegel* removes the ability for an injured patient to sue the manufacturer of the faulty or dangerous medical device for recovery. The case arose when Mr. Riegel was seriously injured by an exploding angioplasty balloon during surgery. He and his wife sued Medtronic, the catheter and balloon manufacturer on the grounds that Medtronic's product was unreasonably dangerous and without adequate warnings and instructions.

Riegel does more than just cut off state law recovery: the decision puts future medical device users in danger. The FDA is currently overburdened and underfunded, meaning that Administration reviewers and researchers do not have adequate time or resources to analyze each new product. Many new drugs and devices enter the US market without a full evaluation of their potential risks. Even worse, FDA researchers tend to rely on studies paid for by the device or drug manufacturers that often obscure negative information.

The Medical Device Safety Act of 2008 would restore patients' rights to sue under state law and preserve their rights to seek compensation for their injuries from the manufacturer by overruling the Riegel decision. The Act would restore Congress's original 1976 intent to the act creating the FDA: Congress intended that traditional state law remedies would operate in tandem with FDA regulation of medical devices. The House version, HR 6381, is sponsored by Representatives Henry Waxman (D-California) and Frank Pallone (D-New Jersey). Senators Kennedy (D-Massachusetts) and Leahy (D-

Vermont) are anticipated to sponsor the Senate version shortly.

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